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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

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TECHNICAL REPORT

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

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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.

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- withdrawn,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.]

3.19
MEDICAL ELECTRICAL SYSTEM
MES
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is MEE to be inter-connected by functional connection or by use of a multiple socket-outlet

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.64, modified – Note deleted.]

3.20
MEDICAL ROBOT
ROBOT intended to be used as MEE or MES

3.21
MISUSE
use of MEE or an MES not intended by the MANUFACTURER

Note 1 to entry: Includes reasonably foreseeable MISUSE and not foreseeable MISUSE.

3.22
MOBILE
term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.65, modified – Note deleted.]

3.23
MONITOR, verb
to collect and interpret necessary information to perceive the status of MEE or MES, PATIENT, OPERATOR, or environment

Note 1 to entry: Derived from Kaber and Endsley [70], which defined the term as 'which includes taking in all information relevant to perceiving system status (e.g. scanning visual displays)'.

3.24
NORMAL CONDITION
condition in which all means provided for protection against HAZARDS are intact

[SOURCE: IEC 60601-1:2005, 3.70]

3.25
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73, modified – Note deleted.]

3.26
OPTION
TASK strategy able to achieve the desired CLINICAL FUNCTION

3.27
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an OPERATOR.

[SOURCE: IEC 60601-1:2005, 3.76]

3.28
PHYSIOLOGIC CLOSED-LOOP CONTROLLER
element of a physiologic closed-loop control system in which a feedback variable is compared with a reference variable, and their difference is transformed to set the controller output variable

[SOURCE: IEC 60601-1-10:2007, 3.20, modified – Definition simplified to remove variable notation and informative reference to Figure 1 of IEC 60601-1-10:2007.]

3.29
PHYSIOLOGIC VARIABLE
quantity or condition from a PATIENT whose value is subject to change and can usually be measured

[SOURCE: IEC 60601-1-10:2007, 3.21, modified – Note deleted]

3.30
PROCESS
set of interrelated or interacting activities which transform inputs into outputs

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.89]

3.31
PROCESS STANDARD
standard that establishes a framework within which the MANUFACTURER is able to design and develop MEE or MES of consistent SAFETY and effectiveness

Note 1 to entry: Definition modified from ISO/IEC Guide 63:2012, 3.3.2.

3.32
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM
PEMS
MEE or an MES containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

[SOURCE: IEC 60601-1:2005, 3.90]

3.33
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS
system based on one or more central processing units, including their software and interfaces

[SOURCE: IEC 60601-1:2005, 3.91]

3.34
RISK
combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.102]

3.35
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.103]

3.36
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: ISO 14971:2007, 2.18]

3.37
RISK CONTROL
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: ISO 14971:2007, 2.19]

3.38
RISK EVALUATION
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.106]

3.39
RISK MANAGEMENT
systematic application of management policies, PROCEDURES and practices to the TASKS of analysing, evaluating and controlling RISK

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.107]

3.40
ROBOT
programmed actuated mechanism with a DEGREE OF AUTONOMY, moving within its environment, to perform intended TASKS

[SOURCE: ISO 8373:2012, 2.6, modified (based on Stuttgart June 2015 Resolution) – The phrase "actuated mechanism programmable in two or more axes" was replaced with "programmed actuated mechanism".]

3.41
SAFETY
freedom from unacceptable RISK

[SOURCE: ISO 14971:2007, 2.24]

3.42
SELECT, verb
to decide on a particular OPTION from those GENERATED

Note 1 to entry: Derived from Kaber and Endsley [70], which defined the term as 'deciding on a particular OPTION or strategy'.

3.43
SEVERITY
measure of the possible consequences of a HAZARD

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.114]

3.44
SINGLE FAULT CONDITION
condition of MEE in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.116, modified – Note deleted.]

3.45
STATE OF THE ART
developed stage of technical capability at a given time as regards products, PROCESSES and services, based on the relevant consolidated findings of science, technology and experience

[SOURCE: ISO/IEC Guide 2:2004, 1.4]

3.46
SUPPLY MAINS
source of electrical energy not forming part of MEE or MES

Note 1 to entry: This also includes battery systems and converter systems in ambulances and the like.

[SOURCE: IEC 60601-1:2005, 3.120]

3.47
TASK
a single piece of work that needs to be done

[SOURCE: IEC 62304:2006, 3.31]

3.48
TRANSPORTABLE
term referring to equipment that, once installed and put into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.130, modified – Note and example deleted.]

3.49
USABILITY
characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the INTENDED USE environment

[SOURCE: IEC 62366-1:2015, 3.16, modified – Note deleted.]

3.50
USABILITY ENGINEERING
HUMAN FACTORS ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and TASKS to achieve adequate USABILITY

Note 1 to entry: Achieving adequate USABILITY can result in acceptable RISK related to use.

[SOURCE: IEC 62366-1:2015, 3.17]

4 DEGREE OF AUTONOMY (DOA)

4.1 Introduction to DEGREE OF AUTONOMY

This clause provides guidelines and examples (presented in Annex C) on how to classify AUTONOMY through the definition of DEGREE OF AUTONOMY. The rationale for the definition of DOA is presented in Annex A, and the usage of DOA and similar terms in MEE and MES standards is presented in Annex B. In summary, the following are assumed to apply:

– the DOA can vary from low to high; and
– DOA can be classified at different levels (e.g. TASK level, CLINICAL FUNCTION level, MEE or MES level) depending on where and how it is implemented in the MEE or MES.

The methodologies described in Annex C are not meant to be exhaustive, but to provide examples.

4.2 Methodology to determine DEGREE OF AUTONOMY

When AUTONOMY is applied to fulfil the INTENDED USE, the DOA can be examined.

A method for classification of DOA can be formulated. (Annex C presents several exemplar methods.) The methods should be based on an approach where four generic functions (or TASKS) are distinguished, which are:

a) MONITORING,
b) GENERATING OPTIONS,
c) SELECTING an OPTION, and
d) EXECUTING the selected OPTION.

Each of these generic TASKS can employ a different DOA. When using a method for classification, the resulting DOA of the MEE or MES is the composition of the DOA of the separate functions.

Exemplar methods of how the DOA can be classified are presented in Annex C where C.1 presents a descriptive method to characterize the varying DOA, which can then be applied in various analysis strategies.

Annex C presents a binary method of classifying different DOAs per generic function, where each function is classified as either "OPERATOR" (low DOA) or "MEE" (high DOA) depending on how the function is performed. Table C.2 translates the classification of each function into an overall DOA for the MES.

Annex C presents a weighting factor-based method to classify the DOA of the generic functions in order to come to a weighted DOA for the MEE or MES.

4.3 Relationship between DOA and RISK

When performing the RISK MANAGEMENT PROCESS according to ISO 14971, DOA should be taken into consideration. The DOA has no direct correlation with level of RISK, but it can impact the RISK MANAGEMENT PROCESS. For example, the MEE or MES could accomplish an AUTONOMOUS TASK better (e.g. safer, faster, more accurately) than an OPERATOR. Alternatively, an unintended consequence of increasing DOA is that it might increase RISK via loss of an OPERATOR's situation awareness [70]. For example, if an OPERATOR is required to assert control over an MEE or MES when there is an error or malfunction, and if there is a loss of OPERATOR situation awareness, then the OPERATOR might not be able to adequately control the situation. Two principles of HAZARDS related to DOA are "shared responsibility" between the OPERATOR and MEE or MES and "failures of functions" realized by the MEE or MES having DOA. Annex D provides detailed considerations of the effects that DOA could have on the RISK MANAGEMENT PROCESS by studying a variety of MEE/MES examples.

5 PROCESS STANDARDS supporting DOA

5.1 General

DOA has potential for modifying RISK or adding clinical benefits to the MEE or MES. For an MEE or MES with a higher DOA, PEMS integrity and performance become more important to SAFETY, depending on the possible HARM that can arise during the execution of the CLINICAL FUNCTION.

The following PROCESS STANDARDS are important for DOA:

1) ISO 14971;
2) IEC 62366-1;
3) IEC 62304; and
4) IEC 80001-1,

and are explained in 5.3, 5.4, 5.5 and 5.6. The role of the OPERATOR will shift related to his/her TASKS and interactions with the MEE or the MES. Maintaining the situation awareness of the OPERATOR becomes more challenging in the design of MEE or MES with a higher DOA. The OPERATOR should:

– be aware of possible errors, alarms and failures of an MEE or MES with a higher DOA,
– be aware when intervention is required,
– be able to intervene in higher DOA actions, and
– when intervening, be able to SELECT and perform a proper corrective action or abort.

This requires adequate situation awareness of higher DOA actions and knowing what to do in "out-of-the-loop" situations for the OPERATOR [70]. The MANUFACTURER should consider the shift of the OPERATOR TASKS as per the RISK MANAGEMENT PROCESS related to DOA.

Kaber and Endsley [70] have described "situation awareness" and the ability/inability of the OPERATOR to intervene in an AUTONOMOUS PROCESS as an important OPERATOR-related RISK due to high DOA. This should be scrutinized by the RISK MANAGEMENT and USABILITY ENGINEERING PROCESSES.

Annex D presents examples of MEE illustrating the relationship between DEGREE OF AUTONOMY and BASIC SAFETY and ESSENTIAL PERFORMANCE.

During the RISK MANAGEMENT PROCESS, the criticality of DOA is dependent on its effect on SEVERITY of HARM and not on the classification of DOA.

The MANUFACTURER should reconsider and review all relevant RISK- and HAZARD-related PROCESSES when the MEE or MES will have a different DOA following a design change.

5.2 RISK MANAGEMENT PROCESS

5.2.1 Defining INTENDED USE

MANUFACTURERS should be prudent when defining the INTENDED USE of their MEE or MES including DOA. The INTENDED USE is the most important claim to be defined precisely by the MANUFACTURER. One key part of the INTENDED USE is the type of PATIENTS addressed by the MEE or MES. Existing and upcoming new MEE or MES with a higher DOA should define clearly the type of PATIENTS which their MEE or MES addresses in their INTENDED USE.

5.2.2 INTENDED USE and characteristics related to SAFETY

5.2.2.1 INTENDED USE and the RISK MANAGEMENT PROCESS

The MANUFACTURER should identify the INTENDED USE of the MEE or the MES with a DOA and address the characteristics related to SAFETY through the RISK MANAGEMENT PROCESS (see 4.2 of ISO 14971:2007).

5.2.2.2 PATIENT characteristics related to SAFETY

Additional characteristics concerning PATIENTS should be taken into consideration when designing all types of MEE or MES, with or without a higher DOA including:

– PATIENT types,
– PATIENTS' sensory abilities,
– PATIENTS' physical abilities,
– PATIENTS' cognitive abilities, and
– PATIENTS' allergies.

An explanation of these characteristics can be found in Annex E.

5.2.2.3 PATIENT physiological signals

5.2.2.3.1 Use of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

The use of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS in MEE and MES are expected to provide a successful strategy to improve PATIENT SAFETY. HAZARDS that are not directly addressed by existing standards could emerge in the development of new MEE or MES.

MEE or MES with a high DOA can be linked to PATIENT physiological signals, and physiological feedback signals would be processed by the MEE or MES, and the MANUFACTURER would need to consider this in the RISK MANAGEMENT PROCESS.

NOTE Requirements for PHYSIOLOGIC CLOSED-LOOP CONTROLLERS can be found in IEC 60601-1-10.

5.2.2.3.2 Typical PATIENT physiological signals

Physiological signals (PATIENT sensory inputs) are as follows:

a) temperature (e.g. ISO 80601-2-56 or IEC 80601-2-59);
b) muscle reflex (e.g. IEC 60601-2-10);
c) blood pressure (non-invasive: e.g. IEC 80601-2-30; invasive: e.g. IEC 60601-2-34);
d) blood oxygen saturation (e.g. SPO_2: e.g. ISO 80601-2-61);
e) transcutaneous partial pressure (CO_2 value: e.g. IEC 60601-2-23);
f) inspiration/ respiration (frequency and volume: e.g. IEC 80601-2-55, ISO 80601-2-12);
g) electrophysiological signals (ECG, EEG, EMG: e.g. IEC 60601-2-25, IEC 60601-2-26, IEC 60601-2-27, IEC 60601-2-40, IEC 60601-2-47, IEC 60601-2-49);

h) sensorial (sensing pain, heat, cold, pressure);

i) hemodynamic signals (e.g. IEC 60601-2-16);

j) hearing (e.g. IEC 60601-2-66);

k) eye reaction (dilation); and

l) PATIENT sounds (verbal and non-verbal).

NOTE IEC standards indicated above contain requirements for physiological signals.

5.2.2.3.3 Chemistry physiological signals

PATIENTS' inputs via lab results are needed for the following:

a) blood glucose and electrolytes,

b) urine (indirect – laboratory results needed),

c) saliva (indirect – laboratory results needed), and

d) other laboratory/pharmaceutical analysis (DNA, pathologies, tissue, etc.).

5.3 RISK CONTROL

5.3.1 General

RISK CONTROL options are not necessarily mutually exclusive or appropriate in all circumstances. The RISK CONTROL options as they relate to DOA can include the following as appropriate:

a) avoiding the HAZARD by deciding not to start or continue with the DOA activity that gives rise to the RISK;

b) taking an increased RISK via higher DOA, ensuring that the clinical benefit outweighs the RISK;

c) removing the HAZARD source in the MEE or MES related to the DOA;

d) changing the probability of occurrence of HARM due to the DOA;

e) changing the SEVERITY of HARM due to the DOA;

f) sharing the RISK due to the DOA between several sub-systems of the MEE or MES; and

g) retaining the RISK due to the DOA by informed decision via RISK-benefit analysis.

A RISK MANAGEMENT PROCESS should be carried out to identify any known or foreseeable HAZARDS that might be present in the MEE or MES. During the HAZARD identification PROCESS, a focus on application-specific aspects should be performed. As a minimum, particular consideration of DOA when used to perform a CLINICAL FUNCTION as part of the INTENDED USE or to address reasonable foreseeable MISUSE situations with regard to, but not limited to:

h) the uncertainty of the AUTONOMOUS decisions made by the MEE or MES and possible HAZARDOUS SITUATIONS from wrong decisions being made;

i) the different levels of knowledge, experience, characteristics and physical conditions of OPERATORS, PATIENTS and other exposed persons, as described in Annex E;

j) the normal, but unexpected, actions of the MEE or MES due to DOA;

k) the unexpected or unintended actions from the environment (e.g. someone moving into the working area of the MEE or MES employing DOA);

l) the unexpected travel surfaces and environmental conditions in the case of MOBILE MEE or MES employing DOA;

m) the uncertainty of operation of the MEE or MES employing DOA with respect to PATIENT, OPERATOR, other exposed persons, animals, property and the environment;

n) the conformity to human anatomy and its variability, as described in Annex E;

o) power failure or shutdown and the re-application of power (11.8 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012) for the MEE or MES employing DOA;

p) HAZARDS arising from stress, posture, usage or PATIENT critical situations. HAZARDS can arise from both physical and mental aspects of using or applying the MEE or MES (IEC 62366-1:2015, 3.29); and

q) HAZARDS arising from the OPERATOR'S loss of situation awareness concerning MEE or MES with a higher DOA.

5.3.2 RISK CONTROL hierarchy

5.3.2.1 RISK CONTROL options

The RISK CONTROL options described in the subclauses below are in descending order with regard to their generally recognized effectiveness in reducing RISK. The MANUFACTURER should take this and other factors into account before decisions are made on which combination of MONITOR, GENERATE, SELECT and EXECUTE (MGSE) measures will be used.

The outcome of RISK CONTROL can introduce additional HAZARDS. A significant RISK could be the failure or ineffectiveness of the RISK CONTROL measures. The MONITORING TASK needs to be an integral part of the RISK CONTROL plan to give assurance that the measures remain effective.

NOTE Documenting and recording ("black-box") the TASKS of the MEE or MES could help to perform an assessment following an incident as well as improve RISK MANAGEMENT over the LIFE CYCLE of the MEE or MES.

5.3.2.2 Inherently safe design

The following measures should be applied where appropriate when introducing DOA:

a) eliminating a particular HAZARD, e.g. constraining the operational scenarios to avoid HAZARDOUS SITUATIONS due to DOA leading to incorrect TASKS;

b) reducing the probability of occurrence of the HARM, e.g. use of unique identifiers for PATIENT, OPERATOR, third persons, animals and SAFETY-related objects (e.g. property or relevant aspects of the environment), travel paths (ISO TR 24971 [55]);

c) reducing the SEVERITY of the HARM, e.g. reducing the MEE speed;

d) adjust the capability or reliability of the activities during the MONITORING TASK of the MEE or MES (i.e. DOA should be in- or decreased to a level so that there is no unacceptable RISK);

e) designing algorithms for the GENERATE OPTIONS TASK in a way that the probability of a certain decision being acceptable is calculated and can be monitored based on post-market data. OPTIONS GENERATED with a high uncertainty outcome should be re-evaluated using alternative methods or additional information. If after the re-evaluation the uncertainty remains unacceptable, the OPTION can be discarded; and

f) ensuring the SELECT OPTIONS TASK is based on appropriate criteria for optimal balance between RISK and benefits to fulfil CLINICAL FUNCTIONS.

5.3.2.3 Protective measures

The following measures should be taken into consideration when introducing DOA:

a) using a visual or auditory alarm signal to alert the OPERATOR or PATIENT of a HAZARDOUS SITUATION, including when ESSENTIAL PERFORMANCE cannot be maintained;

b) ensuring that the intended CLINICAL FUNCTION is maintained within defined parameters while the EXECUTE TASK is being performed; and

c) adding features such as collision detection systems, speed or other parameters variations, stability control, etc., based on the overall RISK MANAGEMENT PROCESS outcomes.

5.3.2.4 Information for SAFETY

The following not exhaustive list of measures can be used to increase SAFETY when introducing DOA:

a) placing applicable warnings regarding MONITOR – GENERATE – SELECT – EXECUTE (MGSE);

b) restricting the use of MGSE according to the RISK MANAGEMENT PROCESS and providing the OPERATOR with clear information on the RESIDUAL RISK;

c) providing notice about improper use, HAZARDS that can occur, or other information that can help reduce RISK as related to DOA, where a timely response is not required;

d) emphasizing the importance of using proper personal protective equipment, such as gloves and eye-glasses;

e) providing training for the OPERATORs to improve their performance or their capability in detecting errors as related to DOA and the situation awareness of the OPERATOR in his/her changed role by adding DOA to MEE or MES in the direction of more supervising than interacting; and

f) specifying necessary maintenance and maintenance intervals, maximum EXPECTED SERVICE LIFE, and how to dispose of the MEE or MES properly.

