IEC TR 60601-4-1

Edition 1.0 2017-05

TECHNICAL REPORT

colour inside

Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-4329-9

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

® Registered trademark of the International Electrotechnical Commission

CONTENTS

FOREWORD 5
INTRODUCTION 7
1 Scope 9
2 Normative references 9
3 Terms and definitions 10
4 DEGREE OF AUTONOMY (DOA) 17
4.1 Introduction to DEGREE OF AUTONOMY 17
4.2 Methodology to determine DEGREE OF AUTONOMY 17
4.3 Relationship between DOA and RISK 18
5 PROCESS STANDARDS supporting DOA 18
5.1 General 18
5.2 RISK MANAGEMENT PROCESS 19
5.2.1 Defining INTENDED USE 19
5.2.2 INTENDED USE and characteristics related to SAFETY 19
5.3 RISK CONTROL 20
5.3.1 General 20
5.3.2 RISK CONTROL hierarchy 21
5.4 USABILITY engineering considerations for MEE or MES having a higher DOA 22
5.4.1 General 22
5.4.2 OPERATOR situation awareness 22
5.4.3 OPERATOR reaction time 23
5.4.4 OPERATOR sensory input and response 23
5.4.5 Detectability by OPERATOR of malfunction or errors of MEE or MES with a higher DOA 23
5.5 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) and software development LIFE CYCLE (IEC 62304) 23
5.6 Application of RISK MANAGEMENT for IT-networks incorporating medical devices 24
6 BASIC SAFETY and ESSENTIAL PERFORMANCE related to DOA 25
6.1 GENERAL 25
6.2 BASIC SAFETY related to DOA 25
6.3 ESSENTIAL PERFORMANCE related to DOA 26
Annex A (informative) Rationale for defining the AUTOMATIC, AUTONOMY and DOA framework and the distinction between a MEDICAL ROBOT and other MEE or MES 28
A.1 General 28
A.2 Existing definitions and limitations 28
A.3 New approaches 29
A.4 Definition of MONITOR – GENERATE – SELECT – EXECUTE 30
A.5 Approaches to define ROBOT and MEDICAL ROBOT 31
A.6 Conclusions 31
Annex B (informative) DOA and relevant terms used in MEE standards 32
B.1 General 32
B.2 Procedure 32
B.3 Results 32
B.3.1 Summary 32
B.3.2 Tables 33
Annex C (informative) Exemplar methods for classifying DEGREE OF AUTONOMY 42

C.1 Descriptive method 42
C.2 Binary method 43
C.3 Weighted method 44
Annex D (informative) Examples of introducing DOA to MEE/MES 50
D.1 General 50
D.2 Example 1 – Lower extremity exoskeleton 50
D.2.1 Description of the medical procedures 50
D.2.2 DOA classification method 50
D.2.3 Effect of DOA on the RISK MANAGEMENT PROCESS 52
D.3 Example 2 – Orthopaedic MEE/MES/MEDICAL ROBOT for reshaping bone 54
D.3.1 Description of the medical procedures 54
D.3.2 DOA classification method 54
D.3.3 Effect of DOA on the RISK MANAGEMENT PROCESS 55
D.3.4 Summary and conclusions 55
D.4 Example 3 – Instrument exchange on robotically-assisted surgical equipment 55
D.4.1 Description of the medical procedures 55
D.4.2 DOA classification method 56
D.4.3 Effect of DOA on the RISK MANAGEMENT PROCESS 56
D.4.4 Summary and conclusions 57
D.5 Example 4 – Master–slave robotically-assisted surgical equipment 57
D.5.1 Description of the medical procedures 57
D.5.2 DOA classification method 58
D.5.3 Effect of DOA on RISK MANAGEMENT PROCESS 58
D.5.4 Summary and conclusions 58
D.6 Example 5 – Image-guided radiotherapy equipment 58
D.6.1 Description of the medical procedures 58
D.6.2 DOA classification method 59
D.6.3 RISK ANALYSIS for each level of DOA 61
D.6.4 Effect of DOA on the RISK MANAGEMENT PROCESS 61
D.6.5 Summary and conclusions 61
D.7 Example 6 – Automated external defibrillator (AED) 62
D.7.1 Description of the medical procedures 62
D.7.2 DOA classification method 63
D.7.3 Effect of DOA on the RISK MANAGEMENT PROCESS 64
D.7.4 Summary and conclusions 64
Annex E (informative) PATIENT SAFETY characteristics to be taken into account during RISK MANAGEMENT for MEE or MES employing DOA 65
E.1 Types of PATIENTS 65
E.2 Additional attention for child (PATIENT) SAFETY 65
E.3 PATIENT abilities and variability of physiological signals 66
E.3.1 ISO/IEC Guide 71 66
E.3.2 Changing need and abilities of PATIENTS 66
E.3.3 PATIENT'S sensory abilities 66
E.3.4 PATIENT'S PHYSICAL ABILITIES 67
E.3.5 PATIENT'S COGNITIVE ABILITIES 67
E.3.6 PATIENT ALLERGIES 67
ANNEX F (informative) PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM AND DOA 69
Annex G (informative) Examples of distributed ESSENTIAL PERFORMANCE 72
Bibliography 75

