This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

PD IEC/TR 80001-2-5:2014

BSI Standards Publication

Application of risk management for IT-networks incorporating medical devices

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

bsi.

...making excellence a habit.™

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

This Published Document is the UK implementation of IEC/TR 80001-2-5:2014.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Sub-committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.
Published by BSI Standards Limited 2015

ISBN 978 0 580 85983 0
ICS 11.040.01; 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 January 2015.

Amendments/corrigenda issued since publication

Date	Text affected

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

Edition 1.0 2014-12

TECHNICAL REPORT

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

PRICE CODE W

ICS 11.040.01; 35.240.80

ISBN 978-2-8322-1969-0

Warning! Make sure that you obtained this publication from an authorized distributor.

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Normative references 8
3 Terms and definitions 8
4 Functions of the distribution of ALARM CONDITIONS 16
4.1 General 16
4.2 SOURCES and their ALARM CONDITIONS 17
4.3 INTEGRATOR 17
4.4 COMMUNICATOR 17
4.5 MEDICAL IT-NETWORK 18
5 Types of systems for distributing ALARM CONDITIONS 18
5.1 General 18
5.2 DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS 19
5.3 DISTRIBUTED ALARM SYSTEM 19
5.4 DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION 19
6 RISK MANAGEMENT 20
6.1 General explanation 20
6.2 Determining the RESPONSIBLE ORGANIZATION'S objective purpose 20
6.3 HAZARDS and HAZARDOUS SITUATIONS related to DIS, DAS and CDAS 21
6.4 Causes and resulting HAZARDOUS SITUATIONS 21
6.5 RISK CONTROL measures related to the integration of ALARM CONDITIONS 23
6.5.1 Technical RISK CONTROL measures implemented in equipment 23
6.5.2 Typical RISK CONTROL measures for implementation by the RESPONSIBLE ORGANIZATION 25
6.5.3 Organizational policies and procedures as RISK CONTROL measures for implementation by the RESPONSIBLE ORGANIZATION 26
Annex A (informative) Correspondence between the RISK CONTROL measures of this technical report and IEC 60601-1-8 28
Annex B (informative) Types of SOURCES 29
B.1 MEDICAL DEVICES 29
B.2 NURSE CALL SYSTEM 30
ANNEX C (informative) Applicability of types of system for the distribution of ALARM CONDITIONS 32
Annex D (informative) Scalability of types of system for the distribution of ALARM CONDITIONS 35
Bibliography 37
Index of defined terms used in this technical report 38

Figure 1 – Focus of this technical report 6
Figure 2 – Functions of a MEDICAL IT-NETWORK incorporating SOURCES, an INTEGRATOR and COMMUNICATORS to distribute ALARM CONDITIONS 7
Figure C.1 – Cascading structure of system for the distribution of ALARM CONDITIONS 32
Figure C.2 – Example for INTEGRATOR of a PATIENT monitor with central monitoring station to distribute ALARM CONDITIONS in a physically isolated IT-NETWORK in a CDAS 33

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

Figure C.3 – Example for INTEGRATOR of a PATIENT monitor to distribute ALARM CONDITIONS in a NURSE CALL SYSTEM, and via a PBX with handsets 34

Figure D.1 – Example hospital-wide DISTRIBUTED ALARM SYSTEM 36

Table 1 – General comparison of system properties for ALARM CONDITION integration 18

Table A.1 – Correspondence of the technical RISK CONTROL measures of this technical report for a CDAS and IEC 60601-1-8 for a DAS 28

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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

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

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.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

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.

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

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].

