EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-8:2007/A2

July 2021

ICS 11.040.01

English Version

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/A2:2020)

Appareils électromédicaux - Partie 1-8 : exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux
(IEC 60601-1-8:2006/A2:2020)

Medizinische elektrische Geräte - Teil 1-8: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Alarmsysteme - Allgemeine Festlegungen, Prüfungen und Richtlinien für Alarmsysteme in medizinischen elektrischen Geräten und in medizinischen Systemen
(IEC 60601-1-8:2006/A2:2020)

This amendment A2 modifies the European Standard EN 60601-1-8:2007; it was approved by CENELEC on 2020-08-27. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-1-8:2007/A2:2021 E

European foreword

The text of document 62A/1392/FDIS, future IEC 60601-1-8/A2, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-8:2007/A2:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1-8:2006/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 80001-1	NOTE	Harmonized as EN 80001-1
ISO 9000:2015	NOTE	Harmonized as EN ISO 9000:2015 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Replace Annex ZA by the following one:

Publication	Year	Title	EN/HD	Year
IEC 60417	-	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	-	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
IEC 61672-1	2013	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	2013
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	2020
ISO 3744	2010	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane	EN ISO 3744	2010
ISO 7000	-	Graphical symbols for use on equipment - Registered symbols	-	-

IEC 60601-1-8

Edition 2.0 2020-07

INTERNATIONAL STANDARD

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AMENDMENT 2

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/AMD2:2020-07(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

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Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC 60601-1-8

Edition 2.0 2020-07

INTERNATIONAL STANDARD

colour inside

AMENDMENT 2

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

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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.

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.

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".

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:

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

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.

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.

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

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".

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.*

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:

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

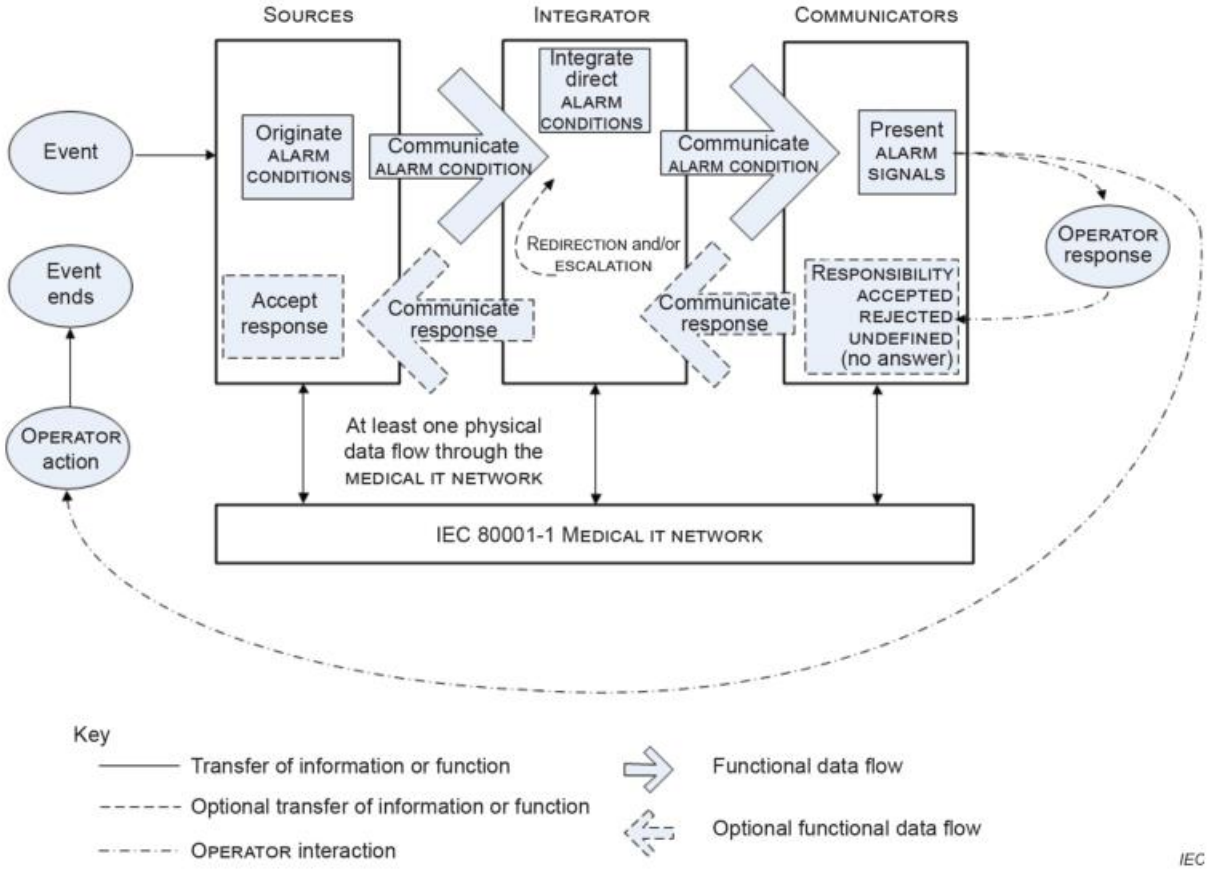
Replace the existing title and the entire subclause 6.11 with:

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].



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.

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.

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.

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;

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.

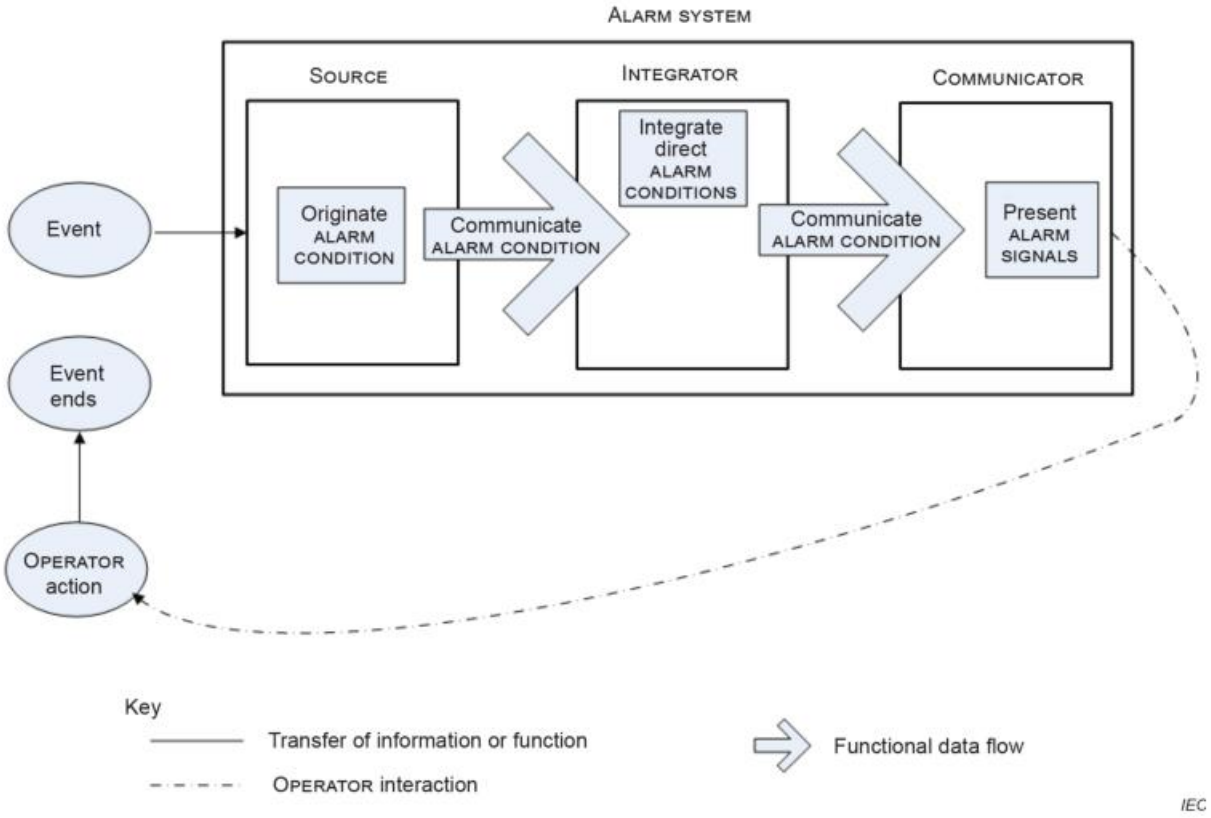


Figure 3 – Functions of an ALARM SYSTEM

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);

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.

A.1.2 ALARM SYSTEMS

Replace the existing NOTE in item d) with the following new notes:

NOTE 1 Causing too many ALARM SIGNALS from FALSE POSITIVE ALARM CONDITIONS can cause ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [73], [74], [75].

NOTE 2 ALARM FLOOD can lead to ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [56], [57].

Replace the existing first line of item g) with the following new line:

g) ALARM SIGNALS should be CLINICALLY ACTIONABLE and help the OPERATOR:

Replace the existing item h) with the following new item:

h) The algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be designed to minimize the number of FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS. FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS are potentially hazardous. Too many TRUE POSITIVE ALARM CONDITIONS but CLINICALLY NONACTIONABLE ALARM SIGNALS can result in inappropriate OPERATOR action or reduce vigilance. TRUE POSITIVE ALARM CONDITIONS that are CLINICALLY NONACTIONABLE lead to ALARM FATIGUE. Algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be carefully optimized to provide, on balance, an overall benefit to PATIENT care [55], [58].

A.1.3 Algorithm quality and performance

Replace the second and third sentences of the existing first paragraph with:

The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS, CLINICALLY NONACTIONABLE ALARM CONDITIONS or nuisance ALARM CONDITIONS. CLINICALLY NONACTIONABLE ALARM CONDITIONS are TRUE POSITIVE ALARM CONDITIONS that are unhelpful because they indicate states that the OPERATOR is already aware of or does not need to know about [11], [29].

Replace, in the existing second paragraph, "FALSE POSITIVE and FALSE NEGATIVE" *with* "FALSE POSITIVE, FALSE NEGATIVE, TRUE POSITIVE and TRUE NEGATIVE".

A.2 Rationale for particular clauses and subclauses

Definition 3.5 – ALARM PAUSED

Replace, in the existing first paragraph, "avoid nuisance generation of ALARM SIGNALS" *with* "avoid generation of NUISANCE ALARM SIGNALS".

Definition 3.17 – DISTRIBUTED ALARM SYSTEM

Replace the entire text of the rationale with the following new text:

In simple equipment, the SOURCE, INTEGRATOR and COMMUNICATOR are all within that single piece of equipment. Typical examples would be a stand-alone PATIENT monitor or a stand-alone ventilator.

In networked equipment, in a system with a central station, or with COMMUNICATORS for caregivers (OPERATORS) at some distance from the PATIENT, more complicated ALARM SYSTEMS are used.

In a DISTRIBUTED ALARM SYSTEM, one of the following functions is located in a different part of the ME SYSTEM:

a) the SOURCE;

b) the INTEGRATOR; or

c) the COMMUNICATOR.

A DISTRIBUTED ALARM SYSTEM typically comprises at least two devices:

d) a SOURCE and INTEGRATOR (and likely a COMMUNICATOR) that is generally connected directly to the PATIENT, and

e) a remote COMMUNICATOR (part of an ME SYSTEM) that might or might not be in the vicinity of the PATIENT.

Thus, in a network of bedside PATIENT monitors, one bedside PATIENT monitor can act as a COMMUNICATOR for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can act as a COMMUNICATOR for ALARM CONDITIONS from multiple PATIENTS. A two-way wireless communication system can act as a COMMUNICATOR for ALARM CONDITIONS to a caregiver in an area far removed from the PATIENT. All these are examples of DISTRIBUTED ALARM SYSTEMS.

