

American National Standard



ANSI/AAMI/ IEC 62366-1: 2015/(R)2021 +AMD1:2020

(Consolidated Text)

Medical devices—Part 1:
Application of usability
engineering to medical
devices, including
Amendment 1

Medical devices—Part 1: Application of usability engineering to medical devices + Amendment 1

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AAMI

Approved 7 July 2020 and reaffirmed 14 December 2021 by
American National Standards Institute

Abstract: The amendment included in this consolidated version of ANSI/AAMI/IEC 62366-1:2015 and ANSI/AAMI/IEC 62366-1:2015/A1:2020 corrects identified inaccuracies in ANSI/AAMI/IEC 62366-1:2015 while making no fundamental changes to the usability engineering process as originally conceived in that document.

Keywords: human factors, usability engineering, medical device design

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Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering

The adoption of IEC 62366-1:2015/Amendment 1 as an amendment to an American National Standard was initiated by the AAMI Human Factors Engineering Committee. AAMI HE provides input to the U.S. TAG to IEC/SC 62A which is the responsible group for providing the U.S. input to the relevant group in IEC/SC 62A/JWG 4. U.S. representatives from the AAMI Human Factors Engineering Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Human Factors Engineering Committee** has the following members:

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Molly Story

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Tor Alden, HS Design Inc
Jahan Azizi, Healthmark Industries Company Inc
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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 62366-1:2015 and IEC 62366-1:2015/A1:2020

As indicated in the foreword to the main body of this document (page viii), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard and amendment, which was developed by IEC/SC 62A/JWG 4 to specify a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. The amendment was developed to correct inaccuracies in IEC 62366-1:2015.

U.S. participation in IEC/SC 62A/JWG 4 is organized through the U.S. Technical Advisory Group to IEC/SC 62A, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of usability engineering. Upon review of IEC 62366-1:2015/Amendment 1:2020, the TAG to IEC/SC 62A and the AAMI Human Factors Committee decided to adopt it verbatim, as an amendment to ANSI/AAMI/IEC 62366-1:2015.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the IEC foreword on page viii, this American National Standard amendment is identical to IEC 62366-1:2015+AMD1:2020.

Foreword

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 62366-1 edition 1.1 contains the first edition (2015-02) [documents 62A/977/FDIS and 62A/988/RVD] and its corrigendum (2016-07), and its amendment 1 (2020-06) [documents 62A/1386/FDIS and 62A/1397/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 62366-1 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC technical committee 62: Electrical medical equipment in medical practice, and ISO technical committee 210: Quality management and corresponding general aspects for MEDICAL DEVICES.

It is published as double logo standard.

This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014).

Part 1 has been updated to include contemporary concepts of **USABILITY ENGINEERING**, while also streamlining the process. It strengthens links to **ISO 14971:2019** and the related methods of **RISK MANAGEMENT** as applied to **SAFETY** related aspects of **MEDICAL DEVICE USER INTERFACES**. Part 2 contains tutorial information to assist **MANUFACTURERS** in complying with Part 1, as well as offering more detailed descriptions of **USABILITY ENGINEERING** methods that can be applied more generally to **MEDICAL DEVICES** that go beyond safety-related aspects of **MEDICAL DEVICE USER INTERFACES**.

This publication has been drafted in accordance with the **ISO/IEC Directives, Part 2**.

In this International Standard, the following print types are used:

- Requirements and definitions: roman type.
- *Means to assess compliance: 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 OR AS NOTED: SMALL CAPITALS.**

The requirements are followed by means to assess compliance.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the **ISO/IEC Directives, Part 2**. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses and subclauses for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the **IEC 62366** series, published under the general title *Medical devices*, can be found on the **IEC** website.

The committee has decided that the contents of the base publication and its amendment 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.

NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised **IEC** or **ISO** publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

Introduction

Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS are non-intuitive, difficult to learn and difficult to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. The design of the USER INTERFACE to achieve adequate USABILITY requires a different PROCESS and skill set than that of the technical implementation of the USER INTERFACE.

The USABILITY ENGINEERING PROCESS is intended to identify and minimise USE ERRORS and thereby reduce use-associated RISKS. Some, but not all, forms of incorrect use are suited to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.5.

This International Standard describes a USABILITY ENGINEERING PROCESS to provide acceptable RISK related to USABILITY of a MEDICAL DEVICE. It is intended to be useful not only for MANUFACTURERS of MEDICAL DEVICES, but also for technical committees responsible for the preparation of particular MEDICAL DEVICE standards.

This International Standard strictly focuses on applying the USABILITY ENGINEERING PROCESS to optimize MEDICAL DEVICE USABILITY as it relates to SAFETY. The companion technical report (IEC 62366-2¹) is comprehensive and has a broader focus. It focuses not only on USABILITY as it relates to SAFETY, but also on how USABILITY relates to attributes such as TASK accuracy, completeness and EFFICIENCY, and USER satisfaction.