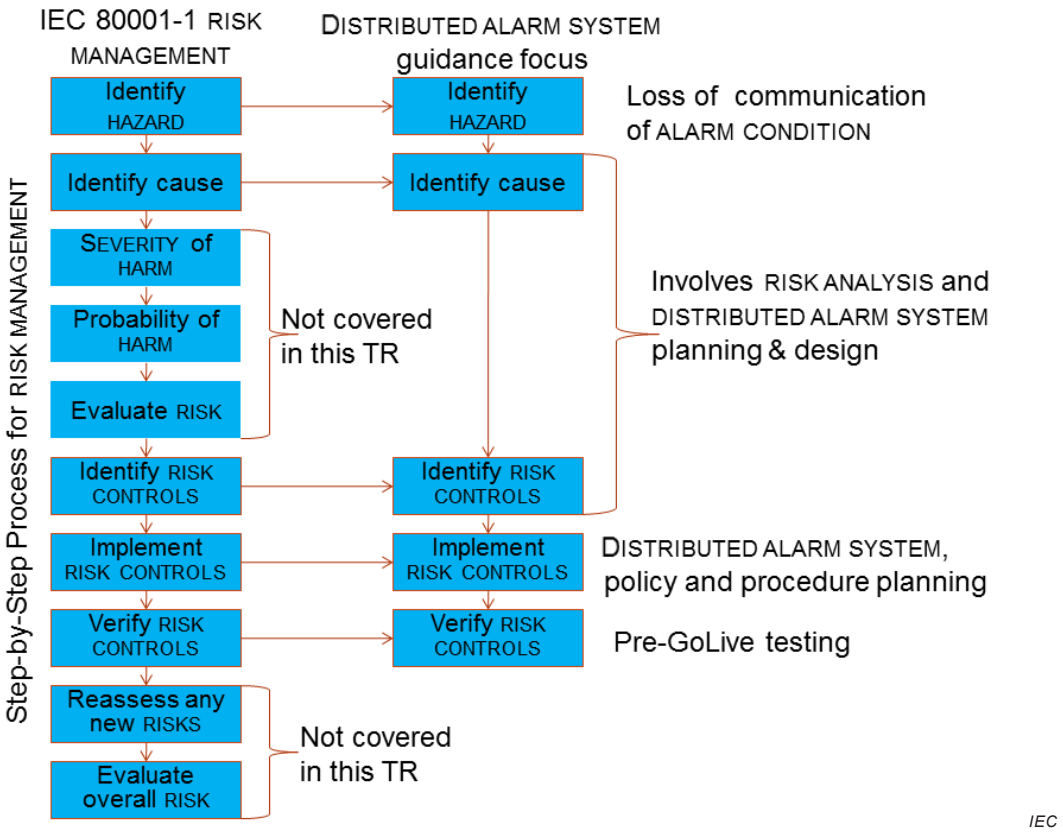


Figure 1 – Focus of this technical report

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

This is a preview of "PD IEC/TR 80001-2-5:...". Click here to purchase the full version from the ANSI store.

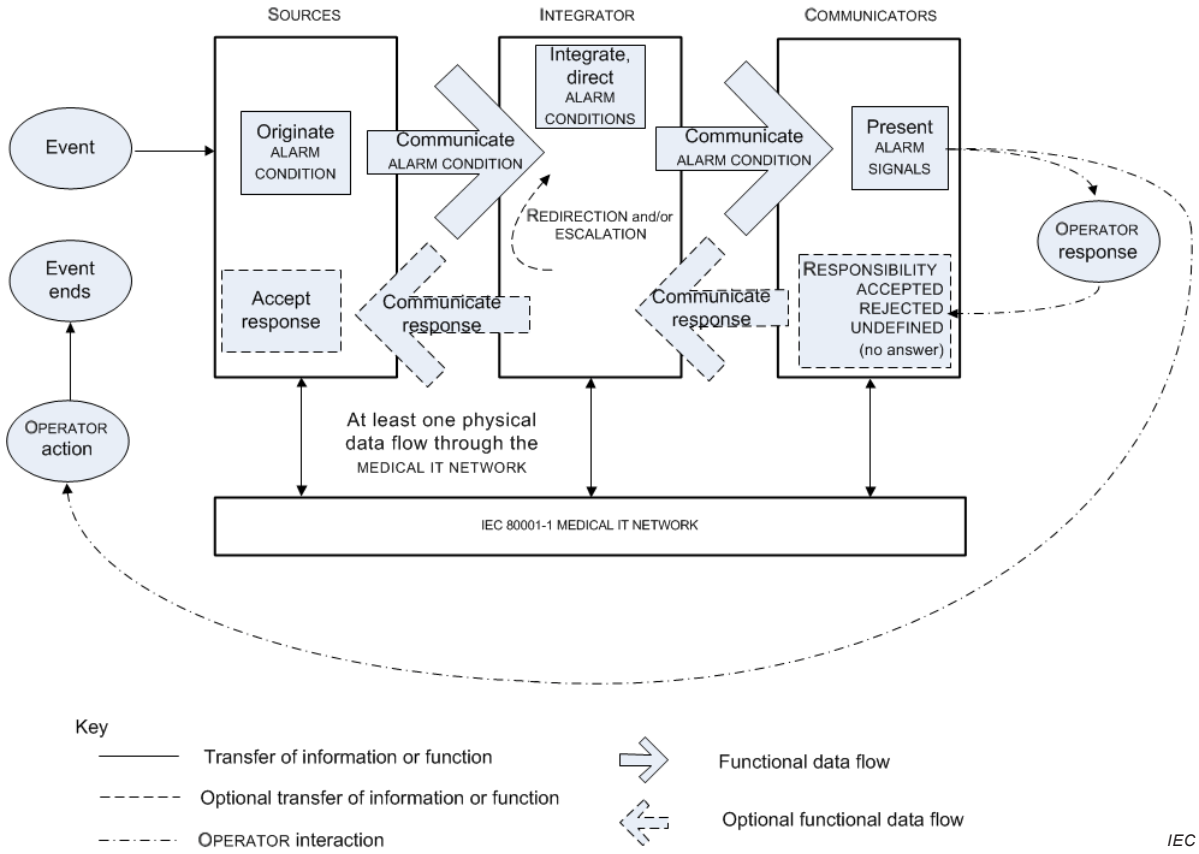
APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS INCORPORATING MEDICAL DEVICES –

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