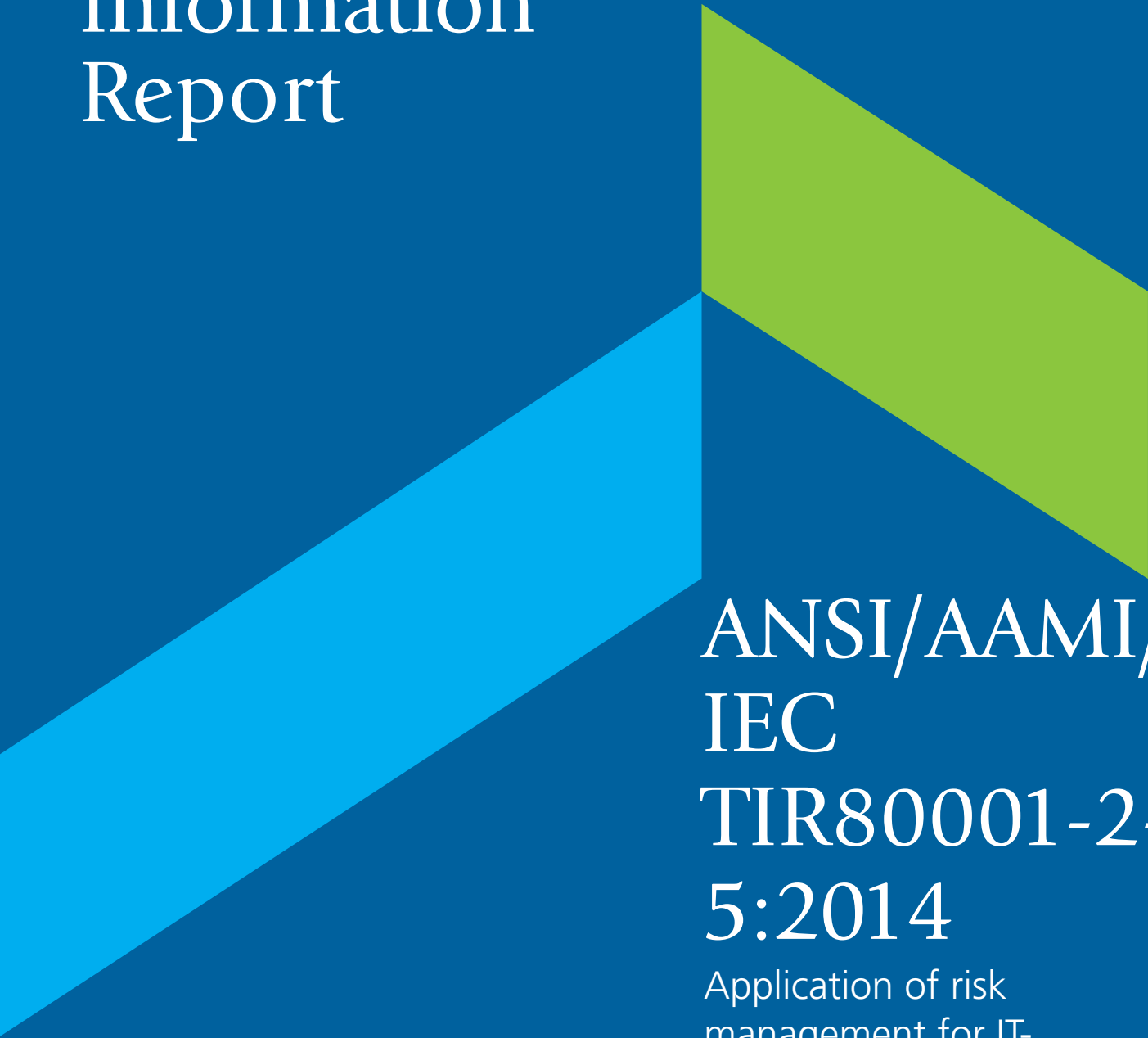


Technical Information Report



ANSI/AAMI/ IEC TIR80001-2- 5:2014

Application of risk
management for IT-
networks incorporating
medical devices – Part 2-5:
Application guidance –
Guidance on distributed
alarm systems

Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems

Approved 24 October 2014 by
Association for the Advancement of Medical Instrumentation

Approved 24 December 2014 by
American National Standards Institute

Abstract: This Technical Report gives guidance and practical techniques for responsible organizations, medical device manufacturers and providers of other information technology in the application of IEC 80001-1:2010 for the risk management of distributed alarm systems. This Technical Report applies to the transmission of alarm conditions between sources, integrator and receivers where at least one source is a medical device and at least one communication path utilizes a medical IT-network. It provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety, effectiveness and data and systems security.

