



BSI Standards Publication

Medical devices

Part 2: Guidance on the application of
usability engineering to medical devices

National foreword

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TECHNICAL REPORT



**Medical devices –
Part 2: Guidance on the application of usability engineering to medical devices**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICES –**Part 2: Guidance on the application of usability engineering to medical devices**

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62366-2, which is a technical report, has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and technical committee ISO/TC 210: Quality management and corresponding general aspects for medical devices.

It is published as a double logo standard.

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

Enquiry draft	Report on voting
62A/1015/DTR	62A/1040A/RVC

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. In ISO, the standard has been approved by 23 P-members out of 36 having cast a vote.

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

In this Technical Report, the following print types are used.

- Guidance for the implementation of a **USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS** required by IEC 62366-1:2015 and definitions): roman type.
- *Additional information about USABILITY ENGINEERING best practices: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Text of tables is also in a smaller type.
- **TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.**

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

This technical report is to be read in conjunction with IEC 62366-1:2015.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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.

A bilingual version of this publication may be issued at a later date.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This technical report provides MEDICAL DEVICE MANUFACTURERS with guidance on how to integrate USABILITY ENGINEERING (also called HUMAN FACTORS ENGINEERING) principles and USER INTERFACE design practices into their overall MEDICAL DEVICE development PROCESSES. The technical report recognizes that all MEDICAL DEVICES involving human interaction present opportunities for optimization through the application of USABILITY ENGINEERING and seeks to guide the MEDICAL DEVICE MANUFACTURERS efforts.

This report concerns the quality of USER interactions with MEDICAL DEVICES that are as varied as acquiring information on a display, pressing a physical button or on-screen touch target button, selecting items on a software menu, attaching ACCESSORIES to a MEDICAL DEVICE and interpreting warnings as well as understanding relevant aspects for the proper use of the MEDICAL DEVICE by reading the ACCOMPANYING DOCUMENTATION. USABILITY ENGINEERING programs, if properly implemented, can increase the likelihood that USERS are able to perform such actions correctly and without hindrance.

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 PROCESS are non-intuitive, difficult to learn and difficult to use. In addition, MEDICAL DEVICES developed without applying USABILITY ENGINEERING or developed with incomplete or inadequate application of USABILITY ENGINEERING can include design shortcomings that can lead to USE ERRORS, particularly with varied USERS and USE ENVIRONMENTS, which can lead to HARM.

As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. While MEDICAL DEVICES become increasingly sophisticated, they can be more likely to induce USE ERRORS. If not properly designed or safeguarded, MEDICAL DEVICES could contribute to HAZARDOUS SITUATIONS and can be a source of HARM. An appropriate-tailored investment in USABILITY ENGINEERING ensures that MEDICAL DEVICES will have acceptable RISK and USABILITY and that design shortcomings are identified and removed from the USER INTERFACE. Accordingly, this technical report emphasizes the importance of designing for USABILITY, with an emphasis placed on ensuring SAFETY.

Ascribing to this report helps MANUFACTURERS respond effectively to regulatory expectations that call for the application of USABILITY ENGINEERING during the MEDICAL DEVICE development PROCESS. It also helps MANUFACTURERS produce MEDICAL DEVICES that have well designed USER INTERFACES that satisfy USERS. As such, it can propel a MANUFACTURER beyond a common sense approach to USER INTERFACE design to an approach that fully embraces USABILITY ENGINEERING as an essential step toward design excellence. Other beneficiaries of this document's guidance include authorities having jurisdiction (AHJ) and MEDICAL DEVICE consumers who share a common interest in safe and effective MEDICAL DEVICES.

The guidance provided in this report applies to all MEDICAL DEVICES, including those used by laypersons and/or healthcare professionals; MEDICAL DEVICES that perform just one function and those that perform many functions; USER INTERFACES in the form of hardware, software, documentation, and packaging; MEDICAL DEVICES that fit in a pocket, sit on a table, ride on a cart, or fill a room; and MEDICAL DEVICES that require no prior operational knowledge or call for training before use. Accordingly, it applies to a pen injector, glucose meter, infusion pump, PATIENT monitor, anaesthesia workstation, and radiation therapy system, just to name a few MEDICAL DEVICES.

MEDICAL DEVICES –

Part 2: Guidance on the application of usability engineering to medical devices

1 Scope and purpose

1.1 Scope

This Part of IEC 62366, which is a Technical Report, contains background information and provides guidance that addresses specific areas that experience suggests can be helpful for those implementing a **USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS** both as defined in IEC 62366-1:2015 *and as supporting goals other than SAFETY*. This technical report is not intended to be used for regulatory purposes. It contains no requirements and only provides guidance and tutorial information.

NOTE 1 **SAFETY** is freedom from unacceptable **RISK**, which is described in ISO 14971. Unacceptable **RISK** can arise from **USE ERROR**, which can lead to exposure to direct physical **HAZARDS** or to loss or degradation of clinical performance.

NOTE 2 The **PROCESS** for a **MANUFACTURER** to analyse, specify, develop and evaluate the **USABILITY** of a **MEDICAL DEVICE**, as it relates to **SAFETY** is found in IEC 62366-1:2015.

This technical report has two main themes:

- information about efficient ways to implement elements required by IEC 62366-1:2015; and
- *additional information, in particular how **USABILITY** relates to attributes such as **TASK EFFICIENCY** and **USER satisfaction**, which can enhance a **MEDICAL DEVICE'S** commercial success.*

This technical report discusses the business benefits of **USABILITY ENGINEERING**, the basics of applicable analysis and design techniques, **MEDICAL DEVICE USABILITY EVALUATION** approaches, efficient ways to address **USABILITY ENGINEERING** project implementation issues (e.g. integration into a quality management system) and provides a list of useful **USABILITY ENGINEERING** resources.

This technical report also can be useful for other healthcare products (e.g. drug packaging and drug **LABELLING**, drug-**MEDICAL DEVICE** combination products and health IT software).

1.2 Purpose

The intent of this technical report is to provide guidance related to:

- the essential elements of a **USABILITY ENGINEERING PROCESS** as required by IEC 62366-1:2015, including:
 - **USER** research techniques,
 - analysis techniques,
 - design techniques, and
 - **MEDICAL DEVICE USABILITY EVALUATION** approaches (e.g. **USABILITY TESTING**);
- *the planning and implementation of the **USABILITY ENGINEERING PROCESS**;*
- *the benefits of applying **USABILITY ENGINEERING**; and*
- *improve **USER satisfaction**.*

This technical report is intended to be read in conjunction with IEC 62366-1:2015.

The intended reader for this technical report includes the people or organisations that are involved with *planning, funding, managing, and performing research*, design, evaluation and *regulatory-related activities* (i.e. approbation) related to MEDICAL DEVICES, including, but not limited to:

- company, department, project, and product managers;
- design and engineering professionals (e.g. human factors engineers, industrial designers, technical writers, information designers, software developers, mechanical engineers, electrical engineers, packaging engineers);
- medical researchers and other interested clinicians;
- marketers and other business professionals in the MEDICAL DEVICE industry;
- quality or regulatory staffs of MEDICAL DEVICE MANUFACTURERS (for example, regulatory affairs, RISK MANAGEMENT or quality management roles); and
- writers of product standards.

This technical report is neither intended as the sole source of USABILITY ENGINEERING guidance for MEDICAL DEVICE MANUFACTURERS, nor a complete substitute for human factors expertise. Rather, it is intended to provide readers with a general understanding of how to perform USABILITY ENGINEERING in an economic manner. Readers are advised to supplement the knowledge they gain from this report with knowledge acquired from complementary documents including those specific to the MEDICAL DEVICE of interest. A list of useful USABILITY ENGINEERING resources and further readings is provided in Annex A.

This report does not address detailed USABILITY ENGINEERING design guidance or requirements, such as recommendations on the proper size of text on a computer screen, appropriate ways to arrange a workstation's displays and controls, or characteristics of an appropriate ALARM SIGNAL. Such information can be found in other documents, such as [1][2][3][4]¹.

