IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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 60601-1-8:2006-10+AMD1:2012-11+AMD2:2020-07 CSV(en)

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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

INTERNATIONAL
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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

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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1-8 edition 2.2 contains the second edition (2006-10) [documents 62A/519/CDV and 62A/537A/RVC], its amendment 1 (2012-11) [documents 62A/824/FDIS and 62A/837/RVD] and its amendment 2 (2020-07) [documents 62A/1392/FDIS and 62A/1407/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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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.

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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.

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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~~ origin 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.

INTRODUCTION to Amendment 1

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.

1) Figures in brackets refer to the bibliography.

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INTRODUCTION to Amendment 2

The second edition of IEC 60601-1-8 was published in 2006 and amended in 2012. Since the publication of IEC 60601-1-8:2006+A1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-8, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 20 items were presented to the National Committees present. All 20 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-8.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-8 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 2. JWG 2 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-8:2006, the style in force at the time of publication of IEC 60601-1-8 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

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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, including any amendments;
– "this standard" designates the combination of the general standard and this collateral standard.

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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
Amendment 2:2020

~~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 60651:1979[4], *Sound level meters*~~
~~Amendment 1 (1993)~~
~~Amendment 2 (2000)~~

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

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

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

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*

ISO 7000~~:1989~~, *Graphical symbols for use on equipment ~~– Index and synopsis~~*. Available from: <http://www.graphical-symbols.info/equipment>

~~[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.~~

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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.~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, 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 131.

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

3.8
ALARM SETTINGS
ALARM SYSTEM configuration, including but not limited to:

~~[5] To be published. See footnote 2.~~

~~[6] To be published. See footnote 3.~~

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– 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**
DAS
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate TECHNICAL ALARM CONDITIONS are created as described in 6.11.2.2.1.

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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~~ ALARM SYSTEM 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 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Immediate implies the interruption of current workflow is expected [59], [60].

3.23
*** INFORMATION SIGNAL**
any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

NOTE An ADVISORY is a type of INFORMATION SIGNAL.

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 and Figure G.1)

NOTE For the purposes of this document, when an AUDITORY ICON is used, the INTERBURST INTERVAL begins at the end of the AUDITORY ICON.

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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 and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Awareness implies the planning of future workflow is expected [59], [60].

3.28
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Prompt implies the re-planning of current workflow is expected [59], [60].

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

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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 or until a predetermined time interval has elapsed

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

3.38
*** ADVISORY**
ADVISORY SIGNAL
INFORMATION SIGNAL notifying the OPERATOR of a condition of the PATIENT or ME EQUIPMENT providing contextual awareness that is intended to improve the clinical workflow or understanding of the PATIENT condition, the awareness not being intended as a means of RISK CONTROL

NOTE 1 A notification that a lab result is available, where the lab result requires immediate clinical action is not an ADVISORY. It is an ALARM CONDITION.

NOTE 2 A signal associated with an ADVISORY, which is an INFORMATION SIGNAL, is required by this document to be designed so that an OPERATOR does not confuse it with an ALARM SIGNAL. See 6.3.2.2.2 and 6.3.3.2.

EXAMPLE 1 A notification that it is time to draw the next blood sample.

EXAMPLE 2 A battery status notification that replacement will be needed in a day.

EXAMPLE 3 A notification that it is time to bathe the PATIENT.

EXAMPLE 4 A notification that a lab result is available, where the lab results are normal.

3.39
*** ALARM FATIGUE**
situation wherein the presence of frequent ALARM SIGNALS desensitizes an OPERATOR to an ALARM SIGNAL

NOTE 1 A desensitized OPERATOR can fail to perceive, recognize or act on an ALARM SIGNAL.

NOTE 2 The response of a desensitized OPERATOR can be inadequate, delayed or non-existent.

NOTE 3 ALARM FLOOD can cause ALARM FATIGUE.

3.40
ALARM FLOOD
situation wherein OPERATORS receive more ALARM SIGNALS in a time period than they can manage appropriately

NOTE See [56], [57].

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3.41
*** ALERT**
synonym for the combination of PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS and ADVISORIES

[SOURCE: ISO/IEEE 11073-10201:2020 [76], 3.3, modified – Replaced "alarms" with "ALARM CONDITIONS", "equipment-user advisory signals" with "ADVISORIES" and deleted "patient related".]

3.42
AUDITORY ICON
sound that creates a strong semantic link to the category it represents

NOTE 1 An AUDITORY ICON is typically a real-world sound or mimics a real-world sound.

NOTE 2 An AUDITORY ICON can aid in locating the COMMUNICATOR and the SOURCE type.

3.43
AUDITORY POINTER
sound that attracts attention, denotes the priority and aids in localization of the COMMUNICATOR

3.44
*** CLINICALLY ACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is necessary to prevent HARM within the timeframe implied by the priority communicated by the ALARM SYSTEM

NOTE 1 An OPERATOR action can include assessment of a PATIENT or the changing of ALARM LIMITS when they are inappropriately set for the state of the PATIENT.

NOTE 2 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 3 A FALSE POSITIVE ALARM CONDITION is never considered CLINICALLY ACTIONABLE even though an unrelated OPERATOR action might be required to prevent a future FALSE POSITIVE ALARM CONDITION.

NOTE 4 A CLINICALLY ACTIONABLE ALARM CONDITION is generally considered useful by the OPERATOR.

3.45
*** CLINICALLY NONACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is not expected within a timeframe equal to or shorter than the timeframe implied by its priority

NOTE 1 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 2 CLINICALLY NONACTIONABLE ALARM CONDITIONS are considered detrimental to OPERATOR performance and PATIENT safety.

NOTE 3 ALARM SIGNALS for an ALARM CONDITION of which the OPERATOR is already aware are considered CLINICALLY NONACTIONABLE.

3.46
COMMUNICATOR
COM
ANNUNCIATOR
function of the ALARM SYSTEM that generates ALARM SIGNALS to notify an OPERATOR (e.g. to the presence of an ALARM CONDITION)

NOTE 1 A COMMUNICATOR can receive an OPERATOR response.

NOTE 2 An OPERATOR response is not limited to direct OPERATOR action.

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NOTE 3 See Figure 2.

3.47
DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION
CDAS
DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

3.48
*** DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS**
DIS
system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS.

3.49
INTEGRATOR
INT
ALARM MANAGER
function of the ALARM SYSTEM that distributes ALARM CONDITIONS, combines ALARM CONDITIONS from SOURCES or handles the communication between those SOURCES and COMMUNICATORS

NOTE 1 An INTEGRATOR can direct or redirect an ALARM CONDITION to another COMMUNICATOR and hence OPERATOR.

NOTE 2 An INTEGRATOR can send the acceptance of responsibility from a COMMUNICATOR to a SOURCE.

NOTE 3 See Figure 2.

3.50
*** NUISANCE ALARM SIGNAL**
ALARM SIGNAL for which a panel of experts would agree that the HARM associated with the ALARM SIGNAL is greater than the benefit associated with action resulting from the ALARM SIGNAL

NOTE 1 A NUISANCE ALARM SIGNAL contributes to ALARM FATIGUE.

NOTE 2 A NUISANCE ALARM SIGNAL can arise from a FALSE POSITIVE ALARM CONDITION.

