

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 1-6: General requirements for basic safety and essential performance –
Collateral standard: Usability**

**Appareils électromédicaux –
Partie 1-6: Exigences générales pour la sécurité de base et les performances
essentielles – Norme collatérale: Aptitude à l'utilisation**

WILLOW



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 1-6: General requirements for basic safety
and essential performance –
Collateral Standard: Usability**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-1-6 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice.

This second edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This document cancels and replaces the first edition of IEC 60601-1-6.

This edition of IEC 60601-1-6 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62A/550/FDIS	62A/557/RVD

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

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

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: 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 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes subclauses 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

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

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

Withdrawn

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL ELECTRICAL EQUIPMENT USABILITY have become an increasing cause for concern. 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 an element of the RISK MANAGEMENT PROCESS.

This collateral standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide BASIC SAFETY and ESSENTIAL PERFORMANCE as it relates to USABILITY of MEDICAL ELECTRICAL EQUIPMENT. It is intended to be useful not only for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT, but also for technical committees responsible for the preparation of particular standards.

Withdrawn

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

1 Scope, object and related standards

1.1 Scope

This International Standard specifies requirements for a PROCESS to analyse, design, verify and validate the USABILITY, as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT. This collateral standard addresses NORMAL USE and USE ERRORS but excludes ABNORMAL USE.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-6 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following referenced documents are indispensable for the 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.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-8:2006 and the following definitions apply.

NOTE An index of defined terms is found beginning on page 145.

3.1

ABNORMAL USE

intended act or intended omission of an act by the RESPONSIBLE ORGANIZATION or OPERATOR of ME EQUIPMENT as a result of conduct that is beyond any reasonable means of RISK CONTROL by the MANUFACTURER

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

NOTE 2 It is possible for the PATIENT to be the OPERATOR, e.g. when ME EQUIPMENT is used in the PATIENT'S home.

NOTE 3 ABNORMAL USE is not considered REASONABLY FORESEEABLE MISUSE.

3.2

EFFECTIVENESS

accuracy and completeness with which OPERATORS achieve specified goals

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

3.3

EFFICIENCY

resources expended in relation to the accuracy and completeness with which OPERATORS achieve goals

[ISO 9241-11:1998, definition 3.3 modified]

3.4

*** OPERATOR-EQUIPMENT INTERFACE**

means by which the OPERATOR and the ME EQUIPMENT communicate

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

NOTE The ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and the OPERATOR-EQUIPMENT INTERFACE.

3.5

OPERATOR PROFILE

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

3.6

*** PRIMARY OPERATING FUNCTION**

function that involves OPERATOR interaction that is either frequently used or related to the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT in NORMAL USE

3.7

*** REASONABLY FORESEEABLE MISUSE**

use by the OPERATOR in a way not intended by the MANUFACTURER but which can result from readily predictable human behaviour

[ISO/IEC Guide 51:1999, definition 3.14, modified]

NOTE 1 REASONABLY FORESEEABLE MISUSE is an intended action.

NOTE 2 Use refers to a product, PROCESS or service.

NOTE 3 Slips, lapses, mistakes and ABNORMAL USE can also be reasonably foreseeable, but are not considered REASONABLY FORESEEABLE MISUSE.

NOTE 4 See also Annex B.

3.8

TRAINING

application-specific OPERATOR-oriented instruction or exercises required for the safe and effective use of the ME EQUIPMENT

3.9

USE ERROR

act or omission of an act that has a different ME EQUIPMENT response than intended by the MANUFACTURER or expected by the OPERATOR

NOTE 1 USE ERROR includes slips, lapses, mistakes, and REASONABLY FORESEEABLE MISUSE.

NOTE 2 See also Annex B and D.1.3.

NOTE 3 The physiological response of the PATIENT is not considered part of USE ERROR.

3.10

USE SCENARIO

sequence of events and tasks used to specify and test the USABILITY of the ME EQUIPMENT

3.11

* USABILITY

characteristic that establishes EFFECTIVENESS, EFFICIENCY and OPERATOR learnability and satisfaction

3.12

USABILITY ENGINEERING

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

3.13

* USABILITY ENGINEERING FILE

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

3.14

USABILITY SPECIFICATION

documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

3.15

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]

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT

The ME EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERROR are acceptable. See also 7.1.1 and 12.2 of the general standard.