This technical report does not describe a specific set of USABILITY ENGINEERING activities that suit all design projects. Instead, it gives guidance for a general USABILITY ENGINEERING PROCESS requiring further shaping and tailoring to suit a given development project's needs. USABILITY ENGINEERING practice varies widely throughout the world and even within specific countries, companies, and company units. This variation is partly due to the diversity found among USABILITY ENGINEERING practitioners who can have a background in one or more of various professional fields, such as engineering, psychology, or design. Practice differences also exist due to the wide variety of MEDICAL DEVICES, which range from seemingly simple syringes to complex imaging systems, some of which are used in hospitals, clinics, and/or the home by various types of medical professionals as well as laypersons (e.g. PATIENTS and caregivers who take care of PATIENTS, such as a child or spouse).

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 Informative references are listed in the bibliography beginning on page 98.

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

¹ Numbers in square brackets refer to the Bibliography.

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

3 Terms and definitions

For the purposes of this document, the terms given in IEC 62366-1, ISO 14971, as well as the following apply.

NOTE An index of defined terms is found beginning on page 101.

3.1

ACCESSORY

additional part for use with MEDICAL DEVICE in order to:

- achieve the INTENDED USE,
- adapt it to some special use,
- facilitate its use,
- enhance its performance, or
- enable its functions to be integrated with those of other MEDICAL DEVICE

[SOURCE: IEC 60601-1:2005, 3.3, modified – ‘equipment’ is replaced by ‘MEDICAL DEVICE’] [5]

3.2

ADVERSE EVENT

event associated with a MEDICAL DEVICE that led to death or serious injury of a PATIENT, USER or other person, or that might lead to death or serious injury of a PATIENT, USER or other person if the event recurs

Note 1 to entry: This definition is consistent with guidance in GHTF/SG2/N54/R8:2006. [6]

Note 2 to entry: This definition includes malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

[SOURCE: ISO TS 19218-1:2011, 2.1] [7]

3.3

ALARM CONDITION

state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

Note 1 to entry: An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

Note 2 to entry: An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 3.1] [1]

3.4

ALARM LIMIT

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

[SOURCE: IEC 60601-1-8:2006, 3.3] [1]

3.5

ALARM SIGNAL

type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[SOURCE: IEC 60601-1-8:2006, 3.9] [1]

3.6**ALARM SYSTEM**

parts of the MEDICAL DEVICE that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[SOURCE: IEC 60601-1-8:2006, 3.11, modified – ‘ME EQUIPMENT or a ME SYSTEM’ has been replaced by ‘MEDICAL DEVICE’] [1]

3.7**CLOSE CALL**

case in which a USER almost commits a USE ERROR while performing a TASK, but recovers in time to avoid making the USE ERROR

EXAMPLE A USER might initially place his or her thumb on the wrong end of an injection pen, but then rotates the pen into the proper position enabling a safe and effective injection.

Note 1 to entry: A CLOSE CALL does not include a case in which an initial USE ERROR evokes an ALARM CONDITION, for example, leading the USER to correct the USE ERROR; this is a case of a RISK CONTROL working properly.

3.8**CONCEPTUAL MODEL DIAGRAM**

graphical description of the underlying organization and relationships in a USER INTERFACE design.

EXAMPLE A diagram that simply shows labelled circles – perhaps as few as three to five.

3.9**FIDELITY**

degree to which a model or SIMULATION reproduces the state and behaviour of a real world object or the perception of a real world object, feature or condition

Note 1 to entry: Low-FIDELITY models share only a limited number of common elements with the actual MEDICAL DEVICE of interest.

Note 2 to entry: High-FIDELITY models share many common elements with the actual MEDICAL DEVICE of interest.

[SOURCE: ISO 16781:2013, 2.4, modified – deleted ‘, or chosen standard in a measurable or perceivable manner’ and added Notes 1 and 2 to entry.] [8]

3.10**FUNCTION ANALYSIS**

analysis of MEDICAL DEVICE-related functions that occur to accomplish operational goals and particularly which functions are (or should be) performed automatically by the MEDICAL DEVICE or manually by the USER, or by a combination of both based on their known strengths and weaknesses

3.11**KNOWLEDGE TASK STUDY**

a study performed by questioning USERS to understand and interpret important information in the USER INTERFACE that will be applied to make use-related decisions

3.12**LABELLING**

written, printed or graphic matter

- affixed to a MEDICAL DEVICE or any of its containers or wrappers, or
- accompanying a MEDICAL DEVICE,

related to identification, technical description, and use of the MEDICAL DEVICE, but excluding shipping documents

Note 1 to entry: For the purposes of this International Standard, the term “marking” as used in ISO 9001 is interpreted to mean “LABELLING”.

Note 2 to entry: Some regional and national regulations use the term “LABELLING” more comprehensively to include for example, promotional materials and training.

[SOURCE: ISO 13485:2003², 3.6, modified – Deleted existing note, and Note 1 to entry and Note 2 to entry have been added.] [9]

3.13

SIMULATION

conceptualization and use of an abstraction or model that behaves in a way similar to a real MEDICAL DEVICE in its SYSTEM

3.14

TASK ANALYSIS

analysis employed to determine the USER goals and the specific behaviours required of USERS when operating equipment or doing work

Note 1 to entry: The documentation of a TASK ANALYSIS can take a narrative, tabular, or flow chart form.

Note 2 to entry: Example interactions include acquiring information, processing information, making decisions and performing physical actions.

[SOURCE: ISO 9241-5:1998, 3.22, modified – replaced ‘people’ with ‘the USER goals and’ and added Notes 1 and 2.] [10]

3.15

USABILITY GOAL

desired quality of a USER-MEDICAL DEVICE interaction

NOTE 1 TO ENTRY: USABILITY GOALS can be expressed in written form, stipulating a particular USABILITY attribute (e.g. TASK compliance rate, TASK speed, learning time, accuracy, visual appeal, comfort) and performance criterion (e.g. number of seconds, USE ERROR rate, average subjective ratings).

NOTE 2 TO ENTRY: USABILITY GOALS can address objective (observable) and subjective (opinion-based) aspects of interaction and can be used as a basis for planning and judging the results of USABILITY TESTS.

3.16

USABILITY SPECIALIST

professional competent on the basis of appropriate education, training, skills or experience to perform USABILITY ENGINEERING activities

Note 1 to entry: A USABILITY SPECIALIST applies knowledge of human characteristics and USABILITY ENGINEERING methods to support the development of safe, effective, usable, and satisfying MEDICAL DEVICES.

3.17

USER INTERFACE REQUIREMENT

testable technical design requirement for a USER INTERFACE characteristic

Note 1 to entry: A USER INTERFACE requirement can be USER INTERFACE design feature or medical device performance level.

Note 2 to entry: A USER INTERFACE REQUIREMENT is typically derived from a USER need.

² The reference to ISO 13485:2003 was retained to maintain alignment with IEC 62366-1:2015. At the next revision of IEC 62366-1, the references will be updated to the latest edition of ISO 13485.

4 Mapping between the requirements of IEC 62366-1 and the guidance of IEC TR 62366-2

Table 1 provides a mapping between the requirements of IEC 62366-1 and the guidance of this technical report.

NOTE Not all of the content of this technical report maps directly to the normative parts of IEC 62366-1. This technical report also contains additional information about good USABILITY ENGINEERING practices.

5 Background and justification of the USABILITY ENGINEERING program

5.1 How SAFETY relates to USABILITY

The application of USABILITY ENGINEERING is widely recognized as essential to producing MEDICAL DEVICES that are safe and effective to use. Past analyses of ADVERSE EVENTS (i.e. injuries, deaths, and property loss) involving MEDICAL DEVICES have shown that USER INTERFACE design shortcomings can lead to USE ERRORS and, consequently, injuries and deaths, as reported in many sources. For example:

- tubing connector shortcomings and the resulting misconnections of incompatible MEDICAL DEVICES and ACCESSORIES have led to air emboli, poisoning, and asphyxiation;
- confusing menu systems within infusion pumps have led to drug delivery errors, including underdoses, overdoses, and treatment with the wrong drug;
- visual ALARM SIGNAL message ambiguities and the option to override ALARM SIGNALS in dialysis equipment have led clinicians to overlook and misjudge the signs of PATIENT distress.

