

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



Medical devices – Application of usability engineering to medical devices

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



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Medical devices – Application of usability engineering to medical devices

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040

ISBN 978-2-8322-1371-1

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Medical devices – Application of usability engineering to medical devices

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

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APPLICATION OF USABILITY ENGINEERING
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This Consolidated version of IEC 62366 bears the edition number 1.1. It consists of the first edition (2007-10) [documents 62A/574/FDIS and 62A/579/RVD] and its amendment 1 (2014-01) [documents 62A/889/FDIS and 62A/897/RVD]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted is available in this publication.

This publication has been prepared for user convenience.

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

It is published as double logo standard.

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

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

- Requirements and definitions: roman type.
- *Means to assess compliance: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type
- TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The requirements are followed by means to assess compliance.

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

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INTRODUCTION

Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING PROCESS are non-intuitive, difficult to learn and to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. In simpler times, the USER of a MEDICAL DEVICE might be able to cope with an ambiguous, difficult-to-use USER INTERFACE. The design of a usable MEDICAL DEVICE is a challenging endeavour, yet many organizations treat it as if it were just “common sense”. The design of the USER INTERFACE to achieve adequate (safe) USABILITY requires a very different skill set than that of the technical implementation of that interface.

The USABILITY ENGINEERING PROCESS is intended to achieve reasonable USABILITY, which in turn is intended to minimise USE ERRORS and to minimise use-associated RISKS. Some, but not all, forms of incorrect use are amenable to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.1.

This International Standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide SAFETY in MEDICAL DEVICES. It is intended to be useful not only for MANUFACTURERS of MEDICAL DEVICES, but also for technical committees responsible for the preparation of particular MEDICAL DEVICE standards.

Amendment 1 updates the standard to add urgently needed requirements to deal with legacy devices where the USER INTERFACE design is of unknown provenance.

INTRODUCTION TO THE AMENDMENT

The first edition of IEC 62366 was published in 2007. This amendment is intended to add urgently needed requirements to deal with legacy devices for which the user interface design is of unknown provenance. Work is continuing in parallel to develop the second edition of IEC 62366.

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

This International Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to SAFETY of a MEDICAL DEVICE. This USABILITY ENGINEERING PROCESS assesses and mitigates RISKS caused by USABILITY problems associated with CORRECT USE and USE ERRORS, i.e. NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

NOTE For the purposes of this standard, USABILITY (see 3.17) is limited to characteristics of the USER INTERFACE.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of a MEDICAL DEVICE are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2).

This International Standard does not apply to clinical decision-making relating to the use of a MEDICAL DEVICE.

2 Normative references

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

NOTE Informative references are listed in the bibliography beginning on page 96.

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

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 14971:2007 and the following apply.

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

3.1

ABNORMAL USE

intentional act or intentional omission of an act by the RESPONSIBLE ORGANIZATION or USER of a MEDICAL DEVICE as a result of conduct that is beyond any further reasonable means of RISK CONTROL by the MANUFACTURER

NOTE 1 See also 4.1.3 and Annex B. Examples are given in Annex C.

NOTE 2 It is possible for the PATIENT to be the USER, e.g. when the MEDICAL DEVICE is used in the PATIENT'S home.

3.2

ACCOMPANYING DOCUMENT

document accompanying a MEDICAL DEVICE and containing information for those accountable for the installation, use and maintenance of the MEDICAL DEVICE or the USER, particularly regarding SAFETY

[ISO 14971:2007, definition 2.1, modified]

3.3

ALARM LIMIT

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

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

NOTE This term is only used in notes and informative annexes.

3.4

ALARM OFF

state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.4]

NOTE This term is only used in notes and informative annexes.

3.5

ALARM SIGNAL

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

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

NOTE This term is only used in notes and informative annexes.

3.6

ALARM SYSTEM

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

[IEC 60601-1-8:2006, definition 3.11, modified]

NOTE This term is only used in notes and informative annexes.

3.7

CORRECT USE

NORMAL USE without USE ERROR

3.8

EFFECTIVENESS

measure of accuracy and completeness with which USERS achieve specified goals

[ISO 9241-11:1998, definition 3.2, modified]

NOTE This is a different concept than the 'clinical effectiveness'.

3.9

EFFICIENCY

EFFECTIVENESS in relation to the resources expended

3.10

INFORMATION SIGNAL

any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

[IEC 60601-1-8:2006, definition 3.23]

NOTE This term is only used in notes and informative annexes.

3.11

MEDICAL DEVICE

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
- supporting or sustaining life,
- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its function by such means.

[ISO 13485:2003, definition 3.7]

3.12

* NORMAL USE

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

[IEC 60601-1:2005, definition 3.71, modified]

NOTE 1 USE ERROR can occur in NORMAL USE.

NOTE 2 MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

3.13

* PATIENT

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

[IEC 60601-1:2005, definition 3.76, modified]

3.14

* PRIMARY OPERATING FUNCTION

function that involves USER interaction that is either frequently used or related to the SAFETY of the MEDICAL DEVICE

3.15

REMINDER SIGNAL

periodic signal that reminds the USER that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

[IEC 60601-1-8:2006, definition 3.34, modified]

NOTE This term is only used in notes and informative annexes.

3.16**RESPONSIBLE ORGANIZATION**

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

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

NOTE 2 Education and training is included in "use."

[IEC 60601-1:2005, definition 3.101, modified]

3.17*** USABILITY**

characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction

3.18**USABILITY ENGINEERING**

application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

3.19*** USABILITY ENGINEERING FILE**

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

3.20**USABILITY SPECIFICATION**

documentation defining the USER INTERFACE requirements related to USABILITY

3.21**USE ERROR**

act or omission of an act that results in a different MEDICAL DEVICE response than intended by the MANUFACTURER or expected by the USER

NOTE 1 USE ERROR includes slips, lapses, and mistakes.

NOTE 2 See also Annex B and D.1.3.

NOTE 3 An unexpected physiological response of the PATIENT is not in itself considered USE ERROR.

3.22**USE SCENARIO**

specified sequence of events and tasks as performed by a specified USER in a specified environment

3.23*** USER**

person using, i.e. operating or handling, the MEDICAL DEVICE

NOTE 1 This includes, but is not limited to, cleaners, maintainers and installers.

NOTE 2 PATIENTS or other laypersons can be USERS.

3.24*** USER INTERFACE**

means by which the USER and the MEDICAL DEVICE interact

[ANSI/AAMI/HE 74:2001, definition 3.24, modified]

NOTE The ACCOMPANYING DOCUMENT is considered part of the MEDICAL DEVICE and its USER INTERFACE

3.25

USER PROFILE

summary of the mental, physical and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

3.26

VALIDATION

confirmation, through the provision of OBJECTIVE EVIDENCE, that the requirements for a specific INTENDED USE or application have been fulfilled

NOTE 1 The term “VALIDATED” is used to designate the corresponding status.

NOTE 2 The use conditions for VALIDATION can be real or simulated.

[ISO 9000:2000, definition 3.8.5]

3.27

USER INTERFACE OF UNKNOWN PROVENANCE

UOUP

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

4 * Principles

4.1 General requirements

4.1.1 * USABILITY ENGINEERING PROCESS

The MANUFACTURER shall establish, document and maintain a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY. The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT, including, but not limited to:

- * transport;
- * storage;
- installation;
- operation;
- maintenance and repair; and
- disposal.

NOTE See also D.3.1.

Consider compliance with the requirements of this clause to exist when the criteria of the relevant inspections and tests in this International Standard are achieved.

4.1.2 RESIDUAL RISK

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9), then, for the purposes of ISO 14971, the RESIDUAL RISKS associated with USABILITY of the MEDICAL DEVICE shall be presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 1 Such OBJECTIVE EVIDENCE can subsequently originate from post-market surveillance.

NOTE 2 ISO 14971:2007, Subclause 6.6 requires that design changes resulting from the USABILITY ENGINEERING PROCESS be reviewed to determine if other HAZARDS or HAZARDOUS SITUATIONS have been generated.

NOTE 3 ISO 14971:2007, Clause 7 requires that all RESIDUAL RISK be considered when evaluating the overall RESIDUAL RISK of the MEDICAL DEVICE, including the RESIDUAL RISK associated with USABILITY of the MEDICAL DEVICE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

4.1.3 Information for SAFETY

If information for SAFETY is used as a RISK CONTROL measure, the MANUFACTURER shall subject this information to the USABILITY ENGINEERING PROCESS.

EXAMPLE 1 Warnings or limitation of use in the ACCOMPANYING DOCUMENT

EXAMPLE 2 Markings

Disregarding such information for SAFETY shall be considered beyond any further reasonable means of RISK CONTROL. See also Annex B.

NOTE 1 Information for SAFETY is one element in a hierarchical approach to RISK CONTROL in which the MANUFACTURER uses one or more of the following in the priority listed (see ISO 14971:2007, 6.2):

- a) inherent SAFETY by design;
- b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS, e.g. ALARM SYSTEMS;
- c) information for SAFETY, e.g. warnings in the instructions for use, display of a monitored variable, training and materials for training, maintenance details.

NOTE 2 The need to include information for SAFETY can be an input to the USABILITY ENGINEERING PROCESS (e.g. imposed by some other standard) or it can be discovered during the USABILITY ENGINEERING PROCESS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENT and the USABILITY ENGINEERING FILE.

4.2 * USABILITY ENGINEERING FILE

The results of the USABILITY ENGINEERING PROCESS shall be recorded in the USABILITY ENGINEERING FILE. The RECORDS and other documents that form the USABILITY ENGINEERING FILE may form part of other documents and files.

EXAMPLE 1 MANUFACTURER'S product design file

EXAMPLE 2 RISK MANAGEMENT FILE

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

4.3 Scaling of the USABILITY ENGINEERING effort

The USABILITY ENGINEERING PROCESS may vary in form and extent based on the nature of the MEDICAL DEVICE, its intended USER and its INTENDED USE (see D.3.2). In the case of the modification of a MEDICAL DEVICE design, the USABILITY ENGINEERING PROCESS may be scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS (see D.3.2.2).

NOTE 1 The MANUFACTURER should conduct iterative design and development. USABILITY ENGINEERING, including USABILITY VALIDATION, should begin early and continue through the MEDICAL DEVICE design and development lifecycle.

NOTE 2 Due to the iterative nature of the USABILITY ENGINEERING PROCESS, the activities described in Clause 5 can be carried out in any convenient order (see Clause D.2).

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5 * USABILITY ENGINEERING PROCESS

5.1 * Application specification

The MANUFACTURER shall specify the application of the MEDICAL DEVICE in the USABILITY ENGINEERING FILE.

This specification shall include:

- * intended medical indication;

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

- intended PATIENT population;

EXAMPLE 2 age

EXAMPLE 3 weight

EXAMPLE 4 health

EXAMPLE 5 condition

- intended part of the body or type of tissue applied to or interacted with;
- * intended USER PROFILE;
- * intended conditions of use; and

EXAMPLE 6 environment including hygienic requirements

EXAMPLE 7 frequency of use

EXAMPLE 8 location

EXAMPLE 9 mobility

- * operating principle.

NOTE Requirements for disclosing a summary of the MEDICAL DEVICE APPLICATION SPECIFICATION in the ACCOMPANYING DOCUMENT are found in Clause 6.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.2 * Frequently used functions

The MANUFACTURER shall determine the frequently used functions that involve USER interaction with the MEDICAL DEVICE and record them in the USABILITY ENGINEERING FILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.3 Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY

5.3.1 Identification of characteristics related to SAFETY

An identification of characteristics related to SAFETY (part of a RISK ANALYSIS) that focuses on USABILITY shall be performed according to ISO 14971:2007, 4.2.

During the identification characteristics related to SAFETY, the following shall be considered:

- application specification, including USER PROFILE(S) (see 5.1); and
- frequently used functions (see 5.2).

The results of this identification characteristics related to SAFETY shall be recorded in the USABILITY ENGINEERING FILE.

NOTE 1 See also D.4.3, D.4.6.4, D.5.2, and D.5.4 for a discussion of methods that might be useful in identifying characteristics related to SAFETY.

