IEC 62366-1

Edition 1.0 2020-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical devices –
Part 1: Application of usability engineering to medical devices

Dispositifs médicaux –
Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

IEC 62366-1:2015-02/AMD1:2020-06(en-fr)

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FOREWORD

This amendment has been prepared by 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 210: Quality management and corresponding general aspects for medical devices.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1386/FDIS	62A/1397/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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FOREWORD

In the fourth paragraph, replace “ISO 14971:2007” *with* “ISO 14971:2019”*, format “*medical device user interfaces*” in small caps and replace “*manufactures*” with “*MANUFACTURERS*” to correct the spelling and the format.*

INTRODUCTION to Amendment 1

The first edition of IEC 62366-1 was published in 2015. Since its publication, experts working in the field have identified several inaccuracies that warrant correction. In total, 22 issues were identified and presented to the National Committee members of IEC/SC 62A and to the Member Bodies of ISO/TC 210. A majority of the members of both committees that stated a position supported developing this amendment to address the identified issues while making no fundamental changes to the USABILITY ENGINEERING PROCESS as originally conceived in IEC 62366-1:2015.

To assist the USER to implement the USABILITY ENGINEERING PROCESS, the technical report IEC TR 62366-2 is available, which contains tutorial information to assist MANUFACTURERS in complying with this document, as well as more generally to design MEDICAL DEVICES that goes beyond SAFETY-related aspects of USER INTERFACES and offers more detailed descriptions of USABILITY ENGINEERING methods that can be applied.

INTRODUCTION

Replace, in the second paragraph, “Figure A.4” *with* “Figure A.5”.

Replace, in the NOTE, “functionality” *with* “performance”.

Replace, in the last paragraph, “benefits” *with* “advantages”.

Replace the existing footnote 1 with the following:

1 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.

1 * Scope

In the second sentence, replace “with CORRECT USE and USE ERRORS, i.e., NORMAL USE” *with* “with NORMAL USE, i.e., CORRECT USE and USE ERROR”.

Replace NOTE 1 with the following:

NOTE 1 SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to HAZARDS including loss or degradation of clinical performance.

Replace the existing footnote 2 with the following:

2 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.

2 Normative references

Replace “ISO 14971:2007” *with* “ISO 14971:2019”.

3 Terms and definitions

Replace, in the first paragraph, “ISO 14971:2007” *with* “ISO 14971:2019”.

3.1
*** ABNORMAL USE**

Replace, in the existing definition and its example, “intentional” *with* “deliberate” *in 3 places.*

3.2
ACCOMPANYING DOCUMENTATION

Replace the existing definition, notes to entry and source with the following:

3.2
ACCOMPANYING DOCUMENTATION
materials accompanying a MEDICAL DEVICE and containing information for the USER or those accountable for the installation, use, maintenance, decommissioning and disposal of the MEDICAL DEVICE, particularly regarding safe use

Note 1 to entry: The ACCOMPANYING DOCUMENTATION can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: ACCOMPANYING DOCUMENTATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

Note 3 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: ISO 14971:2019, 3.1, modified – Note 3 to entry has been added.]

3.20
USE ENVIRONMENT

Add, in Note 1 to entry, the following second sentence:

Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

3.23
*** USE SPECIFICATION**

Replace, in Note 3 to entry, "ISO 14971:2007" *with* "ISO 14971:2019".

3.25
USER GROUP

Replace the definition with the following:

subset of USERS who are differentiated from other USERS by factors that are likely to influence their interactions with the MEDICAL DEVICE

NOTE 1 to entry: Attributes of USER GROUPS can include age, culture, expertise.

3.29
USER PROFILE

Replace the existing definition with the following:

summary of the mental, physical and demographic traits of a USER GROUP, as well as characteristics, such as knowledge, skills and abilities, which can have a bearing on design decisions

4.1.1 * USABILITY ENGINEERING PROCESS

Replace, in the third paragraph, "ISO 13485:2003" *with* "ISO 13485:2016".

Replace, in NOTE 1, "ISO 13485:2003" *with* "ISO 13485:2016".

Replace, in the fourth paragraph, "ISO 14971:2007" *with* "ISO 14971:2019" *and* "Figure A.4" *with* "Figure A.5".

Replace, in the fifth paragraph, "Figure A.4" *with* "Figure A.5" *and* "carried out" *with* "carried out iteratively or".

4.1.2 * RISK CONTROL as it relates to USER INTERFACE design

Replace the first paragraph and list items a) to c) with the following:

To reduce use-related RISK, the MANUFACTURER shall use one or more of the following options, in the priority listed (as required by ISO 14971:2019, 7.1):

a) inherently safe design and manufacture;

b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and

c) information for SAFETY and, where appropriate, training to USERS.

4.1.3 Information for SAFETY as it relates to USABILITY

Replace, in the second paragraph, “intentional” *with* “deliberate” *in 2 places.*

4.3 Tailoring of the USABILITY ENGINEERING effort

Delete the compliance check.

