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Edition 1.0 2016-04

TECHNICAL REPORT

colour inside

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

IEC TR 62366-2:2016-04(en)

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INTERNATIONAL
ELECTROTECHNICAL
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MEDICAL DEVICES –

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

FOREWORD

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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- withdrawn,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 13485:2003[2], 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.

a) *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.*

b) *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.*

c) *Improved sales because customers perceive the MANUFACTURER'S MEDICAL DEVICE(S) as more "USER friendly" than other MANUFACTURERS' MEDICAL DEVICE offerings.*

d) *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.

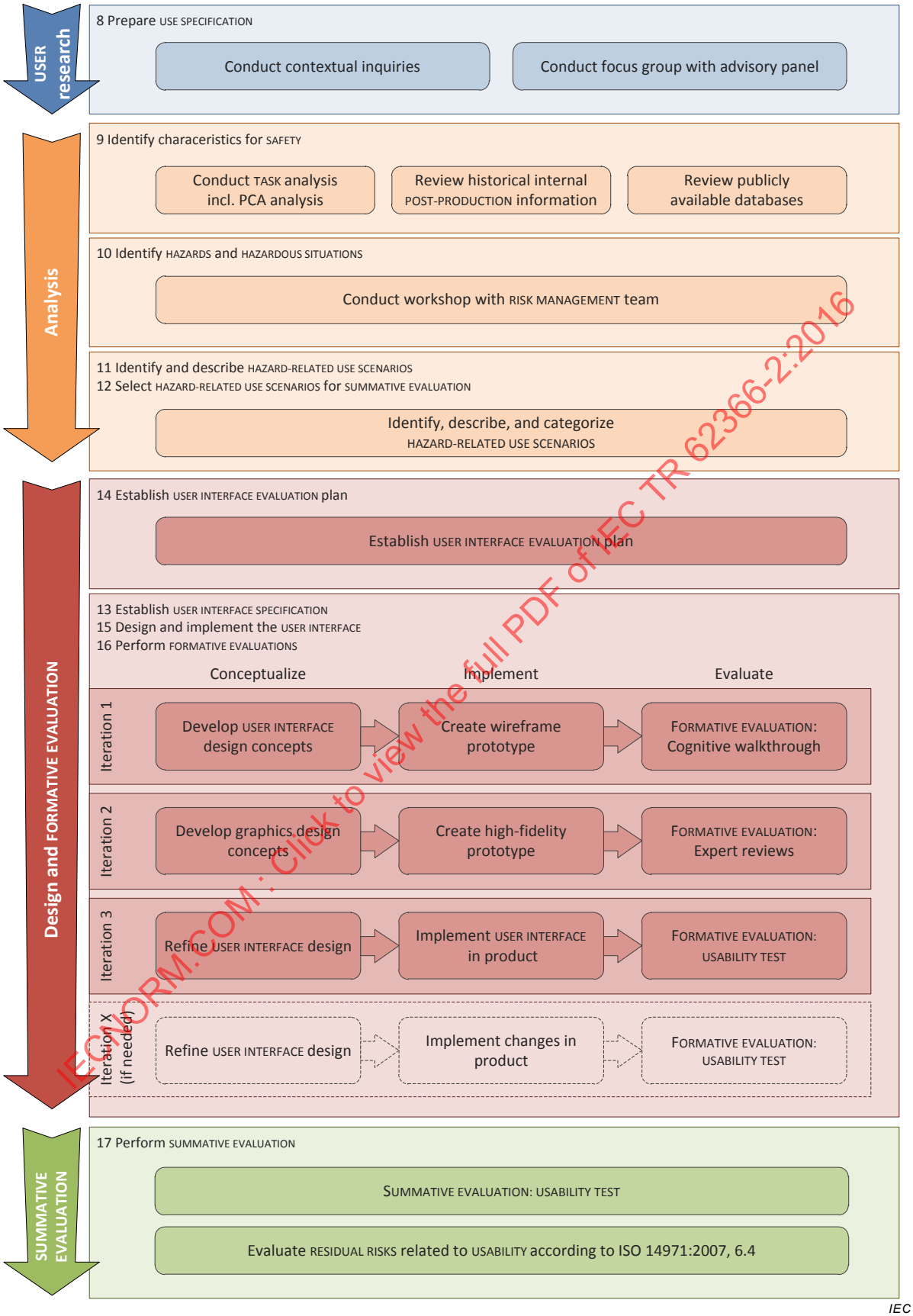
d) SUMMATIVE EVALUATION – the quantity and complexity of SUMMATIVE EVALUATIONS performed and the quantity of participants included in those tests. In some cases, a single USABILITY TEST with a single USER GROUP could serve to assess all the HAZARD-RELATED USE SCENARIOS relevant for all the intended USERS. 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.



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;

EXAMPLE 2 Age group, weight range, health, or condition.

c) intended part of the body or type of tissue applied to or interacted with;

EXAMPLE 3 Finger, sublingual, subcutaneous or interarterial.

d) intended USER PROFILES;

EXAMPLE 4 Nurse, doctor, geriatric lay USER, service personnel or cleaning technician.

e) intended USE ENVIRONMENT; and

EXAMPLE 5 Environment including hygienic requirements, frequency of use, location or mobility

f) operating principle.

NOTE 1 The rationale to 5.1 of IEC 62366-1:2015 contains additional information.

The following additional information can be helpful to support subsequent USABILITY ENGINEERING activities:

a) anticipated TASKS of USERS in the operation of the MEDICAL DEVICE; and

b) the set of USER needs derived from the anticipated TASKS.

Much or all of the USE SPECIFICATION is likely to be input to design and development. As the USER INTERFACE development PROCESS proceeds, the USE SPECIFICATION should be reviewed and updated as needed.

The USE SPECIFICATION is used as one input for the USER INTERFACE SPECIFICATION.

NOTE 2 The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the 'statement of INTENDED USE'.

8.4 Recommended methods for developing the USE SPECIFICATION

8.4.1 General

Subclauses 8.4.2 to 8.4.6 describe the USABILITY ENGINEERING methods that are available to enhance and finalize the USE SPECIFICATION. Additional material on USER research methods can be found in reference [13].

8.4.2 Contextual inquiry and observation

Contextual inquiries are a common and effective way to learn about prospective or actual USERS, the USER'S TASKS, and the USE ENVIRONMENT. A contextual inquiry is an interview technique, which is conducted in the USER'S actual workplace. The researcher observes USERS, while they are performing their TASKS and discusses with them what they do and why.

The method is typically used in the early stages of the development PROCESS (often within the research phase) and helps to gain a thorough understanding about the USER'S work practice, TASKS, tools, and the context of use, related to the MEDICAL DEVICE that is planned to be developed.

Clause E.5 contains additional considerations on using contextual inquires and observations.

8.4.3 Interview and survey techniques

In contrast to contextual inquiries, interviews and surveys can be conducted at any place and are not necessarily bound to the USER'S workplace. They help to gain insight into the USER'S knowledge, perceptions or opinions. Interviews can be used as a stand-alone method or to supplement other methods (e.g. contextual inquiries or USABILITY TESTS) by following up on the observations made during the prior session.

Since interviews can be conducted at any place or even over a phone line they are often less expensive compared to contextual inquires and can target a larger group of respondents, but often the resulting data is also less rich.

Interviews can be conducted in a one-on-one manner or as group interviews. A very large group of USERS or stakeholders can be approached by conducting surveys. When surveys are conducted in written form, the resulting data is often less rich than the data gathered through interviews.

Clauses E.9, E.13 and E.18 contain additional considerations on using interview and survey techniques.

8.4.4 Expert reviews

While preparing the use specification, expert reviews can be a rapid means to identify the strengths and weaknesses (i.e. opportunities for improvement) of a comparable USER INTERFACE. Such reviews can take various forms ranging in formality from an expert examining a MEDICAL DEVICE and citing its strength and weaknesses in a brief memorandum to engaging several experts to review independently the MEDICAL DEVICE, identify potential improvements, prioritize the improvements, and then report their consensus findings. The latter approach is often termed a heuristic analysis (see Clause E.11).

Expert review can be conducted at various stages of MEDICAL DEVICE development, focusing on initial design concepts, preliminary designs, and near-final designs.

8.4.5 Advisory panel reviews

In some cases – particularly when conducting a long-term and critical development project – a MANUFACTURER can choose to convene an advisory panel. An advisory panel typically includes 6 to 12 people who have diverse perspectives on the MEDICAL DEVICE in development. During an advisory panel review, the panel members discuss design considerations with the development team and can provide advice on design options. Through continual interactions with the development team along the development PROCESS the advisory panel members are exposed to various development stages of the MEDICAL DEVICE and have the opportunity to gain an understanding for design limitations and trade-offs. This can have advantages and disadvantages for optimizing the MEDICAL DEVICE'S USABILITY.

Clause E.2 contains additional considerations on using advisory panel reviews.

8.4.6 USABILITY TESTS

For the MANUFACTURER it can be valuable to perform USABILITY TESTS on comparable MEDICAL DEVICES that are available on the market. The FORMATIVE EVALUATION USABILITY TEST method (Clause 16) can be used. The USABILITY TESTS can identify the strengths and weaknesses of comparable MEDICAL DEVICES and can provide an understanding of the mental model USERS have of the use of the comparable MEDICAL DEVICES.

9 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

9.1 General

Subclause 5.2 of IEC 62366-1:2015 requires that the MANUFACTURER identify those characteristics of the USER INTERFACE that could affect SAFETY. Consideration of these characteristics is an essential step, together with the USE SPECIFICATION, in identifying potential USE ERRORS. Identification of potential USE ERRORS should be done iteratively and can be updated in the course of creating the USER INTERFACE.

Possible ways of identifying USER INTERFACE characteristics related to SAFETY and potential USE ERRORS are techniques described in this clause. Factors that should be considered are USER INTERFACE design features that can contribute to USE ERROR.

9.2 TASK ANALYSIS

TASK ANALYSIS is a set of systematic methods that produce detailed descriptions of the sequential and simultaneous manual and intellectual activities of personnel who are operating, maintaining, or controlling devices or systems. Similar to FUNCTION ANALYSIS, there are many ways to perform a TASK ANALYSIS, and so less experienced analysts are advised to review the literature on the topic. Typically, the MANUFACTURER with a relatively high-level TASK (e.g. prepare the DEVICE to deliver a treatment) and then defines the sub-TASKS involved. A single sub-TASK might involve a sequence of steps such as acquiring information from a display (e.g. reading a parameter value on a display), processing the information (e.g. performing a mental calculation), making a decision, formulating an action plan, taking action (e.g. pressing a button), and acquiring feedback (e.g. hearing an electronically generated click and observing a display change). To define the scope for a TASK ANALYSIS, the intention of the USER for each TASK should be in focus. To further use TASK ANALYSIS for assessment of potential USE ERROR, conditions of use as defined in the USE SPECIFICATION and in RISK MANAGEMENT PROCESS play an important role. Clause E.19 contains additional considerations on using TASK ANALYSIS as well as references [14] and [15].

TASK ANALYSES are particularly challenging when designing a new MEDICAL DEVICE for which there is no similar model, but are made possible by making educated assumptions. TASK ANALYSIS results can take a narrative, tabular, or flowchart form, the latter two being most common. Sometimes, the TASK ANALYSIS also defines the flow of USER perceptions (e.g. hearing an ALARM SIGNAL, reading text on a screen, feeling a button click), cognitive steps (e.g. recalling information, performing mental calculations, applying rules to reach a decision), and actions (e.g. selecting a menu option, pressing a button, adding fluid to a reservoir). Such an analysis is referred to as a PCA (perception, cognition, action) analysis. Clause E.15 contains additional considerations on using PCA analysis.

MANUFACTURERS should pay close attention to TASKS that have the potential to exceed USERS' capabilities and hinder the given MEDICAL DEVICE'S USABILITY or cause an unacceptable RISK. TASKS that appear to be vulnerable to performance problems (e.g. USE ERRORS) indicate the need to reassess whether or not MEDICAL DEVICE functions have been appropriately assigned to the USER. For example, concerns about USERS vigilantly checking for MEDICAL DEVICE operation problems might suggest the need for automation (i.e. designing the MEDICAL DEVICE to continually monitor for problems and present an ALARM SIGNAL if one occurs. The potential for such USE ERRORS should be documented during the TASK ANALYSIS and considered during the subsequent RISK ANALYSIS.

TASK ANALYSIS, much like RISK ANALYSIS, should be updated as the MANUFACTURER develops new insights about USER-MEDICAL DEVICE interactions and a design evolves.

9.3 FUNCTION ANALYSIS

The purpose of a FUNCTION ANALYSIS is to identify those functions a MEDICAL DEVICE should perform automatically or semi-automatically, functions that should be assigned only to USERS and functions that should be shared between the MEDICAL DEVICE and the USER. Functions allocated to USERS are called TASKS. Table 2 explains the relative strengths of machines and humans. Reference [16] describes levels of automation that could be shared between machines and humans or allocated only to one or the other.

In contrast, a purpose of a TASK ANALYSIS is to identify the sequence of TASKS USERS complete to perform their assigned functions, as well as what information and control capabilities they need to complete those TASKS. A TASK ANALYSIS can be used to examine how the USER performs the assigned functions.

A FUNCTION ANALYSIS should produce a complete list of important functions, including PRIMARY OPERATING FUNCTIONS listed in applicable product standards, to be performed by the USER along with an estimate of the frequency that those functions are performed.

Literature describes many ways to perform a FUNCTION ANALYSIS. Typically, the MANUFACTURER begins by identifying a MEDICAL DEVICE'S key functions, particularly those affecting clinical performance, and then assigns the functions to the MEDICAL DEVICE or the USER based on the known competencies of each.

EXAMPLE *MEDICAL DEVICES are particularly good at continually monitoring parameter values and alerting USERS to values that exceed an established limit. USERS are good at recognizing unique conditions (i.e. anomalies) and responding in an appropriate manner.*

Table 2 – Human versus machine capabilities

Humans do not excel in	Machines excel in
Force: Limited strength.	Great forces possible.
Endurance: Fatigues easily.	Does not fatigue easily.
Speed: Significant time needed for decision-making and movement.	High speed.
Accuracy: Unreliable, makes constant and variable errors.	Great accuracy attainable.
Computing: Slow and error-prone.	Large short-term working memory.
Decision-making: Best strategy not always adapted; emotions interfere.	For narrow applications, superior long-term memory.
Information processing: Basically a single-channel processor that is easily overloaded; performance greatly dependent on motivation.	Complex problems can be handled deductively.
Limited short-term working memory; long-term memory, although large, has unreliable and slow access.	Excellent for repetitive work; unaffected by emotions and motivational needs.
	Can perform simultaneous operations easily.
Humans excel in	**Machines do not excel in**
Visual acuity and range very good.	
Visual information processing system extremely logical and flexible.	Need to be monitored.
Range of detection extremely wide with good sensitivity for audition and vision.	
Perception: Ability to make order out of complex situations; detection possible under high noise.	Decision-making limited.
Can reason inductively; can follow up intuition.	Inductive reasoning not possible.
Very flexible; can easily change rules of operation with changes in situation.	All activities need to be planned and pre-programmed thoroughly.
Attention is easily shifted; only essential information can be selected for processing.	
When highly motivated, can perform under adverse conditions with parts out of order (injuries).	Needs to get careful maintenance. Might not operate at all, if some parts are broken.

The key in the USER INTERFACE design PROCESS is to assign appropriate functions to the given MEDICAL DEVICE and its intended USERS based on the known strengths and weaknesses of each (e.g. speed, accuracy, reliability), especially when the functions are RISK-critical. Poor assignments have led to numerous problems such as the following.

– *USERS depending too heavily on a MEDICAL DEVICE'S automatic functions and losing perspective on the MEDICAL DEVICE'S operational state and PATIENT'S condition; what USABILITY SPECIALISTS call "loss of situational awareness".*

– *A MEDICAL DEVICE functioning at such high speed that the USER cannot perform his or her function in a timely manner.*

– *A USER failing to detect a small but critical change in a large data set.*

9.4 Identify and analyse known problems

As a preamble to MEDICAL DEVICE design, USABILITY ENGINEERING practitioners can study the strengths and weaknesses of comparable MEDICAL DEVICES. This benchmarking exercise can help them formulate a vision of an improved MEDICAL DEVICE and identifying USER needs to fulfil that vision.

One way to assess the USER INTERFACE qualities of comparable MEDICAL DEVICES is to perform a USER INTERFACE review (i.e. critique or expert review) that calls for the reviewer, who is usually a USABILITY SPECIALIST, to cite good versus poor features. As discussed in Clause E.11, a relatively formal review method is called a heuristic analysis.

Another way to assess comparable USER INTERFACES is to conduct a benchmark USABILITY TEST, or perhaps a less formal product assessment exercise, during which representative USERS interact with multiple, existing MEDICAL DEVICES and share their opinions about the MEDICAL DEVICES' acceptable RISK, EFFECTIVENESS, USABILITY, and appeal. In addition to collecting opinions about the existing MEDICAL DEVICES, the MANUFACTURER can also quantitatively measure TASK performance (i.e. benchmark an existing MEDICAL DEVICE'S performance) as a basis for identifying use-related problems that ideally should be avoided by the new MEDICAL DEVICE.

Field experience and incident reports can provide further valuable information about problems that have occurred in the past with comparable MEDICAL DEVICES and previous models of the MEDICAL DEVICE in development.

Information can be drawn from:

a) interviews with MEDICAL DEVICE USERS;

b) interviews with trainers, who have insights into problems that new USERS encounter;

c) a review of pertinent literature;

d) analysing complaint files; and

e) performing online searches e.g. using the resources listed in Annex B.

Available information sometimes indicates a USER interaction problem associated with a particular USE SCENARIO and the underlying cause (e.g. a USER INTERFACE design shortcoming). These findings should be an input to the RISK MANAGEMENT PROCESS and the USER INTERFACE design PROCESS to avoid a USER INTERFACE design that has the same vulnerability. The results of the identification and analysis of known problems serves as input for the identification of the known or foreseeable HAZARDS and HAZARDOUS SITUATIONS.

More information on how to generate data on known problems from POST-PRODUCTION experience is found in Clause 18.

