SLOVENSKI STANDARD
SIST EN 60601-1-8:2008/A2:2021

01-september-2021

Medicinska električna oprema - 1-8. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Splošne zahteve, preskušanje in navodila za alarmne sisteme v medicinski električni opremi in medicinskih električnih sistemih - Dopolnilo A2 (IEC 60601-1-8:2006/A2:2020)

Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006/A2:2020)

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

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

Ta slovenski standard je istoveten z: **EN 60601-1-8:2007/A2:2021**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-8:2008/A2:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-8:2007/A2

July 2021

ICS 11.040.01

English Version

Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006/A2:2020)

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

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

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

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

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

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

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

European foreword

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

The following dates are fixed:

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

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

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

Endorsement notice

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

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

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

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

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

Replace Annex ZA by the following one:

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

IEC 60601-1-8

Edition 2.0 2020-07

INTERNATIONAL STANDARD

colour inside

AMENDMENT 2

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-8631-9

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

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

FDIS	Report on voting
62A/1392/FDIS	62A/1407/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by 15 P members out of 15 having cast a vote.

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

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

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION TO AMENDMENT 2

The second edition of IEC 60601-1-8 was published in 2006 and amended in 2012. Since the publication of IEC 60601-1-8:2006+A1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-8, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 20 items were presented to the National Committees present. All 20 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-8.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-8 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 2. JWG 2 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-8:2006, the style in force at the time of publication of IEC 60601-1-8 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

INTRODUCTION

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

1.3.1 IEC 60601-1

Replace the first two existing dashes with the following new dashes:

– "the general standard" designates IEC 60601-1 alone, including any amendments;
– "this collateral standard" designates IEC 60601-1-8 alone, including any amendments;

2 Normative references

Replace the existing references to IEC 60601-1, IEC 61672-1 and IEC 62366-1 by the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

3 Terms and definitions

Replace the existing first paragraph with the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, and the following definitions apply.

3.17
*** DISTRIBUTED ALARM SYSTEM**

Replace the existing term and definition with the following new entry:

3.17
*** DISTRIBUTED ALARM SYSTEM**
DAS
ALARM SYSTEM that involves more than one item of equipment in a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate TECHNICAL ALARM CONDITIONS are created as described in 6.11.2.2.1.

3.20
FALSE NEGATIVE ALARM CONDITION

Replace, in the existing note, "the equipment itself" *with* "the ALARM SYSTEM itself".

3.22
HIGH PRIORITY

Replace the existing note with the following new notes:

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Immediate implies the interruption of current workflow is expected [59], [60].

3.23
***INFORMAL SIGNAL**

Add, after the existing Example 3, the following new note:

NOTE An ADVISORY is a type of INFORMATION SIGNAL.

3.25
INTERBURST INTERVAL

Replace, in the existing parenthetical, "Figure 1" *with* "Figure 1 and Figure G.1"*.*

Add the following new note:

NOTE For the purposes of this document, when an AUDITORY ICON is used, the INTERBURST INTERVAL begins at the end of the AUDITORY ICON.

3.27
LOW PRIORITY

Replace the existing term, definition and note with the following new entry:

3.27
LOW PRIORITY

indicating that OPERATOR awareness is required and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Awareness implies the planning of future workflow is expected [59], [60].

3.28
MEDIUM PRIORITY

Replace the existing note with the following new notes:

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Prompt implies the re-planning of current workflow is expected [59], [60].

