INTERNATIONAL STANDARD

IEC 60601-1-8

First edition
2003-08

Medical electrical equipment –

Part 1-8:
General requirements for safety – Collateral standard:
General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Appareils électromédicaux –

Partie 1-8:
Règles générales de sécurité –
Norme collatérale:
Règles générales, essais et guides
pour les systèmes d'alarme dans l'équipement
électromédical et les systèmes électromédicaux

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-8: General requirements for safety – 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, 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 a Joint Working Group of 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 SC3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

This first edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the general standard.

This standard replaces the following standards:

ISO 9703-1 Anesthesia and respiratory care alarm signals – Part 1: Visual alarm signals

ISO 9703-2 Anesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals

ISO 9703-3 Anesthesia and respiratory care alarm signals – Part 3: Guidance on application of alarms

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

FDIS	Report on voting
62A/424/FDIS	62A/432/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 16 P-members out of 18 having cast a vote.

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).

The numbering of sections, clauses and subclauses of this collateral standard corresponds with that of the general standard.

Clauses, subclauses, tables, and figures which are additional to those of the general standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

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

– requirements and definitions: roman type;

– notes, examples, explanations, advice, introductions, general statements and references: smaller roman type;

– *test specifications and guidance in Annex AAA: italic type; and*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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

The committee has decided that the contents of this publication will remain unchanged until 2008. 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 potential 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 USER. It is important that the USER 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 safety – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

SECTION ONE – GENERAL

1 * Scope and object

1.201 Scope

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

It also provides guidance for the application of ALARM SYSTEMS.

1.202 Object

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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.

NOTE See IEC 60513:1994 [4] for a description of basic safety and essential performance.

This collateral standard does not specify:

– whether any particular MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL 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.

1.203 Relationship to other standards

1.203.1 IEC 60601-1

For MEDICAL ELECTRICAL EQUIPMENT, 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.

1.203.2 Particular standards

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

1.203.3 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-DB:2000-10 [2], *Graphical symbols for use on equipment*

IEC 60601-1:1988 *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-6:— [3], *Medical electrical equipment – Part 1-6: General requirements for safety – 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*

2 Terminology and definitions

For the purposes of this collateral standard, the following definitions apply. [5]

NOTE This collateral standard uses the term "equipment" to mean MEDICAL ELECTRICAL EQUIPMENT or non-MEDICAL ELECTRICAL EQUIPMENT in the context of a MEDICAL ELECTRICAL SYSTEM.

2.201
*** 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.

2.202
*** 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

2.203
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

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2) "DB" refers to the IEC on-line database.

3) To be published

4) A consolidated edition (1.2) exists including IEC 60651 (1997) and its Amendment 1 (1993) and Amendment 2 (2000)

5) An index of defined terms is found beginning on page 70.

2.204
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

2.205
*** ALARM PAUSED**
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate ALARM SIGNALS

2.206
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

2.207
ALARM RESET
OPERATOR action that causes the cessation of an ALARM SIGNAL for which no associated ALARM CONDITION currently exists

2.208
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.

2.209
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

2.210
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNALS

2.211
ALARM SYSTEM
parts of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

2.212
AUDIO OFF
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

2.213
AUDIO PAUSED
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

2.214
BURST
group of PULSES with a distinctive rhythm or pattern

2.215
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

2.216
DEFAULT ALARM PRESET
ALARM PRESET that can be activated by the ALARM SYSTEM without OPERATOR action

NOTE Manufacturer- or USER-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

2.217
*** DISTRIBUTED ALARM SYSTEM**
ALARM SYSTEM that involves more than one item of equipment of a MEDICAL ELECTRICAL SYSTEM

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

2.218
ESCALATION
process by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

2.219
FALL TIME
t_f
interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 201)

2.220
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.

2.221
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.

2.222
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE The priority is assigned through risk analysis.

2.223
*** 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

2.224
*** 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.

2.225
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 201)

2.226
LATCHING ALARM SIGNAL
ALARM SIGNAL that continues to be generated after its triggering event no longer exists until stopped by deliberate OPERATOR action

2.227
LOW PRIORITY
indicating that OPERATOR awareness is required

NOTE The priority is assigned through risk analysis.

2.228
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE The priority is assigned through risk analysis.

2.229
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

2.230
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.

2.231
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.

2.232
PULSE
brief continuous sound having a specific spectral content

2.233
PULSE FREQUENCY
f_o
fundamental frequency (first harmonic) of a PULSE

2.234
*** REMINDER SIGNAL**
periodic signal that reminds the OPERATOR that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

2.235
RISE TIME
t_r
interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 201)

2.236
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.

6 Identification, marking and documents

6.3 Marking of controls and instruments

Addition:

NOTE Additional requirements for the marking on controls and instruments are specified in this collateral standard, together with the technical requirements, giving rise to requirements on markings. These requirements are also listed in BBB.1.

6.7 Indicator lights and push-buttons

a) Colors of indicator lights

Addition, after the first sentence:

See also 201.3.2.2.

Addition, after the second sentence:

See also 201.3.2.2.

6.8.1 ACCOMPANYING DOCUMENTS

Addition:

NOTE Additional requirements on ACCOMPANYING DOCUMENTS are specified in this collateral standard, together with the technical requirements, giving rise to requirements on ACCOMPANYING DOCUMENTS. These requirements are also listed in Table BBB.2.

6.8.2 Instructions for use

Addition:

aaa) ALARM SYSTEMS

Instructions for use shall:

– * provide an overview of the ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and, as appropriate for the intended OPERATOR, a summary of how it is determined;

– indicate any delay inherent in the determination of an ALARM CONDITION;

– disclose the OPERATOR'S POSITION; and

– * include how and when to verify the functionality of the ALARM SYSTEM.

As applicable, the instructions for use shall:

– caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless.

NOTE Additional requirements on instructions for use are specified in this collateral standard, together with the technical requirements, giving rise to requirements on instructions for use. These requirements are also listed in Table BBB.3.