IEC 60601-1-8

Edition 2.0 2006-10

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

IEC 60601-1-8:2006

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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;
- "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

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.

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.

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;

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

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

IEC 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 60651:1979 [4)], *Sound level meters*
Amendment 1 (1993)
Amendment 2 (2000)

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:---- [5)], IEC 60601-1-6:---- [6)], 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 155.

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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.

5) To be published. See footnote 2.

6) To be published. See footnote 3.

3.1
*** ALARM CONDITION**
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists

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

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

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:

– ALARM LIMITS;
– the characteristics of any ALARM SIGNAL inactivation states; and
– the values of variables or parameters that determine the function of the ALARM SYSTEM

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

3.9
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

3.10
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNAL(S)

3.11
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

3.12
AUDIO OFF
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.13
AUDIO PAUSED
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.14
BURST
group of PULSES with a distinctive rhythm or pattern

3.15
DE-ESCALATION
PROCESS by which an ALARM SYSTEM decreases the priority of an ALARM CONDITION or decreases the sense of urgency of an ALARM SIGNAL

3.16
DEFAULT ALARM PRESET
ALARM PRESET that can be activated by the ALARM SYSTEM without OPERATOR action

NOTE MANUFACTURER- or RESPONSIBLE ORGANIZATION-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

3.17
*** DISTRIBUTED ALARM SYSTEM**
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM

NOTE The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

3.18
ESCALATION
PROCESS by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

3.19
FALL TIME
t_f
interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 1)

3.20
FALSE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE An ALARM CONDITION can be rejected or missed because of spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the equipment itself.

3.21
FALSE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE A FALSE POSITIVE ALARM CONDITION can be caused by spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

3.22
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

3.23
*** INFORMATION SIGNAL**
any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

3.24
*** INTELLIGENT ALARM SYSTEM**
ALARM SYSTEM that makes logical decisions based on monitored information without OPERATOR intervention

EXAMPLE 1 An ALARM SYSTEM that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An ALARM SYSTEM that suppresses an ALARM CONDITION when a related ALARM CONDITION of higher priority has recently generated an ALARM SIGNAL.

3.25
INTERBURST INTERVAL
t_b
period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL (see Figure 1)

3.26
LATCHING ALARM SIGNAL
ALARM SIGNAL that continues to be generated after its triggering event no longer exists until stopped by deliberate OPERATOR action

3.27
LOW PRIORITY
indicating that OPERATOR awareness is required

NOTE The priority is assigned through RISK ANALYSIS.

3.28
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

3.29
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

3.30
OPERATOR'S POSITION
intended position of the OPERATOR with respect to the ALARM SIGNAL generating part of the ALARM SYSTEM

NOTE A DISTRIBUTED ALARM SYSTEM can have multiple OPERATOR'S POSITIONS.

3.31
PHYSIOLOGICAL ALARM CONDITION
ALARM CONDITION arising from a monitored PATIENT-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

3.32
PULSE
brief continuous sound having a specific spectral content

3.33
PULSE FREQUENCY
f_o
fundamental frequency (first harmonic) of a PULSE

3.34
*** REMINDER SIGNAL**
periodic signal that reminds the OPERATOR that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

3.35
RISE TIME
t_r
interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 1)

3.36
TECHNICAL ALARM CONDITION
ALARM CONDITION arising from a monitored equipment-related or ALARM SYSTEM-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

4 General requirements

If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose. See also 12.3 of the general standard.

The RISK ASSESSMENT shall also consider HAZARDS to PATIENTS, OPERATORS, and other persons arising from the ALARM SYSTEM (see 6.8.3).