Compliance with this subclause is considered to exist when compliance with the other clauses and subclauses of this collateral standard is demonstrated.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT

When performing the RISK ANALYSIS step of the RISK MANAGEMENT PROCESS required by 4.2 of the general standard, the analysis shall consider the following:

- application specification (see 6.2.2.1);
- OPERATOR PROFILE;
- predictable USE ERRORS (see ANNEX C for a list of predictable USE ERRORS);
- * task related requirements;
- * context of use;
- information on HAZARDS known for existing OPERATOR-EQUIPMENT INTERFACES for ME EQUIPMENT of a similar type, if available;
- results of the review of the OPERATOR-EQUIPMENT INTERFACE (see D.2.2 in this document and D.7 of ISO 14971:2000).

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

5 ME EQUIPMENT identification, marking and documents

5.1 * ACCOMPANYING DOCUMENTS

A brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY, shall be included in the instructions for use. The same information shall also be included in the technical description, if this is provided as a separate document.

ACCOMPANYING DOCUMENTS for ME EQUIPMENT may be provided electronically, e.g. by electronic file format or CD-ROM. If the ACCOMPANYING DOCUMENTS are 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 ME EQUIPMENT, e.g. to cover emergency operation.

The ACCOMPANYING DOCUMENTS shall include a description of the OPERATOR PROFILE. The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the intended OPERATOR PROFILE.

Compliance is checked by inspecting the ACCOMPANYING DOCUMENTS and the USABILITY ENGINEERING FILE.

5.2 * TRAINING and materials for TRAINING

If ME EQUIPMENT specific TRAINING is required for the PRIMARY OPERATING FUNCTIONS of the ME EQUIPMENT, the MANUFACTURER shall:

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

NOTE 1 ME EQUIPMENT-specific TRAINING provides the knowledge and skills required for safe and effective use of ME EQUIPMENT in addition to the OPERATOR PROFILE.

The INTENDED USE shall be the basis for TRAINING and TRAINING material. The instructions for use shall indicate whether specific TRAINING for this ME EQUIPMENT is required and shall indicate the available TRAINING options.

NOTE 2 See IEC 61258 [1]. 1)

6 * USE ERROR and USABILITY

6.1 * Safety for the PATIENT, OPERATOR and other persons

A USABILITY ENGINEERING PROCESS shall be conducted to provide safety for the PATIENT, OPERATOR and other persons related to USABILITY of the OPERATOR-EQUIPMENT INTERFACE.

NOTE 1 To guide the application of USABILITY ENGINEERING principles, the HAZARDS to PATIENTS, OPERATORS and other persons as listed in ISO 14971 should be considered.

NOTE 2 The following are examples of HAZARDS for the PATIENT:

- unintentional setting of the diagnostic or therapeutic ME EQUIPMENT, e.g. inappropriate X-ray exposure setting requiring an additional exposure;
- unintentional interruption of delivery of therapy;
- misinterpretation of displayed values followed by an inappropriate treatment;
- confusing data presentation contributing to mental fatigue resulting in increased USE ERROR.

NOTE 3 The following are examples of HAZARDS for the OPERATOR:

- poor anthropometric design leading to musculoskeletal injury;
- repetitive-motion resulting in nerve/tendon injuries;
- poor display contrast resulting in eye fatigue;
- loud noise emanating from the ME EQUIPMENT resulting in hearing impairment.

Compliance with this subclause is considered to exist when compliance with the other clauses and subclauses of this collateral standard is demonstrated.

6.2 * USABILITY ENGINEERING PROCESS

6.2.1 General

The results of the USABILITY ENGINEERING PROCESS shall be recorded in the USABILITY ENGINEERING FILE. The USABILITY ENGINEERING PROCESS may vary in form and extent based on the nature of the ME EQUIPMENT, its intended OPERATOR and its INTENDED USE (see D.3.2). The records and other documents that make up the USABILITY ENGINEERING FILE may form part of other documents and files, e.g. a MANUFACTURER'S product file or RISK MANAGEMENT FILE.

1) Figures in square brackets refer to the Bibliography.