5.1 * Prepare USE SPECIFICATION

Replace the fifth dash with:

– * intended USE ENVIRONMENT; and

5.2 * Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

Replace, in the first paragraph, “ISO 14971:2007, 4.2” *with* “ISO 14971:2019, 5.3”.

Replace the last sentence of the first paragraph with the following:

This identification shall include consideration of the PRIMARY OPERATING FUNCTIONS if they are provided in applicable product-specific MEDICAL DEVICE SAFETY standards.

Replace, in NOTE 1, “ISO 14971:2007, C.2.29 to C.2.34” *with* “ISO/TR 24971:—[6], A.2.31 to A.2.37”.

Insert the following footnote:

[6] Under preparation. Stage at the time of circulation: ISO /TR APUB 24971:2020.

Replace the paragraph preceding the compliance check with the following:

The results of this identification of characteristics related to SAFETY and potential USE ERRORS shall be stored in the USABILITY ENGINEERING FILE.

5.3 * Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Replace the last sentence of the first paragraph with the following:

This identification shall be conducted as part of a RISK ANALYSIS performed according to ISO 14971:2019, 5.4.

5.5 * Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION

Replace the text of the subclause with the following:

The MANUFACTURER shall select the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION.

The MANUFACTURER shall select:

– all HAZARD-RELATED USE SCENARIOS;

– a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed); or

NOTE 1 The SEVERITY of HARM is determined in ISO 14971:2019, 5.5.

– a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM and based on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER.

NOTE 2 Examples of selection schemes are given in Annex A, 5.5, and IEC TR 62366-2.

A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.7.1 General

Delete, in the first sentence, "SPECIFICATION".

Replace the first dash under list item b), including Examples 1 and 2, with the following:

– document which USER GROUPS are intended to be included in the test;

EXAMPLE 1 In a FORMATIVE EVALUATION, clinical personnel who are employees of the MANUFACTURER are used to represent a nurse-USER GROUP.

EXAMPLE 2 In a SUMMATIVE EVALUATION, a panel of practicing intensive care nurses is used to represent a critical care nursing USER GROUP.

Multiple USER PROFILES may be combined into a USER GROUP for the purposes of a USABILITY TEST;

Add, in the penultimate dash under list item b) "and" *after the semicolon.*

Replace, in NOTE 3, "scaling" *with* "tailoring".

5.7.3 * SUMMATIVE EVALUATION planning

Replace list item e) with the following:

e) * for a USABILITY TEST,

– how the characteristics of the test participants are representative of the intended USER PROFILES;
– justifying how the test participants are grouped into distinct USER GROUPS for the purpose of determining the number of test participants;
– the test environment and conditions of use and a rationale for how they are adequately representative of the intended USE ENVIRONMENT;
– the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and
– the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS and use difficulties.

Delete the existing NOTE 5.

5.8 * Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION

Replace, in NOTE 1, "ISO 14971:2007, Subclause 6.6" *with* "ISO 14971:2019, 7.5".

5.9 * Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE

Replace the second paragraph with the following:

The MANUFACTURER shall analyse the data of the SUMMATIVE EVALUATION and shall identify all USE ERRORS and use difficulties that occurred. If a USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION, the root cause of any such USE ERROR or use difficulty shall be determined. The root causes should be determined based on methods including observations of USER performance as well as subjective comments from the USER.

NOTE 1 A use difficulty where a USER almost commits a USE ERROR while performing a TASK, but recovers in time to avoid making the USE ERROR is sometimes called a "close call".

Renumber NOTES 1 to 5 as 2 to 6.

Replace item i), without modifying the note, with the following:

i) document why improvement is not necessary or not practicable;

Replace, in NOTE 3, "ISO 14971:2007, 6.2" *with* "ISO 14971:2019, 7.1 and ISO/TR 24971:—[7]*,* Annex C"*.*

Insert the following footnote:

[7] Under preparation. Stage at the time of circulation: ISO/TR APUB 24971:2020.

Replace item iii) with the following:

iii) evaluate the RESIDUAL RISK according to ISO 14971:2019, 7.3.

Replace, in NOTE 4, "ISO 14971:2007, Subclause 6.6" *with* "ISO 14971:2019, 7.5".

Replace, in NOTE 5, "ISO 14971:2007, Clause 7" *with* "ISO 14971:2019, Clause 8".

Replace, in the compliance check, "ISO 14971:2007, 6.4" *with* "ISO 14971:2019, 7.3".

A.2 Rationale for requirements in particular clauses and subclauses

Clause 1 – Scope

In the sixth paragraph, set benefits in small caps in 2 places.

Replace, in the last paragraph, "benefits" *with* "advantages".

Definition 3.1 – ABNORMAL USE

Replace, in the third dash, "RISK benefit" *with* "BENEFIT-RISK".

Replace, in Example 2, "RISK/benefit" with "BENEFIT and RISK*".*

Replace, in the first sentence of the last paragraph, "inaction" *with* "lack of USER action".