NOTE 3 A NUISANCE ALARM SIGNAL can arise from a CLINICALLY NONACTIONABLE ALARM CONDITION.

NOTE 4 A NUISANCE ALARM SIGNAL can cause an inappropriate OPERATOR action.

EXAMPLE Causing the OPERATOR to set ALARM LIMITS to inappropriate settings.

NOTE 5 An ALARM SIGNAL that unnecessarily irritates or startles the PATIENT or OPERATOR can be a NUISANCE ALARM SIGNAL.

3.51
REDIRECTION
means by which an INTEGRATOR provides a response hierarchy for directing an ALARM CONDITION to a COMMUNICATOR or transfers an ALARM CONDITION to another COMMUNICATOR

NOTE See Figure 2.

3.52
RESPONSIBILITY ACCEPTED
state created by an OPERATOR response accepting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY ACCEPTED can be used to initiate an ALARM SIGNAL inactivation state.

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NOTE 2 See Figure 2.

3.53
RESPONSIBILITY REJECTED
state created by an OPERATOR response rejecting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY REJECTED can be used to initiate an ESCALATION or REDIRECTION.

NOTE 2 See Figure 2.

3.54
RESPONSIBILITY UNDEFINED
state, automatically initiated when neither a RESPONSIBILITY ACCEPTED nor RESPONSIBILITY REJECTED is received within a specified period, which indicates that an OPERATOR is not responding

NOTE 1 RESPONSIBILITY UNDEFINED is not used as an indication that the COMMUNICATOR and INTEGRATOR cannot communicate.

NOTE 2 See Figure 2.

3.55
SOURCE
SRC
function that has the capability to initiate an ALARM CONDITION

NOTE 1 The SOURCE transfers the ALARM CONDITION to the INTEGRATOR.

NOTE 2 See Figure 2.

3.56
TRUE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

3.57
TRUE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

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 colours of indicator lights and their meanings in 7.8.1 of the general standard, the requirements of 6.3.2.2 apply.

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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 lights (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~~ Determination of ALARM CONDITIONS and assignment of 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.~~

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.

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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 RISK MANAGEMENT FILE.

Table 1 – Determination of ALARM CONDITION and assignment of 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 or 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.~~

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 ALARM CONDITION [e]	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL

[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.

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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:

a) 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.);

b) 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);

c) changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);

d) changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and

e) changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency, AUDITORY ICON category).

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 by a COMMUNICATOR 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 colour 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.

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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 colour	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 ofan 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 colour 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 62366-1.

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. When they are intended to convey different meanings, care needs to be taken to ensure that visual ALARM SIGNALS cannot be confused with visual INFORMATION SIGNALS.

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 centre 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:~~

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~~a) is priority encoded and meets the requirements of Table 3 and Table 4; or~~

~~a) 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 a COMMUNICATOR of 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 of that COMMUNICATOR 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 of that COMMUNICATOR 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 COMMUNICATOR shall have at least one set of ALARM SIGNALS that:

1) complies with Annex G; or

i) * A COMMUNICATOR with means to provide more than one set of auditory ALARM SIGNALS should be equipped with at least one set of auditory ALARM SIGNALS that complies with Annex G.

2) * 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); or

3) * meets the requirements of Table 3 and Table 4.

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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 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th 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 t_d, x and y within a BURST shall ~~be~~ not exceed ± ~~5~~ 20 %, 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~~ origin 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.

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

~~Characteristic~~	~~Value~~
~~PULSE FREQUENCY (f_o)~~	~~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 % of t_d~~
~~FALL TIME[a] (t_f)~~	~~$t_f \leq t_o - t_r$~~
~~NOTE The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.~~	
~~[a] Prevents overlap of PULSES.~~	

Characteristic	Value
Frequency component in the range of 150 Hz to 1 000 Hz	At least one that is among the four frequency components with the largest sound pressure level
Number of peaks in the frequency range of 150 Hz to 4 000Hz	At least four peaks in the frequency domain
Effective PULSE duration (t_d) (see Figure 1) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r) (see Figure 1)	[a]
FALL TIME (t_f) (see Figure 1)	[b]
Within the frequency range of 150 Hz to 4 000 Hz, the relative sound pressure levels of the four frequency components with the largest sound pressure levels should be within 15 dB of each other. NOTE Care is needed to ensure that the MEDIUM PRIORITY ALARM SIGNAL cannot be confused with the audible emergency evacuation signal specified in ISO 8201:2017 [30]. [a] The RISE TIME should not be so short as to create mechanical speaker noise. [b] The FALL TIME should be short enough to ensure that the PULSES do not overlap.	

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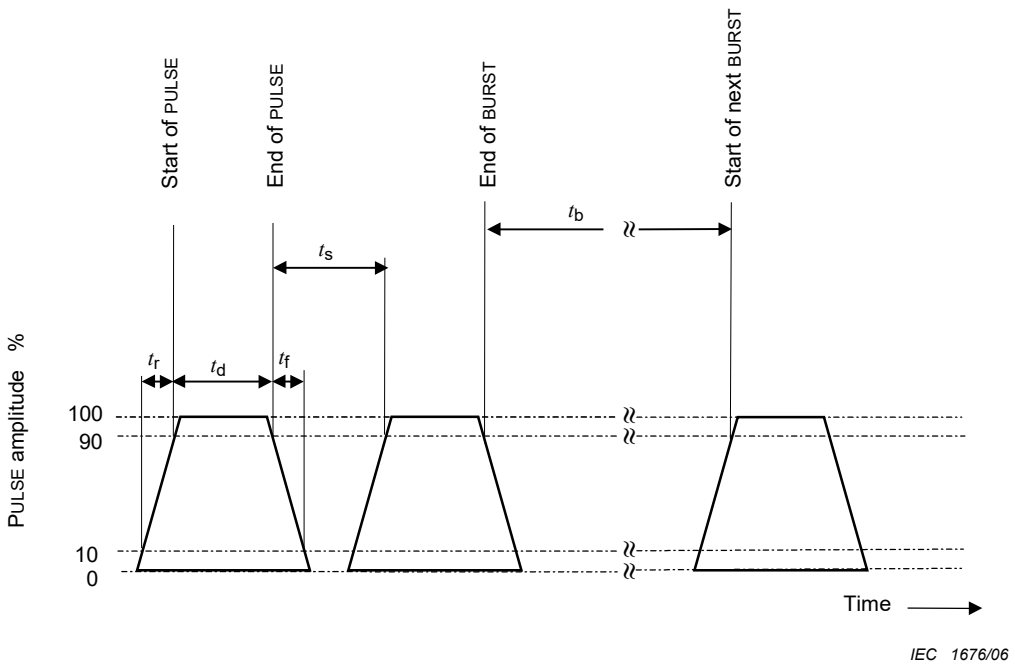

NOTE 1 Figure 1 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL.

NOTE 2 See Figure G.1 and Figure G.2 for additional information.

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;~~

~~f~~e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;

~~g~~f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and

~~h~~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 62366-1.

~~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.

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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. Confirm the values of x, y, t_b, t_s, t_f and t_d in Table 3 and Table 4. When the sound files of Annex G are utilized, only testing of t_b is required and testing of the acoustic signal is permitted.

