SEK Teknisk rapport 80001-2-5

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

(IEC Technical Report 80001-2-5:2014)

Denna publikation ingår i en serie med tekniska rapporter som ansluter till standarden SS-EN 80001-1, Riskhantering tillämpad på IT-nätverk som innehåller eller är kopplade till medicintekniska produkter – Del 1: Roller, ansvar och aktiviteter. Den är avsedd att ge vårdgivare vägledning beträffande grunderna för riskhantering för ett medicintekniskt IT-nätverk.

För närvarande finns fem tekniska rapporter i serien. De är:

Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples

Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls

Part 2-3: Guidance for wireless networks

Part 2-4: Application guidance – General implementation guidance for healthcare delivery organizations

Part 2-5: Application guidance – Guidance on distributed alarm systems

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Upplysningar om **sakinnehållet** i rapporten lämnas av
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FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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 '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

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].

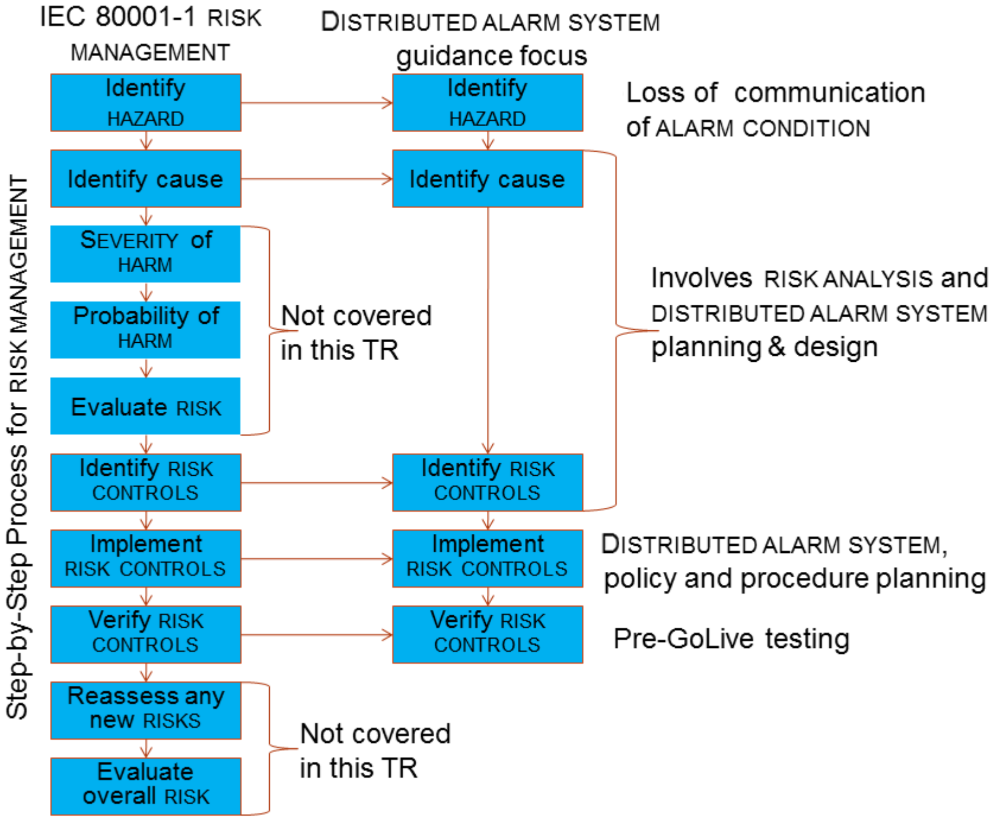


Figure 1 – Focus of this technical report

[1] Numbers in square brackets refer to the Bibliography.