In the case of the modification of existing ME EQUIPMENT design, the USABILITY ENGINEERING PROCESS may be scaled based on the significance of the modification depending on the results of the RISK ANALYSIS (see D.3.2.2).

NOTE 1 The MANUFACTURER should conduct iterative design and development. USABILITY ENGINEERING should begin early and continue through the ME EQUIPMENT design and development life cycle.

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

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

6.2.2 Input for the USABILITY ENGINEERING PROCESS

6.2.2.1 * ME EQUIPMENT application specification

The MANUFACTURER shall specify the application of the ME EQUIPMENT in the USABILITY ENGINEERING FILE.

This specification shall include:

- medical purpose (e.g. conditions(s) or disease(s) to be screened, monitored, treated, or diagnosed);
- PATIENT population (e.g. age, weight, region of body, health, condition);
- part of the body or type of tissue applied to or interacted with;
- * intended OPERATOR PROFILE; and
- application (e.g. environment, frequency of use, location, mobility).

NOTE This specification contains elements of the INTENDED USE.

A summary of the ME EQUIPMENT application specification shall be included in the instructions for use.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE and the instructions for use.

6.2.2.2 PRIMARY OPERATING FUNCTIONS

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

NOTE 1 See also D.5.3, D.5.5, D.5.9, D.5.10 and D.5.14 for a discussion of methods that might be useful in determining PRIMARY OPERATING FUNCTIONS.

NOTE 2 PRIMARY OPERATING FUNCTIONS should be easily recognizable and self-explanatory to the OPERATOR.

NOTE 3 See element 1.2 of Figure E.1 for an example of PRIMARY OPERATING FUNCTIONS for a hypothetical ME EQUIPMENT.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

6.2.2.3 * Information for safety as a RISK CONTROL

For RISK CONTROL related to USABILITY, the MANUFACTURER shall decide what information is required for BASIC SAFETY or ESSENTIAL PERFORMANCE, e.g. warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc. Any such information shall be subject to the USABILITY ENGINEERING PROCESS. Disregarding this information shall be considered ABNORMAL USE. See also Annex B.

NOTE 1 RISK CONTROL consists of an integrated approach in which the MANUFACTURER uses one or more of the following in the priority listed:

- a) inherent SAFETY by design;
- b) protective measures in the ME EQUIPMENT 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.

The results of the RISK ANALYSIS or a reference to the location of the results of the RISK ANALYSIS shall be recorded in the USABILITY ENGINEERING FILE.

NOTE 2 The RISK ANALYSIS for the ME EQUIPMENT or for the corresponding generic device type is an input for the USABILITY SPECIFICATION as required for the USABILITY ENGINEERING PROCESS. Any RESIDUAL RISK evaluation should consider the results of the USABILITY VALIDATION.

NOTE 3 The evaluation of post-production information (post-market surveillance) should include USABILITY (see ISO 14971:2000, Clause 9).

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

6.2.3 * USABILITY SPECIFICATION

As part of the USABILITY ENGINEERING PROCESS, the MANUFACTURER shall develop a USABILITY SPECIFICATION. The USABILITY SPECIFICATION shall be recorded in USABILITY ENGINEERING FILE. The USABILITY SPECIFICATION may be integrated into other specifications.

The USABILITY SPECIFICATION shall be based on the following:

- application specification (see 6.2.2.1);
- HAZARDS related to the use of the ME EQUIPMENT (results from RISK ANALYSIS as described in 4.2); and
- predictable USE ERRORS associated with the ME EQUIPMENT.

The USABILITY SPECIFICATION shall describe at least:

- * USE SCENARIOS for the ME EQUIPMENT;
- OPERATOR actions related to the PRIMARY OPERATING FUNCTIONS;
- OPERATOR-EQUIPMENT INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS; and
- requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the OPERATOR.

NOTE 1 The USABILITY SPECIFICATION should include references to context of use (see the rationale for Subclause 4.2 and D.4.1.2.4).

NOTE 2 For guidance, see D.2.6.

