



IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD



**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](https://standards.iteh.ai/catalog/standards/sist/b0b940dc-0ad3-4682-8088-1017bbcc4c08/iec-60601-1-8-2006)

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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.....	97
Annex C (normative) Symbols on marking.....	100
Annex D (informative) Guidance for auditory ALARM SIGNALS	109
Annex E (informative) Verbal ALARM SIGNALS.....	111
Annex F (normative) * Reserved melodies for ALARM SIGNALS.....	113
Annex G (normative) * Auditory ALARM SIGNALS	114
Annex H (informative) VALIDATION of AUDITORY ICONS	119
Bibliography.....	125
Index of defined terms used in this collateral standard.....	131
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	116
Figure G.2 – Illustration of temporal characteristics of an AUDITORY POINTER	117
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	96
Table B.1 – Cross-reference of marking.....	97
Table B.2 – Cross-reference of ACCOMPANYING DOCUMENTS	98
Table B.3 – Cross-reference of instructions for use.....	98
Table B.4 – Cross-reference of technical description	99
Table C.1 – Graphical symbols for ALARM SYSTEMS.....	100
Table C.1 – Graphical symbols for ALARM SYSTEMS (<i>continued</i>).....	101
Table C.1 – Graphical symbols for ALARM SYSTEMS (<i>continued</i>).....	102
Table C.2 – Alternative ALARM SYSTEM related markings.....	108
Table D.1 – Attributes of perceived urgency.....	109
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	115
Table G.2 – Characteristics of the PULSE of the AUDITORY POINTER.....	116
Table G.3 – Characteristics of the AUDITORY POINTER	117
Table G.4 – * Characteristics of the AUDITORY ICON	118
Table G.5 – Characteristics of the auditory ALARM SIGNAL	118
Table H.1 – Performance levels of three AUDITORY POINTERS and seven AUDITORY ICONS based on available data	120

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

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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.

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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~~ 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.

IEC 60601-1-8:2006

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.

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 ~~referenced~~ documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the~~ its 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, *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

~~IEC 60601-1-2:—²⁾, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*~~

~~IEC 60601-1-6:—³⁾, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*~~

~~IEC 60651:1979⁴⁾, *Sound level meters*
Amendment 1 (1993)
Amendment 2 (2000)~~

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

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

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

ISO 3744:~~1994~~2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering method ~~in~~ for an essentially free field over a reflecting plane*

ISO 7000:~~1989~~, *Graphical symbols for use on equipment – ~~Index and synopsis~~*. Available from: <<http://www.graphical-symbols.info/equipment>>

²⁾ ~~A second edition of IEC 60601-1-2 exists, published in 2004 under the title *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests*. A third edition under the title given above is currently to be published. References to IEC 60601-1-2 in this standard refer to the new edition.~~

³⁾ ~~A first edition of IEC 60601-1-6 exists, published in 2004 under the title *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability*. A second edition under the title given above is currently to be published. References to IEC 60601-1-6 in this standard refer to the new edition.~~

⁴⁾ ~~IEC 60651:1979 has been withdrawn and replaced by IEC 61672-1:2002 and IEC 61672-2:2003. Future editions of this publication will be amended to take this fact into account.~~

3 Terms and definitions

~~For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012 and IEC 62366:2007, IEC 60601-1-2:-----⁵⁾, IEC 60601-1-6:-----⁶⁾, and the following definitions apply.~~

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 131.

3.1

* ALARM CONDITION

state of the ALARM SYSTEM when it has determined that a potential or actual ~~HAZARD~~ 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

3.4

ALARM OFF

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

3.5

* ALARM PAUSED

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

3.6

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

3.7

ALARM RESET

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

3.8

ALARM SETTINGS

ALARM SYSTEM configuration, including but not limited to:

~~⁵⁾ To be published. See footnote 2.~~

~~⁶⁾ To be published. See footnote 3.~~