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TECHNICAL REPORT

Medical electrical equipment – Part 4-4: Guidance and interpretation – Guidance for writers of particular standards when creating alarm system-related requirements

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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IEC 60601-4-4, which is a technical report, has been prepared by a Joint Working Group of 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 equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/1186/DTR	62A/1197/RVDTR

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

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

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

Terms used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

It has become apparent in reviewing various particular standards in the IEC 60601 and IEC 80601 or ISO 80601 series of standards that there is inconsistency in the references to ALARM SYSTEM-related requirements. This inconsistency is especially challenging for MANUFACTURERS whose products have multiple applicable particular standards.

This document was generated to address this problem by providing model language, with examples, for common ALARM SYSTEM-related requirements that have been needed in existing particular standards. It is hoped that writers of particular standards will use this model language when ALARM SYSTEM-related requirements need to be provided in these standards.

This document contains 13 recommendations, numbered 1 to 13 (see Table 1). All these recommendations are based upon IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012. The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 with the prefix “208” (e.g. 208.1 in this document addresses the content of Clause 1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012). Similarly, IEC 60601-1:2005 and IEC 60601-1:2005/ AMD1:2012 are indicated with the prefix “201” (e.g. 201.4 in this document addresses the content of Clause 4 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012). Changes to the rationale for a clause or subclause are indicated with the prefix "Subclause" (e.g. Subclause 208.6.8.5 indicates rationale for Subclause 208.6.8.5).

The changes to the text are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the reference is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of the reference.

"*Amendment*" means that the clause or subclause of the reference is amended as indicated by the text of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-4: Guidance and interpretation – Guidance for writers of particular standards when creating alarm system-related requirements

1 Scope and object

1.1 Scope

This document is intended to assist writers when drafting ALARM SYSTEM-related requirements for particular standards in the IEC 60601 and IEC 80601 or ISO 80601 series of standards.

1.2 Object

The object of this document is to encourage consistent references to ALARM SYSTEM-related requirements when introducing those requirements to particular standards. This is accomplished by providing suggested model language, with examples, for common ALARM SYSTEM-related requirements. Each of the recommendations is based upon text that has been used in existing particular standards. The expectation is that this model language will be used when ALARM SYSTEM-related requirements are needed in particular standards.

The collateral standard for ALARM SYSTEMS, IEC 60601-1-8, contains the horizontal ALARM SYSTEM-related requirements for ME EQUIPMENT and ME SYSTEMS. The recommendations in this document are intended to aid the writers of particular standards when referencing IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

2 Normative references

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

IEC 60601-2-34:2011, *Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use – Part 1: Salt test method to assess filtration performance*

ISO 80601-2-12:2011, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-55:2011, *Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-61:2011, *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

ISO 80601-2-72:2015, *Medical electrical equipment – Part 2-72:Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-2-27:2011, IEC 60601-2-34:2011, ISO 23328-1:2003, ISO 80601-2-12:2011, ISO 80601-2-55:2011, ISO 80601-2-61:2011 and ISO 80601-2-72:2015 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 22.

4 Overview

Table 1 provides an overview of the recommendations in this document listed in the order of the subclauses of the collateral standard, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

In these recommendations, text in a field with

- square brackets [ ] represents where the writers should choose an appropriate phrase.
- curly brackets { } represents a field where the choices are listed inside the brackets or later in the text.

Table 1 – Recommendations for particular standard references to the collateral standard IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD:2012

Subclause of the particular standard	Recommendation number	Topic	Page
201.7.9.2.8.101	5.6	Requiring disclosure of a means for testing ALARM SIGNALS	14
201.7.9.3.101	5.7	Requiring disclosure of a means for testing the ALARM SYSTEM	15
208.6.6.2.101	5.5	Requiring a restriction for the adjustment range of an ALARM LIMIT	13
208.6.8.1	5.13	Requiring the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state	18
208.6.8.1	5.1	Prohibiting the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state	9
208.6.8.2	5.8	Requiring REMINDER SIGNALS, option 1	16
208.6.8.2	5.9	Requiring REMINDER SIGNALS, option 2	16
208.6.8.5	5.3	Requiring a maximum pause duration, option 1	11
208.6.8.5	5.4	Requiring a maximum pause duration, option 2	11
208.6.12	5.12	Requiring ALARM SYSTEM logging	18
—[a]	5.11	Requiring a maximum ALARM SIGNAL GENERATION DELAY	17
—[a]	5.2	Requiring an ALARM CONDITION and its priority	9
—[b]	5.10	Requiring the capability for a connection to a DISTRIBUTED ALARM SYSTEM	17

[a] Generally placed in a particular standard subclause calling out the ALARM CONDITION.

