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Medical electrical equipment –

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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International standard IEC 60601-1-8 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

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

This second edition cancels and replaces the first edition of IEC 60601-1-8, published in 2003, of which it constitutes a technical revision.

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

The text of this collateral standard is based on the following documents:

CDV	Report on voting
62A/519/CDV	62A/537A/RVC

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 18 P-members out of 18 having cast a vote.

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

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

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

– Requirements and definitions: roman type.

– *Test specifications: italic type. In addition, in Annex A text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.3.1 are all subclauses of Clause 6).

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

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

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

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

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

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

The committee has decided that the contents of this collateral standard will remain unchanged until the maintenance result 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

INTRODUCTION

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are increasingly used in medical practice. ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM or to warn the OPERATOR of HAZARDS to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. INFORMATION SIGNALS convey information that is independent of an ALARM CONDITION.

Surveys of healthcare personnel have indicated significant discontent with ALARM SIGNALS. Problems include difficulty in identifying the source of an ALARM SIGNAL, loud and distracting ALARM SIGNALS, and the high incidence of FALSE POSITIVE or NEGATIVE ALARM CONDITIONS [16] [1]. Surveys of MANUFACTURERS of medical monitors demonstrated a wide variety of DEFAULT ALARM PRESETS. The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS. See also bibliography.

Safety of PATIENTS depends on the ability of the OPERATOR to correctly discern the characteristics of ALARM SIGNALS. USABILITY is an important element in the design of ALARM SIGNALS that are readily discernible without being unnecessarily distracting or disturbing. This approach is intended to rationalize the current situation, to reduce confusion by limiting proliferation of ALARM SIGNALS and their control states, and to minimize distraction for other people. This collateral standard was developed with contributions from clinicians, engineers and applied psychologists.

The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for particular standards.

The effectiveness of any ALARM SYSTEM depends critically on its implementation by the RESPONSIBLE ORGANIZATION. It is important that the RESPONSIBLE ORGANIZATION configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

1) Figures in brackets refer to the bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

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

1 * Scope, object and related standards

1.1 Scope

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

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

It also provides guidance for the application of ALARM SYSTEMS.

1.2 Object

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

This collateral standard does not specify:

– whether any particular ME EQUIPMENT or ME SYSTEM is required to be provided with ALARM SYSTEMS;

– the particular circumstances which initiate an ALARM CONDITION;

– the allocation of priorities to a particular ALARM CONDITION; or

– the means of generating ALARM SIGNALS.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone;

– "this collateral standard" designates IEC 60601-1-8 alone;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

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

2 Normative references

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

IEC 60417, *Graphical symbols for use on equipment*

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

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

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

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

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

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:---- [5)], IEC 60601-1-6:---- [6)], and the following definitions apply.

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

NOTE 2 An index of defined terms is found beginning on page 155.

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

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

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

5) To be published. See footnote 2.

6) To be published. See footnote 3.

3.1
*** ALARM CONDITION**
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists

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

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

3.2
*** ALARM CONDITION DELAY**
time from the occurrence of a triggering event either in the PATIENT, for PHYSIOLOGICAL ALARM CONDITIONS, or in the equipment, for TECHNICAL ALARM CONDITIONS, to when the ALARM SYSTEM determines that an ALARM CONDITION exists

3.3
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

3.4
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

3.5
*** ALARM PAUSED**
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate ALARM SIGNALS

3.6
ALARM PRESET
set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the ALARM SYSTEM

3.7
ALARM RESET
OPERATOR action that causes the cessation of an ALARM SIGNAL for which no associated ALARM CONDITION currently exists

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

– ALARM LIMITS;

– the characteristics of any ALARM SIGNAL inactivation states; and

– the values of variables or parameters that determine the function of the ALARM SYSTEM

NOTE Some algorithmically-determined ALARM SETTINGS can require time to be determined or re-determined.

3.9
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

3.10
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNAL(S)

3.11
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

3.12
AUDIO OFF
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.13
AUDIO PAUSED
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.14
BURST
group of PULSES with a distinctive rhythm or pattern

3.15
DE-ESCALATION
PROCESS by which an ALARM SYSTEM decreases the priority of an ALARM CONDITION or decreases the sense of urgency of an ALARM SIGNAL

3.16
DEFAULT ALARM PRESET
ALARM PRESET that can be activated by the ALARM SYSTEM without OPERATOR action

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

3.17
*** DISTRIBUTED ALARM SYSTEM**
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM

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

3.18
ESCALATION
PROCESS by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

3.19
FALL TIME
t_f
interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 1)

3.20
FALSE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE An ALARM CONDITION can be rejected or missed because of spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the equipment itself.

3.21
FALSE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE A FALSE POSITIVE ALARM CONDITION can be caused by spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

3.22
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

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

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

3.24
*** INTELLIGENT ALARM SYSTEM**
ALARM SYSTEM that makes logical decisions based on monitored information without OPERATOR intervention

EXAMPLE 1 An ALARM SYSTEM that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An ALARM SYSTEM that suppresses an ALARM CONDITION when a related ALARM CONDITION of higher priority has recently generated an ALARM SIGNAL.

3.25
INTERBURST INTERVAL
t_b
period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL (see Figure 1)

3.26
LATCHING ALARM SIGNAL
ALARM SIGNAL that continues to be generated after its triggering event no longer exists until stopped by deliberate OPERATOR action

3.27
LOW PRIORITY
indicating that OPERATOR awareness is required

NOTE The priority is assigned through RISK ANALYSIS.

3.28
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE The priority is assigned through RISK ANALYSIS.

3.29
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

3.30
OPERATOR'S POSITION
intended position of the OPERATOR with respect to the ALARM SIGNAL generating part of the ALARM SYSTEM

NOTE A DISTRIBUTED ALARM SYSTEM can have multiple OPERATOR'S POSITIONS.

3.31
PHYSIOLOGICAL ALARM CONDITION
ALARM CONDITION arising from a monitored PATIENT-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

3.32
PULSE
brief continuous sound having a specific spectral content

3.33
PULSE FREQUENCY
f_o
fundamental frequency (first harmonic) of a PULSE

3.34
*** REMINDER SIGNAL**
periodic signal that reminds the OPERATOR that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

3.35
RISE TIME
t_r
interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 1)

3.36
TECHNICAL ALARM CONDITION
ALARM CONDITION arising from a monitored equipment-related or ALARM SYSTEM-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

4 General requirements

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

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

5 ME EQUIPMENT identification marking and documents

NOTE Additional requirements for the marking on controls and instruments are specified in this collateral standard, together with the technical requirements, giving rise to requirements on markings. These requirements are also listed in Annex B.

5.1 Indicator lights and controls

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

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

5.2 ACCOMPANYING DOCUMENTS

NOTE Additional requirements on ACCOMPANYING DOCUMENTS are specified in this collateral standard, together with the technical requirements, giving rise to requirements on ACCOMPANYING DOCUMENTS. These requirements are also listed in Table B.2.

5.2.1 Instructions for use

The instructions for use shall:

- * provide an overview of the ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and, as appropriate for the intended OPERATOR, a summary of how it is determined;
- indicate any delay inherent in the determination of an ALARM CONDITION;
- disclose the OPERATOR'S POSITION; and
- * include how and when to verify the functionality of the ALARM SYSTEM.

As applicable, the instructions for use shall caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless.

NOTE Additional requirements on instructions for use are specified in this collateral standard, together with the technical requirements, giving rise to requirements on instructions for use. These requirements are also listed in Table B.3.

Compliance is checked by inspection of the instructions for use.

5.2.2 Technical description

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

6 ALARM SYSTEMS

6.1 ALARM CONDITION

6.1.1 * General

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

Compliance is checked by inspection of the instructions for use.

6.1.2 * ALARM CONDITION priority

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

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

Table 1 – ALARM CONDITION priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY or no ALARM SIGNAL
An INFORMATION SIGNAL may also be used to indicate the potential for delayed minor injury or discomfort.			

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

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

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

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

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

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

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

a) determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advanced processing (including, but not limited to, algorithms, neural networks, fuzzy logic, etc.);

b) generates ALARM SIGNALS for two or more ALARM CONDITIONS of equal priority (including, but not limited to, internal ranking, effect on generation of ALARM SIGNALS);

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

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

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

Compliance is checked by inspection of the instructions for use.

6.3 Generation of ALARM SIGNALS

6.3.1 General

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

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

Compliance is checked by inspection of the ALARM SYSTEM.

6.3.2 * Visual alarm signals

6.3.2.1 General

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

6.3.2.2 * Characteristics of visual ALARM SIGNALS

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

a) indicates the priority of the highest priority ALARM CONDITION; and

b) can be perceived correctly at a distance of 4 m from the ALARM SYSTEM.

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

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

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

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

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

Table 2 – Characteristics of alarm indicator lights

Alarm category	Indicator colour	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or yellow	Constant (on)	100 % on

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

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

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

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

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

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

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

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

– *the OPERATOR has a visual acuity of 0 on the logMAR* [17] *scale or 6-6 (20/20) vision (corrected if necessary),*

– *the viewpoint is at the OPERATOR'S POSITION or at any point within the base of a cone subtended by an angle of 30° to the axis horizontal to or normal to the centre of the plane of display of the monitoring display or visual indication, and*

– *the ambient illuminance in the range* [21] *of 100 lx to 1 500 lx.*

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

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

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

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

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

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Figure 1)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB
Where x shall be a value between 50 ms and 125 ms. Where y shall be a value between 125 ms and 250 ms. The variation of x and y within a BURST shall be ± 5 %. MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.			

[a] See also Table 4 for characteristics of the PULSE.

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

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION.

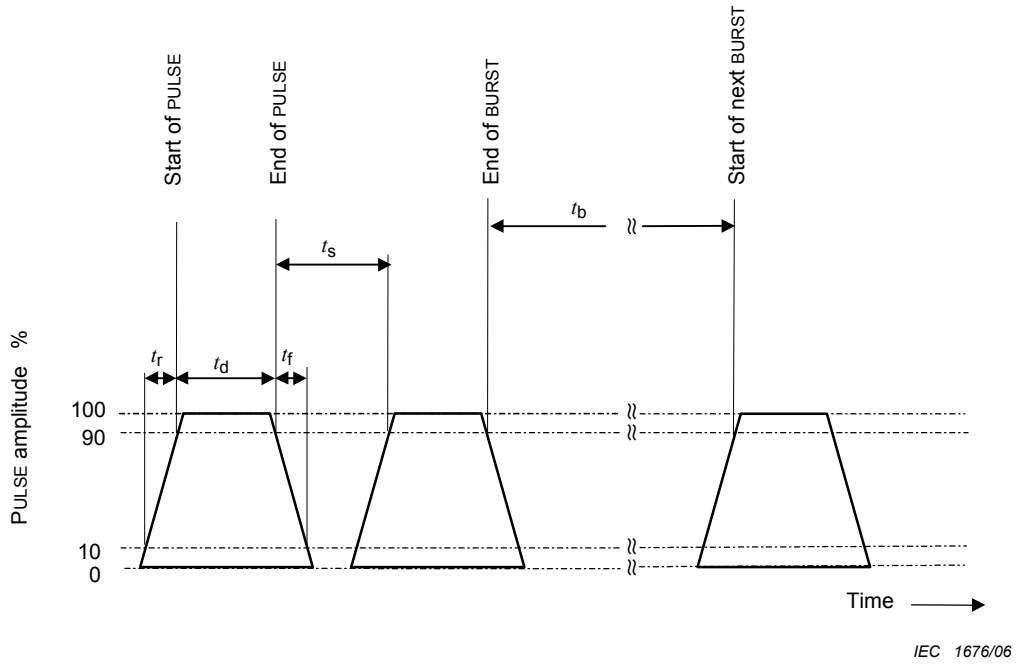
[d] The generation of the auditory component of a LOW PRIORITY ALARM CONDITION is optional.

[e] Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

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

Characteristic	Value
PULSE FREQUENCY (f_o)	150 Hz to 1 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	Minimum of 4
Effective PULSE duration (t_d) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r)	10 % – 20 % of t_d
FALL TIME[a] (t_f)	$t_f \leq t_s - t_r$
NOTE The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.	

[a] Prevents overlap of PULSES.



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

Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS

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

c) auditory ALARM SIGNALS shall be priority encoded;

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

e) MEDIUM PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set;

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

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

h) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to IEC 60601-1-6.

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

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

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

Compliance is checked by inspection and functional testing of the ALARM SYSTEM and inspection of any relevant VALIDATION documentation.

6.3.3.2 * Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

The auditory ALARM SIGNAL sound pressure range, as measured in accordance with this subclause, shall be disclosed in the instructions for use.

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

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

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

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

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

6.3.4 * Characteristics of verbal ALARM SIGNALS

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

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

6.4 * Disclosure of delays

6.4.1 * ALARM SYSTEM delays

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

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

Compliance is checked by inspection of the instructions for use.

6.4.2 * Delays to or from a DISTRIBUTED ALARM SYSTEM

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

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

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

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

c) from the onset of the ALARM CONDITION;

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

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

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

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

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

6.5 ALARM PRESETS

6.5.1 * General requirements

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

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

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

a) can only retain current ALARM SETTINGS, and

b) does not otherwise provide ALARM PRESETS, and

c) displays each adjustable ALARM SETTINGS continuously.

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

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

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

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

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

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

6.5.2 MANUFACTURER-configured ALARM PRESETS

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

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

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

6.5.3 * RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

6.5.3.1 ALARM SYSTEMS with one ALARM PRESET

If the ALARM SYSTEM can store only one ALARM PRESET:

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

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

Compliance is checked by inspection.

6.5.3.2 ALARM SYSTEMS with more than one ALARM PRESET

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

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

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

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

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

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

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

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

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

Compliance is checked by inspection.

6.5.4 DEFAULT ALARM PRESET

6.5.4.1 General requirements

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

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

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

Compliance is checked by inspection.

6.5.4.2 * Selection of DEFAULT ALARM PRESET

Whenever:

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

b) the ALARM SYSTEM is enabled; or

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

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

then:

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

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

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

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

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

6.5.5 * Interruptions of less than or equal to 30 s

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

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

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

6.6 ALARM LIMIT

6.6.1 General requirements

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

Compliance is checked by inspection.

6.6.2 * Adjustable ALARM LIMIT

6.6.2.1 Indication of OPERATOR-adjustable ALARM LIMIT

If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action.

Compliance is checked by inspection.

6.6.2.2 * Indication of automatically set ALARM LIMIT

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

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

b) recent values of a monitored variable; or

c) a current control setting.

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

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

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

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

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

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

Compliance is checked by functional testing.

6.7 * ALARM SYSTEM security

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

EXAMPLE 1 Access controlled by a tool.

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

EXAMPLE 3 Access controlled by individual OPERATOR password.

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

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

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

Compliance is checked by inspection of the technical documentation.

6.8 * ALARM SIGNAL inactivation states

6.8.1 * General

Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF or AUDIO OFF) or timed (i.e., ALARM PAUSED or AUDIO PAUSED). Flashing visual ALARM SIGNALS specified in 6.3.2.2 may be inactivated by AUDIO PAUSED or AUDIO OFF.