Definition 3.11 – PRIMARY OPERATING FUNCTION

Replace the entire paragraph with the following:

For the purposes of this document, a PRIMARY OPERATING FUNCTION is a function that is directly related to the SAFETY of the MEDICAL DEVICE. PRIMARY OPERATING FUNCTIONS are identified in some product-specific MEDICAL DEVICE SAFETY standards. These standards require those

identified PRIMARY OPERATING FUNCTIONS to be an input to the USABILITY ENGINEERING PROCESS. This document does not require any further identification of PRIMARY OPERATING FUNCTIONS because this document requires the identification, description and evaluation of HAZARD-RELATED USE SCENARIOS. However, TASKS to be performed within a HAZARD-RELATED USE SCENARIO might be related to a function that has been identified as a PRIMARY OPERATING FUNCTION.

Definition 3.17 – USABILITY ENGINEERING or HUMAN FACTORS ENGINEERING

Delete the second sentence of the first paragraph and combine the first and second paragraphs.

Definition 3.21 – USE ERROR

Replace the first and second sentences of the first paragraph with:

USE ERRORS often can be an indication of USER INTERFACE design flaws that affect the interaction of a USER with a MEDICAL DEVICE.

Definition 3.22 – USE SCENARIO

Add the following sentence to the end of the second paragraph:

A TASK in a HAZARD-RELATED USE SCENARIO, in which a USE ERROR can lead to significant HARM, can be thought of as a 'critical task' [48] [49].

Clause 5 – USABILITY ENGINEERING PROCESS

Replace the entire rationale for Clause 5 including Figure A.4 with the following:

The purpose of the USABILITY ENGINEERING PROCESS, as described in this document, is to provide use-related SAFETY of the MEDICAL DEVICE for the PATIENT, USER and others. To achieve this purpose, the USABILITY ENGINEERING PROCESS mitigates RISK caused by USER interaction problems associated with NORMAL USE, such as USE ERROR.

Figure A.4 illustrates the types of use as described in this document and their relationship to the concept of “reasonably foreseeable misuse” in ISO 14971.

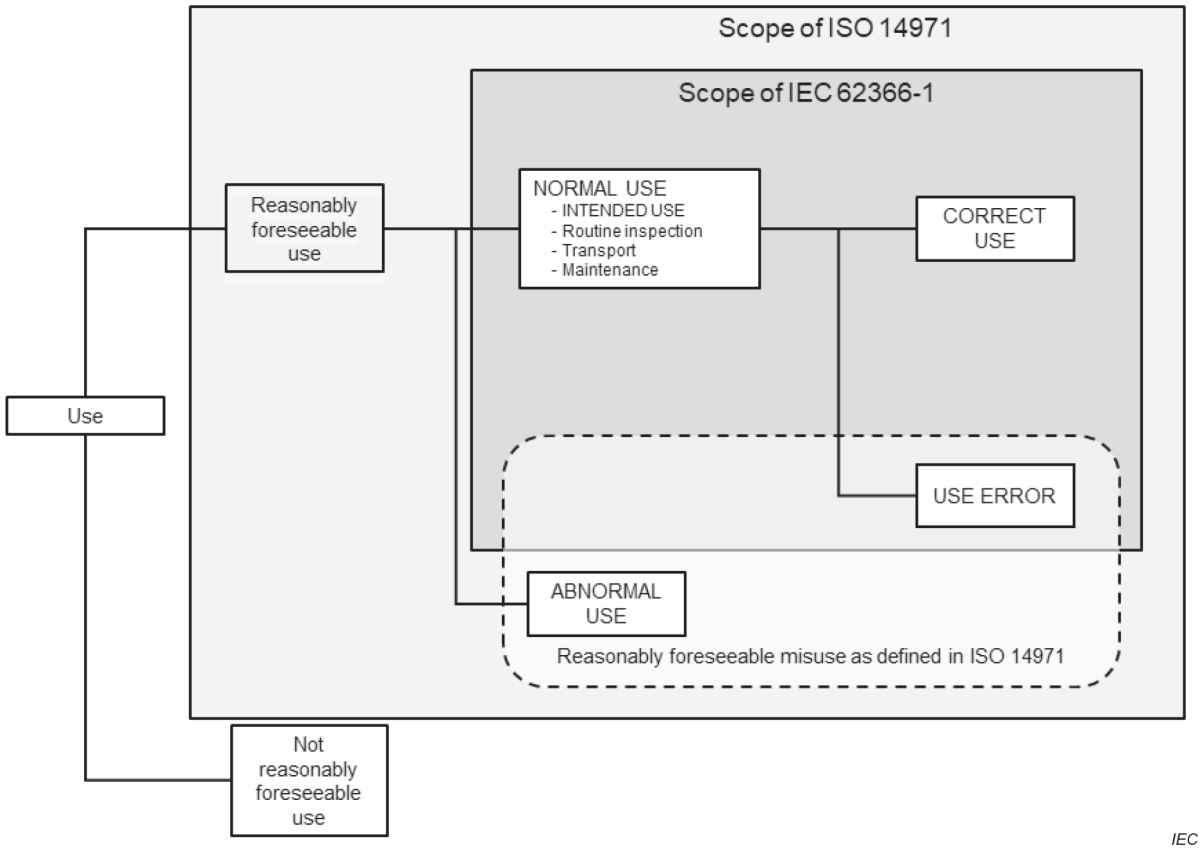


Figure A.4 – Types of use as described in this document and their relationship to the concept of "reasonably foreseeable misuse" in ISO 14971

OBJECTIVE EVIDENCE to support the determination that use-related RESIDUAL RISK has been reduced to acceptable levels is generated by conducting SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE.

