

American National Standard



ANSI/AAMI/ IEC 60601- 1-8:2006 & A1:2012

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

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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

Approved 18 October 2013 by
Association for the Advancement of Medical Instrumentation

Approved 21 October 2013 by
American National Standards Institute, Inc.

Abstract: This standard defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness, and data and system security.

Keywords: medical device, risk management, information technology, interoperability

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: 703-525-4890; Fax: 703-525-1067.

Printed in the United States of America

ISBN 1-57020-517-5

CONTENTS

Glossary of equivalent standards.....	v
Committee representation.....	vi
Background of ANSI/AAMI adoption of IEC 60601-1-8:2006 & A1:2012	viii
FOREWORD	ix
INTRODUCTION TO THE AMENDMENT	7
INTRODUCTION	xii
1 * Scope, object and related standards	1
1.1 Scope	1
1.2 Object	1
1.3 Related standards	1
2 Normative references	2
3 Terms and definitions	3
4 General requirements	7
5 ME EQUIPMENT identification marking and documents	7
5.1 Indicator lights and controls	7
5.2 ACCOMPANYING DOCUMENTS	7
6 ALARM SYSTEMS	8
6.1 ALARM CONDITION	8
6.2 * Disclosures for INTELLIGENT ALARM SYSTEM	9
6.3 Generation of ALARM SIGNALS	10
6.4 * Disclosure of delays	17
6.5 ALARM PRESETS	18
6.6 ALARM LIMIT	21
6.7 * ALARM SYSTEM security	22
6.8 * ALARM SIGNAL inactivation states	22
6.9 * ALARM RESET	25
6.10 * NON-LATCHING and LATCHING ALARM SIGNALS	25
6.11 * DISTRIBUTED ALARM SYSTEM	26
6.12 * ALARM ~~CONDITION~~ SYSTEM logging	28
Annex A (informative) General guidance and rationale	30
Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	69
Annex C (normative) Symbols on marking	73
ANNEX D (informative) Guidance for auditory ALARM SIGNALS	79
ANNEX E (informative) Verbal ALARM SIGNALS	81
ANNEX F (normative) * Reserved melodies for ALARM SIGNALS	83
Bibliography	84

Index of defined terms used in this collateral standard.....	86
Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS	14
Figure A.1 – Graphical representation of components of ALARM SYSTEM delay.....	50
Table 1 – ~~ALARM CONDITION priorities~~ Determination of ALARM CONDITIONS and assignment of priorities	9
Table 2 – Characteristics of alarm indicator lights.....	11
Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS	13
Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS	14
Table 5 – ALARM SIGNAL inactivation states	25
Table A.1 – Reference interpretation of Table F.1	68
Table A.2 – Reference interpretation of Table F.2	68
Table B.1 – Cross-reference of marking	69
Table B.2 – Cross-reference of ACCOMPANYING DOCUMENTS.....	70
Table B.3 – Cross-reference of instructions for use	71
Table B.4 – Cross-reference of technical description	72
Table C.1 – Graphical symbols for ALARM SYSTEMS.....	73
Table C.2 – Alternative ALARM SYSTEM related markings	78
Table D.1 – Attributes of perceived urgency	79
Table F.1 – * Equipment encoded auditory ALARM SIGNALS categorized by ALARM CONDITION and priority complying with Table 3 and Table 4	83
Table F.2 – * Auditory LOW PRIORITY ALARM SIGNAL complying with Table 3 and Table 4	83

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Information Technology Networks Incorporating Medical Devices Committee

The adoption of IEC 60601-1-8 as an American National Standard was initiated by the AAMI Medical Device Alarms Committee. The AAMI Medical Device Alarms Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Electrotechnical Commission (IEC). U.S. representatives from the AAMI Medical Device Alarms Committee (U.S. Sub-TAG for IEC/SC62A/JWG 2-ISO/TC 121/SC 3) played an active part in developing the IEC standard.

Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Medical Device Alarms Committee** had the following members:

<i>Cochairs</i>	Frank E Block, Jr., MD David G. Osborn, Philips Electronics North America
<i>Members</i>	Pat Anglin-Regal, Massachusetts General Hospital Emily Arnould, RN BSN, Hospira Worldwide Inc. Shashi Avadhani, CBET CCE MBA, Crothall Clinical Equipment Services Nancy Blake, RN, Children's Hospital Los Angeles Patricia Bourie, RN MS, Beth Israel Deaconess Medical Center J. Tobey Clark, CCE, University of Vermont Christopher S. Connelly, Miami Valley Hospital Todd Cooper, West Health Institute Randolph J. Cremer, CBET, Deborah Heart & Lung Center Conor Curtin, Fresenius Medical Care Renal Therapies Group David DeBelser, Smiths Medical James E. Eberhart, BSEE, Meritus Medical Center Judy Edworthy, BA PhD, University of Plymouth School of Psychology Jane Foley, RN, Beth Israel Deaconess Medical Center Shawn Forrest, FDA/CDRH Marjorie Funk, Yale University School of Nursing Daryle Jean Gardner-Bonneau, PhD, Bonneau and Associates Karen Giuliano, Fluidnet Corporation Rodolfo I. Godinez, MD, PhD James Greenberg, Cincinnati Children's Hospital Medical Center Brian Gross, Philips Electronics North America David Hengl, Draeger Medical Systems Inc. David H. Hoffmeister, Baxter Healthcare Corporation Dean A. Hooper, HE Consulting Elizabeth Howard, DaVita Total Renal Care Inc. Xiao Hu, PhD, UCLA Chantal Kangudie, Sunnybrook Health Sciences Centre Ted J. Klefisch, Covidien Todd Konieczny, Intertek Colleen Lindell, RN, Regions Hospital Alan Lipschultz, CCE PE CSP, HealthCare Technology Consulting LLC Shawn O'Connell, MS, RN, B Braun of America Inc. Yashaswini Patwardhan, Baxter Healthcare Corporation Melanie Quinton, Kaiser Permanente (US) Cadathur Rajagopalan, PhD SMIEEE, Mindray DS USA Inc. Sue E. Sendelbach, PhD RN, Abbott Northwestern Hospital Elena Simoncini, VA New England Healthcare System Bob Steurer, Spacelabs Medical Inc. Katherine Tindall, RN, Welch Allyn Inc. Sandra Tobar, RN, St John Providence Health System Stephen Treacy, GE Healthcare

Steven A. White, NxStage Medical Inc.
Daidi Zhong, PhD, Chongqing University

Alternates

Robert J. Alberte, Jr., GE Healthcare
Keith B. Anderson, BSEE, Smiths Medical
Martin Crnkovich, Fresenius Medical Care Renal Therapies Group
Julian M. Goldman, MD, Massachusetts General Hospital
Randy Good, Covidien
Thomas M. Judd, MS PE CCE CPHQ FACCE, Kaiser Permanente (US)
Joshua Kim, Welch Allyn Inc.
Gary N. Mills, Hospira Worldwide Inc.
Yashaswini Patwardhan, Baxter Healthcare Corporation
Linda Ricci, FDA/CDRH

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/A1:2012

As indicated in the foreword to the main body of this document (page ix), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard and its amendment, which was developed by IEC Technical Committee 62, Electrical equipment in medical practice, Subcommittee (SC) 62A, Common aspects of electrical equipment used in medical practice, to provide terminology, requirements, general recommendations and guidance for medical electrical equipment and medical electrical systems manufacturers and for technical committees responsible for particular standards.

U.S. participation in IEC/SC 62A is organized through the U.S. Technical Advisory Group to IEC/SC 62A, administered by AdvaMed. Experts from the United States made a considerable contribution to this standard.

ANSI/AAMI/IEC 60601-1-8:2013 was approved by the American National Standards Institute (ANSI) on 21 October 2013.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr. Suite 301, Arlington, VA 22203-1633.

NOTE—Beginning with the foreword on page ix, this American National Standard is identical to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/A1:2012.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 preparation. 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, access 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.