[b] Generally placed in a particular standard in subclause 201.10x.

5 Recommendations

5.1 Prohibiting the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state

5.1.1 General

This recommendation is applicable only for those particular standards that intend to prohibit the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state.

The recommended text would typically be placed in the particular standard at 208.6.8.1.

5.1.2 Recommended text to prohibit the use of the untimed ACKNOWLEDGED ALARM SIGNAL inactivation state

208.6.8.1 General

Amendment (delete from the first paragraph):

or indeterminate (indefinite ACKNOWLEDGED)

Amendment (add to end of the first paragraph):

ME EQUIPMENT shall not be equipped with a means for the clinical OPERATOR to initiate the indeterminate (indefinite) ACKNOWLEDGED ALARM SIGNAL inactivation state.

Check compliance by functional testing.

5.2 Requiring an ALARM CONDITION and its priority

5.2.1 General

This recommendation is applicable only for those particular standards that intend to require an ALARM CONDITION and its associated priority.

The recommended text would typically be placed in the particular standard in a subclause where the source of the ALARM CONDITION is considered (e.g. 201.12.1.xxx, 201.12.4.xxx or 208.6.1.2.xxx).

5.2.2 Recommended text to require an ALARM CONDITION and its priority

ME EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate [describe the ALARM CONDITION here]. The [describe the ALARM CONDITION here] ALARM CONDITION shall be at least {choose a priority from the choices below}, unless an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the [describe the ALARM CONDITION here] ALARM CONDITION is suppressed or its priority is changed.

Choices:

- HIGH PRIORITY,
- MEDIUM PRIORITY,
- LOW PRIORITY with auditory ALARM SIGNAL,
- LOW PRIORITY.

Check compliance by functional testing.

5.2.3 Example 1 for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

208.6.1.2.101 Additional requirements for ALARM CONDITION priority

ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate cardiac standstill (asystole). The cardiac standstill (asystole) ALARM CONDITION shall be HIGH PRIORITY, unless an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the cardiac standstill (asystole) ALARM CONDITION is supressed or its priority is changed.

EXAMPLE The invasive pressure measurement indicates that there is a valid pulse rate so the cardiac standstill (asystole) ALARM CONDITION is suppressed.

Check compliance by functional testing.

5.2.4 Example 2 for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

208.6.1.2.102 Additional requirements for ALARM CONDITION priority

ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate ventricular tachycardia. The ventricular tachycardia ALARM CONDITION shall be HIGH PRIORITY, unless an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the ventricular tachycardia ALARM CONDITION is suppressed or its priority is changed.

EXAMPLE The ECG algorithm determines ventricular tachycardia is present, but the arterial invasive pressure measurement indicates that the blood pressure is 120 mmHg (systolic) and 80 mmHg (diastolic) so the ventricular tachycardia ALARM CONDITION priority is changed by the INTELLIGENT ALARM SYSTEM from HIGH PRIORITY to MEDIUM PRIORITY.

Check compliance by functional testing.

5.2.5 Example for PULSE OXIMETER EQUIPMENT

208.6.1.2.101 Additional requirements for ALARM CONDITION priority

If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects PHYSIOLOGICAL ALARM CONDITIONS, then it shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate low SpO_2 level. The low SpO_2 level ALARM CONDITION shall be at least MEDIUM PRIORITY, unless an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the low SpO_2 level ALARM CONDITION is suppressed or its priority is changed.

Check compliance by functional testing.

5.3 Requiring a maximum pause duration, option 1

5.3.1 General

This recommendation is applicable only for those particular standards that intend to require a maximum pause duration.

The recommended text is placed in the particular standard at 208.6.8.5.

5.3.2 Recommended text to require a maximum pause duration, option 1

208.6.8.5 Indication and access

Amendment (add at the end of the third paragraph):

The MANUFACTURER-configured default interval for {choose an ALARM SIGNAL inactivation state from the choices below} of ME EQUIPMENT shall not exceed [place time here].

Choices:

- AUDIO PAUSED,
- ALARM PAUSED,
- timed ACKNOWLEDGED,
- or any combination of the above.

Check compliance by functional testing.