5.4 USABILITY engineering considerations for MEE or MES having a higher DOA

5.4.1 General

For MEE or MES the focus of USABILITY ENGINEERING will typically change with an in- or decreasing DOA. For a higher DOA, USABILITY ENGINEERING will primarily be focused on an overseeing role for the OPERATOR, while for a lower DOA, primarily on the direct involvement of the OPERATOR in performing the CLINICAL FUNCTION. For intermediate values of DOA the USABILITY ENGINEERING PROCESS should be used to identify new HAZARDS and verify the effectiveness of RISK MANAGEMENT controls associated with shared responsibilities.

USABILITY ENGINEERING comprises multiple aspects, such as ensuring adequate situation awareness of the OPERATOR, taking account of OPERATOR reaction time, sensory input and response, and the ability of the OPERATOR to detect malfunction or errors of MEE and MESs with a higher DOA. USABILITY ENGINEERING does not necessarily require the interaction between the PATIENT and MEE or MES without or with very limited OPERATOR interaction. While introducing higher DOA the MANUFACTURER should consider this changed OPERATOR role.

5.4.2 OPERATOR situation awareness

The OPERATOR relying on MEE having a high DOA tends to lose situation awareness [70]. If the MEE or MES with DOA cannot respond to an exceptional situation, the OPERATOR should take control over one or more of the MEE or MES TASKS in order to prevent HARM to the PATIENT, OPERATOR or other persons (e.g. lay person).

In case an OPERATOR action is required to control RISK, it is paramount that the OPERATOR:

– is aware of the situation;

– can define a strategy or response to the exceptional situation within the time needed; and

– is capable of performing the required TASK or to stop the TASK to prevent an unacceptable RISK.

The OPERATOR's situation awareness can be a critical SAFETY issue that should be considered during the RISK MANAGEMENT PROCESS within the design stage of the MEE or MES with DOA, and should be controlled during the USABILITY ENGINEERING PROCESS. The MANUFACTURER should consider the impact of loss of situation awareness on all RISKS and on all RISK CONTROL measures. When loss of situation awareness increases RISK, the probability of loss of situation awareness should be investigated.

In the design of MEE or MES with a high DOA, the situation awareness of the OPERATOR could be increased by involving the OPERATOR in either MONITORING, GENERATING OPTIONS, SELECTING one and EXECUTING it, to accomplish the CLINICAL FUNCTION. The USABILITY ENGINEERING PROCESS should consider these situations.

5.4.3 OPERATOR reaction time

This subclause addresses RISK reduction by imposing requirements on MEE or MES due to its DOA so that it is compatible with the OPERATOR's reaction time, by adjusting its operational timing, or how to deal with HAZARDS in case of incompatibility.

One of the RISK factors of an MEE or MES with a DOA is its ability to react independently of OPERATOR intervention and within a time which might not be compatible with human capability. Two cases are identified: in the first case, the system timing allows the OPERATOR to interrupt the PROCESS or to cause the MEE or MES to move to a safe state; in the second case, the MEE or MES is faster than human reaction time. The MANUFACTURER should address both these cases during the USABILITY ENGINEERING PROCESS.

EXAMPLE 1 MEE having DOA with limited speed, allows the OPERATOR to intervene to stop an unwanted activity (e.g. emergency stopping devices (see subclause 9.2.4 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012)).

EXAMPLE 2 MEE having DOA in which the motion correction functionality to react on organ movements during treatment is much faster than the reaction time of an OPERATOR.

The USABILITY ENGINEERING PROCESS and also the RISK MANAGEMENT PROCESS should consider these situations.

5.4.4 OPERATOR sensory input and response

In addition to primary sensory inputs, like tactile inputs in many cases, OPERATORs base their actions on sensory inputs that have been processed to become visual and/or audible to humans, while the origin of those inputs could be from a source outside of the human sensory scope. In some cases it could nevertheless be helpful to involve the OPERATOR's sensory inputs as a required input in the MONITORING PROCESS of the MEE or MES with higher DOA.

MEE or MES can provide help in the MONITORING TASK and how to SELECT from these sources when the raw input of the sensors cannot be processed by an OPERATOR. In this case, high values of DOA might be necessary to automate (in real time) data selection and filtering, in order to make the sensor data available in a form that humans can understand and work with.

5.4.5 Detectability by OPERATOR of malfunction or errors of MEE or MES with a higher DOA

MEE or MES with a higher DOA could GENERATE OPTIONS available for an OPERATOR to SELECT, or in even higher DOA the MEE or MES might both GENERATE and SELECT the OPTIONS. The role of the OPERATOR would evolve into a supervisory role than an interacting one.

MANUFACTURERS of MEE or MES should take care about the role of the OPERATOR with respect to supervising or interacting, during the whole design and development PROCESS. The result for applicable additional measures should be a result of the RISK MANAGEMENT PROCESS. As examples, the following measures could be included:

– design to maintain OPERATOR'S situation awareness;
– more or exhaustive advice in the OPERATOR manual of the MEE or MES;
– clear methods to ensure that the OPERATOR can detect malfunctions or errors of an MEE or MES with a higher DOA; and
– additional training for the observing role of the OPERATOR.

5.5 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) and software development LIFE CYCLE (IEC 62304)

In an MEE or MES with a high DOA, PEMS integrity is likely to be important to SAFETY, but USABILITY will remain relevant for SAFETY up to the point of an AUTONOMOUS MEE or MES where the OPERATOR is no longer involved with the MEE or MES.

Software is often an integral part of MEE or MES. Establishing the BASIC SAFETY and ESSENTIAL PERFORMANCE of an MEE or MES containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable RISKS.

HAZARDS that could be indirectly caused by software (for example, by providing misleading information that could cause inappropriate treatment to be administered) need to be considered during the RISK MANAGEMENT PROCESS when determining whether software is a contributing factor.

An MEE or MES with a higher DOA is likely to contain more software needed to perform TASKS that would normally be performed by the OPERATOR, and extra intra-operability aspects in the whole software. This increases the size and complexity of the software(s).

The decision to use software to control RISK is made during the RISK MANAGEMENT PROCESS. Software LIFE-CYCLE PROCESSES are an important part of a RISK MANAGEMENT PROCESS. Having additional or different software would necessitate reviewing of RISK MANAGEMENT PROCESSES (ISO 14971 and IEC 62304).

The MEE or MES EXECUTING that CLINICAL FUNCTION or TASK would be required through software to inform the OPERATOR of any abnormality or malfunction. The MANUFACTURER would need to review the software in consequence of the previous USABILITY ENGINEERING requirements. The OPERATOR would need to comprehend the TASKS or CLINICAL FUNCTIONS being EXECUTED by the MEE or MES and the limitations of the MEE or MES during any clinical complication. The OPERATOR should know when his/her interaction is required, especially when the MEE or MES is not EXECUTING the CLINICAL FUNCTION as expected.

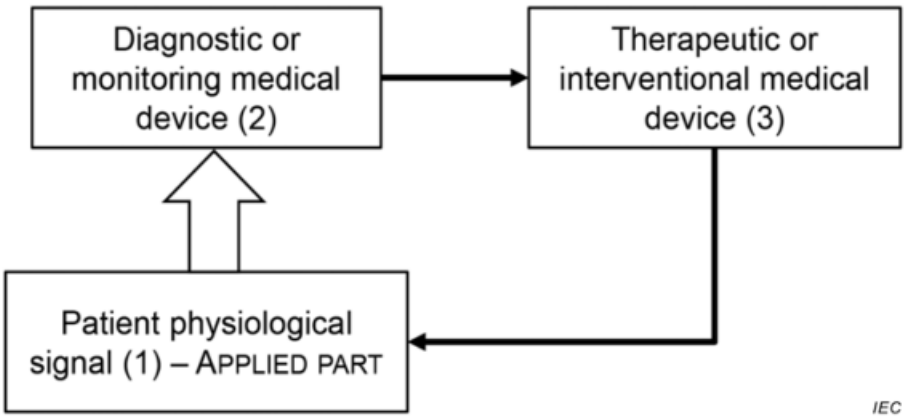
5.6 Application of RISK MANAGEMENT for IT-networks incorporating medical devices

An MEE or MES with a high DOA could also require interaction with other MEE or other non-medical equipment. The MANUFACTURER would need to consider the new MES in the RISK MANAGEMENT PROCESS.

Figure 1 provides an example of a simple basic model that illustrates how MEE or MES could interact between one another.

MEE and MES are essential for the practice of modern medicine. MEE can utilize open networking protocols for communication to provide input and output data. However, unlike the interoperable “plug-and-play” environment of modern computers and consumer electronics, most MEE is not designed to interoperate. MEE typically utilizes proprietary protocols for their own system integration. These types of approaches do not provide adequate integration capabilities necessary for safe, cross-MANUFACTURER MEE integration for data communication between different MEE (link between (2) and (3) in Figure 1). If an MEE MANUFACTURER would like to combine his MEE with other MEE the MANUFACTURER should consider a higher DOA and ISO 14971 requires the RISK MANAGEMENT documents and USABILITY ENGINEERING documents to be reviewed accordingly.

Reference to standards such as IEC 80001 (all parts) could provide additional guidance to MANUFACTURERS.



NOTE The link between (1) and (2) is typical and normally exists, whereas the link between (2) and (3) is usually missing and performed by the OPERATOR (clinical staff). The link (3) to (1) is the outcome/output of the clinical therapeutic/intervention delivered to the PATIENT. Medical devices (1) to (3) above can be an MEE component, a MEE sub-assembly, MEE or MES. Refer to Annex F for a more detailed functional diagram of a PHYSIOLOGICAL CLOSED-LOOP CONTROLLER as per IEC 60601-1-10 and how DOA is likely to be introduced into MEE or MES. Medical device is equivalent to MEE or MES.

Figure 1 – Basic model of interoperability of MEE in an MES (Order of execution: 1 to 3)

The majority of MEE today are not the physiological closed-loop type, but provide diagnostic information or clinical treatment with the interaction of the OPERATOR (clinical staff), and the majority of the MEE or MES which are software-based and dependent on OPERATOR interactions.

An MEE or MES with a higher DOA could allow the MONITORING of CLINICAL FUNCTIONS and ESSENTIAL PERFORMANCES, provides more clinical information for clinical decisions, would reduce OPERATOR interactions, and could reduce OPERATOR errors.

6 BASIC SAFETY and ESSENTIAL PERFORMANCE related to DOA

6.1 GENERAL

Increasing DOA can transfer responsibilities from the OPERATOR to the MEE or MES, which can increase the RISK CONTROLS associated with BASIC SAFETY and ESSENTIAL PERFORMANCES of the MEE or MES.

Adding a DOA feature can add to the specification for:

– CLINICAL FUNCTION, or otherwise INTENDED USE;
– characteristics related to SAFETY; and
– HAZARDOUS SITUATIONS that need to be addressed with RISK CONTROLS.

Performance specifications associated with CLINICAL FUNCTION can increase ESSENTIAL PERFORMANCE yet RISK CONTROLS are related to both BASIC SAFETY and ESSENTIAL PERFORMANCE.

6.2 BASIC SAFETY related to DOA

BASIC SAFETY is associated with use of technologies (e.g. components, software, materials, and energy) incorporated into the design of the MEE or MES. Software algorithms which are incorporated into the MEE or MES designs and their associated RISK CONTROLS have to maintain acceptable RISK (e.g. electrical shock, thermal burns, fire, excessive radiation) levels. They are associated with HARM caused by the MEE or MES, doing what they are not intended to do.

Where DOA enhances the specification for INTENDED USE not associated with CLINICAL FUNCTION, or could increase the RISK CONTROLS associated with the modification of OPERATOR TASKS (increase/decrease) related to the INTENDED USE, which could not be associated with CLINICAL FUNCTIONS, DOA should contribute to an increased specification for BASIC SAFETY.

EXAMPLE 1 An MRI system incorporates a low DOA feature that allows a PATIENT to be moved into the magnet gantry for imaging with an OPERATOR start/stop means that does not require continuous activation by the OPERATOR. As the PATIENT positioning into the gantry is not directly associated with MR imaging, the RISK ASSESSMENT can identify this feature as related to BASIC SAFETY (crush) and not related to the CLINICAL FUNCTION (formation of the image). Instead, it can be seen as an addition to the INTENDED USE. This feature and necessary RISK CONTROLS identified by the RISK MANAGEMENT PROCESS considered BASIC SAFETY features. The trapping zone could become a HAZARDOUS SITUATION and cause HARM (crushing, shearing, or pinching injuries) to PATIENTS.

EXAMPLE 2 A motorised ROBOTIC, flexible endoscope for invasive procedures incorporates a DOA feature to allow the endoscope to be extracted from the oesophagus with an OPERATOR start/stop means, which reverses the pathway taken during insertion, and which does not require continuous activation. As the insertion/extraction of the endoscope is not directly associated with the visual imaging, the RISK ASSESSMENT can identify this feature as not related to a CLINICAL FUNCTION. Instead, it can be seen as an addition to INTENDED USE. This feature and necessary RISK CONTROLS identified by the RISK MANAGEMENT PROCESS are considered BASIC SAFETY. The HARM, which could result, is associated with a trapping zone HAZARDOUS SITUATION, which could result in tearing or cutting injuries to PATIENTS.

6.3 ESSENTIAL PERFORMANCE related to DOA

ESSENTIAL PERFORMANCE is based on a RISK ASSESSMENT PROCESS related to performance of CLINICAL FUNCTIONS employing DOA.

ESSENTIAL PERFORMANCE is associated with the CLINICAL FUNCTION where loss or degradation will result in unacceptable RISK. It is associated with unwanted RISK caused by the MEE or MES employing DOA trying to do what it is intended to do. If there is overlap between ESSENTIAL PERFORMANCE and BASIC SAFETY, it is by definition considered as BASIC SAFETY. Where a DOA feature enhances the specification for CLINICAL FUNCTIONS, or enhances the specification for RISK control associated with the increase in CLINICAL FUNCTION, DOA enhances the specification for ESSENTIAL PERFORMANCE, where this does not overlap with BASIC SAFETY.

EXAMPLE 1 An AUTOMATIC EXTERNAL DEFIBRILLATION (AED) incorporates a DOA feature to synchronize the delivery of the defibrillation energy to the peak of the QRS complex of the electrocardiogram (ECG) signal. As the synchronized delivery of the defibrillation energy is directly associated with the defibrillation therapy, the RISK ASSESSMENT for the added DOA can identify this feature as related to the CLINICAL FUNCTION, and not overlapping with BASIC SAFETY. This added CLINICAL FUNCTION could be identified by the RISK ASSESSMENT as ESSENTIAL PERFORMANCE.

EXAMPLE 2 A linear accelerator device incorporates an IMAGE-GUIDED RADIOTHERAPY (IGRT) DOA feature to synchronize the treatment delivery related to the PATIENT's breathing pattern. As the synchronized delivery of the RADIATION is directly associated with the radiation therapy, the RISK ASSESSMENT PROCESS could identify this feature as related to the CLINICAL FUNCTION, and not overlapping with BASIC SAFETY. The performance limits of the DOA feature might have been defined as latency of the beam off/on function. This DOA feature and the necessary RISK control identified by the RISK MANAGEMENT PROCESS are considered ESSENTIAL PERFORMANCE. The HARM which could result is associated with degraded therapy, or collateral tissue damage outside the therapy target area, which can result in an undesirable or unacceptable clinical outcome.

EXAMPLE 3 A linear accelerator device incorporates a DOA feature to move the radiation source in an arc around the target area and during movement, adjusts the multi-element beam limiting device (BLD) to shape the beam consistent with the cross-sectional area of the target area. As the arc movement and beam-shaping movement are directly associated with the therapy plan, the RISK ASSESSMENT PROCESS can identify this feature as related to the CLINICAL FUNCTION, and not overlapping with BASIC SAFETY. This DOA feature and necessary RISK controls identified by the RISK ASSESSMENT PROCESS are considered ESSENTIAL PERFORMANCE. The HARM which could result, is associated with degraded therapy or collateral tissue damage outside the therapy target area, which can result in an undesirable or unacceptable clinical outcome. Alternatively, the arc movement of the radiation source can be considered as overlapping with BASIC SAFETY, as there is a HAZARDOUS SITUATION associated with collision with the PATIENT or other equipment. The HARM which might result also includes a trapping zone HAZARDOUS SITUATION, which might result in crushing, shearing, or pinching injuries to a PATIENT. In this alternative case, the beam-shaping movement might be seen to be related to ESSENTIAL PERFORMANCE, and the arc movement related to BASIC SAFETY. In any case, whether the arc movement is ESSENTIAL PERFORMANCE or BASIC SAFETY, it does not change the importance of verifying that RISK controls are effective.

Some particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE (IEC 60601-2-XX) standards include tables related to distributed ESSENTIAL PERFORMANCE requirements. These tables address the minimal ESSENTIAL PERFORMANCE requirements as applicable to the particular MEE or MES. The MANUFACTURER through a RISK MANAGEMENT PROCESS could also find additional ESSENTIAL PERFORMANCE related to his particular MEE or MES.

For a better understanding of ESSENTIAL PERFORMANCE, a collection of ESSENTIAL PERFORMANCES has been extracted from the IEC ISO 60601-2-XX/80601-2-XX series and inserted into a list presented in Annex G. This list provides informative guidance related to the most commonly known ESSENTIAL PERFORMANCES. Refer to the list of ESSENTIAL PERFORMANCE of MEE or MES with DOA.

It has been reported that some MEE or MES claim to have no ESSENTIAL PERFORMANCE. This claim should be demonstrated through the ISO 14971 RISK MANAGEMENT PROCESS to ensure that the MEE or MES has no ESSENTIAL PERFORMANCE.

All ESSENTIAL PERFORMANCES are addressed through a RISK MANAGEMENT PROCESS if there is a transfer of the HAZARD from the OPERATOR to the MEE or MES with a DOA. Table 1 provides examples of ESSENTIAL PERFORMANCE for MEE or MES with a DOA derived from particular standards. The MANUFACTURER is responsible for evaluating via the RISK MANAGEMENT PROCESS whether ESSENTIAL PERFORMANCE changes or not if there is a transfer of the HAZARD from the OPERATOR to the MEE or MES with a DOA.