A central station that processes incoming signals from multiple PATIENTS and as a SOURCE passes ALARM CONDITIONS back to bedside ME EQUIPMENT to act as a COMMUNICATOR is a DISTRIBUTED ALARM SYSTEM.

Definition 3.34 – REMINDER SIGNAL (see also the rationale for 6.8.1)

Replace, in the existing fourth paragraph, "the GENERATION OF ALARM SIGNALS" *with* "the COMMUNICATOR".

Add, after the existing last paragraph, the following new paragraph:

Depending on the design of the ALARM SYSTEM and the INTENDED USE of the ME EQUIPMENT, REMINDER SIGNALS can be auditory, visual, a combination of both or by another means.

Definition 3.37 – ACKNOWLEDGED

Replace, in the existing Example 1, added by Amendment 1, "other sources" *with* "other causes".

Add the following rationales 3.38, 3.39, 3.41, 3.44, 3.45, 3.48 and 3.50:

Definition 3.38 – ADVISORY

See the rationale for Definition 3.41.

Definition 3.39 – ALARM FATIGUE

There is no universally accepted definition of ALARM FATIGUE. The term is commonly used to describe one or more related conditions that cause degradation of OPERATOR response to ALARM SIGNALS. The degraded response can be delayed, inadequate, inappropriate or absent. ALARM FATIGUE means a degraded response caused by one or more of the following:

– ALARM FLOOD;
– high number of FALSE POSITIVE ALARM SIGNALS;
– high number of CLINICALLY NONACTIONABLE ALARM SIGNALS, including receiving ALARM SIGNALS from other PATIENTS in the area for whom the OPERATOR is not responsible;
– high number of auditory ALARM SIGNALS that are insufficient for detection, identification, localization or prioritization;
– volume (sound pressure level) of the auditory ALARM SIGNAL (too quiet or too loud);
– ALARM SIGNALS that contain insufficient information to support planning a response to the underlying cause of the ALARM CONDITION (e.g. single ALARM SIGNAL to announce a large number of ALARM CONDITIONS or a visual ALARM SIGNAL that is non-specific); or
– other environmental aspects (i.e. ambient noise, ambient light and glare, level of OPERATOR rest, work area temperature, additional workflow interrupts) that impair the OPERATOR's cognitive abilities.

Given OPERATORS' response to the ALARM SIGNAL is based on the percentage of ALARM CONDITIONS they believe are not false [77], it stands to reason that ALARM SYSTEM design is a key factor to help prevent an OPERATOR from experiencing ALARM FATIGUE, and the resulting potential for HARM.

While it stands to reason that the total rate of ALARM SIGNALS is a contributor to ALARM FATIGUE [73], [74], [75], there exists some controversy to contradict that position [78]. There is available evidence that ALARM FATIGUE can be mitigated through the usage of better ALARM SYSTEMS, algorithms and ALARM SETTINGS, and careful consideration to deployment environment, policy, training, and technology selection [58], [59], [79], [80].

Definition 3.41 – ALERT

The committees received comments requesting that a definition for ALERT be added to the document. It is recognized that the terms ALERT and ALARM CONDITION have been used interchangeably and typically, the MANUFACTURERS of electronic medical record software have purposefully used the term ALERT instead of ALARM CONDITION so that their products are not construed as being part of the PATIENT monitoring system regardless of whether or not the notification was being used as a RISK CONTROL. Some standards [76] have defined an ALERT as a synonym for both what this document calls an ALARM CONDITION and an ADVISORY. These standards also define an ALERT as a signal while this document considers both an ALARM CONDITION and an ADVISORY to be a state that are communicated by signals.

The committees discussed the fact that an ALARM CONDITION is defined as providing a means of RISK CONTROL relating to HARM while a condition resulting in an ADVISORY does not, but the committees agreed that definitions should be provided to clarify the difference. And, it is noted that this document had not previously used the term ALERT or ADVISORY in any context. Since a direct RISK CONTROL is not an outcome of an ADVISORY notification, the definitions have been carefully worded to ensure that an ADVISORY would not be confused with ALARM CONDITION. ADVISORIES are then a type of INFORMATION SIGNAL that notifies an OPERATOR of conditions that relate to the PATIENT, equipment or workflow, but are not an indicator of potential HARM.

The examples provided are types of ADVISORIES that help the OPERATOR's workflow or raise the OPERATOR's cognitive awareness of a condition of the PATIENT, equipment or system.

EXAMPLE 1 An ADVISORY that the next blood draw is needed in approximately two hours notifies the OPERATOR that workflow includes obtaining a blood sample. This ADVISORY does not provide a RISK CONTROL, but rather is a notification to the OPERATOR that in the near future they should perform that task.

EXAMPLE 2 The battery status indicator shows the amount of battery charge remaining which notifies the OPERATOR of the condition of the ME EQUIPMENT and can notify them of a step in their workflow that will need to be done hours in the future, but they have not yet received an ALARM CONDITION for the state of the battery. A low battery LOW PRIORITY TECHNICAL ALARM CONDITION would be treated differently in that continued use of the ME EQUIPMENT will result in loss of power (and therefore loss of monitoring capability) and there is a RISK of PATIENT HARM.

EXAMPLE 3 Consider the case where a PATIENT has a high INR (International Normalised Ratio, an indication of clotting time). In the order entry system, the notification to the OPERATOR that an additional anticoagulant dose is contraindicated could be an ADVISORY since there are many additional workflow steps prior to the administration of the anticoagulant. The type of OPERATOR notification depends on where the anticoagulant dose administration is in the clinical workflow. If the dose is hours away, the notification to the clinical OPERATOR can be an ADVISORY – an INFORMATIONAL SIGNAL. On the other hand, if the clinical OPERATOR is about to administer the dose, a HIGH PRIORITY or at least MEDIUM PRIORITY ALARM CONDITION is appropriate because immediate or prompt action will be needed to prevent the HARM that would likely result from an overdose of anticoagulant.

Definition 3.44 – CLINICALLY ACTIONABLE

It can sometimes be difficult to determine if an event is CLINICALLY ACTIONABLE or not. One specific caregiver (physician, nurse, respiratory therapist, other) can notice an ALARM SIGNAL and make their own decision about whether to take action or not. Other caregivers can or might not agree with the decision of that caregiver. Indeed, reasonable, well-trained, expert caregivers frequently have different opinions about optimal PATIENT care.

For the purposes of this document, a single caregiver does not suffice to determine if an event is CLINICALLY ACTIONABLE or not. Instead, one needs to defer to a hypothetical "panel of experts" (physicians, nurses, respiratory therapists, or others) to make that determination. The hypothetical "panel of experts" is analogous to the concept of state-of-the-art. For the purposes of this document, such a panel is not required to be convened by any group (MANUFACTURER, RESPONSIBLE ORGANIZATION, OPERATOR, etc.) under any circumstances. It should be noted, however, that such panels are commonly convened by RESPONSIBLE ORGANIZATIONS to review situations of potential or actual PATIENT injury. A common example is a Hospital Quality Assurance Committee. In any case, if a majority of a hypothetical "panel of experts" would agree that action should be taken, then the event can be considered CLINICALLY ACTIONABLE. Table A.1 maps ALARM SYSTEM output to perceived OPERATOR action [29].

Table A.1 – ALARM SYSTEM output to perceived OPERATOR action

ALARM SYSTEM output	Resulting OPERATOR perception	Scientific definition	CLINICALLY ACTIONABLE ALARM CONDITION?
ALARM SYSTEM generates an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION	ALARM SYSTEM made a mistake	FALSE POSITIVE ALARM CONDITION	No
	ALARM SYSTEM performed correctly but the OPERATOR decides no action is required to prevent HARM.	Irrelevant POSITIVE ALARM CONDITION A valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes that no action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes action.	TRUE POSITIVE ALARM CONDITION	Yes
ALARM SYSTEM does not generate an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION [a]	ALARM SYSTEM made a mistake	FALSE NEGATIVE ALARM CONDITION	Yes
	ALARM SYSTEM performed correctly but the OPERATOR decides action is required.	Relevant NEGATIVE ALARM CONDITION [b] Absence of an ALARM CONDITION when a valid triggering event has not occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes an action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes no action.	TRUE NEGATIVE ALARM CONDITION	No

[a] It could be that the ALARM SYSTEM reports a LOW PRIORITY ALARM CONDITION or no ALARM CONDITION – No action.

[b] It is recognized that a special case of the relevant FALSE NEGATIVE ALARM CONDITION can effectively be caused by an ALARM SIGNAL inactivation state.

Definition 3.45 – CLINICALLY NONACTIONABLE

See the rationale for 3.44.

Definition 3.48 – DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS

A DIS is equivalent to "a DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS" as described in IEC 60601-1-8:2006+A1:2012, 6.11.2.2.2.

Definition 3.50 – NUISANCE ALARM SIGNAL

See the rationale for 3.44.

Subclause 6.2 – Disclosures for INTELLIGENT ALARM SYSTEM

Replace the last sentence of the existing second paragraph with the following sentences.

The use of INTELLIGENT ALARM SYSTEMS can be an effective way of reducing the number of ALARM SIGNALS that are generated during transient events, thus reducing the number of CLINICALLY NONACTIONABLE ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS also can be an effective way of reducing the number of FALSE NEGATIVE ALARM CONDITIONS.

Delete, in the existing third paragraph, "sources of".

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

Subclause 6.3.3 – Auditory ALARM SIGNALS

Replace, in the third dash, "device" *with* "COMMUNICATOR".

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

Add, at the beginning of the rationale, modified by Amendment 1, the following new text:

[List element d), 1) i)]

It is the intent of the committees to make the ALARM SIGNALS of Annex G mandatory at the next amendment or edition of this document. MANUFACTURERS that utilize the ALARM SIGNALS of Annex G should report their experiences to the committees. IEC/62A can be reached at https://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID:1359 [viewed 2020-07-09]. ISO/SC3 can be reached at: https://www.iso.org/committee/52012.html [viewed 2020-07-09].

[List element d), 2)]

A different technology implies something other than electronically generated tones. There are a variety of means for generating auditory ALARM SIGNALS, including buzzers, electronic sound generators and speech synthesizers. At least some of the methods described above can be used to indicate priority regardless of the means of generating the signal.

Replace the existing heading "[List element d) first dash)]" *with the following new heading:*

[List element d), 3)]

Replace, in the first sentence of the existing third paragraph, "that complies with Table 3" *with* "that complies with Annex G, Table 3".

Replace, in the second sentence of the existing third paragraph, "Annex F" *with* "Annex G".

Replace, in the existing sixth paragraph, "Table 4" *with* "Table 4 or Annex G".

Replace the last eight paragraphs, including the title "[List element d), second dash)]"*, modified by Amendment 1, with the following new paragraphs:*

Often (as has already been stated), many ALARM SYSTEMS generate ALARM SIGNALS in one PATIENT care area [23]. Even if the pitch of all PULSES in a BURST is the same, many OPERATORS can learn to recognize differences in tone, overall pitch, and repetition rate. If the pitch of individual PULSES is varied in such a way as to create simple standard "melodies", the average person can learn to recognize approximately six to eight melodies and to associate them with categories of equipment.

Multifunctional equipment can either use one ALARM SIGNAL that indicates the primary function of the equipment or can apply a different ALARM SIGNAL to each functional sub-system of the equipment. A specific ALARM SIGNAL that indicates equipment failure or power down can additionally be used on any equipment in addition to the ALARM SIGNAL indicating the primary function of the equipment.

Table 3 – Characteristics of the BURST of auditory ALARM SIGNALS
Table 4 – Characteristics of the PULSE of auditory ALARM SIGNALS

Replace the existing second paragraph with the following new paragraph:

Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the origin of the ALARM SIGNAL promptly. Ensuring that at least four different frequency components are audible, the upper limit for them is set to 4 000 Hz. In addition, for one frequency component of them, the upper limit is set to 1 000 Hz, which makes it audible in distant areas (e.g. outside of an open door). *An even better approach is to create multiple notes at the same time (i.e. a chord), with each note having several harmonics. The more audible peaks in the frequency domain within the indicated band, the better the localization.*

Replace, in the third sentence of the existing third paragraph, "the source of the ALARM CONDITION" *with* "the origin of the ALARM SIGNAL"

Replace, in the last sentence of existing list item c), "the source of the ALARM CONDITION" *with* "the origin of the ALARM SIGNAL".