NOTE 2 See 4.3 for scaling of the USABILITY ENGINEERING effort.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.3.2 * Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

The MANUFACTURER shall identify known or foreseeable HAZARDS (part of a RISK ANALYSIS) related to USABILITY according to ISO 14971:2007, 4.3. The identification of HAZARDS shall consider HAZARDS to PATIENTS, USERS and other persons (see Annex E and Annex F).

Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE shall be identified. The SEVERITY of the resulting possible HARM shall be determined.

During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following shall be considered:

- application specification, including USER PROFILE(S) (see 5.1);
- * task related requirements;
- * context of use;
- information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available;
- preliminary USE SCENARIOS;
- possible USE ERRORS (see C.2 for some examples of potential USE ERRORS);
- * if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION; and
- * results of the review of the USER INTERFACE (see C.4 and D.2.2).

The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY shall be recorded in the USABILITY ENGINEERING FILE.

NOTE 1 See also D.5.9, D.5.14 and D.5.17 for a discussion of methods that might be useful in identifying known or foreseeable HAZARDS or HAZARDOUS SITUATIONS.

NOTE 2 The identification of HAZARDS and HAZARDOUS SITUATIONS for the MEDICAL DEVICE or for the corresponding generic device type is an input for the USABILITY SPECIFICATION as required for the USABILITY ENGINEERING PROCESS.

NOTE 3 During the identification of HAZARDS or HAZARDOUS SITUATIONS, ABNORMAL USE conditions can be identified. See also C.1.

NOTE 4 The evaluation of post-production information (post-market surveillance) should include USABILITY (see ISO 14971:2007, Clause 9).

NOTE 5 See 4.3 for scaling of the USABILITY ENGINEERING effort.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.4 PRIMARY OPERATING FUNCTIONS

The MANUFACTURER shall determine the PRIMARY OPERATING FUNCTIONS and record them in the USABILITY ENGINEERING FILE.

The inputs to the PRIMARY OPERATING FUNCTIONS shall include the following:

- frequently used functions (see 5.2); and
- functions related to SAFETY of the MEDICAL DEVICE.

NOTE 1 See also D.5.7 for discussion of a method that might be useful in determining PRIMARY OPERATING FUNCTIONS.

NOTE 2 See H.2.2 for an example of PRIMARY OPERATING FUNCTIONS for a hypothetical MEDICAL DEVICE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.5 * USABILITY SPECIFICATION

The MANUFACTURER shall develop the USABILITY SPECIFICATION. The USABILITY SPECIFICATION shall provide:

- testable requirements for USABILITY VERIFICATION; and
- testable requirements for USABILITY of the PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.

NOTE 1 Testable requirements for USABILITY of the PRIMARY OPERATING FUNCTIONS can be expressed as USABILITY goals. For examples see Table D.5, Table D.6, and Annex G.

NOTE 2 The criteria for determining adequacy correspond to the criteria for RISK acceptability in ISO 14971:2007, 3.4 d).

NOTE 3 Guidance on the evaluation of the adequacy of RISK CONTROL measures can be found in ISO 14971:2007, D.4.

The USABILITY SPECIFICATION shall be recorded in the USABILITY ENGINEERING FILE. The USABILITY SPECIFICATION may be integrated into other specifications.

The inputs to the USABILITY SPECIFICATION shall include the following:

- application specification (see 5.1);
- PRIMARY OPERATING FUNCTIONS (see 5.4);
- HAZARDS and HAZARDOUS SITUATIONS related to USABILITY (see 5.3); and
- known or foreseeable USE ERRORS associated with the MEDICAL DEVICE.

The USABILITY SPECIFICATION shall describe at least:

- USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS, including;
 - * frequent USE SCENARIOS; and
 - reasonably foreseeable worst case USE SCENARIOS;
- USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK;
- requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER.

NOTE 3 See also D.2.6, D.3.3 and D.4.4 for guidance in preparing USABILITY SPECIFICATIONS.

NOTE 4 The USABILITY SPECIFICATION should describe the context of use (see the rationale for 5.3 and D.4.1.2.4).

NOTE 5 See Annex H for an example of a USABILITY SPECIFICATION for a hypothetical MEDICAL DEVICE.

NOTE 6 See 4.3 for scaling of the USABILITY ENGINEERING effort.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.6 USABILITY VALIDATION plan

The MANUFACTURER shall prepare and maintain a USABILITY VALIDATION plan. The USABILITY VALIDATION plan shall specify:

- any method used for VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS.

- the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION; and

NOTE 1 The acceptance criteria for VALIDATION of the PRIMARY OPERATING FUNCTIONS correspond to the criteria for RISK acceptability in ISO 14971:2007, 3.4 d).

- the involvement of representative intended USERS.

USABILITY VALIDATION methods may be quantitative or qualitative. USABILITY VALIDATION may be performed in a laboratory setting, in a simulated use environment or in the actual use environment.

NOTE 2 See also D.4.4 and D.4.7.3 for guidance on preparing a USABILITY VALIDATION plan.

NOTE 3 The MANUFACTURER should apply one or more methods for the USABILITY VALIDATION of PRIMARY OPERATING FUNCTIONS of the MEDICAL DEVICE depending on the INTENDED USE. Examples of these methods are found in D.5.

NOTE 4 Findings based on any single method can be insufficient, e.g. in a clinical evaluation it might not be possible to explore some high-RISK situations.

The USABILITY VALIDATION plan shall address:

- frequent USE SCENARIOS, and
- reasonably foreseeable worst case USE SCENARIOS,

that are identified in the USABILITY SPECIFICATION.

NOTE 5 See 4.3 for scaling of the USABILITY ENGINEERING effort.

The USABILITY VALIDATION plan shall be recorded in the USABILITY ENGINEERING FILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.7 * USER INTERFACE design and implementation

The MANUFACTURER shall design and implement the USER INTERFACE as described in the USABILITY SPECIFICATION utilizing, as appropriate, USABILITY ENGINEERING methods and techniques.

NOTE 1 See also D.4 and D.5 for guidance in preparing USER INTERFACE design and implementation.

NOTE 2 The MANUFACTURER should conduct iterative design and development. USABILITY ENGINEERING, including USABILITY VALIDATION, should begin early and continue through the MEDICAL DEVICE design and development lifecycle.

NOTE 3 In considering the options for RISK CONTROL, ISO 14971:2007, 6.2 requires that the MANUFACTURER uses one or more of the following in the priority listed:

- a) inherent SAFETY by design;
- b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS, e.g. ALARM SYSTEMS;
- c) information for SAFETY, e.g. warnings in the instructions for use, display of a monitored variable, training and materials for training, maintenance details.

Consider compliance with the requirements of this subclause to exist when the requirements of 5.8 and 5.9 have been fulfilled.

5.8 * USABILITY VERIFICATION

As part of the MEDICAL DEVICE design VERIFICATION PROCESS, the MANUFACTURER shall VERIFY the implementation of the MEDICAL DEVICE USER INTERFACE design against the requirements of the USABILITY SPECIFICATION. The results of the VERIFICATION shall be recorded in USABILITY ENGINEERING FILE.

NOTE 1 See also D.5.2, D.5.4, D.5.6, D.5.8 and D.5.15 for guidance on USABILITY VERIFICATION.

NOTE 2 See 4.3 for scaling of the USABILITY ENGINEERING effort.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.9 * USABILITY VALIDATION

The MANUFACTURER shall VALIDATE USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan. The results shall be recorded in the USABILITY ENGINEERING FILE.

NOTE 1 See also D.5.13 and D.5.15 for guidance on performing a USABILITY VALIDATION.

NOTE 2 ISO 14971:2007, Subclause 6.6 requires that design changes resulting from the USABILITY ENGINEERING PROCESS be reviewed to determine if other HAZARDS or HAZARDOUS SITUATIONS have been generated.

NOTE 3 An accompanying document is part of the medical device user interface and is subject to activities for validating usability.

NOTE 4 Individuals that were not directly responsible for the USER INTERFACE design should be involved in the USABILITY VALIDATION.

If the acceptance criteria documented in the USABILITY VALIDATION plan are not met:

- further USER INTERFACE design and implementation activities shall be performed (see 5.6); or
- if further improvement is not practicable, the MANUFACTURER may gather and review data and literature to determine if the medical benefits of the INTENDED USE outweigh the RISK arising from USABILITY problems. If this evidence does not support the conclusion that the MEDICAL benefits outweigh the RISK, then the RISK is unacceptable.

NOTE 5 To perform this step, the MANUFACTURER needs to estimate the RISK arising from USABILITY problems.

NOTE 6 The results of the USABILITY VALIDATION PROCESS should be used in the evaluation of RESIDUAL RISK (see ISO 14971:2007, Subclause 6.4).

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5.10 * USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)

Instead of all of the requirements of 5.1 through 5.9, UOUP may be evaluated according to Annex K.

Compliance is checked by application of Annex K.

6 * ACCOMPANYING DOCUMENT

If provided, the ACCOMPANYING DOCUMENT shall include a summary of the MEDICAL DEVICE application specification (see 5.1).

NOTE 1 The summary of the MEDICAL DEVICE application specification is referred to in some regulatory schemes as the 'statement of intended use'.

If provided, the ACCOMPANYING DOCUMENT shall include a concise description of the MEDICAL DEVICE which includes, where relevant to its use:

- operating principle;
- significant physical characteristics;
- significant performance characteristics; and
- intended USER PROFILE.

NOTE 2 An important purpose of this description is to help the USER to develop a correct mental model of the MEDICAL DEVICE (see the rationale for 5.3.2 and D.5.14.3).

If provided, the ACCOMPANYING DOCUMENT shall be written at a level consistent with the USER PROFILE.

The ACCOMPANYING DOCUMENT may be provided electronically. If the ACCOMPANYING DOCUMENT is provided electronically, the USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the MEDICAL DEVICE.

EXAMPLE Information to cover emergency operation

Compliance is checked by inspection of the ACCOMPANYING DOCUMENT and the USABILITY ENGINEERING FILE.

7 * Training and materials for training

If training on the specific MEDICAL DEVICE is required for the safe and effective use of a PRIMARY OPERATING FUNCTION by the intended USER, the MANUFACTURER shall do at least one of the following:

- provide the materials necessary for training;
- ensure that the materials necessary for training are available; or
- provide the training.

If such training is required, the ACCOMPANYING DOCUMENT shall describe the available training options and should include the suggested duration and frequency of such training.

If such training is required, the INTENDED USE and USER PROFILE(S) shall be the basis for training and training material.

NOTE 1 Training on the specific MEDICAL DEVICE can be used to provide the knowledge and skills required for safe and effective use of the MEDICAL DEVICE beyond the knowledge and skills defined by the intended USER PROFILE(S).

NOTE 2 See IEC 61258 [3] ¹.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENT and the USABILITY ENGINEERING FILE.

¹ Figures in square brackets refer to the bibliography.

Annex A (informative)

General guidance and rationale

A.1 Introduction

This annex provides a rationale for this International Standard. Its purpose is to promote effective application of the standard by explaining the reasons for the requirements and definitions and to provide additional guidance where appropriate.

A.2 Rationale for requirements in particular clauses and subclauses

Clause 1 – Scope

This International Standard focuses on the **USABILITY** of the **USER INTERFACE** of a **MEDICAL DEVICE**. **USABILITY**, in general, includes attributes such as **USER** satisfaction and **EFFICIENCY** that are not directly related to the **USER INTERFACE** of a **MEDICAL DEVICE** and its **SAFETY** and are not considered by this standard. An example of device attributes that are not considered could include the aesthetics of the device or the amount of supplies consumed.

This International Standard uses the concept of **USE ERROR**. The term was chosen over the more commonly used terms of “user error” or “human error” because not all errors associated with the use of a **MEDICAL DEVICE** are the result of oversight or carelessness on the part of the **USER** of the **MEDICAL DEVICE**. Much more commonly, **USE ERRORS** are the direct result of poor **USER INTERFACE** design.

Some **USER INTERFACE** designs contribute to **USE ERROR** because they employ non-intuitive or counter-intuitive displays or controls. The consequences of such design flaws often only become apparent when the **USER** is using the **MEDICAL DEVICE** in an emergency or stressful situation, is fatigued, or uses the **MEDICAL DEVICE** only rarely.