Table 1 – Mapping between the requirements of IEC 62366-1 and the guidance of IEC TR 62366-2

Subclause of IEC 62366-1:2015	Subclauses of IEC TR 62366-2:2016
4.1.1 USABILITY ENGINEERING PROCESS	6 How to implement a USABILITY ENGINEERING program 6.1 Effective USABILITY ENGINEERING programs 6.2 Effective USABILITY ENGINEERING projects and plans 6.4 Ensure the necessary resources are available 6.5 RISK MANAGEMENT as it relates to USABILITY ENGINEERING
4.1.2 Risk CONTROL as it relates to USER INTERFACE design	6.5.2 Risk CONTROL
4.1.3 Information for SAFETY as it relates to USABILITY	6.5.3 Information for SAFETY
4.2 USABILITY ENGINEERING FILE	6.6 USABILITY ENGINEERING FILE
4.3 Tailoring of the USABILITY ENGINEERING effort	6.7 Tailoring the USABILITY ENGINEERING effort
5 USABILITY ENGINEERING PROCESS	7 Overview of the USABILITY ENGINEERING PROCESS
5.1 Prepare USE SPECIFICATION	8 Prepare the USE SPECIFICATION
5.2 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS	9 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS
5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS	10 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS
5.4 Identify and describe HAZARD-RELATED USE SCENARIOS	11 Identify and describe HAZARD-RELATED USE SCENARIOS
5.5 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION	12 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION
5.6 Establish USER INTERFACE SPECIFICATION	13 Establish USER INTERFACE SPECIFICATION

Subclause of IEC 62366-1:2015	Subclauses of IEC TR 62366-2:2016
5.7 Establish USER INTERFACE EVALUATION plan	14 Establish USER INTERFACE EVALUATION plan
5.8 Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION	15 Design and implement the USER INTERFACE and training 16 Perform FORMATIVE EVALUATIONS
5.9 Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE	17 Perform SUMMATIVE EVALUATION 6.5.4 Overall evaluation of RESIDUAL RISK

The application of USABILITY ENGINEERING is a principle means to reduce MEDICAL DEVICE unacceptable RISK and improve PATIENT care by reducing the potential for harmful USE ERROR through enlightened USER INTERFACE design. This viewpoint applies to MEDICAL DEVICES used by medical professionals, such as ventilators, PATIENT monitors, and X-ray machines. It also applies to MEDICAL DEVICES used by laypersons (e.g. PATIENTS and caregivers who take care of PATIENTS, such as a child or spouse), such as nebulizers, glucose meters, and insulin pen injectors.

Annex B lists external resources of reports that MANUFACTURERS can review to identify known problems with USER INTERFACES to avoid when developing a MEDICAL DEVICE of the same or similar type.

MEDICAL DEVICE SAFETY and MEDICAL DEVICE USABILITY are interrelated. For instance, features that help to ensure SAFETY, such as high and low dosing limits built into an infusion pump's software, can also increase a MEDICAL DEVICE'S USABILITY. In addition to protecting a PATIENT from a harmful underdose or overdose, a feature such as dose limits gives USERS a helpful indication of the allowable dosing range. This can reduce the burden on the USERS' memory and increase their confidence when programming the pump.

USER INTERFACE design features intended to increase TASK speed – a traditional USABILITY attribute – might also reduce unacceptable RISK because slow TASK performance might delay an urgent therapy (e.g. treating a PATIENT who is unconscious due to an opioid overdose by injecting a reversal agent). Conversely, it might introduce new HAZARDOUS SITUATIONS because critical confirmation steps were not implemented. Slow TASK performance could also lead a well-meaning USER to pass over steps in a PROCEDURE to increase speed of the PROCEDURE. This can result in a higher probability of USE ERROR linked to a potentially unacceptable RISK. The USABILITY ENGINEERING PROCESS should be used to help ensure that this does not happen.

As such, USABILITY ENGINEERING activities usually serve the dual purpose of reducing MEDICAL DEVICE unacceptable RISK and enhancing USABILITY. A MEDICAL DEVICE'S increased appeal is a predictable by-product of the USABILITY ENGINEERING PROCESS.

5.2 Reasons to invest in USABILITY ENGINEERING

In promoting the development of safe and effective MEDICAL DEVICES, many MANUFACTURERS perform more extensive application of USABILITY ENGINEERING principles because they consider it a good practice for business. Potential, business-related benefits include the following.

- Reduced time to market due to the prevention of product launch delays associated with the late detection of USER INTERFACE design shortcomings that require time-consuming correction.*
- Reduced time to market due to reduced regulatory review times, owing to the creation of a complete and convincing submission package from a USABILITY ENGINEERING perspective.*
- Improved sales because customers perceive the MANUFACTURER'S MEDICAL DEVICE(S) as more "USER friendly" than other MANUFACTURERS' MEDICAL DEVICE offerings.*
- Simpler training because a MEDICAL DEVICE's intuitive operation and integrated procedural guidance enable USERS to master operation concepts and PROCEDURES quickly.*

- e) *Reduced demand for customer support because customers are better able to operate and troubleshoot a MEDICAL DEVICE without seeking outside support.*
- f) *Fewer returned products that are deemed "defective" by USERS, when there is no technical failure of the MEDICAL DEVICE.*
- g) *Better treatment compliance rates (fewer PATIENTS abandoning the treatment).*
- h) *Better application of currently available technology to MEDICAL DEVICES.*
- i) *Increased utilization of available features which can otherwise be unknown to the USER, or can be combined in creative ways.*

6 How to implement a USABILITY ENGINEERING program

6.1 Effective USABILITY ENGINEERING programs

It is recommended that the MANUFACTURER develop, implement and maintain a USABILITY ENGINEERING program to ensure the consistent and broad application of USABILITY ENGINEERING PROCESS, potentially across multiple product development efforts. Steps can include:

- a) *assigning organisational roles and responsibilities relating USABILITY ENGINEERING PROCESS;*
- b) *establishing general PROCEDURES for major USABILITY ENGINEERING PROCESSES; and*
- c) *allocating the necessary resources during budgeting cycles to perform the activities.*

6.2 Effective USABILITY ENGINEERING projects and plans

As part of an effective USABILITY ENGINEERING program, it is highly recommended that the MANUFACTURER develop a USABILITY ENGINEERING project plan for each product development effort. It describes all USABILITY ENGINEERING-related activities that are planned to take place during MEDICAL DEVICE development from concept to final design. The USABILITY ENGINEERING project plan should define activity timelines, team member roles and responsibilities as well as costs as tailored for the specific project (see 6.7). This facilitates the integration of USABILITY ENGINEERING into the MEDICAL DEVICE project development plan and avoids the problems arising from USABILITY ENGINEERING being considered a separate independent PROCESS. Annex D summarizes the USABILITY ENGINEERING project end products. USABILITY ENGINEERING project plans can be integrated into a general MEDICAL DEVICE project plans.

Effective USABILITY ENGINEERING projects address the need to demonstrate that the RISKS related to USE ERRORS of the MEDICAL DEVICE are reduced to acceptable levels. *They also facilitate the development of MEDICAL DEVICES that are satisfying to use.*

A particular USABILITY ENGINEERING project can focus on developing the following.

- a) An update to an existing (i.e. legacy) MEDICAL DEVICE without the addition of significant new features.
- b) A MEDICAL DEVICE representing a line extension because it has a USER INTERFACE that is similar to one on an existing MEDICAL DEVICE, but incorporates new features.
- c) A next generation version of a MEDICAL DEVICE (i.e. replacement model) that represents a major conceptual departure from the MEDICAL DEVICE it replaces.
- d) An altogether new MEDICAL DEVICE with no predicate (i.e. no other MEDICAL DEVICE works in a similar way to serve the same purpose).

Such projects typically generate a comprehensive set of USABILITY ENGINEERING RECORDS comprising a USABILITY ENGINEERING FILE. As discussed later, MANUFACTURERS should ensure that USABILITY ENGINEERING documentation, such as the USER INTERFACE SPECIFICATION, facilitates good USABILITY ENGINEERING rather than becoming an intensive paperwork exercise that eclipses the actual USER INTERFACE design effort. The key to achieving this goal is to follow a USABILITY ENGINEERING PROCESS that serves the need.