10 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

The identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS is part of the RISK MANAGEMENT PROCESS as described in ISO 14971. The USABILITY ENGINEERING PROCESS contributes to the identification of USE ERRORS as potential causes for HAZARDOUS SITUATIONS. The goal is to identify and describe the potential effect that a USE ERROR might have and how

it can contribute to HARM. A HAZARDOUS SITUATION occurs if a person (often the PATIENT) is exposed to this HAZARD.

According to ISO 14971, the MANUFACTURER is required to analyse all HAZARDOUS SITUATIONS (including those deriving from or triggered by a USE ERROR). ISO 14971 further explains that the probability of a HAZARDOUS SITUATION occurring and probability of HARM occurring are not the same. In order for HARM to occur, an additional sequence of events that can include USER TASKS also needs to occur.

11 Identify and describe HAZARD-RELATED USE SCENARIOS

11.1 Define USE SCENARIOS

In order to identify and describe HAZARD-RELATED USE SCENARIOS, it is helpful to establish a general understanding of what USE SCENARIOS are, how they are written and how they relate to RISK MANAGEMENT.

A USE SCENARIO is a description of a USER from a specific USER PROFILE interacting with the MEDICAL DEVICE to achieve a certain result in a specific USE ENVIRONMENT. USE SCENARIOS can be written in many different forms, ranging from story-like narratives to simple lists of USER TASKS or steps in a TASK. The purpose of a USE SCENARIO is to illustrate how the functions of a MEDICAL DEVICE are used by USERS while they are trying to achieve a result. USE SCENARIOS can cover a wide range of situations, including positive situations, which illustrate the intended CORRECT USE of the MEDICAL DEVICE, and negative situations, which illustrate how a USE ERROR could lead to an undesired result. When a USE SCENARIO leads to a HAZARDOUS SITUATION, the USE SCENARIO is called a HAZARD-RELATED USE SCENARIO.

For example, in the case of night-time use of a dialysis equipment, the USE SCENARIO takes into consideration that the USER might be asleep when the equipment emits an ALARM SIGNAL and then awake in a disoriented or "fuzzy headed" state. By comparison, the TASK in this case would be to respond to a given ALARM SIGNAL, the large context (i.e. USE SCENARIO) notwithstanding.

USE SCENARIOS are typically written in plain language from the USER'S point of view and try to avoid technical details. USE SCENARIOS can be understood by people who do not have any technical background. They are therefore suitable for use during participatory design activities. The activity of writing USE SCENARIOS as a team effort can help to create a shared understanding for everyone in the team about what a USER might want to do and how the USER might do it. USE SCENARIOS, which could involve USE ERRORS, can foster a common understanding of what might go wrong during MEDICAL DEVICE use.

USE SCENARIOS serve as vital input to a number of activities in the USABILITY ENGINEERING PROCESS. They provide the necessary insights to write appropriate USER INTERFACE REQUIREMENTS for the MEDICAL DEVICE'S USER INTERFACE. They help the USER INTERFACE design as they display sequences of interactions USERS want to perform with the USER INTERFACE. USE SCENARIOS are also valuable input for engineers during MEDICAL DEVICE development, including ACCOMPANYING DOCUMENTATION and training strategies creation.

Finally, they also provide valuable input to USABILITY EVALUATIONS, such as USABILITY TESTS. Since USE SCENARIOS provide detailed information of realistic DEVICE use, they can be easily translated into test scenarios for USABILITY TESTS. The TEST SCENARIOS used for SUMMATIVE EVALUATIONS are required to address a selected number of HAZARD-RELATED USE SCENARIOS. Refer to Clause 12 for how to select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION.

11.2 USE SCENARIOS as they relate to RISK MANAGEMENT

While writing USE SCENARIOS is a common practice in the USABILITY ENGINEERING community, the term HAZARD-RELATED USE SCENARIO is introduced by IEC 62366-1. A USE SCENARIO

describes how a USER interacts with the MEDICAL DEVICE in order to achieve a certain result. A USE SCENARIO becomes HAZARD-RELATED USE SCENARIO by including a description of circumstances that could lead to a HAZARDOUS SITUATION and can include the USE ERRORS leading to the HAZARDOUS SITUATION. IEC 62366-1:2015 Figure A.2 and Figure A.3 illustrate the difference between a USE SCENARIO and a HAZARD-RELATED USE SCENARIO.

The preliminary analysis of HAZARD-RELATED USE SCENARIOS, which examines HAZARDS and HAZARDOUS SITUATIONS resulting from USE ERRORS, should begin early in the design PROCESS. This approach enables preliminary steps of the RISK MANAGEMENT PROCESS to influence subsequent design activities, which are likely to include implementing changes to reduce or prevent USE ERRORS.

For example, one step of the RISK MANAGEMENT PROCESS for a glucose monitor might be to identify the HAZARDOUS SITUATION that could result from a USER misreading the display. The result of the USER'S incorrectly sensing or interpreting the display value can lead to delayed treatment, mistreatment or no treatment of the PATIENT'S blood sugar level, which are known HAZARDS. This should lead the MANUFACTURER to improve the legibility of the readout to reduce or prevent the USE ERROR.

Additional information is contained in Clause 12 regarding the selection of HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION.

11.3 Identify HAZARD-RELATED USE SCENARIOS

Based on the identified HAZARDS and HAZARDOUS SITUATIONS, the MANUFACTURER identifies preliminary HAZARD-RELATED USE SCENARIOS that can occur at various stages of USER interaction with the MEDICAL DEVICE and that could lead to a HAZARDOUS SITUATION or HARM. The preliminary HAZARD-RELATED USE SCENARIOS can include the anticipated sequence of events, the TASKS involved, the type of USER who performs these TASKS and the conditions under and environments in which these TASKS are performed. Also included should be a description of the USER INTERFACE for which these preliminary HAZARD-RELATED USE SCENARIOS have been identified.

11.4 Methods to define and analyse HAZARD-RELATED USE SCENARIOS

There are several methods to define and analyse HAZARD-RELATED USE SCENARIOS. Each method has the potential to identify related HAZARDOUS SITUATIONS that might not otherwise be identified by another method. Therefore, despite the likelihood of producing overlapping findings, the MANUFACTURER should employ multiple HAZARD-RELATED USE SCENARIO identification methods for thoroughness sake, such as:

a) brainstorm USE SCENARIOS (see E.3);
b) contextual inquiry (see E.5);
c) day-in-the-life analysis (see E.6);
d) FMEA and FTA (see E.8);
e) focus groups (see E.9);
f) FUNCTION ANALYSIS (see E.10);
g) literature reviews;
h) observation (see E.12);
i) one-on-one interviews (see E.13); and
j) TASK ANALYSIS (see E.19).

12 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION

12.1 General

In order to plan the SUMMATIVE EVALUATION, the MANUFACTURER needs to determine which HAZARD-RELATED USE SCENARIOS to be included. The purpose of this determination is to ensure that the SUMMATIVE EVALUATION includes all USE SCENARIOS needed to demonstrate SAFETY related to the USER INTERFACE of the MEDICAL DEVICE. IEC 62366-1 provides three options to the MANUFACTURER.

a) Option 1: include all HAZARD-RELATED USE SCENARIOS.

b) Option 2: include a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR.

c) Option 3: include a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY and additional circumstances specific to the MEDICAL DEVICE and the MANUFACTURER.

These options are provided to account for the fact that the number of HAZARD-RELATED USE SCENARIOS can vary depending on the complexity of the MEDICAL DEVICE. While a relatively simple MEDICAL DEVICE might have only a small number of HAZARD-RELATED USE SCENARIOS, a more complex MEDICAL DEVICE might have a considerably higher number of HAZARD-RELATED USE SCENARIOS.

For simpler MEDICAL DEVICES, it might be possible to include in the SUMMATIVE EVALUATION all the HAZARD-RELATED USE SCENARIOS or even all the USE SCENARIOS, regardless of the SEVERITY of potential HARM that could be caused by USE ERROR (option 1). For more complicated MEDICAL DEVICES, the MANUFACTURER might limit the HAZARD-RELATED USE SCENARIOS included in the SUMMATIVE EVALUATION to those with a SEVERITY for which medical intervention would be needed (option 2). Sometimes, the MANUFACTURER might also want to consider other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER when selecting the most critical HAZARD-RELATED USE-SCENARIOS (option 3).

The identification of USER INTERFACE elements related to HAZARDS that is conducted early in the design PROCESS is likely to have the possibility to overlook some important HAZARD-RELATED USE SCENARIOS. This is even true when the analysis is performed well and it considers available POST-PRODUCTION data. For this reason, it is important to update the identification based on the results of USABILITY TESTS of the MEDICAL DEVICE in development, which are likely to identify previously unidentified HAZARD-RELATED USE SCENARIOS. Unfortunately, USABILITY TESTS that include only the previously identified HAZARD-RELATED USE SCENARIOS might not include TASKS involving unacceptable RISKS that were not previously recognized. A HAZARD-RELATED USE SCENARIO considered to have an acceptable RISK, perhaps resulting from a low likelihood of occurrence estimate, might in fact be unacceptable. For this reason, it is recommended to conduct a series of FORMATIVE EVALUATIONS (e.g. USABILITY TESTS) to examine the most complete set of USER-MEDICAL DEVICE interactions practicable in order to identify all HAZARD-RELATED USE SCENARIOS.

It should be noted that when selecting HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION either based on SEVERITY or based on RISK, some “low RISK” MEDICAL DEVICES could seem to have no relevant HAZARD-RELATED USE SCENARIOS to be considered. Additional information regarding when a USABILITY TEST is not required for SUMMATIVE EVALUATION is found in 17.1.

The appropriate selection scheme used to select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION depends on circumstances specific to the MEDICAL DEVICE and is part of the MANUFACTURER’S obligations for due care and responsibility.

In all cases, it is important to understand that SUMMATIVE EVALUATION also should cover a demonstration that USERS are able to accomplish the intended purpose of the MEDICAL DEVICE as described in the USE SPECIFICATION.

12.2 Selection of the HAZARD-RELATED USE SCENARIOS based on SEVERITY

ISO 14971:2007 defines RISK as the combination of the probability of occurrence of HARM and the consequences (i.e. SEVERITY) of that HARM. However, probability of encountering a HAZARD can be very difficult to determine, especially for a novel MEDICAL DEVICE for which no POST-PRODUCTION data are available. For this reason, the selection of HAZARD-RELATED USE SCENARIOS included in SUMMATIVE EVALUATION should be based primarily on the SEVERITY of HARM that could be caused by USE ERROR. If during development the USER INTERFACE is modified to eliminate the HAZARD or HAZARDOUS SITUATION, then the HAZARD-RELATED USE SCENARIO no longer exists.

ISO 14971:2007 includes schemes for categorizing SEVERITY. Table 3 shows one example adapted from ISO 14971:2007.

Table 3 – Example of five qualitative SEVERITY levels (adapted from Table D.3 of ISO 14971:2007)

Common terms	Possible description
Negligible	Inconvenience or temporary discomfort
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Serious	Results in injury or impairment requiring professional medical intervention
Critical	Results in permanent impairment or life-threatening injury
Catastrophic	Results in PATIENT death

EXAMPLE Using the SEVERITY scheme shown in Table 3, a MANUFACTURER limits the HAZARD-RELATED USE SCENARIOS included in the SUMMATIVE EVALUATION to those with a SEVERITY of “Serious”, “Critical”, or “Catastrophic”.

SEVERITY estimates are obtained from the analysis of HAZARDOUS SITUATIONS done according to ISO 14971:2007 (4.3 and 4.4) and communicated to the IEC 62366-1 PROCESS (as arrow D in Figure A.4 of IEC 62366-1:2015). Other data can be identified both as part of the ISO 14971 decision making PROCESS and the IEC 62366-1 design PROCESS.

12.3 Selection of HAZARD-RELATED USE SCENARIOS based on other circumstances

IEC 62366-1 mentions the possibility of using other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER, if data are available and the scheme and the rationale are documented. For example, selection of the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION can be based on RISK levels (generated from the combination of the probability of occurrence of HARM and the SEVERITY of the consequences of that HARM) rather than on SEVERITY alone.

The ISO 14971 PROCESS can provide data on the EFFECTIVENESS of existing RISK CONTROL measures that can justify estimating probability that the RISK CONTROL measure prevents HARM.

For some HAZARDS, the effects of time can be taken into consideration. The example provided in IEC 62366-1 (taken from IEC 60601-1-8 [1]) explains that the RISK associated with an ALARM CONDITION is dependent on the amount of time that elapses between the ALARM CONDITION occurring and when the HARM occurs. Similarly, the RISK associated with a USE ERROR occurring can depend on the amount of time that elapses between the USE ERROR occurring and when the HARM occurs. This resembles the decreasing of probability of HARM by the amount of events or RISK CONTROL measure breakdowns needed before HARM occurs.

Probability estimates can also be derived from POST-PRODUCTION data on current or previous versions of the MEDICAL DEVICE. These data can be used to estimate both probability of USE ERROR and probability of resulting HARM, depending on the nature of data, its volume and dependability. Refer to Clause 19 for further guidance.

Probability estimates can also be derived from knowledge about factors affecting the probability of the occurrence of USE ERROR or of the probability of the occurrence of resulting HARM.

13 Establish USER INTERFACE SPECIFICATION

13.1 Development of the USER INTERFACE SPECIFICATION

The USER INTERFACE SPECIFICATION is a document consisting of USER INTERFACE REQUIREMENTS. The USER INTERFACE SPECIFICATION can physically consist of one or more documents.

USER INTERFACE REQUIREMENTS are a principal means to ensure that a USER INTERFACE design ascribes to good USABILITY ENGINEERING principles as well as meets specific needs identified during earlier USER research activities and preferences expressed by the intended USERS. USER INTERFACE REQUIREMENTS can also be drawn from USABILITY ENGINEERING resources. Reference [4] is a particularly rich source, because it contains extensive data, such as the size (anthropometry) and strength (biomechanics) of human beings at the extremes (e.g. fifth-percentile female and ninety-fifth-percentile male) and in between. Other sources include other USABILITY ENGINEERING standards, USABILITY ENGINEERING textbooks, and USER INTERFACE design style guides. Specific, quantitative USER INTERFACE REQUIREMENTS tend to be most helpful.

MANUFACTURERS might develop just a few or many USER INTERFACE REQUIREMENTS depending on the extent to which USERS interact with the given MEDICAL DEVICE. For example, they might develop many more USER INTERFACE REQUIREMENTS as a basis for designing a ventilator used in critical care as compared to an otoscope used in a physician's office to look into a PATIENT'S ear. Annex I contains examples of expressed needs and associated USER INTERFACE REQUIREMENTS.

A USER INTERFACE SPECIFICATION is based on several RECORDS described earlier, including:

a) the USE SPECIFICATION;

b) the known or foreseeable USE ERRORS associated with the MEDICAL DEVICE; and

c) the selected HAZARD-RELATED USE SCENARIOS.

MANUFACTURERS are well served to develop a library of USER INTERFACE REQUIREMENTS that can be drawn upon, as appropriate, during particular development efforts. The USER INTERFACE REQUIREMENTS should be updated as new information about USER'S needs and preferences becomes available, as well as when new RISKS are identified.

The USER INTERFACE SPECIFICATION should be developed ahead of the USER INTERFACE, but then evolve with the ensuing design. Otherwise, it quickly becomes outdated.

13.2 ACCOMPANYING DOCUMENTATION and training

Because the instructions for use and other ACCOMPANYING DOCUMENTATION are considered part of the MEDICAL DEVICE, USER INTERFACE REQUIREMENTS should be developed for instructions for use and other ACCOMPANYING DOCUMENTATION as part of the USER INTERFACE SPECIFICATION. It is important that attention be paid to instructions for use and other ACCOMPANYING DOCUMENTATION requirements early in development, as such requirements can serve as drivers during USER INTERFACE design, for example, when decisions are made to embed instructions for use or help within the MEDICAL DEVICE itself, as opposed to incorporating it only in printed manuals or on-line information.

IEC 62366-1:2015, 5.6, requires the USER INTERFACE SPECIFICATION to include whether ACCOMPANYING DOCUMENTATION or training are required for the safe use of the MEDICAL DEVICE. MANUFACTURERS should determine the instructions for use and other ACCOMPANYING DOCUMENTATION content that is needed for each group of USERS identified for the MEDICAL

DEVICE, taking into consideration the environment(s) of use of the MEDICAL DEVICE. MANUFACTURERS should also determine the delivery mechanisms (i.e. media) that are most effective to meet the particular needs identified.

MANUFACTURERS should develop USER INTERFACE REQUIREMENTS for information for SAFETY material considering all elements of the USE SPECIFICATION. Considerations include the amount of information needed (e.g. book, single sheet of paper, cards, several of these options), media (e.g. video, audio, electronic text, printed text), packaging and storing of the information for SAFETY (for larger MEDICAL DEVICES this could be, for instance, a shelf incorporated into the MEDICAL DEVICE design), attributes of the media chosen (e.g. mobility, screen size, paper weight, font size), as well as target reading level for the information for SAFETY (i.e. based on general and health literacy of the intended USERS).

MANUFACTURERS should include the activities related to the evaluation of the information for SAFETY in the USER INTERFACE EVALUATION plan.

USER INTERFACE REQUIREMENTS should be developed for training and materials necessary for training, when needed, as part of the USER INTERFACE SPECIFICATION. It is important that attention be paid to training requirements early in development, as such requirements can serve as drivers during USER INTERFACE design, for example, when decisions are made to embed training and instruction within the MEDICAL DEVICE itself, as opposed to incorporating it only in class room training or on-line interactive materials.

MANUFACTURERS should determine the training content that is needed for each group of USERS identified for the MEDICAL DEVICE, taking into consideration the environment(s) of use of the MEDICAL DEVICE. MANUFACTURERS should also determine the delivery mechanisms (i.e. media) that are most effective to meet the particular training needs identified. Training requirements should be expressed in terms of USER performance, not simply in terms of the content contained in the training materials. Therefore, requirements for training are best expressed in language such as "Following instruction about X, the USER shall be able to demonstrate PROCEDURE X unassisted and without errors." Reference [17] provides detailed guidance on the development of training materials, including the requirements development phase of the PROCESS.

In some cases, training requirements can be relatively simple; in others (e.g. home dialysis equipment; surgical robots), much more extensive requirements are needed. As is the case with other aspects of the USER INTERFACE, training requirements evolve over the course of design and should be updated as the design progresses.