NOTE A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 The ALARM SIGNALS of all currently active ALARM CONDITIONS.

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.

Compliance is checked by inspection.

6.8.2 * REMINDER SIGNALS

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

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

b) the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):
   - to enable and disable the REMINDER SIGNAL; and
   - to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.

c) the ALARM SYSTEM may include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):
   - to permit designated (see 6.7) OPERATORS to enable and disable the REMINDER SIGNAL;
   - to permit any OPERATOR to enable and disable the REMINDER SIGNAL.

Compliance is checked by inspection.

6.8.3 * Global indefinite ALARM SIGNAL inactivation states

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

a) a REMINDER SIGNAL; and

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

NOTE 1 A global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state affects all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM with multiple PHYSIOLOGICAL ALARM CONDITIONS.

NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.

Compliance is checked by inspection.

6.8.4 * Termination of inactivation of ALARM SIGNALS

Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state. An ALARM SIGNAL inactivation state may terminate automatically, when the ALARM CONDITION that was generating an ALARM SIGNAL when this state was entered, ceases.

When an ALARM SIGNAL inactivation state is terminated, the ALARM SIGNALS of any current ALARM CONDITION shall cause the re-generation of ALARM SIGNALS.

Compliance is checked by functional testing.

6.8.5 * Indication and access

The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, and ALARM OFF shall be visually indicated (marked) with the appropriate symbol referenced in Table 5. This indication shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.

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

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

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

Compliance is checked by inspection.

Table 5 – ALARM SIGNAL inactivation states

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

6.9 * ALARM RESET

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

Compliance is checked by inspection.

6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

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

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

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

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

– a visual ALARM SIGNAL that indicates the specific ALARM CONDITION and which continues to be generated for a limited period of time (e.g., 30 s) after the ALARM CONDITION has cleared;

– an ALARM CONDITION log that the OPERATOR can view, print, or record;

– an ALARM CONDITION trend that the OPERATOR can view, print, or record.

Auditory ALARM SIGNALS shall cease being generated when:

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

b) an OPERATOR has ALARM RESET the ALARM CONDITION.

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

Compliance is checked by functional testing.

6.11 * DISTRIBUTED ALARM SYSTEM

6.11.1 * Existence of DISTRIBUTED ALARM SYSTEM

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

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

EXAMPLE 1 A central station.

EXAMPLE 2 An electronic record-keeping device.

EXAMPLE 3 Remote viewing from home or office.

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

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

Compliance is checked by inspection of the technical description.

6.11.2 Requirements for DISTRIBUTED ALARM SYSTEM communication of ALARM CONDITIONS

6.11.2.1 Source and identification of ALARM CONDITIONS

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

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

Compliance is checked by inspection.

6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

A DISTRIBUTED ALARM SYSTEM 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 create a TECHNICAL ALARM CONDITION in any affected parts of the DISTRIBUTED ALARM SYSTEM that can generate ALARM SIGNALS, or the DISTRIBUTED ALARM SYSTEM 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.

6.12 * ALARM CONDITION logging

If an ALARM SYSTEM is provided with a log of the occurrence of ALARM CONDITIONS:

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

NOTE The ALARM SYSTEM should log:

– the time of occurrence;

– the associated ALARM LIMITS;

– ALARM SIGNAL inactivation states;

– PHYSIOLOGICAL ALARM CONDITIONS;

– TECHNICAL ALARM CONDITIONS.

b) the MANUFACTURER shall disclose in the instructions for use whether the log is maintained when the ALARM SYSTEM is powered down; and

c) the MANUFACTURER shall disclose in the instructions for use 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.

Compliance is checked by inspection.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

A.1.1 Overview

This annex provides a rationale for the important requirements of this collateral standard. Its purpose is to promote effective application of the standard by explaining the reasons for the requirements, providing examples of how they address certain alarm-related HAZARDS and providing additional guidance where appropriate.

From the standpoint of PATIENT safety, ALARM SYSTEMS can be hazardous for PATIENTS or OPERATORS if they fail to effectively warn of potential or actual HAZARDS, cause inappropriate responses, reduce vigilance or interfere with the performance of the OPERATOR, RESPONSIBLE ORGANIZATION, or other persons.

In addition, in this annex text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.

A.1.2 ALARM SYSTEMS

As part of the RISK MANAGEMENT PROCESS, the MANUFACTURER identifies RISK CONTROL measure(s) that are appropriate for reducing the RISK(S) to an acceptable level.

Risk control consists of an integrated approach in which the MANUFACTURER uses one or more of the following in the priority order listed.

a) inherent safety by design;

b) protective measures in the equipment;

c) information for safety, e.g., warnings and instructions for use, values of monitored variables.

ALARM SYSTEMS as described in this collateral standard, address b) and c) above by communicating information that requires a response or awareness by the OPERATOR. The following general principles apply.

d) The ALARM SYSTEM should result in a greater probability that the OPERATOR will correctly detect and appropriately respond to the condition that requires their awareness or action than would be the case in the absence of the ALARM SIGNALS.

   NOTE Causing too many ALARM SIGNALS from FALSE POSITIVE ALARM CONDITIONS can reduce the effectiveness of an ALARM SYSTEM.

e) ALARM SIGNALS should indicate the onset and continuing presence of an ALARM CONDITION.

f) ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response (or awareness).

g) Alarm signals should help the operator:
   - determine the urgency of the response required;
   - locate the room or part of the room where a response or awareness is required;
   - locate the specific PATIENT or equipment where a response or awareness is required;
   - determine or categorize the cause of the ALARM CONDITION; and
   - determine or categorize the nature of the response or awareness that is required.

h) The algorithms that determine ALARM CONDITIONS should be designed to minimize the number of FALSE NEGATIVE and FALSE POSITIVE ALARM CONDITIONS. Both FALSE NEGATIVE and FALSE POSITIVE ALARM CONDITIONS are potentially hazardous. Too many true positive but unhelpful ALARM SIGNALS can result in inappropriate OPERATOR action or reduce vigilance. Algorithms that determine ALARM CONDITIONS should be carefully optimized to provide, on balance, an overall benefit to PATIENT care.

i) ALARM SYSTEMS that are continuously attended by an OPERATOR in NORMAL USE should have different characteristics from ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE.

j) The design of an ALARM SYSTEM should be based on the TRAINING and skill of the OPERATOR who is intended to use it.

k) The ALARM SYSTEM should reflect the problems and needs of the intended environment of use.

l) ALARM SIGNALS should not be excessively intrusive or degrade the performance of the OPERATOR.

A.1.3 Algorithm quality and performance

ALARM SYSTEM algorithms should aim at approaching 100 % sensitivity and 100 % specificity. [7],[8],[9],[10] The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS, unhelpful ALARM CONDITIONS, or nuisance ALARM CONDITIONS. Nuisance ALARM CONDITIONS are true positives that are unhelpful because they indicate states that the OPERATOR is already aware of or does not need to know about. [11] They commonly occur when the ALARM LIMITS have been set inappropriately close to an acceptable value but also occur when multiple redundant ALARM CONDITIONS occur in response to a single underlying problem. Often, ALARM SIGNALS are more confusing than enlightening. Many OPERATORS respond to ALARM SIGNALS by disabling the ALARM SYSTEM or by adjusting an ALARM LIMIT to such an extreme value that the ALARM SYSTEM is effectively disabled. [12]

Where practical, MANUFACTURERS or writers of particular standards are encouraged to utilize standardized physiological databases to validate the algorithms used to determine ALARM CONDITIONS. Determining and reporting the FALSE POSITIVE and FALSE NEGATIVE ALARM CONDITION accuracy in a standardized format allows OPERATORS and RESPONSIBLE ORGANIZATIONS to understand the performance of equipment.

EXAMPLE ANSI/AAMI EC57:1998*, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.[5]*

Other techniques to reduce the number of FALSE POSITIVE and FALSE NEGATIVE ALARM CONDITIONS include:

a) marking the ALARM SYSTEM with symbol ISO 7000-0435 when an algorithm cannot classify or resolve the available data; or

b) using an ALARM CONDITION DELAY to delay the generation ALARM SIGNALS for an ALARM CONDITION to ensure that it remains valid.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Clause 1 – Scope, object and related standards

This collateral standard provides the general requirements for the implementation of ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS to provide information necessary for the safety of PATIENTS, OPERATORS and others involved with PATIENT care. As the urgency of the OPERATOR'S attention is dependent on the cause of the ALARM CONDITION, this collateral standard specifies ALARM CONDITION priorities and their ALARM SIGNAL characteristics so that the OPERATOR can perceive the urgency of the situation and the necessary action independent of the type, brand, etc. of the ME EQUIPMENT that is generating ALARM SIGNALS. [13], [14], [15], [16] In addition, a standardized unambiguous ALARM SYSTEM vocabulary is presented as a means to improve PATIENT safety that will be used in ME EQUIPMENT and ME SYSTEM design and markings as well as in the ACCOMPANYING DOCUMENTS.

Because this standard applies equally to simple INTERNAL ELECTRICAL POWER SOURCE operated or home-care ME EQUIPMENT as well as complex LIFE-SUPPORTING ME EQUIPMENT, it has not been possible to provide specific requirements for many important issues. Particular standards should provide, as appropriate, more detailed requirements for their equipment category. The nomenclature and basic requirements of this standard should ensure a consistent approach for ALARM SYSTEMS across a wide range of equipment types.

Definition 3.1 – ALARM CONDITION

One consideration was the fact that an ALARM SYSTEM might generate ALARM SIGNALS for an ALARM CONDITION when no valid ALARM CONDITION existed (i.e. a FALSE POSITIVE ALARM CONDITION). A second was the issue that non-numerical values or conditions, or the use of an INTELLIGENT ALARM SYSTEM, might be used to determine the presence of an ALARM CONDITION, yet these factors might not have been included in previous definitions of ALARM LIMIT.

On this basis, the committee defined ALARM CONDITION as: “state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists.” This definition recognizes that the ALARM SYSTEM can be correct or incorrect in its determination. It also indicates that this state will cause the ALARM SYSTEM, if it is enabled, to generate ALARM SIGNALS for the ALARM CONDITION to bring about OPERATOR response or awareness.

The committee then defined ALARM LIMIT as: “threshold used by an ALARM SYSTEM to determine an ALARM CONDITION.” The obvious example would be a numerical threshold (such as a threshold for a high heart rate ALARM CONDITION), but some thresholds might be non-numerical. Non-numerical conditions, such as a switch in the incorrect position, failure of the OPERATOR to enter certain data or the failure of the ALARM SYSTEM, can also cause an ALARM CONDITION. Furthermore, an INTELLIGENT ALARM SYSTEM can be used to determine an ALARM CONDITION, using an algorithm rather than a simple threshold value. Such an algorithm may have multiple inputs, perform logic-based or time-dependent averaging, use intelligent artefact filtering or employ other techniques so that the actual threshold changes over time or in response to other circumstances.

Definition 3.2 – ALARM CONDITION DELAY

Filtering in the algorithm that is monitoring for an ALARM CONDITION often causes ALARM CONDITION DELAY. For instance, a heart rate monitor can average the R-R interval for several heartbeats. An abrupt change in R-R interval will not immediately cause a heart rate ALARM CONDITION because it will take several consecutive heartbeats for the calculated heart rate to exceed the ALARM LIMIT. Similarly, a median filter will cause an ALARM CONDITION DELAY. See also the rationale for Subclause 6.10.

Definition 3.3 – ALARM LIMIT

ALARM LIMIT refers to the criteria that cause the ALARM SYSTEM to generate ALARM SIGNALS. For a simple variable with a single level of urgency, a value selected by the OPERATOR can constitute the ALARM LIMIT. ALARM LIMIT can also refer to algorithmically determined criteria, the exact nature of which the OPERATOR cannot be aware, as well as the criteria structure applicable to a simple ALARM CONDITION variable for which there are multiple urgencies. See also the rationale for Definition 3.1.

Definition 3.5 – ALARM PAUSED

An OPERATOR can use ALARM PAUSED to avoid nuisance generation of ALARM SIGNALS before performing an action that is known to likely cause an ALARM CONDITION.

EXAMPLE 1 Intentional disconnection of a PATIENT breathing circuit to perform suction of the trachea.

EXAMPLE 2 Opening a transducer to air for zero calibration.

Definition 3.10 – ALARM SIGNAL GENERATION DELAY

Operating systems, microprocessor speed, software or network performance can influence the time between the onset of the ALARM CONDITION and generation of ALARM SIGNALS. If the delay is significant, the OPERATOR needs to know not only the mean time but also the distribution of times of the ALARM SIGNAL GENERATION DELAY, since with modern equipment it cannot always be possible to determine the absolute maximum time. If equipment is provided with a DISTRIBUTED ALARM SYSTEM, this duration should be for a typical set-up in its intended area of use. Problems that can be beyond the control of the MANUFACTURER include the speed and throughput of the network components. See also the rationale for Definition 3.2.

Definition 3.17 – DISTRIBUTED ALARM SYSTEM

In simple equipment, ALARM CONDITIONS are detected, processed and ALARM SIGNALS are generated 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 of devices with a central station, or with devices that generate ALARM SIGNALS for caregivers (OPERATORS) at some distance from the PATIENT, more complicated ALARM SYSTEMS are used.

In a DISTRIBUTED ALARM SYSTEM one of the following takes place in different parts of the ME SYSTEM:

a) the detection of an ALARM CONDITION;

b) the processing of an ALARM CONDITION; or

c) generation of ALARM SIGNALS.

A DISTRIBUTED ALARM SYSTEM typically comprises at least two devices:

d) equipment which detects and processes ALARM CONDITIONS and that is generally connected directly to the PATIENT, and

e) a remote device (part of a ME SYSTEM) that generates ALARM SIGNALS and that may or may not be in the vicinity of the PATIENT.

Thus in a network of bedside PATIENT monitors, one bedside PATIENT monitor can generate ALARM SIGNALS for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can generate ALARM SIGNALS for ALARM CONDITIONS from multiple PATIENTS. A two-way wireless communication system can generate ALARM SIGNALS 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 analog or digital signals from multiple PATIENTS and passes ALARM CONDITIONS back to bedside ME EQUIPMENT for generation of ALARM SIGNALS is a DISTRIBUTED ALARM SYSTEM.

Definition 3.23 – INFORMATION SIGNAL

ALARM SIGNALS are only generated because of the presence of ALARM CONDITIONS. In contrast, INFORMATION SIGNALS are those which are generated regardless of whether or not an ALARM CONDITION is present, e.g. the tone of the pulse oximeter, the tone of the electrocardiograph, the waveform of the electrocardiograph, the heart rate numeric. INFORMATION SIGNALS are independent of ALARM CONDITIONS, although INFORMATION SIGNALS can frequently convey information that is “alarming” to the OPERATOR.

EXAMPLE 1 The decreasing tonal frequency of the auditory INFORMATION SIGNAL of some pulse oximeters. The decreased tone is “alarming” to the OPERATOR, but in itself is not an ALARM SIGNAL.

