



BSI Standards Publication

Medical electrical equipment

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

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.

© The British Standards Institution 2017
Published by BSI Standards Limited 2017

ISBN 978 0 580 94478 9

ICS 11.040.01

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2017.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------



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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-4685-6

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope and object.....	7
1.1 Scope.....	7
1.2 Object.....	7
2 Normative references.....	7
3 Terms and definitions.....	8
4 Overview.....	8
5 Recommendations.....	
5.1 Prohibiting the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state.....	9
5.1.1 General.....	9
5.1.2 Recommended text to prohibit the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state.....	9
5.2 Requiring an ALARM CONDITION and its priority.....	10
5.2.1 General.....	10
5.2.2 Recommended text to require an ALARM CONDITION and its priority.....	10
5.2.3 Example 1 for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT.....	10
5.2.4 Example 2 for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT.....	10
5.2.5 Example for PULSE OXIMETER EQUIPMENT.....	11
5.3 Requiring a maximum pause duration, option 1.....	11
5.3.1 General.....	11
5.3.2 Recommended text to require a maximum pause duration, option 1.....	11
5.3.3 Example.....	11
5.4 Requiring a maximum pause duration, option 2.....	11
5.4.1 General.....	11
5.4.2 Recommended text to require a maximum pause duration, option 2.....	12
5.4.3 Example for a critical care VENTILATOR.....	12
5.5 Requiring a restriction for the adjustment range of an ALARM LIMIT.....	13
5.5.1 General.....	13
5.5.2 Recommended text to restrict the adjustment range of an ALARM LIMIT, option 1, limit the range.....	13
5.5.3 Example for a RESPIRATORY GAS MONITOR (RGM).....	13
5.5.4 Recommended text to restrict the adjustment range of an ALARM LIMIT, option 2, ensure that the range is wide enough.....	14
5.5.5 Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT.....	14
5.6 Requiring disclosure of a means for testing ALARM SIGNALS.....	14
5.6.1 General.....	14
5.6.2 Recommended text to require disclosure of a means of testing ALARM SIGNALS.....	14
5.6.3 Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT.....	15
5.7 Requiring disclosure of a means for testing the ALARM SYSTEM.....	15
5.7.1 General.....	15
5.7.2 Recommended text to require disclosure of a means of testing the ALARM SYSTEM.....	15
5.7.3 Example for a critical care VENTILATOR.....	15
5.8 Requiring REMINDER SIGNALS during ALARM SIGNAL inactivation, option 1.....	16
5.8.1 General.....	16

5.8.2	Recommended text to require the generation of REMINDER SIGNALS during ALARM SIGNAL inactivation	16
5.8.3	Example for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	16
5.9	Requiring REMINDER SIGNALS during ALARM SIGNAL inactivation, option 2	16
5.9.1	Recommended text to require the generation of REMINDER SIGNALS during ALARM SIGNAL inactivation	16
5.9.2	Example	17
5.10	Requiring the capability for a connection to a DISTRIBUTED ALARM SYSTEM	17
5.10.1	General	17
5.10.2	Recommended text to require the capability for a connection to a DISTRIBUTED ALARM SYSTEM	17
5.10.3	Example for a VENTILATOR FOR A VENTILATOR-DEPENDENT PATIENT	17
5.11	Requiring a maximum ALARM SIGNAL GENERATION DELAY	18
5.11.1	General	18
5.11.2	Recommended text to require a maximum ALARM SIGNAL GENERATION DELAY	18
5.11.3	Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT	18
5.12	Requiring ALARM SYSTEM logging	18
5.12.1	General	18
5.12.2	Recommended text to require ALARM SYSTEM logging	18
5.12.3	Example for a life-supporting homecare VENTILATOR	19
5.13	Requiring the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state	20
5.13.1	General	20
5.13.2	Recommended text to require the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state	20
	Bibliography	21
	Index of defined terms used in this document	22
Table 1 – Recommendations for particular standard references to the collateral standard IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD:2012		9

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 preparatory work. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, accept to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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 correspond 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 208.6.8.1).

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 example, 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 the 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 referenced 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*