Amongst the required frequency components with the largest sound pressure levels, acoustically confirm the presence of at least one frequency component in range of 150 Hz to 1 000 Hz and at least the required components in the range of 150 Hz to 4 000 Hz in the auditory ALARM SIGNAL at 1 m or the intended OPERATOR's POSITION. Only the AUDITORY POINTERS need be tested when evaluating the ALARM SIGNALS of Annex G.

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 and measurement radius~~, 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:

- ~~*Place a microphone of a sound level meter complying with the requirements for a type 1 instrument as specified in IEC 60651 at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the front of the part of the equipment that contains the auditory ALARM SIGNAL generating device at a radius of 1 m or at the OPERATOR'S POSITION. Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter. The indicated sound pressure level when measuring BURSTS is corrected in accordance with Clause 7 of IEC 60651:2001 or a test PULSE of continuous duration is used for purposes of the measurement. Take measurements in a free field over a reflecting plane as specified in ISO 3744. The A-weighted background level of extraneous noise, including any INFORMATION SIGNALS, is to be at least 10 dB below that measured during the test.*~~
- ~~*Simulate a HIGH PRIORITY ALARM CONDITION.*~~
- ~~*Measure the sound pressure level.*~~
- ~~*Repeat above with MEDIUM and LOW PRIORITY ALARM CONDITIONS.*~~
- ~~*Confirm that the HIGH PRIORITY ALARM SIGNAL sound pressure level ≥ MEDIUM PRIORITY ALARM SIGNAL sound pressure level ≥ LOW PRIORITY ALARM SIGNAL sound pressure level.*~~

a) Set the ALARM SIGNAL sound pressure level (volume level) to its maximum setting.

b) If the ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION, simulate a HIGH PRIORITY ALARM CONDITION.

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c) Place the equipment containing the COMMUNICATOR on the floor and use a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at least at positions 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10, as specified in Figure B.1 and Table B.1 of ISO 3744:2010, in a hemisphere with a radius of 1 m from the geometric centre of the COMMUNICATOR. For a large COMMUNICATOR, where d_O, as calculated in Figure 1 a) of ISO 3744:2010, is greater than 0,5 m, utilize a radius such that the distance from the surface of the COMMUNICATOR to the hemisphere is at least 0,5 m everywhere, extended to the next higher value in the series 1,5 m, 2 m, 2,5 m, 3 m, 3,5 m, 4 m.

d) Measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}).

e) For ALARM SIGNALS utilizing AUDITORY POINTERS complying with Annex G, confirm that the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument is not clipped.

f) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

g) If the ALARM SYSTEM is provided with a MEDIUM PRIORITY ALARM CONDITION, simulate a MEDIUM PRIORITY ALARM CONDITION and repeat c) to f).

h) If the ALARM SYSTEM is provided with a LOW PRIORITY ALARM CONDITION, simulate a LOW PRIORITY ALARM CONDITION and repeat c) to f).

i) Set the ALARM SIGNAL sound pressure level (volume level) to its minimum setting.

j) Repeat b) to h).

k) Confirm that the criteria for background noise, including any INFORMATION SIGNALS, specified in 4.2 of ISO 3744:2010 are fulfilled.

l) Confirm that the measured sound pressure level range is in compliance with the values indicated in the ACCOMPANYING DOCUMENTS.

6.3.3.3 * OPERATOR-adjustable sound pressure level

If an ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION and an OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, the instructions for use shall include a warning to the effect that auditory alarm signal sound pressure levels that are less than ambient levels can impede OPERATOR recognition of ALARM CONDITIONS and the ALARM SYSTEM shall:

a) provide a restricted means for the RESPONSIBLE ORGANIZATION to configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level (see 6.7); or

b) provide a visual indication that the current sound pressure level might be inaudible when the auditory ALARM SIGNAL sound pressure level is below a threshold that is configured:

   – by a means restricted to the RESPONSIBLE ORGANIZATION (see 6.7); or

   – by the MANUFACTURER.

   This condition may be visually indicated (marked) with symbol IEC 60417-5576 (2002-11) (see Symbol 5 of Table C.1). If this symbol is used as that visual indication, an INFORMATION SIGNAL or other additional visual indication may be provided to distinguish this state from AUDIO OFF.

An ALARM SYSTEM may be equipped with a dynamically algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7) to enable and disable the algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the instructions for use shall describe the algorithm and the minimum and maximum levels.

EXAMPLE 1 An algorithm that sets the minimum auditory ALARM SIGNAL sound pressure level in response to current ambient sound pressure levels, time of day, evidence of OPERATOR attendance or other variables.

EXAMPLE 2 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time.

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Compliance is checked by inspection.

6.3.4 * Characteristics of verbal ALARM SIGNALS

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with verbal ALARM SIGNALS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

6.4 * Disclosure of delays

6.4.1 * ALARM SYSTEM delays

If the sum of the maximum ALARM CONDITION DELAY plus the maximum ALARM SIGNAL GENERATION DELAY is greater than 10 s, then the statistics of each distribution or statistics of the distribution of the sum shall be disclosed in the instructions for use.

If the sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is greater than 5 s, then each delay or their sum shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.4.2 * Delays to or from a DISTRIBUTED ~~ALARM SYSTEM~~ INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)

~~If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DISTRIBUTED ALARM SYSTEM:~~

~~a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and~~

~~b) the maximum remote ALARM SIGNAL GENERATION DELAY or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2 item 6.11.2.2.1 b)) shall be disclosed in the instructions for use.~~

~~For a DISTRIBUTED ALARM SYSTEM, the ALARM SIGNAL GENERATION DELAY may be measured and reported, as applicable:~~

~~c) from the onset of the ALARM CONDITION;~~

~~d) from the time of the local ALARM SIGNAL generation;~~

~~e) to or from the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART;~~

~~f) to or from the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART; or~~

~~g) to the time of the remote ALARM SIGNAL generation.~~

~~*Compliance is checked by functional testing and inspection of the instructions for use.*~~

If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DIS or DAS:

a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and

b) the maximum ALARM SIGNAL GENERATION DELAY of the COMMUNICATOR, including the method used to determine the maximum ALARM SIGNAL GENERATION DELAY, or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2.1 b)) shall be disclosed in the instructions for use.

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The following methods may be used to determine the ALARM SIGNAL GENERATION DELAY contribution for each component of a DIS or DAS, as applicable:

c) from:

1) the onset of the ALARM CONDITION;

2) the time of the ALARM SIGNAL generation at the SOURCE;

3) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR; or

4) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR;

d) to:

1) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR;

2) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR; or

3) the time of the ALARM SIGNAL generation at the COMMUNICATOR.

Compliance is checked by functional testing under maximum load conditions of NORMAL USE and inspection of the instructions for use.

6.5 ALARM PRESETS

6.5.1 * General requirements

Any ALARM PRESET that uses mechanical adjustment is exempt from the requirements of 6.5.

Example 1 A switch that indicates the value of a set point.

An ALARM SYSTEM is exempt from the requirements of 6.5 if in NORMAL USE it:

a) can only retain current ALARM SETTINGS, and

b) does not otherwise provide ALARM PRESETS, and

c) displays each adjustable ALARM SETTINGS continuously.

EXAMPLE 2 A simple monitor that always initializes with the previous ALARM LIMIT and that limit is continuously displayed.