EXAMPLE 2 An electrocardiograph waveform indicating ventricular fibrillation.

EXAMPLE 3 A heart rate of 20 beats per minute.

Definition 3.24 – INTELLIGENT ALARM SYSTEM

An INTELLIGENT ALARM SYSTEM can use one or more variables or patterns of a variable or variables to make decisions that determine the presence or absence of an ALARM CONDITION and its priority. INTELLIGENT ALARM SYSTEM methodologies can include but are not restricted to analysis of trends, limit comparisons, data redundancy, data fusion, rules, fuzzy logic controllers and neural networks. INTELLIGENT ALARM SYSTEMS are also known as smart ALARM SYSTEMS.

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

A REMINDER SIGNAL reminds an OPERATOR that an ALARM CONDITION still exists although an ALARM SIGNAL is not being generated because it has been previously acknowledged by an ALARM SIGNAL inactivation state. Appropriate application of REMINDER SIGNALS should reduce the chance that the ALARM SYSTEM is unintentionally left in an ALARM SIGNAL inactivation state, thereby reducing the incidence of FALSE NEGATIVE ALARM CONDITIONS, without unreasonably increasing the chance that the REMINDER SIGNAL will itself be a nuisance signal.

A REMINDER SIGNAL should be considered when the equipment is expected to have multiple OPERATORS or when the equipment is expected to be unattended by an OPERATOR in NORMAL USE.

There are two possible modes of operation for a REMINDER SIGNAL. In the first mode, the REMINDER SIGNAL signals periodically when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state, whether or not any ALARM CONDITION is present. In the second mode, the REMINDER SIGNAL signals only when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state and an ALARM CONDITION is present.

The second mode provides the advantage of less signal pollution in the healthcare environment. There is a HAZARD with the second mode, however, if the OPERATOR forgets to enable the generation of ALARM SIGNALS at the appropriate time.

An example of this situation is when an intubated and ventilated PATIENT requires suctioning in a critical care unit. In order to perform the suctioning, the ventilator is disconnected from the PATIENT. This would cause several ALARM SIGNALS to be generated. The time to repeatedly suction the PATIENT can take longer than the maximum AUDIO PAUSE interval and the OPERATOR would instead choose the AUDIO OFF state. After the suctioning is finished, the OPERATOR would have no auditory ALARM SIGNAL. In this situation, it might be preferable to have a REMINDER SIGNAL that the ALARM SYSTEM was put into AUDIO OFF state. After suctioning the PATIENT, the OPERATOR would hear the REMINDER SIGNAL and would be reminded to terminate the AUDIO OFF state.

In other settings, however, the second mode might be appropriate.

Subclause 5.2.1 – Instructions for use

[First dash]

OPERATORS have found that in legacy equipment the terminology for the ALARM SIGNAL inactivation states has been ambiguous [18]. This has caused confusion and OPERATOR error when an OPERATOR has accidentally indefinitely inactivated (ALARM OFF, AUDIO OFF) instead of temporarily inactivating the generation of ALARM SIGNALS (ALARM PAUSED, AUDIO PAUSED) due to terminology confusion and inconsistent markings of controls (mode error).

EXAMPLE Some legacy equipment uses the control marking “silence” for ALARM OFF while other equipment uses the control marking “silence” for ALARM PAUSED.

When providing an overview of the ALARM SYSTEM in the instructions for use, it is highly desirable that MANUFACTURERS use the terminology for the ALARM SIGNAL inactivation states that are used in this collateral standard. Writers of particular standards should also use this terminology.

[Forth dash]

The instructions for use should provide details of any pre-use checks necessary for safe use. [19] These checks could be automatic or be provided by a pre-use checklist. Most equipment will not be fail-safe against a single functional failure such as loudspeaker failure. A faulty loudspeaker can result in an ALARM CONDITION not being recognized due to the absence of an auditory ALARM SIGNAL. To reduce the probability of a FALSE NEGATIVE ALARM CONDITION, the ALARM SYSTEM should be checked at regular intervals.

Long and difficult pre-use checkouts will be resisted by OPERATORS. [20],[22],[24] Ideally, equipment would have an automated or semi-automated checkout to reduce the burden on the OPERATOR. This checkout could include testing of the ALARM SYSTEM, for instance by testing auditory and visual ALARM SIGNALS and asking the OPERATOR to verify their function.

Alternatively, the checkout might include setting the ALARM LIMITS and deliberately introducing a condition that violates those limits, or other means to deliberately generate an ALARM SIGNAL.

Subclause 6.1.1 – General

It can be difficult to classify some ALARM CONDITIONS as to whether they are a PHYSIOLOGICAL ALARM CONDITION (PATIENT-related) or a TECHNICAL ALARM CONDITION (equipment–related).

Subclause 6.1.2 – ALARM CONDITION priority

ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response or awareness of the situation that triggered the ALARM CONDITION. Priority is assigned through RISK ANALYSIS, either by the writer(s) of a particular standard or by the MANUFACTURER.

NOTE Some ALARM SYSTEMS have OPERATOR-configured or RESPONSIBLE ORGANIZATION-configured priorities.

MANUFACTURERS assign ALARM CONDITION priorities based on RISK ANALYSIS. This RISK ANALYSIS should primarily consider the severity and rapidity of onset of HARM if the ALARM CONDITION is not corrected. It should also consider other factors such as the sensitivity and specificity of the ALARM CONDITION for the actual event in the PATIENT or the equipment. The level of the priority of ALARM SIGNAL only suggests to the OPERATOR the speed at which the OPERATOR should respond to, or be aware of, an ALARM CONDITION. The actual speed of response or awareness required is ultimately based on the assessment by the OPERATOR.

"Immediate" category problems are those that are likely to cause PATIENT injury or death within seconds to several minutes if uncorrected. Few problems fall into the "immediate" category.

EXAMPLE 1 Asystole

EXAMPLE 2 Ventricular fibrillation

EXAMPLE 3 Failure of a cardiac support device (intra-aortic balloon pump, cardiopulmonary bypass machine)

EXAMPLE 4 Sustained high airway pressure

EXAMPLE 5 Extreme hypoxemia

EXAMPLE 6 Sustained high-energy radiation beam

"Prompt" category problems, on the other hand, do not cause PATIENT injury or death until at least several to many minutes have elapsed.

EXAMPLE 7 Many cardiac arrhythmias

NOTE Most cardiac arrhythmias would be prompt or delayed.

EXAMPLE 8 High or low blood pressure

EXAMPLE 9 Apnea (unless prolonged or associated with extreme hypoxia)

EXAMPLE 10 Mild hypoxemia

EXAMPLE 11 High or low pCO_2

"Delayed" category problems cause PATIENT injury only after many minutes to hours have passed.

EXAMPLE 12 Failure of an infusion pump for maintenance of intravenous fluids

EXAMPLE 13 Failure of an enteral feeding pump

EXAMPLE 14 Failure of a PATIENT weighing system

The choice of priority should be based upon RISK ANALYSIS. In general, the lowest priority compatible with the RISK ANALYSIS should be selected. In particular, HIGH PRIORITY ALARM SIGNALS should be reserved for those few ALARM CONDITIONS that truly require immediate response for PATIENT safety—that is, a response within seconds to a couple of minutes. Many types of equipment will not require any HIGH PRIORITY ALARM SIGNALS.

ME EQUIPMENT ALARM SYSTEMS are a protective measure used to minimize risks to PATIENT, personnel, and equipment. In certain therapeutic ME EQUIPMENT, a HAZARDOUS SITUATION could develop so rapidly, and cause injury or damage so rapidly, that OPERATOR response to even a well-designed ALARM SYSTEM would be too slow. In such ME EQUIPMENT, an automatic system of mitigating the HAZARDOUS SITUATION is highly desirable, if not essential. The general standard and many particular standards require such safety mechanisms. It is recognized, however, that no ME EQUIPMENT could have protection against every possible HAZARD, or in the presence of multiple fault conditions.

Subclause 6.2 – Disclosures for INTELLIGENT ALARM SYSTEM

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

An INTELLIGENT ALARM SYSTEM need not simultaneously generate ALARM SIGNALS for all active ALARM CONDITIONS. The equivalent safety objective can be achieved by priority ranking and generating ALARM SIGNALS for a subset of the current active ALARM CONDITIONS. When multiple concurrent ALARM CONDITIONS exist, the relative importance of each ALARM CONDITION can be used to internally rank the ALARM CONDITION within a given priority. This internal priority ranking can be used to determine which particular ALARM CONDITION is causing the generation of ALARM SIGNALS or can be used to suppress the generation of ALARM SIGNALS for lower internal priority ALARM CONDITIONS. Multiple ALARM CONDITIONS of the same priority and the same or very similar meaning can also be incorporated into a single message (visual ALARM SIGNAL). These techniques are used to reduce the number of ALARM SIGNALS that an OPERATOR is required to respond to on ALARM SYSTEMS with multiple, related ALARM CONDITIONS. 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 nuisance or FALSE POSITIVE or FALSE NEGATIVE ALARM CONDITIONS.

To assign an ALARM CONDITION priority, an algorithm of an INTELLIGENT ALARM SYSTEM might consider the magnitude of the deviation of a monitored variable from the ALARM LIMIT, the rate of change of the variable, the duration of the ALARM CONDITION and the presence or absence of any other concurrent ALARM CONDITIONS, redundant sources of information or values of other variables.

After an ALARM CONDITION has generated ALARM SIGNALS, subsequent or persisting ALARM CONDITION(S) can cause the ALARM SYSTEM to change the priority of the ALARM CONDITION or to reassess the initial ALARM CONDITION (and perhaps cancel its ALARM SIGNAL generation) through the use of an INTELLIGENT ALARM SYSTEM algorithm.

INTELLIGENT ALARM SYSTEMS are permitted change characteristics of the ALARM SIGNALS to indicate a change in urgency. These changes can include, but are not limited to, changing the intensity of BURST volume, INTERBURST INTERVAL or PULSE FREQUENCY.

The algorithms of INTELLIGENT ALARM SYSTEMS should be evaluated and validated to ensure that the equipment meets the operational needs of the expected OPERATOR in the expected environment of its INTENDED USE. For methods of evaluation of USABILITY see IEC 60601-1-6.

Subclause 6.3.2 – Visual ALARM SIGNALS

Visual ALARM SIGNALS should indicate to the OPERATOR the presence and level of urgency of any ALARM CONDITION, help the OPERATOR to locate the specific PATIENT or equipment where an OPERATOR response or awareness is required, and identify to the OPERATOR the specific ALARM CONDITION.

There are two requirements for visual ALARM SIGNALS:

- *a "distant" requirement that the presence of an ALARM CONDITION and its priority are correctly perceived from a distance of 4 m (far away); and*
- *an "OPERATOR'S POSITION" requirement that the visual ALARM SIGNAL indicating the specific ALARM CONDITION and its priority are legible from at least 1 m or from the OPERATOR'S POSITION.*

It is possible to comply with the requirements of this collateral standard using either a single visual ALARM SIGNAL or with separate "distant" and "OPERATOR'S POSITION" visual ALARM SIGNALS.

The "distant" requirements are only required when they are necessary to allow the OPERATOR to locate the part of the ALARM SYSTEM that is generating ALARM SIGNALS. The ability to identify the priority of visual ALARM SIGNALS from a distance of 4 m allows the OPERATOR to decide which equipment to respond to first when simultaneous ALARM SIGNALS occur in a multi-equipment environment without having first to go to the OPERATOR'S POSITION.

The ability to discriminate between specific ALARM CONDITIONS and their priorities from a distance of 1 m or the OPERATOR'S POSITION aids the OPERATOR in deciding what actions need to be taken. MANUFACTURERS can choose to also make this "OPERATOR'S POSITION" visual ALARM SIGNAL legible from a distance of 4 m.

The committee considered the use of the standard general alarm symbol and urgent alarm symbol (triangle with 1 or 2 and extended to 3 curved lines) to represent LOW, MEDIUM or HIGH PRIORITY ALARM CONDITIONS. Concern was raised that they are too similar and would be impossible to distinguish on many displays at a viewing distance of 1 m to 4 m.

The committee recognized this limitation, and decided that adding optional elements could be used to indicate the priority.

MANUFACTURERS are free to enhance legibility by any of several means. For instance, the symbols could be coloured red or yellow, or placed on a red or yellow background. Additional symbols, letters, or words could be added to these symbols to enhance distinctiveness. One suggestion was to use three identical symbols to indicate HIGH PRIORITY, two identical symbols for MEDIUM PRIORITY and a single symbol for LOW PRIORITY.

Subclause 6.3.2.2 – Characteristics of visual ALARM SIGNALS

The committee considered using the triangle symbol (IEC 60417-5307) with 1, 2 (IEC 60417-5308) or 3 curved lines to represent the presence of LOW, MEDIUM OR HIGH PRIORITY ALARM CONDITIONS. Some comments suggested that such symbols were too similar and would be impossible to distinguish on many displays, particularly at a viewing distance of 4 m.

The committee recognized this limitation and decided to allow other methods to indicate priority. For instance, the visual ALARM SIGNAL representing a HIGH PRIORITY ALARM CONDITION could be coloured red, or placed on a red background. Additional symbols, letters or words could be added to improve distinctiveness. One suggestion was to use three identical triangles for HIGH PRIORITY ALARM CONDITION, two identical triangles for MEDIUM PRIORITY and a single triangle for LOW PRIORITY.

In Table 2, cyan is added as an option for indicating LOW PRIORITY. Differentiating LOW PRIORITY from MEDIUM PRIORITY by colour is an improvement in USABILITY. Historically, only red, yellow and green coloured lamps were readily available. A much broader range of colours is readily available today. The committee has chosen one of the complementary colours that is readily available.

Subclause 6.3.3 – Auditory ALARM SIGNALS

The primary purpose of auditory ALARM SIGNALS is to get the OPERATOR'S attention. Additionally, they should help the OPERATOR identify:

– the onset or presence of ALARM CONDITIONS;

– the urgency of the required OPERATOR response; and

– the location of the device generating ALARM SIGNALS.

The requirements of this subclause are intended to ensure that auditory ALARM SIGNALS in equipment are able to fulfill this purpose.

Equipment that is continuously attended by the OPERATOR in NORMAL USE has different auditory ALARM SIGNAL requirements from equipment that is unattended by the OPERATOR in NORMAL USE.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List element a)]

Distinctively different auditory ALARM SIGNALS for HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY are specified in Table 3 and Table 4. For any OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, they should be audibly different from other sounds in the PATIENT care area. The HIGH PRIORITY auditory ALARM SIGNAL is designed to be very different from most other sounds (e.g. pagers, telephones, etc.).

The ALARM SIGNALS are priority encoded so that the OPERATOR can readily discern the priority of the associated ALARM CONDITION by auditory means alone.

Mandating the presence of at least one set of auditory ALARM SIGNALS that complies with Table 3 and Table 4 or uses alternative technology (i.e., not based on PULSES and BURSTS) such as voice synthesis ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting one recognizable, standard set of auditory ALARM SIGNALS on all ALARM SYSTEMS. Additional sets that comply with Table 3 and Table 4 and Annex F can be provided without any need for VALIDATION. Additional sets that do not comply with Table 3 and Table 4 can be provided so long as they are priority encoded and are appropriately validated. The RESPONSIBLE ORGANIZATION can configure any one of these as the DEFAULT ALARM PRESET.

