

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**Medical electrical equipment –
Part 1-8: General requirements for basic safety and essential performance –
Collateral standard: General requirements, tests and guidance for alarm systems
in medical electrical equipment and medical electrical systems**

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**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**



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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 SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

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

FDIS	Report on voting
62A/824/FDIS	62A/837/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 standard has been approved by 19 P-members out of 21 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- withdrawn,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.

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INTRODUCTION TO THE AMENDMENT

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

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

Foreword

Add the following note at the end of the Foreword:

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

1.2 Object

In the first paragraph, change the print type of the defined terms "basic safety" and "essential performance" to small caps.

1.3.1 IEC 60601-1

Replace the existing first dash with:

- "the general standard" designates IEC 60601-1 alone (latest edition including any amendments);

2 Normative references

Replace the introductory paragraph with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Replace the normative references for IEC 60417 and IEC 60601-1 with the following:

IEC 60417, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* [IEC 60601-1-8:2006/AMD1:2012](https://standards.iteh.ai/catalog/standards/sist/d2d8873b-c17e-4fc0-ae90-d13db3c8cb07/iec-60601-1-8-2006-amd1-2012)
Amendment 1:2012

Delete the normative references for IEC 60601-1-2, and IEC 60601-1-6.

Replace the normative reference to IEC 60651:1979 and its Amendment 1 (1993) and Amendment 2 (2000) with the following:

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

Add the following normative reference:

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

Replace the normative references for ISO 3744:1994 and ISO 7000:1989 with the following:

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*

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

3 Terms and definitions

Replace the existing first paragraph with the following:

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

3.1

* ALARM CONDITION

Replace the existing definition with the following:

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

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

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

Add the following new definition:

3.37

* ACKNOWLEDGED

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

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

NOTE 2 ACKNOWLEDGED can terminate after a predetermined time interval has elapsed.
<https://standards.iteh.ai/catalog/standards/sist/d2d8873b-c17e-41e0-ac90-d13db3c8cb07/iec-60601-1-8-2006-amd1-2012>

6 Alarm systems

6.1 ALARM CONDITION

6.1.2 * ALARM CONDITION priority

Replace the existing title and text of this subclause including Table 1 with the following:

6.1.2 * Determination of ALARM CONDITIONS and assignment of priority

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

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

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

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

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

Table 1 – Determination of ALARM CONDITIONS and assignment of priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM ^a		
	Immediate ^b	Prompt ^c	Delayed ^d
Death or irreversible injury	HIGH PRIORITY ALARM CONDITION ^e	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL

^a Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

^b Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

^c Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

^d Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

^e Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

6.3.2 * Visual ALARM SIGNALS

6.3.2.2 Characteristics of visual ALARM SIGNALS

Restructure the content of this subclause by creating two new subclauses as follows:

6.3.2.2.1 * 4 m (distant) visual ALARM SIGNALS

Under this subclause place the existing text of 6.3.2.2 through Table 2.

In the second paragraph delete the last sentence reading "Alternatively, this indication may be generated by some other type of visual display or device".

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

Under this subclause place the remainder of the existing text of 6.3.2.2.

Renumber Notes 4 through 7 as Notes 1 through 4.

In Note 3, replace "IEC 60601-1-6" with "IEC 62366".

Replace the last paragraph before the compliance test with the following:

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

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

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Replace the first paragraph, including items a) and b), with the following:

If an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

- a) all auditory ALARM SIGNALS shall be priority encoded;
- b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;
- c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;
- d) the ALARM SYSTEM shall have at least one set of ALARM SIGNALS that
 - meets the requirements of Table 3 and Table 4; or
 - is generated by means of different technology (e.g., voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g., by clinical or simulated clinical USABILITY testing).

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

Replace the existing fifth row of the table with the following:

Where: x shall be a value between 50 ms and 125 ms,
 y shall be a value between 125 ms and 250 ms,
 the variation of x and y within a BURST shall not exceed $\pm 5\%$, and
 MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.

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

In the fourth row, replace the value "20 %" with "40 %".

Replace the existing sixth row of the table with the following:

NOTE 1 The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.

NOTE 2 In practice, the RISE TIME should not be less than 10 ms to prevent mechanical speaker noise.