This consolidated version of IEC 60601-1-8 consists of the second edition (2006) [documents 62A/519/CDV and 62A/537A/RVC] and its amendment 1 (2012) [documents 62A/824/FDIS and 62A/837/RVD]. It bears the edition number 2.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

International standard IEC 60601-1-8 has been prepared by 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 SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

IEC 60601-1-8 constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereafter referred to as the general standard.

This edition of IEC 60601-1-8 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62 A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

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

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).

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

- Requirements and definitions: roman type.
- *Test specifications: italic type. In addition, in Annex A, text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.3.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

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

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The “color inside” logo on the cover page of this publication indicates that it contains colors that are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a color printer.

INTRODUCTION TO THE AMENDMENT

The second edition of IEC 60601-1-8 was published in 2006. Since its publication, an issue has been identified with respect to pulse and burst testing. In addition, issues have been raised by IEC/62D/MT 22, *Electromedical diagnostic and patient monitoring equipment*, during implementation of alarm system requirements in particular standards within their scope of work.

At the Brussels meeting, IEC/SC 62A accepted a proposal, based on ISO/TC 121/SC 3 Resolution Orebro 6, to develop the 1st amendment to IEC 60601-1-8:2006 to address the issues identified above. IEC/SC 62A – ISO/TC 121/SC 3 Joint Working Group 2, *Alarms*, was reactivated as a maintenance team to develop this amendment.

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 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 RESPONSIBLE ORGANIZATION. It is important that the RESPONSIBLE ORGANIZATION 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 basic safety
and essential performance –****Collateral Standard: General requirements, tests and guidance for alarm
systems in medical electrical equipment and medical electrical systems****1 * Scope, object and related standards****1.1 Scope**

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

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

It also provides guidance for the application of ALARM SYSTEMS.

1.2 Object

The object of this collateral standard is to specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME 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.

This collateral standard does not specify:

- whether any particular ME EQUIPMENT or ME 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.

1.3 Related standards**1.3.1 IEC 60601-1**

For ME EQUIPMENT and ME SYSTEMS, 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 (latest edition including any amendments);
- "this collateral standard" designates IEC 60601-1-8 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

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

2 Normative references

The following ~~referenced~~ documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the its~~ 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, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

~~IEC 60601-1-2:---²⁾, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests~~

~~IEC 60601-1-6:---³⁾, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability~~

~~IEC 60651:1979⁴⁾, Sound level meters
Amendment 1 (1993)
Amendment 2 (2000)~~

IEC 61672-1:2002, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

ISO 3744:~~1994~~ 2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering method in for an essentially free field over a reflecting plane*

²⁾ ~~A second edition of IEC 60601-1-2 exists, published in 2004 under the title Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests. A third edition under the title given above is currently to be published. References to IEC 60601-1-2 in this standard refer to the new edition.~~

³⁾ ~~A first edition of IEC 60601-1-6 exists, published in 2004 under the title Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability. A second edition under the title given above is currently to be published. References to IEC 60601-1-6 in this standard refer to the new edition.~~

⁴⁾ ~~IEC 60651:1979 has been withdrawn and replaced by IEC 61672-1:2002 and IEC 61672-2:2003. Future editions of this publication will be amended to take this fact into account.~~

ISO 7000, *Graphical symbols for use on equipment*—~~Index and synopsis.~~ Available from: <http://www.graphical-symbols.info/equipment>

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012 and IEC 62366:2007, ~~IEC 60601-1-2:—⁵⁾~~, ~~IEC 60601-1-6:—⁶⁾~~, and the following definitions apply.

NOTE 1 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 2 An index of defined terms is found beginning on page 86.

3.1

* ALARM CONDITION

state of the ALARM SYSTEM when it has determined that a potential or actual ~~HAZARD~~HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

3.2

* 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

3.3

* ALARM LIMIT

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

3.4

ALARM OFF

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

3.5

* ALARM PAUSED

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

3.6

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

3.7

ALARM RESET

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

⁵⁾ ~~To be published. See footnote 2.~~

⁶⁾ ~~To be published. See footnote 3.~~

3.8

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.