Table 3 and Table 4 indicate the difference in priority primarily by the number of PULSES in a BURST and their rhythm. A HIGH PRIORITY BURST comprises 10 PULSES, repeating two identical groups of 5 PULSES with a pause between each group. A MEDIUM PRIORITY BURST comprises 3 PULSES and LOW PRIORITY BURSTS can contain one or two PULSES. Other factors can be used to provide additional priority or relative urgency information. Examples include inter-PULSE interval, inter-BURST interval, PULSE width and other PULSE characteristics. Higher priority auditory ALARM SIGNALS should use faster BURSTS with shorter PULSES that are repeated more frequently than lower priority ALARM SIGNALS.

Auditory ALARM SIGNALS that comply with this standard should sound almost identical to auditory ALARM SIGNALS that comply with ISO 9703-2.

Mandating auditory ALARM SIGNALS in Table 3 and Table 4 ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting recognizable, standard auditory ALARM SIGNALS for an ALARM SYSTEM.

Urgency of the required OPERATOR response is indicated by the different BURST patterns, BURST speeds, PULSE widths, repetition rates and relative volumes that are specified for LOW, MEDIUM and HIGH PRIORITY ALARM SIGNALS in Table 3 and Table 4. Annex D indicates factors that affect the perceived urgency of a BURST. MANUFACTURERS can find this helpful when choosing values that comply with Table 3 and Table 4 and are appropriate for the relative degree of urgency of OPERATOR response to a particular ALARM CONDITION. ESCALATION of ALARM CONDITION urgency within a priority ranking can be indicated to the OPERATOR by similar means.

Auditory ALARM SIGNALS that comply with Table 3 and Table 4 are not required to incorporate melodies. However, if melodies are used, their meanings are required to be as specified in Annex F or be designed so as to preclude the possibility of confusion with Annex F. Annex F therefore attempts to standardize pitch pattern (melody) for the majority of ALARM SIGNALS complying with Table 3 and Table 4.

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.

If melodies are restricted in number and are reliably associated with defined equipment categories, OPERATORS are likely to "learn" what a particular melody means and to use this information to help them locate the source of an ALARM CONDITION. If unrestrained proliferation of melodies were to occur, a potentially large number of different melodies would likely be presented to the OPERATOR. This would generate such confusion as to render them useless and potentially hazardous. On the other hand, if all equipment of a given type made exactly the same sound, it might be difficult to identify the source of the ALARM SIGNAL by auditory means in situations where many similar items of equipment are present in one location.

The committee was of the opinion that the RISK ANALYSIS favoured some degree of regulation of melodies for ME EQUIPMENT. The challenge was to choose an appropriate degree of regulation without being excessively design restrictive.

The melodies of Annex F were derived by a musically trained subgroup of the experts from the committee. Each melody was chosen to be distinctively different from the others. The assignment of particular melodies to categories was deliberate and based upon a psychoacoustic association between the melody and the category. For more information, see the rationale to Annex F.

MANUFACTURERS intending to use melodies are encouraged to select the most appropriate melody from those in Annex F on the basis of the primary function of their equipment. If they intend to use some other melody, it should not be easily confused with any other melody of Annex F unless the meaning (category) is the same. Note that the defining characteristic of a melody is the relative difference in pitch between successive PULSES in a BURST. Absolute pitch variation is acceptable.

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

[List element b)]

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.

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

Table 3 and Table 4 are based on the requirements for auditory ALARM SIGNALS that were found in ISO 9703-2 [26]. These distinctive patterns or rhythms have been used for more than a decade and have been well accepted clinically. Table 3 and Table 4 are slightly different from the equivalent tables in ISO 9703-2. The modifications were intended to simplify interpretation and increase flexibility rather than introduce significant change. Auditory ALARM SIGNALS that complied with ISO 9703-2 should also comply with this collateral standard.

Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the source of the ALARM CONDITION promptly. Ensuring that four or more audible higher-frequency harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. Spatial localization is poor at low frequencies, so the lower acceptable limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz.

Selection of the INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration. Shorter INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for equipment that is intended to be continuously attended by the OPERATOR in NORMAL USE. On the other hand, longer INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to identify, in a timely manner, the source of the ALARM CONDITION. This is particularly true for equipment intended to be unattended by the OPERATOR in NORMAL USE. 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.

The main differences between ISO 9703-2 and this collateral standard and the reasons for the current requirements, are described below:

a) The new PULSE spacing intervals are defined differently from ISO 9703-2 and provide greater design flexibility. PULSE spacing is now defined as the time from the end of one PULSE to the start of the next. As a result there is no possibility of overlap, which could occur in ISO 9703-2. The actual values permit all auditory ALARM SIGNALS complying with ISO 9703-2 except for HIGH PRIORITY ALARM SIGNALS in which the PULSES almost overlap. For obvious reasons, very few MANUFACTURERS actually did this. The committee considered that PULSES should have reasonable gaps between them, and that near-overlapping of PULSES should not be permitted.

b) In ISO 9703-2, the intended rhythm could not be achieved if each PULSE spacing was the same. The redrafted Table 3 addresses this problem. To ensure that the distinctive pattern is achieved, yet provide some flexibility in overall timing, this standard requires all INTERBURST INTERVALS within a BURST to have the same duration. A tolerance of ±5 % seemed appropriate.

c) The time between the two five-PULSE groups that comprise a HIGH PRIORITY ALARM SIGNAL (time between 5th and 6th PULSES) is now defined as the time from the end of the last PULSE in the first group to the start of the first PULSE in the next. The equivalent requirement in ISO 9703-2 was defined as the time from the start of the first group to the start of the next. In practice, this time could be unacceptably short. Therefore, few MANUFACTURERS actually complied with this ISO 9703-2 requirement. Instead, they chose the interpretation that is now used in this collateral standard. The intent of the pause was that the first group of PULSES would attract the OPERATOR'S attention, and the second group would emphasize the importance of the ALARM CONDITION and aid in identifying the source of the ALARM CONDITION once the OPERATOR'S attention had been gained.

d) A greater range of INTERBURST INTERVALS is permitted. The existing requirement in ISO 9703-2 is not suitable for ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE. Selection of the most appropriate INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration of the clinical requirement for the ALARM CONDITION in its intended environment of use. Short INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for ALARM SYSTEMS that are always attended by the OPERATOR in NORMAL USE. On the other hand, long INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to promptly identify the source of the ALARM CONDITION. MANUFACTURERS and writers of particular standards are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Factors to consider include:

   – whether the ALARM SYSTEM is intended to be always attended by the OPERATOR in NORMAL USE. In this case a longer INTERBURST INTERVAL is appropriate;

     EXAMPLE Anesthesia machines.

   – the kind of equipment involved;

     EXAMPLE An enteral feeding pump should have a longer INTERBURST INTERVAL than a critical care ventilator.

   – whether the ALARM SYSTEM is connected to a remote DISTRIBUTED ALARM SYSTEM, e.g. a central monitoring system. An ALARM SYSTEM that is not so connected (standalone equipment) should consider a shorter INTERBURST INTERVAL, in order to facilitate identification;

     the presence and effectiveness of additional or alternative notification systems (secondary visual ALARM SIGNALS, vibratory ALARM SIGNALS, ALARM SIGNAL lights in hallways, alarm paging systems, etc). Effective alternative generation of ALARM SIGNALS will permit longer INTERBURST INTERVALS.

e) HIGH PRIORITY auditory ALARM SIGNAL PULSES should be “faster” than MEDIUM PRIORITY auditory ALARM SIGNAL PULSES to ensure that they are perceived as being more urgent. Hence, the requirement that the effective PULSE duration for HIGH PRIORITY ALARM SIGNALS is less than that for MEDIUM PRIORITY.

f) The LOW PRIORITY auditory ALARM SIGNAL is optional, but if present can comprise one or two PULSES. It should be relatively unobtrusive and perceived as less urgent than a MEDIUM PRIORITY ALARM SIGNAL.

g) Pitch is now permitted to rise and fall during a BURST. ISO 9703-2 required that changes in pitch proceed in one direction only. The committee considered this to be without safety advantage and excessively design restrictive.

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 signals can make it very difficult to find where they are coming from. Ensuring that four or more audible harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. These harmonics should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of harmonic content 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 level of the fundamental and the sound pressure level of the harmonics because they are commonly used to describe relative sound pressure levels. The choice of harmonic content is very flexible and permits sounds of very different tonal quality to be created.

i) Fall time for pulses is now less restrictive. It can be any duration that does not overlap the next pulse. In contrast, ISO 9703-2 sounds were required to have the same fall time as rise time. The committee found this to be excessively design restrictive. Manufacturers are now permitted to create sounds with more distinctive envelopes (e.g., bell-like decays or reverberation effects).

   – RISE TIME for PULSES is specified as 10 % to 20 % of PULSE duration. There is no significant change from ISO 9703-2. More rapid RISE TIME can be intrusive and startling, but can express greater urgency.

   – There is no change in the PULSE frequency requirement. Spatial localization is poor at low frequencies, so the lower limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz. MANUFACTURERS can choose any frequency they like from within this range. Higher pitch is associated with greater urgency. [11]

   – The difference in amplitude between any two PULSES in a BURST should not exceed 10 dB. Again, this refers to a relative sound pressure level ratio (i.e., not an absolute volume difference in dBA). This requirement is unchanged from ISO 9703-2. It is easier to make all PULSES the same amplitude, but if the amplitude of the early PULSES in a BURST is a little less than subsequent PULSES, it can be less startling.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List elements c) to f)]

The MANUFACTURER can provide more than one set of auditory ALARM SIGNALS. VALIDATION by USABILITY testing is not required if each set complies with Table 3 and Table 4 (or Annex F). If additional non-standard auditory ALARM SIGNAL sets (i.e., those that do not comply with Table 3 and Table 4 or Annex F) are provided, they require clinical VALIDATION to ensure that they provide at least an equivalent degree of safety as the standard sounds. Permission to provide non-standard sounds is intended to allow a RESPONSIBLE ORGANIZATION to continue to use non-standard but "historically validated" sound sets that have been successfully used for significant periods of time in their PATIENT care areas, and to ensure that this collateral standard is not excessively design restrictive. For example, the RESPONSIBLE ORGANIZATION might prefer some ventilators in their ICU to make one ALARM SIGNAL sound and ventilators of another type to make a different sound. Finally, this flexible approach should ensure that this collateral standard is not excessively design restrictive and that future development of improved auditory ALARM SIGNALS is not hindered.

When choosing an auditory ALARM SIGNAL set, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the medical auditory ALARM SIGNALS of that set unless their meaning is the same.

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

Sounds from non-medical devices, such as pagers and telephones can resemble medical ALARM SYSTEM auditory ALARM SIGNALS. Care needs to be taken when designing auditory ALARM SIGNALS that the spectral content and amplitude of the ALARM SIGNALS facilitate the localization and identification of the source of the ALARM SIGNAL, taking into account the usual environmental conditions in which the equipment is intended to be used. (See also Annex D.)

NOTE 1 When auditory ALARM SIGNALS are provided, this collateral standard requires that one set of auditory ALARM SIGNALS be encoded to convey the level of urgency of OPERATOR response required. In addition, other sets of auditory ALARM SIGNALS have been devised based on categorization of the nature of the response or awareness and the level of urgency of response required. [18]

A USABILITY test differs significantly from a clinical trial, but is equally important in producing usable, safe equipment. This test spotlights the OPERATOR interface and reactions of the OPERATOR to it. A USABILITY test can take up to a week per use model, depending on the number of OPERATORS involved. Such tests can be conducted in an office-like setting, away from the medical practice environment. This eliminates interference that would occur in the actual-use environment. While USABILITY test formats vary, typically one individual at a time performs self-exploration as well as directed tasks with the equipment. Test administrators can provide special prompts and feedback as required to add realism. As the OPERATOR performs tasks with the equipment, researchers observe and record results. The PROCESS gives the OPERATOR time to concentrate on using the equipment. An OPERATOR can spend weeks learning to use the equipment. Whether they encounter operating difficulties or causes for dissatisfaction over this time depends largely on how much they use the equipment and which tasks they perform. A USABILITY test compresses the initial use experience into a shorter time frame, usually 1 h to 4 h.

In hunting for USABILITY problems, researchers ask OPERATORS to talk their way through each task, describing what they are thinking, decisions they are contemplating, irritants, advantages, and so on. Sometimes USABILITY problems surface immediately, such as when an OPERATOR tries to turn on the equipment and cannot find the power switch. In such a case the OPERATOR can say:

> *Now, I'll turn the power on. I am looking at the front panel but nothing jumps out at me. I see a switch labelled "standby," but I don't think that turns it on. You probably press that button to save power without turning it off. I'm reaching around the back for a switch, but I don't feel anything. I would expect to find a switch right here [OPERATOR points to lower right side of control panel]. This green light probably illuminates when you turn the power on. Oh, I see [OPERATOR presses the light]. This light is the switch. You press it in to turn the power on. That wasn't obvious to me.*

USABILITY test protocols should include frequent USE SCENARIOS and critical USE SCENARIOS. The effect of stress on how an OPERATOR uses the equipment can be studied by introducing time limits, removing equipment labelling, or the OPERATOR'S manual, and introducing equipment failures. Researchers can create a worst-case scenario and see how OPERATORS react. Test outcomes can be compared across several OPERATORS. MANUFACTURERS performing such tests commonly find that researchers collect a large set of USABILITY problems that may have escaped detection during a clinical trial, since such trials do not explicitly address USABILITY. [25]

NOTE 2 Attention is drawn to IEC 60601-1-6.

[List element g)]

When an ALARM SYSTEM is provided with more than one auditory ALARM SIGNAL set, the MANUFACTURER is required to select one set for the DEFAULT ALARM PRESET. The committee chose to require this because it can be hazardous when ALARM SYSTEMS have inconsistent or unknown sounds following resets and power failures.

The RESPONSIBLE ORGANIZATION should be able to change that selection and choose their desired auditory ALARM SIGNAL set for the DEFAULT ALARM PRESET, e.g., RESPONSIBLE ORGANIZATIONS need to be able select the auditory ALARM SIGNAL set that is familiar to their OPERATORS or to differentiate between different types of equipment.

[List element h)]

An ALARM PRESET can store any configuration parameters that affect the performance of the ALARM SYSTEM. One such configuration parameter can be the selection between auditory ALARM SIGNAL sets. A particular set can then become active when a particular ALARM PRESET is loaded. RESPONSIBLE ORGANIZATIONS may find this capability helpful when defining ALARM PRESETS for equipment that is used in a variety of PATIENT care areas. If OPERATORS can store ALARM PRESETS they can find this capability helpful to quickly configure ALARM SYSTEMS with the auditory ALARM SIGNALS that they are most familiar with.