14 Establish USER INTERFACE EVALUATION plan

14.1 Specify how the USER INTERFACE design will be explored and evaluated

MANUFACTURERS should establish a plan for how they intend to develop, explore and evaluate the USER INTERFACE design (FORMATIVE EVALUATION) as well as confirm the final USER INTERFACE design (SUMMATIVE EVALUATION). These steps are described later in this technical report in USER INTERFACE EVALUATION and planning.

The USER INTERFACE EVALUATION plan helps to synchronize USER INTERFACE EVALUATION activities with other development activities. The plan should include information about the timing of the USER INTERFACE EVALUATIONS and their relationships with the overall development project. For example, it is important that a prototype is available prior to USABILITY TEST execution. It is therefore vital to synchronize the prototype development activities with USER INTERFACE EVALUATION activities. It is often advisable to integrate both sets of activities into one project plan.

USER INTERFACE EVALUATION can vary in scope and complexity. Additional information about methods is found in Table E.1. While simple USER INTERFACE EVALUATION methods conducted

as FORMATIVE EVALUATIONS such as expert reviews, can be conducted quite cost effectively, more extensive USER INTERFACE EVALUATIONS can require greater resources (i.e. time, money, staff, material, premises, test participants, etc.). The USER INTERFACE EVALUATION plan helps to make MANUFACTURERS aware of resource needs and to allocate necessary resources well enough in advance.

USER INTERFACE confirmation involves conducting a SUMMATIVE EVALUATION—ideally as a follow-up to a series of FORMATIVE EVALUATIONS used to explore the design—to ensure that the USABILITY is acceptable (i.e. that use-related RISKS have either been eliminated or reduced to an acceptable level). Experience among USABILITY SPECIALISTS suggests that SUMMATIVE EVALUATIONS usually produce findings that warrant design changes when a MEDICAL DEVICE has not undergone one or more FORMATIVE EVALUATIONS.

The USER INTERFACE EVALUATION plan can be a standalone document or integrated into the USABILITY ENGINEERING project plan.

14.2 FORMATIVE EVALUATION planning

FORMATIVE EVALUATION is an effective way to “filter-out" USER INTERFACE design shortcomings that could induce potentially harmful USE ERRORS. The appropriate number of FORMATIVE EVALUATIONS depends on many factors including the MEDICAL DEVICE’S complexity, the potential for USE ERRORS that could be harmful, and the development schedule and budget. To be conservative, MANUFACTURERS can plan to conduct at least 2 to 3 FORMATIVE EVALUATIONS. Notably, it can be more productive to conduct many (i.e. more than 2 to 3), small-scale FORMATIVE EVALUATIONS rather than fewer, large-scale FORMATIVE EVALUATIONS.

Although FORMATIVE EVALUATIONS are generally small-scale and informal compared to a SUMMATIVE EVALUATION, they tend to grow larger and more formal as a design evolves from an early concept to a production-equivalent prototype. Many USABILITY ENGINEERING practitioners choose to have the last FORMATIVE EVALUATION match the SUMMATIVE EVALUATION methodology (i.e. an early version of a SUMMATIVE EVALUATION plan). The methodology calls for test participants to work independently (i.e. without assistance and without the kind of test moderator-test participant dialogue that clarifies USER preferences during many FORMATIVE EVALUATIONS) and to perform what analyses have determined to be the TASKS associated with the highest RISKS. Accordingly, the last FORMATIVE EVALUATION can be called a pre-SUMMATIVE EVALUATION. It is the time to discover any remaining USER INTERFACE shortcomings that would need to be addressed so that no new findings are discovered during the SUMMATIVE EVALUATION. *It is also a good time to assess the given MEDICAL DEVICE'S performance against established USABILITY GOALS (related to commercialization issues and not SAFETY issues) if the MANUFACTURER has not already done so in preceding FORMATIVE EVALUATIONS.*

14.3 SUMMATIVE EVALUATION planning

SUMMATIVE EVALUATION is used to confirm the SAFETY of the USER INTERFACE. SUMMATIVE EVALUATION is frequently a part of the design validation activities in the development of a MEDICAL DEVICE.

MANUFACTURERS conduct a SUMMATIVE EVALUATION to make what is typically their final evaluation of a MEDICAL DEVICE so to determine whether or not the USER INTERFACE has acceptable use-related RISK and EFFECTIVENESS.

The SUMMATIVE EVALUATION, viewed from an acceptable RISK perspective rather than business standpoint, seeks to confirm that the USER INTERFACE enables effective use and protects against potentially harmful USE ERRORS. Such testing can only take place on the final or production-equivalent USER INTERFACE. A successful test generates the evidence necessary to demonstrate that the USER INTERFACE is acceptable (i.e. RISK CONTROLS are effective and that overall RISK has been reduced to an acceptable level). Some AHJ will review SUMMATIVE EVALUATION results in detail.

The SUMMATIVE EVALUATION is the final check that a MEDICAL DEVICE can be used safely on humans, that is unless there is a need for further USABILITY EVALUATION in a clinical study to produce adequate evidence of a MEDICAL DEVICE'S acceptable use-related RISK. Therefore, such testing can be required before a MANUFACTURER is permitted to use the MEDICAL DEVICE in a clinical study or, later on, market the MEDICAL DEVICE.

If a MANUFACTURER has developed an updated version of a pre-existing MEDICAL DEVICE, the SUMMATIVE EVALUATION can focus on confirming the adequacy of the USER INTERFACE'S new portion and/or modifications, presuming that the balance of the USER INTERFACE was previously evaluated by means of a SUMMATIVE EVALUATION. This is sometimes referred to as a 'bridging study'. However, if the previous MEDICAL DEVICE version did not undergo a SUMMATIVE EVALUATION, the MANUFACTURER should conduct a comprehensive SUMMATIVE EVALUATION to confirm the adequacy of the entire USER INTERFACE. Older portions of the USER INTERFACE are not "grandfathered" as far as USABILITY TESTING is concerned, regardless of whether the original MEDICAL DEVICE'S has an exemplary use history. It is considered USABILITY OF UNKNOWN PROVENANCE and is evaluated according to Annex C of IEC 62366-1:2015.

14.4 USABILITY TEST planning

FORMATIVE and SUMMATIVE EVALUATIONS often involve USABILITY TESTS. These USABILITY TESTS should be planned to provide the data needed to evaluate the USER INTERFACE.

The plan for each USABILITY TEST should be documented in the form of a protocol that explains the goals of and the methods to be used in the USABILITY TEST. As required in IEC 623661:2015, 5.7.1, such protocols include descriptions of the following:

a) participants in the USABILITY TEST, to be representative of each intended USER GROUP;

b) test environment and other use conditions, to be representative of the intended USE ENVIRONMENTS;

c) the ACCOMPANYING DOCUMENTATION to be provided during the USABILITY TEST, if any; and

d) the training to be provided during the USABILITY TEST, if any, and the minimum elapsed time between the training and the beginning of the USABILITY TEST.

USABILITY TEST protocols can be structured in a variety of ways. Well-structured USABILITY TEST protocols serve the important purpose of describing the details of how a USABILITY TEST is conducted, thereby ensuring its quality.

14.5 Example USABILITY TEST protocol and report

Table 4 contains an example USABILITY TEST protocol outline. It is just one example and is not intended to be the model for every type of USABILITY TEST. The example outline is for a SUMMATIVE EVALUATION, which is why it is so comprehensive. FORMATIVE EVALUATIONS could have a shorter protocol with a simpler outline that leaves out some of the details needed for SUMMATIVE EVALUATION.

Table 4 – Example outline of a USABILITY TEST protocol

Item nb	Protocol element
1	Introduction
2	Test purpose
3	Test method overview
4	Test Items (MEDICAL DEVICE and ACCESSORIES being evaluated including configuration)
5	Test materials (supporting materials needed for the test)
6	Test environment
7	Test participants (USER GROUPS, number and selection criteria)
8	Test personnel (staff roles and responsibilities)
9	List of TASKS based on selected HAZARD-RELATED USE SCENARIOS
10	Data collection techniques and methods (both objective and subjective)
11	Data analysis methods
12	USABILITY test script (moderator guide)
13	Test protocol templates (data collection forms necessary for conducting the USABILITY TEST)
14	Participant training protocol, if required

When USABILITY TESTS include 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. [18] [19]

USABILITY TEST reports can be structured in a variety of ways. Well-structured test reports are the OBJECTIVE EVIDENCE generated from the test results and do not necessarily describe how the USER INTERFACE problems identified during the test might be solved.

Table 5 contains an example of one of many possible outlines for a USABILITY TEST report. The example report is suited for SUMMATIVE EVALUATION, and therefore is very comprehensive. FORMATIVE EVALUATIONS can have shorter test reports.

Table 5 – Example outline of a USABILITY TEST report

Item nb	Report element
1	Executive summary
2	Introduction
3	Summary of test protocol
4	Deviations from test protocol
5	Detailed test results (USE ERRORS identified and TASK performance data)
6	Analysis of results (USE ERRORS, CLOSE CALLS, areas for improvement)
7	Conclusions (results of USABILITY TEST)

15 Design and implement the USER INTERFACE and training

15.1 General

The USER INTERFACE design should meet the established USER INTERFACE REQUIREMENTS, thereby ensuring a solution that is well suited to the intended USERS, rather than designing the USER INTERFACE primarily based on technological capabilities and constraints. The USER

INTERFACE design PROCESS is iterative. Figure 2 presents an example USER INTERFACE design progression. Eventually, the USER INTERFACE design leads to USER INTERFACE REQUIREMENTS implicitly meeting the USER needs and ensuring that the USER INTERFACE permits the USER to perform acceptably all HAZARD-BASED USE SCENARIOS.

The best way to prevent USE ERROR and the possible resulting HARM is to eliminate a HAZARD or HAZARDOUS SITUATION altogether. Another way is to produce a design with built-in protections against USE ERRORS, such as physical guards over a critical control, an interlock preventing accidental control actions, requiring USERS to confirm critical actions. These types of RISK CONTROL measures should be carefully used and thoroughly analysed to make sure that when implemented no new HAZARDOUS SITUATIONS are added such as delaying operation.

When USE ERRORS occur despite other RISK CONTROLS, ALARM SIGNALS can be an effective way to draw the USERS' attention and give them a chance to correct the problem before HARM can occur. However, MANUFACTURERS should avoid making warnings, instructions, and training the primary means of preventing USE ERROR.

Consistent with the goal to ensure MEDICAL DEVICE SAFETY and USABILITY, MANUFACTURERS should focus on producing a high-quality USER INTERFACE, drawing on data about human capabilities and preferences that can be found in USABILITY ENGINEERING standards (e.g. references [4], [20] [21] and [22]) and textbooks. MANUFACTURERS should also establish PROCEDURES to ensure that engineering and manufacturing decisions take full account of USER INTERFACE requirements.

The MANUFACTURER should keep USER INTERFACE design from becoming a bureaucratic exercise focused more on producing documents to fill the USABILITY ENGINEERING FILE than producing design excellence. USER INTERFACE design warrants a structured approach, such as that described in this technical report. However, designing safe, *usable, and satisfying* MEDICAL DEVICES calls for the application of design expertise.

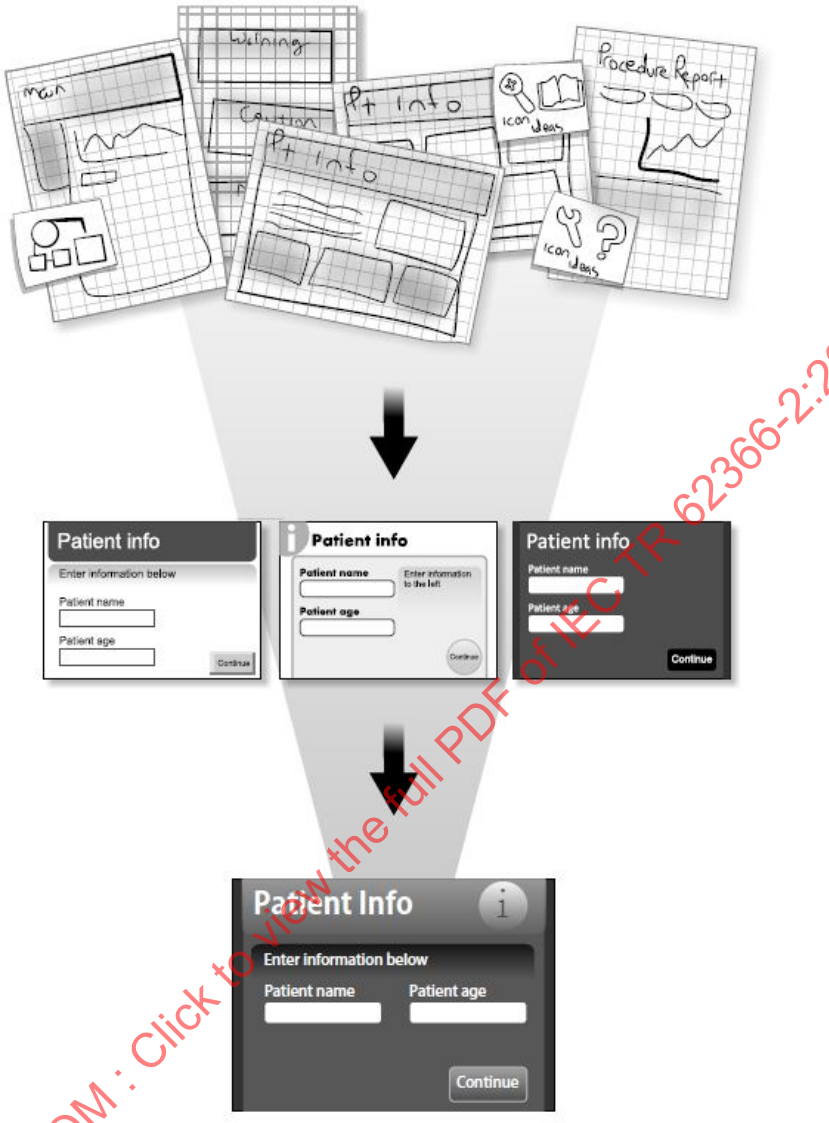


Figure 2 – Progression of a USER INTERFACE design from multiple concepts to a few concepts to a preferred concept

MANUFACTURERS should design the ACCOMPANYING DOCUMENTATION and, in particular, the information for use, in an iterative PROCESS based on iterative USABILITY EVALUATION of both information for SAFETY and the MEDICAL DEVICE itself. Requirements can evolve or change during the course of the USABILITY ENGINEERING PROCESS.

15.2 Develop conceptual model(s)

A MEDICAL DEVICE'S conceptual model describes the general organization of the USER INTERFACE. CONCEPTUAL MODEL DIAGRAMS can be used to document these concepts. Conceptual models can be expressed as a USER INTERFACE structure (e.g. screen flow) diagram or more simply as elements (e.g. circles) with labels such as set-up, treatment, maintenance and history. Conceptual models need not distinguish between hardware and software USER INTERFACE elements.

MANUFACTURERS should be mindful that a coherent conceptual model is the foundation of a good USER INTERFACE design and that USERS can help choose an appropriate one by judging them in more abstract forms, such as Figure 2, or simple instantiations, such as alternative

control panel layouts or a limited set of computer screens. USER feedback on these instantiations can be collected through FORMATIVE EVALUATION.

Subclause 15.3 discusses software and 15.4 hardware USER INTERFACE development efforts, noting that a given MEDICAL DEVICE might have one or the other or both. However, they should be designed in parallel and the MANUFACTURER should ensure that the hardware-software integration is adequately synchronized to avoid compromising the MEDICAL DEVICE'S ultimate SAFETY and USABILITY.

15.3 Design software USER INTERFACES (if applicable)

15.3.1 General

There are many ways to approach software USER INTERFACE design. The best approach might depend on whether the MANUFACTURER is modifying existing software USER INTERFACE or creating a new one. This subclause describes an approach to the latter that can then be tailored, as needed, to apply to the PROCESS of modifying an existing software USER INTERFACE. [21]

15.3.2 Review USER INTERFACE REQUIREMENTS and constraints

As a precursor to developing the software USER INTERFACE, MANUFACTURERS should review the USER INTERFACE REQUIREMENTS, which should be rooted in an understanding of USER needs, MEDICAL DEVICE USE SCENARIOS, and the possible USE ENVIRONMENTS. Sample software-related USER INTERFACE REQUIREMENTS for a hypothetical MEDICAL DEVICE (and not necessarily other MEDICAL DEVICES) include the following.

a) Every screen shall have a meaningful title to help USERS recognize their location in the software hierarchy and their progress in the TASK at hand.

b) When an on-going function requires the USER to wait more than 3 s, the associated screen shall provide a progress indication.

c) Every screen shall have at least one dynamic element so that USERS can detect if a screen has failed (i.e. stopped updating).

d) Text shall be at least 14 point or larger to ensure legibility among individuals with less than normal visual acuity (e.g. USERS who are farsighted and might not to be wearing their reading glasses).

The review of the USER INTERFACE REQUIREMENTS sets the stage for a USER-centred software USER INTERFACE design effort, with all participants cognizant of the USABILITY ENGINEERING-related design expectations.

15.3.3 Develop software USER INTERFACE structure(s)

Building on the conceptual model, MANUFACTURERS should explore multiple software USER INTERFACE structures and high-level navigation schemes. This structure can be depicted as screen flows that depict the related USER navigation methods. The design focus would be on the general purpose of various screens types rather than the functional detail of any particular screen.

The following principles from reference [10] should be considered while designing software USER INTERFACES:

a) suitability for the TASK;

b) self-descriptiveness;

c) conformity with USER expectations;

d) suitability for learning;

e) controllability;

f) error tolerance; and

g) suitability for individualization.

15.3.4 Design wireframes

Software screens and a navigational structure should be designed to match the USER INTERFACE structure. One option for initial design of the screens is to create “stripped-down” screens, or what are often called wireframes, that present content via generic forms to represent screen items. These wireframes can be used directly as a vehicle to facilitate discussion of the content of the screens, and they can be built into working prototypes to demonstrate the proposed navigational structure. With such an approach, visual design of the screens can proceed in parallel by choosing a few representative screens and creating multiple visual design solutions to represent alternative approaches to the “look and feel” of the screens. The advantage of this design PROCESS is that it avoids investing the time and effort necessary for creating alternative versions of the whole array of necessary screens.