3.9

ALARM SIGNAL

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

3.10

*** ALARM SIGNAL GENERATION DELAY**

time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNAL(S)

3.11

ALARM SYSTEM

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

3.12

AUDIO OFF

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

3.13

AUDIO PAUSED

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

3.14

BURST

group of PULSES with a distinctive rhythm or pattern

3.15

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

3.16

DEFAULT ALARM PRESET

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

NOTE MANUFACTURER- or RESPONSIBLE ORGANIZATION-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

3.17

*** DISTRIBUTED ALARM SYSTEM**

ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM

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

3.18

ESCALATION

PROCESS by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

3.19

FALL TIME

t_f

interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 1)

3.20

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.

3.21

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.

3.22

HIGH PRIORITY

indicating that immediate OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

3.23

* INFORMATION SIGNAL

any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

3.24

* 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.

3.25

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 1)

3.26

LATCHING ALARM SIGNAL

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

3.27

LOW PRIORITY

indicating that OPERATOR awareness is required

NOTE The priority is assigned through RISK ANALYSIS.

3.28

MEDIUM PRIORITY

indicating that prompt OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

3.29

NON-LATCHING ALARM SIGNAL

ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

3.30

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.

3.31

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.

3.32

PULSE

brief continuous sound having a specific spectral content

3.33

PULSE FREQUENCY

f_o

fundamental frequency (first harmonic) of a PULSE

3.34

*** REMINDER SIGNAL**

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

3.35

RISE TIME

t_r

interval over which the PULSE increases from 10 % to 90 % of its maximum amplitude (see Figure 1)

3.36

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.

3.37

* ACKNOWLEDGED

state of an ALARM SYSTEM initiated by OPERATOR action, where the auditory ALARM SIGNAL associated with a currently active ALARM CONDITION is inactivated until the ALARM CONDITION no longer exists

NOTE 1 ACKNOWLEDGED only affects ALARM SIGNALS that are active at the time of the OPERATOR action.

NOTE 2 ACKNOWLEDGED can terminate after a predetermined time interval has elapsed.

4 General requirements

If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose. See also 12.3 of the general standard.

The RISK ASSESSMENT shall also consider HAZARDS to PATIENTS, OPERATORS, and other persons arising from the ALARM SYSTEM (see 6.8.3).

5 ME EQUIPMENT identification marking and documents

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 Annex B.

5.1 Indicator lights and controls

In addition to the requirements for colors of indicator lights and their meanings in 7.8.1 of the general standard, the requirements of 6.3.2.2 apply.

NOTE Dot matrix or other alphanumeric displays are not considered to be an alarm indicator light unless those displays are used to simulate an alarm indicator light (see 6.3.2.2).

5.2 ACCOMPANYING DOCUMENTS

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 B.2.

5.2.1 Instructions for use

The 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 B.3.

Compliance is checked by inspection of the instructions for use.

5.2.2 Technical description

NOTE Additional requirements on technical description are specified in this collateral standard, together with the technical requirements, giving rise to requirements on technical description. These requirements are also listed in Table B.4.

6 ALARM SYSTEMS

6.1 ALARM CONDITION

6.1.1 * General

If ALARM CONDITIONS are grouped into PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS or other ALARM CONDITION groups by the MANUFACTURER, this shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.1.2 * ~~ALARM CONDITION priority~~

~~ALARM CONDITIONS shall be assigned to one or more of the following priorities: HIGH PRIORITY, MEDIUM PRIORITY, or LOW PRIORITY. Unless a particular ALARM CONDITION priority is specified in a relevant particular standard, the assignment of priorities is part of the RISK MANAGEMENT PROCESS and shall be based on Table 1. The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.~~

~~Compliance is checked by inspection of the instructions for use and RISK MANAGEMENT FILE.~~

Table 1 — ALARM CONDITION priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM ^a		
	Immediate ^b	Prompt ^c	Delayed ^d
Death or irreversible injury	HIGH PRIORITY ^e	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY OF NO ALARM SIGNAL
An INFORMATION SIGNAL may also be used to indicate the potential for delayed minor injury or discomfort.			
^a—Onset of potential HARM refers to when an injury occurs and not to when it is manifested. ^b—Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action. ^c—Having the potential for the event to develop within a period of time usually sufficient for manual corrective action. ^d—Having the potential for the event to develop within an unspecified time greater than that given under “prompt”. ^e—Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.			