5.3.3 Example

208.6.8.5 Indication and access

Amendment (add at the end of the third paragraph):

The MANUFACTURER-configured default interval for AUDIO PAUSED, ALARM PAUSED or timed ACKNOWLEDGED of ME EQUIPMENT shall not exceed 2 min.

Check compliance by functional testing.

5.4 Requiring a maximum pause duration, option 2

5.4.1 General

This recommendation is applicable only for those particular standards that intend to require a maximum pause duration.

The recommended text is placed in the particular standard at 208.6.8.5.

5.4.2 Recommended text to require a maximum pause duration, option 2

208.6.8.5 Indication and access

Amendment (add at the end of the third paragraph):

The duration of {choose an ALARM SIGNAL inactivation state from the choices below} for the ALARM CONDITIONS required by this document shall not exceed [place duration here] without OPERATOR intervention.

NOTE This makes it possible for an OPERATOR to deliberately extend the duration of {choose an ALARM SIGNAL inactivation state from the choices below} by OPERATOR action.

Choices:

- AUDIO PAUSED,
- ALARM PAUSED,
- timed ACKNOWLEDGED,
- or any combination of the above.

Check compliance by functional testing.

Subclause 208.6.8.5 – Additional requirements for termination of ALARM SIGNAL inactivation

Permitting very long pauses of ALARM SIGNALS can be hazardous for the PATIENT since the OPERATOR will not be notified of the existence of an ALARM CONDITION. However, PATIENT management often requires delicate procedures that can be disrupted by auditory ALARM SIGNALS. Therefore, extending AUDIO PAUSED by OPERATOR action is useful to prevent the ME EQUIPMENT from disturbing the OPERATOR or others in the vicinity.

ME EQUIPMENT should be equipped with an {choose an ALARM SIGNAL inactivation state from the choices above} capability that permits the OPERATOR to pause the ALARM SIGNALS prior to the creation of an ALARM CONDITION. Such a capability permits the OPERATOR to minimize nuisance auditory ALARM SIGNALS in situations that are known to be associated with creation of ALARM CONDITIONS that are neither clinically relevant nor helpful. [Place a description of a typical situation for this type of ME EQUIPMENT where the OPERATOR would be present and likely creating ALARM CONDITIONS by virtue of what is being done.]

5.4.3 Example for a critical care VENTILATOR

208.6.8.5 Indication and access

Amendment (add at the end of the third paragraph):

The duration of AUDIO PAUSED for the ALARM CONDITIONS required by this document shall not exceed 2 min without OPERATOR intervention.

NOTE This makes it possible for an OPERATOR to deliberately extend the duration of AUDIO PAUSED by OPERATOR action.

Check compliance by functional testing.

Subclause 208.6.8.5 – Additional requirements for termination of ALARM SIGNAL inactivation

Permitting very long pauses of ALARM SIGNALS can be hazardous for the PATIENT since the OPERATOR will not be notified of the existence of an ALARM CONDITION. However, PATIENT management often requires delicate procedures that can be disrupted by auditory ALARM SIGNALS. Therefore, extending AUDIO PAUSED by OPERATOR action is useful to prevent what would otherwise be nuisance ALARM SIGNALS from disturbing the OPERATOR or others in the vicinity.

VENTILATORS should be equipped with an AUDIO PAUSED capability that permits the OPERATOR to pause the ALARM SIGNALS prior to the creation of ALARM CONDITIONS that are expected to occur. Such a capability permits the OPERATOR to minimize nuisance auditory ALARM SIGNALS in situations that are known to be associated with creation of ALARM CONDITIONS that are neither clinically relevant nor helpful. A 'planned' disconnection is a common situation where this capability is needed. Examples include open suctioning, BREATHING SYSTEM FILTER change, or insertion of a medication treatment. A closed suctioning mode should also include such a capability.

5.5 Requiring a restriction for the adjustment range of an ALARM LIMIT

5.5.1 General

This recommendation is applicable only for those particular standards that intend to restrict the adjustment range of an ALARM LIMIT.

The recommended text would typically be placed in the particular standard at 208.6.6.2.101.