Figure 1 – Basic model of interoperability of MEE in an MES (Order of execution: 1 to 3) 25
Figure A.1 – ALFUS approach applied to MEE or MES applications 30
Figure C.1 – Application of weighted method to the "MONITOR" TASK 45
Figure C.2 – Application of weighted method to "GENERATE OPTIONS" 46
Figure C.3 – Application of weighted method to "SELECT OPTION" TASK 47
Figure C.4 – Application of weighted method to the "EXECUTE" TASK 48
Figure F.1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM (PCLCS) utilizing a PCLC 69
Figure F.2 – Examples of introducing DOA into the MONITORING TASK via PCLCS 70
Figure F.3 – Examples of introducing DOA into the GENERATING TASK via PCLCS 70
Figure F.4 – Examples of introducing DOA into the SELECTION TASK via PCLCS 70
Figure F.5 – Examples of introducing DOA into the EXECUTION TASK via PCLCS 71

Table 1 – Examples of ESSENTIAL PERFORMANCE of MEE or MES with a DOA 27
Table B.1 – List of terms that indicate the use of AUTONOMY 33
Table B.2 – List of reviewed standards – sorted by standard number *(1 of 4)* 34
Table B.3 – List of identified inconsistencies in reviewed standards *(1 of 2)* 40
Table C.1 – Descriptive classification of DOA 43
Table C.2 – Binary classification of DOA 44
Table D.1 – Example 1 – Effect of DOA on the RISK MANAGEMENT PROCESS 52
Table D.2 – Example 1 – Physical and cognitive capability of individual and CLINICAL FUNCTION needed 52
Table D.3 – Example 1 – Sub-function TASK example 53
Table D.4 – Example 2 – Effect of DOA on the RISK MANAGEMENT PROCESS 55
Table D.5 – Example 3 – Comparison of instrument exchange design implementations 57
Table D.6 – Example 3 – Effect of DOA on the RISK MANAGEMENT PROCESS 57
Table D.7 – Example 4 – Effect of DOA on the RISK MANAGEMENT PROCESS 58
Table D.8 – Example 5 – Descriptive classification of DOA for IGRT MEE 60
Table D.9 – Example 5 – Binary classification of DOA for IGRT MEE 60
Table D.10 – Example 5 – Effect of DOA on the RISK MANAGEMENT PROCESS 62
Table D.11 – Example 6 – Descriptive method classification of DOA in external defibrillators 63
Table D.12 – Example 6 – Effect of DOA on the RISK MANAGEMENT PROCESS 64
Table G.1 – Examples of distributed ESSENTIAL PERFORMANCE *(1 of 3)* 72

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy

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 60601-4-1, which is a technical report, has been prepared by a Joint Working Group of IEC 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 299: Robotics.