To establish criteria for the acceptability of RESIDUAL RISKS related to USABILITY, the MANUFACTURER considers relevant available data (e.g., the state of technology, experience with similar MEDICAL DEVICES, POST-PRODUCTION surveillance reports). The MANUFACTURER can apply these criteria according to ISO 14971, which additionally considers RESIDUAL RISK relative to the BENEFIT of the MEDICAL DEVICE.

A comprehensive RISK MANAGEMENT PROCESS, such as that defined in ISO 14971, requires that a MANUFACTURER establish, implement, document and maintain a PROCESS for identifying HAZARDS and HAZARDOUS SITUATIONS associated with a MEDICAL DEVICE, estimating and evaluating the associated RISKS, controlling those RISKS, and monitoring how effective those controls are throughout the LIFE CYCLE. Such a PROCESS includes the following elements:

– RISK ANALYSIS;
– RISK EVALUATION;
– RISK CONTROL; and
– production and POST-PRODUCTION activities.

When applying a comprehensive RISK MANAGEMENT PROCESS to the USER INTERFACE, estimating the RISK associated with each USE ERROR can be problematic, particularly because no validated techniques are known to exist to predict, in advance, the likelihood of a person committing a USE ERROR. However, this document provides a PROCESS that a MANUFACTURER can use to analyse, specify, design and evaluate the USABILITY of a MEDICAL DEVICE. Implementing this PROCESS permits the MANUFACTURER to address the unpredictability of a

USER and minimize USE ERROR. This PROCESS helps the MANUFACTURER accomplish these objectives by:

a) discovering HAZARDS and HAZARDOUS SITUATIONS related to the USER INTERFACE;

b) designing and implementing measures to control the RISKS related to the USER INTERFACE; and

c) evaluating that these RISK CONTROL measures are effective in reducing RISK.

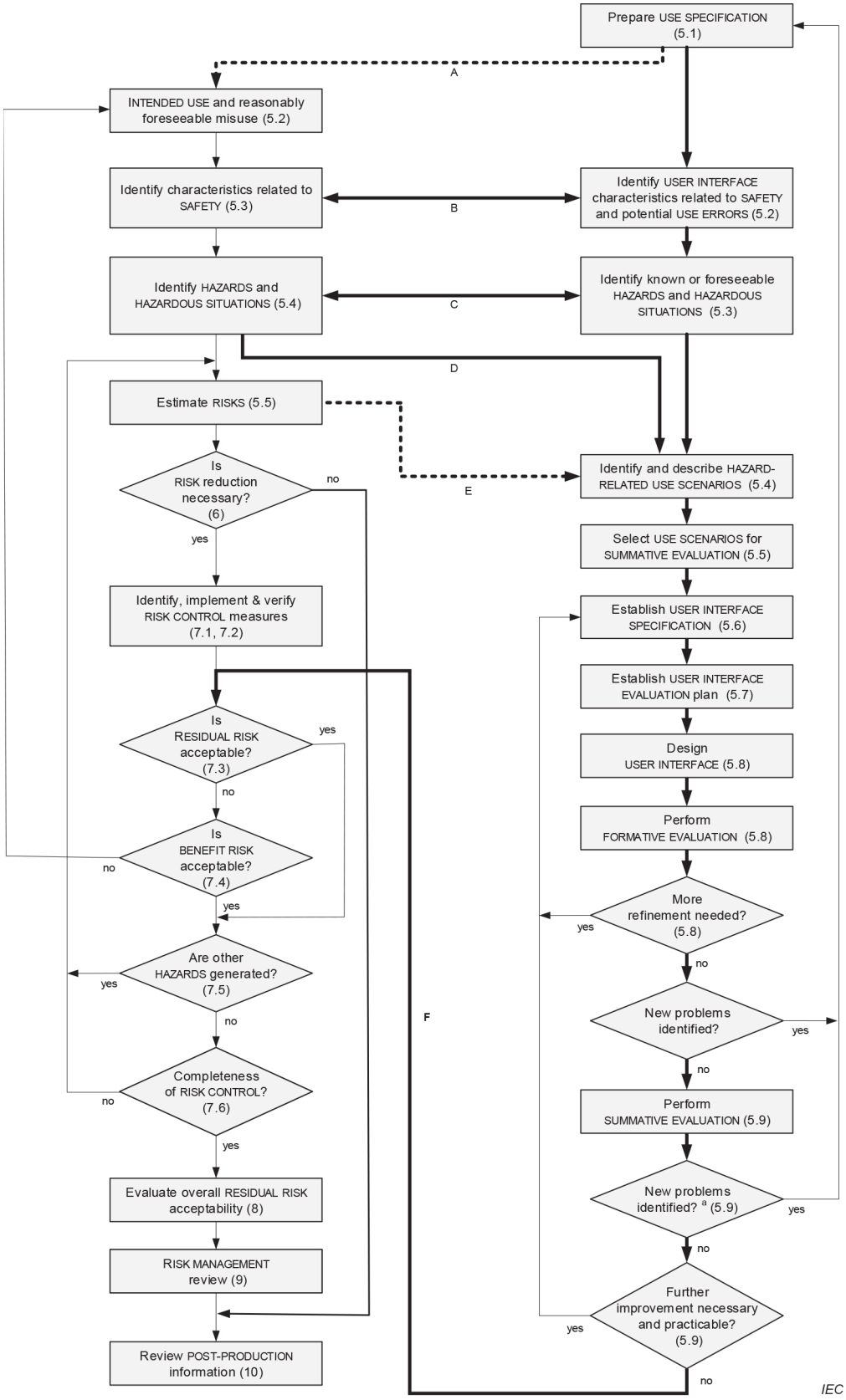
Other advantages of the USABILITY ENGINEERING PROCESS can include improved customer satisfaction, but these aspects are beyond the scope of this document.