5.5.2 Recommended text to restrict the adjustment range of an ALARM LIMIT, option 1, limit the range

Additional subclause:

208.6.6.2.101 Additional requirements for adjustable ALARM LIMIT

ME EQUIPMENT shall be equipped with means to adjust the {choose a type of ALARM LIMIT from the choices below} [describe the ALARM CONDITION here] ALARM LIMIT[S] by deliberate action. The {choose a type of ALARM LIMIT from the choices below} ALARM LIMIT[S] for [describe the ALARM CONDITION here] ALARM CONDITION shall not permit OPERATOR adjustment {higher than or lower than} [put value[s] here] without an additional confirmation from the OPERATOR.

Choices:

- upper,
- lower,
- upper and lower.

Check compliance by functional testing.

5.5.3 Example for a RESPIRATORY GAS MONITOR (RGM)

Additional subclause:

208.6.6.2.101 Additional requirements for adjustable ALARM LIMIT

An RGM shall be equipped with a means to adjust the low inspired oxygen gas reading ALARM LIMIT by deliberate action. The ALARM LIMIT for low inspired oxygen gas reading ALARM

CONDITION shall not permit OPERATOR adjustment lower than 18 % without an additional confirmation from the OPERATOR.

Check compliance by functional testing.

5.5.4 Recommended text to restrict the adjustment range of an ALARM LIMIT, option 2, ensure that the range is wide enough

Additional subclause:

208.6.6.2.101 Additional requirements for adjustable ALARM LIMIT

ME EQUIPMENT shall be equipped with a means to adjust the {upper or lower} [describe the ALARM CONDITION here] ALARM LIMIT. The {upper or lower} [describe the ALARM CONDITION here] ALARM LIMIT shall permit OPERATOR adjustment {higher than or lower than or between} [put value or values here].

Check compliance by functional testing.

5.5.5 Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

Additional subclause:

208.6.6.2.101 Additional requirements for adjustable ALARM LIMIT

ME EQUIPMENT shall be equipped with means to adjust the upper heart rate ALARM LIMIT. The ALARM LIMIT range for the upper heart rate ALARM CONDITION shall permit OPERATOR adjustment between 100 min^{-1} and 200 min^{-1}. The ALARM LIMIT range for the lower heart rate ALARM CONDITION shall permit OPERATOR adjustment between 30 min^{-1} and 100 min^{-1}.

Check compliance by functional testing.

5.6 Requiring disclosure of a means for testing ALARM SIGNALS

5.6.1 General

This recommendation is applicable only for those particular standards that intend to require disclosure of a means for testing ALARM SIGNALS.

The recommended text would typically be placed in the particular standard at 201.7.9.2.8.101.

5.6.2 Recommended text to require disclosure of a means of testing ALARM SIGNALS

Additional subclause:

201.7.9.2.8.101 Additional requirements for the start-up PROCEDURE

NOTE For the purposes of this document, a start-up PROCEDURE is a pre-use functional test that is used to determine whether the ME EQUIPMENT is ready for use.

The instructions for use shall disclose how the clinical OPERATOR can check for proper operation of the ME EQUIPMENT on a daily or per shift basis.

In addition, the instructions for use for ME EQUIPMENT shall disclose how all the ALARM SIGNALS can be functionally tested by the clinical OPERATOR to determine if they are operating correctly. Portions of this test may be automatically performed by the ME EQUIPMENT or may require OPERATOR action.

EXAMPLE Combination of the power-on self-test routines and OPERATOR action.

Check compliance by inspection of the instructions for use.

5.6.3 Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

Additional subclause:

201.7.9.2.8.101 Additional requirements for the start-up PROCEDURE

NOTE For the purposes of this document, a start-up PROCEDURE is a pre-use functional test that is used to determine whether the ME EQUIPMENT is ready for use.

The instructions for use shall disclose how the clinical OPERATOR can check for proper operation of the ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT on a daily or per shift basis.

In addition, the instructions for use for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT shall disclose how all of the ALARM SIGNALS can be functionally tested by the clinical OPERATOR to determine if they are operating correctly. Portions of this test may be automatically performed by the ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT or may require OPERATOR action.

EXAMPLE Combination of the power-on self-test routines and OPERATOR action.

Check compliance by inspection of the instructions for use.

5.7 Requiring disclosure of a means for testing the ALARM SYSTEM

5.7.1 General

This recommendation is applicable only for those particular standards that intend to require disclosure of a means of testing the ALARM SYSTEM.

The recommended text would typically be placed in the particular standard at 201.7.9.3.101.

