

Australian/New Zealand Standard™

Medical electrical equipment

Part 1.8: General requirements for safety—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems



AS/NZS 3200.1.8:2005

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 5 September 2005 and on behalf of the Council of Standards New Zealand on 28 October 2005.

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Australasian College of Physical Scientists and Engineers in Medicine
Australian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

The objective of this Standard is to specify basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application.

This Standard is identical with, and has been reproduced from IEC 60601-1-8:2003, *Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*. It is supplementary to AS/NZS 3200.1.0:1998, *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*.

IEC 60601-1-8 modifies and supplements the corresponding Clauses of IEC 60601-1:1988: *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998 *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard* and is herein referred to as the General Standard.

IEC 60601-1-8 is a Collateral Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

In the text of this Standard, the following print types are used:

- (a) Requirements and definitions..... in large roman type
- (b) Notes, examples, explanations, advice, introductions, general statements and references
..... in smaller roman type
- (c) Test specifications and guidance in Annex AAA in italic type
- (d) Terms defined in Clause 2 of the General Standard, or in this Collateral Standard or as note
.....IN SMALL CAPITALS

An asterisk (*) is placed before each Clause or sub clause for which additional information is included in Annex AAA.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is show only on the cover.

For the purpose of this Standard, the IEC text should be modified as follows:

- (i) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the word ‘this International Standard’ wherever they appear.
- (ii) *Decimal marker* Substitute a full point (.) for a comma (,) where it appears as a decimal marker.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the appendix or annex to which they apply. A ‘normative’ appendix or annex is an integral part of a Standard, whereas an ‘informative’ appendix or annex is only for information and guidance.

References to international Standards should be replaced by reference to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS	
60417	Graphical symbols for use on equipment	60417	Graphical symbols for use on equipment
60417-2	Part 2: Symbol originals	60417.2.1	Part 2.1: General application
		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-1	Part 1-1: Collateral Standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1: Collateral Standard: Safety requirements for medical electrical systems
60601-1-6	Part 1-6: Collateral Standard: Usability	—	
		AS IEC	
60651	Sound level meters	61672	Electroacoustics—Sound level meters
		61672.1	Part 1: Specifications
ISO			
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—	
7000	Graphical symbols for use on equipment—Index and synopsis	—	

CONTENTS

SECTION ONE – GENERAL

1	* Scope and object	1
1.201	Scope	1
1.202	Object	1
1.203	Relationship to other standards.....	1
1.203.1	IEC 60601-1.....	1
1.203.2	Particular standards	2
1.203.3	Normative references	2
2	Terminology and definitions.....	2
6	Identification, marking and documents.....	6
6.3	Marking of controls and instruments.....	6
6.7	Indicator lights and push-buttons	6
6.8.1	ACCOMPANYING DOCUMENTS.....	7
6.8.2	Instructions for use.....	7
6.8.3	Technical description.....	7

SECTION TWO TO TEN – NOT USED

201	ALARM SYSTEMS	7
201.1	* ALARM CONDITION	7
201.1.1	* General	7
201.1.2	* ALARM CONDITION priority.....	8
201.2	* Disclosures for INTELLIGENT ALARM SYSTEM	8
201.3	Generation of ALARM SIGNALS.....	9
201.3.1	General	9
201.3.2	* Visual ALARM SIGNALS	9
201.3.3	* Auditory ALARM SIGNALS.....	10
201.3.4	* Characteristics of verbal ALARM SIGNALS.....	13
201.4	* Disclosure of delays	14
201.4.1	* ALARM SYSTEM delays.....	14
201.4.2	* Delays to or from a DISTRIBUTED ALARM SYSTEM	14
201.5	ALARM PRESETS	14
201.5.1	General requirements.....	14
201.5.2	Manufacturer-configured ALARM PRESETS	15
201.5.3	* USER- and OPERATOR-configured ALARM PRESETS	15
201.5.4	DEFAULT ALARM PRESET	16
201.5.5	* Interruptions of less than or equal to 30 s	17
201.6	ALARM LIMIT	17
201.6.1	General requirements.....	17
201.6.2	* Adjustable ALARM LIMIT	17
201.7	* ALARM SYSTEM security.....	18
201.8	* ALARM SIGNAL inactivation states	18
201.8.1	* General.....	18
201.8.2	* Termination of inactivation of ALARM SIGNALS	19

