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Medical electrical equipment

Part 4-4: Guidance and interpretation — Guidance for writers of particular standards when creating alarm system-related requirements

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National foreword

This Published Document is the UK implementation of IEC TR 60601-4-4:2017.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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IEC 60601-4-4, which is a technical report, has been prepared by a Joint Working Group of 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 equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/1186/DTR	62A/1197/RVDTR

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

Terms used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

It has become apparent in reviewing various particular standards in the IEC 60601 and IEC 80601 or ISO 80601 series of standards that there is inconsistency in the references to ALARM SYSTEM-related requirements. This inconsistency is especially challenging for MANUFACTURERS whose products have multiple applicable particular standards.

This document was generated to address this problem by providing model language, with examples, for common ALARM SYSTEM-related requirements that have been needed in existing particular standards. It is hoped that writers of particular standards will use this model language when ALARM SYSTEM-related requirements need to be provided in these standards.

This document contains 13 recommendations, numbered 1 to 13 (see Table 1). All these recommendations are based upon IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012. The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 with the prefix “208” (e.g. 208.1 in this document addresses the content of Clause 1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012). Similarly, IEC 60601-1:2005 and IEC 60601-1:2005/ AMD1:2012 are indicated with the prefix “201” (e.g. 201.4 in this document addresses the content of Clause 4 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012). Changes to the rationale for a clause or subclause are indicated with the prefix "Subclause" (e.g. Subclause 208.6.8.5 indicates rationale for Subclause 208.6.8.5).

The changes to the text are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the reference is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of the reference.

"*Amendment*" means that the clause or subclause of the reference is amended as indicated by the text of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-4: Guidance and interpretation – Guidance for writers of particular standards when creating alarm system-related requirements

1 Scope and object

1.1 Scope

This document is intended to assist writers when drafting ALARM SYSTEM-related requirements for particular standards in the IEC 60601 and IEC 80601 or ISO 80601 series of standards.

1.2 Object

The object of this document is to encourage consistent references to ALARM SYSTEM-related requirements when introducing those requirements to particular standards. This is accomplished by providing suggested model language, with examples, for common ALARM SYSTEM-related requirements. Each of the recommendations is based upon text that has been used in existing particular standards. The expectation is that this model language will be used when ALARM SYSTEM-related requirements are needed in particular standards.

The collateral standard for ALARM SYSTEMS, IEC 60601-1-8, contains the horizontal ALARM SYSTEM-related requirements for ME EQUIPMENT and ME SYSTEMS. The recommendations in this document are intended to aid the writers of particular standards when referencing IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-8:2006, *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/AMD1:2012

IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

IEC 60601-2-34:2011, *Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use – Part 1: Salt test method to assess filtration performance*