[Signals in case of failure]

There are some failures, such as a power failure of the ALARM SYSTEM, which make it impossible for the ALARM SYSTEM to perform its intended function. In these cases, other means, such as a simple battery-backed tone generator, can be used to generate an ALARM SIGNAL to indicate such a TECHNICAL ALARM CONDITION. 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 failure or power down" melody from Annex F, but it is recognized that this can be impractical and that a non-standard auditory ALARM SIGNAL can be acceptable for this purpose.

A power or ALARM SYSTEM failure auditory ALARM SIGNAL should be generated for at least 120 s. This is particularly important for LIFE-SUPPORTING EQUIPMENT or life-sustaining equipment where the loss of function without immediate OPERATOR action can lead to a HAZARDOUS SITUATION for the PATIENT. Such a signal should also be considered for vital signs monitors to ensure that the OPERATORS are aware of the malfunction and can alter their clinical practice appropriately.

Allowing the OPERATOR to select LATCHING versus NON-LATCHING ALARM SIGNALS other than those determined to be appropriate by the RESPONSIBLE ORGANIZATION, can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

Subclause 6.3.3.2 – Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

For the OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, those signals need to be audible above the background noise level and different from other sounds.

High background noise levels can mask or conceal the presence of auditory ALARM SIGNALS to such an extent that the OPERATOR can fail to hear them. Conversely, an auditory ALARM SIGNAL can be excessively intrusive or startling if its level is very high in relation to the background noise level. The OPERATOR might then seek to inappropriately disable or deactivate the ALARM SYSTEM.

In any PATIENT care environments where the background noise level is known and constant, a fixed auditory ALARM SIGNAL volume can be reasonable. The volume level of such a fixed auditory ALARM SIGNAL should exceed the background noise level to such an extent that it will be reliably detected but not to such an extent that it would be excessively startling or intrusive. Clinical experience has shown that values between 45 dB and 85 dB can be reliably detected without being too intrusive in most situations.

In many PATIENT care environments the background noise level is not constant. In operating rooms the background noise can vary from 50 dBA to 85 dBA. Additionally, one type of equipment can be used in several different kinds of PATIENT care environments; for example a ventilator that can be used in the home, in the intensive care area or for PATIENT transport.

Given the wide range of possible background noise levels in all possible PATIENT care environments, the committee did not consider it appropriate to specify any absolute volume level or range of levels for auditory ALARM SIGNALS. Designers of ALARM SYSTEMS should therefore be aware of the typical background noise level (and how variable it can be) in the intended environments of use. ALARM SYSTEMS that are to be used when background noise levels are variable should be provided with means for manual adjustment of the auditory ALARM SIGNAL level or should automatically adjust the auditory ALARM SIGNAL level so that the perceived loudness remains the same despite changes in background noise levels.

Because louder sounds are generally perceived to be more urgent, lower priority auditory ALARM SIGNALS should not be louder than higher priority ALARM SIGNALS. If higher priority auditory ALARM SIGNALS are much louder than lower priority signals, they can be startling or intrusive. A reasonable compromise is for HIGH PRIORITY auditory ALARM SIGNALS to be approximately +6 dB louder than MEDIUM PRIORITY auditory ALARM SIGNALS, with an acceptable range from equal in volume (0 dB) to a maximum of +12 dB louder. MEDIUM and LOW PRIORITY ALARM SIGNALS should be equal in volume, but if they are different, MEDIUM PRIORITY auditory ALARM SIGNALS should not be more than 6 dB louder than LOW PRIORITY auditory ALARM SIGNALS.

It should be possible to adjust the volume level of auditory INFORMATION SIGNALS (e.g., pulse oximeter "beeps" or the "in-use" indicators on electro-surgical units) and the volume level of auditory ALARM SIGNALS independently, so that both can be set to appropriate levels. If the volume levels of auditory ALARM SIGNALS and auditory INFORMATION SIGNALS are not independently adjustable, then INFORMATION SIGNALS should have no greater volume level than LOW PRIORITY auditory ALARM SIGNALS, and both should have lower volume levels than those of MEDIUM PRIORITY and HIGH PRIORITY auditory ALARM SIGNALS. The auditory INFORMATION SIGNAL should be non-intrusive, non-startling and discontinuous in nature.

The volume (and range of adjustment of volume, if provided) of auditory ALARM SIGNALS in an ALARM SYSTEM are required to be disclosed to the OPERATOR so that the OPERATOR will be able to determine if the volume of the auditory ALARM SIGNALS is appropriate for the intended environment of use.

Subclause 6.3.4 – Characteristics of verbal ALARM SIGNALS

Verbal ALARM SIGNALS are permissible for HIGH, MEDIUM or LOW PRIORITY ALARM SIGNALS as well as INFORMATION SIGNALS. See also Annex E.

Verbal ALARM SIGNALS should only be considered for an ALARM SYSTEM intended for continuous OPERATOR attendance.

Subclause 6.4 – Disclosure of delays

If an event occurs in the PATIENT or the equipment that should result in the generation of ALARM SIGNALS, the generation should occur promptly. For example, clinicians would expect an ALARM SIGNAL soon after an abrupt fall in heart rate to a value below the lower ALARM LIMIT for heart rate, or once apnea or asystole has occurred. This is usually the case.

However, in some situations, ALARM SIGNAL generation can be delayed to such an extent that the delay can be clinically significant. This collateral standard recognizes that there are two fundamentally different potential causes for these delays.

First, it can take some time for the ALARM SYSTEM to determine that an ALARM CONDITION is present after the occurrence of a valid triggering event in the PATIENT. This delay is defined as the ALARM CONDITION DELAY. It can be due to:

– *artifact rejection algorithms, or*

– *INTELLIGENT ALARM SYSTEMS that include event duration as part of the algorithm, or*

– *aperiodic measurement (e.g., intermittent non-invasive blood pressure monitoring).*

When the ALARM SYSTEM is aperiodically measuring rather than continuously monitoring a variable, there can be a significant delay between the time that an event occurs in the PATIENT and when that event is detected. If the OPERATOR is unaware of this, incorrect treatment decisions can occur. The time between measurements is considered to be part of the ALARM CONDITION DELAY.

In the case of apnea or asystole, the valid triggering event in the PATIENT has not occurred until the absence of respiration or heart rate has existed for a defined period of time. Because this defined period of time is required to pass before the event itself exists, it is not included as part of the ALARM CONDITION DELAY. See also the rationale for Definition 3.2.

Second, the generation of ALARM SIGNALS can lag some time after the ALARM SYSTEM has determined that an ALARM CONDITION exists. This delay is defined in this document as the ALARM SIGNAL GENERATION DELAY. In most ALARM SYSTEMS this delay is usually clinically insignificant, but can be important, for example, when paging systems or networked remote devices are used to generate ALARM SIGNALS. See also the rationale for Subclause 6.10.

A further complication can occur when the ALARM SYSTEM is not continuously monitoring, but is aperiodically measuring the variable that causes an ALARM CONDITION, e.g. a non-invasive blood pressure monitor. There can be a significant delay between when an event occurs in the PATIENT and when that event is detected. If OPERATORS are unaware of this likelihood, incorrect treatment decisions can occur.

In that case, the time between measurements is considered to be part of the ALARM CONDITION DELAY.

Figure A.1 illustrates the components of ALARM SYSTEM delay for a PHYSIOLOGICAL ALARM CONDITION normalized variable.

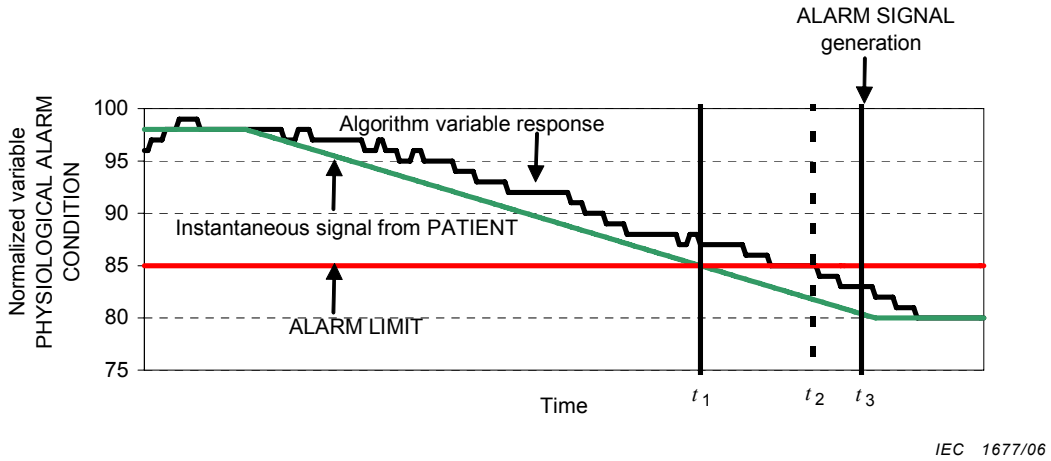


Figure A.1 – Graphical representation of components of ALARM SYSTEM delay

A valid triggering event occurs in the PATIENT at t_1. At t_2 the ALARM SYSTEM determines that an ALARM CONDITION exists.

NOTE In this example, the ALARM LIMIT is less than 85, not less than or equal to 85.

The ALARM CONDITION DELAY is $t_2 - t_1$. This delay is due to the ALARM SYSTEM processing and averaging. The ALARM SIGNAL GENERATION DELAY is $t_3 - t_2$. This delay is attributed to the ALARM SYSTEM strategy and the communication time to the ALARM SYSTEM generating device or DISTRIBUTED ALARM SYSTEM (e.g. PATIENT monitor or central station). At t_3 the ALARM SYSTEM begins to generate ALARM SIGNALS. Thus, the overall ALARM SYSTEM delay time is $t_3 - t_1$.

Subclause 6.4.1 – ALARM SYSTEM delays

The delay times are based on clinical judgement. Delay times shorter than those specified in this collateral standard are considered clinically insignificant.

Subclause 6.4.2 – Delays to or from a DISTRIBUTED ALARM SYSTEM

DISTRIBUTED ALARM SYSTEMS further complicate the consideration of ALARM SYSTEM delays. See also the rationale for Definition 3.2. When an OPERATOR is depending on remote generation of ALARM SIGNALS from a DISTRIBUTED ALARM SYSTEM for treatment decisions, then knowledge about the delays associated with DISTRIBUTED ALARM SYSTEMS is necessary for safety.

DISTRIBUTED ALARM SYSTEMS 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 SYSTEMS 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 ALARM SIGNAL generating device.*

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

Ideally, the maximum time interval added to the original ALARM SIGNAL GENERATION DELAY should be reported as the remote ALARM SIGNAL GENERATION DELAY. It is recognized, though, that some components can have unpredictable, stochastic delays because of the nature of their non-deterministic networks. Still these components should have a "time out" function as described in the following paragraph.

Any component in a DISTRIBUTED ALARM SYSTEM might fail or experience a delay in passing along the indication of the ALARM CONDITION. ALARM SYSTEMS should be designed so that a communication failure (lack of receipt of an acknowledgement signal or failure of a "handshake" or other "time-out" function) results in a TECHNICAL ALARM CONDITION after a finite period. In lieu of the time to pass along the indication of the ALARM CONDITION (that is, the ALARM SYSTEM'S contribution to the ALARM SIGNAL GENERATION DELAY), the MANUFACTURER can disclose the time from detection of the indication of the ALARM CONDITION or receipt of the indication of the ALARM CONDITION to creation of the TECHNICAL ALARM CONDITION. When appropriate, both times (contribution to the ALARM SIGNAL GENERATION DELAY and the time to TECHNICAL ALARM CONDITION) should be disclosed.

It is important for the OPERATOR and the RESPONSIBLE ORGANIZATION to know both of these times for the safety of the PATIENT.

Subclause 6.5.1 – General requirements

It is important for OPERATORS to know the how the ALARM SYSTEM will operate when they start to use equipment. As a result, an ALARM SYSTEM is required to have a known priority and ALARM LIMIT for each ALARM CONDITION in every ALARM PRESET.

Subclause 6.5.3 – RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

Allowing the OPERATOR to change RESPONSIBLE ORGANIZATION-configured or other OPERATOR-configured ALARM PRESETS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

A MANUFACTURER-configured default ALARM LIMIT should be sufficiently wide to minimize unnecessary ALARM CONDITIONS and sufficiently narrow to alert the OPERATOR to a situation that can be dangerous.

Subclause 6.5.4.2 – Selection of DEFAULT ALARM PRESET

The start-up sequence of an ALARM SYSTEM needs careful design to prevent nuisance ALARM SIGNALS. In older ME EQUIPMENT, when it was switched on, any ALARM LIMIT in violation immediately caused an ALARM SIGNAL, even though no PATIENT was connected to the ME EQUIPMENT! Later ME EQUIPMENT, when it was switched on, entered a state of ALARM OFF, or AUDIO OFF, and the state had to be deliberately terminated by OPERATOR action. Additional safety was provided with the introduction of ME EQUIPMENT with automatic enabling of the ALARM SYSTEM when a PATIENT was connected to the ME EQUIPMENT, or when a valid physiologic signal was first present (for instance, five normal breaths or five heartbeats within a certain time interval), or through an "admit new PATIENT" function which was activated by the OPERATOR.

Another situation is the desire to set up the ME EQUIPMENT, including the ALARM SYSTEM, before the PATIENT is connected. In this instance, it is desirable for the OPERATOR to select the ALARM PRESET, and perhaps to modify values from the ALARM PRESET for the PATIENT planned, without enabling the ALARM SYSTEM. The ALARM SYSTEM would then be enabled, either manually or preferably automatically, when the PATIENT is later connected to the ME EQUIPMENT.

A final situation is when the ALARM SYSTEM, or part of the ALARM SYSTEM, is in separate equipment. For instance, a gas delivery system might incorporate a separate gas monitor with its own ALARM SYSTEM, or an electronic recordkeeper or another equipment might combine the signals from several items of ME EQUIPMENT into a single ALARM SYSTEM. In this instance the primary ME EQUIPMENT and its ALARM SYSTEM might be switched on separately. Another example is a DISTRIBUTED ALARM SYSTEM of a PATIENT monitor with a central station. The ALARM SYSTEM of a central station should not be enabled when no PATIENT is connected! As in the earlier example, it would not be desirable to have the ALARM SYSTEM enabled until the ME EQUIPMENT is in actual clinical use.

When choosing the DEFAULT ALARM PRESET, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the auditory ALARM SIGNALS that are being chosen, unless their meaning is the same.

Subclause 6.5.5 – Interruptions of less than or equal to 30 s

For equipment with ALARM SYSTEMS, interruption of the SUPPLY MAINS for 30 s or less is considered NORMAL CONDITION. 30 s is sufficient time to restore power to the equipment by either plugging it back into SUPPLY MAINS or having the emergency generator initiate operation. Equipment with an OPERATOR-exchangeable INTERNAL ELECTRICAL POWER SOURCE, when they can be quickly replaced, is also expected to maintain its ALARM SETTINGS. The ALARM PRESET is expected to remain unchanged after such interruptions.