Thus, waiting to implement a preferred visual style until later in the design PROCESS is a common practice among many software USER INTERFACE designers. However, there is a RISK associated with use of wire frames: prospective USERS and design reviewers within the development organization might have difficulty interpreting wireframes, struggling to react strictly to screen content instead of visual appeal (i.e. aesthetics). Also, subtleties of the visual designs might significantly affect USER interactions, something that would not be identified by testing solely with wireframes. Therefore, it is common to strike a balance, initially creating simple screens reflecting a reasonably realistic but still flexible visual style. This approach enables designers to use visual design elements, such as colour and a more nuanced arrangement of onscreen features, to communicate important information that could not be represented in a monochrome wireframe.

As discussed in Clause 16, MANUFACTURERS should seek USER feedback on the USER INTERFACE structure and sample screens of increasing FIDELITY. One approach is to conduct a FORMATIVE EVALUATION using a cognitive walkthrough – having representative USERS interpret what they see on static screens (e.g. printouts, digital images, slide presentations) and describe what actions they would take. Another approach, made possible by the availability of a wide variety of “rapid-prototyping” tools, is to create one or more early computer-based working prototypes that incorporate screens and the navigational structure into a “usable” SIMULATION for FORMATIVE EVALUATION. The advantage of the latter is that it reduces the chances of USABILITY problems failing to become apparent because of the unrealistic nature of static screens.

15.3.5 Design screen templates

After the appropriate screen content has been well defined (albeit subject to future refinement), the MANUFACTURER develops screen templates that provide a consistent framework for specific screen development. Screen templates help to ensure design consistency. They define the standardized position and appearance of on-screen elements, such as titles, headings, data labels, USER prompts, illustrations, visual ALARM SIGNALS, and data input and output fields. It is typical to produce 5 to 10 templates to facilitate the development of screens such as those that welcome USERS during machine start-up, present PATIENT/treatment status information, enable parameter adjustments, enable a review of past parameter values and ALARM CONDITIONS, and indicate equipment power-down.

15.4 Design hardware USER INTERFACES (if applicable)

15.4.1 General

Hardware USER INTERFACE design can be approached in a top-down or bottom-up manner, the former being preferred. The top-down approach starts by envisioning how USERS interact with hardware in a broad sense, considering the USER INTERFACE’S general organization, and then shifting focus to the detailed hardware elements. The bottom-up approach selects components to address functional needs and then organizes them in a logical manner. The latter approach can work, but might produce a USER INTERFACE that does not function very well

as an integrated whole, particularly for complex USER INTERFACES. It can be useful for the design to be developed using both approaches in parallel. [4] [22]

15.4.2 Review USER INTERFACE REQUIREMENTS and constraints

Before developing the hardware USER INTERFACE, the MANUFACTURER should review the USER INTERFACE REQUIREMENTS, which should be rooted in an understanding of USER needs, MEDICAL DEVICE USE SCENARIOS and possible USE ENVIRONMENTS. Examples of hardware-related USER INTERFACE REQUIREMENTS include the following:

a) mechanisms shall not have exposed pinch points;

b) connectors and connector ports shall preclude misconnections;

EXAMPLE Fluid connectors that comply with ISO 80369-1. [23]

c) guards or interlocks shall protect the MEDICAL DEVICE from control inputs by unauthorized USERS;

d) guards or interlocks shall protect the PATIENT or USER from unintended outputs of the MEDICAL DEVICE.

15.4.3 Develop concept sketches

A hardware USER INTERFACE can take many forms that reflect different design trade-offs, such as the trade-off between providing a dedicated, surface-level control to actuate a function versus complicating a control panel and possibly intimidating new USERS. For this reason, it can be beneficial to generate multiple hardware design sketches or 3-D prototypes and obtain USER feedback on them (e.g. through FORMATIVE EVALUATION). This feedback can complement the results of engineering analyses performed to determine which concept is most promising and warrants further development. Figure 3 illustrates the progression of concepts from multiple concepts to a few concepts to a preferred concept.

15.5 Design materials necessary for training and training

15.5.1 General

If training is necessary for the safe use of the MEDICAL DEVICE, the MANUFACTURER should determine the scope of the training, the scope of the training materials and the USER GROUPS who need to be trained. In some cases, the extent of training can be simple. In other cases (e.g. home dialysis equipment or surgical robots) more extensive training can be needed.

It is important that attention is paid to training requirements early in the development of a MEDICAL DEVICE. Training requirements can serve as drivers during USER INTERFACE design, for example, when decisions are made to embed training materials within the MEDICAL DEVICE itself.

As is the case with other aspects of the USER INTERFACE, training requirements evolve over the course of design and should be updated as the design progresses.

15.5.2 Training materials

Work on a MEDICAL DEVICE'S training materials, such as embedded, computer-based help, quick reference cards, and the ACCOMPANYING DOCUMENTATION, which includes the instructions for use and technical description, should start as soon as practical during the design PROCESS. Work on training materials cannot be fully developed until the software and hardware USER INTERFACE designs have matured sufficiently. However, early conceptual work on the training materials can clarify design issues such as the:

a) extent of an embedded help system, which could provide basic or detailed guidance;

b) need for on-MEDICAL DEVICE warnings; and

c) need for a storage space for the quick reference cards and ACCOMPANYING DOCUMENTATION within or attached to the MEDICAL DEVICE itself.

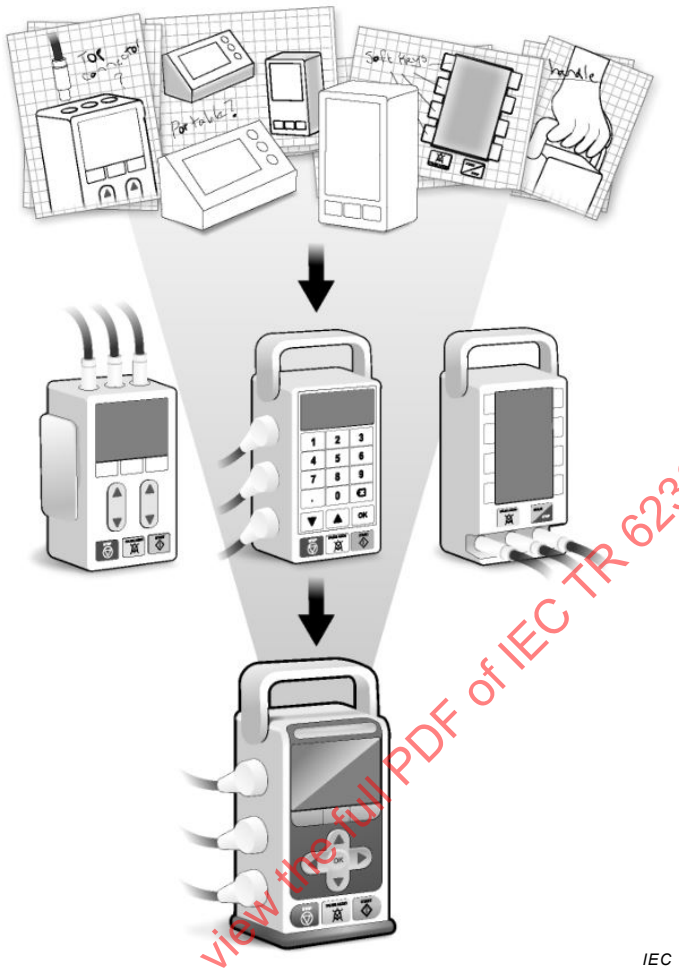


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Figure 3 – Progression of concepts from multiple concepts to a few concepts to a preferred concept

The training requirements contained in the USER INTERFACE SPECIFICATION guide the development of training materials. As the design PROCESS proceeds, those developing training materials should make use of the results of the TASK and USE ERROR analyses in order to accomplish the detailed design of the training materials.

As with other parts of the USER INTERFACE, it is important that training materials be tested in FORMATIVE EVALUATION during the detailed design phase and before SUMMATIVE EVALUATION of the MEDICAL DEVICE. This is especially important when training materials are RISK CONTROL measures for the MEDICAL DEVICE, which means that they become information for SAFETY. When developing such 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 and what should be done or avoided to prevent HARM.

In developing the information, the MANUFACTURER should consider:

a) the level of priority appropriate to classify an action: danger, warning, caution or notice;
b) the level or detail of information needed;
c) the location for the information for SAFETY;
d) the wording or pictures to be used to ensure clarity and understandability;
e) the immediate recipients (e.g. USERS, service personnel, installers, PATIENTS);
f) the appropriate media for providing the information, (e.g. instructions for use, labels); and

g) the regulatory requirements, etc.

Selection of training media is one of the major decisions that should be made during the design of training materials. MANUFACTURERS have more choices than ever before in terms of training media, and different forms of media have their strengths and weaknesses in delivering information, depending on the type of USER, the use context of the MEDICAL DEVICE, and the particular information being conveyed during instruction. For example, it is very difficult to teach the PROCEDURE for using an auto-injector to a novice lay USER based on printed instructions alone. To convey adequately the sound and physical actions involved in delivering an injection, video and audio have many advantages over print. Reference [17] provides substantial guidance on the selection of media.

Detailed design guidance is available for the design of specific types of training materials. References [4], [17] and [24] provide detailed USABILITY ENGINEERING design guidance on print and electronic USER manuals as well as quick-start guides and reminder cards. The guidance includes information on the organization of the material as well as the wording and formatting of instructions. Additional detailed design guidance can be found in reference [25]. Finally, USABILITY ENGINEERING guidance on the design of multi-media training and instruction is available in references [17], [26], [27] and [28].

15.5.3 Training

Although the MANUFACTURER might view training as something to be developed once a MEDICAL DEVICE development effort is near completion, it is useful to consider training early in the DEVELOPMENT PROCESS. For example, it is important to determine if all, some, or none of the intended USERS are intended to be trained prior to using the given MEDICAL DEVICE. This determination could have a strong influence on the degree to which the given MEDICAL DEVICE should be easily understandable to a first-time USER or require a predefined level of operational knowledge and skill. The determination of the need for training should be realistic, taking into consideration the MEDICAL DEVICE's USE SPECIFICATION.

The goal of any MEDICAL DEVICE training is to provide the USERS with sufficient knowledge and skill to be able to use it in a safe and effective way. Trainers strive to move new USERS along the "learning curve," including getting beyond any obstacle that trainees might face if they try to use an unfamiliar MEDICAL DEVICE based only on intuition or related experiences. However, the MANUFACTURER neither assume that trainees will immediately master a given MEDICAL DEVICE, nor that they will recall all of the important details at the time at which they need to use the MEDICAL DEVICE. While the time period between training and actual MEDICAL DEVICE use might be just a few hours in some cases, in other cases the gap could be a few months, during which trainees might forget or confuse portions of what they learned about using the MEDICAL DEVICE.

When defining an appropriate level of training, the MANUFACTURER clarify the following questions:

a) Who among the intended USERS (defined by group or sub-group) are intended to receive training?

b) When in the course of a USER introduction to the MEDICAL DEVICE formal training should occur?

c) How much training will be provided and how many sessions are needed?

d) The training media (e.g. documents, slideshows, videos)?

e) Who will provide the training (e.g. MANUFACTURER-employed nurse educator, salesperson)?

f) What topics training will cover to ensure that all necessary HAZARD-RELATED USE SCENARIOS are addressed?

g) What competency checks (if any) should be performed to confirm that the trainee is prepared to operate the MEDICAL DEVICE safely and effectively?

h) How much time might pass between training and actual MEDICAL DEVICE use (i.e. the period of time during which the learning from training could decay)?

i) Is there a need for recurrent training sessions?

The MANUFACTURER should document the assumptions and intentions listed above in a training plan that can serve as a foundation for writing USER INTERFACE REQUIREMENTS – particularly related to initial MEDICAL DEVICE use and analysis of HAZARD-RELATED USE SCENARIOS. The training plan can subsequently serve as a basis for developing the actual training curriculum. Also, the plan can guide decisions regarding what kind of training (if any) to give USABILITY TEST participants.

MANUFACTURERS should ensure through testing that the training materials, in addition to being effective, do not create additional HAZARDS or HAZARDOUS SITUATIONS to the PATIENT or USER.

15.6 Develop detailed designs

The next step in the MEDICAL DEVICE design PROCESS is to develop detailed and integrated software and hardware USER INTERFACE designs, as well as the training materials and training. These items can be simple or complex. These designs should evolve from preliminary concepts to a refined design by means of iterative development efforts and evaluation efforts (i.e. FORMATIVE EVALUATIONS). Annex J, Clause 13 and Clause 16 provide additional detail for these efforts. [29]

15.7 Verify the design of the USER INTERFACE

Design verification requires the MANUFACTURER to confirm that the MEDICAL DEVICE design conforms to each element of the previously established specifications. Design verification is a requirement of the product realization PROCESS requirements of a quality management system. [9] Since the USER INTERFACE is part of the MEDICAL DEVICE, these PROCESS requirements suggest that the MANUFACTURER verifies the USER INTERFACE against the USER INTERFACE SPECIFICATION. This verification is not part of the USABILITY ENGINEERING PROCESS requirements of IEC 62366-1:2015.

Design verification of the USER INTERFACE involves confirming that USER INTERFACE REQUIREMENTS—for example, overall MEDICAL DEVICE dimensions, display parameters such as font size or luminance, control parameters such a button resistance and computer-interface parameters such as response time—are met. It is restricted to those verifiable parameters that do not require USABILITY TESTS to determine that they are met, which, in practice, means that they do not entail behavioural specifications, such as the time required to learn a PROCEDURE.

Design verification of the USER INTERFACE is typically integrated into design verification activities of the product realization PROCESS. This should be done, when possible, to support a consistent and proper level of effort.

Verification of the USER INTERFACE also can be a part of the verification of EFFECTIVENESS *or implementation of RISK CONTROL measures as required by ISO 14971 (e.g. verification of a maximum limit of force, implemented to reduce a use-related RISK). Note that verification of* EFFECTIVENESS *of a RISK CONTROL measure can also involve USABILITY TESTS, which is outside the scope of the design verification.*

16 Perform FORMATIVE EVALUATIONS

16.1 Conduct multiple FORMATIVE EVALUATIONS

A FORMATIVE EVALUATION seeks to evaluate USER INTERFACE designs during their development (i.e. during their “formation”) rather than when they are considered complete. A FORMATIVE EVALUATION can be a simple activity, noting that the goal is to learn about design solutions’ strengths and opportunities for improvement. FORMATIVE EVALUATIONS usually takes the form of USABILITY TESTS (see 16.2.4), cognitive walkthroughs (see 16.2.3), expert reviews (see E.7), and other evaluation techniques. FORMATIVE EVALUATION can support MEDICAL DEVICE concept

development, refinement and inform various types of design decisions. FORMATIVE EVALUATION is most beneficial when conducted iteratively throughout the development of the MEDICAL DEVICE.

FORMATIVE EVALUATIONS are completed prior to the SUMMATIVE EVALUATION and should be initiated early in the MEDICAL DEVICE research and development cycle. At an early stage of USER INTERFACE design, FORMATIVE EVALUATION serves to identify design strengths and opportunities for improvement. At the latter stage of USER INTERFACE design, FORMATIVE EVALUATION enables the MANUFACTURER to determine whether the MEDICAL DEVICE meets SAFETY, *USABILITY, USER and business needs* and ultimately supports successful SUMMATIVE EVALUATION of the MEDICAL DEVICE.

It is expected that FORMATIVE EVALUATIONS occur iteratively so that the MANUFACTURER can identify USER interaction problems and implement effective solutions prior to the SUMMATIVE EVALUATION.

FORMATIVE EVALUATIONS usually include TASKS or HAZARD-RELATED USE SCENARIOS in which USE ERRORS could occur and help to determine if the RISK CONTROLS designed into the MEDICAL DEVICE have been successful.

FORMATIVE EVALUATION data can include:

a) customer preference survey responses;

b) focus group participants' inputs (i.e. comments);

c) USABILITY TEST participants' comments, made while performing hands-on TASKS as well as upon reflection on their TASK performance afterward; and

d) USABILITY TEST participants' ratings and rankings pertaining to hands-on TASKS, specific MEDICAL DEVICE characteristics and the MEDICAL DEVICE in general.

The MANUFACTURER is required by IEC 62366-1:2015 to establish and maintain a USER INTERFACE EVALUATION plan to guide FORMATIVE EVALUATIONS. Results should be documented in a test report supported by raw and processed data sets (e.g. a spread sheet containing TASK performance data) and, if collected, video recordings and photographs of the test sessions. Design shortcomings identified during testing should be formally tracked to ensure they are resolved and re-evaluated as needed.

It is a best practice for MANUFACTURERS to conduct enough FORMATIVE EVALUATIONS prior to a SUMMATIVE EVALUATION to minimize the likelihood of discovering new problems. The goal is to conduct FORMATIVE EVALUATIONS at a time in the development PROCESS when they can have a greater level of influence on the USER INTERFACE design. Performing only the minimum possible amount of USABILITY ENGINEERING at the end of the development PROCESS, a time when designs are relatively inflexible and MANUFACTURERS are hesitant to change a USER INTERFACE, increases the likelihood that the SUMMATIVE EVALUATION will discover that the use-related RISKS have not been adequately controlled.

FORMATIVE EVALUATION also can focus on any aspect of USER interaction with a MEDICAL DEVICE that concerns a MANUFACTURER, including interactions influencing USER satisfaction and those that could affect a MEDICAL DEVICE'S commercial success.

16.2 Recommended methods for FORMATIVE EVALUATION

16.2.1 General

There are number of methods available to conduct FORMATIVE EVALUATIONS. The most commonly used methods are:

a) various types of reviews, such as
   - expert reviews (E.7),

- standards reviews (E.17), and
- heuristic analyses (16.2.2 and E.11);

b) cognitive walkthroughs (16.2.3 and E.4); and

c) USABILITY TESTS (16.2.4).

16.2.2 Conduct heuristic analysis

During design development, the MANUFACTURER intermittently assess (i.e. inspect or audit) the evolving USER INTERFACE design based on established design principles. The assessment (the aforementioned USER INTERFACE inspections) can be conducted in either a simple or elaborate manner, and be based on established USABILITY ENGINEERING principles and MEDICAL DEVICE-specific USER INTERFACE REQUIREMENTS. Such assessments are an effective way to detect design shortcomings at a stage when it is relatively easy and inexpensive to fix them as compared to fixing them when a design is presumably complete.