The scope of this International Standard applies when a **MEDICAL DEVICE** is used according to the instructions for use, i.e. **NORMAL USE**. The **USER** can make a **USE ERROR** (i.e., a slip, lapse or mistake) while attempting to use a **MEDICAL DEVICE** in accordance with its instructions for use. Since a **USE ERROR** can occur in **NORMAL USE**, this standard introduces the new concept and term, **CORRECT USE**, to describe the situation where the **USER** follows the instructions for use without committing a **USE ERROR**.

A **MEDICAL DEVICE** can also be used in ways contrary to those described in the instructions for use. For the purposes of this standard, such use is described as **ABNORMAL USE**. While the **USABILITY ENGINEERING PROCESS** can be used to identify **ABNORMAL USE**, this International Standard does not require the **USABILITY ENGINEERING PROCESS** to be used to assess or mitigate **RISKS** associated with **ABNORMAL USE**.

The scope of this International Standard does not apply to clinical decision-making relating to the use of a **MEDICAL DEVICE**. The decision to use a **MEDICAL DEVICE** in the context of a particular clinical procedure requires the **RESIDUAL RISKS** to be balanced against the anticipated benefits of the procedure. Such judgments should take into account the **INTENDED USE**, performance, and **RISKS** associated with the **MEDICAL DEVICE**, as well as the **RISKS** and benefits associated with the clinical procedure or the circumstances of use. Some of these judgments can be made only by a qualified medical practitioner with knowledge of the state of health of an individual **PATIENT** or the **PATIENT’S** own opinion.

Definition 3.12 – NORMAL USE

NORMAL USE is differentiated from CORRECT USE because a USE ERROR (i.e., a slip, lapse or mistake) can occur while attempting to use a MEDICAL DEVICE in accordance with its instructions for use.

NORMAL USE encompasses all foreseeable USER actions when a USER is operating a MEDICAL DEVICE according to the MANUFACTURER'S INTENDED USE for that device. It specifically excludes ABNORMAL USE. See also Figure B.1. NORMAL USE is simply what is expected from a USER under normal conditions of use, which includes actions that are either correct or in error, but not contrary to the design intentions of the MANUFACTURER.

There are MEDICAL DEVICES that can be used safely without instructions for use, e.g. forceps, scalpel. For such devices, NORMAL USE is established by use in accordance with generally accepted practice.

Definition 3.13 – PATIENT

The definition in IEC 60601-1 includes animals. To harmonize with the ISO 13485 definition of MEDICAL DEVICE, animals were removed from the definition of PATIENT.

Definition 3.14 – PRIMARY OPERATING FUNCTION

For the purposes of this International Standard, a PRIMARY OPERATING FUNCTION is a function that is directly related to the SAFETY of the MEDICAL DEVICE or a function that is frequently used. Examples of PRIMARY OPERATING FUNCTION that directly relate to SAFETY include:

- inactivation of an ALARM SIGNAL (temporarily or indefinitely);
- adjustable ALARM LIMITS;
- adjustable X-ray exposure parameters (e.g. kV_p, mA);
- adjustable infusion parameters (e.g. flow rate);
- adjustable gas flow rates and anaesthetic vaporizer concentration.

Frequently used functions are included in the PRIMARY OPERATING FUNCTIONS because inadequate USABILITY of the frequently used functions adds to USERS' workloads and can be a source of frustration, increasing the probability of USE ERRORS affecting SAFETY-related functions.

Definition 3.17 – USABILITY

USABILITY is a measure of the EFFECTIVENESS, EFFICIENCY, and satisfaction with which specified USERS achieve specified goals in particular environments, within the scope of the INTENDED USE of the MEDICAL DEVICE. Many of these factors can influence SAFETY to various extents.

The time needed to become acquainted with the MEDICAL DEVICE and its operation is called "learnability" (ISO 9241-11:1998, Table B.2). Freedom from discomfort and positive attitude towards the use of the MEDICAL DEVICE is called "satisfaction" (ISO 9241-11:1998, definition 3.4).

NOTE How easy it is to remember the operational details of a MEDICAL DEVICE can be thought of as "memorizability" [29]. Memorizability becomes important when a particular MEDICAL DEVICE is infrequently used by the USER.

To determine if the MEDICAL DEVICE exhibits adequate USABILITY, specifications for the following influencing factors are required:

- USER;
- task/goals; and

- conditions and setting in which the USER interacts with the MEDICAL DEVICE.

This is because a change in a single factor could change the USABILITY significantly.

EXAMPLE An AC / battery-powered ECG monitor that works perfectly well in the relatively protected environment of an ICU ward could exhibit severe drawbacks in USABILITY if it were to be used outside at night. This is a change in the conditions and setting. In the new location of use, the influencing factors vary for:

- power up / pre-check needs;
- ambient light (night, bright sunlight), reflections; or
- requirements for handling, transportation, weight.

Definition 3.19 – USABILITY ENGINEERING FILE

The USABILITY ENGINEERING FILE is often part of the RISK MANAGEMENT FILE. There is no requirement for the USABILITY ENGINEERING FILE to be independently stored from the RISK MANAGEMENT FILE. The USABILITY ENGINEERING FILE need not physically contain all the RECORDS and other documents produced by USABILITY ENGINEERING activities. However, it should contain at least references or pointers to all required documentation.

Definition 3.23 – USER

USER is the commonly used term in the USABILITY ENGINEERING profession for all and any humans that might handle, operate or otherwise interact with a device. There can be a wide diversity of such individuals for any particular device including: installers, engineers, technicians, clinicians, PATIENTS, care givers, cleaners, sales, marketing, etc. A USER interacts with a MEDICAL DEVICE through its USER INTERFACE. A USER is distinct from the entity called RESPONSIBLE ORGANIZATION. USERS can be members of the RESPONSIBLE ORGANIZATION.

However, for the purposes of this International Standard, we need a term and definition that encompasses all of the persons who operate or handle MEDICAL DEVICES. As noted above, other standards have used the verb interact in addition to operate or handle. The PATIENT interacts with a MEDICAL DEVICE by virtue of being the individual receiving treatment, being monitored or diagnosed. This interaction can be independent of operating or handling the MEDICAL DEVICE. However, there are situations when the PATIENT is the USER, for example, a home glucose monitor.

In many situations the person operating or handling the MEDICAL DEVICE is performing tasks unrelated to treating, monitoring or diagnosing the PATIENT, for example, installing, cleaning, moving, maintaining.

Definition 3.24 – USER INTERFACE

The USER INTERFACE includes all means of interaction between the MEDICAL DEVICE and the USER. These means include, but are not limited to:

- manual manipulation;
- handles;
- markings and ACCOMPANYING DOCUMENT;
- lights;
- video displays;
- push buttons;
- touch screens;
- auditory and visual INFORMATION SIGNALS;
- ALARM SIGNALS;
- vibratory signals;
- speech, e.g. voice recognition, speech synthesis;

- keyboard and mouse; and
- haptic controls.

Clause 4 – Principles

This International Standard specifies requirements addressing RISKS associated with USABILITY.

In addition to the common USE SCENARIOS involving installation, operation and maintenance, SAFETY of a MEDICAL DEVICE can be impacted by many different interactions including transportation and storage.

Subclause 4.1.1 – USABILITY ENGINEERING PROCESS

(transport)

During transportation, design-induced USE ERRORS can lead to damage of a MEDICAL DEVICE by, for example, improper use of carrying handles while it is being transported. Another example of design-induced USE ERROR is packing the MEDICAL DEVICE in an improper position prior to shipping that leads to damage while in transit.

(storage)

Similarly, USE ERRORS due to improper configuration during storage of a MEDICAL DEVICE can cause damage. For example, a design can lead a USER to stack a MEDICAL DEVICE in a way that causes damage. Design-induced USE ERRORS could also lead a USER to store a MEDICAL DEVICE in an inappropriate condition, such as leaving a door open while in storage thereby causing damage.

Subclause 4.2 – USABILITY ENGINEERING FILE

The standard uses the term USABILITY ENGINEERING FILE to signify where the MANUFACTURER can locate or find the locations of all the RECORDS and other documents applicable to USABILITY ENGINEERING. This facilitates the USABILITY ENGINEERING PROCESS and enables more efficient auditing to this standard. Traceability is necessary to demonstrate that the USABILITY ENGINEERING PROCESS has been applied.

Clause 5 – USABILITY ENGINEERING PROCESS

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

- RISK ANALYSIS;
- RISK EVALUATION;
- RISK CONTROL; and
- production and post-production information.

When applying a comprehensive RISK MANAGEMENT PROCESS to the USER INTERFACE, estimating the RISK for each USE ERROR is problematic, particularly because no VALIDATED techniques are known to exist to predict, in advance, the likelihood of a person committing a USE ERROR. However, this International Standard provides a PROCESS that a MANUFACTURER can use to analyze, specify, design, VERIFY and VALIDATE the USABILITY of a MEDICAL DEVICE. Implementing this PROCESS and meeting the USABILITY goals established early in this PROCESS,

permits the MANUFACTURER to deal with the unpredictability of a USER and minimize USE ERRORS. This PROCESS helps the MANUFACTURER accomplish these objectives by:

- a) discovering HAZARDS and HAZARDOUS SITUATIONS related to the USER INTERFACE;
- b) designing and implementing measures to control the RISKS related to the USER INTERFACE; and
- c) VERIFYING and VALIDATING of the RISK CONTROL measures.

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

Figure A.1 provides an overview of the RISK MANAGEMENT PROCESS in ISO 14971 and the USABILITY ENGINEERING PROCESS of this standard. When comparing the two PROCESSES, it is important to understand the difference between the RISK MANAGEMENT PROCESS in ISO 14971 and the USABILITY ENGINEERING PROCESS in this standard. RISK MANAGEMENT is a decision-making PROCESS for determining acceptable RISK whereas USABILITY ENGINEERING is a design and development PROCESS for the USER INTERFACE that also addresses RISKS associated with USABILITY.

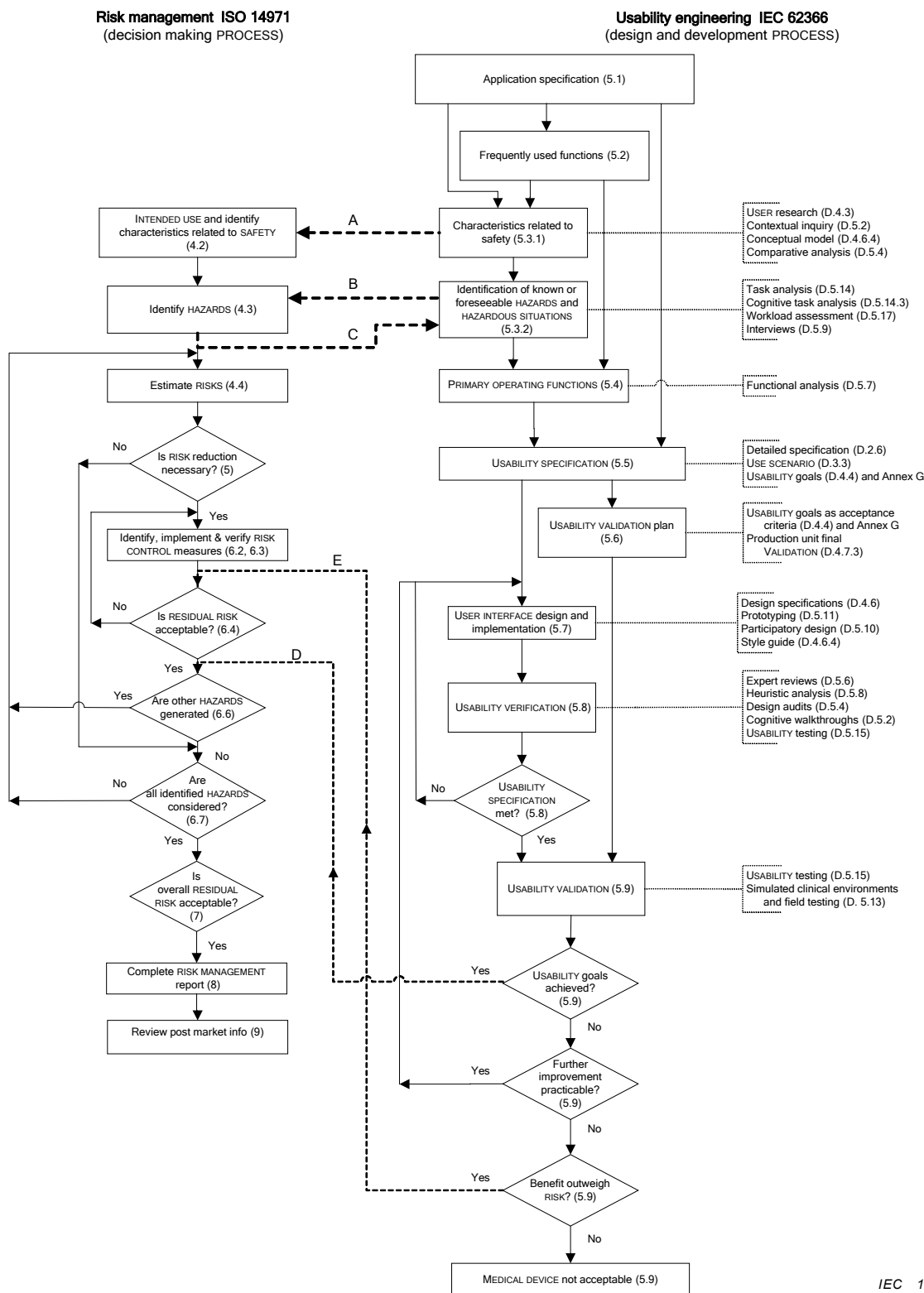
When the MANUFACTURER is identifying the characteristics related to SAFETY of the MEDICAL DEVICE in accordance with the requirements of ISO 14971:2007, 4.2, the USABILITY ENGINEERING PROCESS can provide the detail necessary (5.3.1) to accomplish this step for the USER INTERFACE of the MEDICAL DEVICE.