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

MANUFACTURERS can choose to implement a USABILITY ENGINEERING program focused narrowly on SAFETY or more broadly on SAFETY and other attributes, such as those cited above. A broader focus might also be useful to address specific USABILITY ENGINEERING expectations, such as the need to confirm that USERS can successfully perform non-SAFETY-related TASKS. A MANUFACTURER might also implement a broader program to realize the commercial advantages of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

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.

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

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

1 * Scope

This part of IEC 62366 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated with NORMAL USE, i.e., CORRECT USE and USE ERROR. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

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.

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2², which addresses not only SAFETY but also aspects of USABILITY not related to SAFETY.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with, then the USABILITY of a MEDICAL DEVICE as it relates to SAFETY is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 3 Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography beginning on page 38.

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 14971:2019 and the following apply.

NOTE An index of defined terms is found beginning on page 41.

3.1

* ABNORMAL USE

conscious, deliberate act or deliberate omission of an act that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER

EXAMPLES Reckless use or sabotage or deliberate disregard of information for SAFETY are such acts.

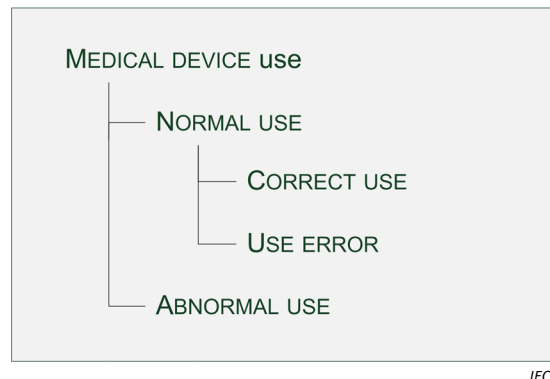
Note 1 to entry See also 4.1.3.

Note 2 to entry: An intended but erroneous action that is not ABNORMAL USE is considered a type of USE ERROR.

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

Note 3 to entry: ABNORMAL USE does not relieve the MANUFACTURER from considering non-USER INTERFACE-related means of RISK CONTROL.

Note 4 to entry: Figure 1 shows the relationships of the types of use.



NOTE Figure D.1 contains additional detail

Figure 1 – Relationship of the types of use

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.]

3.3

CORRECT USE

NORMAL USE without USE ERROR

Note 1 to entry: Deviation from instructions for use is only considered USE ERROR if it leads to a MEDICAL DEVICE response that is different than intended by the MANUFACTURER or expected by the USER.

Note 2 to entry: Figure 1 shows the relationships of the types of use.

3.4

EFFECTIVENESS

accuracy and completeness with which USERS achieve specified goals

Note 1 to entry: This is a different concept than 'clinical effectiveness'.

[SOURCE: ISO 9241-11:1998, 3.2, modified – Added the note to entry.]

3.5

*** EFFICIENCY**

resources expended in relation to EFFECTIVENESS

[SOURCE: ISO 9241-11:1988, 3.3, modified – the term "EFFECTIVENESS" has replaced the original phrase, which here constitutes the definition of 3.4 EFFECTIVENESS.

3.6

EXPECTED SERVICE LIFE

time period specified by the MANUFACTURER during which the MEDICAL DEVICE 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.28, modified – In the definition, 'ME EQUIPMENT and ME SYSTEM' have been replaced with 'MEDICAL DEVICE'.]

3.7

FORMATIVE EVALUATION

USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS

Note 1 to entry: FORMATIVE EVALUATION is generally performed iteratively throughout the design and development PROCESS, but prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary.

3.8

HAZARD-RELATED USE SCENARIO

USE SCENARIO that could lead to a HAZARDOUS SITUATION or HARM

Note 1 to entry: A HAZARD-RELATED USE SCENARIO can often be linked to a potential USE ERROR.

Note 2 to entry: A HAZARD-RELATED USE SCENARIO is not related to a failure of the MEDICAL DEVICE, unless the MEDICAL DEVICE failure was caused by a USE ERROR.

3.9

*** NORMAL USE**

operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: USE ERROR can occur in NORMAL USE.

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.

Note 4 to entry: Figure 1 shows the relationships of the types of use.

[SOURCE: IEC 60601-1:2005, 3.71, modified – Notes 2, 3 and 4 to entry have been added, and in the definition 'OPERATOR' has been replaced with 'USER' and the entire phrase after "instructions for use" has been added.]

3.10

*** PATIENT**

living being (person) undergoing a medical, surgical or dental PROCEDURE

Note 1 to entry: A PATIENT can be a USER.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76, modified – The phrase 'or animal' has been deleted from the definition and "USER" has been substituted for "operator" in the note to entry.]