Subclause 6.6.2 – Adjustable ALARM LIMIT

Care should be used in the design of an ALARM SYSTEM if an OPERATOR is permitted to set an ALARM LIMIT to extreme values. Such action by the OPERATOR can have the effect of defeating both the auditory and visual ALARM SIGNALS, without providing a visual indication that the ALARM CONDITION is effectively disabled (see the second paragraph of 5.2.1).

Care also needs to be taken that any absolute lower and upper ALARM LIMITS will not be reached by PATIENTS in clinical practice, as this would cause a situation in which an ALARM CONDITION is continuously and erroneously indicated by ALARM SIGNALS.

The provision and use of a pre-use checklist to verify ALARM LIMIT(S) is encouraged.

Subclause 6.6.2.2 – Indication of automatically set ALARM LIMIT

Care should be used in the design of means to automatically set an ALARM LIMIT to help prevent FALSE POSITIVE or NEGATIVE ALARM CONDITIONS. In some cases, a wider or narrower ALARM LIMIT can be required.

Subclause 6.6.2.3 – ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

It is important for an ALARM SYSTEM to continue to function normally while the OPERATOR adjusts one part of the ALARM SYSTEM. In the past, some equipment has been designed such that all ALARM CONDITIONS were effectively disabled while the ALARM LIMITS for one ALARM CONDITION were being adjusted. Furthermore in this equipment, once the change had been completed, ALARM CONDITIONS that occurred during the adjustment PROCESS did not generate ALARM SIGNALS.

Subclause 6.7 – ALARM SYSTEM security

The need for and complexity of security for ALARM PRESETS depend on the complexity of the ALARM SYSTEM and the importance of the ALARM SYSTEM to PATIENT or OPERATOR safety. The effectiveness of any security system depends critically on its implementation by the RESPONSIBLE ORGANIZATION. Only the RESPONSIBLE ORGANIZATION can adequately control the security system so that OPERATORS cannot compromise it.

In some legacy equipment, access to configuration of an ALARM PRESET (including DEFAULT ALARM PRESET) has not been restricted. In such instances, OPERATORS have, intentionally or unintentionally, changed an ALARM PRESET (including the DEFAULT ALARM PRESET). PATIENT safety can be compromised when an OPERATOR expects certain ALARM PRESETS on equipment, but the equipment actually has different ALARM PRESETS.

To prevent this problem, MANUFACTURERS need to use care in designing the means to store ALARM PRESETS. Access to configuration of an ALARM PRESET is restricted to authorized persons. There can be more than one level of restriction. For example, OPERATORS should be able to store OPERATOR-configured ALARM PRESETS, but should not be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. RESPONSIBLE ORGANIZATIONS should be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. Only MANUFACTURERS should be able to store MANUFACTURER DEFAULT ALARM PRESETS.

In some instances, the password for RESPONSIBLE ORGANIZATION-configured ALARM PRESETS has been printed in the technical description (service manual). These manuals have then been placed where they are accessible to an OPERATOR, and the OPERATOR has learned the password. Such passwords should be made available only to the RESPONSIBLE ORGANIZATION. Both the MANUFACTURER and RESPONSIBLE ORGANIZATION should avoid disclosure of such passwords to an OPERATOR. Therefore, the MANUFACTURER should emphasize the need to maintain password privacy in the technical description (instructions to RESPONSIBLE ORGANIZATIONS).

Similarly, an OPERATOR should not be permitted to change the OPERATOR-configured ALARM PRESETS of other OPERATORS. One solution would be password-protection for each OPERATOR to store his or her own OPERATOR-configured ALARM PRESETS.

Subclause 6.8 – ALARM SIGNAL inactivation states

The committee spent extensive time in discussion of the names of the ALARM SIGNAL inactivation states. In the past, equipment has used a variety of names to describe these inactivation states:

- Silence
- Silence/Reset
- Pre-Silence
- Mute
- Suspend
- Disable
- Inhibit
- Prevent
- Pause
- Off

The situation is problematic because different MANUFACTURERS have used these names to mean different things. “Silence” has been used to mean both a temporary or limited duration (timed) and a permanent (indefinite) state. In addition, some MANUFACTURERS have used these terms and states to apply only to those ALARM CONDITIONS which are generating ALARM SIGNALS, while others have used them to apply to every possible ALARM CONDITION in the ALARM SYSTEM. Also, some MANUFACTURERS used the term “alarms” to mean only the auditory ALARM SIGNALS, while others used it to mean both auditory and visual ALARM SIGNALS. The result has been confusion among OPERATORS about what the various names really mean.

Previous standards used terms such as “Suspend”, “Disable”, and “Inhibit”. These terms had two problems: first, they were not intuitively obvious as to their meaning. Second, they sometimes applied to the auditory ALARM SIGNALS only, and sometimes to both the auditory and visual ALARM SIGNALS. As a result, the confusion continued.

Additional difficulties were encountered in trying to translate these terms into multiple languages.

Early drafts of this collateral standard described multiple ALARM SIGNAL inactivation states, with tables with multiple columns to indicate the effect of each state on ALARM SIGNAL generation and non-generation, present and future ALARM CONDITIONS, recurrent or persisting ALARM CONDITIONS, auditory ALARM SIGNALS, and both near- and far-visible ALARM SIGNALS. There was no consensus on the correct content of the cells of the table and, even if there had been a consensus, OPERATORS would never have remembered the distinction among the multiple various states.

The committee therefore decided to use a small set of names with the same obvious meanings in various languages.

The names selected were:

- AUDIO OFF
- AUDIO PAUSED
- ALARM OFF
- ALARM PAUSED

The use of the distinctive terms “Audio” and “Alarm” should make clear to OPERATORS that “Audio” refers only to the auditory ALARM SIGNAL, while “Alarm” refers to both the auditory and visual ALARM SIGNALS. Similarly, the use of the terms “Off” and “Paused” should be intuitively obvious. Intuitively, one would anticipate that something that is “Off” remains off until it is turned back on again. Something that is “Paused” is expected to start again at a later time. By using a simple two-by-two matrix of “Audio/Alarm” and “Off/Paused,” all the ALARM SIGNAL inactivation states can be reasonably described.

Great simplification also occurred with the decision that these states might apply to a single ALARM CONDITION, a group of ALARM CONDITIONS or the entire ALARM SYSTEM. Thus all the legacy names for the ALARM SIGNAL inactivation states used in legacy ME EQUIPMENT, and in various standards, can be understood in terms of these new names.

MANUFACTURERS are strongly encouraged to use the provided names for the ALARM SIGNAL inactivation states in their equipment and its instructions for use when they have inactivation states as defined in this collateral standard. In this way, OPERATORS will learn to understand the consistent names for consistent functions across all ALARM SYSTEMS.

Subclause 6.8.1 – General

The continuous presence of ALARM SIGNALS can degrade task performance, and impair detection of new ALARM CONDITIONS and the ability to distinguish between existing and new ALARM CONDITIONS. It is important to provide any OPERATOR with deliberate means to initiate states such as AUDIO PAUSED, ALARM PAUSED, AUDIO OFF and ALARM OFF, by which they can stop the generation of ALARM SIGNALS.

An ALARM SYSTEM is not required to have OPERATOR control functions that initiate all of these states. An ALARM SYSTEM is required to have at least one means to inactivate the generation of ALARM SIGNALS.

The presence of unnecessary visual ALARM SIGNALS can clutter the display and degrade the response to new ALARM SIGNALS. The OPERATOR can want to inactivate visual ALARM SIGNALS when some:

– functions of the equipment or system are not in use;
– functions of the equipment or system are not functional;
– monitored variables are generating frequent FALSE POSITIVE ALARM CONDITIONS; or
– monitored variables are known to be in ALARM CONDITION.

In recognition of this, MANUFACTURERS should consider whether the AUDIO PAUSED or AUDIO OFF ALARM SIGNAL inactivation states affect visual ALARM SIGNALS and in particular alarm indicator lights.

The committee wrestled with the behaviour of currently generated ALARM SIGNALS of ALARM CONDITIONS with respect to one, some or all non-currently generated ALARM SIGNALS and other issues. The consensus was that the inactivation could apply to one, a group or to all ALARM CONDITIONS, or (in the case of a DISTRIBUTED ALARM SYSTEM) to part or all of the ALARM SYSTEM. It was further recognized that the definition of a “group” of ALARM SIGNALS need not follow the traditional physiological grouping such as respiratory, cardiac, temperature, and so on. Instead a group could be defined as all currently generated ALARM SIGNALS, all ALARM SIGNALS chosen from a list by the OPERATOR, etc.

Subclause 6.8.2 – REMINDER SIGNALS

REMINDER SIGNALS are not desirable in all equipment. For example, for operating room monitors that are continuously attended, REMINDER SIGNALS can be annoying, distracting, and disturb other operating room personnel.

ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not REMINDER SIGNALS are appropriate for use. Allowing one OPERATOR to disable REMINDER SIGNALS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment.

Allowing the OPERATOR to set the duration of a REMINDER SIGNAL interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.8.3 – Global indefinite ALARM SIGNAL inactivation states

The provision of a global ALARM OFF or AUDIO OFF function requires a careful RISK ANALYSIS. The RISK ANALYSIS needs to weigh the RISK of frequent or constant ALARM SIGNALS (including those from FALSE POSITIVE ALARM CONDITIONS) versus the RISK of an ALARM CONDITION with inadequate or no ALARM SIGNALS being generated. In addition, whether or not the ALARM SYSTEM is intended to be continuously attended by an OPERATOR in NORMAL USE and the presence or absence of a DISTRIBUTED ALARM SYSTEM need to be considered.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide periodic REMINDER SIGNALS to mitigate the RISK of an OPERATOR forgetting that all auditory ALARM SIGNALS are inactivated.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide the RESPONSIBLE ORGANIZATION with means to enable or disable the global function. ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not global ALARM SIGNAL inactivation states are appropriate for use.

Subclause 6.8.4 – Termination of inactivation of ALARM SIGNALS

It is important for an OPERATOR to be able to undo an action made in error. PATIENT safety requires this, as human error is inevitable and the ability to mitigate error needs to be provided.

Subclause 6.8.5 – Indication and access

The committee strongly believed that the markings required for ALARM SIGNAL inactivation states needed to be standardized. This is even more important than the standardization of the names of ALARM SIGNAL inactivation states that are standardized to eliminate the confusion of multiple names with different meanings. OPERATOR confusion regarding the status of an ALARM SIGNAL inactivation state is a known HAZARD. The committee has chosen internationally standardized symbols for this marking. Overall, safety will be increased when OPERATORS find consistent marking (symbols) with consistent meaning for the ALARM SIGNAL inactivation states across all equipment.

This collateral standard does not specify how the various ALARM SIGNAL inactivation states are to be invoked. Many approaches currently exist. They include:

– single-function hard keys;

– hard keys that cycle through various states (e.g., AUDIO PAUSED, AUDIO OFF, and all ALARM SIGNALS active);
– soft keys;
– menu selections.

The committee anticipates that ALARM SYSTEMS designed to comply with this collateral standard will continue to use these methods and also might use new methods such as voice recognition.

When a "control" is used to invoke an ALARM SIGNAL inactivation state, this collateral standard permits that it be marked with the appropriate symbol as indicated in Table 5. Certainly, the symbols from Table 5 should only be used for the functions indicated. In the case of a multifunction control, a different marking (symbol or wording) can be used, e.g., a hard key that cycles through ALARM PAUSED, ALARM OFF, and all ALARM SIGNALS active could be marked with IEC 60417-5307(DB:2002-10).

The committee faced a dilemma in the choice of symbols for ALARM CONDITIONS and for ALARM SIGNAL inactivation states. The familiar Bell-X symbol (IEC 60417-5576 (DB:2002-10)) has been used for many years, but some MANUFACTURERS have used it to mean "AUDIO OFF" or "AUDIO PAUSED" while other MANUFACTURERS have used it to mean "ALARM OFF" or "ALARM PAUSED". Thus there is substantial confusion about what the symbol means among clinicians (OPERATORS). Both what is off (just auditory signals or auditory signals and visual signals), as well as whether this is a permanent loss or a timed loss of ALARM SIGNALS, have been indicated by Bell-X. In either case, however, OPERATORS have recognized that the Bell-X includes the loss of alarm sound.

A HAZARD occurs, however, if an OPERATOR looks for the familiar Bell-X, does not see it, and mistakenly concludes that the auditory ALARM SIGNALS are on. In other words, OPERATORS can not understand that the Triangle-X symbol (IEC 60417-5319 (DB:2002-10)) indicates that part of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. On that basis, the committee decided to permit, or perhaps encourage, the use of the Bell-X as an additional symbol whenever the Triangle-X is used. In that way, OPERATORS would see the familiar Bell-X at any time that a portion of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. Alternatively or additionally, a text message could be added.

Another possible symbol that the committee considered is the Loudspeaker-X (IEC 60417-5436 (DB:2002-10)). This has traditionally been used to mean "sound mute" and it could be interpreted to produce an effect upon both ALARM SIGNALS and INFORMATION SIGNALS. This collateral standard requires that if this symbol is used as an indicator for muting both INFORMATION SIGNALS and ALARM SIGNALS, the appropriate Bell-X is also indicated.

In the event of ALARM PAUSED or AUDIO PAUSED, the X becomes a dashed-X where the dashed-X means limited duration or timed rather than the solid-X that means permanent.

Concern was raised about the amount of dark and light spaces of the dashed-X so that it can be legible on displays of differing resolution. MANUFACTURERS are reminded that icons made from symbol graphics need to be adapted to the display resolution when used.

The use of a countdown timer (which shows the time remaining in ALARM or AUDIO PAUSED state), adjoining the icon, is encouraged. The presence of a countdown timer adds additional distinctiveness to the icon for ALARM PAUSED or AUDIO PAUSED so that they can more easily be distinguished from ALARM OFF or AUDIO OFF.

Allowing the OPERATOR to set duration of an AUDIO PAUSED or ALARM PAUSED interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.9 – ALARM RESET

The committee received many comments on LATCHING ALARM SIGNALS and ALARM RESET and discussed the topic at length. There were two different philosophies on the operation of the ALARM RESET that the committee considered.

One philosophy holds that ALARM RESET should:

– terminate a LATCHING ALARM SIGNAL and should be the only means of terminating the LATCHING ALARM SIGNAL;

– cause the ALARM SYSTEM to be enabled or re-enabled to respond to future ALARM CONDITIONS;

– terminate any existing AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF state thus re-enabling the ALARM SYSTEM.

In addition, if the OPERATOR wished to enter the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF, a second, deliberate action should be required. It is believed that this two-step PROCESS should be required at least for the clearing of visual LATCHING ALARM SIGNALS. The concern was that an OPERATOR might cause the removal of visual ALARM SIGNALS before they had had an opportunity to identify the source of the ALARM CONDITION.