16.2.3 Conduct cognitive walkthrough

A cognitive walkthrough can be the first step taken to obtain USER feedback on a MEDICAL DEVICE'S USER INTERFACE. The technique calls for a MANUFACTURER to present its early design solution to a relatively small number of people, one at a time in sessions that might be brief or extended, noting that an hour-long session is not uncommon when only a lower-FIDELITY USER INTERFACE prototype (e.g. model) is available. The early design solution might take the form of a storyboard (e.g. a series of printed screens) or computer-based SIMULATION, perhaps complemented by a physical model. The technique depends on research participants, representing USERS, thinking through and verbalizing their thoughts, reactions and imagined actions based on static or marginally interactive representations of the early design solution. In place of touching a physical control, the participant would describe the control action and the test moderator would describe the MEDICAL DEVICE'S response, or perhaps swap one drawing for another one that depicts the MEDICAL DEVICE'S new state.

16.2.4 Conduct USABILITY TESTS

USABILITY TESTS involve observing USERS while they perform TASKS with the MEDICAL DEVICE.

USABILITY TESTS involve recruiting USERS of a specific USER GROUP and asking those USERS to complete a set of TASKS. The test moderator conducts the USABILITY TEST via a test script. The session can be recorded through audio and video to enable later review to confirm or supplement data collected during the test session.

USABILITY TESTS are usually conducted with representative USERS performing specific TASKS of interest or following TASK-based USE SCENARIOS that involve important MEDICAL DEVICE functions. USABILITY TESTS are normally conducted in simulated-use conditions that could affect the USERS' interactions with the MEDICAL DEVICE. For some USABILITY TESTS, USERS need to have specific domain, product or application-specific knowledge and experience. For example, when testing a diabetes management software app, it can be informative to use participants who have been using paper-based RECORDS to manage their diabetes for many years.

Choosing an appropriate sample size is a key consideration when planning FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS (i.e. USABILITY TESTS). USABILITY TESTS for FORMATIVE EVALUATIONS can be beneficial using a small sample (e.g. 5-8) of test participants representing the entire USER population. Many USABILITY SPECIALISTS recommend small sample sizes when conducting FORMATIVE EVALUATIONS because it is usually sufficient to uncover major USER INTERFACE design issues. Sample size is more thoroughly discussed in Annex A of AAMI HE-75:2009 [4] and reference [30]. Standard practice and supporting research studies suggest that after five participants are tested, the law of diminishing returns applies, where participants will identify the same design shortcomings with increasing little additional USABILITY information gained from each additional participant. Annex K contains additional information regarding sample size.

A USABILITY TEST can be conducted on one or more prototypes with varying degrees of FIDELITY such as paper sketches, wireframes, hardware or software mock-ups, a functional prototype or a completed MEDICAL DEVICE. A MANUFACTURER can also conduct USABILITY TESTS on similar MEDICAL DEVICES on the market to understand their strengths and weaknesses. Additional information on USABILITY TESTS of MEDICAL DEVICES is provided in reference [31].

16.3 Analysis of FORMATIVE EVALUATION results

Table 6 presents example USE ERRORS that could arise from USER INTERFACE design shortcomings and suboptimal characteristics and be uncovered during FORMATIVE EVALUATION. Certain USE ERRORS that might appear to have been caused by the USER can ultimately be traced to a design shortcoming. Good designs take into consideration and limit the potential effects of human fallibilities, including such common and predictable ones as forgetting a procedural detail or overlooking a visual indication.

Table 6 – USE ERRORS caused by sample USER INTERFACE design shortcomings

USE ERROR	USER INTERFACE design shortcomings
USER presses the wrong button.	Push buttons on a control panel are too closely spaced.
USER misinterprets the icon and selects the wrong function.	Two icons on a software screen look too similar.
USER enters incorrect sequence and fails to initiate therapy.	A USER INTERFACE requires a complex, lengthy, and arbitrary sequence of button pushes to initiate a therapy.
USER repeatedly opens the door and presses the reset key instead of clearing air from the infusion line.	Infusion pump displays misleading “Open Door-Reset” message when air is in the infusion line.
USERS fail to detect a dangerous increase in heart rate because ALARM LIMIT is set too high and USERS do not look at MEDICAL DEVICE display because they are over-reliant on the ALARM SYSTEM.	USER-adjusted high and low ALARM LIMITS on a heart-rate monitor are not continuously displayed.
USER cracks catheter connector during catheter attachment.	Typical USER-applied force exceeds breaking strength of catheter connector.
USER forgot to replace a critical component when reassembling a MEDICAL DEVICE after cleaning it.	The MEDICAL DEVICE could be assembled and powered-up with a critical component missing.
USER ignored a warning label telling the USER to disconnect the PATIENT tube before turning the MEDICAL DEVICE off.	The MEDICAL DEVICE did not require the USER to confirm PATIENT disconnection before powering-off.
USER disregarded a warning symbol and allowed a portable MEDICAL DEVICE to run out of battery power.	The warning symbol was not sufficiently attention-getting.
USER forgot to confirm the new parameter settings.	The MEDICAL DEVICE reset the parameters to the previous settings after “timing-out” without notifying the USER that the new settings had been discarded and the previous ones were in effect or asking the USER to confirm the new settings.

The MANUFACTURER should continue to iterate the design and perform FORMATIVE EVALUATION until it is believed that all use-related RISKS have been adequately controlled, no further refinement is needed and the MEDICAL DEVICE is ready to proceed to SUMMATIVE EVALUATION.

17 Perform SUMMATIVE EVALUATION

17.1 General

The purpose of a SUMMATIVE EVALUATION is to evaluate the USABILITY of the USER INTERFACE as it relates to the successful completion of the TASKS associated with the HAZARD-RELATED USE SCENARIOS. A SUMMATIVE EVALUATION has no testable requirements in the sense used with a laboratory test. It is an evaluation of data that usually includes USABILITY TEST data. The requirement is that the data from the SUMMATIVE EVALUATION allows the MANUFACTURER to

conclude that no further improvement of the USER INTERFACE is necessary or practicable. These results are then transferred to the RISK MANAGEMENT PROCESS to determine whether the RESIDUAL RISK is acceptable.

A SUMMATIVE EVALUATION usually follows one or more FORMATIVE EVALUATIONS. A successful SUMMATIVE EVALUATION demonstrates that a MEDICAL DEVICE is not vulnerable to potentially harmful USE ERRORS. However, a SUMMATIVE EVALUATION might reveal that a MEDICAL DEVICE remains vulnerable to potentially harmful USE ERRORS, either because USABILITY TEST participants committed USE ERRORS on HAZARD-RELATED USE SCENARIOS or because testing revealed a pattern of CLOSE CALLS. Such USABILITY TEST results indicate the need for further USER INTERFACE improvement and re-testing unless RESIDUAL RISKS are deemed to be acceptable in relation to the benefit of using the MEDICAL DEVICE.

SUMMATIVE EVALUATION generally involves performing a USABILITY TEST under conditions of simulated use.

EXAMPLE 1 A USABILITY TEST of a MEDICAL DEVICE using a manikin as the PATIENT.

EXAMPLE 2 A USABILITY TEST on an injection MEDICAL DEVICE that does not contain a needle or any drug.

For some MEDICAL DEVICES, it can be difficult to conduct a USABILITY TEST because it is not practicable to simulate the use and it is unethical to conduct a USABILITY TEST in actual use. In these cases, it can be justifiable to use other evaluation methods.

EXAMPLE 3 Expert and highly experienced cardiac surgeons can perform an expert review of a very specialized cardiac surgical instrument where an empirical performance based SUMMATIVE EVALUATION by USABILITY TEST of heart surgery success cannot be practically simulated.

Additionally, expert reviews can be considered when the scope of the SUMMATIVE EVALUATION is limited to minor changes to the USER INTERFACE that do not involve HAZARD-RELATED USE SCENARIOS associated with serious HARM or in the case where the MEDICAL DEVICE has no HAZARD-RELATED USE SCENARIOS.

USABILITY TEST participants include appropriately screened representatives of the given MEDICAL DEVICE'S distinct USER GROUPS (e.g. PATIENTS, nurses, and technicians who might all use a home dialysis machine). A typical USABILITY TEST protocol calls for participants to perform hands-on TASKS associated with the selected HAZARD-RELATED USE SCENARIOS. Satisfying the goal of observing USERS interact realistically with a MEDICAL DEVICE, without actually delivering medical care, sometimes requires elaborate USE ENVIRONMENT SIMULATION. Otherwise, USABILITY TESTS can take place in a SIMULATION laboratory or even a conference room.

USABILITY TEST data collected should include:

a) TASK completion (and, where related to SAFETY, time to complete);

b) descriptions of observed USE ERRORS, CLOSE CALLS *and use difficulties*;

c) participants' comments (e.g. anecdotal remarks) about their MEDICAL DEVICE interactions; and

d) participants' reported root causes of their USE ERRORS and CLOSE CALLS.

USABILITY TEST data also can include:

e) *subjective ratings about the USER INTERFACE, if a MANUFACTURER wants to assess MEDICAL DEVICE attributes not related to SAFETY, such as USER satisfaction.*

17.2 Conduct a SUMMATIVE EVALUATION

A SUMMATIVE EVALUATION is a formal activity that follows a USER INTERFACE EVALUATION plan. The testing should follow the plan as precisely as possible. Any deviations from the plan should be cited in the associated test report.

Ultimately, there is one SUMMATIVE EVALUATION. If new problems are found or known problems persist in a SUMMATIVE EVALUATION, the evaluation is redefined to be one more in the series of FORMATIVE EVALUATIONS. In such a case, the MANUFACTURER should make the necessary design refinements and then conduct a SUMMATIVE EVALUATION.

USABILITY TESTS for SUMMATIVE EVALUATIONS are qualitative investigations that can be reported in the form of objective data from observations of USER interactions with the USER INTERFACE and their descriptions of their experiences afterward. These data can be supplemented with statistics, but only simple descriptive statistics (e.g. USE ERROR counts, *TASK times*) rather than inferential statistics (i.e. confidence limits, standard error measurements, statistical significance, Type I or II error rates, etc.).

To evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY, a USABILITY TEST in a SUMMATIVE EVALUATION should have an appropriate probability of observing a USE ERROR caused by a design defect. The number of participants used in the test (sample size) affects the probability of observation. For example, using the methodology of Annex K, assuming for a USER GROUP that a USE ERROR occurs with a probability of 15 % for a single test participant, this USE ERROR would be observed with a probability of 91 % when the sample size is 15 test participants.

To determine the appropriate sample size, the MANUFACTURER should consider the potential consequences of USE ERROR, the complexity of the design and degree of similarity to existing MEDICAL DEVICES as well as the expected heterogeneity of each USER GROUP. Confidence in the test findings of the adequacy of a USER INTERFACE increases when the sample size is increased.

The primary reasons for increasing sample sizes would be to:

a) reveal expectedly subtle USER INTERFACE design shortcomings;

b) involve people with a wider range of secondary selection characteristics; and

c) draw incrementally more reliable conclusions about a design's merits when one expects TASK performance *and USER preference* to vary widely.

Test results should be documented in a report, which can be augmented by raw and processed data sets (e.g. a spreadsheet containing data) and video recordings and photographs of the test sessions, presuming that the MANUFACTURER obtains permission from the test participants to use their images.

17.3 Data collection

17.3.1 General

USABILITY TEST data collection to support evidence that the "MEDICAL DEVICE, as designed, can be used safely and effectively" includes USABILITY TEST participant:

a) performance data (observational); and

b) comments (subjective).

Observational and subjective data are complementary inputs to assessing adequacy, strengths, weaknesses, SAFETY and EFFECTIVENESS of the USER INTERFACE. USE ERRORS are investigated and explained such that subjective assessment by USABILITY TEST participants is used to help identify the root cause of each observed USE ERROR. Additional information is found in 17.3.3.

17.3.2 Observational data

During a USABILITY TEST for SUMMATIVE EVALUATION, the test participants are asked to perform the USE SCENARIOS previously selected (see Clause 12).

While they perform each USE SCENARIO, the study moderator should observe the test participants and record their performance on each study TASK and sub-TASK or step as one of the following: CORRECT USE, USE ERROR, CLOSE CALL *or use difficulty*. It is important to collect the observational data at a sufficient level of interaction detail to enable identification of the source of any use problems that occur.

During the SUMMATIVE EVALUATION session, it is important that the moderator not influence the participants' behaviour. The purpose of SUMMATIVE EVALUATION is to approximate realistic use situations so as to learn how USERS are likely to interact with the MEDICAL DEVICE in actual use. The moderator should be neutral to the outcome of the test and seek to ascertain the truth. For example, the moderator should not ask the participant to "think aloud" because this interferes with realistic use; however, the moderator should record any comments the participant makes spontaneously, if any.

Sometimes it is difficult to avoid the occurrence of test participant behaviour that is caused by the artificial nature of simulated use. For example, test participants sometimes fail to check the expiration date of a medication because they do not expect it to have expired or because it does not matter since the medication is not actually delivered to a PATIENT. The MANUFACTURER should seek to minimize the occurrence of such events (sometimes called "test artefacts") but if the events are unavoidable, these aspects of the USER INTERFACE can be assessed through KNOWLEDGE TASK STUDIES (see 17.3.3.6).

Not all observational data is necessarily objective. Some assessments of USER behaviour are a subjective interpretation of an observation based on professional expertise and experience of the USABILITY SPECIALIST.

17.3.3 Subjective data

17.3.3.1 General

Subjective data should be collected through debriefing interviews with the test participants following a USABILITY TEST performed for SUMMATIVE EVALUATION. Simply counting the USE ERRORS does not support understanding of the root cause of a USE ERROR, which can be only understood with clarification derived from the perspective of the test participants involved with the USE ERROR.

Post USABILITY TEST interview data can be used to establish the root causes where USERS were observed to commit a USE ERROR, experience CLOSE CALLS or *have use difficulties* completing important USER TASKS. Post USABILITY TEST interview data is often the best or only available data for assessing USE ERRORS, CLOSE CALLS *or use difficulties* that occurred but were not observed during testing. The purpose of the interview is to identify unobserved use problems and also any errors in perception or cognition that the test participants might have made because such errors are not observable. Obtaining the USER'S perspective in an interview provides information to help determine whether the observed USE ERROR, CLOSE CALL *or use difficulty* might have been caused by an error of perception or cognition. It is also essential for determining whether previously unknown use-related HAZARDS exist in the design of the USER INTERFACE.

Post USABILITY TEST interview data collection should be "active" rather than "passive" such that test participants are asked questions directly by test moderators rather than being simply allowed to comment voluntarily, given rating scale instruments or invited to respond to electronic questionnaires or surveys. Care needs to be taken to ask the questions in an unbiased way so as to not lead the participants.

17.3.3.2 Impression of the overall use of the MEDICAL DEVICE

Test participants should be asked and allowed to respond. This data is valuable because USERS can be aware of specific concerns as well as positive impressions regarding their use of the MEDICAL DEVICE that are valuable for evaluating the SAFETY and EFFECTIVENESS of use as well as ease of use and USER satisfaction.

17.3.3.3 Instances of confusion or difficulty

Test participants should be asked and allowed to respond. This data is valuable because USERS can be aware of specific concerns as well as positive impressions regarding their use of the MEDICAL DEVICE that are valuable for evaluating the SAFETY and EFFECTIVENESS of use as well as ease of use and USER satisfaction.

17.3.3.4 USE ERRORS and CLOSE CALLS observed during simulated use testing

USE ERRORS, which occur during simulated use USABILITY TESTS, should be followed up by collecting subjective data to enable clarification and root cause analysis of the USE ERROR that includes essential experience and insight from test participants. Likewise, USE ERRORS should be similarly followed up as well as to determine if previously unknown use-related HAZARDS exist in the design of the USER INTERFACE.

17.3.3.5 CLOSE CALLS (not observed)

Test participants should be asked whether they experienced CLOSE CALLS since the CLOSE CALL can be "cognitive" and might not have been observable. If test participants report such CLOSE CALLS, the interview should proceed to 17.3.3.4.

17.3.3.6 KNOWLEDGE TASK STUDY data

Some HAZARD-RELATED USE SCENARIOS cannot be evaluated by only using observation if TASKS involve important knowledge USERS need to operate the MEDICAL DEVICE SAFELY and effectively. KNOWLEDGE TASK STUDIES assess the content of the ACCOMPANYING DOCUMENTATION as it would be typically used by USERS during actual use and the knowledge that is necessary for USERS to enable safe and effective use of the MEDICAL DEVICE.

17.4 Data analysis

It is common for SUMMATIVE EVALUATIONS to result in the occurrence of some USE ERRORS, CLOSE CALLS *and use difficulties* suggesting that no MEDICAL DEVICE or its USERS are perfect. USE ERRORS, CLOSE CALLS *and use difficulties* can reflect USER INTERFACE design shortcomings (i.e. flaws). Sometimes, they reflect shortcomings in the test participants' behaviour, such as conscious disregard for the instructions for use, which are not necessarily related to the USER INTERFACE design or within the MEDICAL DEVICE MANUFACTURER'S control.

Although human beings are imperfect, it is inappropriate to blame the USER when problems occur during SUMMATIVE EVALUATION. The key in any analysis of USE ERRORS, CLOSE CALLS *or use difficulties* is to intensely search for a design-based root cause before attributing the USE ERROR to the USER.

USABILITY TESTS are mostly qualitative rather than a statistically based activity. Any and all USABILITY problems uncovered, particularly those found in a SUMMATIVE EVALUATION, should be thoroughly analysed to determine root causes, and their impact on HAZARD-RELATED USE SCENARIOS should be carefully considered. Regardless of the root cause(s), the MANUFACTURER should conduct a follow-up RISK ANALYSIS of all USE ERRORS, CLOSE CALLS *and use difficulties* that arise during a SUMMATIVE EVALUATION. Root cause analysis of MEDICAL DEVICE USE ERRORS is discussed in detail in reference [32].

The MANUFACTURER should look for any new USE ERRORS or interaction difficulties that would suggest the need for a design change. If new HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered or improvement is necessary and practicable, then IEC 62366-1:2015 instructs the MANUFACTURER to perform additional USABILITY ENGINEERING effort.