Replace, in the fifth sentence of existing list item d), "the source of the ALARM CONDITION" *with* "the origin of the ALARM SIGNAL"

Delete, in the first line of the third dash of existing list item d), "remote".

Replace, in the last sentence of existing list item d), "alternative generation of ALARM SIGNALS " *with* "alternative COMMUNICATORS".

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

h) The ISO 9703-2 requirement for the presence of four harmonics has been slightly modified. Reflections and standing waves from pure sine wave auditory ALARM SIGNALS can make it very difficult to determine where they are coming from. Ensuring that four or more audible frequencies are present in an auditory ALARM SIGNAL enhances spatial localization. These frequencies should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of frequency can be extremely difficult in simple systems, a value of plus or minus 15 dB (relative sound pressure level) was chosen as a reasonably achievable goal. Decibels were used to express the ratio between the sound pressure levels of the frequencies because they are commonly used to describe relative sound pressure levels. The choice of frequency content is very flexible and permits sounds of very different tonal quality to be created. *Using chords instead of single notes is another means to increase the frequency content of the sound and thereby improving localizability.*

Add, after the final dash of existing list item i), the following new paragraph:

The MEDIUM PRIORITY auditory ALARM SIGNAL can be better differentiated from the auditory emergency evacuation signal as specified in ISO 8201:2017 [30] if the three tones use different pitches or if the PULSE pacing and PULSE duration are short. Annex G ALARM SIGNALS are designed to be clearly distinct from the emergency evacuation signal.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List elements a) to c) and f)]

Replace, in the existing first paragraph, "Annex F" *with* "Annex G"*, in two places.*

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

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

[Signals in case of failure]

Replace the last sentence of the first paragraph with the following new sentence:

It would be best, if possible, for the ALARM SYSTEM to generate an auditory ALARM SIGNAL that complies with Table 3 and Table 4 and the "equipment or supply failure" ALARM SIGNAL from Annex G, but it is recognized that this can be impractical and that a non-standard auditory ALARM SIGNAL can be acceptable for this purpose.

Add, after the last paragraph, the following new text:

[Compliance test for timing]

In the past, there have been different test methods used for the verification of the timing of the AUDITORY POINTER. There are four different methods under use that have given different results. They are:

– analyzing of the timing of the sound file (e.g. .wav);
– analyzing of the electrical signal (e.g. loudspeaker input, sound chip output);
– analyzing of the acoustical time signal (sound pressure vs. time); and
– analyzing of the acoustical signal using sound pressure level vs. time analysis.

These different methods create non-comparable measurement results and have caused discussions between test labs, MANUFACTURERS and authorities having jurisdiction. The acoustic methods for determining timing are not very reproducible. For these reasons, the committees made the decision that the acoustical methods are inappropriate and that standardizing on measuring the drive signal of the audio transducer would give the most consistent results. Furthermore, when the wave files of Annex G are used, no testing is needed as those files are known to have appropriate timing.

Subclause 6.4 – Disclosure of delays

Replace, in the existing sixth paragraph, "networked remote devices" *with* "networked COMMUNICATORS".

Subclause 6.4.2 – Delays to or from a DISTRIBUTED ALARM SYSTEM

Replace the existing title and the first three paragraphs with the following new title and paragraphs:

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

A DIS or DAS further complicates the consideration of ALARM SYSTEM delays. See also the rationale for 3.2. When an OPERATOR is depending on a remote COMMUNICATOR from a DISTRIBUTED ALARM SYSTEM for treatment decisions, then knowledge about the delays associated with DISTRIBUTED ALARM SYSTEMS is necessary for safety.

ALARM SIGNALS are being delivered to caregivers (OPERATORS) that are at short, medium or long distances away from the PATIENT. Such DISTRIBUTED ALARM SYSTEMS can include ALARM SYSTEM components made by several different MANUFACTURERS, for example:

– *a PATIENT monitor and a central station network;*
– *a specialized system that connects to the central station network and transmits ALARM CONDITIONS over another network; or*
– *a wireless transmission system that picks up an ALARM CONDITION from the network and transmits it to a wireless COMMUNICATOR.*

Each component of such a DISTRIBUTED ALARM SYSTEM can add to the ALARM SIGNAL GENERATION DELAY. The MANUFACTURER of each component of a DISTRIBUTED ALARM SYSTEM should disclose its contribution to the ALARM SIGNAL GENERATION DELAY. Depending upon which ALARM SYSTEM is considered, the contribution to the ALARM SIGNAL GENERATION DELAY can be the time from the:

– *ALARM CONDITION to the ALARM SIGNALS of the COMMUNICATOR at the SOURCE or to the time that the indication of the ALARM CONDITION leaves a communications interface on the ALARM SYSTEM at the SOURCE; or*
– *receipt of the indication of the ALARM CONDITION by a component to its retransmission; or*
– *receipt of the indication of the ALARM CONDITION by a COMMUNICATOR to its ALARM SIGNAL generation.*

Subclause 6.5.4.2 – Selection of DEFAULT ALARM PRESET

Replace, in the second sentence of the existing third paragraph, "the signals from" *with* "the ALARM CONDITIONS from".

Replace, in the third sentence, "the primary ME EQUIPMENT" *with* "the ME EQUIPMENT with the SOURCE".

Subclause 6.8.1 – General

Replace the second sentence of the existing second paragraph with the following new sentence:

An ALARM SYSTEM is required to have at least one means to inactivate the generation of ALARM SIGNALS from each COMMUNICATOR.

Replace, in the existing twelfth paragraph modified by Amendment 1, "nuisance ALARM CONDITIONS" *with* "NUISANCE ALARM SIGNALS".

Subclause 6.9 – ALARM RESET

Delete, in the last line of the existing third paragraph, modified by Amendment 1, "the source of".

Subclause 6.11 – DISTRIBUTED ALARM SYSTEM

Replace the entire existing rationale (modified by Amendment 1), including the title, with the following new title and rationale:

Subclause 6.11 – DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS

The use of DISTRIBUTED ALARM SYSTEMS is increasing. New ideas and new technology are bringing rapid advances and changes in this area. Long-, medium- and short-range two-way wireless communication opens new opportunities and new challenges for DISTRIBUTED ALARM SYSTEMS. At the same time, OPERATORS with different clinical training and new roles for OPERATORS will change the way that OPERATORS respond to ALARM SIGNALS. In many instances, remote OPERATORS can be at a distance from the PATIENT such that they might not be able to respond personally to a PATIENT or equipment problem. DISTRIBUTED ALARM SYSTEMS are enabling significant changes in the clinical workflow.

A MANUFACTURER should use the RISK MANAGEMENT PROCESS to be sure that their DISTRIBUTED ALARM SYSTEMS serve their primary purpose: to improve the ability of the correct, qualified OPERATOR to respond appropriately to a specific ALARM CONDITION, thereby ensuring that every ALARM CONDITION is responded to in a timely manner.

DISTRIBUTED ALARM SYSTEMS can include transmission of ALARM SIGNALS via wired or wireless local area networks, wired or wireless devices connected to the Internet, commercial landline and cellular telephone networks, commercial one-way or two-way paging systems, and other systems. In all these systems, there can be delays in ALARM CONDITION transmission because of demands on networks and other systems. In every case, there will be a delay before the SOURCE detects an ALARM CONDITION, a delay before generation of ALARM SIGNALS at the COMMUNICATOR at the SOURCE, a delay before the ALARM CONDITION is transmitted within the DISTRIBUTED ALARM SYSTEM and a delay before the remote COMMUNICATOR generates ALARM SIGNALS. Since these delays can vary at times due to factors outside the control of the MANUFACTURER and many of these delays are not deterministic, a statistical analysis is required to determine the time before the ALARM CONDITION is indicated with ALARM SIGNALS to the appropriate OPERATOR. It might not be possible to guarantee a maximum time.

Any system of transmission of information is subject to failure. In the event of failure of a component of a DISTRIBUTED ALARM SYSTEM or of the link between the affected SOURCE and a DISTRIBUTED ALARM SYSTEM, any relevant COMMUNICATORS are required to generate TECHNICAL ALARM SIGNALS. If the ALARM SYSTEM of the SOURCE had been placed in the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF and the system had been relying on a DISTRIBUTED ALARM SYSTEM for the notification to OPERATORS to ALARM CONDITIONS (e.g. the DISTRIBUTED ALARM SYSTEM is not inactivated), then if the DISTRIBUTED ALARM SYSTEM fails, the ALARM SYSTEM of the SOURCE should be automatically re-enabled.

EXAMPLE The ALARM SYSTEM of the SOURCE is AUDIO OFF (auditory ALARM SIGNAL volume set to zero) while the DISTRIBUTED ALARM SYSTEM is relied on to notify the OPERATOR. Upon detection of the failure, the ALARM SYSTEM of the SOURCE should return the volume to an audible level.

Some members of the committee argued that ALARM SIGNALS should always be delivered to the appropriate OPERATOR under SINGLE-FAULT CONDITION, at least for life-supporting equipment. The committee felt it to be impossible to specify requirements and tests for every such situation in this collateral standard.

In any event, as noted above, a RISK MANAGEMENT PROCESS should be used. Furthermore, MANUFACTURERS are required to disclose the characteristics, limitations and possible failure modes of their DISTRIBUTED ALARM SYSTEMS.

Subclause 6.11.1 – Existence of DISTRIBUTED ALARM SYSTEM

Replace the entire existing rationale, including the title, with the following new title and rationale:

Subclause 6.11.1 – Existence of DIS or DAS

DISTRIBUTED ALARM SYSTEM COMMUNICATORS can be provided by equipment to allow ALARM SIGNAL generation at a distance from the PATIENT. Remote COMMUNICATORS notify OPERATORS who are not currently in the PATIENT ENVIRONMENT but who are reasonably expected to be able to respond (or notify and request others to respond) in a timely fashion to the presence of ALARM CONDITIONS.

Subclause 6.11.2.2 – Failure of remote communication of ALARM CONDITIONS

Replace, in the second sentence, "remote generation of ALARM SIGNALS" *with* "remote COMMUNICATOR".

Subclause 6.11.2.2.1 – DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS

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

Subclause 6.11.2.2.1 – DAS or CDAS

Replace, in the second sentence of the existing first paragraph, added by Amendment 1, "as a source of" *with* "as a means of".

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

If the ALARM SYSTEM at the SOURCE has lost its link to a DISTRIBUTED ALARM SYSTEM, care is needed so that the ALARM SYSTEM at the SOURCE and the ME SYSTEM revert to a safe mode of operation. In other words, if the DISTRIBUTED ALARM SYSTEM which was being used as the means of OPERATOR notification of ALARM CONDITIONS is now inoperative, then the COMMUNICATOR of the ALARM SYSTEM at the SOURCE is the only COMMUNICATOR that can notify the OPERATOR. In this instance, auditory ALARM SIGNALS that are in an inactivated state (AUDIO OFF, AUDIO PAUSED, ALARM OFF, ALARM PAUSED, ACKNOWLEDGED) only in the ALARM SYSTEM at the SOURCE can need to have those states automatically terminated. Even so, as was discussed above, it is generally not necessary for every ALARM SYSTEM at the SOURCE in the unit to generate auditory ALARM SIGNALS when the link is lost.

Replace, in the existing fourth paragraph, added by Amendment 1, "bedside auditory ALARM SIGNALS" *with* "auditory ALARM SIGNALS at the SOURCE".