The second philosophy holds that the desired response of an OPERATOR to an auditory ALARM SIGNAL is to cause it to stop. This philosophy holds that activation of the states of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should serve as the acknowledgement by the OPERATOR of any auditory ALARM SIGNAL, and that a separate ALARM RESET function is unnecessary. This second philosophy thus holds that activation of the functions AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should terminate the generation of any auditory ALARM SIGNAL, and that the ALARM SIGNAL should not recur at the end of AUDIO PAUSED or ALARM PAUSED unless the ALARM CONDITION is still present. This second philosophy holds that, if the ALARM RESET function is provided, it should terminate the generation of any ALARM SIGNAL, but it should not cause the ALARM SYSTEM to be re-enabled. This philosophy also holds that, if an ALARM RESET function was provided and activated, it should not terminate any existing state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF (for other parts of the ALARM SYSTEM). These states would thus remain as they had been previously.

The first philosophy prefers a single way to accomplish this task. The second philosophy argues for multiple ways to accomplish this task and holds that this is comparable to the “any button answer” function that is found on many cellular telephones. The second philosophy is consistent with the behaviour of most existing equipment.

In summary, the first philosophy holds that the ALARM RESET function should cause the ALARM SYSTEM to be enabled, while the second philosophy holds that the ALARM RESET function should be combined into AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF.

Thus, the committee faced two incompatible visions of the operation of the ALARM RESET function. It was noted that this collateral standard describes means of activating the states of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED, ALARM OFF or alarms enabled, but that it does not specify what means are required. These states might be entered by separate, specific controls, by a single control that cycles through various states, by voice recognition, etc.

The decision was made to require that an ALARM SYSTEM have a means to perform the ALARM RESET function, but does not specify how this function should be accomplished. This collateral standard thus recognizes that the ALARM RESET function can be accompanied by causing the ALARM SYSTEM to be enabled or re-enabled, or by the opposite concept: by entering the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF.

Subclause 6.10 – NON-LATCHING and LATCHING ALARM SIGNALS

Auditory ALARM SIGNALS are required to complete a full BURST (or ½ BURST for HIGH PRIORITY ALARM SIGNALS) to help an OPERATOR to identify a transient ALARM CONDITION.

Example 1 A momentary obstruction of a breathing system (the surgeon leans on it).

Example 2 A pair of premature ventricular beats (which only lasts for 2 heartbeats).

Nonetheless, the auditory ALARM SIGNAL should immediately terminate when the OPERATOR activates any of the ALARM SIGNAL inactivation states.

Auditory LATCHING ALARM SIGNALS cause noise pollution and can cause an OPERATOR to invoke the ALARM OFF state. Auditory LATCHING ALARM SIGNALS should be avoided for an ALARM SYSTEM that is intended to be only continuously attended by an OPERATOR in NORMAL USE, if possible. Auditory LATCHING ALARM SIGNALS can be useful in situations where the ALARM SYSTEM is intended to be unattended by an OPERATOR in NORMAL USE and it is desirable to force the OPERATOR to assess the PATIENT or the ALARM SYSTEM. MANUFACTURERS should provide ALARM CONDITION logs (histories) in addition to, or as an alternative to, LATCHING ALARM SIGNALS.

Allowing the OPERATOR to select auditory ALARM SIGNAL sets other than those determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

Subclause 6.11 – DISTRIBUTED ALARM SYSTEM

The application of DISTRIBUTED ALARM SYSTEMS is in its infancy. 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 cannot personally respond to a PATIENT or equipment problem.

The committee believed that the field was too immature to write a large number of specific requirements. Perhaps a future edition of this collateral standard will be able to include more specific requirements, when the technology has matured. In the meantime, a MANUFACTURER is left to use good RISK ANALYSIS to be sure that their DISTRIBUTED ALARM SYSTEMS serve their primary purpose: to improve the ability of a qualified OPERATOR to respond in an appropriate and timely manner to every ALARM CONDITION.

Future 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 ALARM SYSTEM detects an ALARM CONDITION, a delay before generation of ALARM SIGNALS at the primary ALARM SYSTEM, a delay before the ALARM CONDITION is transmitted to a DISTRIBUTED ALARM SYSTEM, and a delay before the DISTRIBUTED ALARM SYSTEM 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 will be required to determine the time before the ALARM CONDITION is indicated with ALARM SIGNALS to the appropriate OPERATOR. It may 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 DISTRIBUTED ALARM SYSTEM or of the link between a primary ALARM SYSTEM and a DISTRIBUTED ALARM SYSTEM, the primary ALARM SYSTEM is required to generate ALARM SIGNALS normally. If the primary ALARM SYSTEM 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 attention to ALARM CONDITIONS (e.g. the DISTRIBUTED ALARM SYSTEM is not inactivated), then if the DISTRIBUTED ALARM SYSTEM fails, the primary ALARM SYSTEM should be automatically re-enabled.

EXAMPLE The local ALARM SYSTEM 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 local ALARM SYSTEM should return the volume to an audible level.

In addition, the primary ALARM SYSTEM and the DISTRIBUTED ALARM SYSTEM should both generate ALARM SIGNALS to alert the OPERATOR(S) to failure of the DISTRIBUTED ALARM SYSTEM.

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, RISK ANALYSIS should be done in this area. 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

DISTRIBUTED ALARM SYSTEM generation of ALARM SIGNALS can be provided by equipment to allow ALARM SIGNAL generation at a distance from the PATIENT. Remote generation of ALARM SIGNALS notifies 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

A DISTRIBUTED ALARM SYSTEM might not receive a message from the ALARM SYSTEM indicating an ALARM CONDITION that was detected by the ALARM SYSTEM. If an OPERATOR is depending on the remote generation of ALARM SIGNALS for treatment decisions, then it is necessary for the ALARM SYSTEM to know when an ALARM CONDITION has been successfully received by the DISTRIBUTED ALARM SYSTEM. When those ALARM CONDITIONS are not successfully received, generating ALARM SIGNALS to indicate a TECHNICAL ALARM CONDITION to warn the OPERATOR of such a fault, is necessary for safety when an ALARM SYSTEM includes a DISTRIBUTED ALARM SYSTEM.

With some technologies, it can be impossible for a primary ALARM SYSTEM to know if a DISTRIBUTED ALARM SYSTEM 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 the equipment not to rely upon the DISTRIBUTED ALARM SYSTEM for generation of ALARM SIGNALS. A DISTRIBUTED ALARM SYSTEM can be useful, even if it does not work 100 % of the time. Still, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS should take precautions that PATIENT safety is not compromised.

Subclause 6.12 – ALARM CONDITION logging

The logging of ALARM CONDITIONS can be useful for several reasons:

a) to determine the cause of a transient ALARM CONDITION when NON-LATCHING ALARM SIGNALS are used;

b) to determine the cause of an ALARM CONDITION when the equipment is unattended by an OPERATOR in NORMAL USE;

c) for quality assurance purposes;

d) for the study of critical incidents, similar to the event logging of aircraft "black-boxes";

e) to determine when an ALARM CONDITION occurred.

LIFE-SUPPORTING EQUIPMENT or life-sustaining equipment as well as vital signs monitors should be equipped with ALARM CONDITION logging. Means should be provided, either within the equipment or remotely through a communications interface, to store a history of ALARM CONDITIONS and their level of priority in an ALARM CONDITION log. The log should also include the value of the variable that caused the ALARM CONDITION as well as the relevant current values of the elements in the ALARM PRESET including the ALARM LIMIT.

If there is a log, all generated ALARM SIGNALS of ALARM CONDITIONS, or all generated ALARM SIGNALS of 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 an ALARM CONDITION source is technical or physiological (e.g., low signal strength).

In the ALARM OFF or ALARM PAUSED state, some equipment does not process signals (monitor for ALARM CONDITIONS) at all. In these instances, ALARM CONDITIONS are not determined, and they cannot be logged. Other equipment does process signals during ALARM OFF and/or ALARM PAUSED, and this equipment can log the ALARM CONDITIONS. In every instance of AUDIO OFF or AUDIO PAUSED, however, ALARM CONDITIONS should be logged. In any case, the entry and exit for each ALARM SIGNAL inactivation state (ALARM OFF, ALARM PAUSED, AUDIO OFF and AUDIO PAUSED) should be recorded.

An example will make this last situation clear. Suppose a monitor has a HIGH PRIORITY ALARM SIGNAL for high heart rate. ALARM CONDITIONS for high heart rate should be logged. If the OPERATOR places the high heart rate ALARM CONDITION in the ALARM OFF or AUDIO OFF state, that fact should be recorded in the log. In other words, the ALARM CONDITION log should reflect high heart rate ALARM CONDITIONS and any period of time in which the ALARM SIGNALS for high heart rate ALARM CONDITIONS were not generated or that auditory ALARM SIGNALS where not generated. Otherwise, the ALARM CONDITION log is meaningless, because review of the log would not reveal if:

f) there were no high heart rate ALARM CONDITIONS during that period, or

g) the ALARM SYSTEM was in an ALARM SIGNAL inactivation state during that period of time.

If the ALARM SYSTEM is provided with a log of ALARM CONDITIONS:

– *the contents of the log can be stored either for a specified period of time or until deleted by RESPONSIBLE ORGANIZATION or OPERATOR action;*

– *the contents of the log should be available for review by the OPERATOR;*

– *short losses of power (less than 30 s) should not cause the loss of the contents of the log.*

The previously stored contents of the log can be deleted when the OPERATOR indicates to the equipment, preferably through an "admit new PATIENT" function, that a different PATIENT has been connected to the equipment.

MANUFACTURERS should consider including a log of TECHNICAL ALARM CONDITIONS that cannot be reset by OPERATOR action for servicing and maintenance purposes.

Annex F

Annex F provides a set of melodies and associated meanings that can be used for equipment-encoded and urgency-encoded auditory ALARM SIGNALS. If a melody from Annex F is used in an auditory ALARM SIGNAL, then the meaning of the melody is required to be consistent with the underlying ALARM CONDITION or equipment category as described in Annex F. The use of melodies other than those defined in Annex F is acceptable if they are constructed and implemented in such a way that they cannot be confused with the melodies from Annex F.

Table A.1 and Table A.2 indicate the interpretation of the melodies of Annex F.

Table A.1 – Reference interpretation of Table F.1

Cause	MEDIUM PRIORITY	HIGH PRIORITY	Mnemonic notes	Examples of type of ALARM SYSTEM
General	**c c c**	**c c c – c c**	Fixed pitch	Other ALARM SYSTEMS that do 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, etc. Optionally this sound is permitted for the ALARM SYSTEM of any kind of equipment.
Cardiac	**c e g**	**c e g – g C**	Trumpet call; Call to arms; Major chord	Anesthesia 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, peripheral perfusion monitors (plethysmographs), transesophageal echo, fetal heart rate monitors.
Artificial perfusion	**c f#c**	**c f#c – c f#**	Artificial sound; Tri-tone	Cardio-pulmonary perfusion pumps (“heart-lung machines”) and associated equipment, intra-aortic balloon pumps, renal dialysis systems.
Ventilation	**c a f**	**c a f – a f**	Inverted major chord; Rise and fall of the lungs	Anesthesia workstations which include ventilators (but which do not include cardiac monitors); lung ventilators, spirometers, CO_2 monitors, ventilator disconnect (airway pressure) monitors, etc.
Oxygen	**C b a**	**C b a – g f**	Slowly falling pitches; Top of a major scale; Falling pitch of an oximeter	Pulse oximeters, transcutaneous / tissue oxygen monitors, oxygen analyzers, oxygen concentrators, oxygen gas supply lines.
Temp / energy delivery	**c d e**	**c d e – f g**	Slowly rising pitches; Bottom of a major scale; Related to slow increase in energy or (usually) temperature	Temperature monitors, heated air humidifiers, infant radiant warmers, neonatal incubators, PATIENT heating or cooling systems, blood or fluid warmers; electrocautery, ultrasound, laser, X-ray or MRI systems, nerve stimulators.
Drug or fluid delivery	**C d g**	**C d g – C d**	Jazz chord (inverted 9th); Drops of an infusion falling and "splashing" back up	Volumetric infusion pumps, syringe drivers, anesthetic agent delivery systems or analyzers.
Equipment or supply failure	**C c c**	**C c c – C c**	Falling or dropping down	Any device when it experiences loss of power or other major failure of the device.

Table A.2 – Reference interpretation of Table F.2

Cause	LOW PRIORITY	Mnemonic, notes
Any	**e c**	Hostess call or door bell ”ding-dong”

Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

B.1 Marking of controls and instruments

The requirements for marking of controls and instruments are found in 7.4 and in Table C.3 of the general standard. Additional requirements for marking of controls and instruments relating to ALARM SYSTEMS in ME EQUIPMENT and in ME SYSTEMS are found in the subclauses listed in Table B.1.

Table B.1 – Cross-reference of marking

Description	Clause or subclause
ALARM CONDITION, priority	6.3.2.2
ALARM CONDITION, visual indication	6.3.2.2
ALARM CONDITION, visual indication, multiple	6.3.2.2
ALARM LIMIT, automatically adjusted	6.6.2.2
ALARM LIMIT, OPERATOR adjusted	6.6.2.1
ALARM OFF, means of control	6.8.5 Table 5
ALARM OFF, state indication	6.8.5 Table 5
ALARM PAUSED, means of control	6.8.5 Table 5
ALARM PAUSED, visual indication	6.8.5 Table 5
ALARM RESET, means of control	6.9
AUDIO OFF, means of control	6.8.5 Table 5
AUDIO OFF, visual indication	6.8.5 Table 5
AUDIO PAUSED, means of control	6.8.5 Table 5
AUDIO PAUSED, visual indication	6.8.5 Table 5
Failure of remote communication of ALARM CONDITION	6.11.2.2
NOTE Guidance on using markings to help avoid FALSE POSITIVE and NEGATIVE ALARM CONDITIONS is given in A.1.3.	

B.2 Accompanying documents, General

The requirements for information to be included in the ACCOMPANYING DOCUMENTS are found in 7.9.1 and Table C.4 of the general standard. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS relating to ALARM SYSTEMS in ME EQUIPMENT and in ME SYSTEMS are found in the subclauses of this standard listed in Table B.2.

Table B.2 – Cross-reference of ACCOMPANYING DOCUMENTS

Description	Clause or subclause
ALARM PRESET, means for configuration and storage	6.5.3.2 d)

B.3 ACCOMPANYING DOCUMENTS, Instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses of this standard listed in Table B.3.

