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

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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

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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.

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[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*

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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)