201.8.3	* Indication and access.....	19
201.9	* ALARM RESET	20
201.10	* NON-LATCHING and LATCHING ALARM SIGNALS.....	20
201.11	* DISTRIBUTED ALARM SYSTEM.....	20
201.11.1	* Existence OF DISTRIBUTED ALARM SYSTEM	20
201.11.2	Requirements for DISTRIBUTED ALARM SYSTEM communication of ALARM CONDITIONS.....	21
201.12	* ALARM CONDITION logging.....	21
Appendix D (normative) Symbols on marking		22
Annex AAA (informative) Rationale and guidance		27
Annex BBB (informative) Cross-reference of identification, marking, and documents		60
Annex CCC (informative) Guidance for auditory ALARM SIGNALS.....		64
Annex DDD (informative) Verbal ALARM SIGNALS		65
Annex EEE (normative) Reserved melodies for ALARM SIGNALS.....		68
Bibliography.....		69
Index of defined terms		71
Figure 201 – Illustration of temporal characteristics of auditory ALARM SIGNALS		12
Figure AAA.1 – Graphical representation of components of ALARM SYSTEM delay		45
Table 201 – ALARM CONDITION priorities.....		8
Table 202 – Characteristics of alarm indicator lights		9
Table 203 – Characteristics of the BURST of auditory ALARM SIGNALS		11
Table 204 – Characteristics of the PULSE of auditory ALARM SIGNALS		11
Table 205 – ALARM SIGNAL inactivation states		19
Table D.201 – Graphical symbols for ALARM SYSTEMS		23
Table D.202 – Alternative ALARM SYSTEM related markings		26
Table AAA.1 – Reference interpretation of Table EEE.1.....		45
Table AAA.2 – Reference interpretation of Table EEE.2.....		58
Table BBB.1 – Cross-reference of Marking		60
Table BBB.2 – Cross-reference of ACCOMPANYING DOCUMENTS		61
Table BBB.3 – Cross-reference of instructions for use		62
Table BBB.4 – Cross-reference of technical description.....		63
Table CCC.1 – Attributes of perceived urgency.....		64
Table EEE.1 – Equipment encoded auditory ALARM SIGNALS categorized by ALARM CONDITION and priority complying with Tables 203 and 204		68
Table EEE.2 – Auditory LOW PRIORITY ALARM SIGNAL complying with Tables 203 and 204		68

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 potential 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 USER. It is important that the USER configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 1.8:

General requirements for safety—Collateral standard:

General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

SECTION ONE – GENERAL

1 * Scope and object

1.201 Scope

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

It also provides guidance for the application of ALARM SYSTEMS.

1.202 Object

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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.

NOTE See IEC 60513:1994 [4] for a description of basic safety and essential performance.

This collateral standard does not specify:

- whether any particular MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL 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.

1.203 Relationship to other standards

1.203.1 IEC 60601-1

For MEDICAL ELECTRICAL EQUIPMENT, 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.

1.203.2 Particular standards

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

1.203.3 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-DB:2002²⁾, *Graphical symbols for use on equipment*

IEC 60601-1:1988 *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

IEC 60651:1979³⁾, *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*

2 Terminology and definitions

For the purposes of this collateral standard, the following definitions apply.⁴⁾

NOTE This collateral standard uses the term “equipment” to mean MEDICAL ELECTRICAL EQUIPMENT OR non-MEDICAL ELECTRICAL EQUIPMENT in the context of a MEDICAL ELECTRICAL SYSTEM.

2.201

* 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.

²⁾ “DB” refers to the IEC on-line database.

³⁾ A consolidated edition (1.2) exists including IEC 60651 (1979), its Amendment 1 (1993) and its Amendment 2 (2000).

⁴⁾ An index of defined terms is found beginning on page 153.

2.202*** 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

2.203*** ALARM LIMIT**

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

2.204**ALARM OFF**

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

2.205*** ALARM PAUSED**

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

2.206**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

2.207**ALARM RESET**

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

2.208**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.

2.209**ALARM SIGNAL**

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

2.210*** ALARM SIGNAL GENERATION DELAY**

time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNALS

2.211**ALARM SYSTEM**

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

2.212**AUDIO OFF**

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

2.213**AUDIO PAUSED**

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

2.214**BURST**

group of PULSES with a distinctive rhythm or pattern

2.215**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

2.216**DEFAULT ALARM PRESET**

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

NOTE Manufacturer- or USER-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

2.217*** DISTRIBUTED ALARM SYSTEM**

ALARM SYSTEM that involves more than one item of equipment of a MEDICAL ELECTRICAL SYSTEM

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

2.218**ESCALATION**

process by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

2.219**FALL TIME**

t_f

interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 201)

2.220**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.

2.221**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.

2.222**HIGH PRIORITY**

indicating that immediate OPERATOR response is required

NOTE The priority is assigned through risk analysis.

2.223*** INFORMATION SIGNAL**

any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

2.224*** 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.

2.225**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 201)

2.226**LATCHING ALARM SIGNAL**

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

2.227**LOW PRIORITY**

indicating that OPERATOR awareness is required

NOTE The priority is assigned through risk analysis.