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

Enquiry draft	Report on voting
62A/1099/DTR	62A/1129A/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.

In this technical report, the following print types are used:

– recommendations and definitions: roman type.
– *test instructions: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THIS TECHNICAL REPORT OR AS NOTED: SMALL CAPITALS.

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

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.

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

This Technical Report is the result of work that began in ISO/TC 184/SC 2/WG 7 in October 2006 on personal care ROBOTS, to address an emerging type of ROBOT that was used outside of an industrial environment. That group was working on a new standard, ISO 13482, which was published as an International Standard (IS) in 2014. While initially focused on non-medical applications, WG 7 recognized that work was likely to be needed on medical devices utilizing robotic technology. In September 2009, ISO/TC 184/SC 2 established a WG 7, *Study Group (SG) on Medical care robots*, comprised of experts from Canada, France, Germany, Japan, Korea, Romania, Switzerland, UK and USA.

The work of ISO/TC 184/SC 2/WG 7 [1] SG cumulated in a proposal to form a Joint Working Group with IEC/SC 62A to develop general requirements and guidance related to the SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that utilize robotic technology. The work would include medical applications (including aids for the disabled) covering invasive and non-invasive procedures such as surgery, rehabilitation therapy, imaging and other ROBOTS for medical diagnosis and treatment. The proposal was approved, resulting in the formation of Joint Working Group (JWG) 9 (*Medical electrical equipment and systems using robotic technology*) and the first meeting was held in Los Angeles in June 2011.

JWG 9 examined the definition of a ROBOT from ISO 8373:2012 (which was later modified to a "programmed actuated mechanism with a DEGREE OF AUTONOMY (DOA), moving within its environment, to perform intended TASKS") and AUTONOMY (the "ability to perform intended TASKS based on current state and sensing, without human intervention"). It was recognized by JWG 9 that these definitions could need further refinement to establish the appropriate boundaries for future standardisation work. AUTONOMY and DEGREE OF AUTONOMY (DOA) were felt to be key ingredients in distinguishing a "MEDICAL ROBOT" from other types of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

However, JWG 9 came to realize that there are currently standardized MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that exhibit a DOA. Therefore, DOA by itself is not a unique characteristic of a MEDICAL ROBOT. This can be stated more clearly as follows:

– not all MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that exhibit a DOA are MEDICAL ROBOTS; but

– all MEDICAL ROBOTS exhibit a DOA.

Hence a MEDICAL ROBOT can be a MEDICAL ELECTRICAL EQUIPMENT or part of a MEDICAL ELECTRICAL SYSTEM, but not all MEDICAL ELECTRICAL EQUIPMENT are MEDICAL ROBOTS.

NOTE The majority of existing MEDICAL ELECTRICAL EQUIPMENT are not considered as MEDICAL ROBOTs.

The MANUFACTURER states clearly the type of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEM through the INTENDED USE of their product. For this INTENDED USE, a definition of MEDICAL ROBOT would be helpful to have a common understanding if this MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM can be tagged as a MEDICAL ROBOT equipment or MEDICAL ROBOT system. The definition of MEDICAL ROBOT is therefore helpful to distinguish if the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM is a MEDICAL ROBOT and the INTENDED USE as indicated by the MANUFACTURER. This distinction is clarified in Annex A.

DOA is normally considered for adoption into MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for the following reasons:

– DOA could give benefits to CLINICAL FUNCTION outcomes;

---

[1] ISO TC 184/SC 2 was reformed to ISO TC 299 in January 2016.

– DOA could give economic value to MEDICAL ELECTRICAL EQUIPMENT;
– DOA could improve the consistency of medical procedures;
– DOA could handle more complex data;
– DOA could lead to faster reaction times;
– DOA could optimise medical procedure times or duration;
– DOA could make it easier to integrate MEDICAL ELECTRICAL SYSTEMS;
– DOA could decrease the overall level of RISK; and
– DOA could change the role of an OPERATOR to a more supervisory than active (hands on) function.