Keywords: alarms, risk management, IT-network

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI/SM/WG 02, Information Technology Working Group

The adoption of the IEC/TR 80001-2-5 as a new AAMI/IEC Technical Information Report was initiated by the AAMI Information Technology Working Group.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, **the AAMI Information Technology Working Group** had the following members:

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Members: John Collins, American Hospital Association
Todd Cooper
Becky Crossley, Susquehanna Health
Conor Curtin, Fresenius Medical Care
Yadin David, Biomedical Engineering Consultants LLC
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Ray Silkaitis, Amgen Inc
Bob Steurer, Spacelabs Medical Inc
Donna-Bea Tillman, Biologics Consulting Group
Daidi Zhong, Chongqing University

Alternates: Denise Adams, B Braun of America Inc
James Dundon, Spacelabs Medical Inc
Brian Fitzgerald, FDA/CDRH
Rich Gardner, GE Healthcare
Andrew Northup, Medical Imaging & Technology Alliance a Division of NEMA
Phil Raymond, Philips Electronics North America
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Chandresh Thakur, CareFusion
Fei Wang, Fresenius Medical Care

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of IEC TR 80001-2-5

As indicated in the foreword to the main body of this document, the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this technical report.

International Technical Report IEC/TR 80001-2-5:2014 was developed jointly by Sub-Committee IEC/SC 62A, Common aspects of electrical equipment used in medical practice and ISO/TC 215, Health informatics, to define the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security.

U.S. participation in this IEC SC is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by AAMI on behalf of the American National Standards Institute (ANSI).

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Information Technology Working Group, together with the U.S. Technical Advisory Group for IEC/SC 62A, reviewed IEC/TR 80001-2-5 to formulate the U.S. position while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62A, the AAMI Information Technology Working Group voted to adopt the IEC Technical Report as written.

The concepts incorporated into this technical report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington VA 22203-1633.

NOTE—Beginning with the IEC foreword on page viii, ANSI/AAMI/IEC TIR80001-2-5, *Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems* is identical to IEC/TR 80001-2-5.

Foreword

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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IEC 80001-2-5, 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 technical committee 215: Health informatics.

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

Enquiry draft	Report on voting
62A/943/DTR	62A/955/RVC

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

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

A list of all parts of the IEC 80001 series, published under the general title *Application of risk management for it-networks incorporating medical devices*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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.

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

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

Introduction

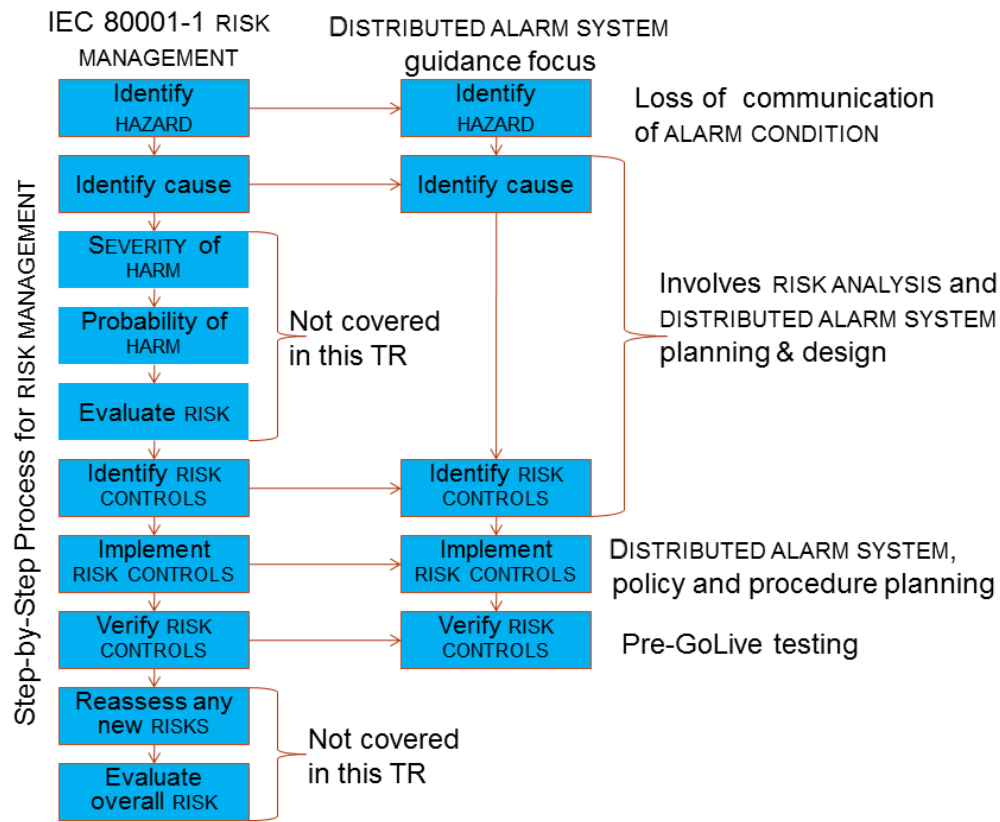
An increasing number of MEDICAL DEVICES are designed to exchange information electronically with other equipment, including other MEDICAL DEVICES. Such information is frequently exchanged through an information technology network (IT-NETWORK) that also transfers data of a more general nature. IEC 80001-1:2010 addresses RISK MANAGEMENT of IT-NETWORKS incorporating MEDICAL DEVICES.

ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL DEVICE or other parts of system to distribute ALARM CONDITIONS, or to warn the OPERATOR of HAZARDS to the PATIENT or OPERATOR. The ALARM CONDITIONS that cause these ALARM SIGNALS are often transmitted across the MEDICAL IT-NETWORK, creating a system to distribute ALARM CONDITIONS.

A system to distribute ALARM CONDITIONS provides great benefits; however, as with any technology, certain RISKS are introduced that can affect the three KEY PROPERTIES of SAFETY, EFFECTIVENESS, and DATA AND SYSTEMS SECURITY.

This technical report is consistent with other guidance documents of this series [1][2][3][4][5]¹.

¹ Numbers in square brackets refer to the Bibliography.



IEC

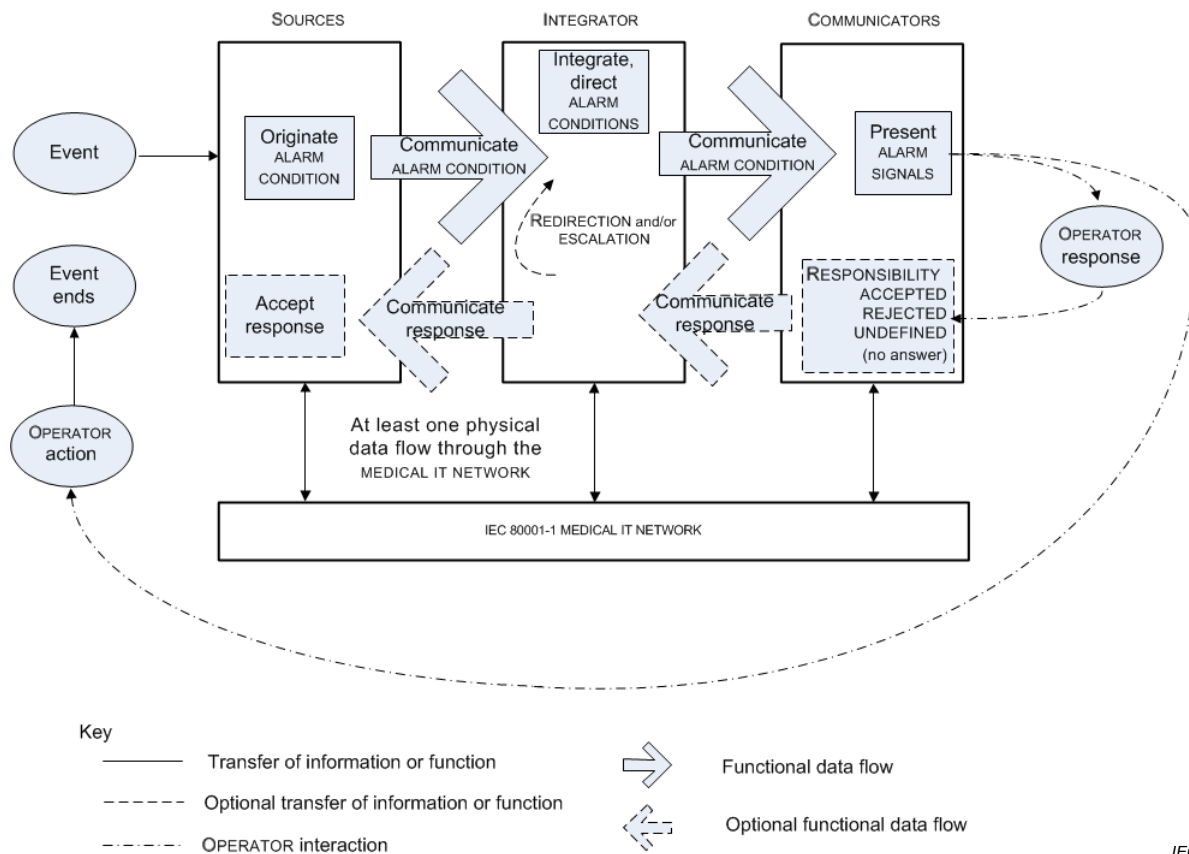
Figure 1 – Focus of this technical report

Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems

1 Scope

This part of IEC 80001, which is a technical report, gives guidance and practical techniques for RESPONSIBLE ORGANIZATIONS, MEDICAL DEVICE manufacturers and providers of other information technology in the application of IEC 80001-1:2010 for the RISK MANAGEMENT of DISTRIBUTED ALARM SYSTEMS. This technical report applies to the transmission of ALARM CONDITIONS between SOURCES, INTEGRATOR and COMMUNICATORS where at least one SOURCE is a MEDICAL DEVICE and at least one communication path utilizes a MEDICAL IT-NETWORK.

This technical report provides recommendations for the integration, communication of responses and REDIRECTION (to another OPERATOR) of ALARM CONDITIONS from one or more SOURCES to ensure SAFETY and EFFECTIVENESS. DATA AND SYSTEMS SECURITY is an important consideration for the RISK MANAGEMENT of DISTRIBUTED ALARM SYSTEMS. Figure 2 illustrates the functions of a MEDICAL IT-NETWORK incorporating SOURCES, an INTEGRATOR and COMMUNICATORS to distribute ALARM CONDITIONS.



NOTE This is a functional diagram and does not imply that these functions are in separate components. It is possible for functionality to be provided in one or more components.

Figure 2 – Functions of a MEDICAL IT-NETWORK incorporating SOURCES, an INTEGRATOR and COMMUNICATORS to distribute ALARM CONDITIONS

The following is a typical chain of events. An event is detected by a SOURCE that initiates an ALARM CONDITION. The SOURCE sends the ALARM CONDITION to the INTEGRATOR. Based on the RESPONSIBLE ORGANIZATION-established assignment protocol, the INTEGRATOR directs the ALARM CONDITION to the assigned COMMUNICATOR. The COMMUNICATOR generates the appropriate ALARM SIGNALS. The INTEGRATOR now waits for an OPERATOR response from the COMMUNICATOR or for the SOURCE to indicate that the ALARM CONDITION no longer exists.

If the COMMUNICATOR is capable of accepting a response and the OPERATOR responds, the OPERATOR indicates that it either accepts or rejects responsibility for the ALARM CONDITION. If the OPERATOR rejects the responsibility, the INTEGRATOR redirects the ALARM CONDITION to a different COMMUNICATOR (i.e. a different OPERATOR) and might also escalate the priority of the ALARM CONDITION. Eventually an OPERATOR accepts responsibility for the ALARM CONDITION. When an OPERATOR has taken appropriate action, the ALARM CONDITION subsequently ends. Alternately, the ALARM CONDITION could end without OPERATOR action in which case when the SOURCE notifies the INTEGRATOR that the ALARM CONDITION is no longer present, the INTEGRATOR instructs the COMMUNICATOR to stop generating ALARM SIGNALS. Should an ALARM CONDITION remain uncorrected for an extended period of time, the ALARM SYSTEM should cause the ESCALATION of the ALARM CONDITION, notify additional OPERATORS, etc.

EXAMPLE A pulse oximeter detects a low SpO₂ level in the PATIENT, initiates an ALARM CONDITION and sends that ALARM CONDITION to the INTEGRATOR via a MEDICAL IT-NETWORK. The INTEGRATOR then directs that ALARM CONDITION to the COMMUNICATOR that is mapped to the clinical OPERATOR assigned to the PATIENT via a MEDICAL IT-NETWORK.

OPERATOR A responds by rejecting responsibility for the ALARM CONDITION. The COMMUNICATOR sends this response information back to the INTEGRATOR, which then redirects the ALARM CONDITION to the COMMUNICATOR of clinical OPERATOR B. OPERATOR B then accepts responsibility for the ALARM CONDITION. The COMMUNICATOR sends this response information back to the INTEGRATOR, which then sends it back to the SOURCE causing an ALARM SIGNAL inactivation state (e.g. AUDIO PAUSED) to be generated. OPERATOR B adjusts the oxygen concentration in the gas going to the PATIENT and the ALARM CONDITION ceases (e.g. the event ends).

2 Normative references

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

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 33.

IEC 80001-1:2010, *Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE An index of defined terms is found beginning on page 34.

3.1

ALARM CONDITION

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

Note 1 to entry: An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

Note 2 to entry: An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 3.1]

3.2

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 1 to entry: Some algorithmically-determined ALARM SETTINGS can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006, 3.8]

3.3

ALARM SIGNAL

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

[SOURCE: IEC 60601-1-8:2006, 3.9, modified – added 'or COMMUNICATOR'.]