ALARM PRESETS shall include the ALARM LIMIT used to trigger each ALARM CONDITION and its priority, or they shall be determined from information available to the ALARM SYSTEM concerning the current PATIENT. ALARM PRESETS may include other parameters that affect or modify performance of the ALARM SYSTEM.

EXAMPLE 3 An ALARM LIMIT calculated from entered data, e.g. PATIENT weight and gender.

EXAMPLE 4 An ALARM LIMIT calculated from current physiological status of the PATIENT, e.g. 1,2 times the current heart rate.

The instructions for use shall contain a warning statement to the effect that a HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.2 MANUFACTURER-configured ALARM PRESETS

An ALARM SYSTEM shall be provided with at least one MANUFACTURER-configured ALARM PRESET.

The ALARM LIMITS and a summary of any algorithms used in any MANUFACTURER-configured ALARM PRESETS shall be disclosed in the instructions for use.

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Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.3 * RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

6.5.3.1 ALARM SYSTEMS with one ALARM PRESET

If the ALARM SYSTEM can store only one ALARM PRESET:

a) means shall be provided to prevent the OPERATOR from saving changes to this ALARM PRESET. Saving changes to this ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the ALARM PRESET to its MANUFACTURER-configured state.

Compliance is checked by inspection.

6.5.3.2 ALARM SYSTEMS with more than one ALARM PRESET

If the ALARM SYSTEM provides means to store or activate one or more RESPONSIBLE ORGANIZATION-configured or OPERATOR-configured ALARM PRESETS in addition to any MANUFACTURER-configured ALARM PRESETS:

a) means shall be provided for the OPERATOR to choose between the available ALARM PRESETS;

b) means shall be provided for the OPERATOR to readily identify which ALARM PRESET is in use;

c) the instructions for use shall contain a warning statement to the effect that the OPERATOR should check that the current ALARM PRESET is appropriate prior to use on each PATIENT;

d) the means for configuration and storage of ALARM PRESETS shall be disclosed in the ACCOMPANYING DOCUMENTS;

e) means shall be provided to prevent the OPERATOR from saving changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET. Saving changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

f) means shall be provided to prevent an individual OPERATOR from saving changes to ALARM PRESETS that were stored by any other OPERATOR (see 6.7); and

g) the ALARM SYSTEM may store the current ALARM SETTINGS for later recall.

EXAMPLE Temporary storage can permit a return to ALARM SETTINGS that were in use prior to choosing an ALARM PRESET.

Compliance is checked by inspection.

6.5.4 DEFAULT ALARM PRESET

6.5.4.1 General requirements

If the DEFAULT ALARM PRESET can be set to values that differ from the MANUFACTURER-configured values:

a) means shall be provided to prevent any OPERATOR from storing changes to the DEFAULT ALARM PRESET. Storing changes to the DEFAULT ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the DEFAULT ALARM PRESET to its MANUFACTURER-configured values.

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6.5.4.2 * Selection of DEFAULT ALARM PRESET

Whenever:

a) the OPERATOR switches the ALARM SYSTEM on after an interval specified by the MANUFACTURER as being longer than might be considered unintentional; or

b) the ALARM SYSTEM is enabled; or

c) the OPERATOR indicates to the ALARM SYSTEM, preferably through an "admit new PATIENT" function, that a different PATIENT has been connected to the ALARM SYSTEM; or

d) power is restored to the ALARM SYSTEM after it has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) beyond the time that it automatically restores the ALARM SETTINGS (see 6.5.5);

then:

e) the DEFAULT ALARM PRESET shall be automatically selected; or

f) means shall be provided for the OPERATOR to select an ALARM PRESET; or

g) means may be provided for the OPERATOR to select the retained ALARM SETTINGS from the previous use.

NOTE Care is needed to ensure that the OPERATOR is aware of which previously retained ALARM SETTINGS are being restored when the OPERATOR selects the retained ALARM SETTINGS.

The MANUFACTURER shall disclose in the instructions for use an estimate of the duration of the power interruption after which the ALARM SYSTEM is unable to restore the ALARM SETTINGS and the subsequent behaviour of the ALARM SYSTEM.

Compliance is checked by observing the equipment's ALARM SETTINGS, then temporarily disconnecting the power ~~source~~ for a period exceeding that indicated in the instructions for use and then inspecting the state of the ALARM SETTINGS. The mains switch, if provided, shall remain in the 'on' position during this test. Inspect the ALARM SETTINGS and compare them to the appropriate behaviour.

6.5.5 * Interruptions of less than or equal to 30 s

When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss shall be restored automatically. This behaviour shall be described in the instructions for use.

NOTE Power refers to external SUPPLY MAINS, any INTERNAL ELECTRICAL POWER SOURCE exchangeable in NORMAL USE, or external batteries.

Compliance is checked by observing the ALARM SYSTEM'S operating mode and ALARM LIMIT(S), then temporarily disconnecting the power ~~source~~ for 30 s – 3 s + 0 s. Then after power is restored, compare the ALARM SETTINGS with those preceding the disconnection. The mains switch, if provided, shall remain in the "on" position during this test.

6.6 ALARM LIMIT

6.6.1 General requirements

An ALARM LIMIT may be non-adjustable, a simple OPERATOR-adjustable setpoint or an algorithmically determined criterion.

Compliance is checked by inspection.

6.6.2 * Adjustable ALARM LIMIT

6.6.2.1 Indication of OPERATOR-adjustable ALARM LIMIT

If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action. The means of control to display the ALARM LIMITS may be

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visually indicated (marked) with symbol IEC 60417-5649 (2002-10) (see symbol 10 of Table C.1), IEC 60417-5650 (2002-10) (see symbol 11 of Table C.1) or IEC 60417-5651 (2002-10) (see symbol 12 of Table C.1), as appropriate.

Compliance is checked by inspection.

6.6.2.2 * Indication of automatically set ALARM LIMIT

An ALARM LIMIT may be automatically set, with or without OPERATOR action, to ranges or percentages above or below:

a) the value of a monitored variable at a point in time; or

b) recent values of a monitored variable; or

c) a current control setting.

If such an automatically set ALARM LIMIT is provided, its value shall be indicated continuously or by OPERATOR action, unless:

d) this ALARM LIMIT is obvious from the associated control setting and the behaviour is described in the instructions for use; or

e) the ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM (see 6.2).

Compliance is checked by functional testing and inspection of the instructions for use.

6.6.2.3 * ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

During adjustment of any ALARM LIMIT or OPERATOR-adjustable ALARM PRESET, the ALARM SYSTEM shall continue to operate normally.

Compliance is checked by functional testing.

6.7 * ALARM SYSTEM security

Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 6.3.3.1, 6.3.3.3, 6.5.3.1, 6.5.3.2, 6.5.4.1, 6.8.2 b) and c), 6.8.3 b), 6.8.5, 6.10, 6.11.2.2.1 and 6.12.3):

EXAMPLE 1 Access controlled by a tool.

EXAMPLE 2 Access controlled by RESPONSIBLE ORGANIZATION password and a technical description that is separate from the instructions for use.

EXAMPLE 3 Access controlled by individual OPERATOR password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed, e.g., one for the RESPONSIBLE ORGANIZATION and one for each OPERATOR.

Compliance is checked by inspection of the technical documentation.

6.8 * ALARM SIGNAL inactivation states

6.8.1 * General

Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF, AUDIO

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OFF) or indeterminate (indefinite ACKNOWLEDGED) or timed (i.e., ALARM PAUSED, AUDIO PAUSED or timed ACKNOWLEDGED). ~~Flashing visual ALARM SIGNALS specified in 6.3.2.2 may be inactivated by AUDIO PAUSED or AUDIO OFF.~~

Means shall be provided for the OPERATOR to determine the ALARM CONDITIONS for which ALARM SIGNALS are inactivated.

NOTE 1 A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 ~~The ALARM SIGNALS of all currently active ALARM CONDITIONS.~~ An ALARM SYSTEM that has not received valid data since it was enabled (e.g. after power-up or before a PATIENT has been connected).

NOTE 2 Additional requirements regarding global ALARM OFF or AUDIO OFF are found in 6.8.3.

If ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, the generation of ALARM SIGNALS from other ALARM CONDITIONS shall be unaffected.

During the ALARM OFF or ALARM PAUSED ALARM SIGNAL inactivation states, the ALARM SYSTEM may discontinue the processing of signals used to generate the inactivated ALARM CONDITIONS.

NOTE 3 If the ALARM SYSTEM discontinues the processing of a signal used to generate an ALARM CONDITION, the ALARM SYSTEM log cannot log that ALARM CONDITION.

AUDIO PAUSED or AUDIO OFF shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

AUDIO PAUSED or AUDIO OFF may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1 or may cause DE-ESCALATION of the ALARM CONDITION priority.

NOTE 4 An INTELLIGENT ALARM SYSTEM can use the OPERATOR'S activation of AUDIO PAUSED or AUDIO OFF to cause DE-ESCALATION or to re-evaluate the need for an ALARM CONDITION.

ACKNOWLEDGED, if provided, shall inactivate the auditory ALARM SIGNALS of currently active ALARM CONDITIONS and shall not affect the ALARM SIGNALS of inactive ALARM CONDITIONS. ACKNOWLEDGED shall terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists. See also 6.8.4.

A timed ACKNOWLEDGED shall terminate after a defined duration. An indefinite ACKNOWLEDGED shall not terminate after a defined duration.

ACKNOWLEDGED shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

ACKNOWLEDGED may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1.

ACKNOWLEDGED may cause the DE-ESCALATION of the ALARM CONDITION priority, including DE-ESCALATION of the ALARM SIGNALS of a LOW PRIORITY ALARM CONDITION into an INFORMATION SIGNAL.

Compliance is checked by inspection and functional testing.

6.8.2 * REMINDER SIGNALS

The ALARM SYSTEM may be provided with a REMINDER SIGNAL. If an ALARM SYSTEM is provided with a REMINDER SIGNAL:

a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use;

b) the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):

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- to enable and disable the REMINDER SIGNAL; and
- to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.

c) the ALARM SYSTEM may include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):

- to permit designated (see 6.7) OPERATORS to enable and disable the REMINDER SIGNAL;
- to permit any OPERATOR to enable and disable the REMINDER SIGNAL.

Compliance is checked by inspection.

6.8.3 * Global indefinite ALARM SIGNAL inactivation states

If deemed acceptable by RISK ASSESSMENT with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with:

a) a REMINDER SIGNAL; and

b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the RESPONSIBLE ORGANIZATION and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 6.7).

NOTE 1 ~~A global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state affects all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM with multiple PHYSIOLOGICAL ALARM CONDITIONS.~~ For the purposes of this standard, a global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state can affect all ALARM CONDITIONS or all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM.

NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.

Compliance is checked by inspection.

6.8.4 * Termination of inactivation of ALARM SIGNALS

Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state.

An ALARM SIGNAL inactivation state may terminate automatically, ~~when the ALARM CONDITION that was generating an ALARM SIGNAL when this state was entered, ceases~~ ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists.

EXAMPLE 1 A non-latching PHYSIOLOGICAL ALARM CONDITION automatically terminates when the monitored parameter returns within its ALARM LIMITS.

EXAMPLE 2 When an ALARM CONDITION has been ACKNOWLEDGED, the resulting state automatically terminates when the underlying ALARM CONDITION no longer exists.

When an ALARM SIGNAL inactivation state is terminated, ~~the ALARM SIGNALS of any current ALARM CONDITION shall cause the re-generation of ALARM SIGNALS~~ the ALARM SYSTEM shall re-evaluate the need for ALARM CONDITIONS and generate ALARM SIGNALS if appropriate.

Compliance is checked by functional testing.

6.8.5 * Indication and access

The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, ALARM OFF and ACKNOWLEDGED shall be visually indicated (marked) with the appropriate symbol referenced in Table 5. This indication 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.

The means of control used to enter one of the ALARM SIGNAL inactivation states may be marked with a symbol referenced in Table 5. If a symbol that is referenced in Table 5 is used, it shall initiate the associated ALARM SIGNAL inactivation state.

The duration of AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED, if provided, shall be disclosed in the instructions for use.

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If the AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED interval is OPERATOR adjustable, means to adjust the maximum interval shall only be provided to the RESPONSIBLE ORGANIZATION (see 6.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.

Compliance is checked by inspection.

Table 5 – ALARM SIGNAL inactivation states

~~State~~	~~Duration~~	~~Visual indication (marking) of state (mandatory) (row of symbol in Table C.1)~~	~~Marking of controls (optional)~~	
			~~(row of symbol in Table C.1)~~	~~(row of marking in Table C.2)~~
~~AUDIO PAUSED~~	~~Time limited~~	~~6~~	~~6~~	~~1~~
~~ALARM PAUSED~~	~~Time limited~~	~~4 or (4 and 6)~~	~~4~~	~~2~~
~~AUDIO OFF~~	~~Indefinite~~	~~5~~	~~5~~	~~3~~
~~ALARM OFF~~	~~Indefinite~~	~~3 or (3 and 5)~~	~~3~~	~~4~~

ALARM SIGNAL inactivation state	**Usual termination event**	**Visual indication (marking) of state (mandatory) (row of symbol in Table C.1)**	**Marking of controls (optional)**	
			(row of symbol in Table C.1)	**(row of marking in Table C.2)**
AUDIO PAUSED	Time interval elapsed	6	6	1
ALARM PAUSED	Time interval elapsed	4 or (4 and 6)	4	2
AUDIO OFF	OPERATOR action	5	5	3
ALARM OFF	OPERATOR action	3 or (3 and 5)	3	4
Indefinite ACKNOWLEDGED	ALARM CONDITION no longer exists	5 or 8 or 14	7 or 13 or 8 or 14	6
Timed ACKNOWLEDGED	ALARM CONDITION no longer exists or time interval elapsed	6 or 9 or 15	7 or 13 or 9 or 15	7

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6.9 * ALARM RESET

The means of ALARM RESET may be marked with symbol IEC 60417-5309 (DB-2002-10) (see symbol 2 of Table C.1) or marking 5 of Table C.2.

Compliance is checked by inspection.

6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

A NON-LATCHING ALARM SIGNAL shall automatically cease being generated when its triggering event no longer exists. A LATCHING ALARM SIGNAL shall continue to be generated after its triggering event no longer exists. An ALARM SYSTEM may consist of a mixture of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS.

NOTE 1 An INTELLIGENT ALARM SYSTEM can decrease the priority of a LATCHING ALARM SIGNAL.

In the case of an ALARM CONDITION of short duration, a MEDIUM PRIORITY auditory ALARM SIGNAL shall complete at least one full BURST and a HIGH PRIORITY auditory ALARM SIGNAL shall complete one half of one full BURST, unless inactivated by the OPERATOR.

NOTE 2 If the ALARM CONDITION clears quickly, the OPERATOR might be unable to discover what event triggered the ALARM CONDITION. Alternatives include:

– a visual ALARM SIGNAL that indicates the specific ALARM CONDITION and which continues to be generated for a limited period of time (e.g., 30 s) after the ALARM CONDITION has cleared;
– an ALARM CONDITION log that the OPERATOR can view, print, or record;
– an ALARM CONDITION trend that the OPERATOR can view, print, or record.

Auditory ALARM SIGNALS shall cease being generated when:

a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF state; or
b) an OPERATOR has ALARM RESET the ALARM CONDITION.

Means shall be provided to prevent the OPERATORS from selecting between LATCHING and NON-LATCHING ALARM SIGNALS. The selection between LATCHING and NON-LATCHING ALARM SIGNALS shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7).

Compliance is checked by functional testing.

6.11 * DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS

~~6.11.1 * Existence of DISTRIBUTED ALARM SYSTEM~~

~~The details necessary for the safe use of a DISTRIBUTED ALARM SYSTEM shall be disclosed in the technical description. A DISTRIBUTED ALARM SYSTEM is a permitted form of an ALARM SYSTEM.~~

~~An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DISTRIBUTED ALARM SYSTEM. A DISTRIBUTED ALARM SYSTEM is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DISTRIBUTED ALARM SYSTEM are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DISTRIBUTED ALARM SYSTEM by wire, by telemetry or by other means.~~

~~EXAMPLE 1 A central station.~~

~~EXAMPLE 2 An electronic record-keeping device.~~

~~EXAMPLE 3 Remote viewing from home or office.~~

~~EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).~~

~~EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell-phones, hand-held computers, etc.~~

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~~*Compliance is checked by inspection of the technical description.*~~

~~6.11.2 Requirements for DISTRIBUTED ALARM SYSTEM communication of ALARM CONDITIONS~~

~~6.11.2.1 Source and identification of ALARM CONDITIONS~~

~~In a DISTRIBUTED ALARM SYSTEM, means shall be provided to identify the source of the remote ALARM CONDITION at every site of ALARM SIGNAL generation.~~

~~NOTE ALARM SIGNALS that indicate urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of PATIENT, equipment or PATIENT'S location should also be generated by the DISTRIBUTED ALARM SYSTEM.~~

~~*Compliance is checked by inspection.*~~

~~6.11.2.2 * Failure of remote communication of ALARM CONDITIONS~~

~~6.11.2.2.1 * DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS~~

~~A DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS shall be so designed that a communications failure or failure in any remote part of the DISTRIBUTED ALARM SYSTEM:~~

~~a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and~~

~~b) shall:~~

~~1) initiate a TECHNICAL ALARM CONDITION in the affected source ME EQUIPMENT; and~~

~~NOTE 1 The ALARM SYSTEM should provide means for the OPERATOR to inactivate the auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.~~

~~2) initiate a TECHNICAL ALARM CONDITION for any affected remote parts of the DISTRIBUTED ALARM SYSTEM that can generate ALARM SIGNALS.~~

~~NOTE 2 MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

~~6.11.2.2.2 * DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS~~

~~A DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS shall be so designed that a communications failure or failure in any remote part of the DISTRIBUTED ALARM SYSTEM:~~

~~a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and~~

~~b) any remote part of a DISTRIBUTED ALARM SYSTEM that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.~~

~~EXAMPLE A one-way paging system requires such a warning.~~

~~NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

~~6.11.2.2.3 * ME EQUIPMENT with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM~~

~~If there is a communications failure between the ME EQUIPMENT with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM intended for OPERATOR notification and confirmed delivery of~~

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~~ALARM CONDITIONS, the affected source ME EQUIPMENT shall terminate the global AUDIO OFF state, if active.~~

~~If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the source ME EQUIPMENT, continuing failure of the link need not cause additional auditory ALARM SIGNALS.~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

~~6.11.2.3 * Remote ALARM SYSTEM controls~~

~~A DISTRIBUTED ALARM SYSTEM may provide remote OPERATOR access to some or all ALARM SYSTEM controls. If provided:~~

~~a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and~~

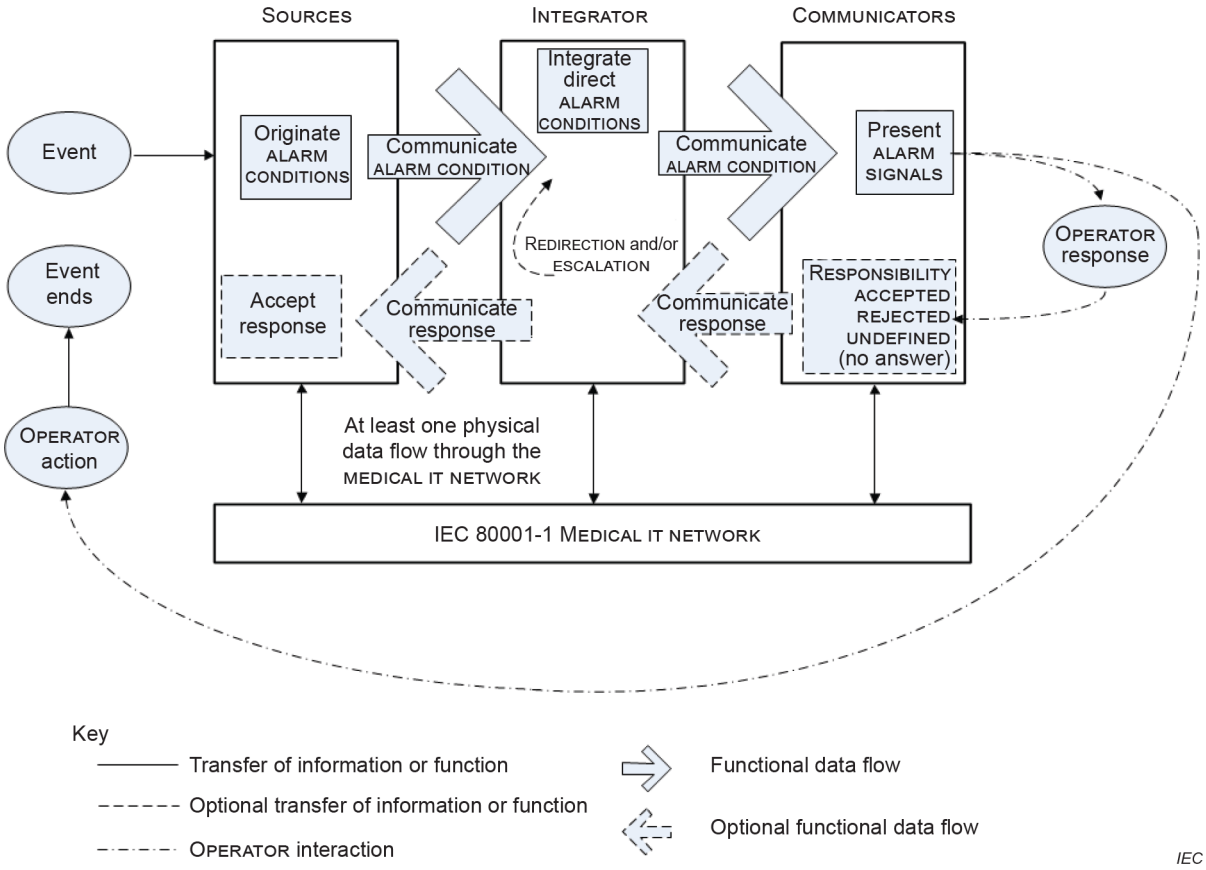
~~b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

6.11.1 * Existence of a DIS or DAS

The details necessary for the safe use of a DIS or a DAS shall be disclosed in the technical description. A DIS or a DAS is a permitted form of an ALARM SYSTEM. Figure 2 illustrates the functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK.

NOTE Additional information is found in IEC 80001-2-5 [31].



NOTE This is a functional diagram and does not imply that these functions are in separate components. It is possible for functionality to be provided in one or more components.

Figure 2 – Functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK

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An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DIS or a DAS. A DIS or a DAS is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DIS or a DAS are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DIS or a DAS by wire, by telemetry or by other means.

EXAMPLE 1 A central station.

EXAMPLE 2 An electronic record-keeping device.

EXAMPLE 3 Remote viewing from home or office.

EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).

EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.

Compliance is checked by inspection of the technical description.

6.11.2 Requirements for communication of ALARM CONDITIONS

6.11.2.1 SOURCE and identification of ALARM CONDITIONS

In a DAS or DIS, means shall be provided to identify the SOURCE of the ALARM CONDITION at every COMMUNICATOR that generates ALARM SIGNALS for that ALARM CONDITION.

ALARM SIGNALS that indicate the urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of the PATIENT, equipment or PATIENT's location should also be generated by the DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection.

6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

6.11.2.2.1 * DAS or CDAS

A DAS or CDAS shall be so designed that a communications failure or failure in any remote component of the DAS or CDAS:

a) shall not adversely affect any part of the DAS or CDAS other than the loss of the distributed functionality; and

b) shall initiate a TECHNICAL ALARM CONDITION for all relevant COMMUNICATORS of the DAS or CDAS.

   1) The ALARM SYSTEM should provide a means for the OPERATOR to inactivate any auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.

MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.2 * DIS

A DIS shall be so designed that a communications failure or failure in any remote component of the DIS:

a) shall not adversely affect any part of the DIS other than the loss of the distributed functionality; and

b) any remote COMMUNICATOR of a DIS that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.

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EXAMPLE A one-way paging system requires such a warning.

NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.3 * SOURCE with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

If there is a communications failure between a SOURCE with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM, the affected SOURCE shall terminate the global AUDIO OFF state, if active.

If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the SOURCE, continuing failure of the link need not cause additional auditory ALARM SIGNALS.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.3 * Remote ALARM SYSTEM controls

A DAS or CDAS may provide remote OPERATOR access to some or all ALARM SYSTEM controls. If provided:

a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and

b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.4 * CDAS

In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION shall have means to create the OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) and transfer them to the INTEGRATOR.

a) In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION and initiates an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) shall indicate the OPERATOR response state (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED).

The means of control used to initiate an OPERATOR response or indication of state may be marked with:

b) symbol ISO 7000-6334A (2015-06) (see Symbol 13 of Table C.1) for RESPONSIBILITY ACCEPTED; or

c) symbol ISO 7000-6335A (2015-06) (see Symbol 16 of Table C.1) for RESPONSIBILITY REJECTED.

Means shall be provided for the OPERATOR to terminate RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED while the related ALARM CONDITION is active. Initiating RESPONSIBILITY REJECTED may be used to terminate RESPONSIBILITY ACCEPTED. Initiating RESPONSIBILITY ACCEPTED may be used to terminate RESPONSIBILITY REJECTED.

In a CDAS, RESPONSIBILITY ACCEPTED may initiate an ALARM SIGNAL inactivation state.

NOTE RESPONSIBILITY ACCEPTED is a different function than an ALARM SIGNAL inactivation state.

In a CDAS, the INTEGRATOR shall have means to accept OPERATOR responses from the COMMUNICATOR.

In a CDAS, the SOURCE may receive OPERATOR responses from the INTEGRATOR.

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Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.12 * ALARM ~~CONDITION~~ SYSTEM logging

~~If an ALARM SYSTEM is provided with an ALARM SYSTEM log:~~

~~a) the ALARM SYSTEM shall log the occurrence and identity of HIGH PRIORITY ALARM CONDITIONS and;~~

~~– the date and time, or~~

~~– the elapsed time since the occurrence of the ALARM CONDITION, or~~

~~– the elapsed time from the start of use of the ME EQUIPMENT;~~

~~b) the instructions for use shall indicate whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log;~~

~~c) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;~~

~~d) the instructions for use shall indicate what happens to the contents of the log as it reaches capacity; and~~

~~EXAMPLE 1 The ALARM SYSTEM generates a TECHNICAL ALARM CONDITION when the log becomes full.~~

~~EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.~~

~~e) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS, if OPERATOR-adjustable, for that ALARM CONDITION and, where feasible, the data that caused the ALARM CONDITION;~~

~~f) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action.~~

~~*Compliance is checked by inspection.*~~

6.12.1 General

An ALARM SYSTEM may be equipped with an OPERATOR ALARM SYSTEM log or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

An OPERATOR ALARM SYSTEM log is intended to be utilized while the ALARM SYSTEM is being used for a PATIENT. A RESPONSIBLE ORGANIZATION ALARM SYSTEM log is intended to be utilized after PATIENT use has been concluded.

An OPERATOR ALARM SYSTEM log is typically a subset of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

6.12.2 * OPERATOR ALARM SYSTEM logging

If an ALARM SYSTEM is provided with an OPERATOR ALARM SYSTEM log:

a) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS for that ALARM CONDITION, if OPERATOR-adjustable and, where feasible, the data that caused the ALARM CONDITION;

EXAMPLE 1 The downstream infusion pressure ALARM CONDITION is logged with start time and date, end time (date stamp), pressure ALARM LIMIT, the pressure value and auditory ALARM SIGNAL volume setting.

b) the ALARM SYSTEM shall log the occurrence and identity of all HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS;

c) for each logged ALARM CONDITION, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION, or

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– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

d) the ALARM SYSTEM should log the occurrence and identity of all ALARM SIGNAL inactivation states and, for a CDAS, OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED);

1) for each logged ALARM SIGNAL inactivation state, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION or ALARM SIGNAL inactivation state, or

– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

e) if a means is provided for the OPERATOR to indicate to the ALARM SYSTEM that a different PATIENT has been connected, then that event should be logged in the OPERATOR ALARM SYSTEM log;

f) means may be provided for the logging of changes to the OPERATOR-adjustable ALARM SETTINGS in the OPERATOR ALARM SYSTEM log;

g) means may be provided for the OPERATOR to add explanatory notes or comments to the OPERATOR ALARM SYSTEM log, and if provided:

– means should be provided to record the identity of the annotator and the date and time of the annotation;

h) means shall not be provided for the OPERATOR to edit or delete entries in the OPERATOR ALARM SYSTEM log, unless a new PATIENT is admitted or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log is provided;

i) the log may be provided either within the equipment or remotely through a communications interface; and

j) the instructions for use shall indicate:

1) the means for the OPERATOR to access the OPERATOR ALARM SYSTEM log,

2) whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log,

3) what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration,

4) the capacity of the log, and

5) what happens to the contents of the log as it reaches capacity.

EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

Compliance is checked by inspection.

6.12.3 * RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

If an ALARM SYSTEM is provided with a RESPONSIBLE ORGANIZATION ALARM SYSTEM log:

a) viewing the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

b) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain all of the information contained in the OPERATOR ALARM SYSTEM log;

c) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain the ALARM SETTINGS and each change of those settings;

EXAMPLE 1 The name of the ALARM PRESET in use and any changes made to it.

d) means shall not be provided for the OPERATOR or RESPONSIBLE ORGANIZATION to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log;

e) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be retained when the ALARM SYSTEM is powered down;

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f) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;

g) the instructions for use shall indicate:

1) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log capacity, and

2) what happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity;

EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

h) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action; and

i) the log may be provided either within the equipment or remotely through a communications interface.

Compliance is checked by inspection.

6.13 ALARM SYSTEM functions

6.13.1 General

An ALARM SYSTEM shall have at least one:

a) SOURCE;

b) INTEGRATOR; and

c) COMMUNICATOR.

Figure 3 illustrates the functions of an ALARM SYSTEM of ME EQUIPMENT.

Compliance is checked with the tests of 6.3.1.

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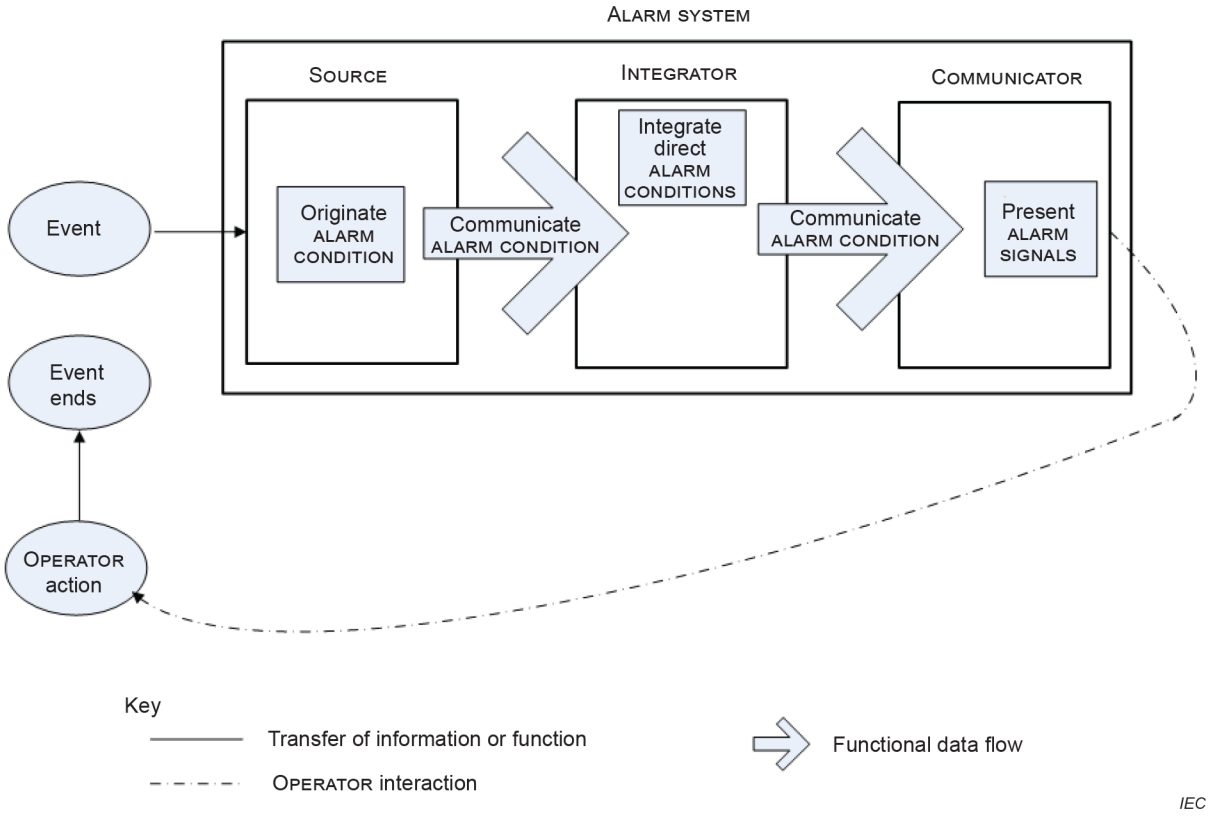

Figure 3 – Functions of an ALARM SYSTEM

6.13.2 SOURCE (SRC)

An ME EQUIPMENT, a DIS or a DAS may have more than one SOURCE.

An ALARM CONDITION shall only originate from a SOURCE.

A SOURCE may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) that was transferred from an INTEGRATOR.

Compliance is checked by inspection.

6.13.3 INTEGRATOR (INT)

An INTEGRATOR shall map SOURCES and their ALARM CONDITIONS to one or more specific COMMUNICATORS.

An INTEGRATOR may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) and may transfer it to a SOURCE.

An INTEGRATOR may provide REDIRECTION to additional or different COMMUNICATORS based on the response or lack of response from COMMUNICATORS. The MANUFACTURER should consider a means for the RESPONSIBLE ORGANIZATION to manage the REDIRECTION to assure an appropriate OPERATOR response.

An INTEGRATOR may:

a) contain a SOURCE that performs the functions of an INTELLIGENT ALARM SYSTEM (see 6.2);

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EXAMPLE 1 Removing redundant ALARM CONDITIONS.

EXAMPLE 2 Creating an ALARM CONDITION from multiple inputs.

EXAMPLE 3 Suppressing superfluous ALARM SIGNALS.

b) generate the RESPONSIBILITY UNDEFINED state;

c) generate an ALARM SIGNAL inactivation state.

The ME EQUIPMENT, a DIS or a DAS may have more than one INTEGRATOR.

Compliance is checked by inspection.

6.13.4 COMMUNICATOR (COM)

A COMMUNICATOR receives ALARM CONDITIONS from one or more INTEGRATORS. A COMMUNICATOR may also PROCESS or direct an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) to the INTEGRATOR.

An OPERATOR response need not be limited to direct OPERATOR action and can be achieved by other means (e.g. an OPERATOR locator system).

If OPERATOR response is achieved by other means than direct OPERATOR action, the ALARM SYSTEM shall provide means to indicate to the corresponding OPERATOR that RESPONSIBILITY ACCEPTED is active for the affected COMMUNICATOR.

An ME EQUIPMENT, a DIS or a DAS may have more than one COMMUNICATOR.

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