2.228**MEDIUM PRIORITY**

indicating that prompt OPERATOR response is required

NOTE The priority is assigned through risk analysis.

2.229**NON-LATCHING ALARM SIGNAL**

ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

2.230**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.

2.231**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.

2.232

PULSE

brief continuous sound having a specific spectral content

2.233

PULSE FREQUENCY

f_o

fundamental frequency (first harmonic) of a PULSE

2.234

* REMINDER SIGNAL

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

2.235

RISE TIME

t_r

interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 201)

2.236

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.

6 Identification, marking and documents

6.3 Marking of controls and instruments

Addition:

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 BBB.1.

6.7 Indicator lights and push-buttons

a) Colors of indicator lights

Addition, after the first sentence:

See also 201.3.2.2.

Addition, after the second sentence:

See also 201.3.2.2.

6.8.1 ACCOMPANYING DOCUMENTS

Addition:

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 BBB.2.

6.8.2 Instructions for use

Addition:

aaa) ALARM SYSTEMS

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 BBB.3.

6.8.3 Technical description

Addition:

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 BBB.4.

SECTION TWO TO TEN – NOT USED

Addition:

201 ALARM SYSTEMS

201.1 * ALARM CONDITION

201.1.1 * 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.

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

NOTE A risk management process for medical devices is given in ISO 14971.

Compliance is checked by inspection of the instructions for use and risk management file.

Table 201 – 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 MEDICAL ELECTRICAL EQUIPMENT with a therapeutic function is usually designed to prevent immediate death or irreversible injury by automatic safety mechanisms.			

201.2 * 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:

- 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.);
- 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);
- changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);
- changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and
- changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency).

Compliance is checked by inspection of the instructions for use.

201.3 Generation of ALARM SIGNALS

201.3.1 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.

201.3.2 * Visual ALARM SIGNALS

201.3.2.1 General

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

201.3.2.2 * 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 color and flashing requirements given in Table 202. 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 202.

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 202 – Characteristics of alarm indicator lights

Alarm category	Indicator color	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 shall be provided that identifies the specific ALARM CONDITION and its priority. 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 of an ALARM CONDITION may be visually indicated (marked) with symbol IEC 60417-5307 (DB:2002-10) (see Symbol 1 of Table D.201). 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 color 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 201.2).

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 center 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.*

201.3.3 * Auditory ALARM SIGNALS

201.3.3.1 * Characteristics of auditory ALARM SIGNALS

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

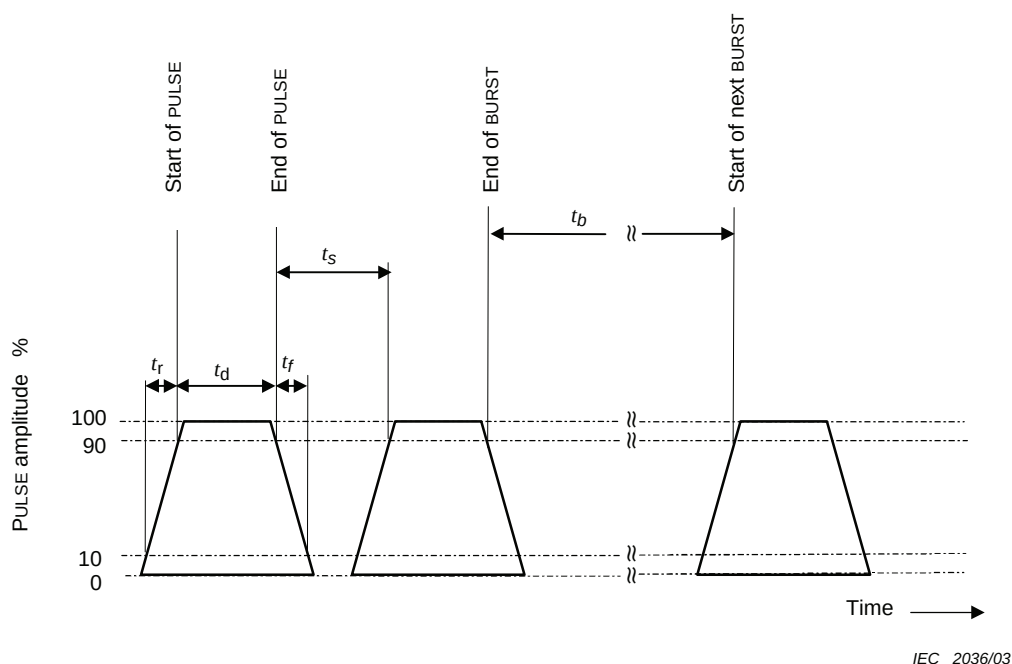
- a) is priority encoded and meets the requirements of Tables 203 and 204; or
- b) is generated by means of different technology (e.g., voice synthesizing of verbal ALARM SIGNALS) and is validated (e.g., by clinical or simulated clinical usability testing).