The USABILITY ENGINEERING plan for a specific project is likely to be one-of-a-kind, its distinctiveness owing to the type and extent of USER interactions with the associated MEDICAL DEVICE. However, a USABILITY ENGINEERING plan should achieve the following common objectives.

- a) Describe a potentially iterative USER INTERFACE development PROCESS that includes research (e.g. identifying USER GROUPS and USE ENVIRONMENTS) and design, modelling (e.g. producing prototypes), and USABILITY EVALUATION cycles.
- b) Focus on identifying and elimination of USE ERRORS leading to a usable and appealing MEDICAL DEVICE.
- c) Address all relevant points of USER interaction (i.e. points of interaction between USERS and hardware, software, and USER support components and LABELLING—embedded help, quick reference card, USER's manual, and other ACCOMPANYING DOCUMENTATION).
- d) *Consider establishment of USABILITY GOALS for commercialization purposes only (i.e. not for SAFETY purposes), and plan relevant design, evaluation and testing. Annex C contains additional information.*
- e) Identify the USABILITY ENGINEERING methods to be utilized. Annex E contains additional information.
- f) Identify the USABILITY ENGINEERING RECORDS that need to be created, which are the core of the USABILITY ENGINEERING FILE.
- g) *Include a schedule indicating how the USABILITY ENGINEERING activities are expected to progress over the course of an overall MEDICAL DEVICE development project.*
- h) Allow for design iteration, as needed, to produce a successful design.
- i) Prepare submissions for AHJ.

6.3 Apply an appropriate level of USABILITY ENGINEERING expertise

It is recommended for a MEDICAL DEVICE development team to have available adequate USABILITY ENGINEERING expertise and include at least one USABILITY SPECIALIST, as needed. The USABILITY SPECIALIST should have relevant, appropriate training (e.g. in USABILITY ENGINEERING) and have appropriate MEDICAL DEVICE domain knowledge. USABILITY ENGINEERING expertise can also be gained through formal USABILITY ENGINEERING education, complemented by applicable experience applying the USABILITY ENGINEERING PROCESS to MEDICAL DEVICE development.

USABILITY ENGINEERING expertise can also be provided by individuals who are self-educated in the field and those who have attended courses intended to teach them important USABILITY ENGINEERING concepts and best practices related to MEDICAL DEVICE development.

Among others, the following types of professionals can also participate actively in USABILITY ENGINEERING activities, such as contributing to the USABILITY ENGINEERING project plan, participating in the analysis of USABILITY problems, designing or modifying a MEDICAL DEVICE'S USER INTERFACE or observing and analysing the results of USABILITY TESTS:

- a) technical writers responsible for developing the learning tools associated with a MEDICAL DEVICE; tools such as quick reference cards, USERS manuals, other ACCOMPANYING DOCUMENTATION, online help, and educational posters;
- b) training course developers and trainers;
- c) marketing specialists who have a strong appreciation for USABILITY ENGINEERING and recognize the important differences between USABILITY ENGINEERING and market research;
- d) clinicians who have a strong understanding of the USER perspective;
- e) developers who build USER INTERFACE prototypes for use in USABILITY TESTS; and
- f) engineers and designers who have learned about USABILITY ENGINEERING to enable their own work or manage the USABILITY ENGINEERING efforts of other development team members.

6.4 Ensure the necessary resources are available and well timed

A USABILITY ENGINEERING project can struggle if it lacks the necessary funds or is given too little time to have a positive effect on the MEDICAL DEVICE development PROCESS. Specifically, the project might fail to produce the results necessary to secure regulatory clearance for a given MEDICAL DEVICE. Therefore, for multiple reasons including launching a MEDICAL DEVICE on schedule, USABILITY ENGINEERING projects should be adequately funded. At a minimum, MANUFACTURERS should invest sufficient resources to ensure that a MEDICAL DEVICE is safe and effective when used as intended by the MANUFACTURER, noting that a larger investment might boost the USABILITY and commercial prospects of a MEDICAL DEVICE. Additional information is found in 5.2.

It is vital to execute the USABILITY ENGINEERING project in a timely manner, rather than perform the work retrospectively when a MEDICAL DEVICE is in the later stages of development. Performing the work late has been shown to produce fewer benefits and increases the RISK that a MEDICAL DEVICE does not meet the needs of USERS.

Another hallmark of an effective USABILITY ENGINEERING project is a high degree of integration with other engineering, design, and even marketing activities. Ideally, a USABILITY ENGINEERING project is structured and timed so that it runs smoothly in conjunction with other MEDICAL DEVICE development activities, such as the exploration of various USER INTERFACE mechanisms, the selection of a display technology, the construction of APPEARANCE MODELS by industrial designers, the choice of USER INTERFACE development tools, and feature selection. In contrast, poorly timed USABILITY ENGINEERING activities can produce useful design insights, but not at a point in the development PROCESS when they can be implemented efficiently and effectively.

6.5 RISK MANAGEMENT as it relates to USABILITY ENGINEERING

6.5.1 RISK ANALYSIS

The MANUFACTURER should integrate USABILITY ENGINEERING and RISK MANAGEMENT efforts. The documentation of USE ERROR HAZARD analysis should be shared by the persons responsible for RISK MANAGEMENT and USABILITY ENGINEERING. For example, a shared USE ERROR HAZARD analysis document can be an input to both the RISK MANAGEMENT team and USABILITY ENGINEERING team.

The MANUFACTURER should treat USE ERRORS in the same manner as other MEDICAL DEVICE failures, such as mechanical or electrical component failures and software anomalies, for example, recognizing that USER INTERFACE design shortcomings can lead to USE ERRORS, which in turn can lead to significant HARM. IEC 62366-1:2015, Table B.2, contains examples of USE ERRORS, which are part of the sequence of events that lead to HAZARDOUS SITUATIONS leading to HARM. The MANUFACTURER should consider a wide range of possible USE ERRORS.

USE ERRORS differ from component failures in that it is typically more difficult to estimate with accuracy the probability of a USE ERROR occurring. Because of the difficulty of determining the probabilities of occurrence of USE ERROR, MANUFACTURERS should focus primarily on the SEVERITY of the potential HARM rather than on the RISK derived from the combination of SEVERITY and USE ERROR probability.

In the development of a MEDICAL DEVICE, the MANUFACTURER should consider potential USE ERRORS such as:

- a) performing an incorrect action (i.e. an error of commission); and
- b) incorrectly omitting a necessary action (i.e. an error of omission).

When designing a MEDICAL DEVICE, a MANUFACTURER should consider the factors that might induce USE ERROR, such as the following:

- c) environmental distractions;
- d) excessive workload;

- e) fatigue;
- f) inattention;
- g) insufficient experience with the type of MEDICAL DEVICE;
- h) insufficient training;
- i) lack of familiarity with terminology;
- j) lack of fluency in the language used by the MEDICAL DEVICE and associated learning tools (e.g. ACCOMPANYING DOCUMENTATION);
- k) USER impairments (e.g. vision, hearing, body movement, cognition);
- l) misapplication of experience using other existing MEDICAL DEVICES (i.e. negative transfer of learning);
- m) overconfidence in one's capabilities;
- n) organisational hierarchy (due to policies, internal relationships or external requirements);
- o) working at a fast pace; and
- p) TASK interruptions.

Additional information is contained IEC 62366-1:2015, Annex A rationale to 3.21, regarding the causes of USE ERROR.

6.5.2 RISK CONTROL

To reduce use-related RISK, a SAFETY principle is that one or more of the following options are used in the priority listed (as required by ISO 14971:2007, 6.2):

- a) inherent SAFETY by design;
- b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and
- c) information for SAFETY.

Inherent SAFETY by design is the first option, because it is most likely to effectively reduce the RISK or even remove it. The best way to prevent a USE ERROR and the possible resulting HARM is to eliminate a HAZARDOUS SITUATION altogether.

Another way to design a MEDICAL DEVICE is with built-in protections against USE ERRORS.

EXAMPLES Physical guards over a critical control, an interlock preventing accidental control actions, requiring USERS to confirm critical actions.

Protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS are the second option. Such measures can fail in some situations or rely on the ability of a human being to react in order for them to be effective.

NOTE 1 A person can fail to react for a number of reasons.

Protective measures however are often used, also as a supplement to design RISK CONTROL measures that by themselves cannot reduce the RISK to an acceptable level. Examples are listed in IEC 62366-1:2015, Table B.2.

The last option is information for SAFETY. The reason it is listed last is because in order for information for SAFETY to be effective, it depends on the following.

- a) The opportunity for the USER to gain access to the information. This is sometimes difficult (e.g. when a paper instructions for use has been separated from the MEDICAL DEVICE or a training session is needed, but not carried out).
- b) The ability of the USER to learn from the information. Even if the information for SAFETY has been demonstrated to be perceivable, be understandable and to support CORRECT USE, it might not always obtain the same level of EFFECTIVENESS as a RISK CONTROL measure by design.

c) The ability of the USER to recall the information for SAFETY.

However, information for SAFETY can be needed and appropriate, both for RISKS that otherwise would be unacceptable, as well as for RISKS that while acceptable are still likely to cause events that USERS therefore should be warned against.

NOTE 2 The generic term 'warning' can refer to one of several specific indications that utilize the signal words danger, warning, caution and notice.

In addition, information for SAFETY is not always a warning, but can be instructions in CORRECT USE of the MEDICAL DEVICE (i.e. not a warning or precaution) and this can be an effective RISK CONTROL measure.

Information for SAFETY can also be required by product standards and other sources. Additional information is found in 6.5.3.

The SAFETY principle of the three options of RISK CONTROL applies both to MEDICAL DEVICE failures and to USER INTERFACE to prevent USE ERRORS. A design change outside the USER INTERFACE to reduce USE ERROR should be applied before a protective measure in the USER INTERFACE. As an example in the design of a MEDICAL DEVICE, where a USE ERROR of touching a live wire could be hazardous, the MANUFACTURER should apply SAFETY by design (e.g. by changing line voltage to battery cells), before introducing a protective measure (e.g. by using a removable hood covering the power supply).

Inherent SAFETY (i.e. a redesign in the USER INTERFACE) should be applied before introducing protective measures (e.g. an ALARM SYSTEM), which again should come before introducing more information for SAFETY.

When choosing whether to apply more than one option, the MANUFACTURER should not only evaluate whether the RISK is acceptable, but also estimate whether the option can further reduce the RISK, acceptable or not. For example, an additional warning against an unlikely event might not be effective, whereas a warning against a likely although acceptable RISK, can better support USER needs and should therefore be implemented.

The MANUFACTURER should use USABILITY ENGINEERING to assess the adequacy of RISK CONTROL measures implemented in the USER INTERFACE, including information for SAFETY (as required by ISO 14971). The USABILITY ENGINEERING PROCESS should also be used to investigate new RISKS arising from RISK CONTROL measures implemented in the USER INTERFACE (as required by ISO 14971). In order to assess the adequacy of RISK CONTROL measures, several techniques capable of identifying possible USE ERROR can be applied ranging from heuristic analysis to USABILITY TESTING. Clause E.11 contains additional considerations on using heuristic analysis.

Information for SAFETY and overall RESIDUAL RISKS weighed against benefit is described in ISO/TR 24971:2013, Clause 5. [3]

6.5.3 Information for SAFETY

Information for SAFETY, including instructions for use and other ACCOMPANYING DOCUMENTATION is considered part of the USER INTERFACE. Information for SAFETY should be considered from the start and subjected to the same USABILITY ENGINEERING PROCESS. Information for SAFETY should also be an input to development of training material.

Proving that information for SAFETY is effective is an important activity. MANUFACTURERS should use iterative FORMATIVE EVALUATION during the course of developing information for SAFETY and conclude the PROCESS by SUMMATIVE EVALUATION of information for SAFETY. The MANUFACTURER determines that this information is effective, meaning it is:

a) perceivable by the USER;

- b) understandable to the USER;
 - c) supports CORRECT USE of the MEDICAL DEVICE; and
- by the intended USER in the intended USE ENVIRONMENT.

This considers both text (cf. general and health literacy) as well as symbols, icons, and images (cf. visual literacy, cultural differences in image perception).

Traditionally, information for SAFETY takes the physical form of a printed document or is provided as markings upon the MEDICAL DEVICE. However, computer-based MEDICAL DEVICES (e.g. PATIENT monitor, ventilator, dialysis machine, infusion pump) can present information for SAFETY in an electronic format. In addition, some MEDICAL DEVICES (e.g. nebulizer, pen injector, glucose meter) are delivered with the expectation that at least some USERS access information for SAFETY using supplemental tools, such as a DVD player or computer connected to the Internet. Refer to 15.5 for more details on how to design information for SAFETY and other training material.

When developing information for SAFETY, it is important to identify to whom this information is to be provided and how it is to be provided. The MANUFACTURER should provide an explanation of the RISK, the consequences of exposure to the HAZARD and what should be done or avoided to prevent HARM. By identifying the RISK and the consequences of exposure and by providing clear instructions to the USERS, which would enable them to avoid the HAZARDOUS SITUATION, the likelihood of the USERS being exposed to that HAZARD can be decreased.

Examples for information for SAFETY that can reduce the likelihood of USE ERROR are:

EXAMPLE 1 WARNING: To avoid the RISK of electrical shock always unplug this device from mains power before cleaning it.

EXAMPLE 2 WARNING: Do not reuse this device or any of its components. Multiple uses can lead to device malfunction or cross-contamination of the PATIENT.

While the standard recognizes that well-designed information for SAFETY can reduce the likelihood of USE ERROR, it is usually less effective at reducing RISK than a design measure (e.g. some USERS might not understand the information for SAFETY or printed information might be separated from the MEDICAL DEVICE) and MANUFACTURERS, when practicable, should avoid making information for SAFETY the primary means of preventing USE ERROR. Information for SAFETY does not always succeed in reducing the likelihood of USE ERROR. There are also cases in which it can be necessary to instruct the USER how to manage an exceptional situation (e.g. an emergency or unusual situation).

An example of explaining a SAFETY feature of a MEDICAL DEVICE:

EXAMPLE 3 The yellow light on top of the C-Arm housing is flashing and the display flashes the yellow ionizing radiation warning sign while the C-arm emits radiation.

An example of information for SAFETY instructing the USER in managing an exceptional situation:

EXAMPLE 4 In case of an emergency evacuation, do the following five steps (in the order listed) before moving the PATIENT:

- 1) Unplug the MEDICAL DEVICE and store the cable.
- 2) Move the bed surface to the lowest level possible by pushing the mechanical release button.
- 3) Monitor the PATIENT during movement of the bed surface.
- 4) Lift-up the side-rail left and right of the bedside.
- 5) Unlock casters and transport PATIENT out of the room.

Despite all efforts the MANUFACTURER might have undertaken to reduce the MEDICAL DEVICE'S RISKS as low as reasonably practicable, there can be still RISKS that cannot be further reduced and remain as the RESIDUAL RISKS. These RISKS are often inherent to the operating principle

and cannot be reduced by any other RISK CONTROL. Information for SAFETY can be used to inform the USER about the existence of such RESIDUAL RISKS.

As with other information for SAFETY, the disclosure of RESIDUAL RISK can be given in various forms such as a written information in the ACCOMPANYING DOCUMENTATION, as a warning label attached to a MEDICAL DEVICE or as a SAFETY message on a display of a USER INTERFACE.

Examples of disclosure of RESIDUAL RISKS (the following examples assume that the RISK described cannot be further reduced by any other RISK CONTROL):

EXAMPLE 5 Do not step on surface, enclosure will break.

EXAMPLE 6 Do not remove cover, RISK of electric shock.

EXAMPLE 7 Serum samples containing more than 60 mg/dl haemoglobin interfere with the test principle, thereby limiting the EFFECTIVENESS of the diagnostic result.

EXAMPLE 8 Hot surface (>80 °C), do not touch.

EXAMPLE 9 This X-ray MEDICAL DEVICE emits stray radiation as shown in the following radiation scatter diagram. While operating this MEDICAL DEVICE use x-ray protective clothing and avoid staying close to the medical device.