Figure A.5 provides an overview of relationship and interactions between the RISK MANAGEMENT PROCESS in ISO 14971 and the USABILITY ENGINEERING PROCESS of this document. RISK MANAGEMENT is a decision-making PROCESS for determining acceptable RISK whereas USABILITY ENGINEERING is a design and development PROCESS for the USER INTERFACE to reduce the possibility of USE ERRORS that could result in HARM.

When the MANUFACTURER is identifying the characteristics related to SAFETY of the MEDICAL DEVICE in accordance with the requirements of ISO 14971:2019, 5.3, the USABILITY ENGINEERING PROCESS can provide the detail necessary (see 5.2) to accomplish this step for the USER INTERFACE of the MEDICAL DEVICE.

Further, when the MANUFACTURER is compiling a list of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS associated with the MEDICAL DEVICE in accordance with the requirements of ISO 14971:2019, 5.4, the USABILITY ENGINEERING PROCESS provides a list of items that are required to be considered (see 5.3) in order to accomplish this step for the USER INTERFACE of the MEDICAL DEVICE.

ISO 14971 requires that RISKS associated with each of the identified HAZARDOUS SITUATIONS be estimated (ISO 14971:2019, 5.5), and evaluated (ISO 14971:2019, Clause 6). If a RISK is not acceptable according to the MANUFACTURER'S RISK acceptability criteria, the MANUFACTURER is required to identify RISK CONTROL measure(s) that are appropriate for reducing the RISK(S) to an acceptable level (ISO 14971:2019, 7.1). The MANUFACTURER is then required to implement the identified RISK CONTROL measures and verify that they are effective in reducing the RISK to an acceptable level (ISO 14971:2019, 7.2).



A, B, C, D, E and F represent information flow between the two PROCESSES. The heavy solid lines (B, C, D and F) represent information flow required by this document. New problems identified should be interpreted to mean new HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS discovered or implemented RISK CONTROL is ineffective.

[a] New problems identified should be interpreted to mean new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS, or HAZARD-RELATED USE SCENARIOS have been identified.

Key

A USE SPECIFICATION is an input to ISO 14971:2019, 5.2

B Identified USER INTERFACE characteristics related to SAFETY (see 5.2)

C Identified foreseeable HAZARD and HAZARDOUS SITUATIONS (see 5.3).

D Identified sequences of events leading to HAZARDOUS SITUATIONS from ISO 14971:2019, 5.4 are an input to determining HAZARD-RELATED USE SCENARIOS (see 5.4).

E The SEVERITY of HARM as determined in ISO 14971:2019, 5.5 is an input to identifying and describing HAZARD-RELATED USE SCENARIOS.

F The SUMMATIVE EVALUATION (see 5.9) produces OBJECTIVE EVIDENCE and data for determining and evaluating RESIDUAL RISK related to use in ISO 14971:2019, 7.3.

Figure A.5 – The relationship between the RISK MANAGEMENT PROCESS (ISO 14971:2019) and the USABILITY ENGINEERING PROCESS (IEC 62366-1)

The USABILITY ENGINEERING PROCESS requires that all known or foreseeable HAZARD-RELATED USE SCENARIOS (see 5.4) are identified and described prior to selecting the HAZARD-RELATED USE SCENARIOS (see 5.5) that are used in preparing the USER INTERFACE EVALUATION plan. In this document, RISK CONTROL options related to use are identified during the development of the USER INTERFACE SPECIFICATION with testable requirements (see 5.6). The HAZARD-RELATED USE SCENARIOS, the RISK CONTROL measures and the USER INTERFACE EVALUATION plan are iteratively updated based on the results from FORMATIVE EVALUATIONS and from the other parts of product realization PROCESS, as appropriate.