3.37
*** ACKNOWLEDGED**

Replace the existing term, definition and notes, added by Amendment 1, with the following new entry:

3.37
*** ACKNOWLEDGED**
state of an ALARM SYSTEM initiated by OPERATOR action, where the auditory ALARM SIGNAL associated with a currently active ALARM CONDITION is inactivated until the ALARM CONDITION no longer exists or until a predetermined time interval has elapsed

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

Add, after 3.37, the following new terms and definitions:

3.38
*** ADVISORY**
ADVISORY SIGNAL
INFORMATION SIGNAL notifying the OPERATOR of a condition of the PATIENT or ME EQUIPMENT providing contextual awareness that is intended to improve the clinical workflow or understanding of the PATIENT condition, the awareness not being intended as a means of RISK CONTROL

NOTE 1 A notification that a lab result is available, where the lab result requires immediate clinical action is not an ADVISORY. It is an ALARM CONDITION.

NOTE 2 A signal associated with an ADVISORY, which is an INFORMATION SIGNAL, is required by this document to be designed so that an OPERATOR does not confuse it with an ALARM SIGNAL. See 6.3.2.2.2 and 6.3.3.2.

EXAMPLE 1 A notification that it is time to draw the next blood sample.

EXAMPLE 2 A battery status notification that replacement will be needed in a day.

EXAMPLE 3 A notification that it is time to bathe the PATIENT.

EXAMPLE 4 A notification that a lab result is available, where the lab results are normal.

3.39
*** ALARM FATIGUE**
situation wherein the presence of frequent ALARM SIGNALS desensitizes an OPERATOR to an ALARM SIGNAL

NOTE 1 A desensitized OPERATOR can fail to perceive, recognize or act on an ALARM SIGNAL.

NOTE 2 The response of a desensitized OPERATOR can be inadequate, delayed or non-existent.

NOTE 3 ALARM FLOOD can cause ALARM FATIGUE.

3.40
ALARM FLOOD
situation wherein OPERATORS receive more ALARM SIGNALS in a time period than they can manage appropriately

NOTE See [56], [57].

3.41
*** ALERT**
synonym for the combination of PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS and ADVISORIES

[SOURCE: ISO/IEEE 11073-10201:2020 [76], 3.3, modified – Replaced "alarms" with "ALARM CONDITIONS", "equipment-user advisory signals" with "ADVISORIES" and deleted "patient related".]

3.42
AUDITORY ICON
sound that creates a strong semantic link to the category it represents

NOTE 1 An AUDITORY ICON is typically a real-world sound or mimics a real-world sound.

NOTE 2 An AUDITORY ICON can aid in locating the COMMUNICATOR and the SOURCE type.

3.43
AUDITORY POINTER
sound that attracts attention, denotes the priority and aids in localization of the COMMUNICATOR

3.44
*** CLINICALLY ACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is necessary to prevent HARM within the timeframe implied by the priority communicated by the ALARM SYSTEM

NOTE 1 An OPERATOR action can include assessment of a PATIENT or the changing of ALARM LIMITS when they are inappropriately set for the state of the PATIENT.

NOTE 2 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 3 A FALSE POSITIVE ALARM CONDITION is never considered CLINICALLY ACTIONABLE even though an unrelated OPERATOR action might be required to prevent a future FALSE POSITIVE ALARM CONDITION.

NOTE 4 A CLINICALLY ACTIONABLE ALARM CONDITION is generally considered useful by the OPERATOR.

3.45
*** CLINICALLY NONACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is not expected within a timeframe equal to or shorter than the timeframe implied by its priority

NOTE 1 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 2 CLINICALLY NONACTIONABLE ALARM CONDITIONS are considered detrimental to OPERATOR performance and PATIENT safety.

NOTE 3 ALARM SIGNALS for an ALARM CONDITION of which the OPERATOR is already aware are considered CLINICALLY NONACTIONABLE.

3.46
COMMUNICATOR
COM
ANNUNCIATOR
function of the ALARM SYSTEM that generates ALARM SIGNALS to notify an OPERATOR (e.g. to the presence of an ALARM CONDITION)

NOTE 1 A COMMUNICATOR can receive an OPERATOR response.

NOTE 2 An OPERATOR response is not limited to direct OPERATOR action.

NOTE 3 See Figure 2.