Table 1 – Examples of ESSENTIAL PERFORMANCE of MEE or MES with a DOA

Potentially applicable ESSENTIAL PERFORMANCE of MEE or MES with DOA
MONITORING PATIENT physiological signals
MEE counter force (sensing real life motion/application)
MEE precision/ accuracy of movement/measurement
MEE accuracy/ delivery of clinical intervention (therapeutic, diagnostic, MONITORING)
MEE time/ execution requirements of clinical intervention (therapeutic, diagnostic, MONITORING)
MEE sensitivity
MEE parameter stability
Detection of improper setup before performing a CLINICAL FUNCTION (e.g. disconnected PATIENT APPLIED PART, wrong PATIENT APPLIED PART, defective PATIENT APPLIED PART)
MEE recovery management (restart where it has been interrupted)
MEE runaway protection (does not return to start of program or anywhere in the program)
Deliberate OPERATOR action required to change settings (manual over-ride – double confirmation)
MEE powering down (EPO) or main power cut in a safe prescribed manner
Able to remove/ retract MEE with no power
MEE transitions to a safe state as defined by MANUFACTURER when an unknown clinical situation occurs (Fallback mode)
NOTE 1 These examples could also be BASIC SAFETY. The identification of ESSENTIAL PERFORMANCE is determined by the MANUFACTURER and depends on the INTENDED USE of the MEE or MES. NOTE 2 The list of examples was derived from Table G.1.

Annex A
(informative)

Rationale for defining the AUTOMATIC, AUTONOMY and DOA framework and the distinction between a MEDICAL ROBOT and other MEE or MES

A.1 General

This document has established that MEE and MES with high DOA were not fully addressed in existing standards. Because the DOA in MEE and MES can have an impact on the RISK MANAGEMENT, USABILITY ENGINEERING PROCESSES and software life cycle PROCESS (PEMS), it needs to be well defined and understood. Furthermore, as technology advances, it is expected that more MEE and MES will incorporate various functions that operate with a DOA. In addition, the term AUTONOMY (or similar terms) found in existing standards, including the recent issue of ISO 8373:2012, needed further refinement.

This annex provides background information on the definitions of AUTONOMY, DEGREE OF AUTONOMY, AUTOMATIC and related terms.

In addition, DOA is introduced due to the emergence of MEDICAL ROBOTS and the fact that DOA is a key part in the definition of ROBOT as presented in ISO 8373:2012. ROBOT is a general and vague term that is used in different ways in plain language. Therefore the use of term ROBOT or its relevant adjunctive "robotic" to describe an MEE or MES needs special attention. This annex addresses this issue and the distinction between a MEDICAL ROBOT and other MEE or MES.

A.2 Existing definitions and limitations

There have been relevant and similar terms regarding AUTONOMY (AUTOMATIC, level of automation, level of AUTONOMY, etc.). In this clause, the appearance of these terms in the literature is reviewed.

Definitions of AUTOMATIC and AUTONOMY are found in a few existing standards and other literature. For example:

AUTOMATIC
PROCESS or equipment that, under specified conditions, functions without human intervention

[SOURCE: IEC 62443-3-3:2013, 3.1.7]

AUTONOMOUS
responding, reacting, or developing independently of the whole; not controlled by others or by outside forces; independent

[SOURCE: IEC TR 61850-90-7:2013, 3.1.1]

AUTONOMY
ability to perform intended TASKS based on current state and sensing, without human intervention

[SOURCE: ISO 8373:2012, 2.2]

As shown in Annex B, there are numerous MEE or MES incorporating functions with a certain DOA or 'AUTOMATIC' functions. Current standards mostly refer to these as 'AUTOMATIC' functions. However, the term AUTOMATIC is binary, which cannot provide any means to classify the DOA and also cannot explain how DOA can affect the RISK MANAGEMENT PROCESS for MEE or MES. From this fact, two key issues are identified, namely:

a) using the term AUTOMATIC is inappropriate to describe this type of technology, because the word has been historically used in different ways as shown in Annex B, and the use can cause misunderstanding and confusion; and

b) methodologies to classify between no to full AUTONOMY are needed.

To address these issues, the concept of DOA is introduced to the IEC 60601 series. AUTONOMY was chosen as the basic term for this new concept because it lacks the historical problems associated with AUTOMATIC. However, none of the existing definitions of AUTONOMY or similar terms is able to satisfy the need to describe the ESSENTIAL PERFORMANCE of MEE or MES and associated RISKS due to the following reasons:

– There is no MEE or MES that works completely independently as per the Merriam-Webster definition of AUTONOMY. Therefore, this definition is not appropriate for the field.

– ISO 8373:2012 defines AUTONOMY; however, it does not define DOA while DOA is included in the definition of ROBOT. Furthermore, it does not specify the relationship of AUTONOMY to the metrics of DOA.

A.3 New approaches

The term DOA appears in the literature in various formats, many of which are summarized in [67]. After thorough review of the different usages, the following concepts were identified as a suitable basis for further considerations:

– NIST ALFUS [68], [69] classified the level of AUTONOMY of unmanned vehicles using three axes, namely “environment complexity”, “TASK complexity” and “human interface”. A similar classification to MEE or MES was applied, where “environment complexity” was translated to a hospital, “complexity” related to the clinical application or treatment and “human interface” was renamed “USABILITY” to relate closer to the medical terminology. Figure A.1 illustrates the ALFUS approach applied to MEE or MES applications. After attempting to apply it to MEE or MES, this concept was found to be too complex to be applied by MANUFACTURERS in a consistent way. Furthermore, it does not provide a single dimension metric for DOA, making its use and interpretation less obvious.

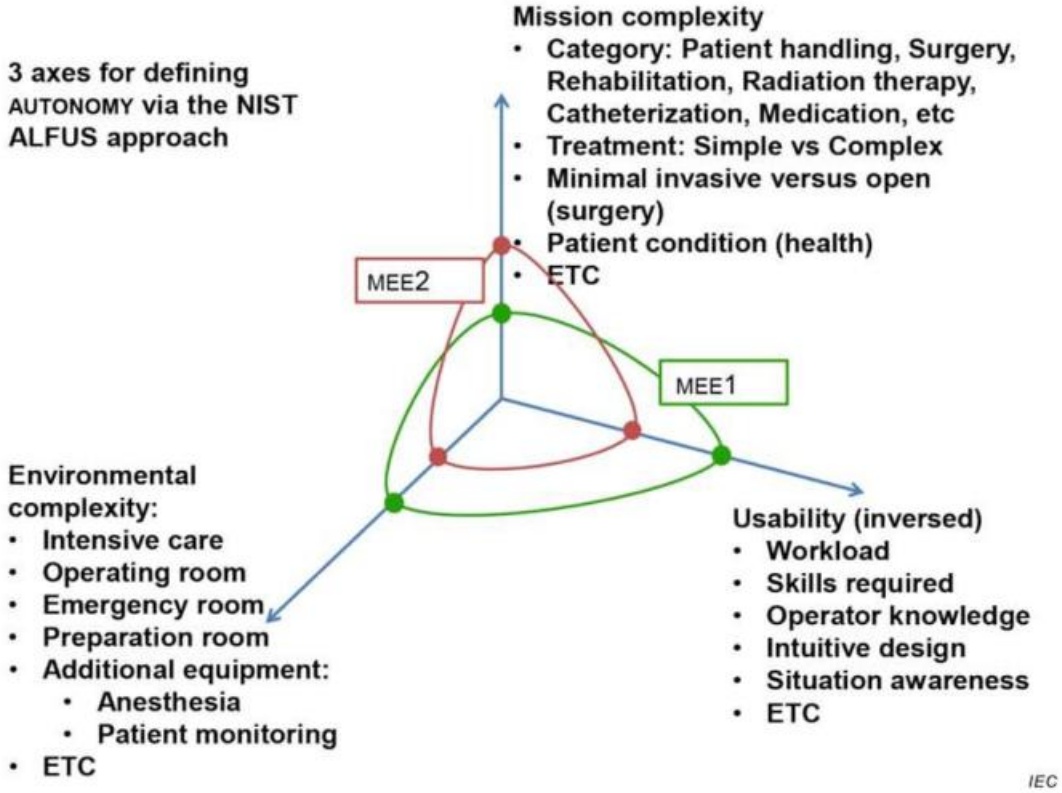


Figure A.1 – ALFUS approach applied to MEE or MES applications

– Kaber and Endsley [70] focused on "human-centred automation", and four generic actions were proposed describing a system's capabilities: monitoring, generating, selecting and implementing. Using these terms, they defined 10 "levels of automation". This "levels of automation" concept was considered to be an applicable framework upon which to base the concept of DOA for MEE or MES.

This document adopts and builds upon Kaber and Endsley's approach to define AUTONOMY and DEGREE OF AUTONOMY classification methods as presented in Annex C.

Regarding these terms, this document recommends the following:

– **AUTOMATIC**: This term could have been used to mean a certain DOA as shown in Annex B. When referring to DOA it is recommended that this term not be used.
– **AUTONOMY, AUTONOMOUS**: These terms in common language are used to mean full DOA. For expressing intermediate DOA, these terms should not be used, and it is strongly advised to use DOA. However, expression null (no, zero) AUTONOMY and full AUTONOMY can be used without confusion.
– **Level of automation**, **level of AUTONOMY**: Although these terms are found in the literature, it is recommended that DOA be used to avoid confusion.

The document also includes special attention on CLINICAL FUNCTIONS. This was needed because in the definition of ESSENTIAL PERFORMANCE in 3.27 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, CLINICAL FUNCTION is mentioned but not defined.

A.4 Definition of MONITOR – GENERATE – SELECT – EXECUTE

Kaber and Endsley [70] describes four generic functions in control systems as the following:

1) monitoring: which includes taking in all information relevant to perceiving system status (e.g. scanning visual displays);

2) generating: formulating OPTIONS or TASK strategies for achieving goals;
3) selecting: deciding on a particular OPTION or strategy; and
4) implementing: carrying out the chosen OPTION through control actions at an interface.

The terms chosen for use in this document are MONITOR, GENERATE, SELECT and EXECUTE and their definitions have been modified for application to MEE and MES.

A.5 Approaches to define ROBOT and MEDICAL ROBOT

This document adopted the definitions of ROBOT and MEDICAL ROBOT as

ROBOT
programmed actuated mechanism with a DEGREE OF AUTONOMY, moving within its environment, to perform intended TASKS

[SOURCE: ISO 8373:2012, 2.6, modified – The phrase "actuated mechanism programmable in two or more axes" was replaced with "programmed actuated mechanism".]

MEDICAL ROBOT
ROBOT intended to be used as MEE or MES

The definition of ROBOT is basically identical to that agreed upon by ISO/TC 299. TC 299 decided to change its definition in ISO 8373:2012 as stated above.

Since the definition of MEDICAL ROBOT is based on that of ROBOT, a MEDICAL ROBOT has the following properties:

– programmed, actuated mechanism;
– a DEGREE OF AUTONOMY; and
– moving within its environment.

These characteristics can be found in vast types of modern machines; therefore this definition is not to set normative boundaries to distinguish ROBOT from other machinery; rather it is a conceptual definition determined by its MANUFACTURER.

A.6 Conclusions

DEGREE OF AUTONOMY is found in many MEE and MES; however, MEDICAL ROBOTS are the most typical examples of MEE and MES with both lower and higher DOA.

An MEE or MES is a MEDICAL ROBOT when the definition of ROBOT is satisfied and the MANUFACTURER intends the MEE or MES to be a ROBOT.

Annex B
(informative)

DOA and relevant terms used in MEE standards

B.1 General

After defining the terms and the framework of DOA, it was applied to the existing standards for MEE by defining a list of keywords, which are similar to AUTOMATIC or AUTONOMOUS (Table B.2).

This is an initial study to focus further investigation so the assessment of the relevance could be more harmonized and the selection of keywords could be improved. The review is likely to grow in content as additional medical standards are included.

B.2 Procedure

The following procedure was performed:

a) a list of 74 standards applicable for medical products with current versions was generated (see Table B.2);

b) a non-exhaustive list of terms that indicate the use of AUTONOMY was generated (see Table B.1). The terms were included (or considered relevant) if they had a relation to the framework set out in this document based on the following characteristics:

   1) use of algorithm(s),

   2) direct relationship to AUTONOMY, and

   3) relationship to the defined framework (MONITOR-GENERATE-SELECT-EXECUTE (MGSE)).

c) all standards were searched for the terms generated in b);

d) the terms identified were assessed regarding their relevance regarding AUTONOMY and DOA as defined in this document.

B.3 Results

B.3.1 Summary

The results are the following:

a) 31 of the 74 standards do not use the keywords for AUTONOMY. It can be assumed they are not using AUTONOMOUS capabilities in MEE or MESS;

b) 43 of the 74 standards use the keywords for AUTONOMY in a relevant way. It can therefore be assumed they are using AUTONOMOUS capabilities in MEE or MESs; and

c) some inconsistencies were found (see Table B.3). It is advisable to review the identified standards in Table B.3 during the next maintenance cycle and align with the proposed DOA framework presented in this document.

NOTE Table B.1 and Table B.2 are as of January 2016, and these are informative and not intended to give the complete list.

B.3.2 Tables

Table B.1 – List of terms that indicate the use of AUTONOMY

Terms	Defined?	Standard	Definition
adaptive	Differently	-	-
algorithm	Yes	IEC TR 62390:2005, 3.1.1	Completely determined finite sequence of instructions by which the values of the output variables can be calculated from the values of the input variables
AUTONOMY	Differently	-	-
automated	Differently	-	-
AUTOMATIC	Yes	IEC 62443-3-3:2013, 3.1.7	PROCESS or equipment that, under specified conditions, functions without human intervention
AUTONOMY	No	-	-
decide	No	-	-
decision	Differently	-	-
detection	Yes	IEC 60947-2:2006, B.2.3.4	Function consisting of sensing the presence of a residual current
GENERATE	Differently	-	-
independent	Yes	IEC 60730-1:2013, H.2.20.4	Not being adversely influenced by the control data flow and not being impaired by failure of other control functions, or by common mode effects
intelligence	No	-	-
intelligent	Differently	-	-
neural network	No	-	-
predetermined	Differently	-	-
ROBOT	No	-	-
self-governed	No	-	-
self-governing	No	-	-
self-operating	No	-	-
without OPERATOR intervention	No	-	-

Table B.2 – List of reviewed standards – sorted by standard number *(1 of 4)*

Standard	Version	Standard name
IEC 60601-1	Edition 3.1 2005/AMD 1:2012	*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1-2	Edition 4.0 2014	*Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-3	Edition 2.1 2008/AMD1:2013	*Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-6	Edition 3.1 2010AMD1:2013	*Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-8	Edition 2.1 2006/AMD1: 2012	*Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-9	Edition 1.1 2007/AMD1:2013	*Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-10	Edition 1.1 2007/AMD1:2013	*Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-11	Edition 2.0 2015	*Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-12	Edition 1.0 2014	*Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-2-1	Edition 3.1 2009/AMD1:2014	*Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
IEC 60601-2-2	Edition 5.0 2009	*Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
IEC 60601-2-3	Edition 3.1 2012/AMD1:2016	*Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment*
IEC 60601-2-4	Edition 3.0 2010	*Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*
IEC 60601-2-5	Edition 3.0 2009	*Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*
IEC 60601-2-6	Edition 2.1 2012/AMD1:2016	*Medical electrical equipment – Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment*
IEC 60601-2-8	Edition 2.1 2010/AMD1:2015	*Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*
IEC 60601-2-10	Edition 2.1 2012/AMD1:2016	*Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*
IEC 60601-2-11	Edition 3.0 2013	*Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*

Table B.2 (*2 of 4*)

Standard	Version	Standard name
ISO 80601-2-12	Edition 1.0 2011	*Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
ISO 80601-2-13	Edition 1.1 2011/AMD1:2015	*Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*
IEC 60601-2-16	Edition 4.0 2012	*Medical electrical equipment – Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*
IEC 60601-2-17	Edition 3.0 2013	*Medical electrical equipment – Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*
IEC 60601-2-18	Edition 3.0 2009	*Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*
IEC 60601-2-19	Edition 2.1 2009/AMD1:2016	*Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*
IEC 60601-2-20	Edition 2.1 2009/AMD1:2016	*Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators*
IEC 60601-2-21	Edition 2.1 2009/AMD1:2016	*Medical electrical equipment – Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers*
IEC 60601-2-22	Edition 3.1 2007/AMD1:2012	*Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*
IEC 60601-2-23	Edition 3.0 2011	*Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment*
IEC 60601-2-24	Edition 2.0 2012	*Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers*
IEC 60601-2-25	Edition 2.0 2011	*Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*
IEC 60601-2-26	Edition 3.0 2012	*Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*
IEC 60601-2-27	Edition 3.0 2011	*Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*
IEC 60601-2-28	Edition 2.0 2010	*Medical electrical equipment – Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis*
IEC 60601-2-29	Edition 3.0 2008	*Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*
IEC 80601-2-30	Edition 1.1 2009/AMD1:2013	*Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*
IEC 60601-2-31	Edition 2.0 2008	*Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source*

Table B.2 (*3 of 4*)

Standard	Version	Standard name
IEC 60601-2-33	Edition 3.2 2010/AMD1:2013/AMD2:2015	*Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*
IEC 60601-2-34	Edition 3.0 2011	*Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*
IEC 80601-2-35	Edition 2.1 2009/AMD1:2016	*Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use*
IEC 60601-2-37	Edition 2.1 2007/AMD1:2015	*Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
IEC 60601-2-39	Edition 2.0 2007	*Medical electrical equipment – Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment*
IEC 60601-2-41	Edition 2.1 2009/AMD1:2013	*Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis*
IEC 60601-2-43	Edition 2.0 2010	*Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
IEC 60601-2-44	Edition 3.2 2009/AMD1:2012/AMD2:2016	*Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
IEC 60601-2-45	Edition 3.1 2011/AMD1:2015	*Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices*
IEC 60601-2-46	Edition 3.0 2016	*Medical electrical equipment – Part 2-46: Particular requirements for the basic safety and essential performance of operating tables*
IEC 60601-2-47	Edition 2.0 2012	*Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*
IEC 60601-2-49	Edition 2.0 2011	*Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*
IEC 60601-2-50	Edition 2.1 2009/AMD1:2016	*Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment*
IEC 60601-2-52	Edition 1.1 2009/AMD1:2015	*Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*
IEC 60601-2-54	Edition 1.1 2009/AMD1:2015	*Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
ISO 80601-2-55	Edition 1.0 2011	*Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
ISO 80601-2-56	Edition 1.0 2009	*Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

Standard	Version	Standard name
IEC 60601-2-57	Edition 1.0 2011	*Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