Online help is yet another common form of information SAFETY. Online help might simply be an electronic manifestation of the printed USER manual, or it might be specially tailored to optimize communication via a computer USER INTERFACE in place of a physical document. Moreover, it can take full advantage of the electronic form by presenting some content in the form of animations, video, and spoken instructions.

Depending on their characteristics and expected use, information for SAFETY could take more forms such as checklists, posters, and package inserts. Training materials that are subject to change over time are not considered to be information for SAFETY if their use is restricted to training sessions but are not expected to be used in the context of actual MEDICAL DEVICE use.

Information for SAFETY can exist in a single place (e.g. USER manual) or duplicative forms that consider the use model. For example, content can be provided both in a concise form (e.g. quick reference guide) used at a point-of-care as well as in a more comprehensive form (e.g. USER manual) used away from the point-of-care (e.g. nurses station, biomedical department).

When considering the design and evaluation of information for SAFETY, there might not be a clear distinction between what many people would consider to be classic USER INTERFACE elements (e.g. parametric displays, menus) versus information for SAFETY (instructions for use). Ultimately, it can be difficult and unproductive to differentiate sharply between:

- a) online help; and
- b) a USER selectable option to read instructions in the course of performing a TASK.

Importantly, both comprise a MEDICAL DEVICE'S overall USER INTERFACE and warrant SUMMATIVE EVALUATION. Additional information is found in Clause 17.

6.5.4 Overall evaluation of RESIDUAL RISK

The subsequent overall evaluation of RESIDUAL RISK, which is required according to IEC 62366-1:2015, 5.9 and ISO 14971:2007, is only possible when considering the entire set of RISKS associated with the MEDICAL DEVICE. These include RISKS caused by MEDICAL DEVICE failures as well as those caused by USE ERROR.

6.6 USABILITY ENGINEERING FILE

MANUFACTURERS should store RECORDS of USABILITY ENGINEERING activities to establish a USABILITY ENGINEERING FILE. The information acquired throughout the USABILITY ENGINEERING PROCESS serves as indispensable resource and inputs for many subsequent development

activities. Having those RECORDS easily available can be of great benefit for the development team. Annex D summarizes the major end product RECORDS created during the USABILITY ENGINEERING PROCESS.

The RECORDS created by conducting the USABILITY ENGINEERING PROCESS also provide OBJECTIVE EVIDENCE for the activities required by IEC 62366-1 and are necessary to demonstrate compliance to that standard.

USABILITY ENGINEERING RECORDS can include written documents but also photographs and video material that might be collected, for example, while interacting with prospective USERS during USER interviews, field observations, or USABILITY TESTS.

In fact, the USABILITY ENGINEERING PROCESS has close relationships to other PROCESSES such as the product realization PROCESS (as described in ISO 13485 [9]) or the RISK MANAGEMENT PROCESS. Results of the USABILITY ENGINEERING activities directly feed into those PROCESSES and supplement their RECORDS. It can be practical to integrate RECORDS from the USABILITY ENGINEERING PROCESS into documents or files of those other PROCESSES, for example the following.

- a) The USER INTERFACE SPECIFICATION can form part of the product specification of the overall product realization PROCESS.
- b) For a software USER INTERFACE, the USER INTERFACE SPECIFICATION can be part of the software requirements specification required by a software development PROCESS.
- c) The USABILITY EVALUATION PLAN can form part of the verification and validation plan of the overall product realization PROCESS.
- d) The analysis of known use problems and the analysis of foreseeable USE ERRORS can be part of the RISK MANAGEMENT FILE.

6.7 Tailoring the USABILITY ENGINEERING effort

It is important to tailor the USABILITY ENGINEERING project to suit a particular MEDICAL DEVICE development effort. Some MEDICAL DEVICES pose little RISK created by USABILITY problems while others could present an unacceptable RISK unless the HAZARDS are prospectively identified and their causes controlled. For this reason, and as mentioned earlier in this report, a USABILITY ENGINEERING project might span just weeks on one extreme and years on the other extreme.

Note that a MEDICAL DEVICE with more functions (e.g. haemodialysis equipment, MRI scanner or anaesthesia workstation) might warrant a more extensive USABILITY ENGINEERING project than a functionally simpler MEDICAL DEVICE (e.g. lancing device, nebulizer or sphygmomanometer). However, a simpler MEDICAL DEVICE might pose greater RISKS associated with USABILITY and call for much more USABILITY ENGINEERING work to control the RISKS. The probability of occurrence of encountering a HAZARD, which is one component of RISK, can be very difficult to estimate, especially for a novel MEDICAL DEVICE for which no POST-PRODUCTION data are available. Therefore, the SEVERITY of the potential HARM associated with the use of a MEDICAL DEVICE, prior to RISK CONTROL, should be the principal consideration when tailoring a USABILITY ENGINEERING project.

Another tailoring consideration is when the development effort modifies an existing USER INTERFACE, which suggests a smaller-scale USABILITY ENGINEERING effort focused on the changed elements of the USER INTERFACE and their effects on the use of the MEDICAL DEVICE. The unchanged elements of the USER INTERFACE might not need additional USABILITY ENGINEERING effort. If the modifications do not affect the USER INTERFACE and the USE SPECIFICATION is unchanged, no additional USABILITY ENGINEERING effort can be needed. Another tailoring situation might arise when modifications are made to an existing USER INTERFACE for which USABILITY ENGINEERING RECORDS according to a previous USABILITY standard (i.e. IEC 62366 or references [11] and [12]) are available.

Accordingly, a MEDICAL DEVICE-specific USABILITY ENGINEERING project might describe activities spanning weeks, months, or even years. Initial USER research efforts and subsequent USABILITY TEST efforts might be limited (e.g. involve less than 10 participants) or more extensive (e.g. involve 50 or many more people). The resulting USER INTERFACE design might have many hardware and software elements, or just a few, and USERS might rely primarily on a comprehensive ACCOMPANYING DOCUMENTATION, a simpler instruction sheet or intuition alone.

USABILITY ENGINEERING activities that can be tailored include the following.

- a) Background USER research – the extent of USER research needed to develop an appropriate and comprehensive set of USER needs. For example, it might or might not be necessary to conduct USER research in all of the intended markets (e.g. multiple countries).
- b) USER INTERFACE design – the number of USER INTERFACE design iterations necessary to converge on an optimal solution. In some cases, a development team might settle on a single design after a few design iterations. In other cases, the nature of the MEDICAL DEVICE in development might warrant many more design iterations to progress effectively from multiple concepts to a small number of preliminary designs to a single refined design and, finally, to a final design.

EXAMPLE 1 For less complex products (e.g. a bedpan), the development team might settle on the final design after few iterations. For more complex products (e.g. a dialysis machine), the development progresses from multiple concepts of each module of the MEDICAL DEVICE through an iterative PROCESS of many cycles to get to the final design of the MEDICAL DEVICE.

- c) FORMATIVE EVALUATION – the quantity and complexity of FORMATIVE EVALUATIONS performed in advance of the SUMMATIVE EVALUATION and the quantity of participants included in those tests.

The need to assess multiple design options and resolve persisting USER interaction problems might lead a development team to conduct several FORMATIVE EVALUATIONS of varying focus and formality.

EXAMPLE 2 A MANUFACTURER established a project plan calling for at least two FORMATIVE EVALUATIONS prior to the SUMMATIVE EVALUATION during a development PROCESS.

EXAMPLE 3 A MANUFACTURER decided not to perform any FORMATIVE EVALUATION because the USER INTERFACE had already undergone SUMMATIVE EVALUATION, and the only change was to add a new (but very similar) intended USER GROUP.

NOTE Good USABILITY ENGINEERING practice suggests conducting at least one FORMATIVE EVALUATION ahead of a SUMMATIVE EVALUATION.