Table 203 – * 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 201)			
between 1 st and 2 nd PULSE	x	y	y
between 2 nd and 3 rd PULSE	x	y	not applicable
between 3 rd and 4 th PULSE	$2x + t_d$	not applicable	not applicable
between 4 th and 5 th PULSE	x	not applicable	not applicable
between 5 th and 6 th PULSE	0,35 s to 1,30 s	not applicable	not applicable
between 6 th and 7 th PULSE	x	not applicable	not applicable
between 7 th and 8 th PULSE	x	not applicable	not applicable
between 8 th and 9 th PULSE	$2x + t_d$	not applicable	not applicable
between 9 th and 10 th 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 $\pm 5\%$. MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.			
^a See also Table 204 for characteristics of the PULSE. ^b Unless otherwise specified in a particular standard for a particular MEDICAL ELECTRICAL 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 204 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
PULSE FREQUENCY (f_0)	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 201 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL.

Figure 201 – 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 CCC.

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 203, Table 204 and Annex EEE, unless their meaning is the same. If any of the melodies of Annex EEE is used to meet the requirements of Tables 203 and 204, its meanings shall be as specified in Annex EEE.

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 USER to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use (see 201.7).

Compliance is checked by inspection of the ALARM SYSTEM and the relevant validation documentation.

201.3.3.2 * 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 center 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 (consolidated edition) 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 $\geq$ MEDIUM PRIORITY ALARM SIGNAL sound pressure level $\geq$ LOW PRIORITY ALARM SIGNAL sound pressure level.*

201.3.4 * Characteristics of verbal ALARM SIGNALS

No general requirement.

201.4 * Disclosure of delays

201.4.1 * 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.

201.4.2 * 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 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 201.11.2.2) 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 OUTPUT PART;
- f) to or from the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT 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.

201.5 ALARM PRESETS

201.5.1 * General requirements

Any ALARM PRESET that uses mechanical adjustment is exempt from the requirements of 201.5.

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

An ALARM SYSTEM is exempt from the requirements of 201.5 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 potential 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 theater.

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

201.5.2 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.

201.5.3 * USER- and OPERATOR-configured ALARM PRESETS

201.5.3.1 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 USER (see 201.7); and
- b) means shall be provided to the USER to restore the ALARM PRESET to its manufacturer-configured state.

Compliance is checked by inspection.

201.5.3.2 ALARM SYSTEMS with more than one ALARM PRESET

If the ALARM SYSTEM provides means to store or activate one or more USER-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 USER-configured or manufacturer-configured ALARM PRESET. Saving changes to any USER-configured or manufacturer-configured ALARM PRESET shall be restricted to the USER (see 201.7);
- f) means shall be provided to prevent an individual OPERATOR from saving changes to ALARM PRESETS that were stored by any other OPERATOR (see 201.7); 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.

201.5.4 DEFAULT ALARM PRESET

201.5.4.1 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 USER (see 201.7); and
- b) means shall be provided to the USER to restore the DEFAULT ALARM PRESET to its manufacturer-configured values.

Compliance is checked by inspection.

201.5.4.2 * 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 201.5.5);

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 behavior 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 behavior.

201.5.5 * 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 behavior 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.

201.6 ALARM LIMIT

201.6.1 General requirements

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

Compliance is checked by inspection.

201.6.2 * Adjustable ALARM LIMIT

201.6.2.1 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.

201.6.2.2 * 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 behavior is described in the instructions for use; or
- e) the ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM (see 201.2).

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

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

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

Compliance is checked by functional testing.

201.7 * ALARM SYSTEM security

Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 201.3.3.1, 201.5.3.1, 201.5.3.2, 201.5.4.1, 201.8.1, 201.8.3, and 201.10):

EXAMPLE 1 Access controlled by a tool.

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

EXAMPLE 3 Access controlled by individual OPERATOR password.

NOTE A password is not considered secure unless the owner of the password is capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

Compliance is checked by inspection of the technical documentation.

201.8 * ALARM SIGNAL inactivation states

201.8.1 * 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 (off) or timed (paused). Flashing visual ALARM SIGNALS specified in 201.3.2.2 may be inactivated by AUDIO PAUSED or AUDIO OFF.

NOTE 1 A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

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

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.

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

- a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use; and
- b) the USER shall be provided with a means to disable the REMINDER SIGNAL; and
- c) the USER shall be provided with a means to allow an authorized OPERATOR to disable the REMINDER SIGNAL in a particular situation (see 201.7); and
- d) with an adjustable REMINDER SIGNAL interval, means to adjust the maximum interval shall only be provided to USER (see 201.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.