Further, when the MANUFACTURER is compiling a list of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS associated with the MEDICAL DEVICE in accordance with the requirements of ISO 14971:2007, 4.3, the USABILITY ENGINEERING PROCESS provides a list of items that are required to be considered (5.3.2) in order to accomplish this step for the USER INTERFACE of the MEDICAL DEVICE. This standard also identifies methods that the MANUFACTURER can use to develop this list.

ISO 14971 requires that RISKS associated with each of the identified HAZARDOUS SITUATIONS be estimated (ISO 14971:2007, 4.4), and evaluated (ISO 14971:2007, Clause 5). If a RISK is not acceptable using the MANUFACTURER'S RISK acceptability criterion, the MANUFACTURER is required to identify RISK CONTROL measure(s) that are appropriate for reducing the RISK(s) to an acceptable level (ISO 14971:2007, 6.2). The MANUFACTURER is then required to implement the identified RISK CONTROL measures and VERIFY that they are effective in reducing the RISK to an acceptable level (ISO 14971:2007, 6.3).

The USABILITY ENGINEERING PROCESS requires that all known or foreseeable HAZARDS or HAZARDOUS SITUATIONS related to the MEDICAL DEVICE USER INTERFACE are addressed in preparing the USABILITY SPECIFICATION, not just those with unacceptable RISK. In this standard, USABILITY-related RISK CONTROL options are identified during the development of a USABILITY SPECIFICATION with testable requirements (5.5). The requirements for design and implementation of the options chosen to meet the USABILITY SPECIFICATION for that HAZARD or HAZARDOUS SITUATIONS are described in 5.6, VERIFIED in 5.8, and VALIDATED in 5.9. The USER INTERFACE is subject to VERIFICATION to the USABILITY SPECIFICATION. The USABILITY SPECIFICATION is subject to VALIDATION, where the USABILITY VALIDATION plan incorporates the acceptance criteria. These steps achieve the same objective as 4.4 through 6.4 of ISO 14971:2007.

Even when the USER INTERFACE meets the USABILITY SPECIFICATION, the MANUFACTURER should perform an evaluation to determine if new HAZARDS or HAZARDOUS SITUATIONS have been generated in the MEDICAL DEVICE, as required in 6.6 of ISO 14971:2007. If that USER INTERFACE does not meet the USABILITY SPECIFICATION, the MANUFACTURER should perform a RESIDUAL RISK evaluation as required in 6.4 of ISO 14971:2007.



IEC 1781/07

Subclause 5.1 – Application specification

The USABILITY ENGINEERING PROCESS as described in this standard begins by identifying the most important characteristics related to the use of the MEDICAL DEVICE. These characteristics are defined by the MANUFACTURER and are based on factors such as intended medical indication, intended PATIENT population and operating principle and are fundamental to the function of the MEDICAL DEVICE. This information is documented in the MEDICAL DEVICE application specification. These attributes are fundamental design inputs for identifying the known and foreseeable HAZARDS and HAZARDOUS SITUATIONS related to the USER INTERFACE. The MEDICAL DEVICE application specification is the foundation for defining the USABILITY SPECIFICATION. The list of characteristics associated with the applications specification is a *subset* of the INTENDED USE as specified in ISO 14971.

(intended medical indication)

The intended medical indication can be very broad or quite narrow. It is important for the MANUFACTURER to clearly specify and indicate in the ACCOMPANYING DOCUMENT the intended medical indication. The USER needs to understand the intended medical indication in order to determine whether a given MEDICAL DEVICE is appropriate for the PATIENT at hand.

Some MEDICAL DEVICES are intended for very broad medical indications.

EXAMPLE 1 Safety syringe: indicated for intramuscular and subcutaneous injections of medication into a PATIENT.

EXAMPLE 2 Multiparameter PATIENT monitor: indicated whenever there is a need for monitoring the physiological parameters of a PATIENT.

Other MEDICAL DEVICES are intended for very narrow medical indications.

EXAMPLE 3 Septostomy catheter: indicated catheterization for angiography of cardiovascular vessels and/or chambers.

EXAMPLE 4 Spinal fluid manometer: indicated for the measurement of the pressure of the cerebrospinal fluid during a lumbar puncture procedure.

(intended USER PROFILE)

It is important to design a MEDICAL DEVICE tailored to the intended USER(S). Factors that should be considered when developing a USER PROFILE include age, gender, linguistic and cultural background, level of education and professional competence. Potential disabilities of the intended USERS should be taken into account. For example, a MEDICAL DEVICE for use by diabetics should consider that they often have poor visual acuity and have a poor sense of touch.

See H.2.1.2.4 for an example of an USER PROFILE.

(intended conditions of use)

The intended conditions for use are indications of the important parameters of use for the particular MEDICAL DEVICE in question. This can include such attributes as:

- sterile or non-sterile,
- single use or reusable,
- single PATIENT use or multiple PATIENT use,
- hospital use or home use,
- ambulance use, in hospital transport or wall mounted,
- general ward or operating theatre use,
- permanent implant or less than one hour contact.

(operating principle)

The operating principle for a MEDICAL DEVICE includes descriptions of:

- physical methods used to accomplish its INTENDED USE; and

EXAMPLE 1 A scalpel using highly focused laser energy.

EXAMPLE 2 A scalpel using sharpened stainless steel blade.

EXAMPLE 3 A scalpel using high-energy HF electromagnetic fields.

- mechanisms by which it works.

EXAMPLE 4 An intravenous infusion pump delivers medication through an intravenous line connected to a PATIENT catheter by a peristaltic mechanism employing rollers and mechanical fingers that squeeze and push fluid through plastic tubing.

EXAMPLE 5 An intravenous infusion pump delivers medication through an intravenous line connected to a PATIENT catheter by a volumetric pump that has plungers connected to a diaphragm on a cassette mechanism connected to PATIENT tubing that draws fluid from an IV bag by creating a vacuum within the cassette mechanism.

Subclause 5.2 – Frequently used functions

Identification of the frequently used functions is an important input to the USABILITY ENGINEERING PROCESS. Inadequate USABILITY of the frequently used functions can adversely impact SAFETY by increasing the probability of USE ERROR. A collection of even relatively minor shortcomings in the design of the USER INTERFACE can raise the probability of USE ERRORS and their consequences, particularly when they involve frequently used functions. Examples of such shortcomings include poor labelling, ambiguous control-display relationships, difficult to read indicators, connectors that lack the proper shape coding, inconsistent software navigation methods, etc. At a minimum, these shortcomings can increase the time required to learn to use the MEDICAL DEVICE and increase the time required to perform frequent tasks (due to an overall increase in mental and physical workload). At worst, these shortcomings can induce USE ERROR because USERS have to focus more attention on operation of the MEDICAL DEVICE, taking attention away from higher-level considerations directly related to PATIENT SAFETY.

As workload increases, there is generally an increased chance of errors of various types. There is less time to check one's work, less time to consider all variables and a greater chance of imprecision and error due to rushing. Frustration with the USER INTERFACE can lead to the user taking shortcuts, improvisation, or well-intentioned "optimizations" (i.e. nescient errors), which in turn can adversely impact SAFETY. It would make sense to review all functions, particularly the most frequent ones, and also infrequently used functions that can only be used in emergency situations, and determine if there could be a problem due to the cumulative effect of USABILITY ENGINEERING deficiencies that could have a negative impact on SAFETY.

Subclause 5.3.2 – Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS***(task related requirements)***

Task related requirements are derived from the task analysis (see D.5.14) and are typically identified as an input to the USABILITY SPECIFICATION (see element H.2.3.4). Examples of task related requirements are:

- exterior surface shall facilitate ease of cleaning;
- markings shall be readable under low lighting conditions;
- the MEDICAL DEVICE shall be transportable with one hand only.

(context of use)

The context of use can have a significant impact on USABILITY of the MEDICAL DEVICE USER INTERFACE. For SAFETY reasons the context of use needs to be analyzed and considered by the MANUFACTURER. When the MEDICAL DEVICE is used in combination with other MEDICAL DEVICES, context of use needs to consider the attributes of the other elements of the system. See also D.2.2 and D.4.1.2.4.

Examples of different contextual factors that need to be addressed are:

- spatial context:
 - architecture: type of building and location in the building, e.g.: hospital (e.g. ward, operating theatre, intensive care unit), office, cinema, home;
 - outdoors;
 - PATIENT transport (e.g. airplane, ship, ambulance, car);
 - smoothness and inclination of floor;
 - location of emergency or accident;
- social context:
 - organization;
 - transition of care (e.g. requirement to receive / forward inputs / outputs for the MEDICAL DEVICE at change of USERS);
 - presence of: unattended children; untrained or curious adults;
 - responsibility (e.g. shared, alone);
- technological context:
 - other technical devices which are required for use of the MEDICAL DEVICE;
 - other technical devices which might influence the use of the MEDICAL DEVICE;
 - other technical devices which are affected by the use of the MEDICAL DEVICE;
 - effect of other devices on the MEDICAL DEVICE;
- hygienic context:
 - requirements for cleanliness, sterile conditions;
 - facilities for cleaning;
 - facilities for waste disposal;
- physical context:
 - climate conditions (e.g. altitude, ambient pressure, temperature, humidity, precipitation, wind);
 - acceleration, movement of frame of reference (e.g. car, ship);
 - light level;
 - ambient noise;
- activity context:
 - distractions;
 - other tasks which can interfere with the operation of the MEDICAL DEVICE;
 - surprise/startle effect;
 - strain and stress;
 - influence on the working environment (e.g. inability to communicate with the PATIENT over the noise of MRI equipment);
 - alterations of the work environment that could affect other MEDICAL DEVICES (e.g. low general lighting during ophthalmic surgery);

- workload and fatigue (e.g. the effects of shift work, such as cognitive degradation, on task performance).

(incorrect mental model)

A mental model is a USER'S conceptual model of how the MEDICAL DEVICE works and is structured. If the USER'S mental model is based on the knowledge of why a MEDICAL DEVICE works in a certain way, it is a structured model and allows the USER to solve problems that might arise during the use of the MEDICAL DEVICE. Ideally, a USER'S mental model can be easily created through interaction with the MEDICAL DEVICE or it can be acquired through explanation from TRAINING or ACCOMPANYING DOCUMENT. The best mental models are self-evident and need no explanation.

The mental model of how a thermostat controls a PATIENT warming system could include two possibilities.

- It is a simple on/off switch that opens and closes under the control of a thermocouple device to maintain a desired temperature.
- It is a tap that controls the rate of flow of hot air such that higher temperature settings allow a larger volume of air to flow, which allows faster warming of the PATIENT.