3.11

*** PRIMARY OPERATING FUNCTION**

function that involves USER interaction that is related to the SAFETY of the MEDICAL DEVICE

Note 1 to entry: Often a PRIMARY OPERATING FUNCTION is interacted with by a series of TASKS that can be broken down into a series of USER interactions.

Note 2 to entry: The concept of SAFETY includes loss or degradation of performance resulting in an unacceptable RISK to the PATIENT, including USE ERROR that prevents the USER from effectively using the MEDICAL DEVICE to achieve its intended medical purpose. In IEC 60601-1, this is referred to as 'essential performance'.

3.12

RESPONSIBLE ORGANIZATION

entity accountable for the use and maintenance of a MEDICAL DEVICE or combination of MEDICAL DEVICES

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a lay person. In home use applications, the PATIENT, USER and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training are included in "use."

[SOURCE: IEC 60601-1:2005, 3.101, modified – The reference in the definition to 'an ME EQUIPMENT or ME SYSTEM' has been replaced with 'a MEDICAL DEVICE OR COMBINATION OF MEDICAL DEVICES' and 'operator' has been replaced by 'USER' in the note to entry.]

3.13

SUMMATIVE EVALUATION

USER INTERFACE EVALUATION conducted at the end of the USER INTERFACE development with the intent to obtain OBJECTIVE EVIDENCE that the USER INTERFACE can be used safely

Note 1 to entry: SUMMATIVE EVALUATION relates to validating the safe use of the USER INTERFACE.

3.14

TASK

one or more USER interactions with a MEDICAL DEVICE to achieve a desired result

Note 1 to entry: A TASK description should include the allocation of activities and operational steps between the USER and the MEDICAL DEVICE.

Note 2 to entry: TASKS should not be described solely in terms of the functions or features provided by the MEDICAL DEVICE.

3.15

UOUP

USER INTERFACE OF UNKNOWN PROVENANCE

USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which adequate RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available

Note 1 to entry: This note applies to the French version only.

3.16

*** USABILITY**

characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT

Note 1 to entry: All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY.

3.17

*** 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.

3.18

*** USABILITY ENGINEERING FILE**

set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

3.19

USABILITY TEST

method for exploring or evaluating a USER INTERFACE with intended USERS within a specified intended USE ENVIRONMENT

3.20

USE ENVIRONMENT

actual conditions and setting in which USERS interact with the MEDICAL DEVICE

Note 1 to entry: The conditions of use or attributes of the USE ENVIRONMENT can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility, and degree of internationalization. Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

3.21

* USE ERROR

USER action or lack of USER action while using the MEDICAL DEVICE that leads to a different result than that intended by the MANUFACTURER or expected by the USER

Note 1 to entry: USE ERROR includes the inability of the USER to complete a TASK.

Note 2 to entry: USE ERRORS can result from a mismatch between the characteristics of the USER, USER INTERFACE, TASK, or USE ENVIRONMENT.

Note 3 to entry: USERS might be aware or unaware that a USE ERROR has occurred.

Note 4 to entry: An unexpected physiological response of the PATIENT is not by itself considered USE ERROR.

Note 5 to entry: A malfunction of a MEDICAL DEVICE that causes an unexpected result is not considered a USE ERROR.

Note 6 to entry: Figure 1 shows the relationships of the types of use.

3.22

* USE SCENARIO

specific sequence of TASKS performed by a specific USER in a specific USE ENVIRONMENT and any resulting response of the MEDICAL DEVICE

3.23

* USE SPECIFICATION

APPLICATION SPECIFICATION

summary of the important characteristics related to the context of use of the MEDICAL DEVICE

Note 1 to entry: The intended medical indication, PATIENT population, part of the body or type of tissue interacted with, USER PROFILE, USE ENVIRONMENT, and operating principle are typical elements of the USE SPECIFICATION.

Note 2 to entry: The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the 'statement of intended use'.

Note 3 to entry: The USE SPECIFICATION is an input to determining the INTENDED USE of ISO 14971:2019.

3.24

* USER

person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners, maintenance and service personnel.

3.25

USER GROUP

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.

3.26

* USER INTERFACE

means by which the USER and the MEDICAL DEVICE interact

Note 1 to entry: ACCOMPANYING DOCUMENTATION is considered part of the MEDICAL DEVICE AND ITS USER INTERFACE.

Note 2 to entry: USER INTERFACE includes all the elements of the MEDICAL DEVICE with which the USER interacts including the physical aspects of the MEDICAL DEVICE as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, a system of MEDICAL DEVICES can be treated as a single USER INTERFACE.

3.27

USER INTERFACE EVALUATION

PROCESS by which the MANUFACTURER explores or assesses the USER interactions with the USER INTERFACE