Both the FORMATIVE EVALUATION and the SUMMATIVE EVALUATION of the implemented USER INTERFACE are planned in the USER INTERFACE EVALUATION plan (see 5.7). FORMATIVE EVALUATION is carried out during USER INTERFACE design and implementation (see 5.8) to explore the USER INTERFACE, identify the need for improvement or to confirm adequacy of the USER INTERFACE. For each selected HAZARD-RELATED USE SCENARIO, the implemented USER INTERFACE is subject to SUMMATIVE EVALUATION (see 5.9) to produce OBJECTIVE EVIDENCE that use-related RESIDUAL RISK has been reduced to acceptable levels. These steps achieve the same objective as 5.5 through 7.2 of ISO 14971:2019.

Subclause 5.1 – Prepare USE SPECIFICATION

Replace, in the first sentence, “standard” *with* “document”.

Replace, in the USE ENVIRONMENT subheading, “*USE ENVIRONMENT*” *with* “*intended USE ENVIRONMENT*”.

Subclause 5.2 – Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

Replace, in the first paragraph, “ISO 14971:2007, C.2.1” *with* “ISO/TR 24971:—[8], A.2.1”.

Replace, in list item a), “ISO 14971:2007, C.2.9” *with* “ISO/TR 24971:—, A.2.9”.

Replace, in list item b), “ISO 14971:2007, C.2.12” *with* “ISO/TR 24971:—, A.2.12”.

Replace, in list item c), “ISO 14971:2007, C.2.26” *with* “ISO/TR 24971:—, A.2.28” *and* “ISO 14971:2007, C.2.27” *with* “ISO/TR 24971:2019, A.2.29”.

Replace, in list item d), replace “ISO 14971:2007, C.2.29” *with* “ISO/TR 24971:—, A.2.31”.

Insert the following footnote:

[8] Under preparation. Stage at the time of circulation: ISO/TR APUB 24971:2020.

Subclause 5.3 – Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Replace, in the third sentence, "Figure E.1 from ISO 14971:2007" *with* "Figure C.1 from ISO 14971:2019".

Subclause 5.6 – Establish USER INTERFACE SPECIFICATION

Replace the entire text with the following:

The detailed and testable design requirements for the USER INTERFACE contained in the USER INTERFACE SPECIFICATION are generated based on the information collected in the preceding PROCESS steps. This information includes the USE SPECIFICATION as well as the identified USE ERRORS and the HAZARD-RELATED USE SCENARIOS. While the USER INTERFACE is evaluated, the USER INTERFACE SPECIFICATION is updated, as needed.

Subclause 5.7.2 – FORMATIVE EVALUATION planning

Replace the entire paragraph with the following:

The purpose of FORMATIVE EVALUATION of the USER INTERFACE, which could include USABILITY TESTS, is to assess portions of or the entire USER INTERFACE to ensure it achieves a specified quality level and to increase the likelihood that the final SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE can be conducted successfully. The results of each FORMATIVE EVALUATION can be used to guide iterations of the design of the USER INTERFACE. The decision to stop iterating the USER INTERFACE design is based on the quality level being measured during the later stages of FORMATIVE EVALUATIONS. No further iterations are required when the quality level has been achieved that gives the MANUFACTURER the confidence that the SUMMATIVE EVALUATION conducted at the end of the iterative design cycle can generate sufficient OBJECTIVE EVIDENCE that use-related RESIDUAL RISK is acceptable.

Subclause 5.7.3 – SUMMATIVE EVALUATION planning

d) (availability of the ACCOMPANYING DOCUMENTATION and provision of training)

Replace the existing note with the following new note:

NOTE 'Effectiveness as a RISK CONTROL measure' relates to ISO 14971:2019, 7.2, and not to the defined term, EFFECTIVENESS.

e) (USABILITY TEST)

Replace the first paragraph with the following paragraph:

This document requires assessment of whether USE ERRORS occurred, the USERS had use difficulties or the USERS successfully completed the TASKS associated with the HAZARD-RELATED USE SCENARIOS (i.e. CORRECT USE) that the MANUFACTURER selected for inclusion in the SUMMATIVE EVALUATION. A use difficulty is a difficulty, or struggle, encountered during use, which is typically momentary and overcome by the USER. When the use difficulty progresses, such as, progresses to failure to complete an action or mismatch in mental models, the use difficulty has progressed to a USE ERROR. A use difficulty where a USER almost commits a USE ERROR while performing a TASK, but recovers in time to avoid making the USE ERROR is sometimes called a "close call".

Subclause 5.9 – Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE

In the fourth paragraph, replace "USE ERRORS" *with* "USE ERRORS or use difficulties" *and add the following as the last sentence of the paragraph:*

See rationale to 5.7.3 e) for additional information regarding use difficulties.

Table B.1 – Glossary of relevant RISK MANAGEMENT terms

Replace, in the heading, "ISO 14971:2007" with "ISO 14971:2019".

Delete, in the meaning of HARM, "physical".

Replace the meaning of HAZARDOUS SITUATION with the following:

circumstance in which people, property, or the environment is/are exposed to one or more HAZARDS

Table B.2 – Examples of HARM due to RISK caused by USE ERROR(S) or poor USABILITY

Correct the Table title to "Examples of HARM caused by USE ERROR(S) or poor USABILITY".