Add, after the existing fourth paragraph, added by Amendment 1, the following new paragraph:

When designing and configuring DAS and CDAS, careful consideration to the care PROCESS and clinical responsibilities should also consider redundancy in COMMUNICATOR coverage. For example, if the care unit is utilizing a private, in-building wireless phone system as the means to distribute ALARM CONDITIONS, the INTEGRATOR needs to be configured by the SOURCE (PATIENT) and by ALARM CONDITION to deliver the ALARM CONDITION to the appropriate COMMUNICATOR (caregiver). In many cases, these assignments should include redundant COMMUNICATORS (caregivers).

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

As a final example, if several COMMUNICATORS (OPERATOR-carried wireless devices) are used as a part of a DISTRIBUTED ALARM SYSTEM, the failure of one COMMUNICATOR need not generate ALARM SIGNALS at every PATIENT bedside, if the rest of the COMMUNICATORS assigned to a PATIENT can cover the loss of one. This can happen if there are several redundant COMMUNICATORS that are able to inform the relevant OPERATORS, or if the INTEGRATOR is able to provide REDIRECTION of the ALARM CONDITION to an appropriate COMMUNICATOR. If a central station and wireless devices are used as part of a DISTRIBUTED ALARM SYSTEM, perhaps the only "relevant" part of the DISTRIBUTED ALARM SYSTEM is really the central station, or perhaps there are some specific beds that would be affected by the failure. It is doubtful that, for example, all 40 PATIENT bedsides would require presentation of ALARM SIGNALS.

Subclause 6.11.2.2.2 – DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS

Replace the entire existing rationale, including the title, modified by Amendment 1, with:

Subclause 6.11.2.2.2 – DIS

With a DIS, it is impossible for the ALARM SYSTEM at the SOURCE to know if the COMMUNICATOR has not received an ALARM CONDITION, or if it has failed. In this case, the MANUFACTURER is required to warn the RESPONSIBLE ORGANIZATION and the OPERATOR by marking on the COMMUNICATOR not to rely upon the DISTRIBUTED ALARM SYSTEM for generation of ALARM SIGNALS. A DIS can be useful, even if it does not work 100 % of the time. Still, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS should take precautions so that PATIENT safety is not compromised.

An example of a DIS is a one-way paging system that uses a commercial paging service. The ALARM SYSTEM or DAS is designed as if the one-way paging system were not present, so that there are always COMMUNICATORS providing ALARM SIGNALS that will notify the OPERATORS of ALARM CONDITIONS in appropriate locations. But if the paging system is working correctly, pages to COMMUNICATORS worn by the OPERATORS allow the OPERATORS to understand the problem more quickly than the DISTRIBUTED ALARM SYSTEM does. In such a system, the OPERATOR is expected to remain in notification range of the rest of the DAS and only use the paging COMMUNICATOR for additional information. Thus the existence of the one-way paging system only decreases OPERATOR response time, and never increases it, compared to the option of deleting the paging system altogether.

Subclause 6.11.2.2.3 – ME EQUIPMENT with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

*Replace, in the title of the rationale, "*ME EQUIPMENT*" with* "SOURCE".

Replace, in the last sentence of the existing second paragraph, "unnecessary ALARM SIGNALS" *with* "NUISANCE ALARM SIGNALS."

Subclause 6.11.2.3 – Remote ALARM SYSTEM controls

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

A remote OPERATOR at a central station ("monitor watcher") can respond to ALARM SIGNALS and examine waveforms or check the PATIENT on a video monitor. The remote OPERATOR then notifies other OPERATORS in the event of a CLINICALLY ACTIONABLE ALARM CONDITION, or does not notify other OPERATORS in the event of a FALSE POSITIVE ALARM CONDITION or CLINICALLY NONACTIONABLE ALARM CONDITION. In either case, the remote OPERATOR commonly invokes ACKNOWLEDGED, uses another ALARM SIGNAL inactivation state, adjusts ALARM LIMITS, changes ALARM PRIORITY, or determines which ALARM CONDITIONS need to generate ALARM SIGNALS. The functions permitted to the remote OPERATOR depend upon the configuration of the DISTRIBUTED

ALARM SYSTEM and upon the policies of the RESPONSIBLE ORGANIZATION [31]. On this basis it is imperative for the RESPONSIBLE ORGANIZATION to determine what powers are or are not granted to the remote OPERATOR and so configure the DISTRIBUTED ALARM SYSTEM.

Add, before the second existing paragraph, the following new rationale:

Subclause 6.11.2.4 – CDAS

The terms RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED, and RESPONSIBILITY UNDEFINED are new to this document. They are most often applicable to a DISTRIBUTED ALARM SYSTEM for use in an intensive care setting or a hospital ward setting, in which each OPERATOR has a COMMUNICATOR (example: pocket pager or phone) that provides an ALARM CONDITION to a specific OPERATOR. If the DISTRIBUTED ALARM SYSTEM presents an ALARM CONDITION to a specific OPERATOR, then there can be three possibilities:

– the specific OPERATOR accepts responsibility for the ALARM CONDITION, and the state RESPONSIBILITY ACCEPTED becomes true;
– the specific OPERATOR is busy and therefore rejects responsibility, the state RESPONSIBILITY REJECTED becomes true, and the DISTRIBUTED ALARM SYSTEM redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR;
– the OPERATOR does not respond to the ALARM SIGNAL within the timeframe established by the RESPONSIBLE ORGANIZATION in the INTEGRATOR, the state RESPONSIBILITY UNDEFINED becomes true, and the INTEGRATOR redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR in this instance also.

A similar configuration might be provided for other DISTRIBUTED ALARM SYSTEMS, for instance, from a bedside monitor to a different bedside monitor, or from a beside monitor to a central station.

Care is needed in the design of a CDAS when there is a non-homogenous set of SOURCES. The logic (REDIRECTION and ESCALATION) behind the processing of RESPONSIBILITY UNDEFINED can become very complex and needs to take into account how each SOURCE responds to the resulting states. These complex systems can inadvertently cause ALARM FLOOD or 'lost' ALARM CONDITIONS (i.e. no assigned COMMUNICATOR).

Such a configuration would not be expected in ME EQUIPMENT without a DISTRIBUTED ALARM SYSTEM. For example, an anaesthesia workstation, for which an OPERATOR is normally present during all PATIENT care, would not be expected to provide these functions.

Subclause 6.12 – ALARM SYSTEM logging

Replace the existing third paragraph with the following new paragraph:

If there is a log, all ALARM CONDITIONS, or all ALARM CONDITIONS at or above a specified priority, should be logged. TECHNICAL ALARM CONDITIONS are as important as PHYSIOLOGICAL ALARM CONDITIONS, since many situations are problematic as to whether the cause of an ALARM CONDITION is technical or physiological (e.g. low signal strength).

Add, at the end of the existing rationale for 6.12, modified by Amendment 1, the following new rationales:

Subclause 6.12.2 – OPERATOR ALARM SYSTEM logging

An OPERATOR ALARM SYSTEM log can be used for reviewing and analysing events that have occurred for a PATIENT, typically while the PATIENT is still connected to the ME EQUIPMENT, or after they are disconnected from the ME EQUIPMENT, but before being discharged from the ME EQUIPMENT. This OPERATOR ALARM SYSTEM log can be used to identify the state of the ALARM SYSTEM, including the activation/inactivation status, at the time of an ALARM CONDITION.

In general, the OPERATOR ALARM SYSTEM log contains HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS but could also contain LOW PRIORITY ALARM CONDITIONS if the RESPONSIBLE ORGANIZATION finds it necessary. For example, LOW PRIORITY ALARM CONDITIONS could include low battery ALARM CONDITIONS for a telemetry transmitter that can be beneficial to aid in analysis or planning of workflow.

The OPERATOR ALARM SYSTEM log can be useful for:

a) reviewing the ALARM CONDITION history of the PATIENT;

b) reviewing the ALARM SETTINGS used for the PATIENT, including ALARM LIMITS and ALARM INACTIVATION STATES;

c) analysis of ALARM CONDITION events associated with a PATIENT, including date, time, and length of the event; and

d) annotation and rationale for adjustments made to the ME EQUIPMENT ALARM SETTINGS based on the clinical acuity of the PATIENT.

The OPERATOR ALARM SYSTEM log is unique for a PATIENT. That is to say, when a new PATIENT is connected, a new log should be established. This is necessary to prevent PATIENT-to-data-association errors and for proper analysis of events and workflows. The identification of a new PATIENT could, and most likely would, occur when a different PATIENT is admitted. A means could be provided, either automatically or manually, for the OPERATOR to enable identification of a different PATIENT.

The OPERATOR ALARM SYSTEM log can provide a means to enable the OPERATOR to insert notes or comments to the log, which can assist in identification or rationale for ALARM SYSTEM adjustments, including ALARM LIMIT SETTINGS and activation/inactivation states of the ALARM SYSTEM. The identification of the OPERATOR who inserted notes or comments in the log is beneficial in the review of ALARM CONDITION events and clinical workflow for further or more detailed analysis of the history of the state of the PATIENT.

Subclause 6.12.3 – RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

A RESPONSIBLE ORGANIZATION ALARM SYSTEM log can be used for analysing events that occurred in the past, typically after a PATIENT has been disconnected and the ME EQUIPMENT is no longer being used for the PATIENT to whom it was connected during an event. Sometimes this is called a forensic log in that it is used to identify a sequence of conditions, or the state of the ME EQUIPMENT ALARM SYSTEM so the RESPONSIBLE ORGANIZATION can analyse how the event occurred in the first place. The cause can have been due to changing an ALARM SETTING in which case the RESPONSIBLE ORGANIZATION needs understanding to assist them in determining their ALARM SYSTEM management PROCESSES.

In general, the RESPONSIBLE ORGANIZATION ALARM SYSTEM log should contain all the elements in the OPERATOR ALARM SYSTEM log plus additional information that can be used to analyse all aspects of suspected events. This can be a necessity to understanding all conditions in place during an event.

The RESPONSIBLE ORGANIZATION ALARM SYSTEM log can be useful for:

a) logging of ALARM CONDITIONS, including any ALARM SIGNAL inactivation state;

b) determining the ALARM SETTINGS and any change that was made to ALARM SETTINGS and the time the changes were made;

c) determining when an ALARM CONDITION began and ended (the amount of time an ALARM CONDITION existed); and

d) identifying TECHNICAL ALARM CONDITIONS in addition to PHYSIOLOGICAL ALARM CONDITIONS.

Since the RESPONSIBLE ORGANIZATION ALARM SYSTEM log files are used to determine the configuration of the ME EQUIPMENT during an event, it should not be possible to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log. To allow this would create an inaccurate representation of the state of the ME EQUIPMENT and could be misleading.

Because many events are analysed after the fact when the ME EQUIPMENT might have been powered down, or a different PATIENT admitted, the RESPONSIBLE ORGANIZATION ALARM SYSTEM log should retain this data for a sufficient period.

The instructions for use should provide a description of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log so the RESPONSIBLE ORGANIZATION has an understanding of how to retrieve the data and the period for which the data is still available in the log. If the data are maintained on a first in, first out basis, the instructions for use should so state.

Delete the existing rationale for Annex F, including the existing Tables A.1 and A.2.

Add, at the end of Annex A, the following new rationales and new Table A.2:

Annex G – Auditory ALARM SIGNAL

A sizeable body of evidence that demonstrates that AUDITORY ICONS are easier to learn and recognize than more abstract ALARM SIGNALS and sounds exists. The main reason for this is that AUDITORY ICONS, which are usually everyday sounds, have much stronger links with the events that they are representing than do abstract sounds. For example, once a user knows that a cardiovascular ALARM CONDITION is indicated by a heartbeat, or a sound that has been developed in order to sound like a heartbeat, they are likely to remember this association rapidly and long-term. A second reason for advocating the use of AUDITORY ICONS is that real-world sounds are often harmonically rich and complex, making them easier to localize and making them more resistant to masking than abstract sounds. A third by-product of the use of AUDITORY ICONS is that the selection of specific AUDITORY ICONS for specific functions means that sounds which might occur naturally in a clinical environment might be avoided, thereby preventing confusion.