Table B.2 (*4 of 4*)

Standard	Version	Standard name
IEC 80601-2-58	Edition 2.1 2014/AMD1:2016	*Medical electrical equipment – Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*
IEC 80601-2-59	Edition 1.0 2008	*Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*
IEC 80601-2-60	Edition 1.0 2012	*Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*
ISO 80601-2-61	Edition 1.0 2011	*Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*
IEC 60601-2-63	Edition 1.0 2012	*Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment*
IEC 60601-2-65	Edition 1.0 2012	*Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*
ISO 80601-2-67	Edition 1.0 2014	*Medical electrical equipment – Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment*
IEC 60601-2-68	Edition 1.0 2014	*Medical electrical equipment – Part 2-68: Particular requirements for basic safety and essential performance of X-ray based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*
ISO 80601-2-69	Edition 1.0 2014	*Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*
ISO 80601-2-70	Edition 1.0 2015	*Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*
ISO 80601-2-72	Edition 1.0 2015	*Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*
IEC 62083	Edition 1.0 2009	*Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*
IEC 62304	Edition 1.1 2006/AMD1:2015	*Medical device software – Software life-cycle processes*
IEC 62366-1	Edition 1.0 2015	*Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-2	Edition 1.0 2016	*Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

Standard	Version	Standard name
IEC TR 80002-1	Edition 1.0 2009	*Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software*
IEC TR 60601-4-3	Edition 1.0 2015	*Medical electrical equipment – Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements*
ISO 10651-6	Edition 1.0 2004	*Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 6: Home-care ventilatory support devices*
ISO TR 24971	Edition 1.0 2013	*Medical devices – Guidance on the application of ISO 14971*
ISO 14971	Edition 2.0 2007	*Medical devices – Application of risk management to medical devices*

Table B.3 – List of identified inconsistencies in reviewed standards *(1 of 2)*

Term	Subclause	Text	Recommendation
IEC 60601-2-1:2009			
AUTOMATIC	201.9.2.1 General	NOTE 1 The phrase "to set-up automatically" or "AUTOMATIC set-up" is used to denote the moving of MEE parts automatically to the positions required for the start of a PATIENT treatment.	The term is inconsistent with the understanding of the term AUTOMATIC and usage within DOA as discussed in this document. Clarification: With the new definition of AUTOMATIC this should be changed to a different term (e.g. auto-assistance), because AUTOMATIC is without OPERATOR intervention and does not require continuous activation.
pre-programmed	201.9.2.1 General	NOTE 2 The term "pre-programmed movements" is used where movement of MEE parts takes place according to a previously planned programme, without intervention by the OPERATOR, during a PATIENT treatment; the treatment is referred to as a "pre-programmed treatment".	The term pre-programmed can be confusing with the use of AUTOMATIC. It is recommended to consider the remaining use of pre-programmed. Clarification: The term "pre-programmed" is understood as AUTOMATIC. It is advisable to change it in the next maintenance cycle of the standard
IEC 60601-2-4:2010			
AUTOMATIC	201.3.201	Automated external defibrillator (AED) that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the PATIENT'S skin, identifies shockable cardiac rhythms, and automatically operates the defibrillator when a shockable rhythm is detected, hereinafter referred to as an AED. NOTE 3 AEDs can provide varying levels of automation and be referred to by various terms. A semi-AUTOMATIC defibrillator requires manual shock activation. A fully AUTOMATIC defibrillator will provide shock without OPERATOR intervention.	These semi-AUTOMATIC and AUTOMATIC functionalities of AEDs have different DOA and can operate even without the OPERATOR. Therefore it can be more than "AUTOMATIC". semi-AUTOMATIC: MONITORING or GENERATING OPTION(S) or EXECUTING is done by the MEE. SELECTING an OPTION is done by the OPERATOR. AUTOMATIC: would be full AUTONOMY because MGSE is all done by the MEE. The term "AUTOMATIC" here is used for full AUTONOMY whereas in this framework the term AUTOMATIC is seen as a low DEGREE OF AUTONOMY Clarification: Instead of "semi-AUTOMATIC" e.g. DOA 13 out of 15 via the binary method (see Annex C) can be used. The term AUTOMATIC can be replaced by the term AUTONOMOUS.

Table B.3 *(2 of 2)*

Term	Subclause	Text	Recommendation
AUTOMATIC	201.3.216	Selected energy: energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an AUTOMATIC protocol	This AUTOMATIC functionality of the AEDs has different DEGREES OF AUTONOMY and can operate even without the OPERATOR. Therefore it can be more than "AUTOMATIC".
detection	201.7.9.2.101 i)	The RRD has continued analysing ECG after the initial shockable rhythm detection and has then detected a non-shockable rhythm;	The term "detection" would be similar to the term "MONITORING" used in the DOA framework.
detection	201.8.5.5.101	Defibrillators requiring an impedance within a certain range to be present at the output of the DISCHARGE CIRCUIT are to be tested connected to a 50 W resistive load. In the case of defibrillators requiring the detection of a shockable ECG in order to deliver a shock, an ECG simulator incorporating a 50 W resistive load is to be used.	The term "detection" would be similar to the term "MONITORING" used in the DOA framework.
ISO 80601-2-12:2011			
AUTOMATIC	201.3.222	VENTILATOR: MEE intended to automatically augment or provide ventilation of the lungs of the PATIENT when connected to the airway of the PATIENT	This function can have different DOA and can operate even without the OPERATOR. Therefore it can be more than "AUTOMATIC". Clarification: Defining DOA of the various ventilator MEE can help to differentiate between the various applications.
IEC 60601-2-68:2014			
AUTOMATIC	201.9.2.1 General	NOTE 4 The phrase 'to set-up AUTOMATICALLY' or 'AUTOMATIC set-up' is used to denote the moving of MEE parts AUTOMATICALLY to the positions required for the start of a PATIENT treatment or imaging.	The term is inconsistent with the understanding of the term AUTOMATIC and usage within DOA as discussed in this document. Clarification: With the new definition of AUTOMATIC this part needs to be reconsidered to be changed to a different term, e.g. auto-assistance, because AUTOMATIC is without OPERATOR intervention and does not require continuous activation.
AUTOMATIC	201.9.2.1 General	NOTE 5 The term "pre-programmed movements" is used where movement of MEE parts takes place according to a previously planned programme, without intervention by the OPERATOR, during a PATIENT treatment; the treatment is referred to as a "pre-programmed treatment".	The term pre-programmed can be confusing with the use of AUTOMATIC. It is recommended to consider the remaining use of pre-programmed. Clarification: The term "pre-programmed" is understood as AUTOMATIC. It is advisable to change it in the next maintenance cycle of the standard.

Annex C
(informative)

Exemplar methods for classifying DEGREE OF AUTONOMY

C.1 Descriptive method

The descriptive method defines 10 degrees of AUTONOMY. This method employs an adapted version of the taxonomy defined by Kaber and Endsley [70]. In order to differentiate between those degrees of AUTONOMY they introduced four generic functions intrinsic to the domains of control and operation, namely:

– MONITOR;

– GENERATE OPTIONS;

– SELECT an OPTION; and

– EXECUTE the chosen OPTION.

The 10 degrees of AUTONOMY of the descriptive method are listed and described in Table C.1. Each generic function can be carried out by a human (abbreviated “H”) or by a computer in the MEE/MES (abbreviated “C”) and M, G, S, E are the MONITOR, GENERATE, SELECT and EXECUTE TASKS.

In many cases it is not possible to assign a generic function completely to the human or to the computer. The responsibility for the generic function is then shared between the human and the computer (indicated by “H/C” in Table C.1). For example, when using a tele-operated (TO) robotic surgical device the surgeon (OPERATOR) monitors the actions visually, while the computer monitors forces and provides feedback to the OPERATOR.

Table C.1 – Descriptive classification of DOA

Degree	Mnem.	Description	M	G	S	E
1	FM	Full manual (FM): No AUTONOMY involved. The OPERATOR performs all TASKS to MONITOR the state of the system, GENERATE performance OPTIONS, SELECT the OPTION to perform (decision making) and EXECUTE the decision made, i.e. physically implementing it.	H	H	H	H
2	TO	Teleoperation (TO): The MEE or MES assists the OPERATOR to EXECUTE the selected action, although continuous OPERATOR control is required. The OPERATOR performs all TASKS to MONITOR the state of the MEE or MES, GENERATE OPTIONS, SELECT the desired OPTION to EXECUTE and then to actually EXECUTE it. (Master–Slave teleoperation.).	H/C	H	H	H/C
3	PE	Pre-programmed execution (PE): The OPERATOR carries out the GENERATE and SELECT activities without any analysis or selection carried out by the MEE or MES.	H/C	H	H	C
4	SD	Shared decision (SD): Both the OPERATOR and the MEE or MES GENERATE possible OPTIONS. The OPERATOR retains full control over the SELECT TASK. Both the OPERATOR and the MEE participate in the EXECUTE TASK.	H/C	H/C	H	H/C
5	DS	Decision support (DS): MEE performs the GENERATE OPTIONS TASK, which the OPERATOR can SELECT from, or the OPERATOR can GENERATE alternative OPTIONS. Once the OPERATOR has SELECTED an OPTION, it is turned over to the MEE or MES to EXECUTE it.	H/C	H/C	H	C
6	BD	Blended decision (BD): The MEE or MES GENERATES OPTIONS, which it SELECTS from and EXECUTES if the OPERATOR consents. The OPERATOR can also GENERATE and SELECT an alternative OPTION; the MEE will then carry out the EXECUTE TASK. BD represents a high-level decision support system that is able to SELECT among alternatives as well as EXECUTE the chosen OPTION.	H/C	H/C	H/C	C
7	GD	Guided decision (GD): The MEE or MES presents a set of actions to the OPERATOR. The OPERATOR'S role is to SELECT from among this set; he/she cannot GENERATE any other additional OPTIONS. The MEE will fully EXECUTE the chosen OPTION.	H/C	C	H	C
8	AD	AUTONOMOUS decision (AD): The MEE or MES SELECTS the best OPTION and EXECUTES it, based on the GENERATE TASK (this list can be augmented by alternatives suggested by the OPERATOR).	H/C	H/C	C	C
9	OM	OPERATOR MONITORING (OM): The MEE or MES GENERATES OPTIONS, SELECTS the OPTION to implement and EXECUTES it. The OPERATOR MONITORS the MEE or MES and intervenes if necessary. Intervention places the human in the role of SELECTING a different OPTION. During the procedure, there can be decision-making points that will be decided by the MEE or MES.	H/C	C	C	C
10	FA	Full AUTONOMY (FA): The MEE or MES carries out all MGSE actions. The OPERATOR does not intervene except to emergency-stop the MEE or MES.	C	C	C	C

C.2 Binary method

The binary method defines 16 degrees of AUTONOMY and is also based on the taxonomy defined by Kaber and Endsley [70]. The four generic functions (MONITOR, GENERATE OPTIONS, SELECT an OPTION, and EXECUTE the chosen OPTION) can be carried out either by an OPERATOR or by the MEE or MES. This constitutes the 16 OPTIONS listed in Table C.2. An increasing "index" in the table reflects increasing DOA; however when applying this method it might be necessary to adapt the order of the indexes when applying it to a specific situation.

The binary method can be used whenever a clear distinction between the assignment of the generic functions to either OPERATOR or MEE or MES is desired. In those cases where it is not possible to assign a generic function completely to the OPERATOR or the MEE or MES, the major share of responsibility is listed.

Table C.2 – Binary classification of DOA

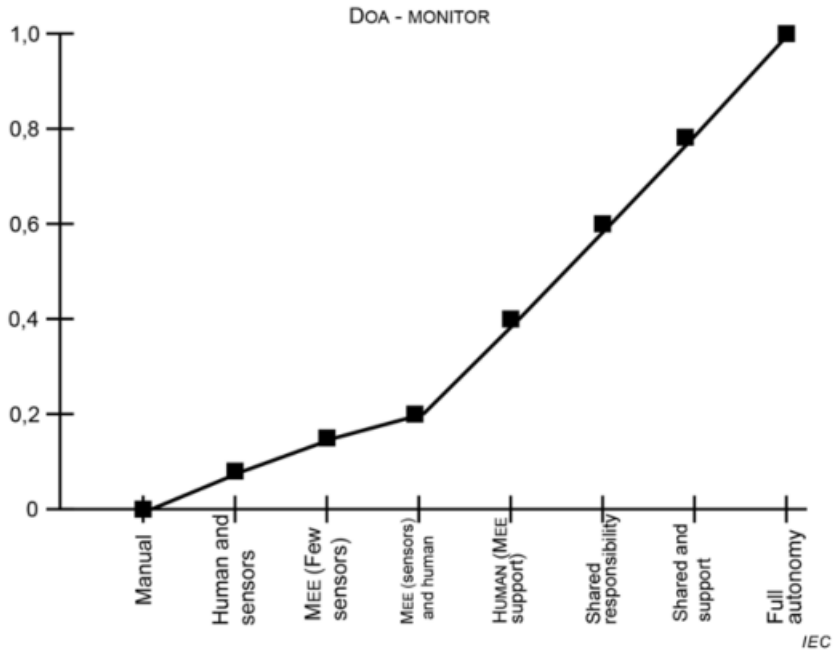
Degree	EXECUTING	SELECTING	GENERATING	MONITORING
0	OPERATOR	OPERATOR	OPERATOR	OPERATOR
1	OPERATOR	OPERATOR	OPERATOR	MEE/MES
2	OPERATOR	OPERATOR	MEE/MES	OPERATOR
3	OPERATOR	OPERATOR	MEE/MES	MEE/MES
4	OPERATOR	MEE/MES	OPERATOR	OPERATOR
5	OPERATOR	MEE/MES	OPERATOR	MEE/MES
6	OPERATOR	MEE/MES	MEE/MES	OPERATOR
7	OPERATOR	MEE/MES	MEE/MES	MEE/MES
8	MEE/MES	OPERATOR	OPERATOR	OPERATOR
9	MEE/MES	OPERATOR	OPERATOR	MEE/MES
10	MEE/MES	OPERATOR	MEE/MES	OPERATOR
11	MEE/MES	OPERATOR	MEE/MES	MEE/MES
12	MEE/MES	MEE/MES	OPERATOR	OPERATOR
13	MEE/MES	MEE/MES	OPERATOR	MEE/MES
14	MEE/MES	MEE/MES	MEE/MES	OPERATOR
15	MEE/MES	MEE/MES	MEE/MES	MEE/MES
NOTE Each cell can have shared control, but in each case the major OPERATOR is listed.				

C.3 Weighted method

The "MONITOR", "GENERATE OPTIONS", "SELECT an OPTION" and "EXECUTE the chosen OPTION" (MGSE) aspects of a SAFETY function of MEE or MES can be allocated a normalised weight (from 0-1) based on its DOA; where 0 implies no AUTONOMY and 1 implies full AUTONOMY. The variation between 0 and 1 will be a continuous function (linear or nonlinear) where different DOAs specific to the application can be specified.

DEGREE OF AUTONOMY: The method should enable allocating a weight to signify the DOA. A continuous mapping method provides flexibility to the DOA decision, and that is described below.

MONITOR: An example of applying the weighted method to the MONITOR TASK is presented in Figure C.1 (the weighting factors in the list of Figure C.1 are examples only).

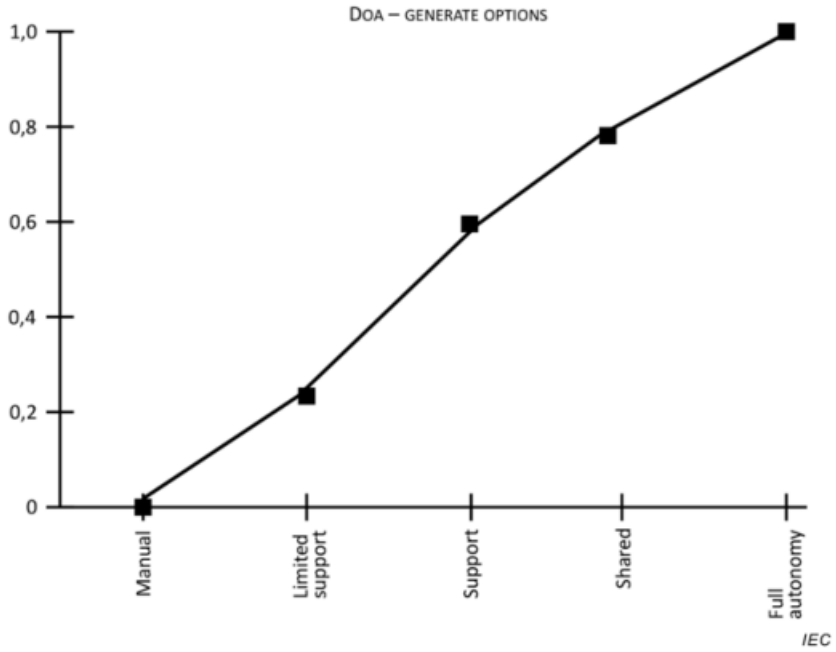


Key

DOA – MONITOR TASK	
0	Human uses own senses and interprets
0,1	Human SELECTS and uses sensor(s) and interprets data
0,15	MEE or MES SELECTS a restricted sub-set of sensor(s) and human interprets data
0,2	MEE or MES SELECTS sensor(s) and human interprets sensor data
0,4	MEE or MES SELECTS sensor(s); human interprets data and MEE or MES suggests alternative
0,6	MEE or MES SELECTS sensor(s); MEE or MES interprets a sub-set of data (human does the rest)
0,75	MEE or MES SELECTS sensor(s); MEE or MES interprets a sub-set of data and suggests alternatives for some of the data
1	MEE or MES SELECTS sensor(s); MEE or MES interprets data

Figure C.1 – Application of weighted method to the "MONITOR" TASK

GENERATING OPTIONS: An example of applying the weighted method to the GENERATE OPTIONS TASK is presented in Figure C.2.