Alternatively, this analysis might determine that no improvement is necessary and practicable for the tested MEDICAL DEVICE. IEC 62366-1:2015 then instructs the MANUFACTURER to perform a RESIDUAL RISK EVALUATION according to ISO 14971:2007.

Modifications of the USER INTERFACE implemented after a SUMMATIVE EVALUATION require follow-up USABILITY EVALUATION. If the change is minor, a desktop analysis might be a sufficient means of confirmation, but only if the modification does not increase the use-related RISK *and does not create the potential for new use difficulties*.

EXAMPLE 1 Revising an on-screen prompt's wording.

EXAMPLE 2 Graphically enhancing a warning by capitalizing the signal word "WARNING".

EXAMPLE 3 Change in logo or branding.

However, even such minor modifications might warrant follow-up USABILITY TESTS, particularly to confirm that a previously detected USER interaction problem has been resolved. For example, if an initial USABILITY TEST showed that USERS misread a button label, the MANUFACTURER would probably need to conduct a follow-up test to demonstrate that they could reliably read the new button labels.

More often, and particularly regarding major design modifications, the best way to confirm that use-related RISKS have been adequately controlled is to conduct a follow-up SUMMATIVE EVALUATION. RISK CONTROLS with far-reaching effects on USER interactions might warrant conducting a complete SUMMATIVE EVALUATION, essentially repeating the previous SUMMATIVE EVALUATION that is redefined as a FORMATIVE EVALUATION. For small modifications with limited effects on USER interaction, a smaller scale, supplemental USABILITY TEST involving fewer test participants and perhaps fewer TASKS than the initial SUMMATIVE EVALUATION can be sufficient.

In unusual cases, the MANUFACTURER might need to study the MEDICAL DEVICE in actual use. Such studies are likely to involve unobtrusive observation of USER-MEDICAL DEVICE interactions, and possibly follow-up interviews with the MEDICAL DEVICE USERS, over a longer period of MEDICAL DEVICE use than is common in simulated-use testing. Annex F contains additional information.

Sample USE ERRORS and possible root causes for those USE ERRORS are listed in Table 7. While in this example the USE ERRORS are described briefly and in a generic manner, actual USE ERROR descriptions should be described in as much detail as possible.

Table 7 – Sample USE ERRORS and their root causes

Sample USE ERROR	Sample root cause for the USE ERROR
1 participant (1 nurse) did not properly secure the syringe in its holder	The syringe clamp required relatively high force to secure the syringe. The nurse tried to engage the clamp, but was not able to apply enough force.
3 participants (1 nurse, 2 PATIENTS) stopped the treatment rather than pausing the treatment	All three USERS drew upon prior experience using a similar MEDICAL DEVICE to operate the new MEDICAL DEVICE, but the new MEDICAL DEVICE did not work the same way (i.e. there was negative transfer).
1 participant (1 technician) programmed ten times the intended dose because he did not add a decimal point when entering the prescribed flow rate	Small text on the display was illegible to the USER who had minor vision impairment (mild cataract). He didn't realize the decimal point was missing.
1 participant (1 PATIENT) did not detect (i.e. notice) that the MEDICAL DEVICE stopped even though the MEDICAL DEVICE repeatedly presented a high-frequency ALARM SIGNAL	ALARM SIGNAL frequency too high to be heard by individual with high frequency hearing loss (presbycusis).
2 participants (1 physician, 1 nurse) did not connect the line to the port	USABILITY TEST artefact: The test participant misunderstood the TASK posed by the test moderator. NOTE USABILITY TEST artefacts are actions induced by an artificiality that would not be present in an actual USE SCENARIO.

18 Document the USABILITY ENGINEERING project

A USABILITY ENGINEERING report can be created to summarize the USABILITY ENGINEERING project for the purposes of communicating with internal and external stakeholders. Importantly, a USABILITY ENGINEERING report is not the same as a SUMMATIVE EVALUATION report, but a USABILITY ENGINEERING report should cite SUMMATIVE EVALUATION results. Such a report should include:

a) *an executive summary;*

b) *a summary of the USE SPECIFICATION;*

c) *a description of the USER INTERFACE;*

d) *a summary of known use problems;*

e) *a description of the HAZARD-RELATED USE SCENARIOS evaluated and why they were chosen;*

f) *a summary of FORMATIVE EVALUATIONS;*

g) *a summary of the SUMMATIVE EVALUATION; and*

h) *a conclusion.*

Annex D provides additional information regarding USABILITY ENGINEERING project end products.

19 POST-PRODUCTION review and analysis

According to ISO 14971, POST-PRODUCTION surveillance is required by the RISK MANAGEMENT PROCESS. This includes evaluating data related to USE ERROR in order to identify strengths and shortcomings of the USER INTERFACE. However, the PROCESS of POST-PRODUCTION surveillance is not included in IEC 62366-1. The design and development PROCESS in IEC 62366-1 for the design and development of a MEDICAL DEVICE ends prior to the POST-PRODUCTION stage.

The POST-PRODUCTION surveillance PROCESS can provide a rich pool of customer complaint data that can be used to support USABILITY ENGINEERING activities. MANUFACTURERS can use these data to identify use-related problems, including those related to USE ERROR. To most MANUFACTURERS, this PROCESS is not new, but it can often be enhanced by collecting more details about events that occur.

In general, USE ERRORS in the field are underreported. This can in part be attributed to the workload involved for RESPONSIBLE ORGANIZATIONS to file reports and the effort needed by a lay USER to file a complaint. MANUFACTURERS should include in the instructions for use contact information for USERS to report ADVERSE EVENTS and complaints.

According to IEC 62366-1, all USE ERRORS should be identified in USABILITY EVALUATION during development. Despite this effort, a MANUFACTURER can attempt to identify previously unidentified USE ERRORS after placing the MEDICAL DEVICE on the market. An example is test market evaluation of new products. This evaluation is usually a limited launch with very tight control of where and to whom the product is initially provided. This effort can allow early intervention on these USE ERRORS, before they cause HARM.

Preparing the specific tools for collecting and managing USE ERROR will be unique for each MANUFACTURER, driven by the RISK associated with use of the MEDICAL DEVICE and the PROCESSES and systems that the MANUFACTURER has available for collecting information.

To fully capture all of the necessary information related to a use-related event, the MANUFACTURER should collect answers to the following questions:

a) *What happened (i.e. what was the unexpected or unwanted result)?*

b) *Was there PATIENT or USER HARM?*

c) *Who was the USER (i.e. which USER PROFILE)?*

d) *What did the USER intend to do (i.e. what TASKS and what USE SCENARIO)?*

e) *What did the USER do? Were workarounds necessary?*

f) *Where did the event happen? Describe the environmental conditions (i.e. what USE ENVIRONMENT).*

g) *What other contributing elements, such as other MEDICAL DEVICES if any were being used at the time of the event?*

Some of this information is sometimes missing in actual filed complaints. When this happens, those initiating a complaint should be asked to provide this information.

The complaint categories relating to MEDICAL DEVICE failure generally relate to physical MEDICAL DEVICE components. USE ERROR complaint categories generally relate to the TASK flow when utilizing the MEDICAL DEVICE. As a result, the MANUFACTURER might need to translate from the failure identified in a complaint to a related USE ERROR.

The MANUFACTURER should anticipate customer complaints and map them to previously identified USE ERRORS. This mapping should be done by taking the USE ERRORS and creating a relationship in the complaint system to the complaint category items. This mapping allows trending of complaints against known USE ERRORS.

The mapping can create at least two types of relationships:

– *a complaint code connected to one USE ERROR;*

– *a complaint code connected to several USE ERRORS. It can be possible to estimate a distribution of the USE ERRORS, or at least identify one or two as the most likely USE ERRORS, based on knowledge from e.g. previous or existent products on the market.*

Some complaints can lack sufficient clarity to identify the related USE ERROR.

Once the MANUFACTURER has obtained information about complaints as well as CLOSE CALLS or customer dissatisfaction it should be transferred to those responsible for analysing USE ERROR. The MANUFACTURER should attempt to establish the root cause of the USE ERROR. Information from complaints sometimes does not have sufficient detail, in which case RISK ANALYSIS and other tools such as TASK ANALYSIS can help. However even without a clear root cause, it is useful to monitor USE ERROR trends.

The MANUFACTURER should then decide whether to initiate actions, based on the result of this assessment including any root cause analysis. Often it is not possible to base the decision directly on the reported frequency of occurrence of USE ERROR and the POST-PRODUCTION surveillance data do not allow more than trending of reported numbers. In addition, POST-PRODUCTION surveillance data can be misleading because events often go unreported. For some MEDICAL DEVICES, it can be possible to estimate an under-reporting factor, which can permit an estimated frequency of USE ERROR to be determined.

Criteria for initiating action should in any case include whether:

– *the USE ERROR is determined to be new (not previously identified); or*

– *the report of this USE ERROR demonstrates an increased occurrence.*

The decision should also take into consideration other sources of information such as ADVERSE EVENTS or results of literature studies and clinical data (see Annex B). This is described in both regulation and standards such as ISO 14971.

Even if no action is required, the USE ERROR should still be monitored and trended. And, even if the USE ERROR is not part of any HAZARD-RELATED USE SCENARIO it should still be monitored as this can contribute to preference and EFFICIENCY improvements in future product releases.

Another potential for requiring additional action is the identification of new elements of the use specification (e.g. a new USER GROUP, a new PATIENT population or new medical indication).

But in most cases, data monitoring and analysis increases the MANUFACTURER'S understanding of how the MEDICAL DEVICE is used, which can be useful for developing new products driving increased USER satisfaction.

Further guidance is found in reference [33].

Annex A
(informative)

Recommended reading list

The following readings are suggested for those not familiar with USABILITY ENGINEERING.

IEC TR 61258:2008, *Guidelines for the development and use of medical electrical equipment educational materials*

ISO IEC Guide 63:2012, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*

ISO 7010, *Graphical symbols – Safety colours and safety signs – Safety signs used in workplaces and public areas*

ISO 9000, *Quality management systems – Fundamentals and vocabulary*

ISO 9001, *Quality management systems – Requirements*

ISO 9241-11:1998, *Ergonomic requirements for office work with visual display terminals (VDTs) – Part 11: Guidance on usability*

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

EN 1041:2008, *Information supplied by the manufacturer of medical devices* EN 1041:2008/Amd1:2013

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Annex B
(informative)

External resources to identify known problems

B.1 General

A sample of external resources providing access to reports of MEDICAL DEVICE USER INTERFACE problems leading to HARM are listed below. The sample resources are listed by region, but a thorough assessment of known problems should have a global reach. This list is not exhaustive. A MANUFACTURER is not expected to review every possible database or information source. A MANUFACTURER should contact the authority having jurisdiction in the markets in which they intend to distribute their MEDICAL DEVICE for guidance on relevant information sources.

NOTE 1 Depending on the type of MEDICAL DEVICE, there can be many more resources upon which to draw insights about potential use-related problems.

NOTE 2 In some cases, use-related problem reports do not explicitly cite or describe USER INTERFACE problems. Rather, they describe an event without providing substantial details that would suggest there is a USER INTERFACE design issue. Moreover, searching databases using terms such as human factors or USABILITY ENGINEERING can not result in findings. Consequently, analysts can need to conduct a broader search for problems and analyse each case to determine if they suggest a pertinent problem to be avoided.

B.2 Austria

CIRS des Österreichischen Roten Kreuzes (Rettungs- und Krankentransportdienst)

B.3 Germany

PaSIS (Patientensicherheits- und Informationssystem) Fachübergreifendes Incident Management System

CIRSmedical Deutschland (Ärztliches Zentrum für Qualität in der Medizin ÄZQ)

Krankenhaus-CIRS-Netz Deutschland (ÄZQ, Aktionsbündnis Patientensicherheit, Deutsche Krankenhaus Gesellschaft, Deutscher Pflegerat)

CIRSmedical WL (Ärztekammer Westfalen-Lippe, ÄZQ)

CIRS-AINS – CIRSmedical Anästhesiologie (Berufsverband Deutscher Anästhesisten, Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin, ÄZQ)

Netzwerk CIRS-Berlin (Ärztekammer Berlin, ÄZQ)

CIRS zur präklinischen Notfallmedizin

CIRS-Pädiatrie (Berufsverband der Kinder- und Jugendärzte(BVKJ), ÄZQ)

Fehler-Berichts- und Lernsystem für Hausarztpraxen (Institut für Allgemeinmedizin, Frankfurt/M, Techniker Kasse)

Fehlerberichtssystem des KDA für die Altenpflege

CIRS der gesetzliche Unfallversicherung im Feuerwehrdienst

CIRS Rettung (bundesweites CIRS Netzwerk Rettungs- und Notarztdienst)

BfArM's Field Corrective Actions database, available at http://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html?nn=3497560

B.4 Sweden

Reidar incidents and accidents database, available at http://www.reidar.se

B.5 Switzerland

CURRENT – Critical Incident Reporting & Reacting NETwork (CH)

B.6 United Kingdom

NHS's Serious Incident Reporting and Learning Framework (SIRL) database, available at http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

B.7 United States

FDA's Manufacturer and User Facility Device Experience (MAUDE) database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

FDA's Medical Device Reporting (MDR) Program Search, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm.

FDA's Adverse Event Reporting Data Files, available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm124064.htm.

FDA's MedSun: Medical Product Safety Network, available at http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm.

CDRH Medical Device Recalls, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

CDRH Alerts and Notices (Medical Devices), available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm.

CDRH Public Health Notifications, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm.

CDRH Safety Communications, available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm.

ECRI's Medical Device Safety Reports, available at http://www.mdsr.ecri.org/.

The Institute of Safe Medical Practices (ISMP's) Medication Safety Alert Newsletters, available at http://www.ismp.org/Newsletters/default.asp.

The Joint Commission's Sentinel Events, available at http://www.jointcommission.org/sentinel_event.aspx.

Annex C
(informative)

Developing USABILITY GOALS for commercial purposes

C.1 General

The main objective according to IEC 62366-1 is USABILITY as it relates to SAFETY, which implies that purpose for USABILITY EVALUATIONS is to mitigate RISKS associated with CORRECT USE and USE ERRORS. *However for strictly commercial purposes, a MANUFACTURER can establish USABILITY GOALS for a MEDICAL DEVICE in development because such goals can concentrate USER INTERFACE designers on the important TASK of engineering USABILITY into a MEDICAL DEVICE, rather than treating USABILITY as a vague and elusive outcome. However, while establishing and endeavouring to meet such goals is the preferred USABILITY ENGINEERING practice, setting USABILITY GOALS is not an essential component of a USABILITY ENGINEERING project.*

Importantly, evidence that USABILITY GOALS have been met should not be cited as evidence of acceptable use-related RISK, specifically because data such as TASK performance times and subjective ratings are not necessarily good indicators of acceptable RISK. For example, a USABILITY TEST participant might give a MEDICAL DEVICE a high rating for TASK EFFICIENCY (i.e. speed of use), unconscious of having taken quite a long time to perform the TASK.

The USABILITY GOAL limitation discussed above does not mean that TASK time is unimportant. In fact, in cases such as using an AED to rescue a person in heart failure, TASK time is critical. However, a certain failure rate (i.e. 10 % of USABILITY TEST participants did not deliver a shock within a critical time limit) does not necessarily represent a passing performance from a SAFETY perspective. Any such failures warrant a RESIDUAL RISK EVALUATION.

There are two basic types of USABILITY GOALS: objective and subjective. They enable MANUFACTURERS to assess a MEDICAL DEVICE'S USABILITY by:

– *objectively measuring USERS' TASK performance, and*
– *seeking USERS' opinions about the MEDICAL DEVICE, respectively.*

Broadly speaking, objective goals carry more weight than subjective goals within a development team because of the value placed on objective performance as compared to perceived MEDICAL DEVICE performance. However, a MEDICAL DEVICE that scores highly in objective USABILITY measures can be rejected by USERS based on subjective measures (e.g. if USERS perceive a MEDICAL DEVICE to be difficult to use).

C.2 Objective goals

Objective goals, which tend to carry more weight with development teams expressly because the goals are more concrete, call for USABILITY SPECIALISTS to observe and document USERS' performance of MEDICAL DEVICE TASKS. Data collection does not require USERS to express their opinions about a MEDICAL DEVICE. Rather, researchers can assess USER performance by direct observation.

Possible TASK performance characteristics include TASK time, TASK completion status (success, success with assistance (which sometimes is considered a type of failure), the number of USE ERRORS, and even such subtle events such as hesitations during MEDICAL DEVICE use. Multiple objective USABILITY GOALS can be written based on a particular characteristic, focusing on different USER TASKS.

Sample goals for which TASK time is the chosen metric and the target performance levels are arbitrary i.e. just (for illustration purposes) are:

– *at least 85 % of trained USERS shall be able to prepare the MEDICAL DEVICE to deliver a treatment in ≤ 10 min;*

– *at least 85 % of trained USERS shall be able to "tear-down" the dialysis equipment following a treatment in ≤ 5 min;*

– *at least 85 % of trained USERS shall be able to resolve an air-in-blood ALARM CONDITION in ≤ 2 min.*

Establishing goals based on USE ERROR rates can be precarious. The following USABILITY GOAL pertains to an automated external defibrillator (AED): "90 % of first-time USERS shall successfully deliver a shock." At first, this goal sounds reasonable because the target performance level sounds ambitious. However, the USABILITY GOAL allows for one in ten attempts to deliver a shock to a person in dire condition to fail. Accordingly, a MANUFACTURER might be leery about setting the target performance level at even 99 % rather than 100 %, the latter target being more desirable when even one USE ERROR in a real USE SCENARIO could lead to severe injury or death. A better approach is to focus USABILITY GOALS on USABILITY-related matters rather than write USABILITY GOALS suggesting that a certain rate of USE ERROR is acceptable. Some rate of residual USE ERROR might be acceptable based on the associated RISK ANALYSIS, but it strikes many USABILITY SPECIALISTS as poor practice to set USE ERROR rate USABILITY GOALS per se.

MANUFACTURERS are dissuaded from establishing objective goals focused on the rate of successful TASK completion for the same reason that goals focused on USE ERROR rates are problematic. Such goals conflict with the premise that USE ERRORS and TASK failures are fundamentally unacceptable at any rate, and warrant follow-up RISK ASSESSMENT and possibly further RISK CONTROL. The exception might be when such goals pertain to TASKS that have absolutely no RISK ramifications but are important from a business standpoint.