5.7.2 Recommended text to require disclosure of a means of testing the ALARM SYSTEM

Additional subclause:

201.7.9.3.101 Additional requirements for the technical description

The technical description for ME EQUIPMENT shall include a description of a method for checking the proper functioning of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this document, if not performed automatically during the start-up PROCEDURE. The technical description shall disclose which checks are performed automatically.

Check compliance by inspection of the technical description.

5.7.3 Example for a critical care VENTILATOR

Additional subclause:

201.7.9.3.101 Additional requirements for the technical description

The technical description for the VENTILATOR shall include a description of a method for checking the proper functioning of the ALARM SYSTEM for each of the ALARM CONDITIONS

specified in this document, if not performed automatically during the start-up PROCEDURE. The technical description shall disclose which checks are performed automatically.

Check compliance by inspection of the technical description.

5.8 Requiring REMINDER SIGNALS during ALARM SIGNAL inactivation, option 1

5.8.1 General

This recommendation is applicable only for those particular standards that intend to require the generation of REMINDER SIGNALS during ALARM SIGNAL inactivation.

The recommended text would typically be placed in the particular standard at 208.6.8.2.

5.8.2 Recommended text to require the generation of REMINDER SIGNALS during ALARM SIGNAL inactivation

208.6.8.2 REMINDER SIGNALS

Amendment (add before the compliance check):

If an ALARM SIGNAL inactivation state is invoked for a duration longer than [place interval here], without OPERATOR action, for the [describe the ALARM CONDITION here] ALARM CONDITION, a REMINDER SIGNAL {shall or should} be generated at least every [place interval here].

5.8.3 Example for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT

208.6.8.2 REMINDER SIGNALS

Amendment (add before the compliance check):

If an ALARM SIGNAL inactivation state is invoked for a duration longer than 5 min, without OPERATOR action, for the PHYSIOLOGICAL ALARM CONDITIONS required by this document, a REMINDER SIGNAL shall be generated at least every 5 min.

5.9 Requiring REMINDER SIGNALS during ALARM SIGNAL inactivation, option 2

5.9.1 Recommended text to require the generation of REMINDER SIGNALS during ALARM SIGNAL inactivation

208.6.8.2 REMINDER SIGNALS

Amendment (add before the compliance check):

If an ALARM SIGNAL inactivation state is invoked for a duration longer than [place interval here] for all {choose the ALARM CONDITION priority} ALARM CONDITIONS, a REMINDER SIGNAL shall be generated every [place interval here]. If an ALARM SIGNAL inactivation state is invoked for a duration longer than [place interval here] for {choose the ALARM CONDITION priority} ALARM CONDITIONS, a REMINDER SIGNAL should be generated at least every [place interval here].

Choices:

- HIGH PRIORITY,
- MEDIUM PRIORITY,
- LOW PRIORITY with auditory ALARM SIGNAL,
- LOW PRIORITY.

5.9.2 Example

208.6.8.2 REMINDER SIGNALS

Amendment (add before the compliance check):

If an ALARM SIGNAL inactivation state is invoked for a duration longer than 2 min for all HIGH PRIORITY ALARM CONDITIONS, a REMINDER SIGNAL shall be provided every 2 min. If an ALARM SIGNAL inactivation state is invoked for a duration longer than 2 min for MEDIUM PRIORITY ALARM CONDITIONS, a REMINDER SIGNAL should be provided at least every 2 min.

5.10 Requiring the capability for a connection to a DISTRIBUTED ALARM SYSTEM

5.10.1 General

This recommendation is applicable only for those particular standards that intend to require the capability for a connection to a DISTRIBUTED ALARM SYSTEM.

The recommended text would typically be placed in the particular standard at 201.10x.1.

5.10.2 Recommended text to require the capability for a connection to a DISTRIBUTED ALARM SYSTEM

Additional subclauses:

201.10x FUNCTIONAL CONNECTION

201.10x.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT shall be maintained if connections to the FUNCTIONAL CONNECTION of the ME EQUIPMENT are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.10x.2 Connection to a DISTRIBUTED ALARM CONDITION

ME EQUIPMENT [should or shall] be equipped with a FUNCTIONAL CONNECTION that permits connection to a DISTRIBUTED ALARM SYSTEM.

Check compliance by inspection.

5.10.3 Example for a VENTILATOR FOR A VENTILATOR-DEPENDENT PATIENT

Additional subclauses:

201.10x FUNCTIONAL CONNECTION

201.10x.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained if connections to the FUNCTIONAL CONNECTION of the VENTILATOR are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.10x.2 Connection to a DISTRIBUTED ALARM CONDITION

A VENTILATOR shall be equipped with a FUNCTIONAL CONNECTION that permits connection to a DISTRIBUTED ALARM SYSTEM.