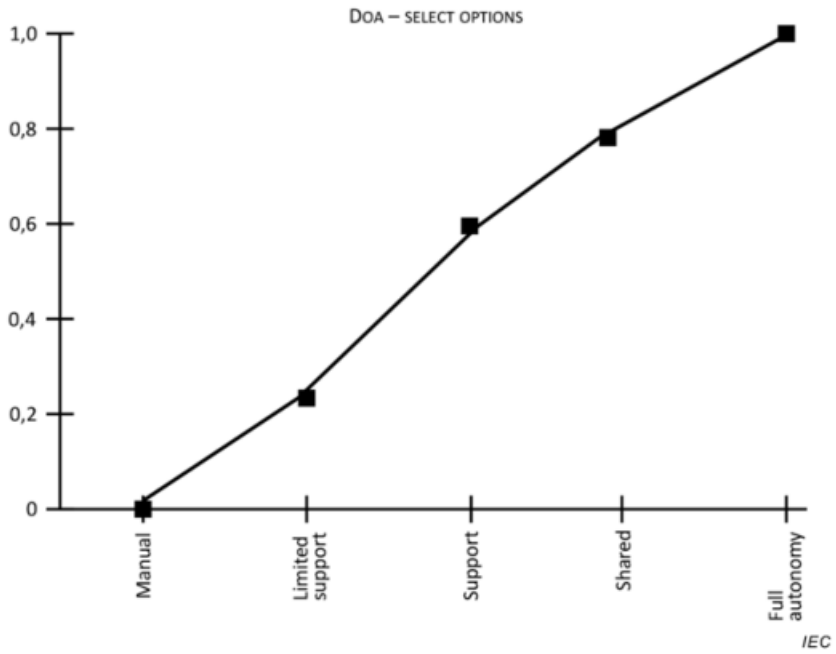


Key

	DOA – GENERATE OPTIONS
0	MEE or MES are not involved in GENERATING OPTIONS
0,3	MEE or MES supports the OPERATOR to GENERATE OPTIONS for limited cases
0,6	MEE or MES supports the OPERATOR to GENERATE OPTIONS for all cases
0,75	MEE or MES GENERATE OPTIONS TASK for limited cases
1	MEE or MES GENERATE OPTIONS TASK for all cases

Figure C.2 – Application of weighted method to "GENERATE OPTIONS"

SELECTING OPTIONS: An example of applying the weighted method to the SELECT OPTION TASK is presented in Figure C.3.

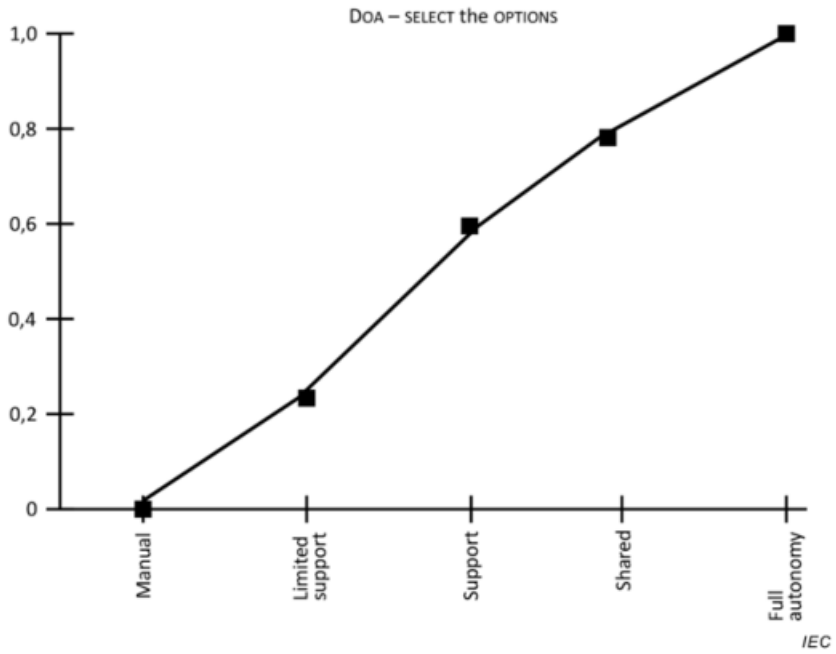


Key

DOA – SELECT OPTION	
0	MEE or MES is not involved in SELECTING the OPTION
0,3	MEE or MES supports the OPERATOR to SELECT OPTION for limited cases
0,6	MEE or MES supports the OPERATOR to SELECT OPTION for all cases
0,75	MEE or MES SELECTS OPTION for limited cases
1	MEE or MES SELECTS OPTION for all cases

Figure C.3 – Application of weighted method to "SELECT OPTION" TASK

EXECUTING OPTIONS: An example of applying the weighted method to the EXECUTE TASK is presented in Figure C.4.



Key

DOA – EXECUTE	
0	MEE or MES has no role in the EXECUTE OPTION
0,3	MEE or MES supports the OPERATOR to EXECUTE TASK in limited cases
0,6	MEE or MES supports the OPERATOR to EXECUTE TASK in all cases
0,75	MEE or MES performs the EXECUTE TASK in limited cases
1	MEE or MES performs the EXECUTE TASK in all cases

Figure C.4 – Application of weighted method to the "EXECUTE" TASK

Overall DOA: The MEE's or MES's overall DOA of the SAFETY function can be obtained by combining the various DOA levels of the "MONITOR", "GENERATE OPTIONS", "SELECT an OPTION" and "EXECUTE the chosen OPTION" parts as follows:

Let w_1, w_2, w_3 and w_4 be the DOA weightings associated with the MONITOR (M), GENERATE OPTIONS (G), SELECT an OPTION (S), and EXECUTE the chosen OPTION (E) TASKS, respectively, where

$$w_1 + w_2 + w_3 + w_4 = 1 \tag{C.1}$$

Thus, the overall DOA for the SAFETY function can be defined as

$$DOA = w_1 M + w_2 G + w_3 S + w_4 E \tag{C.2}$$

The above equation will result in a value in the range 0 to 1, where 0 means no AUTONOMY and 1 means full AUTONOMY for the MEE or MES.

The MANUFACTURER can adopt the key values described in Figures C.1 to C.4 to estimate the impact of DOA in the MGSE steps. The MANUFACTURER can modify these values based on the

INTENDED USE. Then the MANUFACTURER determines the weighting coefficients w_1 to w_4 depending on the characteristics of the MEE or MES in terms of the relative importance of the MGSE aspects.

EXAMPLE Consider a MEE with DOA weightings defined on the basis that the MONITOR and GENERATE OPTIONS TASKS can add to the probability of a HAZARDOUS SITUATION to occur (which can lead to HARM) and EXECUTING the selected OPTION is likely to actually cause HARM in this specific example. In this case we can assume MGSE weights of 0,15, 0,15, 0,25, 0,45 to give:

$$w_1 = 0{,}15,\ w_2 = 0{,}15,\ w_3 = 0{,}25, \text{ and } w_4 = 0{,}45,$$

which can give a realistic estimate of the importance of the MGSE functions to the DOA.

Let the DOA weightings for the MONITORING, GENERATING, SELECTING an OPTION and EXECUTING the chosen OPTION TASKS be given as follows:

M = 0,2 (MEE or MES SELECTS sensor(s) and human interprets sensor data)

G = 0,3 (MEE or MES supports the OPERATOR to GENERATE OPTIONS for limited cases)

S = 0,6 (MEE or MES supports the OPERATOR to SELECT the best OPTION for all cases)

E = 0,75 (MEE or MES performs the EXECUTE TASK in limited cases)

Substituting values into Equation (C.2) yields the DOA for the considered MEE as:

$$\begin{aligned} DOA &= w_1 M + w_2 G + w_3 S + w_4 E \\ &= 0{,}5 \times 0{,}2 + 0{,}15 \times 0{,}3 + 0{,}25 \times 0{,}6 + 0{,}45 \times 0{,}75 = 0{,}5625 \end{aligned}$$

NOTE Such numeric values for DOA allows interpretation of the RISK and possible RISK reduction measures in particular use case scenarios when changes are made to weightings levels and to DOA based on whether increasing DOA increases or reduces RISK in each activity considered.

Annex D
(informative)

Examples of introducing DOA to MEE/MES

D.1 General

Examples are used to describe how the concept of DOA is applied in various MEE and MES. Each example includes:

a) a description of how MEE or MES is used and the rationale for introducing AUTONOMY;

b) an explanation why the MEE under consideration is to be considered a MEDICAL ROBOT or not;

c) application of one or more of the three DOA classification methods described in Annex C in the example;

d) the effect of DOA on the RISK MANAGEMENT PROCESS identifying functions/TASKS involved and associated RISKS with and without DOA; and

e) summary and conclusions.

D.2 Example 1 – Lower extremity exoskeleton

D.2.1 Description of the medical procedures

An assistive lower extremity exoskeleton is a wearable MEE providing support and help for the PATIENT to improve mobility or gait generation, or restore function. It is considered MEDICAL ROBOT when it contains sensing, actuation, and interfacing mechanisms allowing the PATIENT or OPERATOR to interact with the system and initiate/stop the relevant functional operations that are performed with a DOA by the system. A passive exoskeleton, driven only by for example spring elements, is not a MEDICAL ROBOT, as it is not an MEE, nor has a DOA in its operation. Depending on the physical and cognitive capability of the PATIENT, some DOA might need to be introduced into the system at various levels of the MONITORING, GENERATING OPTIONS, SELECTING an OPTION and EXECUTING the OPTION TASKS. This example illustrates the management of RISKS associated with the introduction of DOA at these levels.

This clause contains two examples related to lower extremity exoskeletons. The first considers the DOA of the full exoskeleton, while the second puts focus on one subsection, where the CLINICAL FUNCTION of such an exoskeleton is on the foot placement.

D.2.2 DOA classification method

D.2.2.1 Assistive exoskeleton

Consider the high-level CLINICAL FUNCTION of an elderly PATIENT performing level walking using a lower extremity exoskeleton supporting both legs with 20 % additive assistive force. All the movements are initiated and controlled by the PATIENT, who is simultaneously the OPERATOR of the MEE. The device senses the movement of the leg and the interaction forces. Subsequently it determines the phase of the gait cycle and SELECTS the needed joint torques to provide a predefined level of force assistance.

To establish the DOA of level walking with the exoskeleton, the weighted method presented in Annex C is used. The DOA of each function is chosen based on estimated contributions of MEE versus the OPERATOR, instead of using values associated with the specific descriptions in Figure C.4.

MONITOR: In level walking most of the sensing is done by the PATIENT (e.g. the environmental constraints, the need to make a step and overall stability). The MEE performs the MONITORING

TASK during the walking motion based on movement and forces applied by the PATIENT-OPERATOR. The amount of data monitored by the MEE and its importance can be estimated as 20 %; hence M = 0,2.

GENERATE OPTIONS: When the CLINICAL FUNCTION of level walking is considered, there are several OPTIONS to be produced (e.g. starting, stopping, speed of walking, keeping balance). These high level OPTIONS are produced by the GENERATE OPTION TASK (and the most appropriate chosen) by the PATIENT (also the OPERATOR). The exoskeleton leg has the predefined support OPTIONS (torque profile) for: a) swing leg movement and b) stance leg movement. The amount of OPTIONS GENERATED by the MEE and their importance can be estimated conservatively as 5 %; hence G = 0,05.

SELECT an OPTION: The MEE will decide whether it provides torques according to: a) the swing leg profile, or b) the stance leg profile. Other OPTIONS are selected by the OPERATOR. The amount of OPTIONS that the MEE needs to SELECT and their importance can be estimated as 5 %; hence S = 0,05.

EXECUTE the chosen OPTION: The EXECUTED movements in level walking are performed by the MEE and the OPERATOR in a shared fashion. The amount of assistive torque provided by the MEE can be predefined for each exoskeleton leg. In this example, the MEE provides 20 % of the overall required torque. For level walking, a full coordination of body movements is required and is EXECUTED by the OPERATOR. The percentage of the movement of the legs compared to the full body is estimated as 70 %. So the overall percentage of the MEE in performing the EXECUTE TASK can be estimated as 20 % of 70 %; hence E = 0,14.

There is no strong reason to choose specific weighting factors so all are set equally to 0,25. Hence using Equation (C.2):

$$DOA = w_1 M + w_2 G + w_3 S + w_4 E$$

with w_1 = 0,25, w_2 = 0,25, w_3 = 0,25 and w_4 = 0,25, yields

$$DOA = 0{,}25 \times 0{,}2 + 0{,}25 \times 0{,}05 + 0{,}25 \times 0{,}05 + 0{,}25 \times 0{,}14 \approx 0{,}1$$

D.2.2.2 Foot placement sub-function

One possible CLINICAL FUNCTION in a medical walking exoskeleton for walking is to move the swing leg to a new stable stance position. Here, this specific function is considered, when realized with different levels of DOA. The descriptive method, presented in Annex C, is used here to introduce the DOA.

Moving the swing foot to a stable stance location with DOA = 2 (tele- or master–slave operation), the PATIENT decides the optimal foot placement location and moves the foot, and the MEE supports the movement in PATIENT-decided movements (sharing the EXECUTE TASK).

Moving the swing foot to a stable stance location with DOA = 4 (shared decision with shared operation), the PATIENT and MEE calculate or determine an optimal foot placement location, the PATIENT initiates movement, then the movement is made on a shared basis.

Moving the swing foot to a stable stance location with DOA = 9 (OPERATOR performs the MONITOR TASK), the MEE calculates optimal foot placement location, and EXECUTES the swing leg motion. The PATIENT can intervene if needed.

D.2.3 Effect of DOA on the RISK MANAGEMENT PROCESS

D.2.3.1 Assistive exoskeleton

In an MEE as presented in D.2.2.1, DOA can be increased by moving more components of level walking from the PATIENT or OPERATOR to the MEE, up to a mode where coordination and movement of the legs is fully performed by the MEE with a high-level interface for the OPERATOR to decide, for example, only to start and stop the motion. Table D.1 and Table D.2 describe the effect of DOA on the RISK MANAGEMENT PROCESS for such a lower extremity exoskeleton.

Table D.1 – Example 1 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Support level walking of an elderly PATIENT.	Falling, Stumbling, Tripping, Imbalance, Collision.	Improved joint coordination, Improved gait control, Recovering in case of stumbling, Ability to absorb harmful energy due to collisions.	Taking control from the PATIENT can introduce conflict. Continuous coordination of level walking by the MEE (higher DOA) can lead to a reduction of situational awareness of PATIENT-OPERATOR. This can lead to additional HAZARDS, when the PATIENT-OPERATOR needs to take over control in dangerous situations.	DOA based on a RISK MANAGEMENT PROCESS for the individual in terms of his/her physical/ neurological capability, see Table D.2.

Table D.2 – Example 1 – Physical and cognitive capability of individual and CLINICAL FUNCTION needed

PATIENT'S physical and cognitive capability (SEVERITY)	CLINICAL FUNCTION needed
Physically impaired	Provide physical support as needed
Neurologically impaired	Motor control and physical support as needed
No physical functionality, e.g. spinal cord injury	Provide motor control and physical movement, with PATIENT-specific interface.

D.2.3.2 Foot placement sub-function

Table D.3 describes the effect of DOA on the RISK MANAGEMENT PROCESS for the specific CLINICAL FUNCTION for the foot placement example of the lower extremity exoskeleton.

D.2.4 Summary and conclusions

D.2.4.1 Assistive exoskeleton

The lower extremity exoskeleton exemplified can benefit from DOA depending on the physical and cognitive capability of the PATIENT. Where the PATIENT is capable in physical and cognitive senses, very limited DOA might be incorporated, and higher DOA could come into conflict with the PATIENT'S intentions in certain functions. As the physical/cognitive capability of the PATIENT becomes limited, the use of increased DOA will be important and can be beneficial to the PATIENT. From this example it occurs that the weighted method is only feasible if the quantitative contribution of each component of DOA (MGSE) can be roughly estimated by the MANUFACTURER. The method could allow changes in DOA to be studied by varying the weights and assess where benefits in MGSE are most effectively achieved.

D.2.4.2 Foot placement sub-function

For the specific subfunction of moving the swing foot to a stable stance location, it was shown that based on the DOA of this function, specific RISKS increase, while other RISKS decrease. As in D.2.4.1, the physical and neurological capability of the intended PATIENT to operate the exoskeleton, were shown to be key factors in estimating these RISKS, and determining the DOA with the lowest RISK for this sub-function. From this example it occurs that the descriptive method is especially feasible if the (sub)function under consideration is specific and well defined {, but may also be feasible for the complete system}.

Table D.3 – Example 1 – Sub-function TASK example

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Moving the swing foot to a stable stance location	Collision of foot or leg with environment (possibly leading to a fall)	With a low DOA the support of the MEE can lead to unexpected fast movement of the leg when controlled only by the PATIENT. With higher DOA, MEE controls movement. With a low DOA, shared execution can overshoot the targeted foot location, even if moving in the right direction. With higher DOA, MEE controls movement.	With a high DOA there can be a RISK of collision with the environment (e.g. obstacles) as the MEE controller might not be aware of the environment of operation.	DOA based on RISK MANAGEMENT PROCESS for the individual PATIENT in terms of physical/ neurological capability, see Table D.2
	Fall due to unstable foot placement	With sufficient understanding of the environment, MEE can calculate and EXECUTE stable foot placements.	With a high DOA, a PATIENT with medium/high functionality could perform an action that responds to environmental issues (e.g. a hole in the floor) which is not understood by the MEE, then the objectives of the PATIENT and the MEE can be conflicting and lead to instable foot placement. When the safe movement of the swing leg is fully and continuously performed by the MEE (higher DOA), it can lead to lower situational awareness of the stability of intended foot placements.	
	Failure of performing intended function (if this is walking ability)	With a low DOA, a PATIENT with low functionality might not be able to walk at all.	With a high DOA, a PATIENT with low functionality might be able to walk.	

D.3 Example 2 – Orthopaedic MEE/MES/MEDICAL ROBOT for reshaping bone

D.3.1 Description of the medical procedures

The medical procedures under consideration are total hip arthroplasty or replacement and knee arthroplasty for treatment of joint diseases such as osteoarthritis. This procedure aims to remodel the articular surface of a musculoskeletal joint to an appropriate shape for artificial joint implantation. Preoperative imaging such as CT scanning is used to plan the proper shaping of the remodelled bone. An orthopaedic milling system is used to resurface the bone based on the preoperative imaging data, and two types of system designs are considered here. The first design, a pre-programmed bone resurfacing system, does not adjust to changes in the environment, e.g. unexpected movement of the PATIENT. During treatment, the end-effector is controlled by the MEE without OPERATOR intervention based on pre-programmed parameters. In the second type of design, a bone resurfacing system with haptic guidance, the MEE assists the OPERATOR by guiding and adjusting the motion or the speed of the bone milling instrument attached at the end-effector. Optical or certain types of object tracking systems are utilised as vision input to identify and track the location and movement of the bone during surgery. During treatment, the end-effector is controlled by the OPERATOR under haptic interactive guidance from the system. This haptic guidance gives the OPERATOR a certain type of force feedback with which the OPERATOR can sense virtual walls or boundaries of "safe" regions or planned regions for remodelling. Additionally, the speed of the bone mill is attenuated or the milling blade is covered as the OPERATOR reaches "unsafe" regions so that the resurfacing can be performed only within the planned boundaries.