C.3 Subjective goals

Subjective goals call for USERS to express opinions (i.e. describe their perceptions) about the given MEDICAL DEVICE, typically by rating the MEDICAL DEVICE according to selected USABILITY attributes. Possible USABILITY attributes include ease of use, TASK speed, vulnerability to USE ERROR, and ease of recovering from a USE ERROR. Multiple subjective USABILITY GOALS can be written based on a particular attribute, focusing on different USER TASKS.

Sample goals that employ a 1-7 rating scale (1 = poor, 7 = excellent):

– *at least 80 % trained USERS shall rate the MEDICAL DEVICE'S overall ease of use as 5,5 or better;*

– *at least 80 % USERS shall rate the computer display screens' visual appeal as 5,0 or better;*

– *at least 80 % untrained USERS shall rate the usefulness of the online help content as 4,5 or better.*

Note that the sample percentages and average ratings presented above are only examples of how to set target performance levels, rather than benchmarks for general use. Each MANUFACTURER should set performance levels that are appropriate to the MEDICAL DEVICE in development. Also, note that USABILITY GOALS might or might not be associated with RISK-related TASKS; those that could result in negative clinical effects (including injury or death) if not performed correctly. Regardless, as stated earlier, MANUFACTURERS should not cite meeting the established goals as evidence of the MEDICAL DEVICE'S acceptable use-related RISK. The perception of SAFETY is not evidence of SAFETY. Therefore, while the MANUFACTURER might choose to measure TASK performance against established USABILITY GOALS during a SUMMATIVE EVALUATION (i.e. confirmation), the results should be segregated from data providing evidence of acceptable use-related RISK.

Focused on the commercial and end-USER interests, MANUFACTURERS can choose to write 5 to 10 subjective USABILITY GOALS and 5 to 10 objective USABILITY GOALS, but there is no rule calling for more or fewer goals. MANUFACTURERS are responsible for establishing appropriate

acceptance criteria based on their own desired level of quality. Writing more than 10 to 20 total goals might be counterproductive in terms of the effort required to write them and then track the MEDICAL DEVICE'S performance through the various stages of design and testing. However, some MEDICAL DEVICES might warrant a more intensive USABILITY GOAL-setting effort.

It is usually best to keep USABILITY GOALS focused on broadly described MEDICAL DEVICE attributes and major, integrated TASKS, rather than highly specific MEDICAL DEVICE attributes and sub-TASKS or steps. Target performance levels for USABILITY GOALS can be based on data collected during benchmark USABILITY TESTS of multiple competing MEDICAL DEVICES and perhaps interviews with USERS, as well as on expert judgment.

Note that establishing USABILITY GOALS and then testing to see if a MEDICAL DEVICE meets them is primarily a way to bring discipline to the PROCESS of engineering USABILITY into a MEDICAL DEVICE. Setting such goals can help ensure that MANUFACTURERS pay attention to a MEDICAL DEVICE'S USABILITY in addition to its acceptable use-related RISK.

Annex D
(informative)

USABILITY ENGINEERING project end products

This technical report recommends producing multiple USABILITY ENGINEERING project end products (listed at the end of each methodology subclause). The key word is "recommends," noting that the purpose of this technical report is to promote good USABILITY ENGINEERING rather than turn the USABILITY ENGINEERING PROCESS into a paperwork generation exercise. The main objective of any USABILITY ENGINEERING project is to produce a MEDICAL DEVICE that is safe, *usable, and satisfying to the USERS*. With this goal in mind, this annex suggests which end products the AHJ (e.g. EU's Notified Bodies, testing organizations) might cite as evidence of compliance with the PROCESS specified in IEC 62366-1:2015. Table D.1 summarizes the USABILITY ENGINEERING project end products.

Table D.1 – USABILITY ENGINEERING project end products *(1 of 2)*

USABILITY ENGINEERING project activities and end products	Information recommended by this technical report	Information required by IEC 62366-1:2015
Prepare USE SPECIFICATION		
Reports of research conducted (e.g. contextual inquiry, expert reviews)	X	
USE SPECIFICATION	X	X
Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS		
TASK ANALYSIS	X	
FUNCTION ANALYSIS	X	
USER INTERFACE characteristics related to SAFETY and potential USE ERRORS	X	X
Identify known or foreseeable HAZARDS or HAZARDOUS SITUATIONS		
HAZARD analysis	X	
Collection and analysis of existing POST-PRODUCTION and POST-PRODUCTION surveillance information	X	
Known or foreseeable HAZARDS or HAZARDOUS SITUATIONS	X	X
Identify and describe HAZARD-RELATED USE SCENARIOS		
Reports of research conducted	X	
HAZARD-RELATED USE SCENARIOS	X	X
Select HAZARDS or HAZARDOUS SITUATIONS		
Analysis of HAZARD-RELATED USE SCENARIOS	X	
HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION	X	X
Establish USER INTERFACE SPECIFICATION		
Analysis of USER needs and preferences	X	
USER INTERFACE SPECIFICATION	X	X
Establish USER INTERFACE EVALUATION plan		
Plan for FORMATIVE EVALUATION	X	
Plan for SUMMATIVE EVALUATION	X	
USER INTERFACE EVALUATION plan	X	X

Table D.1 *(2 of 2)*

USABILITY ENGINEERING project activities and end products	**Information recommended by this technical report**	**Information required by IEC 62366-1:2015**
Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION		
USER INTERFACE	X	
Instructional materials	X	
Materials necessary for training	X	
FORMATIVE EVALUATION test protocols, if any	X	
FORMATIVE EVALUATION USABILITY TEST reports, if any	X	X
Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE		
SUMMATIVE EVALUATION test protocol	X	X
SUMMATIVE EVALUATION test report	X	X
Document the USABILITY ENGINEERING project		
USABILITY ENGINEERING report	X	

Annex E
(informative)

USABILITY ENGINEERING methods

E.1 General

Many methods (i.e. techniques, tools, methodologies) help USABILITY ENGINEERING practitioners design safer and more usable MEDICAL DEVICES. No single method is best in all situations, and several different ones are typically used during MEDICAL DEVICE design. Decisions about which methods should be used at what stages in the design cycle are based on the USABILITY ENGINEERING issues of the design and are best made by USABILITY SPECIALISTS.

USABILITY ENGINEERING techniques, tools, and methodologies that generate objective, auditable data are preferred. However, both objective and subjective data are important to a comprehensive understanding of a design's successful and less successful features and characteristics.

When USABILITY ENGINEERING activities include 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. Such reviews are normally performed in advance of USER research, FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS because proper human subject protection includes ensuring that research participants have completed a proper consent and assent form, are aware of their rights, and are aware of any RISKS (including minor ones such as mental stress) posed by the research activity. The fact that USER research, FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS rarely involve the delivery of actual medical care is immaterial. Each person intended to act with the MEDICAL DEVICE (e.g. for transportation, storage; installation; operation; maintenance and repair; and disposal) should be treated as potential USER. Annex F provides additional information on studies in clinical settings.

During site visits, it is advantageous to take video and/or photographs for later reference, presuming that the MANUFACTURER obtains the necessary permission(s) to do so and observes all local privacy requirements regarding the protection of PATIENTS' identities and health information. Generally, it is improper to photograph PATIENTS without permission, as well as photograph MEDICAL DEVICES (e.g. PATIENT monitor, MRI scanner) that display information that could be linked to a particular PATIENT. Sometimes, researchers obtain permission to blur the faces of research participants appearing in photographs and videos that can be viewed by a wider audience than just the MEDICAL DEVICE development team members.

This Annex presents several of the major USABILITY ENGINEERING methods in alphabetical order. Table E.1 suggests when specific methods can be applied to greatest effect.

Table E.1 – Recommended application of USABILITY methods

Method	Subclause	USER research	Analysis	Design conceptualization	Design implementation	FORMATIVE EVALUATION	Design finalization	SUMMATIVE EVALUATION	POST-PRODUCTION analysis
Advisory panel reviews	E.2	X	X	X	X	X	X	X	X
Brainstorm USE SCENARIOS	E.3		X	X		X			
Cognitive walkthrough	E.4	X		X		X			X
Contextual inquiry	E.5	X	X	X					X
Day-in-the-life analysis	E.6	X	X	X					
Expert reviews	E.7			X	X	X	X	X	
FMEA and FTA	E.8	X	X	X	X	X	X	X	X
Focus groups	E.9	X	X	X	X	X	X		
FUNCTION ANALYSIS	E.10	X	X	X	X	X			X
Heuristic analysis	E.11	X		X		X	X		X
Observation	E.12	X	X	X		X		X	X
One-on-one interviews	E.13	X	X	X	X	X	X	X	X
Participatory design	E.14	X		X		X			
PCA analysis	E.15	X	X	X		X		X	X
SIMULATION	E.16	X	X	X	X	X		X	
Standards reviews	E.17			X	X	X	X	X	
Surveys	E.18	X		X		X		X	X
TASK ANALYSIS	E.19	X	X	X	X	X	X	X	X
Time-and-motion studies	E.20	X	X	X	X	X			
USABILITY TESTS	16.2.4	X				X		X	
Workload assessment	E.21	X	X	X	X	X			

E.2 Advisory panel reviews

In some cases – particularly when conducting a long-term and critical development project – a MANUFACTURER can choose to convene an advisory panel. An advisory panel can include 5 to 10 people (the total number of people is not critical) who have diverse perspectives on the MEDICAL DEVICE in development. Care should be taken to include representative USERS on the panel, not just "thought leaders" or "key opinion leaders" and favoured client representatives who might provide skewed input regarding USER characteristics and needs.

Convening an advisory panel early – perhaps from the development project's inception – and often during the development PROCESS enables the MANUFACTURER to collect input from individuals who develop a progressively deeper level of insight into design issues and trade-offs than those individuals who might participate in only one interview or USABILITY TEST

session. However, an advisory panel's input and feedback is not a substitute for input and feedback from other prospective USERS who are initially naïve about the MEDICAL DEVICE in development (i.e. people who have "fresh eyes").

E.3 Brainstorm USE SCENARIOS

One method for identifying HAZARD-RELATED USE SCENARIOS is to conduct a creative exercise, such as brainstorming with separate groups of development personnel and intended USERS of the given MEDICAL DEVICE, which draws upon the participants' creativity and perhaps MEDICAL DEVICE domain knowledge to identify possible HAZARD-RELATED USE SCENARIOS. During such sessions, participants suggest USE ERRORS that they can imagine occurring in various USE SCENARIOS including unusual but still foreseeable ones. The participants' imaginations can be stimulated by structured exercises and can employ device models, such as asking participants to think of USE ERRORS that might occur when USERS are rushing or fatigued, when there is a power failure, or when an untrained or inexperienced USER attempts to use the MEDICAL DEVICE, for example. During such exercises, a participant might suggest a USE ERROR that then stimulates others to think of additional USE ERRORS. It helps to consider MEDICAL DEVICE interactions on a step-by-step basis, which is why it is useful to perform a TASK ANALYSIS ahead of time, thereby enabling researchers to direct participants' attention to predetermined steps.

E.4 Cognitive walkthrough

A cognitive walkthrough involves a researcher attempting to determine what is expected of the USER by:

– walking through a preliminary design completing the TASKS as though the researcher is the USER;
– leading subject matter experts through these TASKS; or
– leading representative USERS through these TASKS (sometimes referred to as a pluralistic evaluation).

The goal is to determine whether USERS understand what they need to do for each TASK, sub-TASK or step and whether they understand when a correct or incorrect course of action has been taken.

In a pluralistic evaluation, the researcher guides the USER through a TASK by describing how they would perform a TASK based on drawings and models presented. The researcher's job is to bring the static USER INTERFACE "to life" by describing how the MEDICAL DEVICE would respond to USER inputs.

The evaluation can use USER INTERFACE design illustrations, such as drawings (printed or on a computer screen) of a control panel and various screens that would appear on a computer-based display. Occasionally, a non-functional hardware model can complement the drawings to give the USERS a more complete sense for MEDICAL DEVICE hardware USER INTERFACE.

A cognitive walkthrough, which is well suited to preliminary design evaluations, can produce surprisingly detailed and useful insights about a USER INTERFACE design's strengths and opportunities for improvement. Additional information is found in 16.2.3.

E.5 Contextual inquiry

A common and effective way to learn about USERS is to observe them interacting with items of interest (e.g. surgical instrument, PATIENT monitor, hospital bed, software application, glucose meter), perhaps while they perform TASKS similar to those that are intended to be performed using the MEDICAL DEVICE in development. For example, a team developing a home therapy MEDICAL DEVICE (e.g. peritoneal dialysis machine) might visit a clinic to observe dialysis

PATIENTS who normally help their caregivers (dialysis nurses and technicians) prepare the dialysis equipment for use. Alternatively, the researchers might visit dialysis PATIENTS at home to observe them administer their own treatments. As another example, a team developing a minimally invasive surgical instrument, such as an endoscope, might visit hospitals to observe surgeons operating with similar MEDICAL DEVICES. In some cases, the USER research team might create a video RECORD of the USER activities of interest to enable subsequent analyses. Video from multiple viewpoints can be very useful when performing detailed analyses (e.g. time-motion analysis).

The kind of research described above is often termed contextual inquiry or ethnographic research. The choice of term depends on the researchers' professional backgrounds, specific style of observation, and data collection practices. The many varieties of USER research, presuming that each is performed well, can produce an equivalent set of USERS' needs.

Researchers should keep in mind that a USE ENVIRONMENT is much more than a workspace to be described just in architectural terms. The term USE ENVIRONMENT in this technical report refers more broadly to the overall context of use, including architectural, social, and climatic factors. USE ENVIRONMENT analysis should include the capture of USE ENVIRONMENT characteristics that impact the TASKS performed with the MEDICAL DEVICE being designed as well as any influence on HAZARD-RELATED USE SCENARIOS. If practicable, the MANUFACTURER should estimate the probability of occurrence of the HAZARD-RELATED USE SCENARIO as well as the probability of it leading to HARM. Figure E.1 illustrates a USE ENVIRONMENT within a hospital, which could place special USER INTERFACE requirements on a MEDICAL DEVICE.

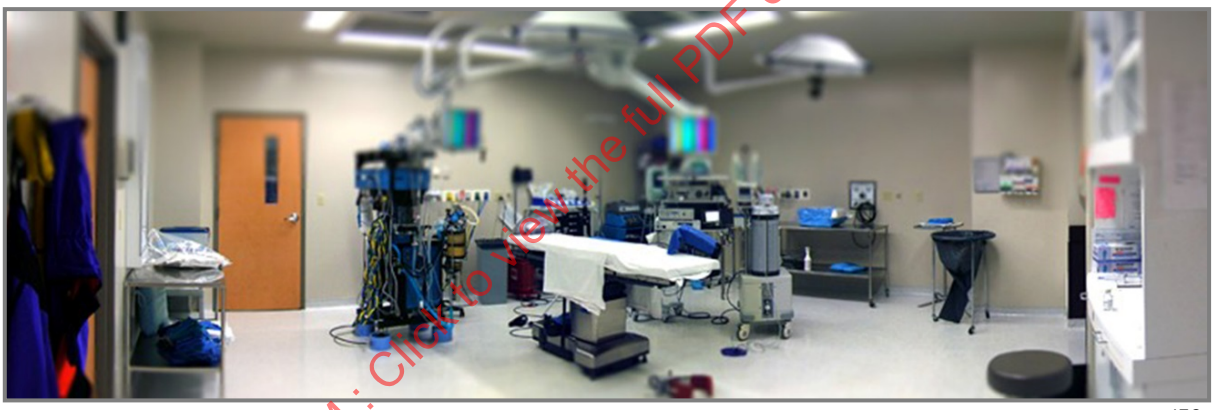

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Figure E.1 – Sample of a USE ENVIRONMENT within a hospital

In some cases, it is useful to perform what some researcher term a day-in-the-life analysis – performing extended USER observations. Additional information is found in E.6 and reference [34].

E.6 Day-in-the-life analysis

A Day-In-The-Life (DITL) analysis is typically performed in the early stages of a MEDICAL DEVICE design. Other terms for a DITL include PROCESS analyses and mission analyses. DITL analysis is appropriate for new MEDICAL DEVICES as well as updates to current MEDICAL DEVICES. The purpose of DITL analysis is to discover and document how USERS interact with a MEDICAL DEVICE during an average day. Such an analysis helps to identify the details of how USERS interact with a given MEDICAL DEVICE during daily use, including the most frequent MEDICAL DEVICE-related TASKS and their sequence, the contexts in which USERS perform TASKS and related USABILITY issues. Such an analysis might be particularly appropriate when evaluating a MEDICAL DEVICE, such as a portable glucose meter, which is used several times a day and possibly in various environments.

If there are several USER GROUPS that might use the product differently, then separate DITL analyses should be completed for each USER GROUP. In addition, DITL analyses should begin with a scenario where everything goes "as expected" (i.e. the MEDICAL DEVICE works as expected [No ALARM SIGNALS, and no unplanned events occur in the person's life]). It should subsequently be expanded to include likely and/or significant events that could occur due to MEDICAL DEVICE malfunctions or unplanned USER events. The DITL analysis provides a useful input into both FUNCTION ANALYSIS and TASK ANALYSIS.

The analysis is performed by identifying all of the interactions that a USER has with the MEDICAL DEVICE over a 24-hour period. USER jobs, TASKS, behaviours, and needs are identified. Typically, analysts start with the first interaction after the USER wakes up in the morning and then chronicles all other significant MEDICAL DEVICE interactions that could occur during the day. For example, if the MEDICAL DEVICE is an insulin pump, the first USER interaction with the MEDICAL DEVICE might be to check his/her blood glucose level prior to eating breakfast or exercising.

The method used to collect DITL data is determined by whether the MEDICAL DEVICE is revolutionary (new product), or evolutionary (enhancement to a MEDICAL DEVICE already on the market). For new MEDICAL DEVICES, prospective USERS can be interviewed or participate in focus groups. The MEDICAL DEVICE concept is represented to USERS and feedback is sought around the functions and features they might want, and when, where, and how they might use the product. Care needs to be taken in the early phases of inquiry to not provide a specific design for the MEDICAL DEVICE concept, but rather determine what USER needs might be met (i.e. what functions are needed, not how they should be implemented). For enhanced MEDICAL DEVICES, interviews of current USERS, focus groups or by conducting ethnographic research are options. The focus should be on determining how current MEDICAL DEVICES are being used, what problems are encountered, and on what additional capabilities might be added to improve utility, USABILITY and/or acceptable use-related RISK.