Check compliance by inspection.

5.11 Requiring a maximum ALARM SIGNAL GENERATION DELAY

5.11.1 General

This recommendation is applicable only for those particular standards that intend to require a maximum ALARM SIGNAL GENERATION DELAY.

The recommended text would typically be placed in the particular standard at 208.6.4.1.

5.11.2 Recommended text to require a maximum ALARM SIGNAL GENERATION DELAY

208.6.4.1 ALARM SYSTEM delays

Amendment (add before the compliance check):

The ALARM SIGNAL GENERATION DELAY for the [describe the ALARM CONDITION here] ALARM CONDITION shall not exceed [place duration here].

Check compliance by functional testing.

5.11.3 Example for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

208.6.4.1 ALARM SYSTEM delays

Amendment (add before the compliance check):

The ALARM SIGNAL GENERATION DELAY for the cardiac standstill (asystole) ALARM CONDITION shall not exceed 10 s.

Check compliance by functional testing.

5.12 Requiring ALARM SYSTEM logging

5.12.1 General

This recommendation is applicable only for those particular standards that intend to require ALARM SYSTEM logging.

The recommended text would typically be placed in the particular standard at 208.6.12.101.

5.12.2 Recommended text to require ALARM SYSTEM logging

Additional subclause:

208.6.12.101 Additional requirements for ALARM SYSTEM logging

Notwithstanding the requirements of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, the ME EQUIPMENT shall

- be equipped with an ALARM SYSTEM log for {choose the type(s) of ALARM CONDITION} ALARM CONDITIONS and all ALARM SIGNAL inactivation states with a capacity of at least [place number of events here] events.
- not lose the contents of the ALARM SYSTEM log during a loss of power for less than [place interval here] unless deleted by RESPONSIBLE ORGANIZATION action.
- not permit the OPERATOR to erase the contents of the ALARM SYSTEM log.

Choices:

- specific ALARM CONDITIONS,
- technical,
- physiological,
- HIGH PRIORITY,
- MEDIUM PRIORITY,
- LOW PRIORITY with auditory ALARM SIGNAL,
- LOW PRIORITY,
- all.

This log [should or shall] include at least the following events:

Choices (these are just examples, other events are possible):

- change of ME EQUIPMENT settings;
- change of ALARM SETTINGS;
- change of PATIENT;
- power supply source change;
- access mode; and
- results of the last pre-use check.

Check compliance by inspection and functional testing.

5.12.3 Example for a life-supporting homecare VENTILATOR

Additional subclause:

208.6.12.101 Additional requirements for ALARM SYSTEM logging

Notwithstanding the requirements of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, the VENTILATOR shall

- be equipped with an ALARM SYSTEM log for all ALARM CONDITIONS and all ALARM SIGNAL inactivation states with a capacity of at least 1 000 events.
- not lose the contents of the ALARM SYSTEM log during a loss of power for less than 365 days unless deleted by RESPONSIBLE ORGANIZATION action.
- not permit the LAY OPERATOR to erase the contents of the ALARM SYSTEM log.

This log shall include at least the following events:

- change of ventilation settings;
- change of ALARM SETTINGS;
- power supply source change;
- access mode; and

- results of the last pre-use check.

Check compliance by inspection and functional testing.

5.13 Requiring the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state

5.13.1 General

This recommendation is applicable only for those particular standards that intend to require the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state.

The recommended text would typically be placed in the particular standard at 208.6.8.1.

5.13.2 Recommended text to require the use of the ACKNOWLEDGED ALARM SIGNAL inactivation state

208.6.8.1 General

Amendment (add to end of the first paragraph):

Means shall be provided for the OPERATOR to initiate the ACKNOWLEDGED ALARM SIGNAL inactivation state.

Check compliance by functional testing.

Bibliography

IEC 60601 (all parts), *Medical electrical equipment*

IEC 80601 (all parts), *Medical electrical equipment*

ISO 80601 (all parts), *Medical electrical equipment*

Index of defined terms used in this document

NOTE The ISO Online Browsing Platform (OBP) [1)] and the IEC Electropedia [2)] provide access to terms and definitions.

1) Available at: https://www.iso.org/obp/ui/#home.

2) Available at http://www.electropedia.org/

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