The correct mental model for a typical PATIENT warming system is that the thermostat is a simple on/off switch and not a tap for controlling rate of airflow. The consequence of having the incorrect mental model is the inefficient use of energy in achieving a desired PATIENT temperature. If a USER has the incorrect mental model of the thermostat being a tap they inefficiently set the thermostat first too high and then too low to try to rapidly achieve a desired steady temperature. See also the rationale for Clause 6.

(review of the USER INTERFACE)

It is important to remember that the USABILITY ENGINEERING PROCESS is iterative (see 5.6). The MANUFACTURER needs to revisit this step during the USER INTERFACE design to ensure that all known or foreseeable HAZARDS have been addressed and that no new HAZARDS have been created.

Subclause 5.5 – USABILITY SPECIFICATION

The purpose of the USABILITY ENGINEERING PROCESS, as described in this standard, is to provide SAFETY for the PATIENT, USER and others related to USABILITY. To achieve this purpose, the USABILITY ENGINEERING PROCESS mitigates RISK caused by USABILITY problems associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE. Success is demonstrated by VERIFYING and VALIDATING the USABILITY of the PRIMARY OPERATING FUNCTIONS to acceptance criteria established in the USABILITY SPECIFICATION. Therefore, in determining these acceptance criteria, the MANUFACTURER considers factors (e.g. state of the art, experience with similar MEDICAL DEVICES, post-market surveillance reports) needed to establish that when meeting these criteria, the RESIDUAL RISKS related to USABILITY are controlled to acceptable levels. The MANUFACTURER can apply the acceptance criteria determined according ISO 14971:2007, 3.4 d).

The USABILITY SPECIFICATION describes two groups of USE SCENARIOS: those USE SCENARIOS that occur frequently and those that represent a reasonably foreseeable worst-case. In identifying those USE SCENARIOS the MANUFACTURER should focus on:

- a) facilitating the specific tasks that the MANUFACTURER intends the USERS and the RESPONSIBLE ORGANIZATION to perform; and
- b) minimising the RISKS that can arise if the intended USER or the RESPONSIBLE ORGANIZATION try to perform other tasks not intended by the MANUFACTURER.

(frequent USE SCENARIOS)

Preliminary USE SCENARIOS are representations of actual tasks that the USER and the RESPONSIBLE ORGANIZATION would perform with the MEDICAL DEVICE. They include the end-result of the task they are trying to achieve, the reason for performing the tasks, the functional state of the MEDICAL DEVICE when a task is initiated and readouts of displays and printouts that the USER sees while performing the task. USE SCENARIOS should include both common routine tasks and rarely used tasks that can be performed in an emergency situation.

Subclause 5.7 – USER INTERFACE design and implementation

The design of the USER INTERFACE should be focused on the USER'S needs and requirements. A multidisciplinary team approach to USER INTERFACE design is required. This team can include actual USERS, engineers, USER-interface specialists, cognitive psychologists, multimedia programmers, USABILITY engineers, marketing and training personnel. See also D.1.1.

Subclause 5.8 – USABILITY VERIFICATION

The purpose of USABILITY VERIFICATION is to confirm that the MEDICAL DEVICE conforms to the USABILITY SPECIFICATION. Given the iterative nature of the USABILITY ENGINEERING PROCESS, USABILITY VERIFICATION can:

- guide the development of parts of the MEDICAL DEVICE such as any ACCOMPANYING DOCUMENT and training, and
- if necessary, make adjustments to the USER INTERFACE.

USABILITY VERIFICATION can be done by inspection of the implemented USER INTERFACE or through a PROCESS of observing and collecting data from intended USERS while they interact with either the MEDICAL DEVICE or a (high fidelity) MEDICAL DEVICE prototype in the intended or simulated environment of use.

USABILITY VERIFICATION tests the USER INTERFACE to determine if it complies with its specifications, whereas USABILITY VALIDATION confirms whether the MEDICAL DEVICE meets the USABILITY requirements for a specific application or INTENDED USE. See also the rationale for 5.9 and D.4.7.2.

Subclause 5.9 – USABILITY VALIDATION

The final phase of the USABILITY ENGINEERING PROCESS is USABILITY VALIDATION. USABILITY VALIDATION is intended to assure that the right product is built. VALIDATION is important for the USER INTERFACE because unexpected interactions between the MEDICAL DEVICE and the USER might occur that can only be discovered by VALIDATION.

VALIDATION activities should occur throughout the MEDICAL DEVICE'S design, beginning in early stages of design conceptualization (see D.4.7).

Clause 6 – ACCOMPANYING DOCUMENT

It is important for the RESPONSIBLE ORGANIZATION and the USER to have a good understanding of the operation of the MEDICAL DEVICE. A good mental model of the MEDICAL DEVICE helps provide a greater degree of SAFETY as the USER better understands the MEDICAL DEVICE'S benefits and limitations, which can reduce USE ERROR, improve error mitigation and aid in troubleshooting. The items listed are considered necessary to help the USER to build such a mental model. See also the rationale for 5.3.2, (*incorrect mental model*).

Clause 7 – Training and materials for training

Some MEDICAL DEVICES are complex, with multiple functions. To help ensure safe use, specific training can be used as a RISK CONTROL measure. Such training and training materials provided with the MEDICAL DEVICE should consider the USER PROFILE and have adequate USABILITY. Means of training can include manuals, cards, videos, interactive computer-based training and lectures. The MANUFACTURER or a third party can provide these materials or deliver this training.

Subclause K.2.1 – Application specification

The application specification is the essential source used to identify the most important characteristics related to the use of a MEDICAL DEVICE. When evaluating a USER INTERFACE including UOUP, the ACCOMPANYING DOCUMENTS can provide a valuable source for retrospectively establishing the application specification.

Furthermore, the application specification needs to be consistent with the ACCOMPANYING DOCUMENTS. Therefore it is best practice to carefully review the ACCOMPANYING DOCUMENTS. Elements of the application specification which cannot be derived (determined) from the ACCOMPANYING DOCUMENTS need to be established using other sources.

Subclause K.2.3 – Review of post-production information

Available post-production information is reviewed to identify known problems with the MEDICAL DEVICE with UOUP that might have been caused by USABILITY problems in the USER INTERFACE. Because the post-production information can be incomplete (e.g., due to under-reporting of adverse events and customer complaints) and the root cause of the problem can be difficult to identify, the MANUFACTURER should analyse the SEVERITY of the potential HARM associated with the identified problem rather than the number of event reports, customer complaints or product recalls.

Annex B (informative)

Categories of USER action

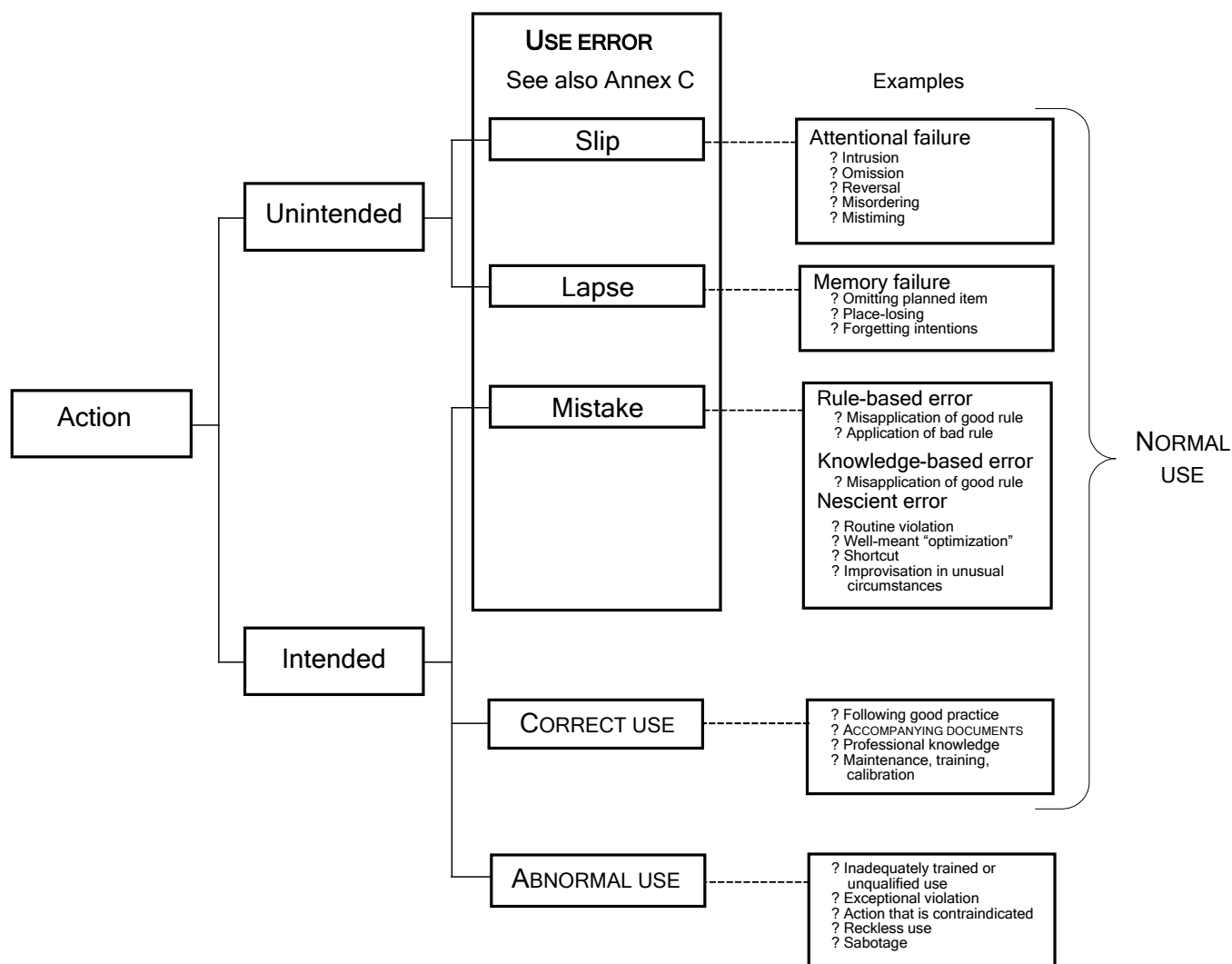
For the purposes of this standard, USER actions or inactions can be broadly categorized into actions that are foreseeable and those that are not foreseeable. Clearly, those USER actions or inactions that are not foreseeable cannot be dealt with by this or any other standard. This International Standard describes a PROCESS that deals with those USER actions or inactions that can be foreseen. These foreseeable events can be further subdivided between intended and unintended USER actions or inactions (see Figure B.1).

In Figure B.1, intended USER actions or inactions that fall within NORMAL USE can be a response that is intended by the MANUFACTURER and expected by the USER, i.e. CORRECT USE. Alternately, the intended action or inaction could result in a mistake or could result from conduct that is beyond any additional means of RISK CONTROL by the MANUFACTURER, i.e., ABNORMAL USE. This does not necessarily mean that ABNORMAL USE results in a poor outcome for the PATIENT. Often the clinical judgement of the USER indicates that such use is in the best interest of the PATIENT. For the purposes of this standard unintended actions or inactions are always classified as slips or lapses.

Slips, lapses, and mistakes are all considered forms of USE ERROR. In the USABILITY ENGINEERING PROCESS, it is helpful to differentiate between these categories while determining the root-cause of a particular USE ERROR to help ascertain those errors that can be mitigated by design.

Slips and lapses are errors that result from some failure in the execution and/or storage stage of an action sequence, regardless of whether or not the plan that guided them was adequate to achieve its objective. Whereas slips are potentially observable as externalized actions-not-as-planned (slips of the tongue, slips of the pen, slips of action), the term lapse is generally reserved for more covert error forms, largely involving failures of memory, that do not necessarily manifest themselves in actual behaviour and can only be apparent to the person who experiences them.

Mistakes can be defined as deficiencies or failures in the judgmental and/or inferential PROCESSES involved in the selection of an objective whether or not the actions directed by this decision-scheme run according to plan (adapted from [30]).



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NOTE 1 In this figure, an action can result from a USER:

- choosing to do something; or
- failing to do something.