Replace the first paragraph after Figure 1, including items c) through h) and Notes 1 and 2, with the following:

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

- e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;
- f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and
- g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to IEC 62366.

Replace the compliance paragraph with:

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

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

6.3.3.2 * Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

Replace the title and the first two paragraphs with the following:

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

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

Replace the steps of the compliance test with the following:

- a) Set the ALARM SIGNAL sound pressure level (volume level) to its maximum setting.
- b) If the ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION, simulate a HIGH PRIORITY ALARM CONDITION.
- c) Using a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2002, measure the sound pressure levels
 - for STATIONARY and MOBILE ME EQUIPMENT, at least at positions 1, 3, 5, and 7, as specified in Table F.1 of ISO 3744:2010, in a circular plane with a radius from the vertical axis of the geometric centre of the ME EQUIPMENT equivalent to a mean distance from the ME EQUIPMENT surfaces of 1 m and at an altitude of 1,5 m.
 - for PORTABLE ME EQUIPMENT, at least at positions 2, 4, 6, 8, 10, and 12 as specified in Table F.1 of ISO 3744:2010 in a hemisphere with a radius from the geometric centre of the ME EQUIPMENT of 1 m.
- d) The indicated sound pressure level when measuring BURSTS is corrected in accordance with Clause C.3 of IEC 61672-1:2002 or a test PULSE of continuous duration is used for purposes of the measurement or a test signal of continuous duration comprised of each PULSE in the BURST without PULSE spacing ($t_s = 0$ s) is used for purposes of the measurement.
- e) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.
- f) If the ALARM SYSTEM is provided with a MEDIUM PRIORITY ALARM CONDITION, simulate a MEDIUM PRIORITY ALARM CONDITION and repeat c) to e).
- g) If the ALARM SYSTEM is provided with a LOW PRIORITY ALARM CONDITION, simulate a LOW PRIORITY ALARM CONDITION and repeat c) to e).
- h) Set the ALARM SIGNAL sound pressure level (volume level) to its minimum setting.
- i) Repeat b) to g).
- j) Verify that the A-weighted background level of extraneous noise, including any INFORMATION SIGNALS, is at least 6 dB below that measured during the tests.
- k) Verify that the measured sound pressure level range is in compliance with the values indicated in the instructions for use.

Add the following new subclause:

6.3.3.3 * OPERATOR-adjustable sound pressure level

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

- a) provide a restricted means for the RESPONSIBLE ORGANIZATION to configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level (see 6.7); or
- b) provide a visual indication that the current sound pressure level might be inaudible when the auditory ALARM SIGNAL sound pressure level is below a threshold that is configured:
 - by a means restricted to the RESPONSIBLE ORGANIZATION (see 6.7); or
 - by the MANUFACTURER.

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

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

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

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

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 Compliance is checked by inspection.

6.4.2 * Delays to or from a DISTRIBUTED ALARM SYSTEM

In item b), replace "(see 6.11.2.2)" with "(see item 6.11.2.2.1 b))".

6.6.2.1 Indication of OPERATOR-adjustable ALARM LIMIT

Replace the existing first paragraph with the following:

If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action. The means of control to display the ALARM LIMITS may be visually indicated (marked) with symbol IEC 60417-5649 (2002-10) (see symbol 10 of Table C.1), IEC 60417-5650 (2002-10) (see symbol 11 of Table C.1) or IEC 60417-5651 (2002-10) (see symbol 12 of Table C.1), as appropriate.

6.7 * ALARM SYSTEM security

Replace the existing first paragraph with the following:

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

6.8 * ALARM SIGNAL inactivation states

6.8.1 * General

Replace the entire existing text of the subclause with the following:

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

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

NOTE 1 A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 An ALARM SYSTEM that has not received valid data since it was enabled (e.g. after power-up or before a PATIENT has been connected).

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

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

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

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

NOTE 3 An INTELLIGENT ALARM SYSTEM can use the OPERATOR'S activation of AUDIO PAUSED or AUDIO OFF to cause DE-ESCALATION or to re-evaluate the need for an ALARM CONDITION.

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

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

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

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

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

Compliance is checked by inspection and functional testing.

6.8.3 * Global indefinite ALARM SIGNAL inactivation states

Replace existing Note 1 with the following:

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

6.8.4 * Termination of inactivation of ALARM SIGNALS

Replace the existing text of the subclause with the following:

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

An ALARM SIGNAL inactivation state may terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists.