The results of a DITL analysis can be used to identify:

– those MEDICAL DEVICE functions that are used most frequently;
– the contexts in which they are experienced;
– the sequence in which functions are typically performed; and
– the gaps in functional design, USABILITY and acceptable use-related RISK that could be included or modified to improve product USABILITY and acceptable RISK.

The format for the analysis can be graphical (e.g. flow chart) or narrative.

E.7 Expert reviews

Expert reviews depend on the knowledge and experience of USABILITY SPECIALISTS to identify design strengths and weaknesses and, subsequently, cite opportunities for design improvement. An expert review can be performed on design-concept sketches, working prototypes, and even MEDICAL DEVICES already in use. In the case of an expert review of an unfinished design, many serious design shortcomings can be detected early and without incurring the higher costs normally associated with USABILITY TESTS. However, if applied alone, this technique is unlikely to detect all of the design shortcomings. Also see standards reviews E.17.

E.8 FMEA and FTA

Among the most widely used of the RISK ANALYSIS tools are failure modes and effects analysis (FMEA) and fault tree analysis (FTA). FMEA helps to define, identify, and reduce the probability of "failure modes" (known or potential failures and errors of the MEDICAL DEVICE in its context of use). Failure modes caused by inadequate USABILITY are possible USE ERRORS

that could occur during the preparation and use of the MEDICAL DEVICE. Each failure mode has the following 3 components:

– occurrence (frequency or probability of failure);
– SEVERITY (seriousness of the HARM that could result from the failure); and
– EFFECTIVENESS of the RISK CONTROL measure. [35]

E.9 Focus groups

Similar to one-on-one interviews, focus groups provide an effective technique for understanding the perceptions, opinions, beliefs and attitudes of MEDICAL DEVICE USERS and PATIENTS. Unlike one-on-one interviews, focus groups engage multiple people at a time, providing the opportunity for participants to discuss topics with each other during the group session. Sessions are led by a moderator and typically engage 4 to 8 participants. The moderator is responsible for setting the scope, introducing discussion topics or exercises, ensuring that all participants are reasonably engaged, and keeping the discussion aligned with study objectives. Participants provide their perspective and opinions in discussion with the moderator and other participants in the group.

Depending upon the research goals, focus groups can be conducted early in the USER research phase of a MEDICAL DEVICE'S development, or during design conceptualization. Focus groups can be used to solicit opinions and attitudes about an existing MEDICAL DEVICE or design concept, to explore attributes of MEDICAL DEVICE design that are important, or to define requirements that a design needs to meet to gain USER or PATIENT acceptance. Moreover, focus groups need not adhere to a question-answer format. The moderator can administer questionnaires, have participants provide ratings or compare competing MEDICAL DEVICES, or conduct hands-on exercises with MEDICAL DEVICE prototypes. These activities can facilitate group discussions.

A research study can include multiple interview sessions, including dozens of participants in total. Group participants can be selected to include a heterogeneous group of MEDICAL DEVICE USERS or PATIENTS in the hope that diverse opinions stimulates discussion and generate new insights. Group members can also be more homogeneous with participants sharing similarities in their education, training, age, or MEDICAL DEVICE experience in an effort to identify a common perspective or explore details more fully.

To conduct a successful focus group study, the researcher needs to clearly define the study goals. A discussion guide can be used to organize discussions around topics of interest. To minimize bias and avoid narrowing a discussion too quickly, the discussion should start broadly before tackling specific questions or issues.

USER researchers who employ this technique should be mindful that group dynamics and individuals with strong personalities and unusual perspectives can dominate discussion. That is why it is important to conduct multiple focus groups and for moderators to manage discussions effectively.

E.10 FUNCTION ANALYSIS

FUNCTION ANALYSIS generates the insights necessary to decide what exclusive and shared roles the MEDICAL DEVICE and USER play in the MEDICAL DEVICE'S overall operation. The first step is to determine the given MEDICAL DEVICE'S required functions. The second step is to consider the kinds of functions best performed by MEDICAL DEVICES versus humans. The final step is to allocate functions appropriately to the MEDICAL DEVICE or USER based on their particular strengths and limitations. For example, MEDICAL DEVICES are good at continuously monitoring parameter values and generating ALARM CONDITIONS if anything exceeds a pre-set limit, and good at detecting unusual patterns in data sets, such as a combination of vital sign values that indicate PATIENT distress. Additional information is found in 9.3.

E.11 Heuristic analysis

Heuristic analysis [36] is a specialized type of expert review. The technique calls for one or more USABILITY SPECIALISTS – perhaps three – to conduct an independent expert review of a given design's USER INTERFACE based on selected USABILITY ENGINEERING design heuristics, such as those found in references [4] and [36] using their professional judgment. After identifying design shortcomings, each USABILITY SPECIALIST estimates the degree of the shortcoming and describes in general terms a potential solution. Finally, the USABILITY SPECIALISTS compare their findings, develop consensus findings, and document their findings in a report. Additional information is found in 16.2.2.

E.12 Observation

Observation, a USABILITY ENGINEERING technique that is discussed earlier, is a powerful way to identify potential HAZARD-RELATED USE SCENARIOS. Observation gives an understanding of the use of MEDICAL DEVICES in the real environment. Observers need to ensure that they do not interfere with the workflow or natural behaviour, which can bias the results. During observations, it is possible to study how the USER actually acts and handles the MEDICAL DEVICE. Through observations, it is possible to gain knowledge about behaviours that the USER is not aware of and therefore cannot clearly articulate in an interview.

It can be difficult to find institutions and individuals who are willing to permit such observations. Such observations also pose the dilemma of researchers deciding what to do if they observe a HAZARD-RELATED USE SCENARIO that is leading to HARM. Accordingly, researchers can choose to perform such observations with the support of a clinician who can interpret events – perhaps unobtrusively citing HAZARD-RELATED USE SCENARIOS when they occur – and intervene when necessary to prevent HARM.

Observations of people at work can be followed immediately (as in the case of contextual inquiry), or perhaps at a later hour during the same workday, by interviews (see E.13) involving the observed individuals. Such interviews can focus on the strengths, shortcomings, and opportunities for improvement of the MEDICAL DEVICES in use, and perhaps broader, system integration issues as well.

E.13 One-on-one interviews

One-on-one interviews are an effective technique for gathering qualitative information about MEDICAL DEVICE use. Interviews involve an interviewer (a researcher) and an interviewee (a subject matter expert, MEDICAL DEVICE USER, or PATIENT). Interviews follow a question-answer model, but are conversational. The researcher leads the interview, by introducing topics and initiating discussion through questions. The interviewee provides their thoughts, opinions, attitudes, and beliefs in response.

Depending on the research goals, one-on-one interviews can be conducted early in the USER research phase of a MEDICAL DEVICE'S development, or during design conceptualization. Interviews can be used to identify characteristics that define different USER or PATIENT groups. Interviews can also be used to map out clinical workflows or typical usage scenarios, to identify problems and frustrations with existing MEDICAL DEVICES, to gather opinions and attitudes about different aspects of MEDICAL DEVICE use, to explore design concepts, and to answer specific questions about a design or design issue. An interview study typically includes a sample of interviewees. Larger samples, with 20 or more interviewees, can provide a heterogeneous, but representative mix of subject matter experts, MEDICAL DEVICE USERS, or PATIENTS. Smaller samples, with 6 to 8 interviewees, can be used to evaluate perceptions of a relatively homogenous group who share a common characteristic that affects MEDICAL DEVICE use, such as a job profile, specific disability, or age range.

An interview plan should specify if the interview is planned to be a structured interview an unstructured or hybrid of the two. Structured interviews follow a list of prepared questions and

an unstructured interview does not. During each interview, there should be at least one question offering respondents the opportunity to provide open feedback on any topic they consider germane to the overall discussion.

To conduct a successful interview, the researcher should clearly define the interview goals, draft an appropriate interview guide, and effectively manage the dynamics of each interview. The interview guide includes questions organized around discussion topics. Interviews should follow the guide but allow for unscripted discussion to explore interviewee responses. Questions should be short and open-ended. Interviewers should keep the discussion conversational and frame questions in a way that encourages the interviewee to relate to their own experience, without leading or biasing their responses. Researchers should limit each interview to no more than two hours. When completed, interviews should be analysed to identify patterns or themes, and to catalogue the full range of participant responses.

Interviews can be conducted in person, which is usually optimal, or possibly remotely via telephone or video conference. The remote communication option can be the most cost-effective and rapid way to interact with prospective MEDICAL DEVICE USERS in multiple geographic locations, with national borders posing little obstacle to useful data collection, and with language differences readily overcome by engaging interpreters. However, conducting USER research in-person is most likely to produce better results because face-to-face communication is often more nuanced and informative.

Interviews enable the researcher to collect the USERS' perspectives, which can complement but cannot necessarily replace observations (see E.12). The two research methods generate different types of information, which can sometimes reinforce each other (i.e. when the interview data confirm the researcher's observations). However, at other times, the information generated by each method might conflict and the USER'S reported reasons for observed activities might be quite different from the reasons presumed by the observer.

E.14 Participatory design

Participatory design seeks to provide subjects with the means to illustrate or demonstrate their ideal MEDICAL DEVICE rather than relying on the subjects to imagine and verbally describe their vision. Depending on the stage of development, the best participatory design tool can range from a schematic set of configurable building block modules representing known technical constraints to USER INTERFACE-specific features that are part of a configurable study model.

One participatory design method calls for representative USERS to combine simple blocks representing technical components (e.g. motors, electronics, bladders, batteries, storage, etc.) into desired forms, as well as to place USER INTERFACE features (e.g. buttons, indicators, knobs, etc.) into desired arrangements. Another method is to provide USERS with a functional MEDICAL DEVICE (e.g. a surgical tool that cauterizes tissue) and ask them to shape associated features, such as the tool's gripping surface, or position additional components, such as a cable, in the desired location. The technique can be adapted to enable research participants to compose screens for computer displays.

When performing participatory design studies, it is important to tell the USERS about the MEDICAL DEVICE'S context of use and any inviolable technical constraints. Researchers prompt the USERS to rationalize their creations and photographed the USERS' idealized designs. Later, researchers look for preference patterns among the idealized designs to generate USER INTERFACE REQUIREMENTS and inform subsequent design efforts.

E.15 PCA analysis

One method to identify the potential for USE ERRORS based on TASKS ANALYSIS is called PCA analysis. The method of PCA analysis is derived from the model of USER-MEDICAL DEVICE interaction that is depicted in Figure E.2. Since the method suggests to work along the three

components of USER interactions “perception”, “cognition” and “action” it is referred to as PCA analysis.

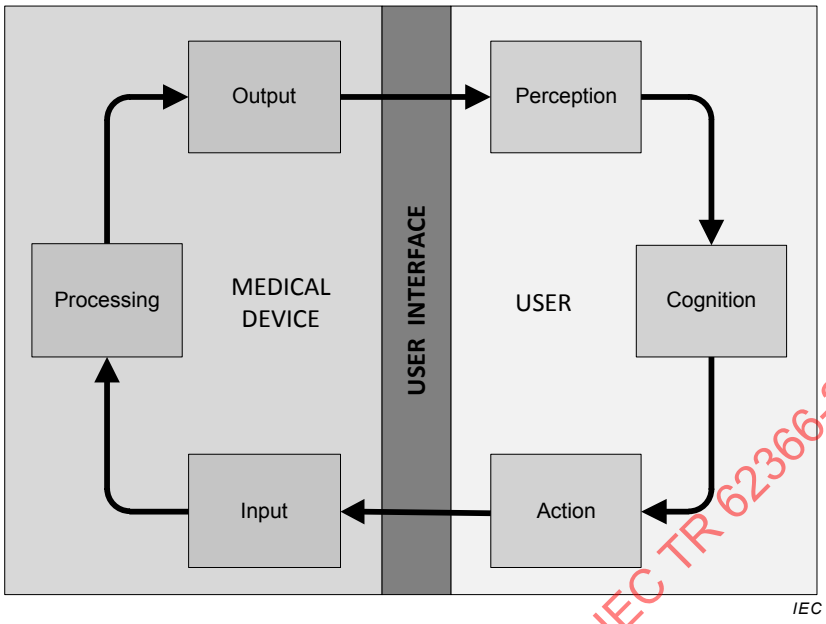

Figure E.2 – Model of USER-MEDICAL DEVICE interaction

For conducting a PCA analysis, the TASKS are decomposed down to the level of individual USER interactions. Individual USER interactions are decomposed into:

– USER perception;

  EXAMPLE 1 Hearing an ALARM SIGNAL, reading text on a screen, feeling a button click.

– cognitive steps; and

  EXAMPLE 2 Recalling information, performing mental calculations, applying rules to reach a decision.

– action.

  EXAMPLE 3 Selecting a menu option, pressing a button, adding fluid to a reservoir.

This decomposition helps the MANUFACTURER to understand what each TASK requires from the USER in terms of perception, cognitive, and physical load. A USE ERROR is likely to occur if the USER is unable to meet one of those TASK requirements. Thus, potential use problems can be identified and become easily apparent by asking the following three questions:

– “What if, the USER is unable to perceive x?”
– “What if, the USER is unable to interpret/process y”
– “What if, the USER is unable to perform the action z?”

By repeating to ask these three questions for every step in a TASK sequence, a preliminary list of potential use problems can be compiled. Not all of these use problems might result in a USE ERROR and not all of the identified potential USE ERRORS might be SAFETY-related.

NOTE As explained in Annex A – 3.21 of IEC 62366-1:2015, a USE ERROR is always bound to erroneous action or inaction. Erroneous perception or cognition are not considered a USE ERROR but can be a cause for a USE ERROR.

However, the list is a beginning of understanding unexpected actions USERS could do with the MEDICAL DEVICE and helps identify those USE ERRORS that are connected to HAZARDOUS SITUATIONS.

E.16 SIMULATION

SIMULATION (as described here) refers to an artificial healthcare environment that is sufficiently realistic to support testing at various stages of MEDICAL DEVICE development, from early stage conceptualization through SUMMATIVE EVALUATION to the evaluation of reported USE ERRORS in marketed MEDICAL DEVICES. SIMULATION requires a physical environment in which clinicians or PATIENTS can interact naturally with a MEDICAL DEVICE or prototype. High-FIDELITY simulators effectively emulate such MEDICAL DEVICE USE ENVIRONMENTS as a PATIENT'S home, clinic treatment room, operating room, emergency department, intensive care unit, dialysis unit, or transport helicopter. An operating room simulator, for example, includes all of the equipment and supplies found in an operating room (bed, tables, lights, electrocautery unit, laparoscopic equipment, anaesthesia machine, drapes, surgical instruments, etc.) as well as human actors (also called confederates), if needed. If the MANUFACTURER were evaluating a surgical MEDICAL DEVICE, the actors might be an anaesthesiologist, scrub technician and circulating nurse, providing prompts, interruptions, distractions, and other attributes that are considered essential (e.g. based on the HAZARD ANALYSIS) to evaluate the MEDICAL DEVICE under a range of high use, high RISK, high cost, or other conditions.

Depending on the goals of the SIMULATION, the simulated "PATIENT" can be played by another actor (a "standardized PATIENT") or by a manikin. SIMULATION manikins range from fully inanimate plastic "dummies" with only a physical human resemblance, to very sophisticated computer controlled electromechanical systems that can talk, tear, sweat, breathe, and manifest all of the typically measured physiological "vital signs" of a real human. Figure E.3 demonstrates examples of PATIENT SIMULATION.

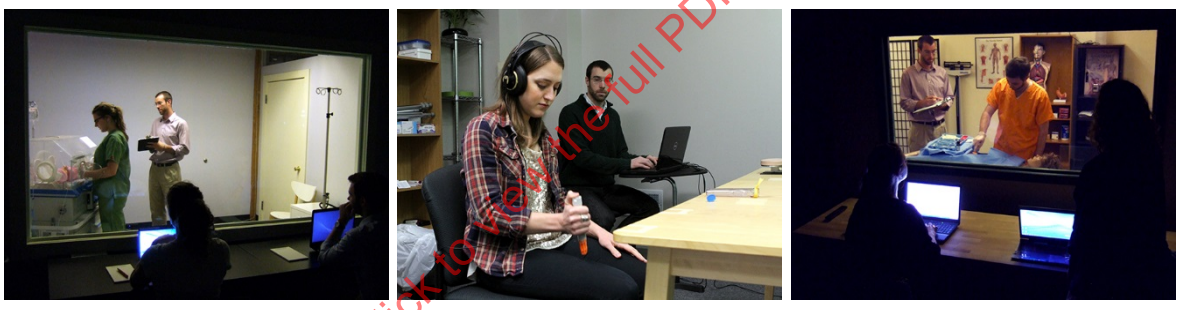

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Figure E.3 – Infant manikin used in a neonatal care unit simulator (left), test participant simulating an auto-injector (centre) and an adult manikin used in a surgery SIMULATION (right)

Conducting high-FIDELITY SIMULATIONS is expensive and thus should be done selectively, with good preparation, and only by those with appreciable experience. Like a USABILITY TEST, the first step is to create a robust plan. SIMULATIONS are based on "scenarios," which are scripts that describe the goals of the SIMULATION, all of the "props" needed, a story or instructions for the SIMULATION participant (e.g. a nurse or a PATIENT), and step-by-step instructions for the engineers running the SIMULATION scenario, including what to do at each step when the participant behaves in different ways. The engineers running the SIMULATION and design teams typically view the participants during the SIMULATION from behind a one-way mirror and/or on video. In fact, a critical aspect of a SIMULATION is the use of high-quality, multi-angle, audio-video recording that can often be annotated in real time by the design team.

E.17 Standards reviews

A standards review calls for one or more USABILITY SPECIALISTS to assess a USER INTERFACE according to established USABILITY ENGINEERING practices, such as those described in Reference [4] as well as style guides. Standards reviews are relatively quick and cost-effective, but can yield only a superficial understanding of USER INTERFACE issues that are better assessed by means of USABILITY TESTS, for example. Also see expert reviews, E.7.