NOTE 2 See Annex C for lists of potential USE ERRORS and ABNORMAL USE or their causes.

NOTE 3 Nescience is used in the context of a lack of awareness of the adverse consequences of a skill-based action.

Figure B.1 – Categories of foreseeable USER action

Annex C (informative)

Examples of USE ERRORS, ABNORMAL USE and possible causes

C.1 Background

The following USE ERRORS and ABNORMAL USE examples are based on adverse event reports collected by several regulatory authorities [13]. These examples are abbreviated descriptions of the actual events and have been modified to highlight the distinction between ABNORMAL USE and USE ERROR. The adverse events were classified as indicated following evaluation of the design and the ACCOMPANYING DOCUMENT of the MEDICAL DEVICES involved.

It is recognized that differentiating USE ERROR from ABNORMAL USE is not always an easy task and so often requires careful investigation, analysis, and documentation. A careful investigation might include trending and root cause analysis as techniques to classify events.

The list of possible causes of USE ERROR was extracted from Table E.2 of ISO 14971:2007.

C.2 USE ERRORS

The following are brief descriptions based on actual events that were determined at the time to be examples of USE ERRORS.

- USER confuses two buttons and presses the wrong button.
- USER misinterprets the icon and selects the wrong function.
- USER enters incorrect sequence and fails to initiate infusion.
- USER fails to detect a dangerous increase in heart rate because the ALARM LIMIT is mistakenly set too high and USER is over-reliant on ALARM SYSTEM.
- USER cracks catheter connector when tightening or loosening the connector.
- A centrifugal pump is cleaned with alcohol. It is made from material that is known to be incompatible with alcohol. It is reasonably foreseeable that alcohol might be used to clean the pump as alcohol is readily available in the hospital and no clear and prominent warning is provided.
- Unintentional use of pipette out of its calibration range.
- Analyzer placed in direct sunlight causing higher reaction temperature than specified.
- Technician brings a steel oxygen tank into the presence of the magnet in the MRI system suite and it moves swiftly across the room into the magnet.
- USER uses a well-intentioned shortcut on procedure or pre-use checklist, etc, thereby omitting important steps. It is not obvious that the shortcut is hazardous.
- USER unintentionally omits an important step in an excessively lengthy or complicated procedure or pre-use checklist.

C.3 ABNORMAL USE

The MANUFACTURER is responsible for applying all reasonable means of RISK CONTROL. These can include information for SAFETY, which is one element in a hierarchal approach to RISK CONTROL. Following the PROCESS in ISO 14971, the MANUFACTURER uses one or more of the following in the priority listed:

- a) inherent SAFETY by design;

- b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS, e.g. ALARM SYSTEMS;
- c) information for SAFETY, e.g. warnings in the instructions for use, display of a monitored variable, training and materials for training, maintenance details.

If, despite the MANUFACTURER having provided VALIDATED information for SAFETY (see 4.1.3), the USER acts contrary to such information for SAFETY, the incorrect use is classified as ABNORMAL USE.

The following are brief descriptions of complaint reports taken from Appendix A of the Global Harmonization Task Force (GHTF) paper on reporting of USE ERRORS [13]. These examples are based on actual events that were determined at the time to be examples of ABNORMAL USE. In each case, it was determined that the MANUFACTURER had addressed the relevant RISKS using reasonable means of RISK CONTROL. These included proper design, proper training, information for SAFETY, and descriptions of CORRECT USE in the ACCOMPANYING DOCUMENTS.

- Deliberate violation of a VALIDATED, simple pre-use safety checklist as specified in the ACCOMPANYING DOCUMENT.
- Failure to stop using an X-ray tube after having ignored a conspicuous warning light that indicates it is overheating. The X-ray MEDICAL DEVICE subsequently stops operating or fails and that delays or prevents completion of a therapeutic procedure.
- Use of a diagnostic ultrasound MEDICAL DEVICE prior to completing installation as specified by the ACCOMPANYING DOCUMENT.
- Continued use of a MEDICAL DEVICE beyond the prescribed maintenance interval as clearly defined in the ACCOMPANYING DOCUMENT because of RESPONSIBLE ORGANIZATION'S failure to arrange for maintenance.
- Contrary to the indications in the ACCOMPANYING DOCUMENT, a MEDICAL DEVICE is not sterilized prior to implantation.
- Use of electrosurgical device on a pacemaker PATIENT while deliberately ignoring the clear warning in the ACCOMPANYING DOCUMENT to take proper precautions, resulting in the need to re-program the pacemaker or replace it.
- The PATIENT is HARMED because the RESPONSIBLE ORGANIZATION allowed an untrained USER to use a MEDICAL DEVICE. The MEDICAL DEVICE is working in accordance with its specifications.
- During placement of a pacemaker lead, an untrained physician perforates the heart.
- The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours in duration. Finding no other pump available, the clinician decides to use the pump in a paediatric extra-corporeal membrane oxygenation (ECMO) procedure that lasts several days. The pump fails due to fatigue cracking and the PATIENT bleeds to death.
- The USER drops an infusion pump, clearly damaging it. The USER uses the pump anyway, injuring a PATIENT.
- A centrifugal pump is made from material that is known to be incompatible with alcohol. The USER cleans the pump with alcohol despite a clear and prominent warning on the pump that alcohol is not to be used.
- Contrary to a clear warning, the RESPONSIBLE ORGANIZATION or USER defeats the SAFETY interlock on a medical laser.
- Contrary to a clear warning, a filter is removed and intentionally not replaced resulting in particulate contamination and subsequent in vitro diagnostic MEDICAL DEVICE failure.
- Use of an automated analyzer without checking calibration in violation of obvious warnings on the screen that calibration is to be checked.
- Pacemaker PATIENT is placed into MRI system with the knowledge of the physician that use of MRI is contraindicated.

- USER inactivates the ALARM SYSTEM and does not properly monitor the condition of the PATIENT, preventing detection of the deterioration of the PATIENT.
- Ventilator ALARM SYSTEM is intentionally disconnected, preventing detection of HAZARDOUS SITUATION.
- PATIENT'S relative intentionally alters infusion pump to deliver a lethal overdose of the infusing drug to the PATIENT.
- Home care worker uses bed rails and mattress to suffocate PATIENT.

NOTE There is a difference between well-intentioned and malevolent ABNORMAL USE. As the examples show, ABNORMAL USE is often well-intentioned (i.e., the USER accepts a certain RISK for the expected benefit of the PATIENT), but can go as far as obvious criminal behaviour. This is distinct from the situation where the USER did not appreciate the RISK involved in their action/inaction because the RISK was not clearly indicated, where the event can be considered a USE ERROR.

C.4 Possible causes of USE ERROR

The following are examples of violations of USER INTERFACE-design heuristics that can lead to USE ERROR.

- Complex or confusing control system
- Ambiguous or unclear MEDICAL DEVICE state
- Ambiguous or unclear presentation of settings, measurements or other information
- Misrepresentation of results
- Insufficient visibility, audibility or tactility
- Poor mapping of controls to action, or of displayed information to actual state
- Controversial modes or mappings

See also Table D.1 for specific examples of design flaws and resulting USE ERRORS.

Annex D (informative)

Guidance on the USABILITY ENGINEERING PROCESS

D.1 Introduction to the USABILITY ENGINEERING PROCESS

D.1.1 General

This annex is introductory guidance to the application of the USABILITY ENGINEERING PROCESS needed to fulfil USER INTERFACE design requirements in the development of a MEDICAL DEVICE, including hardware, software, and documentation. This annex is derived from ANSI/AAMI HE 74:2001 [11].

This annex is not intended as a sole source for USABILITY ENGINEERING guidance or as a substitute for USABILITY ENGINEERING expertise. Rather, it is intended to provide readers with a general understanding of how to perform USABILITY ENGINEERING work in an effective way, drawing extensively on related documents (see Bibliography).

This annex includes an overview of USABILITY ENGINEERING (human factors engineering), a discussion of the benefits of USABILITY ENGINEERING, a review of the USABILITY ENGINEERING PROCESS and associated analysis and design techniques. The annex also incorporates a listing of applicable documents and USABILITY ENGINEERING literature citations.

For the purposes of this annex, the USER INTERFACE includes all aspects of a MEDICAL DEVICE with which USERS interact when operating the MEDICAL DEVICE. The ACCOMPANYING DOCUMENT and other MEDICAL DEVICE labelling are integral parts of the USER INTERFACE. USERS are considered to include maintainers, cleaners, and other service personnel who handle the MEDICAL DEVICE. A USER can be a caregiver (e.g. person who uses a home dialysis machine), a PATIENT (e.g. diabetics who measure their own glucose level), or someone who provides support for either a caregiver or a PATIENT (e.g. a diagnostic ultrasound technician). A caregiver can be a trained clinician or a layperson (e.g. a family member).

This annex addresses the needs of a diverse group of professionals who handle the planning, funding, management, and performance of research, design, and testing activities related to the SAFETY and USABILITY of a MEDICAL DEVICE, including:

- company, department, project, and product managers,
- design and engineering professionals (e.g. USABILITY engineers, industrial designers, technical writers, information designers, software developers, mechanical engineers, electrical engineers, packaging engineers),
- medical researchers and other interested clinicians, and
- marketers and other business professionals in the MEDICAL DEVICE industry.

It should be noted that USABILITY ENGINEERING practice varies widely. This variation is partly due to the diversity of its practitioners, who can have backgrounds in fields such as engineering, psychology, or design. Practice differences are also due to the wide variety and complexity of MEDICAL DEVICES, which range from digital thermometers to imaging systems, and which can be used in hospitals, clinics, homes, and other environments by various professionals and laypersons.

As such, it is impossible to prescribe a single set of USABILITY ENGINEERING methods that are optimal for all design projects. Instead, this document describes a USABILITY ENGINEERING PROCESS that requires additional shaping and scaling to suit particular practitioners, experience and research and design philosophies, as well as project specifications. The

document's ultimate goal is to ensure that MANUFACTURERS approach USER INTERFACE design in a rigorous, effective manner.

D.1.2 The benefits of USABILITY ENGINEERING

The primary goal of a USABILITY ENGINEERING PROCESS tailored to a MEDICAL DEVICE should be making the MEDICAL DEVICE safer, more effective, and easier to use. There are well-established USABILITY ENGINEERING tools and techniques to support the analysis, design, testing and evaluation of both simple and complex systems. These techniques have been successfully applied for many years in such diverse areas as consumer products, military applications, aviation MEDICAL DEVICE, and nuclear power systems. An integrated and structured USABILITY ENGINEERING program can help MEDICAL DEVICE developers make their MEDICAL DEVICE safer and easier to use.

D.1.3 Avoiding design-induced error

MEDICAL DEVICE-related errors usually result from multiple inter-related factors. Adverse event reports confirm that the MEDICAL DEVICE itself often contributes to USE ERRORS, most commonly due to USER INTERFACE design flaws. Table D.1 provides examples of design flaws and associated USE ERRORS. Good design should not only reduce the likelihood of USE ERRORS but also, when USE ERRORS do occur, increase the likelihood of their detection and correction and increase the ability to mitigate their consequences.

The systematic application of USABILITY ENGINEERING design principles, reinforced by tests involving USERS, is an effective means to discover and resolve such design flaws. For example, adherence to established design standards that specify the minimum separation distances between controls helps prevent inadvertent USER activation of adjacent controls. A thorough understanding of the MEDICAL DEVICE use environment garnered by site visits, field interviews, and USABILITY tests (conducted in a laboratory or in the field) could reveal other design flaws that contribute to USE ERROR. Field observations conducted in the earliest phases of the design PROCESS can discover potential MEDICAL DEVICE interaction problems, for example, the possibility of incorrect, perhaps dangerous tubing connections due to common physical fit and appearance. USABILITY tests using MEDICAL DEVICE mock-ups or simulations could discover the possibility of incorrect tubing connections due to common physical fit and appearance, unnecessarily complex input sequences, or ambiguous messages.