The path or trajectory of the bone milling instrument is pre-programmed in the orthopaedic surgery assist ROBOT with PE type AUTONOMY and the "safe" boundary or region information is pre-programmed in the SC type AUTONOMY ROBOT. However, the motion of the milling instrument during the operation is adaptively controlled or adjusted with particular DEGREE OF AUTONOMY such as monitoring whether the instrument and the surgical object under the operation are in planned trajectory or position, executing the reshaping TASK adjusting the milling instrument position, speed and/or force as needed to fulfil the operation plan, guiding surgeon's hand by the haptic feedback or controlling the instrument movement by shared control manner with the surgeon according to the planned safe boundary, and etc.

MEE or MES that automatically moves the bone milling instrument exactly following predefined position trajectory and/or speed/force profile as the example of infusion pump with pre-programmed drug injection speed/volume profile in D.3.4, if exists, can be considered by the MANUFACTURER as a type of computer-controlled milling machine, and not a MEDICAL ROBOT because it performs the operation with a low DEGREE OF AUTONOMY to fulfil the operation plan.

D.3.2 DOA classification method

Two exemplary systems, namely a pre-programmed bone resurfacing MEDICAL ROBOT system and a haptic guidance system, are considered. To classify the overall DOA of the MEE, the descriptive method presented in Annex C is used. The case of a pre-programmed bone resurfacing system can be classified as level 3 – PE (Pre-programmed execution) in Table C.1. The system performs the bone reshaping as pre-programmed or planned by the surgeon. The surgeon can temporarily pause or abort the operation of the MEDICAL ROBOT in the case of an unexpected event or emergency such as unexpected movement of PATIENT or the MEE, unexpected interruption of the vision system, unintended damage to surrounding tissue and resultant bleeding, etc. The haptic guidance system can be classified as level 4 – SD (Shared decision) as per Table C.1. The guidance system GENERATES haptic feedback or makes speed adjustments and provides repulsive force generation or speed attenuation. However, the OPERATOR holds the bone milling end-effector and can override the guiding reaction from the MEE as needed. Although the whole procedure execution is not shared by the OPERATOR and the MEE, the MEE actively participates in the decision-making PROCESS to determine the proper region of operation.

D.3.3 Effect of DOA on the RISK MANAGEMENT PROCESS

Table D.4 describes the effect of DOA on the RISK MANAGEMENT PROCESS for the two bone resurfacing MEE. The haptic guidance system increases the DOA over a pre-programmed implementation due to the MEE performing the GENERATE OPTIONS TASK using real-time sensor data for the MONITOR TASK, and assisting the OPERATOR in the EXECUTE TASK via haptic feedback.

D.3.4 Summary and conclusions

Potential RISKS associated with the DOA in this type of MEE are mainly related to the surgical object identification and tracking precision. The pre-programmed execution system works not much differently as compared to conventional programmable electronic medical devices as long as the resurfacing system and the PATIENT maintain the planned position and pose during the entire medical procedure. As in the case of a conventional drug infusion pump that performs the programmed drug infusion without human intervention for the programmed period with programmed speed value or pattern, the bone resurfacing MES performs bone reshaping as planned. RISKS associated with an unexpected change of the PATIENT's location and pose relative to the resurfacing system, or an unexpected interruption of the tracking device, and so on should be properly analysed and dealt with as part of the RISK MANAGEMENT PROCESS. In the case of adding haptic guidance features to the resurfacing system, the increase in DOA provides precision and accuracy benefits as well as reduced RISK.

Table D.4 – Example 2 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Bone resurfacing	Incorrect re-surfacing Tissue damage.	Haptic guidance system improves precision/accuracy and SAFETY in the tool movement (ROBOT can suggest "correct" boundary – motion guide) Haptic guidance system involves the OPERATOR in the execution and reduces the RISK of loss of situation awareness.		An increase in the DOA puts more reliance on the software to achieve acceptable RISK. This can impact the software SAFETY classification and associated activities shall be in accordance with IEC 62304.
AUTOMATIC tool moving	Error in handling the tool in movement.	Improved precision/accuracy and SAFETY in the tool movement (ROBOT can suggest "correct" boundary – motion guide)	Unexpected interruption in the MES operation could cause critical damage to PATIENT (e.g. vision system error, human interruption, loss of control)	

D.4 Example 3 – Instrument exchange on robotically-assisted surgical equipment

D.4.1 Description of the medical procedures

This example considers a robotically-assisted surgical equipment (RASE) intended to facilitate the accurate movement of surgical instruments in minimally invasive surgical procedures. The equipment incorporates a tele-operative servomechanism, where the surgeon controls the movements of surgical instruments using a master controller, while viewing the surgical site through a stereo viewer. During a surgical procedure, the surgeon will need periodically to exchange one instrument for another in order to perform various

surgical TASKS; for example, scissors might need to replace a forceps in order to cut tissue. This TASK is done by a surgical assistant at the PATIENT'S side and should be done quickly to minimize interruptions to the flow during surgery to decrease operative time. Additionally, the instrument should ideally be returned to approximately the same depth as the removed instrument so that the surgeon can continue operating at the same location without spending time repositioning the instrument. This example looks at adding a DOA to the specific TASK of exchanging instruments for this type of RASE.

NOTE RASE referred to via various names such as surgical ROBOT, computer-assisted surgical system, etc. In some jurisdictions, regulators may not recognize the definition of MEDICAL ROBOT or ROBOT as presented in this document. In these situations, the MANUFACTURER might identify the MEE/MES using more commonly accepted terms such as a RASE.

D.4.2 DOA classification method

In this example, the descriptive method is used to help understand the impact of DOA on the RISK MANAGEMENT PROCESS for the TASK of exchanging an instrument during surgery. The OPERATORS in this example are the surgeon and the PATIENT-side assistant. The following three methods for positioning the instrument during an instrument exchange are considered:

– Full manual: The instrument is always under the full control of the OPERATOR and advancement of the instrument is done under visual feedback by the surgical assistant viewing the instrument(s) on a video display. Additionally, no haptic feedback is provided by the equipment. Using the descriptive classification scheme in Table C.1, the DOA of the instrument exchange TASK example in this case is considered Full Manual (FM, DOA index = 1).

– Manual advance with assistance via "keep out" zones: In this implementation, the MEE is aware of the position of the removed instrument and provides software-controlled haptic feedback to guide the OPERATOR to return the new instrument to the same position as the removed instrument. The OPERATOR still has to manually advance the instrument, but the haptic feedback feels like a hard boundary whenever the trajectory differs from the previous position of the removed instrument. Additionally, a software-controlled hard-stop is also provided at the end of the insertion depth to ensure that the instrument is not positioned any deeper than the removed instrument. This facilitates the OPERATOR in quickly returning the instrument to the previous position and orientation. Using the descriptive classification scheme in Table C.1, the DOA in this case is considered Shared Decision where the MEE determines where to return the instrument and provides haptic feedback to guide the OPERATOR but the OPERATOR ultimately has full control (SD, DOA index = 4).

– Automated positioning by the MEE: In this implementation, the OPERATOR exchanges the instrument and then the MEE automatically returns the instrument to the same position as the removed instrument without any further OPERATOR intervention. This allows for extremely quick exchanges without having to rely on the OPERATOR to advance the instrument. However, the MEE does not account for emergent situations such as tissue movement, and the OPERATOR needs to MONITOR the EXECUTE TASK and stop it if an emergent situation occurs. Using the descriptive classification scheme in Table C.1, the DOA in this case is considered Guided Decision where the OPERATOR has to initiate or SELECT the action but the MEE fully EXECUTES it once initiated by the OPERATOR attaching the instrument to the equipment (GD, DOA index = 7).

D.4.3 Effect of DOA on the RISK MANAGEMENT PROCESS

The primary HAZARD considered in this example is the inadvertent contact with tissue that can result in damage. The SEVERITY can vary, depending on the type of tissue, the insertion force, and the instrument tip configuration; for example, a puncture could result if a sharp instrument is being inserted with sufficient force and is inserted beyond the previous depth. Table D.5 provides a comparative list of the DOA and description of OPERATOR and MEE involvement of three implementations, and identifies potential considerations on RISK. Table D.6 describes the impact of DOA on RISK, and recommends possible actions for mitigating RISK.

Table D.5 – Example 3 – Comparison of instrument exchange design implementations

Implementation	Description	Considerations
Full manual FM DOA = 1	OPERATOR controls insertion movement based on visual feedback	OPERATOR error unchecked Potential high SEVERITY
Assist with haptic feedback (keep out zones) SD DOA = 4	OPERATOR controls insertion movement with software limit on trajectory and insertion depth	DOA (haptic feedback) reduces RISK of OPERATOR error OPERATOR control of advances reduces the RISK of tissue movement or other problems
Automated positioning GD DOA = 7	MEE returns to previous location automatically	DOA (AUTOMATIC positioning) reduces RISK of OPERATOR error OPERATOR intervention might be required in case of tissue movement or other problems

Table D.6 – Example 3 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Instrument exchange	Tissue damage on insertion	Automated (software) insertion limit reduces chance of contact with tissue due to OPERATOR error in positioning the instrument. Both automated insertion limit and automated insertion reduce operative time and associated RISK.	Automated insertion limit or automated insertion is incorrect or incorrectly implemented (overshoots expected insertion depth) OPERATOR loses situational awareness during automated insertion; does not respond to emergent situation quickly (e.g. quick tissue movement).	An increase in the DOA puts more reliance on the software to achieve acceptable RISK. This could impact the software SAFETY classification and associated activities in accordance with IEC 62304.

D.4.4 Summary and conclusions

In this example, an increase in the DOA facilitates the accuracy and speed of instrument exchanges, and could reduce the RISK of tissue damage due to OPERATOR error. Ultimately, the decision on the DOA to be employed in the design will depend on several factors that are specific to the application. Additionally, full AUTOMATIC positioning can result in inattentiveness or a loss of situational awareness of the OPERATOR, which could lead to increased RISK, depending on the need for urgent action during instrument exchanges. USABILITY ENGINEERING in accordance with IEC 62366-1 shall help to inform the development team of the appropriate USABILITY RISKS and trade-offs for design approach. Furthermore, an increase in DOA could increase the reliance on the software implementing the haptic feedback for SAFETY, and the software effort might need to be increased accordingly. IEC 62304 provides guidance on the LIFE-CYCLE PROCESSES for software employed in medical devices.

D.5 Example 4 – Master–slave robotically-assisted surgical equipment

D.5.1 Description of the medical procedures

This example considers a master–slave robotically-assisted surgical equipment (RASE) intended to facilitate the accurate movement of surgical instruments in minimally invasive surgical procedures. The MEE incorporates a tele-operative servomechanism, where the

surgeon (the OPERATOR) controls the movements of surgical instruments using a master controller, while viewing the surgical site through a stereo viewer. In this example, various levels of DOA are considered for one of the procedure steps, locating the target anatomy for the MEE during laparoscopic surgery in order to remove or cut tissue. Table D.7 presents a summary of the effect of DOA on the RISK MANAGEMENT PROCESS for this example.

D.5.2 DOA classification method

The DOA classification method used is the weighted method with each function having equivalent weighting (0,25). The following scenarios are considered:

- visual identification: OPERATOR identifies the target anatomy using visual feedback from the stereo viewer. (DOA = 0,25 / M = 1, G = 0, S = 0, E = 0);
- visual identification with image enhancement: OPERATOR identifies the target anatomy using visual feedback that includes image enhancement to help identify the anatomy. (DOA = 0,55 / M = 1, G = 0,6, S = 0,3, E = 0,3); and
- AUTOMATIC identification with segmentation: The MES identifies the target anatomy within the field of view of the OPERATOR. (DOA = 0,9 / M = 1, G = 1, S = 1, E = 0,6.

The DOA classification method used is the weighted method.

D.5.3 Effect of DOA on RISK MANAGEMENT PROCESS

Table D.7 – Example 4 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Identification of target anatomy	Incorrect location of target anatomy resulting in inadvertent tissue damage	Image enhancement improves identification capability of the OPERATOR Segmentation might be able to identify features not perceptible to human eyes	Enhancement and segmentation can result in false positive identification of target anatomy Segmentation could result in the OPERATOR losing situation awareness	An increase in the DOA puts more reliance on the imaging software. This can impact the software SAFETY classification and associated activities in accordance with IEC 62304

D.5.4 Summary and conclusions

Increasing DOA facilitates identification of the target anatomy and in general reduces the RISK of inadvertently cutting the wrong tissue during laparoscopic surgery. As DOA increases, the reliance on the software implementing the image enhancement and segmentation need to be increased accordingly. IEC 62304 provides guidance on the LIFE-CYCLE PROCESSES for software in medical devices. USABILITY ENGINEERING in accordance with IEC 62366-1 should help inform the development team of the appropriate USABILITY RISKs and trade-offs in the design approach. Additionally, full AUTOMATIC identification with segmentation could result in inattentiveness or a loss of situational awareness of the OPERATOR, which could lead to increased RISK depending on the OPERATOR's reliance on the MEE to identify the target anatomy. USABILITY ENGINEERING in accordance with IEC 62366-1 should help to inform the development team of the appropriate USABILITY RISKs and trade-offs.

D.6 Example 5 – Image-guided radiotherapy equipment

D.6.1 Description of the medical procedures

Image-guided radiotherapy (IGRT) equipment is covered by IEC 60601-2-68 [31]. IGRT is the PROCESS where an image is taken as part of the PATIENT treatment and is then used to adjust

the PATIENT'S target position relative to the radiation source so that the radiation is delivered in the PATIENT's orientation GENERATED in the dose treatment plan.

The MES for the IGRT PROCESS consists of an external beam equipment (EBE) and a connected and interacting IGRT equipment. The offline review workstation(s), which can be remote from the treatment room, is not part of the MES. Treatment is the part after initiating the treatment PROCESS with, e.g. a beam ON button. In this example, the effect of DOA on only the RISK MANAGEMENT PROCESS for the IGRT equipment is discussed.

IGRT equipment is consisting out of an imaging device to acquire 2D or 3D imaging data from the PATIENT. This image acquisition can be done with different kind of fixed, non-movable installed, and independent and movable, or an integrated imaging device. After the image acquisition, the required corrections are calculated and then applied to the EBE.

In this example we consider explicitly the IGRT equipment, where the DOA is focused on the actual image registration and correction calculations. The specific equipment, i.e., EBE, which finally EXECUTES the actual movement to apply the corrections, is outside of the IGRT equipment boundary. In that sense the IGRT example can be considered a non-robotic one.

D.6.2 DOA classification method

When examining the DOA in Table C.1 and Table C.2, as utilized for the image analysis to determine the PATIENT support vector shifts and the transfer of these shifts to the linear accelerator, it was determined that different levels can be grouped into 3 classes based on the OPERATOR'S ability to perform the MONITOR, GENERATE OPTIONS, SELECT an OPTION, and correct the calculated shifts sent to the linear accelerator. The three groups are as follows:

– offline IGRT is when the image for alignment is taken and the PATIENT is allowed to leave while the image is analysed and the shifts are determined. In most cases, the image analysis takes place at another location, by another OPERATOR and is not bound to the MEE. In this case, there is ample time for the OPERATOR to check the calculations that might have been done by the software.
– online IGRT is when the image for alignment is taken and the corrections are calculated and applied while the PATIENT remains in the treatment position on the MEE. In this case, the OPERATOR has a finite amount of time to determine if the corrections being applied are correct, and if not, to either abort the start of the procedure or determine new corrections.
– real-time IGRT is when images for alignment are taken throughout the treatment delivery and the corrections calculated by the IGRT equipment are applied directly to the control of the linear accelerator without OPERATOR intervention. At this level, the OPERATOR might or might not be able to determine if the calculations are correct within the required tolerances of time shifts needed before application.

The descriptive method gives a classification of increasing DOA in IGRT MEE as shown in Table D.8.

The overlap of the DOA for the first two groups is due to the fact that in this situation, DOA by itself is not the only factor leading to increased RISK, another important factor is the amount of time the OPERATOR has to react to the information processed and applied.

When using the binary classification method, the four parts of the medical procedure, namely, MONITOR, GENERATE, SELECT, and EXECUTE TASKS have to be assigned with the correct meaning for the radiotherapy:

– MONITOR: Image registration, acquiring the image information;
– GENERATE: Calculation of the corrections to be applied based on the planning image information and the acquired images;
– SELECT: The corrections calculated can be either reviewed by the OPERATOR and corrected or approved, or the IGRT equipment just uses the GENERATED shift AUTONOMOUS; and

– EXECUTE: Apply the correction by either changing the treatment plan or moving the corresponding linear accelerator's axes.

Table D.8 – Example 5 – Descriptive classification of DOA for IGRT MEE

Degree	Mnemonic			
1	Full Manual (FM)	Offline IGRT	Online IGRT	
2	Teleoperation (TO)			
3	Preprogramed execution (PE)			
4	Shared decision (SD)			
5	Decision support (DS)			
6	Blended decision (BD)			
7	Guided decision (GD)			
8	AUTONOMOUS decision (AD)			Real-time IGRT
9	OPERATOR MONITORING (OM)			
10	Full AUTONOMY (FA)			

The binary method gives a classification of increasing DOA in IGRT MEE as shown in Table D.9.

Table D.9 – Example 5 – Binary classification of DOA for IGRT MEE

Index	EXECUTE	SELECT	GENERATE	MONITOR	Offline IGRT	Online IGRT	Real-time IGRT
0	OPERATOR	OPERATOR	OPERATOR	OPERATOR	x	x	
1	OPERATOR	OPERATOR	OPERATOR	MEE		x	
2	OPERATOR	OPERATOR	MEE	OPERATOR		x	
3	OPERATOR	OPERATOR	MEE	MEE		x	
4	OPERATOR	MEE	OPERATOR	OPERATOR		x	
5	OPERATOR	MEE	OPERATOR	MEE		x	
6	OPERATOR	MEE	MEE	OPERATOR		x	
7	OPERATOR	MEE	MEE	MEE		x	
8	MEE	OPERATOR	OPERATOR	OPERATOR	x		
9	MEE	OPERATOR	OPERATOR	MEE			
10	MEE	OPERATOR	MEE	OPERATOR			
11	MEE	OPERATOR	MEE	MEE			
12	MEE	MEE	OPERATOR	OPERATOR			
13	MEE	MEE	OPERATOR	MEE			
14	MEE	MEE	MEE	OPERATOR			
15	MEE	MEE	MEE	MEE			x

For a better understanding and clear distinction between the three groups, Table D.9 is sorted according to the column related to the "EXECUTE" TASK. Note that the index was kept at the original binary order.

