# IEC TR 60601-4-4

Edition 1.0 2017-08

# TECHNICAL REPORT

## 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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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- withdrawn,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*

ISO 80601-2-12:2011, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-55:2011, *Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-61:2011, *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

ISO 80601-2-72:2015, *Medical electrical equipment – Part 2-72:Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-2-27:2011, IEC 60601-2-34:2011, ISO 23328-1:2003, ISO 80601-2-12:2011, ISO 80601-2-55:2011, ISO 80601-2-61:2011 and ISO 80601-2-72:2015 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp



NOTE An index of defined terms is found beginning on page 22.



## 4 Overview

Table 1 provides an overview of the recommendations in this document listed in the order of the subclauses of the collateral standard, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

In these recommendations, text in a field with

- square brackets [ ] represents where the writers should choose an appropriate phrase.
- curly brackets { } represents a field where the choices are listed inside the brackets or later in the text.

**Table 1 – Recommendations for particular standard references to the collateral standard IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD:2012**

| Subclause of the particular standard | Recommendation number | Topic | Page |
|---|---|---|---|
| 201.7.9.2.8.101 | 5.6 | Requiring disclosure of a means for testing ALARM SIGNALS | 14 |
| 201.7.9.3.101 | 5.7 | Requiring disclosure of a means for testing the ALARM SYSTEM | 15 |
| 208.6.6.2.101 | 5.5 | Requiring a restriction for the adjustment range of an ALARM LIMIT | 13 |
| 208.6.8.1 | 5.13 | Requiring the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state | 18 |
| 208.6.8.1 | 5.1 | Prohibiting the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state | 9 |
| 208.6.8.2 | 5.8 | Requiring REMINDER SIGNALS, option 1 | 16 |
| 208.6.8.2 | 5.9 | Requiring REMINDER SIGNALS, option 2 | 16 |
| 208.6.8.5 | 5.3 | Requiring a maximum pause duration, option 1 | 11 |
| 208.6.8.5 | 5.4 | Requiring a maximum pause duration, option 2 | 11 |
| 208.6.12 | 5.12 | Requiring ALARM SYSTEM logging | 18 |
| —[a] | 5.11 | Requiring a maximum ALARM SIGNAL GENERATION DELAY | 17 |
| —[a] | 5.2 | Requiring an ALARM CONDITION and its priority | 9 |
| —[b] | 5.10 | Requiring the capability for a connection to a DISTRIBUTED ALARM SYSTEM | 17 |

[a] Generally placed in a particular standard subclause calling out the ALARM CONDITION.

[b] Generally placed in a particular standard in subclause 201.10x.



## 5 Recommendations

### 5.1 Prohibiting the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state

#### 5.1.1 General

This recommendation is applicable only for those particular standards that intend to prohibit the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state.

The recommended text would typically be placed in the particular standard at 208.6.8.1.

#### 5.1.2 Recommended text to prohibit the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state

**208.6.8.1 General**

*Amendment (delete from the first paragraph):*

or indeterminate (indefinite ACKNOWLEDGED)

*Amendment (add to end of the first paragraph):*

ME EQUIPMENT shall not be equipped with a means for the clinical OPERATOR to initiate the indeterminate (indefinite) ACKNOWLEDGED ALARM SIGNAL inactivation state.

*Check compliance by functional testing.*