Table D.1 – Sample of design flaws and associated USE ERRORS

Example of design flaw	Possible resultant USE ERROR
Push-buttons on a control panel are too closely spaced	USER presses the wrong button
Two icons on a software screen look too similar	USER misinterprets the icon and selects the wrong function
A USER INTERFACE requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion	USER enters incorrect sequence and fails to initiate infusion
Infusion pump displays misleading "Open Door – Reset" message when there is air in the infusion line	USER repeatedly opens the door and presses the reset key instead of clearing air from the infusion line
USER-adjusted high and low ALARM LIMITS on a heart-rate monitor are not continuously displayed	USER fails to detect a dangerous increase in heart rate because ALARM LIMIT is set too high and USER is over-reliant on ALARM SYSTEM
Typical USER-applied force exceeds breaking strength of catheter connector	USER cracks catheter connector when tightening

D.1.4 Improving USABILITY

MEDICAL DEVICE USERS (e.g. physicians, nurses, therapists, technologists, PATIENTS, and service personnel) regard USABILITY as one of a MEDICAL DEVICE's most important design characteristics. They understand that a MEDICAL DEVICE with good USABILITY is likely to reduce

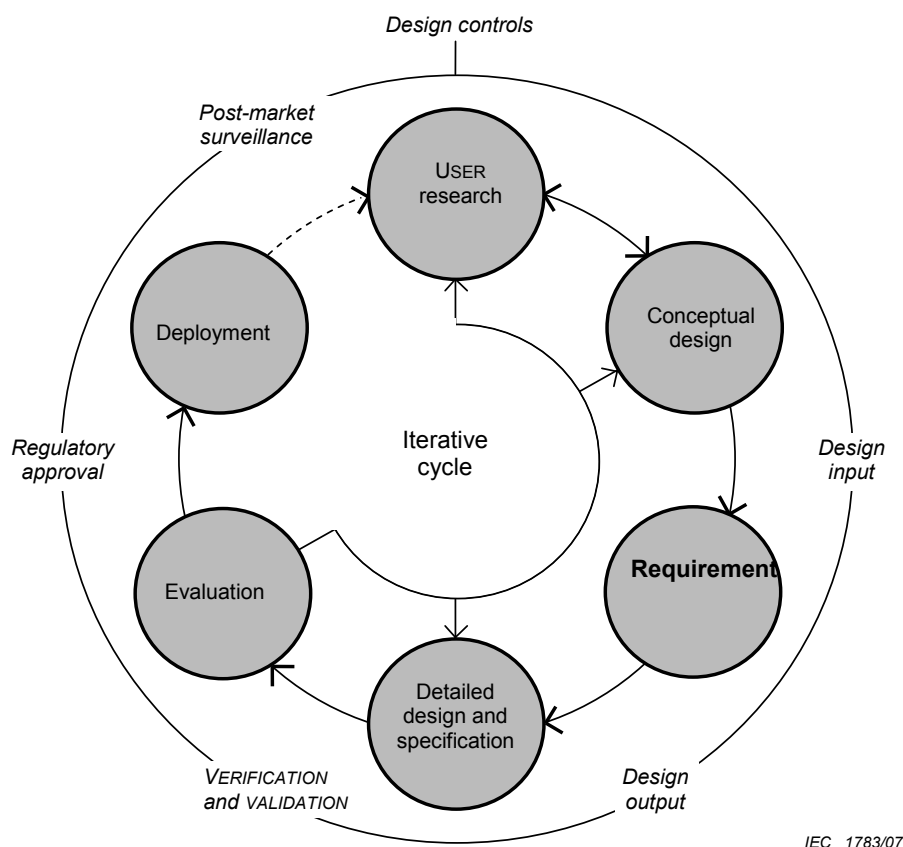
the amount of time for training and increase productivity. For a MEDICAL DEVICE intended to be used by a PATIENT (e.g. home glucose monitors for diabetics), ease of use can affect whether the PATIENT is able to use the MEDICAL DEVICE at all. A MEDICAL DEVICE MANUFACTURER is well served by investing the necessary resources to improve USABILITY. From a business standpoint, the potential payoffs of investing in improved USABILITY can include:

- faster time to market (by avoiding USER INTERFACE problems late in the development cycle);
- simpler USER manuals and related learning tools;
- improved marketing through credible claims about a MEDICAL DEVICE'S USABILITY and associated gains in USER productivity;
- increased sales (due to increased customer satisfaction);
- reduced training and support requirements;
- extended market life;
- clearer compliance with regulatory requirements;
- reduced exposure to liability claims; and
- increased USER satisfaction.

D.2 Overview of the USABILITY ENGINEERING PROCESS

D.2.1 General

Regardless of whether one is designing a revolutionary new product or making minor modifications to an existing product, the associated USABILITY ENGINEERING PROCESS invariably includes several specific USABILITY ENGINEERING elements or steps. Figure D.1 depicts the USABILITY ENGINEERING aspects of MEDICAL DEVICE design as a cycle of steps. This does not imply that every design effort is required to follow a rigid prescription of development activities. On the contrary, the specific USABILITY ENGINEERING activities at each step in the cycle (and the associated time, effort, and expense required) vary with each development effort.



NOTE 1 Input from USERS is typically obtained at nearly every stage in the cycle.

NOTE 2 Table D.2 provides a mapping of the elements in this figure to the subclauses of this International Standard.

Figure D.1 – A USER INTERFACE design cycle

Table D.2 – Mapping of Figure D.1 to the subclauses of this International Standard

Design cycle element	Subclause of this International Standard
USER research /Conceptual design	5.1 Application specification 5.2 Frequently used functions 5.3.1 Identification of characteristics related to SAFETY 5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS
Requirement and criteria development	5.4 PRIMARY OPERATING FUNCTIONS 5.5 USABILITY SPECIFICATION 5.6 USABILITY VALIDATION plan
Detailed design and specification	5.7 USER INTERFACE design and implementation
Evaluation	5.8 USABILITY VERIFICATION 5.9 USABILITY VALIDATION 5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

For each step in the cycle, the USABILITY ENGINEERING team uses evidence, judgement, and experience to determine the appropriate USABILITY ENGINEERING activities and effort.

The same USABILITY ENGINEERING tools and techniques can be successfully employed at several different steps in the USABILITY ENGINEERING cycle. For example, an analysis of the tasks a USER performs when interacting with a MEDICAL DEVICE (i.e. task analysis) can be equally appropriate during early conceptualization of a new MEDICAL DEVICE, when developing specific MEDICAL DEVICE design requirements/criteria, and when evaluating a fully functional prototype. However, the type of task analysis employed and the method in which it is performed will likely vary to fit the specific goals of the USABILITY ENGINEERING PROCESS at each of these steps.

D.2.2 Iterative nature of the USABILITY ENGINEERING cycle

Those who are familiar with systems engineering will appreciate the similarity of the depicted cyclical USABILITY ENGINEERING PROCESS with other types of PROCESS or product development cycles. A fundamental attribute is that as a product evolves throughout its life span, it goes through many such cycles. With regard to a MEDICAL DEVICE, particularly when one considers not only USABILITY ENGINEERING activities but also other RISK MANAGEMENT and design control PROCESSES, every step in the cycle is addressed at least once in any MEDICAL DEVICE development PROCESS.

Additionally, the USABILITY ENGINEERING cycle depicted in Figure D.1 emphasizes the iterative nature of the development PROCESS. Not only do the outcomes (or outputs) of one step feed (i.e. provide input to) the next step, but invariably some steps' outputs feed back to prior steps. For example, during the MEDICAL DEVICE evaluation, issues raised by design VERIFICATION activities (i.e. ascertaining whether the MEDICAL DEVICE design meets previously established design requirements) frequently lead to design changes. Similarly, issues raised during design VALIDATION activities (i.e. ascertaining whether the MEDICAL DEVICE adequately addresses established USER needs) can also precipitate subsequent modifications in design requirements or even in MEDICAL DEVICE conceptualization.

The description of the USABILITY ENGINEERING PROCESS as a step-wise cycle can give the misleading impression that USER INTERFACE development is always a serial PROCESS. In fact, many of these activities commonly occur in parallel. Interaction between steps occurs frequently, rapidly, and often seamlessly. For example, in medical software design, a USABILITY ENGINEERING practitioner can accomplish elements of design criteria/requirement development (e.g. USABILITY goals), MEDICAL DEVICE design (e.g. rapid prototyping), and design VERIFICATION (e.g. USABILITY testing) concurrently.

Figure D.1 suggests that the design cycle typically begins with USER-driven design conceptualization (the two connected, upper-right steps). Whether one is considering a revolutionary new MEDICAL DEVICE or evolutionary modifications of an existing MEDICAL DEVICE, design conceptualization can be driven not only by USER ideas or needs, but also by entrepreneurial creativity or even new technologies searching for useful application. Practically, however, the USABILITY ENGINEERING design cycle can be entered at any step. For example, the development of a new, more cost-effective manufacturing PROCESS can lead to proposed MEDICAL DEVICE design changes that impact USER INTERFACE design specifications. In this circumstance, every step in the USABILITY ENGINEERING design cycle is likely to be addressed, perhaps some more explicitly than others.

D.2.3 USER research

It is critical to involve USERS at the earliest stages of the MEDICAL DEVICE development. For example, people with disabilities using a MEDICAL DEVICE in their homes have special requirements that can only be fully appreciated after careful USER research. USER needs should be a primary motivating force behind both new product conceptualization and existing product enhancements.

USER input can be obtained in a variety of ways, and USABILITY ENGINEERING includes many structured tools and techniques to obtain this critical information effectively. A systems approach to MEDICAL DEVICE development, as advocated in this document, necessitates an understanding of how USERS interact with the MEDICAL DEVICE in the actual use environment.

This understanding can only come from USER input and observation. Formal USER testing, in an actual or simulated setting, is commonly an integral part of the MEDICAL DEVICE development PROCESS.

Efforts to get to know USERS better can be integrated with market research activities. However, market research often focuses on a broader set of issues such as the benefits of alternative feature sets, competitive pricing, and customer service. Additionally, most market-focused efforts to elicit USER preferences (e.g. focus groups) are unacceptable substitutes for appropriately designed USABILITY ENGINEERING testing and evaluation. However, marketing groups can facilitate relationships between prospective USERS, designers and engineers.

D.2.4 Design concept development (conceptual design)

The concept for a MEDICAL DEVICE can come about in many different ways. Most often, a clinical need is identified and this leads to a new or modified MEDICAL DEVICE that addresses the need. In many cases, a very broad need is identified and substantial time and effort is then devoted to developing this into a concept that evolves into a commercially viable MEDICAL DEVICE.

During the earliest phases of design, it is important to define USER needs as clearly and specifically as possible, an often difficult task. USERS can have difficulty articulating their needs precisely and sometimes don't really know what they need. The results of focus groups and USER interviews can be misleading, causing designers to solve the wrong problems and meet perceived as opposed to actual needs. Therefore, other techniques for needs assessment, such as observing the use of precursor systems in the operational environment, are useful in VALIDATING the expressed USER needs prior to design.

D.2.5 Design requirement/criteria development

The development of design criteria/requirements can begin once USER needs and the consequent concept of the MEDICAL DEVICE have been well defined. The design criteria/requirements define the intended operating conditions, USER characteristics, functions, and potential HAZARDOUS SITUATIONS. Typically, the design criteria/requirements, the embodiment of the design input, undergo substantial revision and refinement as the MEDICAL DEVICE design matures, progressing from rather general statements to highly specific and technical requirements.

Design criteria/requirement development requires substantial analysis of how well possible design solutions address USER needs, technical and manufacturing constraints, and market realities. The USABILITY ENGINEERING team concurrently interprets USER input, develops USABILITY ENGINEERING requirements, and provides feedback to other engineers on the USABILITY ENGINEERING implications of design decisions. The USABILITY ENGINEERING team should play a critical role in decisions regarding features and USER INTERFACE attributes.

D.2.6 Detailed design and specification

The design requirements at the beginning of this stage provide sufficient detail to allow hardware and software designers to create the desired product. Equally important, the requirements include measurable test criteria that can be used to ensure that the resulting product meets its intended USER needs. Thus, as the design PROCESS proceeds, rigorous statements of desired MEDICAL DEVICE attributes are converted to engineering or software specifications that enable construction of these attributes; first in prototypes, and ultimately, after design evaluation, in the final product. Throughout this PROCESS, the USABILITY ENGINEERING team should work closely with engineers, industrial designers, and learning tool developers. See Table D.3 for examples of USER INTERFACE requirements.