In order to progress the work of JWG 9, it was agreed to focus on the IEC 60601-1 standard family and see how specific clauses could be extended to cover the additional DOA issues in a possible new Technical Report once fully developed. JWG 9 looked at existing MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that had characteristics of a ROBOT based on the definition, and investigated the suitability of the existing standards to address the HAZARDS associated with their use. As a result of this investigation, it was acknowledged that IEC 60601 (all parts), ISO 14971, IEC 62366-1 and IEC 62304 provide appropriate general requirements and guidance on how to address the HAZARDS; however, emerging functionality associated with increased DOA on MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, whether a ROBOT or not, could result in situations where BASIC SAFETY and ESSENTIAL PERFORMANCE are considered again by the MANUFACTURER.

Current MEDICAL ELECTRICAL EQUIPMENT standards do not fully address higher DOA modes of operation, and this document is intended to provide guidance for MANUFACTURERS and others in this field on how DOA could be introduced into MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. Incorporation of higher levels of AUTONOMY in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is still new and rapidly evolving, and at the time of writing this document does not lend itself to general standardization.

The importance of understanding DOA can be illustrated by examining its effects in other industries. The airline industry is one example in which increasing DOA has often been implemented as a RISK CONTROL measure. However, there are numerous examples in the airline industry in which increased DOA was found to have been a major contributor to a fatal accident [70].[2] To avoid similar mistakes in the field of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, MANUFACTURERS learn from these other fields and not only characterize DOA but also understand its potential for unintentionally increasing RISK.

It is important to point out that this IEC document is an informative document as are all IEC Technical Reports (ISO/IEC Guide 2 [61]). The concept and approach stated in the STATE OF THE ART are not intended to be addressed through this informative document. This document is not used as a normative requirement as per the claimed STATE OF THE ART by any country or community. This document is an **informative** document, which is intended to provide existing and future designers of MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS some guidance and direction concerning the adoption of DOA. This document is not applicable as a base for a testing procedure or writing a test protocol template.

2 Numbers in square brackets refer to the bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy

1 Scope

This Part of IEC 60601 is intended to help a MANUFACTURER through the key decisions and steps to be taken to perform a detailed RISK MANAGEMENT and USABILITY ENGINEERING PROCESSES for MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM, hereafter referred to as MEE or MES, employing a DEGREE OF AUTONOMY (DOA).

This document provides a definition of DOA of MEE or MES and a MEDICAL ROBOT, and also provides guidance on:

– methodologies to perform the RISK MANAGEMENT PROCESS and USABILITY ENGINEERING for an MEE or MES with a DOA;
– considerations of BASIC SAFETY and ESSENTIAL PERFORMANCE for an MEE and MES with a DOA; and
– identifying the use of DOA, and similar concepts in existing ISO/IEC standards dealing with MEE or MES with the goal to facilitate alignment of standards by consistent use of the concept of DOA; and
– distinguishing between MEDICAL ROBOTS, and other MEE and MES.

Unless specified otherwise, this document considers MEE and MES together.

The MANUFACTURER of an MEE or MES with a DOA is expected to design and manufacture an MEE or MES that fulfils its INTENDED USE and does not have unacceptable RISK throughout its LIFE-CYCLE.

This document provides guidance to help the MANUFACTURER in complying with the requirements of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 for MEE and MES with DOA. The document is also intended as guidance for future standard writers.

There are no prerequisites to this document.

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 [3]

[3] There exists a consolidated edition 3.1, including IEC 60601-1:2005 and its Amendment 1:2012.

IEC 62304:2006, *Medical device software – Software life cycle processes*
IEC 62304:2006/AMD1:2015 [4]

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

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

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

4 There exists a consolidated edition 1.1, including IEC 62304:2006 and its Amendment 1:2015.