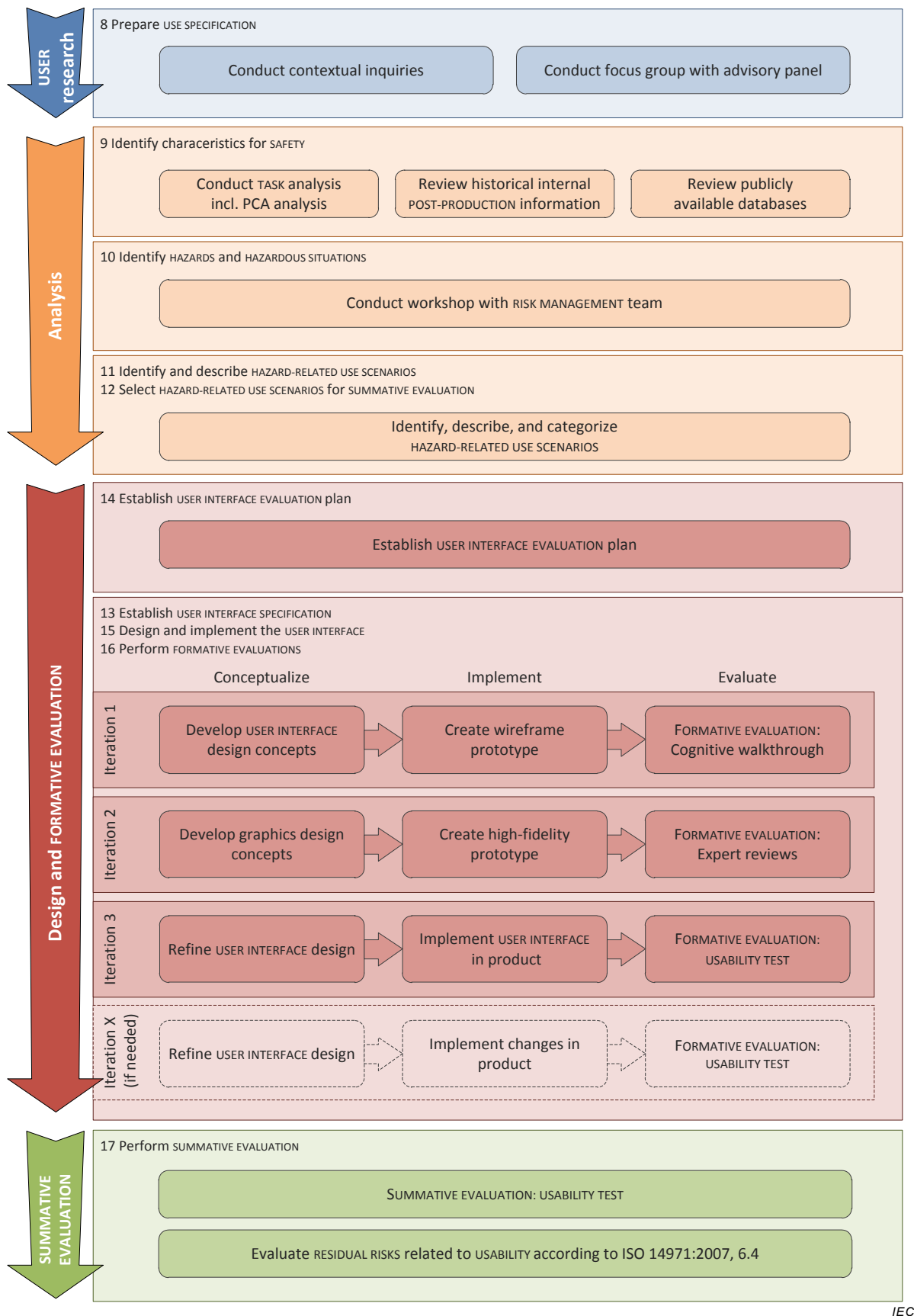
- d) SUMMATIVE EVALUATION – the quantity and complexity of SUMMATIVE EVALUATIONS performed and the quantity of participants included in those tests. In some cases, a single USABILITY TEST with a single USER GROUP could serve to assess all the HAZARD-RELATED USE SCENARIOS relevant for all the intended USERS. In other cases, multiple USABILITY TEST sessions might be required to assess all the HAZARD-RELATED USE SCENARIOS, or different sets of HAZARD-RELATED USE SCENARIOS could be assessed in sessions held with each of the USER GROUPS that has distinct responsibilities relative to the MEDICAL DEVICE (e.g. installation, clinical use or maintenance). If the results of the SUMMATIVE EVALUATION indicate that elements of the USER INTERFACE require modification to reduce the RISKS to acceptable levels, additional SUMMATIVE EVALUATIONS could be performed to assess only those USER interactions and portions of the USER INTERFACE affected by the modifications.

Good USABILITY ENGINEERING practice considers the RISK and complexity of USER INTERFACE for determining how many SUMMATIVE EVALUATIONS (if any) should be performed. Additional information is found in Clause 12.

7 Overview of the USABILITY ENGINEERING PROCESS

USABILITY ENGINEERING PROCESS activities should be aligned with other development activities. Similar to other kinds of projects, such as those developed to ensure manufacturing quality or MEDICAL DEVICE reliability, USABILITY ENGINEERING PROCESS activities are normally described in a detailed plan. The plan can either be a separate plan or be integrated into the overall development plan. Additional information is found in 6.2.

Figure 1 illustrates an example of a USABILITY ENGINEERING project. The example describes a plan for the development of a graphical USER INTERFACE. It demonstrates how the different methods described in this technical report can be used to support the USER INTERFACE development. To help understand how the methods mentioned in this exemplary USABILITY ENGINEERING project relate to the subsequent Clauses of this report, the corresponding clause headings are designated in the respective phases. These corresponding Clauses 8 to 18 provide detailed guidance on the implementation of a USABILITY ENGINEERING project.



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NOTE An explanation of PCA analyses is found in Clause E.15.

Figure 1 – Example of a USABILITY ENGINEERING project for a graphical USER INTERFACE

The example project is laid out in four phases:

- a) USER research;
- b) analysis;
- c) design and FORMATIVE EVALUATION; and
- d) SUMMATIVE EVALUATION.

The implementation phase in this example is planned to have three iterations. However, the example also acknowledges that additional iterations might be necessary in case the FORMATIVE EVALUATION results from previous iterations are not satisfactory.

Detailed descriptions of the methods mentioned in the example can be found in Annex E. IEC 62366-1:2015, 4.1.1, permits the methods and techniques as well as the sequence of activities and phases to vary between individual USER INTERFACE development projects.

Actual USABILITY ENGINEERING projects, which are expected to vary widely in scale, can have different phases, a more or less stringent linear structure, involve more or less design iteration, and call for different prototyping approaches, while fulfilling the same basic goal – ensuring the comprehensive application of USABILITY ENGINEERING in the MEDICAL DEVICE design PROCESS.

8 Prepare the USE SPECIFICATION

8.1 Initiate USE SPECIFICATION

The MEDICAL DEVICE USE SPECIFICATION is the foundation for defining the USER INTERFACE SPECIFICATION. The elements of the USE SPECIFICATION are fundamental for specifying and designing a MEDICAL DEVICE and its USER INTERFACE. These elements aid in identifying the known and foreseeable HAZARDS and HAZARDOUS SITUATIONS related to the USER INTERFACE. Understanding these elements is necessary to develop an adequate USABILITY EVALUATION plan.

A USABILITY ENGINEERING research effort's logical starting point is to draft a preliminary USE SPECIFICATION. The purpose of the preliminary USE SPECIFICATION is to collect enough information necessary to help planning and conducting USER research activities (e.g. observations, interviews, surveys). At this early initial stage, the USE SPECIFICATION is often not yet based on knowledge gained through USER research, but it rather assembles the knowledge that is already available before any USABILITY activities are started. Rather than being a comprehensive and detailed RECORD, the preliminary USE SPECIFICATION is often very high-level. Sometimes it can be as high-level as a preliminary draft of the statement of INTENDED USE. It would for example contain the necessary information:

- a) to identify the USER GROUPS which are going to be approached for interviews;
- b) to identify the USE ENVIRONMENT which is going to be inspected; or
- c) to identify the medical indications which are needed to be further explored.

The USE SPECIFICATION is refined over time while more knowledge is gained through USER research. While the USER research phase progresses, the level of detail and accuracy of the USE SPECIFICATION increases. New USER GROUPS might be discovered during the USER research. If so, these USER GROUPS would be added to the USE SPECIFICATION and they can trigger new USER research activities.