An important role of USABILITY ENGINEERING team members is to apply USABILITY ENGINEERING technical information to the relevant USABILITY questions that inevitably emerge as the design is refined. In doing so, the USABILITY ENGINEERING practitioner relies upon published research

or collects new data on human capabilities, limitations, and tendencies, both physical (e.g. anthropometry and biomechanics) and cognitive (e.g. error tolerances, reaction time).

Table D.3 – Examples of USER INTERFACE requirements

Category	Example
General	Ensure read-only displays differ visually from displays that allow USERS to edit data.
	Read-only text is displayed in black text on white background display while text that can be edited is white text on black background display.
List box	Selected item in the list box is highlighted to ensure clear differentiation from other items.
	List boxes display at least four choices without the need to scroll up or down.
	All menus have a title.
Menu	Menu items are left-justified.
	The upper left corner of the screen is reserved for the ALARM OFF indicator.
Display	The luminance of the display is greater than 35 cd/m ² . Contrast is not less than 7:1 under normal, ambient lighting conditions.
Control device	Control panel buttons are 1,5 cm square with centre to centre spacing of 2 cm.
	The keyboard is adjustable in height, ranging from (measured from floor) 945 mm to 1 190 mm.

D.2.7 Design evaluation

Only through structured evaluation of the resulting MEDICAL DEVICE design can there be assurance that the design is technically sound and also meets the USER'S needs. The former goal, assuring that the design output meets the design input requirements, is often called design VERIFICATION. The latter goal, which assures that the design output addresses USER'S needs and the INTENDED USE, is called design VALIDATION. Thus, all design changes go through the design evaluation step to ensure that the required VERIFICATION and VALIDATION activities occur. In essence, design VERIFICATION and VALIDATION serve as the checkpoints for a good design.

Both VALIDATION and VERIFICATION activities should be initiated early in the design cycle. For example, RISK ANALYSIS should be conducted initially during design conceptualization, repeated (or refined) as the design evolves, and finalized during design VALIDATION. Other design VALIDATION activities typically require substantial USER involvement.

MEDICAL DEVICE markings and the ACCOMPANYING DOCUMENT are considered part of the MEDICAL DEVICE and as such should undergo the same rigorous evaluation as other USER INTERFACE elements.

D.2.8 Design implementation and deployment

The only step in the cycle that is not solely a part of product development is MEDICAL DEVICE implementation and deployment. This step includes manufacturing, marketing, sales, regulatory clearance, and USER training. Design transfer refers to the use of final design specifications to manufacture (and obtain approval to sell) the MEDICAL DEVICE. Design changes occurring after design transfer that deviate from the design specifications require going through the entire design cycle again.

Design evaluation does not stop after sale of the MEDICAL DEVICE. Post-market surveillance and vigilance reporting provide critical data regarding design strengths and shortcomings. Review of these reports as well as other types of USER feedback brings the USABILITY ENGINEERING aspects of MEDICAL DEVICE design full circle. The result is a revised MEDICAL DEVICE design as well as ideas for new MEDICAL DEVICES that address the issues raised.

D.2.9 Case study of the USABILITY ENGINEERING PROCESS – Public access defibrillators

D.2.9.1 Case study context

The following case study on public-access automated external defibrillators (AEDs) exemplifies the benefits of the USER research, conceptual design and evaluation for a device that is designed for unskilled USERS.

D.2.9.2 Design concept development and USER research

Even with increasing use of manual cardiopulmonary resuscitation, most people who suffer life-threatening arrhythmias outside the hospital do not survive. Early defibrillation is thought to be the key intervention to improve the survival rate. Therefore, the concept for public-access automated external defibrillators (AEDs) developed.

USABILITY ENGINEERING methods such as context-dependent observation, prototyping, and error analysis were used in the design of AEDs. The first prototypes were designed through observing defibrillator use in context at fire stations. Storage and access were identified as key issues, and were addressed in the first iteration of design requirements.

D.2.9.3 Design criteria/requirement development

Through research, USABILITY ENGINEERING personnel determined that the AEDs need to be lightweight and portable (briefcase size), easy to use with minimal training, and appropriate for use in public facilities (airplanes, casinos, hotels, etc.).

D.2.9.4 Design evaluation

USER input and observation on early prototypes detected problems such as misplacement of electrode pads and unnecessary defibrillation. People were timed performing rescues with different models and markings (behavioural prototyping). It was discovered that labelling steps 1-2-3 improved performance. Error analysis led to strategies to minimize errors such as forgetting to turn the MEDICAL DEVICE on or not fully connecting the electrodes. Post-market studies with a marketed MEDICAL DEVICE are expected to identify further opportunities for USER INTERFACE design improvement, addressing observed difficulties.

D.2.9.5 MEDICAL DEVICE implementation and deployment

Since AEDs entered the market, tens of thousands of units have been sold to airlines, police departments, hotels, casinos, schools, and hospitals. However, about one-fourth of the buyers are individuals who carry them or have them at home [13]. Twelve-year old children can use commercial AEDs successfully nearly as quickly as emergency medical personnel; 90 s for the children versus 67 s for the professionally trained adults [21]. However, certain AEDs are demonstrably easier and faster to use in specific contexts because the developers followed a USABILITY ENGINEERING PROCESS.

D.3 Planning the USABILITY ENGINEERING PROCESS

D.3.1 Assuring adequate USABILITY ENGINEERING involvement in the design team

USABILITY ENGINEERING professionals should become involved at a project's inception, although the team and its role can evolve throughout the design and development PROCESS. Early in the design PROCESS, once the initial concept has been defined, the range of necessary USABILITY ENGINEERING expertise can be identified, and personnel can be recruited. The USABILITY ENGINEERING effort differs depending on the type of MEDICAL DEVICE, its USABILITY ENGINEERING requirements, and the MANUFACTURER's organizational structure and culture. In some cases, the USABILITY ENGINEERING team can consist of one experienced practitioner who concurrently participates in a number of projects. In other cases, a number of USABILITY ENGINEERING practitioners are part of a multidisciplinary design team. USABILITY ENGINEERING practitioners can be employees of the organization or outside consultants. Some

organizations' USABILITY ENGINEERING practitioners are autonomous while others are embedded within another discipline's department, such as marketing, engineering, industrial design, or software development.

The success of USABILITY ENGINEERING efforts requires strong leadership to advocate appropriate USABILITY ENGINEERING during development and to manage related design efforts. More specifically, there should be a recognized USABILITY ENGINEERING leader who is empowered by management and is able to work effectively with other developers in the pursuit of USER INTERFACE design excellence.

In addition to having USABILITY ENGINEERING expertise, design teams are generally improved by the early involvement of individuals who:

- are responsible for developing the learning tools that are integrated with or accompany the MEDICAL DEVICE, such as on-line help, USER manuals, and quick reference guides;
- are responsible for developing courses and material for training;
- can build (or manage the building of) computer-based USER INTERFACE prototypes;
- can communicate with engineers and developers on a technical level;
- can effectively communicate with the relevant USER population(s).

D.3.2 Scaling the USABILITY ENGINEERING effort

D.3.2.1 General guidance

Similar to other elements of any engineering or design PROCESS, USABILITY ENGINEERING warrants proper scaling. In all circumstances, the goal is to perform sufficient USABILITY ENGINEERING in a traceable manner so that the final product has adequate SAFETY and USABILITY.

More vigorous USABILITY ENGINEERING efforts can be indicated if one is:

- developing a new MEDICAL DEVICE, rather than making minor changes to an existing design;
- developing a MEDICAL DEVICE involving extensive or complex USER interactions, as opposed to a simple MEDICAL DEVICE involving simple USER interactions;
- developing a MEDICAL DEVICE that performs a critical, life-sustaining function, versus one that performs less critical functions;
- introducing an entirely new technology or method that is unfamiliar to USERS, as opposed to one with which people are experienced.

Conversely, if a product requires limited USER interaction, then substantially less USABILITY ENGINEERING work can be warranted. When initiating an evolutionary development effort (i.e. modifying or updating an existing MEDICAL DEVICE), it can be appropriate to make use of past USABILITY ENGINEERING efforts, such as the results of USABILITY testing or post-market surveillance. For example, presuming there were no changes to a MEDICAL DEVICE'S ALARM SYSTEM and no changes in the types of USERS and USE SCENARIOS, it would be justifiable to VERIFY that aspect of the new MEDICAL DEVICE by citing past USABILITY ENGINEERING work (e.g. prior USABILITY testing). However, unrelated design changes can warrant USABILITY ENGINEERING evaluation. Making use of past USABILITY ENGINEERING work is an appropriate but complex matter that poses a trade-off between the potential savings and the extra effort required to justify and document the decision.

Some MEDICAL DEVICES perform a new medical function, combine functions from separate MEDICAL DEVICES or automate previously manual functions. The inherent complexity of a new MEDICAL DEVICE can require a relatively large-scale USABILITY ENGINEERING effort. Generally, the USABILITY ENGINEERING effort in products with new technology is much more substantial than the effort involved in the MEDICAL DEVICE modification – from the initial research, to conceptualization, through final VALIDATION. Also, there is typically relatively little existing data

(e.g. adverse events or RISK ANALYSIS information) from which to establish baseline conditions.

The following case studies illustrate the scaling of the USABILITY ENGINEERING PROCESS.

D.3.2.2 Case study: Minor modifications to a relatively simple MEDICAL DEVICE incorporating established technologies

Consider minor modifications to the design of a syringe pump incorporating established technology. In addition to the requisite task of creating an actual USER INTERFACE design, a responsive USABILITY ENGINEERING program might also include the following activities.

- Conduct structured interviews (individual or group) with representative USERS regarding the MANUFACTURER'S current MEDICAL DEVICE, as well as several competing MEDICAL DEVICES.
- Review reports of adverse incidents to discover RISKS due to USE ERROR and revise the RISK ANALYSIS. Then, ensure that the proposed design addresses these USE ERRORS.
- Apply established USABILITY ENGINEERING principles/guidelines during the design PROCESS, then ensure compliance by conducting a USABILITY ENGINEERING design audit.
- Conduct a USABILITY test of an early prototype (computer simulation or working model) to determine whether the prototype meets SAFETY and USABILITY goals and to discover opportunities for design improvement.
- Conduct a second, abbreviated USABILITY test to VALIDATE the refined near-final design.

Notice that the primary theme of these activities is early and continued involvement of representative USERS, although the actual number of USERS involved can be limited, at least in the case of a relatively simple MEDICAL DEVICE. Also, notice that a MEDICAL DEVICE such as a syringe pump can be less complex in terms of its electromechanical operation than that of a contrast medium injector (see D.3.2.3). However, some of the syringe pump's USER interactions might actually be more complex according to measures such as the number of steps and cognitive processing, thereby posing a potentially higher RISK of USE ERROR. In such cases, an incrementally more rigorous USABILITY ENGINEERING effort than described above might be warranted.

D.3.2.3 Case study: Initiating design of a complex MEDICAL DEVICE incorporating new technologies

Consider the development of a contrast medium injection system for CT scans. Such a system contains an injector that mechanically drives the piston on a syringe, a disposable syringe, a method for filling the syringe with contrast medium, and an electronic screen for controlling and monitoring injections. The development of such a system might involve the following steps.

- Conduct a thorough requirements development effort including appropriate research (e.g. task analysis) on the MEDICAL DEVICE performance characteristics, USER populations, operating environment, reliability, and SAFETY issues. Individuals from the population defined in the INTENDED USE (technicians, PATIENTS, and physicians) should be involved in this effort, as well as in all successive testing. If possible, interviews and observations should be conducted in the intended environment of use. Also, relationships with other MEDICAL DEVICES should be considered. At this stage, the USABILITY ENGINEERING practitioner or team should have a detailed specification of the USER INTERFACE requirements and a preliminary step-by-step summary of the procedures that need to be carried out.
- Determine allocations of functions between the USER and the MEDICAL DEVICE to assure that division of labour between manual and automated tasks is consistent with both human and machine capabilities. In the example of the injection system, it is important to determine what aspects of the injection would be automated, where manual over-rides are necessary, what type of feedback USERS need at what stage of the PROCESS, etc. The result might be a list of functions accompanied by a specification of how each function is