D.6.3 RISK ANALYSIS for each level of DOA

Offline IGRT – the DOA for offline IGRT is ranging from 1 to 7 (descriptive method) or, 0 and 8 (binary method) respectively. In both DOA classification methods the highest DOAS are not used because the SELECT and the EXECUTE TASKS are under the control of the OPERATOR.

Online IGRT – the DOA for online IGRT is ranging from 1 to 7 (descriptive method) or, 0, 2, 4, 6, 8, 10, 12, 14 (binary method) respectively. In both DOA classification methods the highest DOAS are not used because the SELECT and the EXECUTE TASKS are under the control of the OPERATOR. The major difference between the offline and online procedures is the time available for the SELECT TASK.

Real-time IGRT – the DOA for real-time IGRT is ranging from 8 to 10 (descriptive method) or 15 (binary method) respectively. Both DOA classification methods result in a high DOA. This is mainly because the SELECT and EXECUTE TASKS are solely controlled by the MEE.

It is up to the MANUFACTURER to decide whether to use the descriptive or binary methods. In case of uncertainty it is recommended to assume that the higher DOA is appropriate.

D.6.4 Effect of DOA on the RISK MANAGEMENT PROCESS

Based on the above assessment, the effect of DOA in the RISK MANAGEMENT PROCESS for the online IGRT and real-time IGRT use cases is most relevant here. AUTONOMY is mainly utilised to improve the radiation delivery accuracy by detecting and compensating for the target motions before or during the treatment.

Table D.10 presents a summary of the effect of DOA on the RISK MANAGEMENT PROCESS for this type of MEE.

D.6.5 Summary and conclusions

During real-time IGRT treatments, a high DOA is utilised in order to achieve more accurate radiation targeting, allowing the reduction of the planned treatment volume's margin for the PATIENT's benefit. Because the mitigation of the increased RISK is done through display of images or position information to the OPERATOR, USABILITY becomes more important to evaluate if the OPERATOR can handle the increased amount of information. Additionally, as the DOA is increased, the potential for the OPERATOR to lose situation awareness needs to be assessed for the application. Presently, a DOA of full AUTONOMY is not allowed for these systems by IEC 60601-2-1, as it is required that the OPERATOR can always INTERRUPT the procedure at any time.

Table D.10 – Example 5 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Online IGRT	Error in correctly detecting the target position, and inaccurately calculating the anticipated target positions leading to a wrong IRRADIATION position and wrong treatment of the PATIENT	More accurate PATIENT treatment setup position due to a better detection of the target position and a more accurate calculation of the anticipated correction can be achieved by using a better image analysis algorithm and using all available data for the image registration and correction calculation.	Wrong PATIENT setup position because the target position is being miscalculated by either wrong image registration or correction calculation and the OPERATOR fails to detect it prior to the start of the treatment, lack of situational awareness	Online IGRT improves the initial setup positioning but does not take into account PATIENT and target movements, after the correction have been applied and the treatment started.
Real-time IGRT	Error in correctly detecting the target position and movement, inaccurately predicting the anticipated target position and motion, inaccurately calculating the anticipated target positions, and limitations due to the bounds of the EBE not being able to apply the requested changes, leading to a wrong IRRADIATION position and wrong treatment of the PATIENT	Better overall PATIENT treatment, because of the AUTOMATIC adjustments of the treatment parameters relating to the moving target position are applied instantaneously and healthy tissue is spared from being IRRADIATED. The treatment beam is turned off instantaneously when equipment limitations are detected and no unwanted irradiation occurs due to slow reaction times of the OPERATOR.	The automated adjustments of the treatment parameters are delayed or wrong. Collisions between the PATIENT and MEE are more likely to happen due to the repeatedly applied AUTOMATIC adjustments of the treatment parameters. OPERATOR loses situational awareness during real-time IGRT PROCESS and does not respond quickly to emergent situation.	

D.7 Example 6 – Automated external defibrillator (AED)

D.7.1 Description of the medical procedures

An AUTOMATIC external defibrillator aims to normalise the rhythm of the heart by an electrical pulse via electrodes applied to the PATIENT'S skin. It is used in (emergency) treatment of life-threatening cardiac dysrhythmias such as ventricular fibrillation and pulseless ventricular tachycardia. As an AED has no actuated mechanism, nor is moving within its environment, it is not a MEDICAL ROBOT. It is included here as example, as it is an MEE with a high DOA for several of its functions, in contrast with the classical manually operated defibrillators. As defibrillators are typically used in emergency situations, they are usually operated and available in crowded public spaces. As a defibrillator's electric shock can be harmful for a healthy functioning heart, the automated external defibrillator (AED) has been introduced where the defibrillator's actions, once it is activated by the OPERATOR, are automated to analyse the ECG obtained from the electrodes placed on the PATIENT'S skin, identify shockable cardiac rhythms and automatically operate the defibrillator when a shockable rhythm is detected. While a manual defibrillator is intended to be used by a medical professional, an AED is intended to allow the OPERATOR to be a lay person and to reduce the RISK of using the device. The PROCESS of automating the defibrillation PROCESS is explored in this example.

D.7.2 DOA classification method

In situations where a defibrillator is used, the functions of the MONITOR, GENERATE, SELECT and EXECUTE TASKS can be characterized as follows:

– MONITOR: Detection of possible emergency situations (ventricular fibrillation); Measurement of heart rhythm to detect potential ventricular fibrillation; Detect correct moment to apply electrical pulse.
– GENERATE: Electrical pulse of different intensity (energy in joules) or no pulse.
– SELECT: Electrical pulse of selected intensity or no pulse.
– EXECUTE: Bringing and connecting the defibrillator to the PATIENT (done as step 1; i.e. done in the MONITORING TASK); Connecting the electrodes to the PATIENT's skin; and Providing the electrical pulse of selected intensity at the appropriate moment.

The descriptive method presented in Table D.11 is used to introduce DOA into the AED. In Table D.11, the information needed to classify the AED is provided.

The operation of the AED, according to the descriptive method, can be classified as having a DOA = 9, OPERATOR performing the MONITOR TASK (OM): The MEE GENERATES OPTIONS, SELECTS the OPTION to implement and EXECUTES the chosen OPTION. The OPERATOR monitors the MEE and intervenes if necessary. Intervention places the human in the role of making a different OPTION selection. During the procedure there might be decision-making points that will be decided by the MEE.

Table D.11 – Example 6 – Descriptive method classification of DOA in external defibrillators

Function	Description	In manual AED	In AED	DOA for AED
MONITOR	a. Detection of possible emergency situations	a. OPERATOR	a. OPERATOR	Shared, but MEE on CLINICAL FUNCTION (b and c)
	b. Measurement of heart rhythm to detect potential heart fibrillation situations	b. OPERATOR with possible MEE support	b. MEE	
	c. Detection of correct moment to apply electrical pulse	c. OPERATOR	c. MEE	
GENERATE	Electrical pulse of specific intensities at specific moments or no pulse	OPERATOR with limited preselected OPTIONS	MEE, with limited preselected OPTIONS [a]	MEE
SELECT	Electrical pulse of selected intensity at selected moment or no pulse	OPERATOR	MEE	MEE
EXECUTE	a. Bringing the defibrillator to the PATIENT and turning it on	a. OPERATOR	a. OPERATOR	Shared, but MEE on CLINICAL FUNCTION (c)
	b. Placement of the defibrillator probes (electrodes) on the PATIENT'S skin	b. OPERATOR	b. OPERATOR, with guidance of MEE	
	c. Application of the selected pulse (CLINICAL FUNCTION)	c. OPERATOR	c. MEE [b]	

[a] As the OPTIONS were preselected by the MANUFACTURER, the defibrillator can also be classified as AUTOMATIC, but as the functioning of the AED is not necessarily fully understood by its OPERATOR, it is preferable to speak of the device's DOA.

[b] Sometimes the MEE indicates the correct moment for applying the pulse but the OPERATOR needs to allow the shock to be applied by keeping a button pushed, meaning that the OPERATOR can always SELECT the 'no pulse' OPTION.

D.7.3 Effect of DOA on the RISK MANAGEMENT PROCESS

Table D.12 describes the effect of DOA on the RISK MANAGEMENT PROCESS for the AED.

Table D.12 – Example 6 – Effect of DOA on the RISK MANAGEMENT PROCESS

Function/TASK	HAZARDS	Impact of increasing DOA		Additional considerations
		Reduced RISK	Increased RISK	
Applying the electrical pulse of selected intensity at selected moment	Death or impairment of the PATIENT because MEE cannot realize the electrical pulse (INTENDED USE fails)	No impact.	No impact	This depends on actions (mainly placing electrodes correctly) that are performed by OPERATOR or general MEE malfunction for both low and high DOA implementation of MEE
	Death or impairment of the PATIENT because MEE provides a pulse when not required	When device is correctly installed, higher DOA leads to fewer incorrectly applied electrical pulses, especially in the case of lay OPERATORs	With skilled OPERATORs, they might, in some cases, have a better judgment than the AED	
	OPERATOR receives an electrical shock	No impact	No impact	This depends on actions (placing electrodes) that are performed by the OPERATOR for both low and high DOA implementation of MEE
	Death or impairment of the PATIENT because selected OPTION (electrical pulse) is not adequate	DOA GENERATES and SELECTS better OPTIONS than a lay OPERATOR	With a skilled OPERATOR, he/she might, in some cases, have a better judgment than the AED	

D.7.4 Summary and conclusions

As an AED is intended to be used by a lay OPERATOR, increasing its DOA can reduce several SAFETY RISKS associated with its use. Automating these functions and allowing a lay person to use the device requires that the AED instruct the OPERATOR adequately during operation. These instructions facilitate the situation awareness of the OPERATOR with respect to performing the necessary TASKS, and reduce the need to be familiar with device operation details. Automating aspects of the MONITOR, GENERATE, SELECT and EXECUTE TASKS for a skilled OPERATOR could lead to less or no reduction of associated RISKS.

Annex E
(informative)

PATIENT SAFETY characteristics to be taken into account during RISK MANAGEMENT for MEE or MES employing DOA

E.1 Types of PATIENTS

The RISK MANAGEMENT PROCESS for MEE or MES employing DOA can be part of an organization's quality management system. The integration should ensure that information about RISK is used as a basis for decision making at all levels of the organization regarding MEE or MES. Integration does not simply involve introducing established and standardized RISK MANAGEMENT tools and PROCESSES into existing quality management systems. It requires the adaptation and alteration of those tools and PROCESSES to suit the needs of the decision makers and their existing PROCESSES for decision making. A key part of the RISK MANAGEMENT PROCESS is to consider the SAFETY characteristics of the PATIENT to ensure BASIC SAFETY and ESSENTIAL PERFORMANCE of MEE or MES when DOA is introduced, as MEE or MES employing DOA can have algorithms to identify types of PATIENTS and their SAFETY characteristics.

Types of PATIENTS are normally categorized as follows:

1) Premature baby/preborn baby (Preterm birth)
2) Neonate baby/newborn baby (from birth to 1 month of age)
3) Infant (greater than 1 month to 2 years of age)
4) Child (greater than 2 to 12 years of age)
5) Adolescent (greater than 12 to 21 years of age)
6) Adult (greater than 21 to 65 years of age)
7) Geriatric/Elderly (greater than 65 years of age)

NOTE 1 Pediatric subgroups includes: Neonate baby (2), Infant (3), Child (4) and Adolescent (5) groups above.

NOTE 2 The gender of the PATIENT can be an important part of PATIENT characteristics.

NOTE 3 The type of PATIENT years as indicated above are for reference only; there is no international consensus on the age grouping per type of PATIENT.

Higher RISK levels are found at the extremities of the different types of PATIENTS. For PATIENT types 1, 2, 3, 4 and 7, there are commonly higher RISK levels since the RISK CONTROL measure of training/OPERATOR manual and labelling typically cannot be used as RISK control. These PATIENT types cannot read instructions and have limited capabilities to avoid HAZARDS; for more information see ISO TR 22411 [52].

E.2 Additional attention for child (PATIENT) SAFETY

Child SAFETY should be a major concern for society, because childhood and adolescent injuries are a major cause of death and disability in many countries. Children are born into an adult world, without experience or appreciation of RISK but with a natural desire to explore. Consequently, the potential for injury is particularly great during childhood. Since supervision to the degree that always prevents or controls potentially harmful interactions is neither possible nor practical, additional injury prevention strategies are necessary.

Intervention strategies aimed at protecting children should recognize that children are not little adults. Children's susceptibility to injury and the nature of their injuries differ from those of adults. Such intervention strategies should also recognize the fundamental concept that children do not MISUSE products or surroundings. Rather, children interact with them in ways that reflect normal child behaviour, which will vary according to the child's age and level of

development. Therefore, intervention strategies intended to protect children might differ from those intended to protect adults.

As injuries to children are closely related to their developmental stage and their exposure to HAZARDS at various ages, it is important to sort child injury data by age group to identify the patterns that emerge.

The identification of appropriate RISK control measures are based on the methods of epidemiology, engineering and biomechanics as well as by the feedback cycle of gradual improvements in design. When choosing preventive measures, it should be recognized that tolerable levels of RISK for adults might not be sufficient to protect children. When introducing measures designed to protect adults, it is essential to consider any potential effects that might increase RISKS to children (e.g. passenger side air bags in cars). PATIENT characteristics related to the SAFETY of the medical device have to be considered.

The PATIENT characteristics mentioned in Clause E.2 should be addressed through the RISK MANAGEMENT PROCESS, as per 4.2 of ISO 14971:2007.

E.3 PATIENT abilities and variability of physiological signals

E.3.1 ISO/IEC Guide 71

PATIENT abilities and variability are described in detail in Clause 7 of ISO/IEC Guide 71:2014 [63]. Brief details are summarized here, emphasizing the connection to DOA.

E.3.2 Changing need and abilities of PATIENTS

The needs and abilities of PATIENTS change as they advance from childhood to old age and the abilities of individuals in any particular age group vary substantially. It is important to recognize that functional and cognitive limitations vary from comparatively minor impairment to more extreme forms. It should be noted that although some limitations might be minor in nature, in combination, as is the case in ageing, these can pose significant problems, especially when DOA is introduced into MEE or MES for the different types of PATIENTS.

The following subclauses provide descriptions of body functions or PATIENT abilities and the practical implications. This is to inform, increase understanding and raise awareness about how human abilities impact the BASIC SAFETY and the ESSENTIAL PERFORMANCES of MEE and MES when introducing DOA.

E.3.3 PATIENT's sensory abilities

PATIENT's sensory abilities could be important for MGSE in MEE or MES with DOA. Some key sensing abilities are listed.

Seeing – Seeing relates to sensing the presence of light and sensing the form, size, shape and colour of visual stimuli.

Hearing – Hearing functions relate to sensing the presence of sounds and discriminating the location, pitch, loudness, quality and comprehension of sounds.

Touch – Touch functions relate to sensing surfaces and their texture or quality. There will be reliance on other stimuli, particularly visual and auditory.

Taste/smell – Taste and smell are separate senses but have been grouped together because of their similar practical implications. Taste relates to sensing four basic qualities (bitter, sweet, sour and salt) through receptors on the tongue. Smell relates to the use of receptors in the nose to sense odours and smells. The two senses of taste and smell are used together to identify the range of flavours which can normally be distinguished.

Balance – The ability to maintain balance and avoid falling is dependent on a complex system, which involves the brain coordinating visual stimuli, feedback from the balance mechanism in the ears and movement of the limbs. Continuous control of balance is required during virtually all types of activities.

E.3.4 PATIENT'S PHYSICAL ABILITIES

The PATIENT's physical abilities could be important for MONITORING-GENERATING-SELECTING-EXECUTING in MEE or MES with DOA. Some key physical abilities are listed below.

Dexterity – Dexterity relates to activities of hand and arm use, particularly coordinated actions of handling objects, picking them up, manipulating and releasing them, using one hand, fingers and more specifically, thumbs.

Manipulation – Manipulation relates to activities of carrying, moving and manoeuvring objects. It includes actions using legs, feet, arms, and hands – reaching, lifting, putting down, pulling, pushing, kicking, grasping, releasing, turning, throwing and catching.

Movement – Movement relates to activities of changing the body position and transferring oneself from one area to another using legs, feet, arms and hands.

Strength and endurance – Strength relates to the force generated by the contraction of a muscle, or muscle group, when carrying out an activity. Strength can be the force exerted with a specific part of the body in a specific action (e.g. pushing) or applied to a specific object (e.g. opening bottle tops). Activities include pulling, lifting, pressing, gripping, pinching, and twisting. Strength also depends on endurance, the capacity to sustain force. This can be related to heart and lung function. Limited strength is common to many physically disabling conditions and is a common reason for being unable to operate equipment.

Voice – Voice relates to the sound produced by the vocal organs, usually as speech. Speech impairments can influence speech in a general way, or only certain aspects of it such as articulation, volume, fluency, speed, melody and rhythm.

E.3.5 PATIENT'S COGNITIVE ABILITIES

The PATIENT's cognitive abilities could be important for MONITORING-GENERATING-SELECTING-EXECUTING in MEE or MESs with DOA. Some key cognitive abilities are listed.

General – Cognition is the understanding, integrating and processing of information. The information includes abstraction and organization of ideas and time management.

Intellect – Intellect is the capacity to know, understand, and reason.

Memory – Memory relates to specific mental functions of registering and storing information and retrieving it as needed.

Language and literacy – Language and literacy are the specific mental functions of recognizing and using signs, symbols and other components of a language.

E.3.6 PATIENT ALLERGIES

The PATIENT's allergies could be important for MONITORING, GENERATING, SELECTING AND EXECUTING in MEE or MES with DOA. Some key allergies are listed.

Contact allergies – Contact allergies are caused by allergens that enter the body through the skin. They are particularly contained in powders, lotions, perfumes, scented products, cosmetics, household chemicals, some metals, or latex, and can be found in many household,

building and electrical appliances. Contact allergy is prevalent among about 15 % of the population and is often lifelong.

