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

IEC TR 60601-4-1:2017-05(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-4329-9

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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.

It is published as a double logo standard.

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- withdrawn,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.

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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;

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[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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp.

3.1
APPLIED PART
part of MEE that in normal use necessarily comes into physical contact with the PATIENT for MEE or an MES to perform its function

Note 1 to entry: See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive) [of IEC 60601-1:2005].

Note 2 to entry: See also 4.6 [of IEC 60601-1/AMD1:2012] regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

Note 3 to entry: See also 3.78 [of IEC 60601-1:2005] for the definition of the associated term "PATIENT CONNECTION".

[SOURCE: IEC 60601-1:2005, 3.8]

3.2
AUTOMATIC
referring to capabilities that, under specified conditions, function without OPERATOR intervention

Note 1 to entry: Some, but not all MEE and MES have functions with certain DOA stated as AUTOMATIC. Because of possible confusion, it is recommended that the term AUTOMATIC not be used when referring to DOA of MEE or MES.

Note 2 to entry: Definition derived from IEC 62443-3-3:2013, 3.1.7.

3.3
AUTONOMOUS
having full AUTONOMY

Note 1 to entry: The term AUTONOMOUS in common language has been used to indicate 'having high DOA' without specifying what degree is 'high'. It is recommended that the term AUTONOMOUS be used carefully.

Note 2 to entry: This definition of the term AUTONOMOUS was developed taking into account the definition in IEC TR 61850-90-7:2013, 3.1. The rationale for the modification is given in Clause A.2.

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

3.4
AUTONOMY
capacity to MONITOR, GENERATE, SELECT and EXECUTE to perform a CLINICAL FUNCTION with no or limited OPERATOR intervention

Note 1 to entry: The term AUTONOMY in common language has been used to indicate 'null DOA' or 'full DOA' without allowing intermediate capability. It is recommended that the term AUTONOMY be used carefully, and whenever possible, to use the term DOA instead.

Note 2 to entry: The terms 'null (no, zero) AUTONOMY' and 'full AUTONOMY' can be used to mean 'null DOA' and 'full DOA' without confusion.

Note 3 to entry: This definition of the term AUTONOMY was developed taking into account the definition in ISO 8373:2012, 2.2. The rationale for the modification is given in Clause A.2.

3.5
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical HAZARDS when MEE is used under NORMAL CONDITION and SINGLE FAULT CONDITION

[SOURCE: IEC 60601-1:2005, 3.10]

3.6
CLINICAL FUNCTION
medical operation that the MEE or MES is intended to perform

Note 1 to entry: CLINICAL FUNCTION is generally a subset of the INTENDED USE of the MEE or MES related to the PATIENT.

3.7
DEGREE OF AUTONOMY
DOA
taxonomy based on the properties and capabilities of the MEE or MES related to AUTONOMY

3.8
ESSENTIAL PERFORMANCE
performance of a CLINICAL FUNCTION, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.27, modified – Note deleted]

3.9
EXECUTE, verb
carry out the selected OPTION

Note 1 to entry: Derived from Kaber and Endsley [70], which originally used 'implementing' instead of EXECUTE.

3.10
EXPECTED SERVICE LIFE
time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

Note 1 to entry: Maintenance can be necessary during the EXPECTED SERVICE LIFE.

[SOURCE: IEC 60601-1/AMD1:2012, 3.28]

3.11
GENERATE, verb
to formulate possible OPTIONS, based on the result of the MONITOR TASK, for achieving predefined goals

Note 1 to entry: Derived from Kaber and Endsley [70], which defined the term as 'formulating options or TASK strategies for achieving goals'.

3.12
HARM
physical injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.38]

3.13
HAZARD
potential source of HARM

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.39]

3.14
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.40]

3.15
INTENDED USE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.44, modified – Deletion of the term "INTENDED PURPOSE".]

3.16
LIFE-CYCLE
all phases in the life of a MEE or MES, from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7, modified – "Medical device" replaced by "MEE or MES".]

3.17
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of MEE, assembling an MES, or adapting MEE or an MES, regardless of whether these operations are performed by that person or on that person's behalf by a third party

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55]

3.18
MEDICAL ELECTRICAL EQUIPMENT
MEE
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used:

   1) in the diagnosis, treatment, or monitoring of a PATIENT; or

   2) for compensation or alleviation of disease, injury or disability

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.63, modified – Notes deleted.]