The general advantages of using AUDITORY ICONS are described in the literature [34] [35] [36] [37] [38].

The committees know more about the performance of these auditory ALARM SIGNALS than probably any auditory ALARM SIGNALS in history, and the data is available in high-quality peer-reviewed publications that are in the public domain. The performance data of these auditory ALARM SIGNALS is embodied in Table H.1. Most of the data for Table H.1 comes from four key papers [36], [66], [67], [68].

The committees know so much about these auditory ALARM SIGNALS that they can extrapolate from the findings to situations where the auditory ALARM SIGNALS might not have been directly tested. There are three points that are important to note.

1) The two main requirements of the new auditory ALARM SIGNALS are that they are audible and recognizable. Almost everything else is a matter of taste and preference. The committees have considerable data to show that both learnability and audibility are high with regard to all of the proposed new auditory ALARM SIGNALS.
2) In terms of these two principles of audibility and recognisability, the key factors that influence people's ability to detect and recognize the sounds are their age and their hearing ability, rather than their clinical role or some other local variable. There can be some cultural factors around suitability and recognisability, but this document permits development in these areas.

3) There are many principles and known scientific observations which allow the committees to predict outcomes of some features (such as audibility), without the need to test the auditory ALARM SIGNALS in all possible environments. Because the proposed auditory ALARM SIGNALS perform so well on so many counts, it would be correct to say that if it is a struggle to hear and recognize these auditory ALARM SIGNALS, then it would be a struggle to hear and recognize any auditory ALARM SIGNALS and therefore a solution other than auditory ALARM SIGNALS (e.g. vibration, stroboscopic lights) would be appropriate under those circumstances.

Auditory ALARM SIGNALS cannot be imbued with magical properties allowing them to work in all possible environments, regardless of how extreme or unusual that environment might be. However, the committees have used what is known about auditory cognition and perception to develop and test these auditory ALARM SIGNALS. They follow best practice and are the best they can be, given what the committees know and can predict from the science.

Clause G.1 a) 2) – General

Adding an AUDITORY ICON to a LOW PRIORITY ALARM SIGNAL unnecessarily increases the audio burden on the OPERATOR. Additionally, given the short nature of the LOW PRIORITY AUDITORY POINTER, its priority could be masked by the AUDITORY ICON.

Clause G.2 – AUDITORY POINTERS

Table G.1 and Table G.2 specify the spectral, amplitude and timing variables for the HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY AUDITORY POINTERS. The three priority levels are differentiated via the application of acoustic parameters, which are known to be important in determining the perceived urgency and the detectability/resistance to masking of the sounds.

The intent of the AUDITORY POINTER is to identify the COMMUNICATOR generating the ALARM SIGNAL and indicate the ALARM CONDITION priority, whereas the intent of the AUDITORY ICON is to identify the category of the ALARM CONDITION as well as to localize the COMMUNICATOR generating the ALARM SIGNAL. The categories are meant to distinguish between types of ME EQUIPMENT (the type of physiological function affected) generating the ALARM CONDITION. The OPERATOR is able to respond to the ALARM CONDITION more quickly by knowing the type of ME EQUIPMENT that generated the ALARM CONDITION. In order to localize the ALARM SIGNAL, it is important that the AUDITORY ICON be in combination with the AUDITORY POINTER. The reference AUDITORY ICONS use pitch, rhythm and auditory streaming to facilitate separation from the AUDITORY POINTER; the ear readily detects both sounds even when heard together. Table G.4 illustrates the characteristics of the AUDITORY ICONS including their metaphors and descriptions.

Urgency

Many acoustic parameters influence the perceived urgency of sound. These include pitch and frequency, amplitude, speed, repetition, harmonic harshness and musical structure, among other factors. These factors can be used to both differentiate between levels of urgency and influence the absolute level of urgency of a sound. The former is easier to achieve than the latter so consideration should be given to how the AUDITORY POINTERS work in the environment for which they have been designed.

Relative urgency: If one ALARM SIGNAL is higher pitched, louder and faster and repeats more often (and more quickly) than another it will likely be judged more urgent. Equally, the reverse is true: ALARM SIGNALS that are lower pitched, softer, slower and repeat more slowly (or not at all) will likely be judged less urgent. However, caution should be used with using loudness to influence urgency as:

a) if ALARM SIGNALS are too loud, they startle; and

b) the loudness of ALARM SIGNALS should be determined by the typical level of ambient noise, which would be the same for all ALARM SIGNALS, regardless of their urgency. See the rationale for Subclause 6.3.3.2; and

c) OPERATORS cannot compare the loudness of two ALARM SIGNALS unless they are presented adjacent to each other. Therefore, loudness can rarely be used effectively to indicate urgency.

Absolute urgency: If an ALARM SIGNAL is designed according to the known principles of urgency, listeners find it possible to triage (at least) ALARM SIGNALS into HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY – although it is impossible to say exactly where the cut-off between categories occurs. If a HIGH PRIORITY ALARM SIGNAL is perceived as being too urgent, it can be made less urgent by applying the known principles of urgency and, if it is not urgent enough, it is possible to do the reverse. Further refinement of urgency can be achieved by manipulating secondary factors such as harmonic structure and harmonic content, for example, see [39], [40], [41], [42], [43] and [44].

Detectability

The requirement that the PULSES of the AUDITORY POINTERS should possess a fundamental frequency between 150 Hz and 1 000 Hz, with at least four frequency peaks below 4 000 Hz, is primarily for detectability, resistance to masking and localizability (though variation in harmonic content can also influence urgency, as indicated above). One of the major reasons for 4 peaks is that pure tones are irritating to listen to, and are more likely to startle an OPERATOR. In general, the more frequencies (and harmonic peaks) a sound possesses, the more resistant it will be to masking and the more likely it will be localized with some accuracy. This will be true for both AUDITORY POINTERS and AUDITORY ICONS. Frequencies between approximately 800 Hz and 1 600 Hz are not useful for the purposes of localization (but will be useful for resistance to masking) as neither of the two mechanisms the head uses for localization work within this range. In general, the more frequency components a sound possesses, the easier it will be to localize and the more resistant to masking it will be. Software and models that allow the modelling and prediction of masking exist [45] [46] [47] [48] [49] [50].

Most of the audibility issues can be predicted from what is known about the science of detectability. The key to this is the signal-to-noise ratio at which a sound is detectable. The test data shows that the auditory ALARM SIGNALS are detectable at very low signal-to-noise ratios, and this is a consequence of the way the auditory ALARM SIGNALS were designed in the first place [66].

Because the AUDITORY POINTERS (to some extent) and the AUDITORY ICONS (to a larger extent) are complex sounds with many harmonics, they are much more resistant to masking by other sounds than most of the ALARM SIGNALS currently being used. By using many harmonics and ensuring that the auditory ALARM SIGNALS contain some low frequency harmonics, the audibility of the ALARM SIGNALS has been maximised, as the data suggests. Thus, these auditory ALARM SIGNALS are at least as audible as almost any other sound that might be used in the same contexts. This means that their volume can be kept at a reasonable level. There can be some exceptional circumstances where the auditory ALARM SIGNALS might be temporarily masked, but this would be the case for any other auditory ALARM SIGNAL and most other auditory ALARM SIGNALS will be less resistant to masking. The solution to this rare problem is to recommend that auditory ALARM SIGNALS are not made so loud that they are aversive under most other circumstances. In such circumstances, using auditory ALARM SIGNALS might not be appropriate.

Learnability

Early formative testing compared the learnability of Annex F auditory ALARM SIGNALS to new AUDITORY POINTERS as well as the combination of the AUDITORY POINTERS and AUDITORY ICONS. The existing general auditory HIGH PRIORITY ALARM SIGNAL had 65 % accuracy while the new HIGH PRIORITY AUDITORY POINTER had more than 80 % accuracy. The remaining Annex F auditory ALARM SIGNALS had an accuracy that ranged from 25 % to 35 % [36].

Clause G.3 – AUDITORY ICONS

AUDITORY ICONS are presented along with either a HIGH PRIORITY or a MEDIUM PRIORITY AUDITORY POINTER (see Clause G.2), depending on the urgency of the situation being signalled. The reserved AUDITORY ICONS are listed in Table G.3.

An AUDITORY ICON should contain many harmonic components or peaks, and for guidance these should be no less than as indicated in Table G.2. As AUDITORY ICONS are intended to be everyday sounds, it is likely that there will be considerable variation in the amplitude of the spectral peaks so care needs be taken to ensure that an appropriate number of the spectral peaks are within 15 dB of one another.

An advantage of the complex harmonic structure is that the AUDITORY ICONS are easier to localize (to tell the direction from which the sound is coming) than the current auditory ALARM SIGNALS [36] [67].

Table G.4 – Characteristics of the AUDITORY ICON

There are important conceptual issues that need to be considered when using Table G.4 and its information.

The categories in Table G.4 are derived from a "risk-and-response rationale" [51]. Other categories, or subdivisions of categories, can be appropriate for specific environments. The use of more than eight categories is possible with the use of AUDITORY ICONS as they are considerably easier to learn and retain than abstract ALARM SIGNALS and melodies. However, there is always a RISK that as the number of ALARM SIGNALS increases the possibility of masking becomes more likely. Thus, the number of ALARM SIGNALS used in any environment should never be more than the minimum number considered necessary.

However, in a DISTRIBUTED ALARM SYSTEM with multiple SOURCES and multiple COMMUNICATORS, careful consideration is needed to determine the appropriate AUDITORY ICON or AUDITORY ICONS, if any, to use on a COMMUNICATOR.

EXAMPLE 1 A multi-PATIENT central station COMMUNICATOR might not use AUDITORY ICONS, even if some or all of the ALARM SIGNALS are using AUDITORY ICONS at the local COMMUNICATOR of the SOURCE.

EXAMPLE 2 A role-based COMMUNICATOR, such as a mobile app used by the respiratory therapist, where the AUDITORY POINTER and AUDITORY ICON might be used for specific ALARM CONDITIONS, but only the general AUDITORY POINTER for other specific ALARM CONDITIONS.

Generating new or alternative categories is likely to work best if any new categories are developed through the application of an underlying principle or set of principles, rather than being piecemeal. For example, a category might be designated by equipment type, or could represent a subdivision of a basic category. However, if new categories are generated, it is important to be aware of how each new category fits into the ALARM SYSTEM hierarchy or philosophy, and that the mapping of sounds and categories back to the philosophy is recorded and understood at some point in the PROCESS by the MANUFACTURER [52].

The generation of appropriate categories is also likely to lead to greater success if an empirical, user-centred PROCEDURE is used to derive those categories. Two possible methods are reported in the literature [53] [54].

The AUDITORY ICONS have been tested in a number of lab and simulation studies and have been found to perform well in comparison to both the melodies of Annex F and other sounds which themselves are an improvement on the melodies of Annex F [36] [66] [67] [68].

The AUDITORY ICON metaphor has been selected after testing and has been found to be adequate (see Clauses H.1 and H.2).

It is possible for a MANUFACTURER to perform the following.

a) Develop an AUDITORY ICON (sound) for the same category that is different acoustically from the one indicated. As an example, the current temperature sound might be replaced with a different sound, which has a different spectrum – possibly a lower frequency sound, or the introduction of a temporal pattern into the same sound, etc. This does not alter the nature of the metaphor.

b) Develop a new metaphor for one or more categories. For example, the current temperature category might be replaced with another metaphor and AUDITORY ICON (sound) that represents "frying on the stove", which has a different spectrum – possibly a lower frequency sound, or the introduction of a temporal pattern into the same sound, etc. This does not alter the nature of the metaphor as it is also associated with temperature.

Reasons for doing this might include:

– the presence of a complex or unusual noise background (so a new sound or metaphor needs to be developed in order to be heard);

– other sounds in the environment that might be confused with the current sound or metaphor;

– a particular version of the metaphor or a different metaphor is considered to be capable of better performance than the provided sounds.