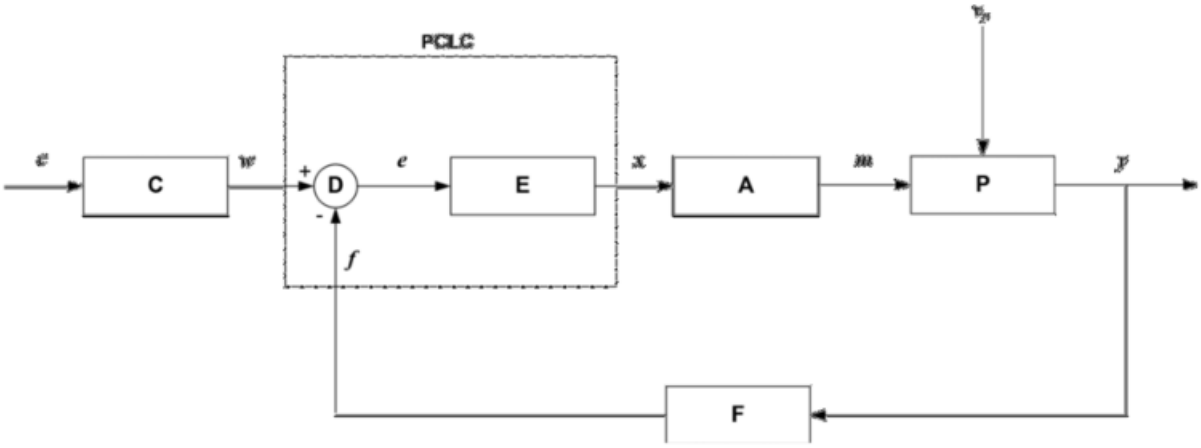
Food allergies – A food allergy is a reaction or intolerance to one or more foodstuffs. A great number of foods can cause allergic reactions, the most common being milk, wheat, soy, egg, peanuts and fish. Food colours, preservatives and additives are also major causes of allergies.

PATIENTS' respiratory allergies – Airborne allergens cover those that are inhaled, such as dust, pollen, mites, moulds and animal detritus. The most typical respiratory allergy is asthma, which results in constriction of the respiratory channels and breathlessness.

Annex F
(informative)

PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM AND DOA

Figure F.1, which is Figure 1 from IEC 60601-1-10:2007, presents a typical closed-loop control system that sets the controller output variable in order to adjust the measured PHYSIOLOGIC VARIABLE by relating it to a reference variable. The closed-loop system has a number of elements which have a role to play in the making the measurement, comparing the actual output with what it should be to generating and implementing the required control output to meet the desired goal.



Elements		VARIABLES	
PCLC	PHYSIOLOGIC CLOSED-LOOP CONTROLLER		
A	ACTUATOR	m	MANIPULATED VARIABLE
C	COMMAND TRANSFER ELEMENT	w	REFERENCE VARIABLE
D	COMPARING ELEMENT	e	ERROR VARIABLE
E	CONTROL TRANSFER ELEMENT	x	CONTROLLER OUTPUT VARIABLE
F	MEASURING TRANSFER ELEMENT	f	FEEDBACK VARIABLE
P	PATIENT TRANSFER ELEMENT	y	PHYSIOLOGIC VARIABLE
		v_p	PATIENT DISTURBANCE VARIABLE
		c	COMMAND VARIABLE

Figure F.1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM (PCLCS) utilizing a PCLC

When DOA is introduced into the MEE or MES, the closed-loop system presents the full range of MONITORING, GENERATING, SELECTING and EXECUTION activities in a holistic manner. When the MONITORING, GENERATING, SELECTING and EXECUTION TASKS are considered individually, only relevant parts of the closed-loop system are active. Figure F.1 shows which elements are relevant for each of the MONITORING, GENERATING, SELECTING and EXECUTION TASKS.

There are various ways of considering how DOA can be included in specific features of MEE/MES. For example, the MONITORING TASK includes the measuring transfer and could include comparing elements from the PATIENT or the CLINICAL FUNCTION being performed; hence if DOA is to be introduced into the MONITORING TASK, it would be appropriate to introduce DOA to these elements and examples (shaded areas) are shown in Figure F.2. Similarly, if DOA is to be introduced into the GENERATING, SELECTING or EXECUTION TASKS, DOA could be introduced to the relevant elements and examples are shown in Figure F.3 to Figure F.5.

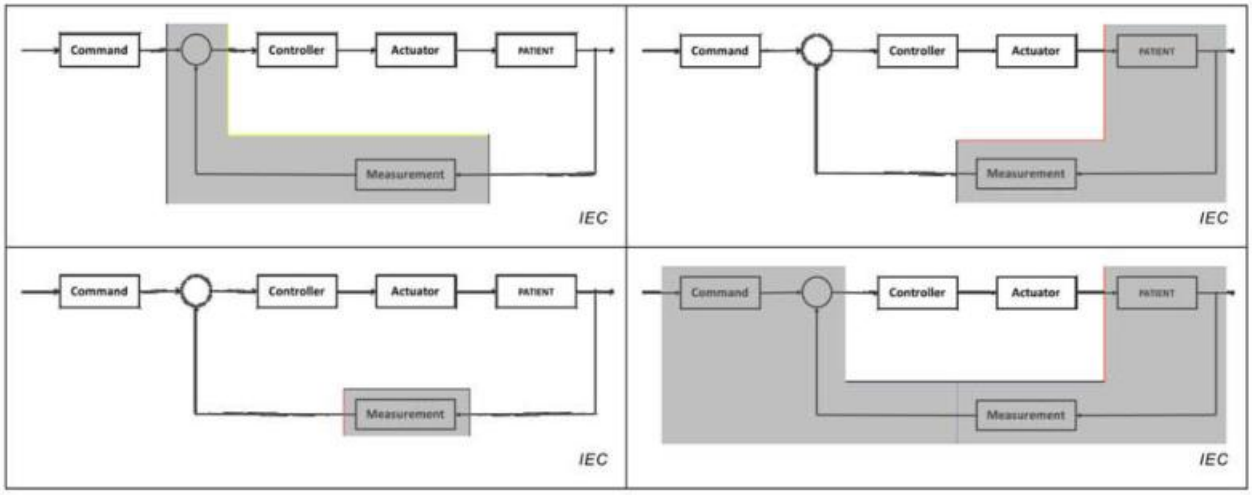


Figure F.2 – Examples of introducing DOA into the MONITORING TASK via PCLCS

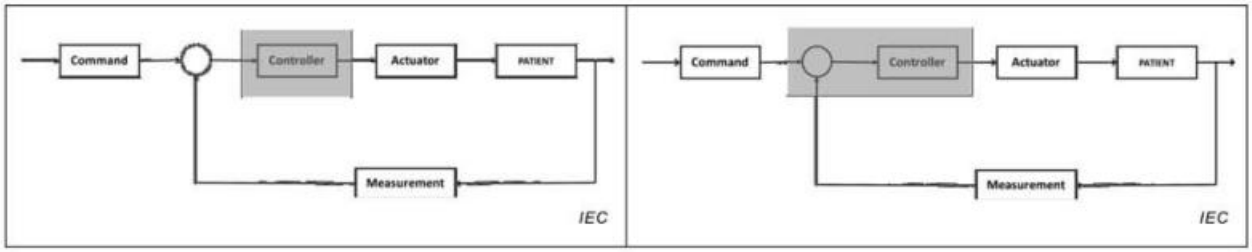


Figure F.3 – Examples of introducing DOA into the GENERATING TASK via PCLCS

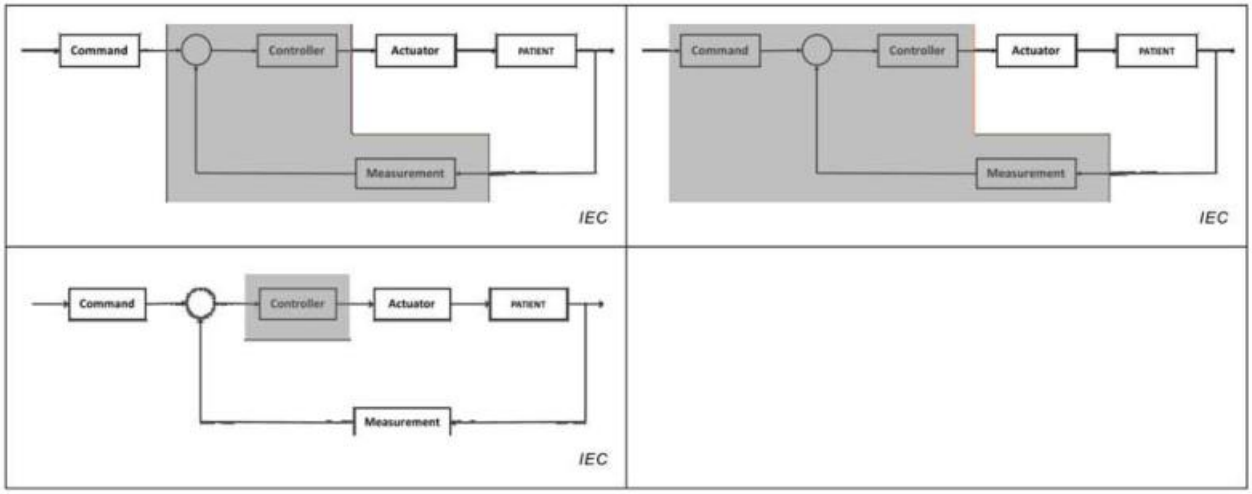


Figure F.4 – Examples of introducing DOA into the SELECTION TASK via PCLCS

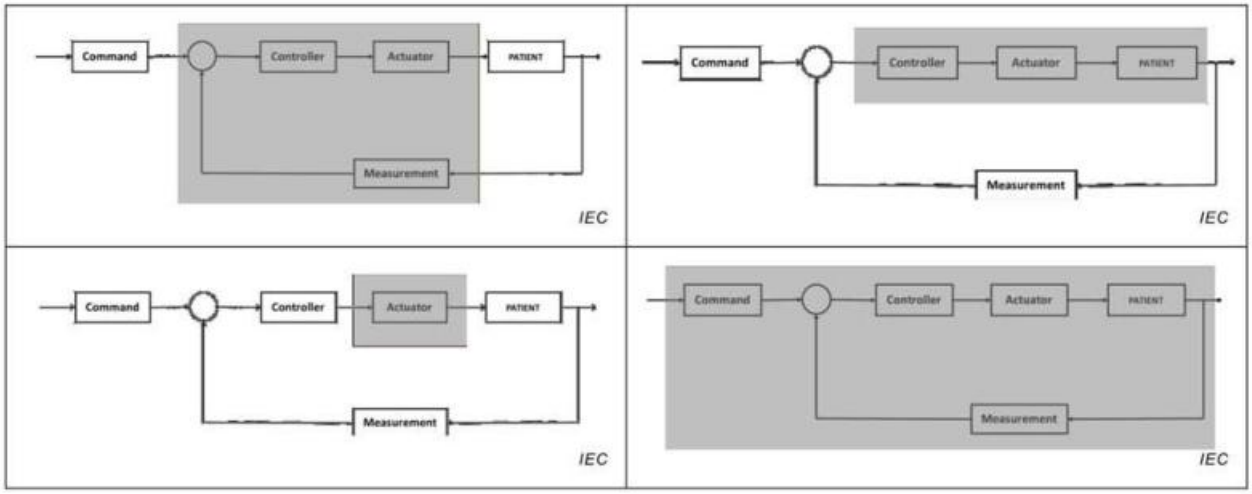


Figure F.5 – Examples of introducing DOA into the EXECUTION TASK via PCLCS

Annex G
(informative)

Examples of distributed ESSENTIAL PERFORMANCE

Table G.1 is an informative list of the ESSENTIAL PERFORMANCES extracted from the 3rd edition series of the IEC 60601-2-XX and IEC ISO 80601-2-XX standards. The following ESSENTIAL PERFORMANCES list has been consolidated to facilitate reading and ESSENTIAL PERFORMANCES identification.

Table G.1 – Examples of distributed ESSENTIAL PERFORMANCE *(1 of 3)*

ESSENTIAL PERFORMANCE	Extracted from MEE particular standard
Accuracy of loading factors	IEC 60601-2-45, IEC 60601-2-54
Accuracy of output	IEC 60601-2-24
Accuracy of pressure measurements	IEC 60601-2-34
Accuracy of signal reproduction	IEC 60601-2-26
Accuracy of the clinical treatment	IEC 60601-2-24
Accurately differentiate between needed output and non-needed output	IEC 60601-2-4, IEC 60601-2-5
Adherence to the accuracy of the volume and flow to PATIENT (inflow/outflow volume)	IEC 60601-2-34, ISO 80601-2-13
Alarm signals of high priority alarm conditions	IEC 60601-2-24
Alarm system that includes the capability to detect a physiological alarm condition: Diagnosis accuracy, pulse rate accuracy and limit alarm conditions or generation of a technical alarm condition	ISO 80601-2-61
Assurance that there is no unacceptable RISK, if there is a lack of, or significant error in, provision of a particular output to provide accurate diagnosis or therapy which is not identifiable by a trained OPERATOR	IEC 60601-2-18
Assurance that there is no unacceptable RISK that the OPERATOR is viewing the live image during a procedure, rather than a recorded image	IEC 60601-2-18
AUTOMATIC control system	IEC 60601-2-45, IEC 60601-2-54
Battery depletion indicator	IEC 60601-2-31
Common rejection mode	IEC 60601-2-26
Conducted disturbances	IEC 60601-2-25
Defibrillation protection	IEC 60601-2-25, IEC 60601-2-27
Delays to or from a distributed alarm system	IEC 60601-2-34, IEC 60601-2-49
Deliberate action required to change settings	IEC 60601-2-31
Delivered air pressure	ISO 80601-2-12
Delivery of a minimum and adequate illumination on the operating field	IEC 60601-2-41
Delivery of synchronized output	IEC 60601-2-4
Delivery of therapy output	IEC 60601-2-4, IEC 60601-2-5
Detection of disconnected PATIENT APPLIED PART	IEC 60601-2-34
Disarming runaway rate protection	IEC 60601-2-31
Electrical supply	ISO 80601-2-12
Electrosurgery interference recovery	IEC 60601-2-25

Table G.1 *(2 of 3)*

ESSENTIAL PERFORMANCE	Extracted from MEE particular standard
Flow requirements for treatment	ISO 80601-2-12
Freedom from display of incorrect numerical values associated with the therapy to be performed	IEC 60601-2-18
Freedom from noise on a wave form or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which can alter the diagnosis/treatment	IEC 60601-2-5, IEC 60601-2-37
Freedom from production of unwanted output	IEC 60601-2-2, IEC 60601-2-5
Freedom from the display of incorrect numerical values associated with the diagnosis to be performed	IEC 60601-2-18
Freedom from the display of incorrect SAFETY-related indications	IEC 60601-2-5
Freedom from the production of unintended or excessive output	IEC 60601-2-37
Freedom from the production of unintended or excessive surface temperature	IEC 60601-2-37
Freedom from the production of unintended or excessive surface temperature of the APPLIED PART	IEC 60601-2-5, IEC 60601-2-37
Freedom from the production of unintended or uncontrolled motion of PATIENT APPLIED PART intended for intra-corporeal use	IEC 60601-2-37
Gas cross flow	ISO 80601-2-12
Gas supply	ISO 80601-2-12
Generation of a technical alarm condition	ISO 80601-2-56
Generation of a visual and audible alarm signal	IEC 60601-2-19, IEC 60601-2-20, IEC 60601-2-21
Imaging performance	IEC 60601-2-45, IEC 60601-2-54
Input dynamic range and differential offset voltage	IEC 60601-2-26
Input noise	IEC 60601-2-26
Interference reversion in the presence of sensed electrical interference	IEC 60601-2-31
Internal electrical power source near depletion alarm condition	ISO 80601-2-12
Level alarm conditions	ISO 80601-2-12
Limitation of energy in the operating field	IEC 60601-2-41
Limits of the change in the error of the treatment pressure determination and low and high physiological alarm conditions or generation of a technical alarm condition	IEC 80601-2-30
Limits of the error or generation of a technical alarm condition	IEC 80601-2-30
Linearity of air kema limited intervals of loading factors	IEC 60601-2-45
Making ambient temperature operating range	ISO 80601-2-56
Means to handle interruption of the power supply/SUPPLY MAINS of MEE	ISO 80601-2-12, IEC 60601-2-27
Measurement accuracy and the reading alarm conditions or generation of a technical alarm condition	ISO 80601-2-55, ISO 80601-2-13
MEE parameter stability	IEC 60601-2-31
Monitoring of an associated alarm	ISO 80601-2-13

Table G.1 *(3 of 3)*

ESSENTIAL PERFORMANCE	Extracted from MEE particular standard
No unacceptable RISK if the view observed by the OPERATOR has an unexpected image orientation	IEC 60601-2-18
Non-linearity and hysteresis	IEC 60601-2-23
Not provided with an alarm system that includes the capability to detect a physiological alarm condition: diagnosis accuracy, pulse rate accuracy or indication of abnormal operation	ISO 80601-2-61
Parameter stability at onset of the battery depletion indicator	IEC 60601-2-31
Physiological alarm conditions, alarm limits and delay time of physiological alarm signals	IEC 60601-2-34
Protection against depletion of battery	IEC 60601-2-27
Protection against unwanted volumes and occlusion	IEC 60601-2-34, ISO 80601-2-13
Protection from electrostatic discharge	IEC 60601-2-25
Protection from electrosurgery interference	IEC 60601-2-25, IEC 60601-2-27
Providing an output temperature	ISO 80601-2-56
Radiation dose documentation	IEC 60601-2-43
Recovery management	IEC 60601-2-43
Reproducibility of the X-radiation output	IEC 60601-2-45, IEC 60601-2-54
Runaway protection	IEC 60601-2-31
Start-up technical alarm condition	ISO 80601-2-59
Technical alarm condition indicating inoperable MEE	IEC 60601-2-27
Temperature requirements for treatment	IEC 60601-2-39
Threshold temperature and the resulting alarm condition	IEC 606012-16, IEC 80601-2-59
Time requirements for treatment	IEC 60601-2-16
Time to alarm of alarm conditions	IEC 60601-2-23, IEC 60601-2-33
NOTE 1 The list in this table does not always contain the exact wording of the MEE particular standards. This was done to ensure that the ESSENTIAL PERFORMANCES could be considered for all types of MEE and MES. NOTE 2 The items have been ordered alphabetically for convenience.	

NOTE Table G.1 is are as of January 2016, and the list is informative

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