*Replace, in the heading of the first column of this table, "*HAZARD*" with "*HAZARD *or* HAZARDOUS SITUATION*" (one correction on each page of the table).*

C.1 General

Replace, in the first paragraph, "scaled" *with* "tailored".

Replace, in the third paragraph, "IEC 62366-1:—' *with* "IEC 62366-1:2015".

Replace, in Example 1, "IEC 62366-1:—" *with* "IEC 62366-1:2015".

Replace, in Example 2, "IEC 62366-1:—" *with* "IEC 62366-1:2015".

Replace, in Example 3, "IEC 62366-1:—" *with* "IEC 62366-1:2015".

Replace, in Example 4, "IEC 62366-1:—" *with* "IEC 62366-1:2015".

C.2.5 RESIDUAL RISK evaluation

Replace, in the first paragraph, "the overall RESIDUAL RISK according to ISO 14971:2007, 6.4" *with* "the RESIDUAL RISK according to ISO 14971:2019, 7.3".

Annex D – Types of MEDICAL DEVICE use, with examples

Replace, in the first paragraph, "inactions" *with* "lack of USER actions". *(2 occurrences)*

Replace, in the third paragraph, the second and third sentences with the following:

Alternately, NORMAL USE could involve a USE ERROR or the use could involve deliberate conduct that is beyond any additional means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER, (i.e., ABNORMAL USE). This does not necessarily mean that ABNORMAL USE results in a poor outcome for the PATIENT.

Figure D.1 – Interrelationships between the different types of MEDICAL DEVICE use, with examples

Replace Figure D.1 with the following:

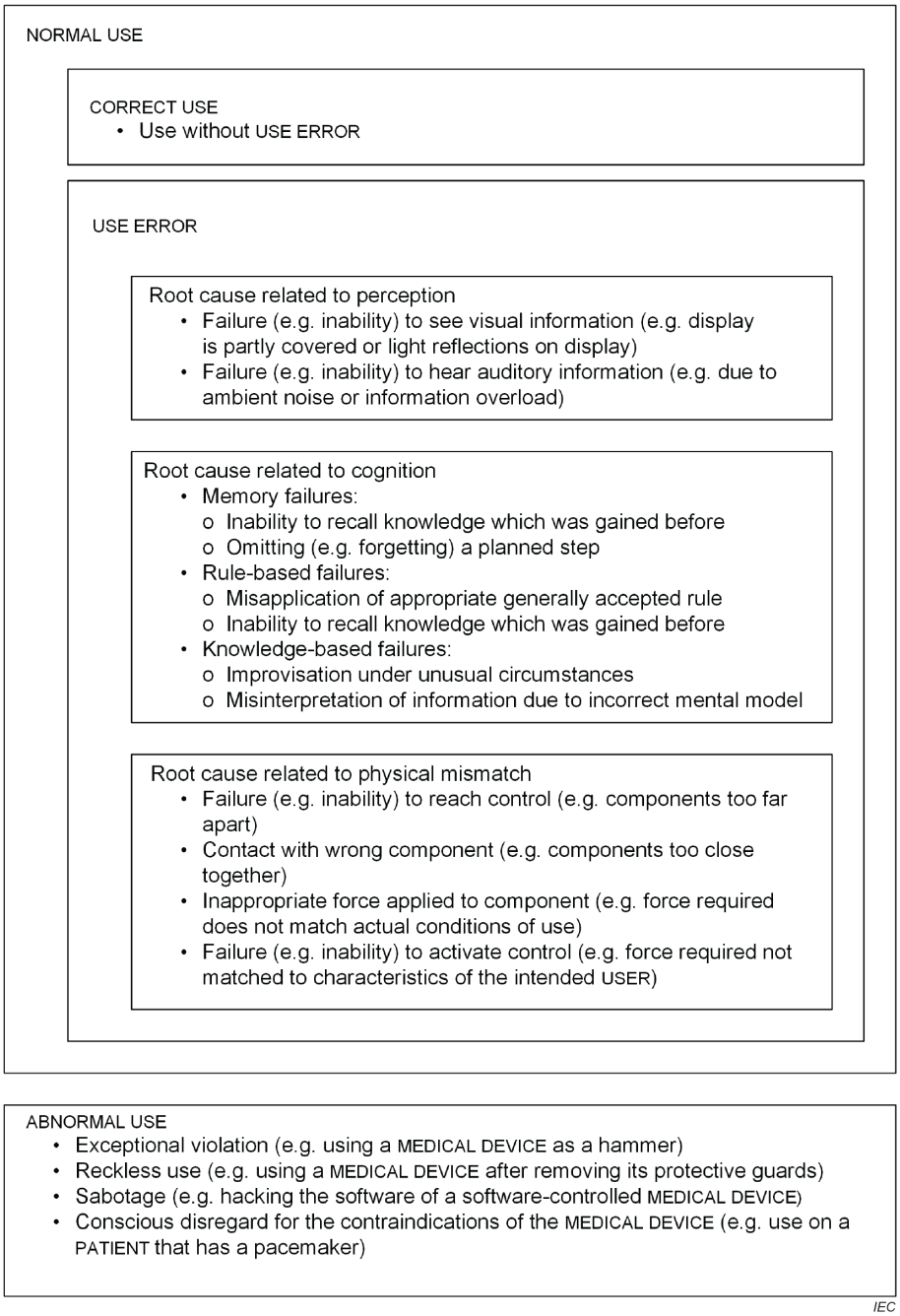


Figure D.1 – Interrelationships between the different types of MEDICAL DEVICE use, with examples