8.2 Analyse the intended USERS, anticipated USER TASKS and intended USE ENVIRONMENTS

8.2.1 Intended USERS

An optimal USER INTERFACE is one that meets USERS' needs. USABILITY ENGINEERING-related USER research is essential to develop safe, usable, and satisfying MEDICAL DEVICES. Therefore, MANUFACTURERS should learn as much as practical about a MEDICAL DEVICE'S prospective USERS by applying research methods that complement a MANUFACTURER'S market research efforts. The information collected from applying these research methods is typically used to help refine the preliminary USE SPECIFICATION.

Recognizing that there are important differences between USABILITY ENGINEERING and market research focussing on a broader range of MEDICAL DEVICE development issues, MANUFACTURERS should also conduct USER research with a USABILITY ENGINEERING focus.

When USER research includes information that might be subject to data security or privacy rules or regulations these rules have to be considered and followed. An Ethics Committee review and informed consent could also be required. Annex F contains additional information.

USERS can include:

- a) laypersons (e.g. PATIENTS, lay caregivers or lay first responders);
- b) physicians;
- c) nurses;
- d) technicians (e.g. radiological, IVD laboratory, dialysis, reprocessing);
- e) therapists;
- f) pharmacists; and
- g) emergency response personnel (EMTs, paramedics, medics).

USERS who might not be considered the primary USERS can also include:

- a) assemblers;
- b) installers;
- c) trainers;
- d) transporters;
- e) biomedical/clinical engineers;
- f) maintenance personnel;
- g) repair personnel;
- h) recyclers (e.g. decommissioning or preparing for end-of-service life handling);
- i) sterile processing personnel; and
- j) administrative personnel.

After defining the intended USERS, the MANUFACTURER should document their common characteristics in the form of USER PROFILES.

A USER PROFILE typically describes the characteristics of a single distinct USER GROUP, such as nurses. A USER PROFILE could describe the following group member characteristics:

- a) occupation;
- b) demographics (e.g. age, education, socioeconomic status, ethnicity, cultural background);
- c) knowledge and skills (including education, experience level, language, literacy and health literacy);
- d) limitations, perhaps due to vision, hearing, cognitive, dexterity and mobility impairments;

- e) performance-shaping factors (e.g. learning style, preferences and tendencies); and
- f) work responsibilities (e.g. TASKS pertinent to the MEDICAL DEVICE in development).

A related concept to a USER PROFILE is called a persona. A persona describes a fictitious USER. It can cover the same general topics as a USER PROFILE, adjusted to describe an individual rather than a group of individuals. As such, it can describe an individual's idiosyncrasies when a USER PROFILE would not. Both USER PROFILES and personas can describe USERS who are expected to have a primary, secondary or supplemental roles with a MEDICAL DEVICE. Distinct USER GROUPS can be derived from either concept.

USER GROUPS can be defined if USERS share characteristics (mental, physical and demographic traits) likely to influence USABILITY. USER PROFILES are used to summarize characteristics of USER GROUPS. Examples include the following.

- a) Age: Sample categories include child (> 2 years to 12 years of age), adolescent (> 12 years to 21 years of age), adult (> 21 years of age). In some cases, it might be appropriate to establish one or more "senior" categories for people over a selected age threshold (e.g. 65, 70, 75, 80, 85).

NOTE There can be differing levels of decline in cognition, perception, etc., as people age.

- b) Occupation: Sample categories include physician, nurse, therapist, technician, PATIENT, installer, and maintainer.
- c) Prior experience using similar MEDICAL DEVICES: Sample categories include new USER (trainee), inexperienced USER (< 6 months), and experienced USER (> 6 months). Note that the experience thresholds vary depending on the type of MEDICAL DEVICE in use.
- d) Level of training: Sample categories are (1) trained to use the given MEDICAL DEVICE, and (2) not trained to use the given MEDICAL DEVICE.
- e) Education:
 - categories based on educational level;
 - general literacy or reading level; and
 - health literacy.

The MANUFACTURER might also segregate USERS based on special training, such as the advanced cardiac lifesaving training provided to critical care nurses or paramedics.

Additional or alternative sorting criteria include native (i.e. first) language, disability type, type of professional practice and USE ENVIRONMENT. Establishing a manageable number of distinct USER GROUPS calls for establishing primary USER and secondary USER differentiation factors.

There is no rule regarding the optimal length of USER PROFILES, but they usually range from a few paragraphs to a couple of pages in length. Annex G provides additional information on USER PROFILES.

The SUMMATIVE EVALUATIONS of MEDICAL DEVICE can include one or more distinct USER GROUPS. The need to separate the USER population into more specific, distinct USER GROUPS is situation dependent. For example, an insulin pen injector might have six distinct USER GROUPS: caregivers (e.g. parents of young children), adolescents, adults, seniors, diabetes educators (who teach PATIENTS to use insulin pens), and pharmacists (who dispense insulin pens and need to recognize one type from another). Secondary differentiation characteristics might be disease-related impairments, such as low visual acuity, hearing loss, mild cognitive impairment, and poor manual dexterity (due to arthritis or fingertip neuropathies). This USER population profile suggests that each distinct USER GROUP should include individuals comprising a good cross section of the secondary characteristics common to the people within that group. For example, a group of older individuals might include males and females, some of whom have particular impairments. Similarly, healthcare professionals can need to be separated into more specific, distinct USER GROUPS.

8.2.2 Anticipated USER TASKS

At the early stage of MEDICAL DEVICE development before there is a design per se, it can help to define anticipated USER TASKS. A TASK list can be developed by examining comparable and predecessor MEDICAL DEVICES. A list can also be extrapolated from functional requirements and various types of creative exercise. The goal is to develop a general sense for how USERS might interact with the MEDICAL DEVICE. Subsequent analyses can serve to refine the TASK list. E.19 and 9.2 provide additional information on TASK ANALYSIS.

8.2.3 Intended USE ENVIRONMENT

The MANUFACTURER should analyse the intended USE ENVIRONMENTS. A majority of MEDICAL DEVICES are used in hospitals, clinics, physician's offices, and PATIENT'S homes. However, it is important to consider alternative use locations (e.g. inside an ambulance, outdoor locations such as a campground), particularly when developing portable MEDICAL DEVICES. Annex H provides additional information regarding USE ENVIRONMENTS.

For example, some environments (e.g. critical care settings) are busy workplaces that might be filled with noisy equipment and people holding loud conversations, while other work environments (e.g. a treatment room in a physician's office) might have a low level of activity and be relatively quiet. Additional environmental conditions to consider include lighting, vibration, temperature, humidity, precipitation, other equipment, and architectural features (e.g. door widths and heights). For example, an air ambulance might require USERS to operate a portable ventilator in a dimly lit and cramped workspace in which there is considerable noise and vibration.

USE ENVIRONMENT descriptions should describe:

- a) physical environment (e.g. gloves, eye protection, heavy clothing);
- b) lighting;
- c) sound (ambient and intermittent);
- d) personnel;
- e) professional and social interactions, responsibilities and local or national variations of work organisation;
- f) additional equipment (other items and equipment present in the room besides the focus of the USABILITY project);
- g) furnishings (chairs, cabinets, etc. that are also in the environment and can result in limited spacing or potential obstacles);
- h) climate (e.g. temperature, humidity); and
- i) distractions (e.g. telephone calls, calls for help).

Meeting with prospective MEDICAL DEVICE USERS during the MEDICAL DEVICE development PROCESS presents opportunities to learn about those USERS but also about the USE ENVIRONMENT and how it might affect USERS' interactions with the MEDICAL DEVICE.

8.3 Finalize the USE SPECIFICATION

The USE SPECIFICATION should be developed based on the results gained through USER research activities. The analysis activities can be performed iteratively and in any convenient order; care should however be taken to address the interdependencies of the elements. For example, adding or removing a USER PROFILE also can influence the relevant TASKS and USE ENVIRONMENTS. IEC 62366-1:2015 requires the USE SPECIFICATION to contain at least the following:

- a) intended medical indication;

EXAMPLE 1 Conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

- b) intended PATIENT population;