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

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

When an ALARM SIGNAL inactivation state is terminated, the ALARM SYSTEM shall re-evaluate the need for ALARM CONDITIONS and generate ALARM SIGNALS if appropriate.

Compliance is checked by functional testing.

6.8.5 * Indication and access

Replace the existing first sentence of the first paragraph with the following:

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

Replace the existing third and fourth paragraphs with the following:

[IEC 60601-1-8:2006/AMD1:2012](https://standards.iteh.ai/catalog/standards/sist/d2d8873b-c17e-4f60-ae90-d13db3c8cb07/iec-60601-1-8-2006-amd1-2012)

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

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

Table 5 – ALARM SIGNAL inactivation states

Replace the existing table with the following:

Table 5 – ALARM SIGNAL inactivation states

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

6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

Replace item a) with the following:

- a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF state; or

6.11 * DISTRIBUTED ALARM SYSTEM**6.11.2 Requirements for DISTRIBUTED ALARM SYSTEM communication of ALARM CONDITIONS****6.11.2.2 * Failure of remote communication of ALARM CONDITIONS**

Replace the existing contents of this subclause with the following:

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

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

- a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and
- b) shall:
 - 1) initiate a TECHNICAL ALARM CONDITION in the affected source ME EQUIPMENT; and

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

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

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

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

6.11.2.2 * DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS

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

- a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and
- b) any remote part of a DISTRIBUTED ALARM SYSTEM that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.

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

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

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

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

If there is a communications failure between the ME EQUIPMENT with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM intended for OPERATOR notification and confirmed delivery of ALARM CONDITIONS, the affected source ME EQUIPMENT shall terminate the global AUDIO OFF state, if active.

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

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

Add the following new subclause: <https://standards.iteh.ai/catalog/standards/sist/d2d8873b-c17e-4fc0-ae90-4f50b3c8cb07/iec-60601-1-8-2006-amd1-2012>

6.11.2.3 * Remote ALARM SYSTEM controls

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

- a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and
- b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).

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

6.12 * ALARM CONDITION logging

Replace the existing title and text of the subclause with the following:

6.12 * ALARM SYSTEM logging

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

- a) the ALARM SYSTEM shall log the occurrence and identity of HIGH PRIORITY ALARM CONDITIONS and;
 - the date and time, or
 - the elapsed time since the occurrence of the ALARM CONDITION, or
 - the elapsed time from the start of use of the ME EQUIPMENT;

- b) the instructions for use shall indicate whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log;
- c) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;
- d) the instructions for use shall indicate what happens to the contents of the log as it reaches capacity; and

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

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

- e) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS, if OPERATOR-adjustable, for that ALARM CONDITION and, where feasible, the data that caused the ALARM CONDITION;
- f) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action.

Compliance is checked by inspection.

Annex A – General guidance and rationale

A.1.2 ALARM SYSTEMS

In the second paragraph change the print type of the defined term "Risk control" to small capitals.

In item g), change the print type of the defined terms "Alarm signals" and "operator" to small capitals.

<https://standards.iteh.ai/catalog/standards/sist/d2d8873b-c17e-4fc0-ac90-d13db3c8cb07/iec-60601-1-8-2006-amd1-2012>

A.2 Rationale for particular clauses and subclauses

Clause 1 – Scope, object and related standards

Replace the first sentence of the second paragraph with the following:

Because this standard applies equally to simple INTERNAL ELECTRICAL POWER SOURCE operated or home-care ME EQUIPMENT as well as complex ME EQUIPMENT or ME SYSTEMS that include at least one function intended actively to keep alive or resuscitate a PATIENT, it has not been possible to provide specific requirements for many important issues.

Definition 3.34 – REMINDER SIGNAL (see also AAA.201.8.1)

Replace the existing title with the following:

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

In the first sentence replace "acknowledged" with "inactivated".

Add, following the rationale for definition 3.34, the following new rationale:

Definition 3.37 – ACKNOWLEDGED

The ALARM SIGNAL inactivation state ACKNOWLEDGED differs significantly from the global AUDIO OFF or AUDIO PAUSE. Therefore using the same indication for either AUDIO OFF or AUDIO PAUSE and for this inactivation state would lead to confusion.