*** Determination of ALARM CONDITIONS and assignment of priority**

For each HAZARDOUS SITUATION where the MANUFACTURER has chosen to use an ALARM SYSTEM as a means of RISK CONTROL, the MANUFACTURER shall assign an ALARM CONDITION and its priority using Table 1.

For HAZARDOUS SITUATIONS where the onset of potential HARM is delayed and the potential result of a failure to respond is discomfort or minor reversible injury, the MANUFACTURER may determine that no ALARM CONDITION is required. In such cases, the MANUFACTURER may implement an INFORMATION SIGNAL.

NOTE Not all LOW PRIORITY ALARM CONDITIONS require prompt notification of the OPERATOR. On this basis an auditory ALARM SIGNAL or repeating auditory ALARM SIGNAL can be omitted, when appropriate, since the OPERATOR is expected to check the ME EQUIPMENT at intervals. In the event that the OPERATOR does not check the ME EQUIPMENT in a timely fashion, the ALARM CONDITION should escalate from LOW PRIORITY to MEDIUM PRIORITY or HIGH PRIORITY, and can additionally increase the sound pressure level of the related auditory ALARM SIGNALS, as appropriate.

The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.

Compliance is checked by inspection of the instructions for use and the RISK MANAGEMENT FILE.

Table 1 – Determination of ALARM CONDITIONS and assignment of priorities

<u>Potential result of failure to respond to the cause of ALARM CONDITION</u>	<u>Onset of potential HARM ^a</u>		
	<u>Immediate ^b</u>	<u>Prompt ^c</u>	<u>Delayed ^d</u>
<u>Death or irreversible injury</u>	<u>HIGH PRIORITY ALARM CONDITION ^e</u>	<u>HIGH PRIORITY ALARM CONDITION</u>	<u>MEDIUM PRIORITY ALARM CONDITION</u>
<u>Reversible injury</u>	<u>HIGH PRIORITY ALARM CONDITION</u>	<u>MEDIUM PRIORITY ALARM CONDITION</u>	<u>LOW PRIORITY ALARM CONDITION</u>
<u>Discomfort or reversible minor injury</u>	<u>MEDIUM PRIORITY ALARM CONDITION</u>	<u>LOW PRIORITY ALARM CONDITION</u>	<u>LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL</u>
^a <u>Onset of potential HARM refers to when an injury occurs and not to when it is manifested.</u> ^b <u>Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.</u> ^c <u>Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.</u> ^d <u>Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.</u> ^e <u>Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.</u>			

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

If an INTELLIGENT ALARM SYSTEM is provided, the instructions for use shall include, as applicable, an overview of how the ALARM SYSTEM:

- determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advanced processing (including, but not limited to, algorithms, neural networks, fuzzy logic, etc.);
- generates ALARM SIGNALS for two or more ALARM CONDITIONS of equal priority (including, but not limited to, internal ranking, effect on generation of ALARM SIGNALS);
- changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);
- changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and
- changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency).

Compliance is checked by inspection of the instructions for use.

6.3 Generation of ALARM SIGNALS

6.3.1 General

Each ALARM CONDITION shall cause the generation of visual ALARM SIGNALS as specified in this collateral standard. If deemed necessary by RISK ASSESSMENT regarding the environment in which the ALARM SYSTEM is intended to be used, additional ALARM SIGNALS shall be generated. These additional ALARM SIGNALS may be auditory, verbal, vibratory or produced by other means.

EXAMPLE ALARM SYSTEMS with HIGH or MEDIUM PRIORITY ALARM CONDITIONS that are intended not to be continuously attended by an OPERATOR in NORMAL USE should generate additional auditory ALARM SIGNALS.