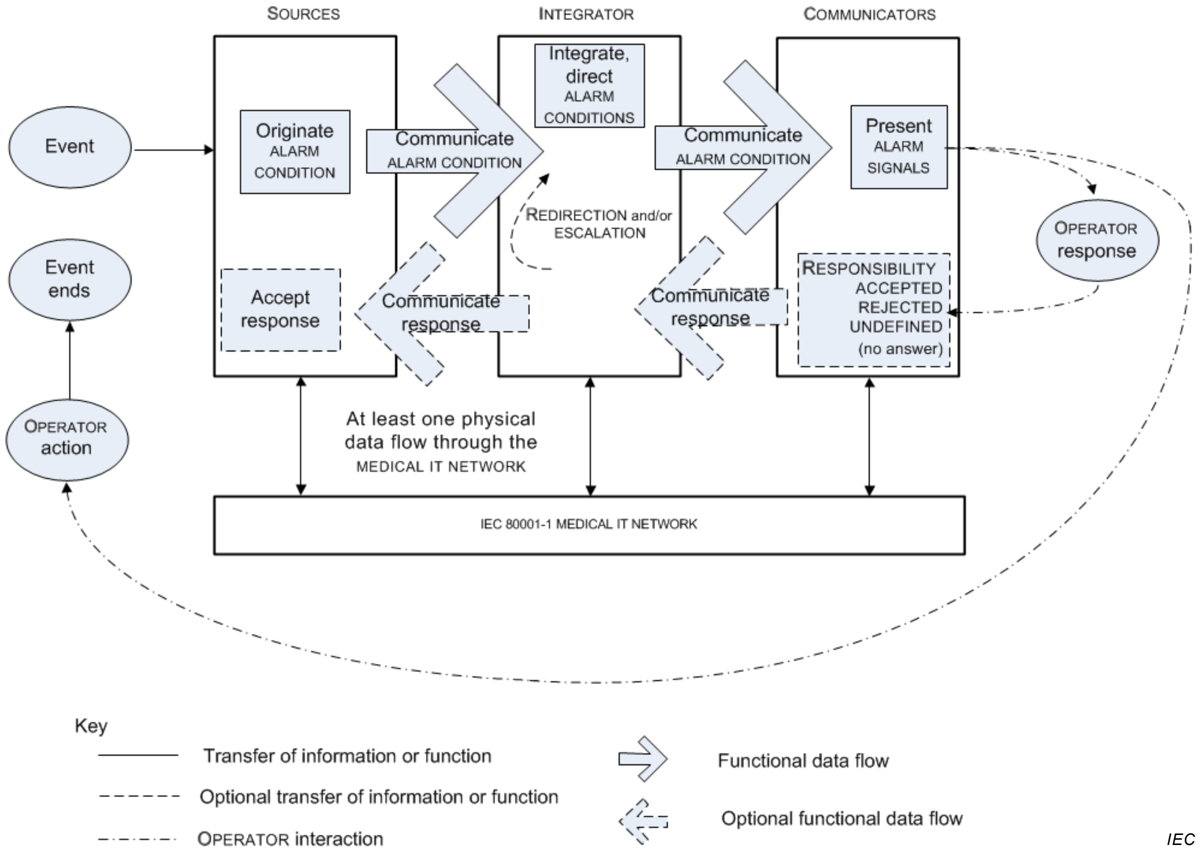
APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS INCORPORATING MEDICAL DEVICES –

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.


SOURCES
INTEGRATOR
COMMUNICATORS
Event
Originate ALARM CONDITION
Communicate ALARM CONDITION
Integrate, direct ALARM CONDITIONS
REDIRECTION and/or ESCALATION
Communicate ALARM CONDITION
Present ALARM SIGNALS
OPERATOR response
Event ends
Accept response
Communicate response
Communicate response
RESPONSIBILITY ACCEPTED REJECTED UNDEFINED (no answer)
OPERATOR action
At least one physical data flow through the MEDICAL IT NETWORK
IEC 80001-1 MEDICAL IT NETWORK
Key
Transfer of information or function
Optional transfer of information or function
OPERATOR interaction
Functional data flow
Optional functional data flow
IEC

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 SpO_2 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 37.

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