Annex E – Reference to the essential principles

Replace the entire annex with the following:

Annex E
(informative)

Reference to the essential principles

E.1 Non-IVD MEDICAL DEVICES

This document has been prepared to support the essential principles of safety and performance of non-IVD MEDICAL DEVICES as MEDICAL DEVICES according to ISO 16142-1:2016 [12]. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1:2016 [12]. Other means are possible. Table E.1 maps the clauses and subclauses of this document with the essential principles of ISO 16142-1:2016.

Table E.1 – Correspondence between this document and the essential principles

Essential principle of ISO 16142-1:2016, Annex B [12]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks /notes
1	All	The part relating to manufacturing is not addressed.
a)	All	
b)	All	
6	All	The part related to known or foreseeable RISKS as they relate to use is addressed.
12.2	—	
a)	All	The part relating to manufacturing is not addressed.
b)	All	The part relating to manufacturing is not addressed.
13.3	All	
13.4	All	The part related to understood by the USERS is addressed.
17.4	All	Addressed as it relates to safe use. The part relating to manufacturing is not addressed
19.1	All	Addressed as it relates to safe use.
19.2	All	
20.1	All	The part relating to manufacturing is not addressed.
20.2	All	The part relating to manufacturing is not addressed.

E.2 IVD MEDICAL DEVICES

This document has been prepared to support the essential principles of safety and performance of IVD MEDICAL DEVICES as MEDICAL DEVICES according to ISO 16142-2:2017 [47]. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-2:2017 [47]. Other means are possible. Table E.2 maps the clauses and subclauses of this document with the essential principles of ISO 16142-2:2017[47].

Table E.2 – Correspondence between this document and the essential principles

Essential principle of ISO 16142-2:2017, Annex B [47]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks /notes
1	All	The part relating to manufacturing is not addressed.
a)	All	
b)	All	
6	All	The part related to known or foreseeable RISKS as they relate to use is addressed.
9.1	—	The part relating to manufacturing is not addressed
a)	All	
b)	All	
c)	All	
11.2	—	
a)	All	The part relating to manufacturing is not addressed.
b)	All	The part relating to manufacturing is not addressed.
c)	All	The part relating to manufacturing is not addressed.
h)	All	The part relating to manufacturing is not addressed.
11.4	All	The part relating to manufacturing is not addressed.
12.3	All	The part related to understood by the USERS is addressed.
16.6	All	Addressed as it relates to safe use. The part relating to manufacturing is not addressed.
17.1	All	Addressed as it relates to safe use. The part relating to manufacturing is not addressed.
17.2	All	Addressed as it relates to safe use. The part relating to manufacturing is not addressed.
18.1	All	Addressed as it relates to safe use.
a)	All	Addressed as it relates to safe use.
18.4	All	The part relating to manufacturing is not addressed.
b)	All	

Bibliography

Add to [1], IEC 60601-1:2005/AMD2:—[9]

Add to [2], IEC 60601-1-6:2010/AMD2:—[10]

Add to [3], IEC 60601-1-8:2006/AMD2:—[11]

Replace [4] with the following:

[4] IEC 60601-1-11:2015, *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 60601-1-11:2015/AMD1:—[12]

Replace [6] with the following:

[6] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

Replace, in reference [8], “2005” *with* “2015”.

Replace “2008”, *in reference [9], with* “2015”.

*Replace, in the existing reference [11], "*2003*" with "*2016*".*

Replace the existing reference [12] with the following:

[12] ISO 16142-1:2016, *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

Replace the existing reference [13] with the following:

[13] ISO/TR 24971:—[13], *Medical devices – Guidance on the application of ISO 14971*

Replace footnotes 3, 4 and 5 with:

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

[9] Under preparation. Stage at the time of circulation of this document: IEC/AFDIS 60601-1:2005/AMD2:2019.

[4] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and Amendment 1:2013.

[10] Under preparation. Stage at the time of circulation of this document: IEC/AFDIS 60601-1-6:2010/AMD2:2019

[5] There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and Amendment 1:2012.

[11] Under preparation. Stage at the time of circulation of this document: IEC/AFDIS 60601-1-8:2006/AMD2:2019

[12] Under preparation. Stage at the time of circulation of this document: IEC/AFDIS 60601-1-11:2015/AMD1:2019

[13] Under preparation. Stage at the time of circulation: ISO/TR APUB 24971:2020.

Add, after the last existing reference [46], the new references as follows:

[47] ISO 16142-2:2017, *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

[48] US FDA, (2016), *Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices*, February 3, 2016

[49] US FDA, (2016), *Draft Guidance for Industry and FDA Staff: Combination Product Design and Development*, February 2016

Index of defined terms

Update the following terms:

Add the following term:

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