Compliance is checked by inspection of the ALARM SYSTEM.

6.3.2 * Visual alarm signals

6.3.2.1 General

ALARM SYSTEMS shall generate visual ALARM SIGNALS to indicate the presence of ALARM CONDITIONS, their priority and each specific ALARM CONDITION.

6.3.2.2 * Characteristics of visual ALARM SIGNALS

6.3.2.2.1 * 4 m (distant) visual ALARM SIGNALS

If a visual indicator is necessary for the OPERATOR to identify the equipment or part of the equipment that requires OPERATOR response or awareness, at least one visual ALARM SIGNAL shall be provided that:

- a) indicates the priority of the highest priority ALARM CONDITION; and
- b) can be perceived correctly at a distance of 4 m from the ALARM SYSTEM.

If an alarm indicator light or graphical simulation of an indicator light is used for these purposes, it shall comply with the color and flashing requirements given in Table 2. ~~Alternatively, this indication may be generated by some other type of visual display or device.~~

ALARM SYSTEMS that do not contain HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITIONS are exempt from this requirement if their visual indication cannot be confused with a HIGH PRIORITY or MEDIUM PRIORITY alarm indicator light complying with Table 2.

NOTE 1 This visual indicator is necessary for ALARM SYSTEMS that are intended to be located in the proximity of other ALARM SYSTEMS.

NOTE 2 This visual indicator is not necessary for ALARM SYSTEMS that are worn, e.g., a paging receiver.

NOTE 3 An indicator light can be simulated, e.g. by a graphical display.

Table 2 – Characteristics of alarm indicator lights

Alarm category	Indicator color	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1.4 Hz to 2.8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0.4 Hz to 0.8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or yellow	Constant (on)	100 % on

6.3.2.2.2 1 m (OPERATOR'S POSITION) visual ALARM SIGNALS and INFORMATION SIGNALS

At least one visual ALARM SIGNAL that identifies the specific ALARM CONDITION and its priority shall be provided. This signal shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION. This visual indication may be text placed beside an indicator light or text on a display. The presence of an ALARM CONDITION may be visually indicated (marked) with symbol IEC 60417-5307 (2002-10) (see Symbol 1 of Table C.1). The priority may be indicated by adding one, two or three optional elements, (e.g., ! for LOW PRIORITY, !! for MEDIUM PRIORITY, and !!! for HIGH PRIORITY).

NOTE ~~4~~ 1 Factors affecting the legibility of a visual indication include the nature and characteristics of the visual indication itself, ambient lighting in the intended environment of use, and viewing angle and distance.

NOTE ~~5~~ 2 The use of text that flashes on and off is discouraged because it is often difficult to read. Flashing text that alternates between normal and reverse video or another color is acceptable.

NOTE ~~6~~ 3 Multiple-purpose computer-generated graphic displays should be designed in accordance with modern human interface design principles. Attention is drawn to ~~IEC 60601-1-6~~ IEC 62366.

NOTE ~~7~~ 4 The identification of the ALARM CONDITION is intended to convey information necessary for PATIENT safety and safe use of the equipment.

If multiple ALARM CONDITIONS occur at the same time, each individual ALARM CONDITION shall be visually indicated, either automatically or by OPERATOR action, unless an INTELLIGENT ALARM SYSTEM is provided that prevents a lower internal rank ALARM CONDITION from generating ALARM SIGNALS when a higher internal rank ALARM CONDITION is generating or has recently generated ALARM SIGNALS (see 6.2).

Visual INFORMATION SIGNALS, if provided, shall be correctly perceived as different from HIGH PRIORITY or MEDIUM PRIORITY visual ALARM SIGNALS at a distance of 1 m from the ALARM SYSTEM or from the OPERATOR'S POSITION.

NOTE 5 It is recognized that visual INFORMATION SIGNALS and visual ALARM SIGNALS can sometimes contain identical or similar information.