Annex H provides an evaluation PROCEDURE for a different sound or metaphor for

c) the existing categories; or

d) new categories.

Table A.2 contains examples of ME EQUIPMENT for each category of the SOURCE of the ALARM CONDITION.

Table A.2 – Examples of ME EQUIPMENT for each category of the SOURCE of an ALARM CONDITION

Category	Examples
General	Other ME EQUIPMENT that does not readily fall into one of the following categories including, but not limited to, electrical or non-oxygen gas supply systems, EEG monitors, intracranial pressure monitors, laparoscopic gas insufflation systems, calf compressor systems, bed exit systems, etc. Additionally, this category is permitted for the ALARM SYSTEM of any kind of equipment.
Cardiovascular	Anaesthesia workstations that include cardiac monitors, multi-parameter monitors which include cardiac monitors, heart rate monitors, invasive or non-invasive blood pressure monitors, cardiac output monitors, external pacemakers, peripheral perfusion monitors (plethysmographs), transoesophageal echo, foetal heart rate monitors.
Artificial perfusion	Cardio-pulmonary perfusion pumps ("heart-lung machines") and associated equipment, intra-aortic balloon pumps or left ventricular assist devices, renal dialysis systems, extracorporeal membrane oxygenation systems and continuous veno-venous haemodialysis
Ventilation	Ventilators, ventilatory support equipment, spirometers, CO_2 monitors, ventilator disconnect (airway pressure) monitors, nitric oxide delivery systems, anaesthesia workstations which include ventilators (but which do not include cardiac monitors) and apnoea monitors
Oxygenation	Pulse oximeters, transcutaneous/tissue oxygen monitors, oxygen analysers, oxygen concentrators, oxygen gas supply lines
Temperature/energy delivery	Temperature monitors, warming blankets, respiratory heated humidifiers, infant radiant warmers, neonatal incubators, PATIENT heating or cooling systems, blood or fluid warmers; electrocautery, ultrasound systems, diagnostic imaging systems, nerve stimulators and laser systems
Drug or fluid delivery/administration	Volumetric infusion pumps, syringe pumps, enteral delivery systems, anaesthetic agent delivery systems and anaesthetic agent analysers
Equipment or supply failure	Any ME EQUIPMENT when it experiences loss of power or other major failure of the ME EQUIPMENT

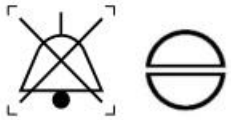
Table B.3 – Cross-reference of instructions for use

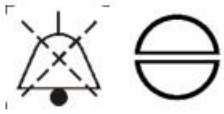
Replace the sixth, seventh and eighth rows, modified by Amendment 1, with the following new rows:

Capacity of the log	6.12.2 j) 4)
Means for the OPERATOR to access the OPERATOR ALARM SYSTEM logALARM CONDITION log after power down	6.12.2 j) 1)
RESPONSIBLE ORGANIZATION ALARM SYSTEM log capacity	6.12.3 g) 1)
What happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power for a finite duration	6.12.2 j) 3)
What happens to the contents of the log as it reaches capacity	6.12.2 j) 5)
What happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity	6.12.3 g) 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	6.12.2 j) 2)

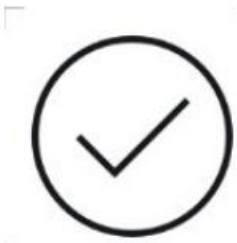
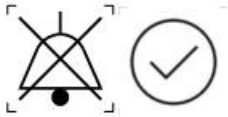
Table C.1 – Graphical symbols for ALARM SYSTEMS

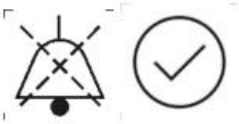
Replace the existing rows 6, 8 and 9, modified by Amendment 1, with the following new rows:

6		IEC 60417-5576-2 (2012-09)	Bell, cancel temporary	To indicate the operating status of the bell being temporarily cancelled.	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of broken lines: AUDIO PAUSED To identify the control for AUDIO PAUSED or to indicate that the ALARM SYSTEM is in the AUDIO PAUSED state. *NOTE 1 The ALARM CONDITION may be indicated inside, below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below or beside the bell.*
8	 Or 	IEC 60417-5576-1 (2012-09) Combination of: ISO 7000-1326 (2004-01) and IEC 60417-5576 (2002-11)	Bell, cancel acknowledged; acknowledged	To identify the control whereby a bell may be acknowledged or to indicate that the bell has been acknowledged. The alarm condition may be indicated below or beside the bell.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state for an indefinite period. *NOTE The ALARM CONDITION may be indicated below or beside the bell.*

9	 Or 	IEC 60417-5576-3 (2012-09) Combination of: ISO 7000-1326 (2004-01) and IEC 60417-5576-2 (2012-09)	Bell, cancel temporary acknowledged; temporary acknowledged	To identify the control whereby a bell may be temporarily acknowledged or to indicate that the bell has been temporarily acknowledged. A numerical time remaining counter may be placed above, below, or beside the symbol.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state until a time interval has elapsed. *NOTE 1 The ALARM CONDITION may be indicated below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below, or beside the bell.*

Add, after the last row, the following new rows:

13		ISO 7000-6334A (2015-06)	Selection; affirmative acknowledgement; success; ACK	To identify the control to acknowledge affirmatively and to indicate the status of acknowledgement, or to indicate the successful status.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED or RESPONSIBILITY ACCEPTED To identify the control for ACKNOWLEDGED or RESPONSIBILITY ACCEPTED or to indicate that the ALARM CONDITION is in the RESPONSIBILITY ACCEPTED state.
14	 Or 	IEC 60417-5576-4 (2019-03) Combination of: ISO 7000-6334A (2015-06) and IEC 60417-5576 (2002-11)	Bell, cancel affirmatively acknowledged; acknowledged Acknowledge-ment Bell cancel	To identify the control whereby a bell cancel may be affirmatively acknowledged for an indefinite period or to indicate that the bell has been affirmatively acknowledged for an indefinite period. *NOTE 1 See also variant IEC 60417-5576-5 as a member of the same group of symbols.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state for an indefinite period. *NOTE The ALARM CONDITION may be indicated below or beside the bell.*

15	 Or 	IEC 60417-5576-5 (2019-03) Combination of: ISO 7000-6334A (2015-06) and IEC 60417-5576-2 (2012-09)	Bell, temporary cancel affirmatively acknowledged; temporarily acknowledged Acknowledge-ment Bell cancel	To identify the control whereby a bell may be affirmatively acknowledged until a time interval has elapsed or to indicate that the bell has been affirmatively acknowledged until a time interval has elapsed. *NOTE 1 The acknowledged state will terminate at the end of a prescribed time interval and the auditory component will reactivate if the alarm conditions have not been cleared.* *NOTE 2 See also variant IEC 60417-5576-4 as a member of the same group of symbols.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state until a time interval has elapsed. *NOTE 1 The ALARM CONDITION may be indicated below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below or beside the bell.*
16		ISO 7000-6335A (2015-06)	Negative acknowledgement; failure; NACK	To indicate the status of negative acknowledgement, or to indicate the failed status.	On medical ALARM SYSTEMS this graphical symbol is used as follows: RESPONSIBILITY REJECTED To identify the control for RESPONSIBILITY REJECTED or to indicate that the ALARM CONDITION is in the RESPONSIBILITY REJECTED state.

Annex F – * Reserved melodies for ALARM SIGNALS

Delete the asterisk from the existing title.

Replace the existing text with the following new text:

The contents of Annex F that were previously included in this document have been deleted. Research has shown that those melodies are not fit for this purpose, which is to say that it is now known that OPERATORS cannot effectively discriminate the melodies [61] [62] [63] [64] [65]. MANUFACTURERS that desire to have equipment-encoded auditory ALARM SIGNALS should use the ALARM SIGNALS of Table G.4 or Table G.5.

Add, after the existing Annex F, the following two new annexes.

Annex G
(normative)

* Auditory ALARM SIGNALS

G.1 General

a) The auditory ALARM SIGNALS shall consist of:

   1) an AUDITORY POINTER complying with Clause G.2;

   2) * for MEDIUM PRIORITY and HIGH PRIORITY ALARM SIGNALS, an AUDITORY POINTER complying with Clause G.2 and an AUDITORY ICON complying with Clause G.3; or

   3) an auditory ALARM SIGNAL complying with Table G.5.

b) The ALARM SIGNALS of any ALARM CONDITIONS of any COMMUNICATOR may utilize an AUDIO POINTER without an AUDITORY ICON (see Table G.3).

Compliance is checked by inspection.

G.2 * AUDITORY POINTERS

The HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY AUDITORY POINTERS shall comply with the requirements of:

a) Table G.1 and Table G.2; or

b) Table G.3.

Figure G.1 and Figure G.2 are intended to show the designation of temporal characteristics and do not illustrate any individual auditory ALARM SIGNAL.

Compliance is checked by inspection.

G.3 * AUDITORY ICONS

For each ALARM CONDITION whose ALARM SIGNAL includes an AUDITORY ICON, the AUDITORY ICON shall:

a) be selected from Table G.4 or Table G.5; or

   1) A COMMUNICATOR need not utilize more than one AUDITORY ICON.

b) be representative of one of the defined categories indicated in Table G.4 and shall be VALIDATED according to Annex H; or

c) be representative of the MANUFACTURER-determined category related to the SOURCE of the ALARM CONDITION and shall be VALIDATED according to Annex H.

Compliance is checked by inspection.

Table G.1 – Characteristics of the BURST of the AUDITORY POINTER

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
Pointer PULSE spacing (t_s) (see Figure G.1)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$4x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,15 s to 0,65 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	$4x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b) (see Figure G.1)	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 12 ms and 50 ms;

y shall be a value between 50 ms and 100 ms;

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

MEDIUM PRIORITY t_s shall be greater than or equal to HIGH PRIORITY t_s; and

the PULSE spacing between the 5th and 6th PULSE shall be greater than the PULSE spacing between the 3rd and 4th PULSE and between the 8th and 9th PULSE.

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 G.2 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

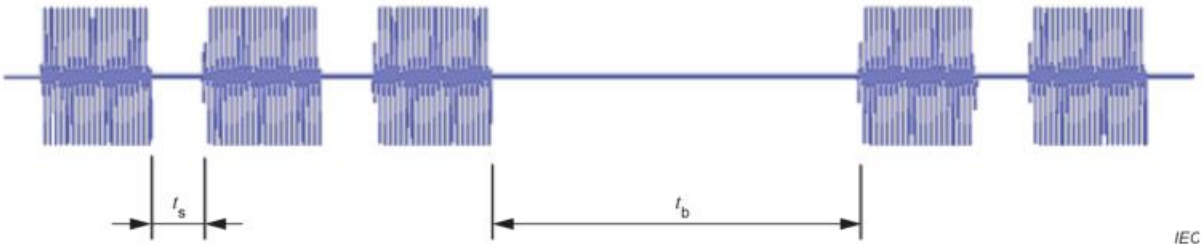
[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the 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 POINTERS shall complete at least one BURST, and a HIGH PRIORITY AUDITORY POINTER shall complete at least half of one BURST.

Table G.2 – Characteristics of the PULSE of the AUDITORY POINTER

Characteristic	Value
Frequency component in the range of 150 Hz to 1 000 Hz	At least one that is among the five frequency components with the largest sound pressure level
Number of peaks in the frequency range of 150 Hz to 4 000 Hz	At least five peaks in the frequency domain
Effective PULSE duration (t_d) (see Figure G.2)	
HIGH PRIORITY	25 ms to 75 ms
MEDIUM PRIORITY	90 ms to 200 ms
LOW PRIORITY	400 ms to 600 ms
RISE TIME (t_r) (see Figure G.2)	[a]
FALL TIME (t_f) (see Figure G.2)	[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.	
[a] The RISE TIME should not be so short as to create mechanical speaker noise. Very fast RISE TIMES can lead to sound distortion.	
[b] The FALL TIME should be short enough to ensure that the PULSES do not overlap.	