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

Description	Clause or subclause
ALARM SIGNAL GENERATION DELAY of DISTRIBUTED ALARM SYSTEM, maximum time or time to TECHNICAL ALARM CONDITION	6.4.2 b)
ALARM SIGNAL GENERATION DELAY, mean	6.4.1
ALARM SIGNAL GENERATION DELAY, statistics of distribution	6.4.1
ALARM CONDITION DELAY, mean time	6.4.1
ALARM CONDITION DELAY, statistics of distribution	6.4.1
ALARM CONDITION log after power down	6.12 b)
ALARM CONDITION log after power failure	6.12 c)
ALARM CONDITION, grouping	6.1.1
ALARM CONDITION, priority of each	6.1.2
ALARM or AUDIO PAUSED interval	6.8.5
ALARM PRESET, MANUFACTURER-configured description and ALARM LIMITS	6.5.2
ALARM PRESET, warn OPERATOR to check values	6.5.3.2 c)
Auditory ALARM SIGNAL, sound pressure range (volume)	6.3.3.2
Auditory INFORMATION SIGNAL, characteristics	6.3.3.2
Behavior of automatically set ALARM LIMIT	6.6.2.2 d)
DISTRIBUTED ALARM SYSTEM, delay from ALARM CONDITION to SIGNAL INPUT/OUTPUT PART	6.4.2 a)
Duration of power loss that causes loss of ALARM SETTINGS	6.5.4.2
INTELLIGENT ALARM SYSTEM, ALARM CONDITIONS of the equal priority, internal ranking	6.2 b)
INTELLIGENT ALARM SYSTEM, ALARM SIGNAL generation change algorithms	6.2 e)
INTELLIGENT ALARM SYSTEM, changes in delay times	6.2 d)
INTELLIGENT ALARM SYSTEM, overview of logic decisions	6.2 a)
INTELLIGENT ALARM SYSTEM, priority assignment algorithms	6.2 c)
Behavior of ALARM SETTINGS for power loss for < 30 s	6.5.5
Multiple ALARM PRESETS, warn OPERATOR to check	6.5.1

Table B.3 *(continued)*

DESCRIPTION	Clause or subclause
REMINDER SIGNAL, characteristics	6.8.2
REMINDER SIGNAL, duration of any interval	6.8.2
Sum of ALARM SIGNAL GENERATION DELAY and ALARM CONDITION DELAY mean	6.4.1
Sum of ALARM SIGNAL GENERATION DELAY and ALARM CONDITION DELAY statistics of distribution	6.4.1

B.4 ACCOMPANYING DOCUMENTS, Technical description

The requirements for general information to be included in the technical description are found in subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for general information to be included in the technical description are found in the subclauses listed in Table B.4.

Table B.4 – Cross-reference of technical description

Description	Clause or subclause
DISTRIBUTED ALARM SYSTEM, details necessary for safe use	6.11.1

Annex C
(normative)

Symbols on marking

The symbol graphics of Table C.1 required by this collateral standard shall conform to the IEC or ISO reference standard, as indicated. Where appropriate, supplemental titles and descriptions have been added for specific application to ME EQUIPMENT and ME SYSTEMS that contain ALARM SYSTEMS. Table C.2 provides an informative reference to symbol graphic, title and description from the reference standard for these graphical symbols as a quick reference. Table C.2 provides a normative reference to the ALARM SYSTEM description and the reference standard for these graphical symbols. See also Annex B.

Table C.1 – Graphical symbols for ALARM SYSTEMS

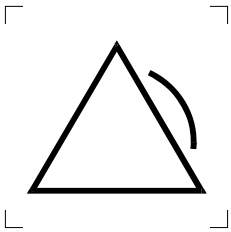
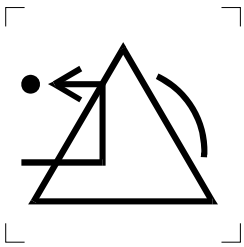
No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
1		IEC 60417-5307 (DB-2002-10)	Alarm, general	To indicate an alarm on a control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 If there is a need to classify alarm signals and symbol 5308 is used, symbol 5307 should be used for the less urgent condition.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ALARM CONDITION To indicate an ALARM CONDITION. *NOTE 1 The ALARM CONDITION may be indicated inside, beside or below the triangle.* *NOTE 2 If there is a need to classify ALARM CONDITIONS according to priority, this may be indicated by adding one, two or three optional elements, e.g., ! for LOW PRIORITY, !! for MEDIUM PRIORITY and !!! for HIGH PRIORITY.*
2		IEC 60417-5309 (DB 2002-10)	Alarm system clear	On alarm equipment: To identify the control by means of which the alarm circuit can be reset to its initial state. *NOTE - The type of alarm may be indicated inside the open triangle or below the triangle.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ALARM RESET To identify the control for ALARM RESET. *NOTE The ALARM CONDITION may be indicated inside, beside, or below the triangle.*

Table C.1 – Graphical symbols for ALARM SYSTEMS (*continued*)

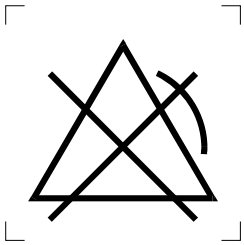
No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
3		IEC 60417-5319 (DB 2002-11)	Alarm inhibit	To identify the alarm inhibit on control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 The graphical symbol may be used for temporary alarm inhibit by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of solid lines: ALARM OFF To identify the control for ALARM OFF or to indicate that the ALARM SYSTEM is in the ALARM OFF state. *NOTE 1 The ALARM CONDITION may be indicated inside, below, or beside the triangle.* *NOTE 2 As far as there is no danger of confusion, this symbol may also be used to identify equipment that has no ALARM SYSTEM.*
4		IEC 60417-5319 (DB 2002-11) variant of according to Note 2	Alarm inhibit	To identify the alarm inhibit on control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 The graphical symbol may be used for temporary alarm inhibit by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of broken lines: ALARM PAUSED To identify the control for ALARM PAUSED or to indicate that the ALARM SYSTEM is in the ALARM PAUSED state. *NOTE 1 The ALARM CONDITION may be indicated inside, below, or beside the triangle.* *NOTE 2 A numerical time remaining counter may be placed above, below, or beside the triangle.*

Table C.1 – Graphical symbols for ALARM SYSTEMS (*continued*)

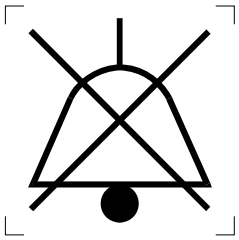
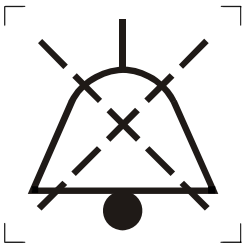
No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
5		IEC 60417-5576 (DB 2002-11)	Bell cancel	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell. *NOTE 1 As far as there is no danger of confusion, this symbol may also be used for "acoustic signal, switched off"* *NOTE 2 The graphical symbol may be used for temporary bell cancel by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of solid lines: AUDIO OFF To identify the control for AUDIO OFF or to indicate that the ALARM SYSTEM is in the AUDIO OFF state. *NOTE The ALARM CONDITION may be indicated inside, below, or beside the bell.*
6		IEC 60417-5576 (DB 2002-11) variant of according to note 2	Bell cancel	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell. *NOTE 1 As far as there is no danger of confusion, this symbol may also be used for "acoustic signal, switched off"* *NOTE 2 The graphical symbol may be used for temporary bell cancel by replacing the negation cross with a cross of broken lines.*	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.*

Table C.2 – Alternative ALARM SYSTEM related markings

No.	Marking	Description
1	**AUDIO PAUSED** **or** **AUDIO ALARM PAUSED**	AUDIO PAUSED To identify the control whereby an auditory ALARM SIGNAL is AUDIO PAUSED.
2	**ALARM PAUSED**	ALARM PAUSED To identify the control whereby an ALARM SIGNAL is ALARM PAUSED.
3	**AUDIO OFF** **or** **AUDIO ALARM OFF**	AUDIO OFF To identify the control whereby an auditory ALARM SIGNAL is AUDIO OFF.
4	**ALARM OFF**	ALARM OFF To identify the control whereby an ALARM SIGNAL is ALARM OFF.
5	**ALARM RESET**	ALARM RESET To identify the control for ALARM RESET.
The text within these markings may be translated into the language of the intended OPERATOR.		

Annex D
(informative)

Guidance for auditory ALARM SIGNALS

D.1 General considerations

Parameters that affect the perceived urgency of a BURST of sound include the inter-PULSE interval, the number of repeating BURSTS, the rhythm of the PULSES in the BURST, changes in intra-PULSE duration within a single BURST, the pitch contour, pitch range and musical structure.

Table D.1 – Attributes of perceived urgency

Parameter	Direction of Effect
Speed	Fast > moderate > slow
Number of repeating BURSTS	4 > 2 > 1
Rhythm	Syncopated > regular
Inter-PULSE duration within a single BURST	Speeding up > regular/slowing
Pitch contour	Random > down/up
Pitch range	Large > moderate> small
Musical structure	Atonal > unresolved > resolved
NOTE Interpret characteristic prior to the > as more urgent than.	

D.2 Frequency range

The frequency range of an ALARM SIGNAL should be between 200 Hz and 5 000 Hz. The preferred range is between 500 Hz and 3 000 Hz. If the ALARM SIGNAL is required to be audible at a long distance, such as a large ward, the frequency should be below 1 000 Hz. If the ALARM SIGNAL is required to be heard around obstacles or through partitions, the frequency should be below 500 Hz. The selected frequency band should differ from the most intense background frequencies in the equipment's expected environment of use.

D.3 Continuous auditory ALARM SIGNALS and INFORMATION SIGNALS

The use of continuous tones for ALARM SIGNALS or INFORMATION SIGNALS should be discouraged as they impede communications between persons, are annoying and provoke a startle reflex. Continuous tones often cause an OPERATOR to invoke the ALARM OFF state of ALARM SYSTEMS.

D.4 Harmonics, timbre, FALL TIME

Despite the restrictive nature of the sound specification in this collateral standard, varying the harmonic content and PULSE FALL TIME, while retaining the distinctive nature of the melody, can create distinctive ALARM SIGNALS. This permits a subtle degree of equipment differentiation, which an OPERATOR can find advantageous.

Sounds with odd harmonics (3,5,7,9,11) have a harsh quality, even harmonics give a church organ type of sound, and combining odd and even results in an oboe-like quality.

Annex E
(informative)

Verbal ALARM SIGNALS

E.1 Guidance

Verbal ALARM SIGNALS should only be considered for equipment intended for continuous OPERATOR attendance.

The use of verbal ALARM SIGNALS in the vicinity of conscious PATIENTS and relatives, who have no way of knowing whether the verbal ALARM SIGNALS refer to them or to another PATIENT can cause increased PATIENT and visitor stress and compromise PATIENT confidentiality.

Verbal ALARM SIGNALS can compete with, or not be heard over other conversations. Verbal ALARM SIGNALS can distract personnel from necessary communication.

The use of verbal ALARM SIGNALS should be validated by USABILITY testing.

E.2 Characteristics of verbal alarm signals

E.2.1 General

Verbal ALARM SIGNALS can consist of an initial auditory ALARM SIGNAL composed of 1 BURST of the appropriate auditory ALARM SIGNAL to attract the attention of the OPERATOR and perhaps to identify the general problem, and a brief verbal message to identify the ALARM CONDITION and optionally specify an appropriate action.

E.2.2 Intensity

The speech interference level is the measure of the effectiveness of noise in masking speech. It is the arithmetic mean of the sound pressure levels of interfering noise (in dB referenced to 20 μPa) in the four octave bands centred on the frequencies 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz, respectively. The unit of speech interference is the decibel (dB). Verbal ALARM SIGNALS should be at least 20 dB above the speech interference level at the OPERATOR'S POSITION in the environment where the equipment is likely to be used, but should not exceed 85 dB(A).

E.2.3 Type of voice

The voice used in recording verbal ALARM SIGNALS should be distinctive and mature.

E.2.4 Delivery style

Verbal ALARM SIGNALS should be presented in a formal, impersonal manner.

E.2.5 Speech processing

Verbal ALARM SIGNALS should be processed only if necessary to increase or preserve intelligibility.

EXAMPLE By increasing the strength of consonant sounds relative to vowel strength.

If a verbal ALARM SIGNAL is required to be relatively intense because of high ambient noise, peak-clipping can be used to protect the listener from auditory overload.

E.2.6 Message content

In selecting words to be used in verbal ALARM SIGNALS, words should be chosen on the basis of vocabulary based on intelligibility, aptness and conciseness, in that order.

E.2.7 HIGH PRIORITY verbal ALARM SIGNALS

HIGH PRIORITY verbal ALARM SIGNALS should be repeated with not more than 10 s between the beginnings of messages until the ALARM CONDITION is responded to by the OPERATOR or is no longer present.

E.2.8 Message priorities

A message priority system should be established so that a message of the highest priority will be generated before any message having a lower priority. If two or more ALARM CONDITIONS occur simultaneously, the one indicating a message of higher priority should be generated first. After generating the highest priority message, remaining messages should be generated in descending order of priority.

E.3 Limitations of verbal ALARM SIGNALS

E.3.1 Privacy and security

In an intensive care or ward setting, a PATIENT might hear the verbal ALARM SIGNAL of another PATIENT'S ALARM CONDITION. This is private information that should be secure. Other PATIENTS might become upset because they think that the verbal ALARM SIGNAL applies to them.

E.3.2 Language

Verbal ALARM SIGNALS should be presented in the language of the OPERATOR. In equipment used all over the world, or in a country with multiple national languages, complex equipment capable of many languages can be required.

E.3.3 Clarity

Verbal ALARM SIGNALS can compete with, and not be heard over other conversations with care team members. Alternatively, verbal ALARM SIGNALS can distract personnel from necessary communication.

E.3.4 Multiple ALARM CONDITIONS

In many situations, when one ALARM CONDITION generates ALARM SIGNALS, several others will soon follow. In this case, there would be multiple verbal ALARM SIGNALS presented sequentially or simultaneously.

E.3.5 Emotional responses

Depending upon the gender of the voice of the verbal ALARM SIGNAL and the gender of the OPERATOR, there can be an emotional response that is counter-productive to the intended message.

Annex F
(normative)

* Reserved melodies for ALARM SIGNALS

The following melodies are reserved for the meanings as indicated in Table F.1 and Table F.2. See also 6.3.3.1.

Table F.1 – * Equipment encoded auditory ALARM SIGNALS categorized by ALARM CONDITION and priority complying with Table 3 and Table 4

Cause	MEDIUM PRIORITY	HIGH PRIORITY
General	**c c c**	**c c c – c c**
Cardiac	**c e g**	**c e g – g C**
Artificial perfusion	**c f# c**	**c f# c – c f#**
Ventilation	**c a f**	**c a f – a f**
Oxygen	**C b a**	**C b a – g f**
Temp / Energy delivery	**c d e**	**c d e – f g**
Drug or fluid delivery	**C d g**	**C d g – C d**
Equipment or supply failure	**C c c**	**C c c – C c**

All PULSES and BURSTS shall comply with the timing and volume requirements of list element a) of 201.3.3.1. The melodies may be sounded in different keys or octaves if the absolute frequency of "c" lies between 150 Hz and 500 Hz.

The "General" BURST may be used for any auditory ALARM SIGNAL in any ALARM SYSTEM.

NOTE 1 The characters c, d, e, f, g, a, b, C refer to relative musical pitches and C is one octave above c.

NOTE 2 A HIGH PRIORITY ALARM SIGNAL is generated with the five PULSES shown, repeated once, for a total of 10 PULSES.

Table F.2 – * Auditory LOW PRIORITY ALARM SIGNAL complying with Table 3 and Table 4

Cause	LOW PRIORITY
Any	**e c**

NOTE The characters c, d, e, f, g, a, b, C refer to relative musical pitches and C is one octave above c.

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Index of defined terms used in this collateral standard