Compliance is checked by inspection of the visual ALARM SIGNAL under the following conditions:

- *the OPERATOR has a visual acuity of 0 on the logMAR [17] scale or 6-6 (20/20) vision (corrected if necessary),*
- *the viewpoint is at the OPERATOR'S POSITION or at any point within the base of a cone subtended by an angle of 30 ° to the axis horizontal to or normal to the center of the plane of display of the monitoring display or visual indication, and*
- *the ambient illuminance in the range [21] of 100 lx to 1 500 lx.*

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

~~An ALARM SYSTEM provided with auditory ALARM SIGNALS shall have at least one set of ALARM SIGNALS that:~~

- ~~a) is priority encoded and meets the requirements of Table 3 and Table 4; or~~
- ~~b) is generated by means of different technology (e.g., voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g., by clinical or simulated clinical USABILITY testing).~~

If an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

- a) all auditory ALARM SIGNALS shall be priority encoded;
- b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;
- c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;
- d) the ALARM SYSTEM shall have at least one set of ALARM SIGNALS that
 - meets the requirements of Table 3 and Table 4; or

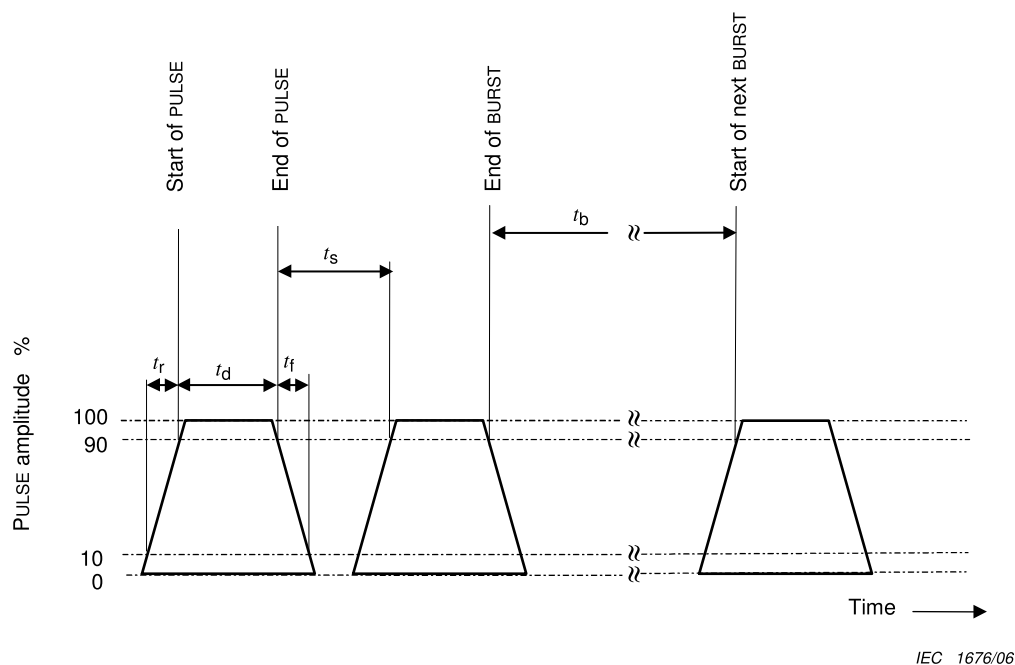
- [is generated by means of different technology \(e.g., voice synthesizing of verbal ALARM SIGNALS\) and is VALIDATED \(e.g., by clinical or simulated clinical USABILITY testing\).](#)

Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL ^d
Number of PULSES in BURST ^{a, e}	10	3	1 or 2
PULSE spacing (t_s) (see Figure 1)			
between 1 st and 2 nd PULSE	x	y	y
between 2 nd and 3 rd PULSE	x	y	Not applicable
between 3 rd and 4 th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4 th and 5 th PULSE	x	Not applicable	Not applicable
between 5 th and 6 th PULSE	0.35 s to 1.30 s	Not applicable	Not applicable
between 6 th and 7 th PULSE	x	Not applicable	Not applicable
between 7 th and 8 th PULSE	x	Not applicable	Not applicable
between 8 th and 9 th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9 th and 10 th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL ^{b, c} (t_b)	2.5 s to 15.0 s	2.5 s to 30.0 s	>15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB
Where: x shall be a value between 50 ms and 125 ms, y shall be a value between 125 ms and 250 ms, the variation of x and y within a BURST shall ~~be~~ not exceed $\pm 5\%$, and MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$. The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS, which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.			
^a See also Table 4 for characteristics of the PULSE. ^b Unless otherwise specified in a particular standard for a particular ME EQUIPMENT. ^c MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION. ^d The generation of the auditory component of a LOW PRIORITY ALARM CONDITION is optional. ^e Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.			

Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
PULSE FREQUENCY (f_0)	150 Hz to 1 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	Minimum of 4
Effective PULSE duration (t_d) HIGH PRIORITY MEDIUM and LOW PRIORITY	75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r)	10 % – ~~20~~ <u>40</u> % of t_d
FALL TIME ^a (t_f)	$t_f \leq t_s - t_r$
NOTE <u>1</u> The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.	
<u>NOTE 2 In practice, the RISE TIME should not be less than 10 ms to prevent mechanical speaker noise.</u>	
^a Prevents overlap of PULSES.	



NOTE Figure 1 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL.

Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS

If the ALARM SYSTEM is additionally provided with other sets of auditory ALARM SIGNALS, the following shall apply:

- ~~c) auditory ALARM SIGNALS shall be priority encoded;~~
- ~~d) HIGH PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set;~~

- ~~e) MEDIUM PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set;~~
- e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;
- f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and
- g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to ~~IEC 60601-1-6~~ [IEC 62366](#).

Any melody shall preclude the possibility of confusion with the auditory ALARM SIGNALS of Table 3, Table 4 and Annex F, unless their meaning is the same. If any of the melodies of Annex F is used to meet the requirements of Table 3 and Table 4, its meanings shall be as specified in Annex F.

When a TECHNICAL ALARM CONDITION that precludes the generation of the usual ALARM SIGNALS occurs, e.g. power or ALARM SYSTEM failure, the ALARM SYSTEM may generate an auditory ALARM SIGNAL that does not comply with the above requirements.

If selection of auditory ALARM SIGNAL sets is provided, means shall be provided for the RESPONSIBLE ORGANIZATION to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use (see 6.7).

Compliance is checked by inspection and functional testing of the ALARM SYSTEM and inspection of any relevant VALIDATION documentation. Measure the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument to cover the frequencies and the RISE and FALL TIMES of the waveform. Verify the values of x , y , t_b , t_r , t_s , t_f and t_d in Table 3 and Table 4. Alternatively, acoustic measurements in an anechoic chamber are permitted.

Acoustically verify the presence of (f_0) and at least 3 additional harmonics in the range of 150 Hz to 4 000 Hz in the auditory ALARM SIGNAL at 1 m or the intended OPERATOR'S POSITION.

6.3.3.2 * Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

The auditory HIGH PRIORITY and MEDIUM PRIORITY ALARM SIGNAL sound pressure level range, ~~as~~ measured in accordance with the method of this subclause shall be disclosed in the ~~instructions for use~~ ACCOMPANYING DOCUMENTS.

~~The sound pressure level of MEDIUM PRIORITY ALARM SIGNALS shall not exceed that of HIGH PRIORITY ALARM SIGNALS. If provided, the sound pressure level of LOW PRIORITY ALARM SIGNALS shall not exceed that of MEDIUM PRIORITY ALARM SIGNALS.~~

If auditory INFORMATION SIGNALS are provided, they shall be distinguishable from those of auditory ALARM SIGNALS and their characteristics shall be disclosed in the instructions for use.

NOTE Unless the sound pressure level of INFORMATION SIGNALS is independently adjustable, it should not exceed that of LOW PRIORITY ALARM SIGNALS.

Compliance is checked by inspection of the instructions for use and with the following test: