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

Amendment No. 1

International adoption identical

Publishing and Approval Dates

Council of Standards Australia Approval: 20 May 2022

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Summary

This Amendment applies to the following elements:

- Front cover
- Preface
- Amendment 2

Amendment Details

AS IEC 60601.1.8:2017 is amended as follows. The amendments should be inserted in the locations as instructed.

Element	Instruction / New text
Front cover	Top right-hand corner, after IEC 60601-1-8:2006+AMD1:2012 CSV (ED. 2.1) *add* the following: IEC 60601-1-8:2006/AMD2:2020 (Incorporating Amendment No. 1)
Preface	After the first paragraph, *add* the following: Amendment No. 1 to this Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment. *Delete* fourth paragraph and *replace* with the following: This Standard is identical with, and has been reproduced from IEC 60601-1-8:2006+AMD1:2012 CSV (ED. 2.1), *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* and its Amendment 2 (2020), which has been added at the end of the source text.
Amd 2 (new)	After Index of defined terms used in this collateral standard, *add* the following Amendment No. 2 (2020):

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

The text of this amendment is based on the following documents of IEC:

FDIS	Report on voting
62A/1392/FDIS	62A/1407/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by 15 P members out of 15 having cast a vote.

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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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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INTRODUCTION

Replace, in the second sentence of the existing second paragraph, "source" *with* "origin".

1.3.1 IEC 60601-1

Replace the first two existing dashes with the following new dashes:

– "the general standard" designates IEC 60601-1 alone, including any amendments;
– "this collateral standard" designates IEC 60601-1-8 alone, including any amendments;

2 Normative references

Replace the existing references to IEC 60601-1, IEC 61672-1 and IEC 62366-1 by the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

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

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

3 Terms and definitions

Replace the existing first paragraph with the following new paragraph:

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.

3.17
*** DISTRIBUTED ALARM SYSTEM**

Replace the existing term and definition with the following new entry:

3.17
*** DISTRIBUTED ALARM SYSTEM**
DAS
ALARM SYSTEM that involves more than one item of equipment in 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.

3.20
FALSE NEGATIVE ALARM CONDITION

Replace, in the existing note, "the equipment itself" *with* "the ALARM SYSTEM itself".

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3.22
HIGH PRIORITY

Replace the existing note with the following new notes:

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
***INFORMAL SIGNAL**

Add, after the existing Example 3, the following new note:

NOTE An ADVISORY is a type of INFORMATION SIGNAL.

3.25
INTERBURST INTERVAL

Replace, in the existing parenthetical, "Figure 1" *with* "Figure 1 and Figure G.1".

Add the following new note:

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

3.27
LOW PRIORITY

Replace the existing term, definition and note with the following new entry:

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

Replace the existing note with the following new notes:

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].

3.37
*** ACKNOWLEDGED**

Replace the existing term, definition and notes, added by Amendment 1, with the following new entry:

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.

Add, after 3.37, the following new terms and definitions:

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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].

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

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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.

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.

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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.

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.

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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

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

Replace the existing list item e) with the following new item:

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

6.3.1 General

Replace, in the first sentence of the existing first paragraph, "ALARM SIGNALS" *with* "ALARM SIGNALS by a COMMUNICATOR".

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

Replace, in the existing Note 3, modified by Amendment 1, "IEC 62366" *with* "IEC 62366-1".

Replace the existing Note 5, added by Amendment 1, with the following new note:

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.

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Replace, in the existing first paragraph, modified by Amendment 1, the first sentence with:

If a COMMUNICATOR of an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

Replace the existing list item b) to d), modified by Amendment 1, with:

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

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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.

Replace, in the existing Note 2, modified by Amendment 1, "IEC 62366" *with* "IEC 62366-1".

Delete the existing paragraph following Note 2.

Replace, in the third sentence of the existing compliance check, modified by Amendment 1, "Verify" *with* "Confirm".

Delete t_r from the compliance check modified by Amendment 1.

Replace the existing last sentence of the compliance check, modified by Amendment 1, with the following new sentence:

When the sound files of Annex G are utilized, only testing of t_b is required and testing of the acoustic signal is permitted.

Replace the existing last paragraph, added by Amendment 1, with the following new paragraph:

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.

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

Replace, in the paragraph at the bottom of the table starting with "Where"*, modified by Amendment 1, the third line with the following new text*:

the variation of t_d, x and y within a BURST shall not exceed ± 20 %, and

Replace, in the existing table footnote c, "source" *with* "origin".

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

Replace the existing Table 4, modified by Amendment 1, with the following new table:

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.	

Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS

Replace, in the existing note, the word "NOTE" with "NOTE 1".

Add, after the existing note, the following new note:

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

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

Replace the existing first paragraph, modified by Amendment 1, with the following new paragraph:

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

Replace the existing list items c) to k), added by Amendment 1, with the following new items:

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.*

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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.

6.4.2 * Delays to or from a DISTRIBUTED ALARM SYSTEM

Replace the existing title and entire subclause 6.4.2, modified by Amendment 1, with the following new text:

6.4.2 * Delays to or from a DISTRIBUTED 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 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.

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.

6.5.4.2 * Selection of DEFAULT ALARM PRESET

Add, after the existing list item g), the following note:

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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.

Delete, in the existing compliance check, the word "source".

6.5.5 * Interruptions of less than or equal to 30 s

Delete, in the existing compliance check, the word "source".

6.7 * ALARM SYSTEM security

Replace, in the existing first paragraph, modified by Amendment 1, "6.10 and 6.11.2.2.1" *with* "6.10, 6.11.2.2.1 and 6.12.3."

6.8.1 * General

Add, after the existing third paragraph, the following new paragraph and note:

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.

Renumber the existing Note 3, modified by Amendment 1, as Note 4.

Table 5 – ALARM SIGNAL inactivation states

Replace the existing fifth and sixth rows of Table 5, modified by Amendment 1, with the following:

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

6.11 * DISTRIBUTED ALARM SYSTEM

Replace the existing title and the entire subclause 6.11 with:

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

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].

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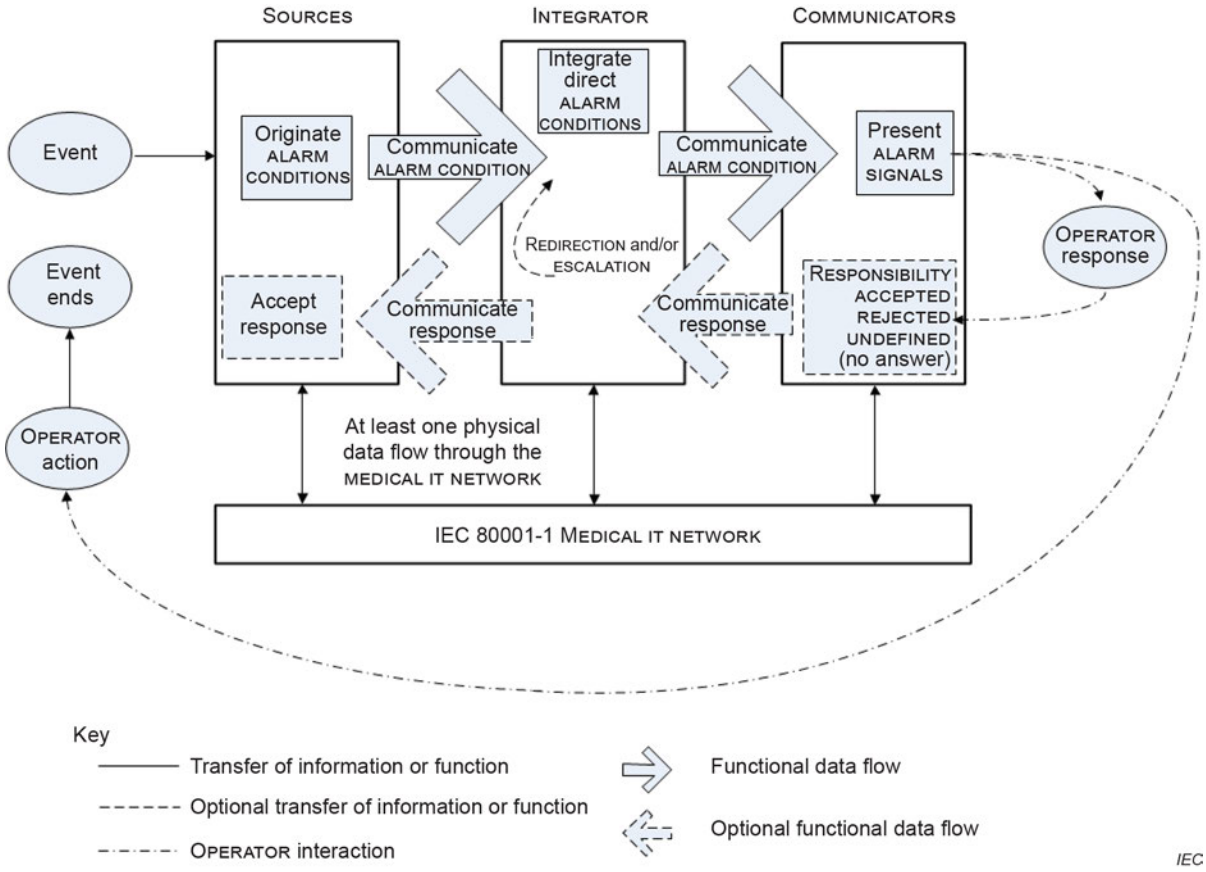

NOTE This is a functional diagram and does not imply that these functions are in separate components. It is possible for functionality to be provided in one or more components.

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

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.

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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.

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.

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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.

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

6.12 * ALARM SYSTEM logging

Replace the existing subclause 6.12, modified by Amendment 1, with:

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

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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
- 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;

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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;

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.

Add, immediately following the existing subclause 6.12, the following new subclause:

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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