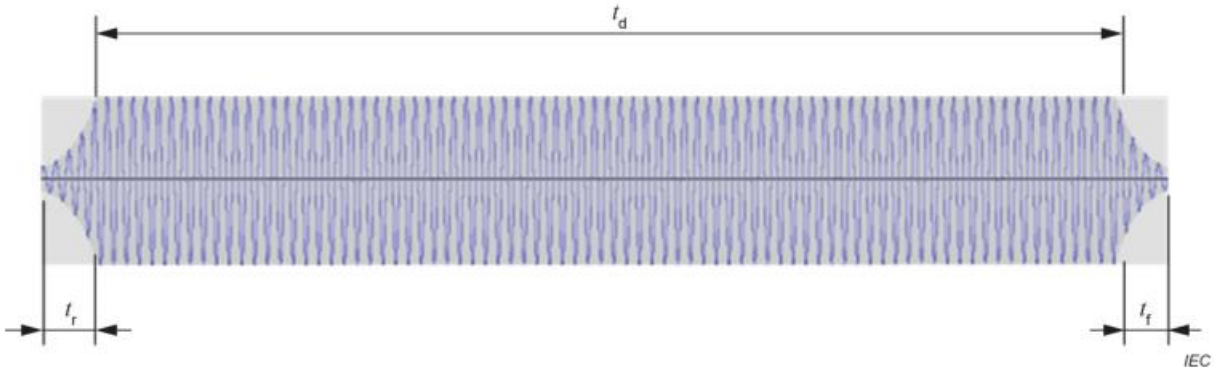
Key

t_s pointer PULSE spacing (time from the end of one PULSE to the start of the next PULSE)

t_b INTERBURST INTERVAL (time from the end of one BURST to the start of the next BURST)

NOTE See Figure 1 for additional information.

Figure G.1 – Illustration of spacing of AUDITORY POINTER



Key

t_d pointer PULSE duration

t_r POINTER RISE TIME

t_f POINTER FALL TIME

NOTE 1 The relative amplitude of a PULSE is a function of time.

NOTE 2 See Figure 1 for additional information.

Figure G.2 – Illustration of temporal characteristics of an AUDITORY POINTER

Table G.3 – Characteristics of the AUDITORY POINTER

ALARM CONDITION priority	File name of AUDITORY POINTER [a]
LOW PRIORITY	low.wav
MEDIUM PRIORITY	medium.wav
HIGH PRIORITY	high.wav
[a] Sound files are available at: https://www.iec.ch/tc62/supportingdocuments or https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1	

Table G.4 – * Characteristics of the AUDITORY ICON

Category of the SOURCE of the ALARM CONDITION	AUDITORY ICON metaphor	AUDITORY ICON description	File name of AUDITORY ICON [a]
General [b]	none	none	—
Cardiovascular	"Lup-dup"; heartbeat sound	A stylized, square/triangle wave-based "heartbeat" sound with no discernible frequency. Six PULSES formed from three 2-PULSE "lup-dup" sequences	cardiovascular.wav
Artificial perfusion	Liquid disturbance, water churning, bubbles	Two approximately 1 s sequences of a strong water bubbling sound, separated by silence	perfusion.wav
Ventilation	A single inhale followed by an exhale	A 1 s inhaling sound (like white noise), followed by a 0,5 s gap, followed by a slow exhale with a long tail	ventilation.wav
Oxygenation	Irregular, stylized dripping/saturation	Stylized irregular temporal pattern with some discernible pitch; a two-tone sequence superimposed on the six-tone pattern	oxygenation.wav
Temperature/energy delivery	Whistling kettle	Complex sound including high frequency harmonics, rising slowly over approximately 2 s	temperature.wav
Drug or fluid delivery/administration	Shaking pill bottle	Two 0,8 s sequences of a 4-rattle shaking sound	drug_delivery.wav
Equipment or supply failure	Starting up a motor that shuts down suddenly	Spectrally complex sound of a motor revving up (increasing in frequency) over approximately 1,2 s then an abrupt stop tailing off for approximately 0,5 s	failure.wav

[a] Sound files are available at:
https://www.iec.ch/tc62/supportingdocuments or
https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1

[b] The "general" category has no AUDITORY ICON; only an AUDITORY POINTER is used.

Table G.5 – Characteristics of the auditory ALARM SIGNAL

Category of the SOURCE of the ALARM CONDITION	File name of AUDITORY POINTER plus AUDITORY ICON [a]	
	HIGH PRIORITY	MEDIUM PRIORITY
Cardiovascular	HP-cardiovascular.wav	MP-cardiovascular.wav
Artificial perfusion	HP-perfusion.wav	MP-perfusion.wav
Ventilation	HP-ventilation.wav	MP-ventilation.wav
Oxygenation	HP-oxygenation.wav	MP-oxygenation.wav
Temperature/energy delivery	HP-temperature.wav	MP-temperature.wav
Drug or fluid delivery/administration	HP-drug_delivery.wav	MP-drug_delivery.wav
Equipment or supply failure	HP-failure.wav	MP-failure.wav

[a] Sound files are available at:
https://www.iec.ch/ tc62/supportingdocuments or
https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1.

Annex H
(informative)

VALIDATION of AUDITORY ICONS

H.1 Background to the AUDITORY POINTERS and AUDITORY ICONS specified in Table G.1 to Table G.5

H.1.1 How the ALARM SIGNALS specified in Table G.1 to Table G.5 were derived

The reserved AUDITORY POINTERS in Table G.1 and Table G.2 and AUDITORY ICONS in Table G.4 have been developed and benchmarked using evidence-based methods. In the first instance, several sets of possible ALARM SIGNALS were developed using principles derived from the relevant literature, and were tested for both learnability and localizability [36] [67]. All of these prototype sets outperformed the reserved ALARM SIGNALS specified in Annex F of IEC 60601-1-8:2006+A1:2012 on these measures. The best performing prototype sets, which consisted of AUDITORY ICONS plus AUDITORY POINTERS, were then developed and tested further. These tests included performance of the eight HIGH PRIORITY AUDITORY ICONS (using the HIGH PRIORITY AUDITORY POINTER as the ALARM SIGNAL for the general category) in a simulated environment approximating real-world use [68] [71]. These included studies to select the optimal AUDITORY ICONS for the functions [69], and detectability in typical background noise studies [66]. The sets of data for the individual reserved sounds are available in the public domain as peer-reviewed papers [38] [66] [67] [68] [71], and as a report [70].

H.1.2 Results of the benchmarking tests

It is important to note that the suitability of an ALARM SIGNAL, or set of auditory ALARM SIGNALS, for specific functions cannot be determined through the apparent optimization of any single parameter (such as urgency or learnability). Suitability depends on a range of measures, which can vary from specific setting to specific setting, though those parameters determined in the benchmarking are likely to be essential for most settings. The benchmarking data is summarized in Table H.1. A performance range is given in each case based on:

– performance of those AUDITORY ICONS during testing;
– adjustments for slight variations to the sounds tested during development; and
– the performance level that has already been achieved for each of the AUDITORY ICONS and AUDITORY POINTERS.

The fact that some scores are lower than others reflects a combination of the relative ease of developing a strong AUDITORY ICON, which typically influences learnability more than other factors (for example, the cardiovascular AUDITORY ICON) and that some of the sounds are abstract and can therefore be imbued with a resilient and tailored harmonic structure, which can influence audibility in noise (for example the HIGH PRIORITY AUDITORY POINTER).

A range of participants in both the simulation and the audibility studies has been tested. Clinical anaesthesia residents in their 1st to 3rd year of study, attendees, student and clinical nurse anaesthetists, student nurses and medical students in the 3rd and 4th year of study have been tested [66] [68].

These tests were carried out in Europe and in the US. No testing has been performed in Asia. MANUFACTURERS are at liberty to modify or indeed change the AUDITORY ICONS that they use for whatever reasons they see fit, and cultural acceptance would be one of the key reasons for doing this. Culture aside, the committees predict that audibility would be the same, and learnability partially depends on how well the AUDITORY ICONS work in terms of representing their functions for the Asian cultures. Given that the AUDITORY ICONS are based on the actual physiological functions, there is no reason to suppose that they would not work as well in Asia as in Europe and the US. They would certainly work better than the current auditory ALARM SIGNALS. There is no scientific reason why the AUDITORY POINTERS should not be effective

globally, because they are highly detectable in noise. The testing has established that all of the auditory ALARM SIGNALS are highly detectable using typical intensive care unit noise [66].

The tests were performed in a simulated intensive care units (ICU) using actual clinical soundscapes derived from the ICU. The tests show that the AUDITORY ICONS and particularly the HIGH PRIORITY AUDITORY POINTER are audible in noise levels significantly higher than the level of the background noise. In fact, the AUDITORY POINTER can be heard in noise four times louder than its own volume. Even the (relatively) least audible AUDITORY ICONS are audible in signal-to-noise levels of –10 dB to –15 dB [66].

H.2 Developing alternative auditory ALARM SIGNALS

H.2.1 General

The standard allows the generation of other AUDITORY ICONS for the eight categories. The MANUFACTURER shall determine that any new AUDITORY ICON performs at least at the levels indicated in Table H.1 on each of the measures indicated, unless there is an important argument for focusing on one or two of the measurements at the expense of others (see Clause H.3). The benchmarking for the reserved sounds indicated in Table G.4 was derived under controlled laboratory circumstances. In order to carry out a complete test, the MANUFACTURER should consult relevant published literature.

Table H.1 – Performance levels of three AUDITORY POINTERS and seven AUDITORY ICONS based on available data

ALARM SIGNAL	Percentage correct recognition over 10 trials [36]	Localizability in front and at 45° [36] [67]	Signal-to-noise ratio (reference)	Simulation [68]
Cardiovascular	90 % to 95 %	> 80 %	–10 dB to –20 dB	70 % to 80 %
Artificial perfusion	75 % to 85 %	> 80 %	–10 dB to –20 dB	70 % to 80 %
Ventilation	80 % to 85 %	> 80 %	–10 dB to –20 dB	60 % to 70 %
Oxygenation	70 % to 80 %	> 80 %	–10 dB to –20 dB	60 % to 70 %
Temperature/energy delivery	85 % to 90 %	> 80 %	–10 dB to –20 dB	80 % to 90 %
Drug or fluid delivery/administration	90 % to 95 %	> 80 %	–10 dB to –20 dB	80 % to 90 %
Equipment or supply failure	90 % to 95 %	> 80 %	–10 dB to –20 dB	50 % to 60 %
HIGH PRIORITY AUDITORY POINTER (general)	85 % to 90 %	> 80 %	–20 dB to –25 dB	[a]
MEDIUM PRIORITY AUDITORY POINTER	90 % to 95 %	> 80 %	–10 dB to –20 dB	[a]
LOW PRIORITY AUDITORY POINTER	90 % to 95 %	> 80 %	–10 dB to –20 dB	[a]

[a] Simulation data is based on identification of individual AUDITORY ICONS so it is not relevant for the AUDITORY POINTERS. For the AUDITORY POINTERS, the task is to identify that an ALARM CONDITION exists and where the COMMUNICATOR is located; hence learnability, detectability and localizability are most relevant (at least in the case of the HIGH PRIORITY AUDITORY POINTER).

H.2.2 Learnability

The following provides a test method for conducting a simplified learnability test.

a) Present each of the sounds to be learned to the participant one by one, with the names/category of the sounds at the same time.

b) Present each of the sounds once in a random order to the participant without naming them.

1) Note whether the participant names the category correctly or incorrectly.

2) Allowing participants to respond more than once can provide extra data on learnability if desired.

c) Repeat b) a number of times; 9 times is suggested so as to allow direct comparison with the data results shown in Table H.1.

d) Calculate the percentage correct score obtained for each of the sounds to be learned, and compare with the results in Table H.1.

H.2.3 Localizability

The following provides a test method for conducting a simplified localizability test.

a) Set up at least three speakers in the following positions:

1) straight ahead of the participant;

2) 45° to the left; and

3) 45° to the right of the participant

NOTE The speakers can be cheap, small speakers or ideally use the speakers intended to be used in the equipment when it is used in a clinical setting or use the equipment itself. If one uses more than three speakers, place them progressively at 45° angles around the participant (if a full circle is made, 8 speakers are needed).

b) Present each of the sounds to be tested one by one from each of the positions in a random order.

c) Measure the number of times the participant correctly identifies the position of the speaker from which the sound is coming.

d) Calculate the percentage correct for each sound. Compare these with the results in Table H.1.

A simpler version of this procedure would be to blindfold the participants before the study starts and for the experimenter to physically move around the same space, playing the sounds and asking the participant to indicate the position from which each sound has come by pointing or other simple means of indicating. For localization, it is not necessary for the participant to know the meaning of the sound.

H.2.4 Detectability

For clinical environments with complex noise spectra, a method whereby the spectrum of the ALARM SIGNAL is compared with the spectrum of the noise as described in H.3.2 is the best approach. Otherwise, detectability in typical noise is probably best determined in a controlled laboratory setting using headphones or listening in close proximity to the ALARM SIGNALS. Only these approaches generate useful signal-to-noise ratios. However, a relatively simple and useful detectability test can be conducted in a real clinical environment using a variation of the Hughson-Westlake 2-up-1-down method [72], using the volume control on any equipment that generates ALARM SIGNALS. If this is done in an actual clinical environment, it would be valuable to do the test on a day when the noise background is judged to be typical, rather than extreme either in loudness or quietness.

Essentially, the test method involves turning the loudness of the ALARM SIGNAL up and down in a systematic and measurable manner.

a) Using the loudness control for a piece of equipment, divide the range of loudness available into discrete steps (for example, numbers on the volume control). The steps should be of equal subjective distance in loudness as far as possible, and if a sound level meter can be used, the steps should ideally be about 5 dB apart. Make a record of the relationship between the volume control and the 5 dB (or other value) steps so that you can use them in testing. As far as possible, treat the changes of 5 dB as steps of 1, where 2 steps are 10 dB.

b) Select a loudness level on the equipment at random. However, it should be fairly audible. Ask the participant whether or not they can hear the sound. If they say yes, then drop the level of the sound by another step. If they say no, increase it by two steps. Make a note of each level tested and whether the participant detected the sound or not.

c) Continue with this procedure, dropping the loudness by one step if they can hear the signal and increasing it by two if they cannot, until you have changed direction (up to down, or down to up) at least 6 times. These changes of direction are called pivots.

d) Detectability is determined by the lowest loudness level at which the listener hears the target at least 50 % of the time when you have been through at least 6 pivots. Signal-to-noise ratios can be calculated if the ambient noise level and the loudness level of the sound are each measured separately and then compared, if necessary.

While it is appealing to increase the loudness of the ALARM SIGNAL further than a detectability test might determine, only relatively small increases are likely to be helpful, after which turning up ALARM SIGNALS well above threshold is distracting and leads to performance deficits [71].

Concerns about hearing deficits in older clinical staff can also be relevant. This is better approached through designing/implementing ALARM SIGNALS with a rich harmonic structure (possessing many different frequencies across the spectral range) rather than increasing the volume of less harmonically rich ALARM SIGNALS to unnecessarily high levels. The test method should assess the range of the intended users/responders (nurses, techs, clinicians, etc.), including a range of user ages to ensure that limitations of older users are assessed.

H.2.5 Simulation/testing in a clinical setting

Carrying out a simulation requires access to simulation facilities and both hardware and software resources. If a simulation is possible, the protocol used to benchmark the reserved sounds should be followed where possible [68]. This involves setting up a simulation with simulated PATIENTS, and providing participants with the relevant medical information (e.g. medical history of simulated PATIENT, medical charts of simulated PATIENT, planned procedures for simulated PATIENTS, etc.) to simulate a real-world clinical environment. See IEC 62366-1 for details regarding defining USE SCENARIOS. In this simulation, the signals to be tested are incorporated into a relevant interface (such as an anaesthesia machine), representative participants (clinical staff of any/all types) are subject to the simulation protocol, which should include several incidences of ALARM SIGNALS being generated, and their responses to the sounds measured in terms of correct identification and possibly other measures such as reaction time and resultant actions. Care needs to be taken to ensure that there is representation of all intended USER GROUPS, including a range of ages to ensure that limitations of older OPERATORS are assessed.

If this is not possible, then testing new sounds in a real or realistic clinical setting is still recommended. There are many ways in which this can be done. For example, new sounds could be presented via middleware or cell phone/paging equipment at intervals during either real or simulated clinical work, and responses recorded.

H.3 Circumstances under which new sounds can be required

H.3.1 Developing a new icon for an existing category

A MANUFACTURER might need to generate new AUDITORY ICONS because the ones indicated in Table G.4 are not considered appropriate for cultural or other reasons which could weaken the auditory ALARM SIGNAL-alarm category link (or because the sound-referent link is too obvious, or the proposed AUDITORY ICON is used for some other common function). Prior to the tests recommended in Clause H.2, ideas for the new AUDITORY ICON need to be generated. This is best achieved by surveying the end users in some way, either through the use of focus group(s) or as a survey. If this is done, some ideas are likely to emerge more than once and these should be considered as suitable candidates for the new AUDITORY ICON. The proposed new AUDITORY ICON(s) should then be tested according to Clause H.2, though some of the tests might not be relevant because of the particular circumstances under which the ALARM SIGNAL is intended to be used. As an example, it might be that a particular ALARM SIGNAL needs to be more coded than an AUDITORY ICON would typically be (so as to hide the meaning from PATIENTS or visitors, but to be clear to clinical staff once learned) and therefore learnability would be expected to be lower.

A few words of caution are necessary here. First, it is important that audibility is not compromised through the use of a new AUDITORY ICON (though again the degree to which audibility is relevant needs to be considered). Secondly, to some extent the learnability of an AUDITORY ICON depends on the other AUDITORY ICONS to be used in the same setting. As an example, if a new AUDITORY ICON is developed and is thought to be a "better" AUDITORY ICON than the reserved AUDITORY ICON, but sounds similar to one already in the set, then this can be a possible source of later confusion.

H.3.2 Generating new AUDITORY ICONS because the ones indicated in Table G.4 are inappropriate acoustically

In some environments, the ALARM SIGNALS might need to be particularly resistant to masking (for example, if a piece of equipment such as a surgical saw is used regularly), or particularly quiet (such as in a paediatric intensive care unit (PICU)). In environments where level setting is an issue, there can be other ways of notifying that are not auditory, so these should be explored. If auditory ALARM SIGNALS are deemed necessary, then it is possible to set the spectrum of the auditory ALARM SIGNALS relative to the background noise in a way that ensures detectability without making the ALARM SIGNAL any louder than it needs to be [49]. Determining an appropriate level for auditory ALARM SIGNALS in these environments requires careful measurements of background noise and the spectrum of any auditory ALARM SIGNAL, which the MANUFACTURER intends to use, appropriate models and software allowing comparison [49], and an ability to adjust the spectrum of ALARM SIGNALS accordingly.

H.4 Developing categories other than those in Table G.4

Equipment that does not fall into any of the existing categories can be developed. Also, different clinical settings can require a subdivision of the existing categories, which could be useful (for example, in a cardiac unit, it might be advantageous to have more than one cardiovascular-related AUDITORY ICON, such as an AUDITORY ICON for asystole, and a different AUDITORY ICON for tachycardia/bradycardia or ventricular fibrillation) [52]. In these situations, rather than introducing new categories on an *ad-hoc* basis, it is advisable to use a more empirical approach to the issue.

Because AUDITORY ICONS are much easier to learn and retain than abstract sounds, it is tempting to assume that a larger number can be used than for traditional ALARM SIGNALS. However, proliferation of AUDITORY ICONS should always be avoided because of nuisance noise and unnecessary distraction. Care should be taken when generating new categories because of this, and when generating new categories thought should also be given to categories that might be removed. In any method used to develop new categories, it is also advisable to put an upper

limit on the number of categories available in order to aid focused thinking as to what categories are really necessary.

One useful, low-tech method of determining the nature of the categories to be used is to implement a card-sorting task with end users (for example, nurses) [54]. With this technique, the participant is given a set of cards, each one signifying one of the conditions which needs to be indicated in an environment. These should have already been determined in an exhaustive manner and simply indicated on the cards. The participant is then asked to sort the cards according to one or another of the following instructions (not exhaustive):

a) sort them according to a single criterion which is pre-specified (for example, urgency, equipment);

b) sort them according to their own criteria (here one can put a limit on the number of categories, or allow the participant to use as many categories as they feel necessary).

In b), once the cards have been sorted, the participant should be questioned as to the rationale for the categories. This gives insight into the mental model used to determine the categories. For example, did the participant sort according to the piece of equipment that would be generating ALARM SIGNALS? Did they sort according to the physiological function underpinning the ALARM CONDITION? Or, something else – such as urgency?

This procedure should be repeated with many participants. There needs to be a maximum number of cards, which can be sorted in any one task, probably about 50.

The logic is that the categories for which ALARM SIGNALS will eventually be used should flow from the categorization study.

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Index of defined terms used in this collateral standard

Replace the following existing terms, modified by Amendment 1:

HARM ..... IEC 60601-1:2005+A2:2020, 3.38
HAZARD ..... IEC 60601-1:2005 +A1:2012+A2:2020, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005+A2:2020, 3.40
INTENDED USE ..... IEC 60601-1:2005+A2:2020, 3.44
MANUFACTURER ..... IEC 60601-1:2005+A2:2020, 3.55
PROCESS ..... IEC 60601-1:2005+A2:2020, 3.89
RISK ..... IEC 60601-1:2005+A1:2012+A2:2020, 3.102
RISK ANALYSIS ..... IEC 60601-1:2005+A1:2012+A2:2020, 3.103
RISK ASSESSMENT ..... IEC 60601-1:2005+A1:2012+A2: 2020, 3.104
RISK CONTROL ..... IEC 60601-1:2005+A1:2012+A2: 2020, 3.105
RISK MANAGEMENT ..... IEC 60601-1:2005+A2: 2020, 3.107
RISK MANAGEMENT FILE ..... IEC 60601-1:2005+A1:2012+A2: 2020, 3.108
USABILITY ..... IEC 60601-1:2005+A2: 2020, 3.136
USE SCENARIO ..... IEC 62366-1:2015, 3.22
VALIDATION (VALIDATED) ..... ISO 9000:2015, 3.8.13

Add the following new terms, modified by Amendment 1:

ADVISORY 3.38
ALARM FATIGUE 3.39
ALARM FLOOD 3.40
ALERT 3.41
AUDITORY ICON 3.42
AUDITORY POINTER 3.43
CLINICALLY ACTIONABLE 3.44
CLINICALLY NONACTIONABLE 3.45
COMMUNICATOR (COM) 3.46
DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION (CDAS) 3.47
DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) 3.48
INTEGRATOR (INT) 3.49
NUISANCE ALARM SIGNAL 3.50
REDIRECTION 3.51
RESPONSIBILITY ACCEPTED 3.52
RESPONSIBILITY REJECTED 3.53
RESPONSIBILITY UNDEFINED 3.54
SOURCE (SRC) 3.55
TRUE NEGATIVE ALARM CONDITION 3.56
TRUE POSITIVE ALARM CONDITION 3.57
USER GROUP ..... IEC 62366-1:2015, 3.25

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

3, rue de Varembé
PO Box 131
CH-1211 Geneva 20
Switzerland

Tel: + 41 22 919 02 11
info@iec.ch
www.iec.ch