3.47
DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION
CDAS
DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

3.48
*** DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS**
DIS
system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS.

3.49
INTEGRATOR
INT
ALARM MANAGER
function of the ALARM SYSTEM that distributes ALARM CONDITIONS, combines ALARM CONDITIONS from SOURCES or handles the communication between those SOURCES and COMMUNICATORS

NOTE 1 An INTEGRATOR can direct or redirect an ALARM CONDITION to another COMMUNICATOR and hence OPERATOR.

NOTE 2 An INTEGRATOR can send the acceptance of responsibility from a COMMUNICATOR to a SOURCE.

NOTE 3 See Figure 2.

3.50
*** NUISANCE ALARM SIGNAL**
ALARM SIGNAL for which a panel of experts would agree that the HARM associated with the ALARM SIGNAL is greater than the benefit associated with action resulting from the ALARM SIGNAL

NOTE 1 A NUISANCE ALARM SIGNAL contributes to ALARM FATIGUE.

NOTE 2 A NUISANCE ALARM SIGNAL can arise from a FALSE POSITIVE ALARM CONDITION.

NOTE 3 A NUISANCE ALARM SIGNAL can arise from a CLINICALLY NONACTIONABLE ALARM CONDITION.

NOTE 4 A NUISANCE ALARM SIGNAL can cause an inappropriate OPERATOR action.

EXAMPLE Causing the OPERATOR to set ALARM LIMITS to inappropriate settings.

NOTE 5 An ALARM SIGNAL that unnecessarily irritates or startles the PATIENT or OPERATOR can be a NUISANCE ALARM SIGNAL.

3.51
REDIRECTION
means by which an INTEGRATOR provides a response hierarchy for directing an ALARM CONDITION to a COMMUNICATOR or transfers an ALARM CONDITION to another COMMUNICATOR

NOTE See Figure 2.

3.52
RESPONSIBILITY ACCEPTED
state created by an OPERATOR response accepting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY ACCEPTED can be used to initiate an ALARM SIGNAL inactivation state.

NOTE 2 See Figure 2.

3.53
RESPONSIBILITY REJECTED
state created by an OPERATOR response rejecting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY REJECTED can be used to initiate an ESCALATION or REDIRECTION.

NOTE 2 See Figure 2.

3.54
RESPONSIBILITY UNDEFINED
state, automatically initiated when neither a RESPONSIBILITY ACCEPTED nor RESPONSIBILITY REJECTED is received within a specified period, which indicates that an OPERATOR is not responding

NOTE 1 RESPONSIBILITY UNDEFINED is not used as an indication that the COMMUNICATOR and INTEGRATOR cannot communicate.

NOTE 2 See Figure 2.

3.55
SOURCE
SRC
function that has the capability to initiate an ALARM CONDITION

NOTE 1 The SOURCE transfers the ALARM CONDITION to the INTEGRATOR.

NOTE 2 See Figure 2.

3.56
TRUE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

3.57
TRUE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

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

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

6.3.1 General

Replace, in the first sentence of the existing first paragraph, "ALARM SIGNALS" *with* "ALARM SIGNALS by a COMMUNICATOR".

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

Replace, in the existing Note 3, modified by Amendment 1, "IEC 62366" *with* "IEC 62366-1".

Replace the existing Note 5, added by Amendment 1, with the following new note:

NOTE 5 It is recognized that visual INFORMATION SIGNALS and visual ALARM SIGNALS can sometimes contain identical or similar information. When they are intended to convey different meanings, care needs to be taken to ensure that visual ALARM SIGNALS cannot be confused with visual INFORMATION SIGNALS.

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Replace, in the existing first paragraph, modified by Amendment 1, the first sentence with:

If a COMMUNICATOR of an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

Replace the existing list item b) to d), modified by Amendment 1, with:

b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

d) the COMMUNICATOR shall have at least one set of ALARM SIGNALS that:

   1) complies with Annex G; or