NOTE 3 See Annex E for an example of a USABILITY SPECIFICATION for hypothetical ME EQUIPMENT.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

6.2.4 * USABILITY VERIFICATION

As part of the ME EQUIPMENT design VERIFICATION PROCESS, the MANUFACTURER shall verify the OPERATOR-EQUIPMENT interface design according to the USABILITY SPECIFICATION. The results of the VERIFICATION shall be recorded in USABILITY ENGINEERING FILE.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

6.2.5 Usability validation plan

The MANUFACTURER shall develop 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 (see Table D.5); and
- the involvement of representative intended OPERATORS (see D.4.3.2).

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 1 The MANUFACTURER should apply one or more methods for the USABILITY VALIDATION of PRIMARY OPERATING FUNCTIONS of the ME EQUIPMENT depending on the INTENDED USE. Examples of these methods are found in Clause D.5.

NOTE 2 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:

- worst case USE SCENARIOS derived from:
 - the application specification (see 6.2.2.1),
 - predictable USE ERRORS, and
 - the results of the RISK ANALYSIS; and
- USE SCENARIOS representing frequent application situations identified in the USABILITY SPECIFICATION.

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

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

6.2.6 * USABILITY VALIDATION

The MANUFACTURER shall validate OPERATOR-EQUIPMENT INTERFACE design according to the USABILITY VALIDATION plan. The results shall be recorded, including any required design modification needed to satisfy the criteria as defined in the USABILITY VALIDATION plan.

NOTE 1 The ACCOMPANYING DOCUMENTS are part of the ME EQUIPMENT and are also subject to activities for validating USABILITY.

NOTE 2 Individuals that were not directly involved in the OPERATOR-EQUIPMENT INTERFACE design should be involved in the USABILITY VALIDATION.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

Annex A (informative)

General guidance and rationale

A.1 General guidance

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

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Definition 3.4 – OPERATOR-EQUIPMENT INTERFACE

The OPERATOR-EQUIPMENT INTERFACE includes all means of communication between the ME EQUIPMENT to the OPERATOR and the OPERATOR to the ME EQUIPMENT. These means include, but are not limited to:

- markings and ACCOMPANYING DOCUMENTS;
- lights;
- video displays;
- push buttons;
- touch screens;
- auditory and visual INFORMATION SIGNALS;
- ALARM SIGNALS;
- vibratory signals;
- keyboard and mouse; and
- haptic controls.

Definition 3.6 – PRIMARY OPERATING FUNCTION

For the purposes of this collateral standard, a PRIMARY OPERATING FUNCTION is a function that is directly related to the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT in NORMAL USE or a function that is frequently used. Examples of PRIMARY OPERATING FUNCTION that directly relate to BASIC SAFETY or ESSENTIAL PERFORMANCE include:

- inactivating an ALARM SIGNAL (temporarily or indefinitely);
- setting ALARM LIMITS;
- setting X-ray exposure parameters (e.g. kV_p, mA);
- setting infusion parameters (e.g. flow rate);
- setting 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 OPERATORS' workloads and can increase the probability of USE ERRORS affecting safety-related functions. A collection of relatively minor shortcomings in the design of OPERATOR-EQUIPMENT INTERFACES 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 ME EQUIPMENT and increase the time required to perform frequent tasks due to an overall increase in mental and physical workload. At worse, these shortcomings can induce USE ERROR because OPERATORS have to focus more attention on operational mechanics, 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 blundering due to rushing. Accordingly, it makes sense to review all functions, particularly the most frequent ones, and determine if there could be a problem due to the cumulative effect of USABILITY ENGINEERING deficiencies that could have a negative impact on BASIC SAFETY or ESSENTIAL PERFORMANCE.

Definition 3.7 – REASONABLY FORESEEABLE MISUSE

There is often a thin line between ABNORMAL USE and REASONABLY FORESEEABLE MISUSE. What might look to be a case of ABNORMAL USE can later turn out to be REASONABLY FORESEEABLE MISUSE after investigation and closer examination by experts trained in the USABILITY ENGINEERING PROCESS and the science of human error. The RISK MANAGEMENT PROCESS of ME EQUIPMENT defines within the context of that particular ME EQUIPMENT what is REASONABLY FORESEEABLE MISUSE and what is ABNORMAL USE, and documents what RISK CONTROL measures have been taken to mitigate the REASONABLY FORESEEABLE MISUSE.

A MANUFACTURER needs to exercise judgement in selecting the appropriate RISK CONTROL measure to avoid unnecessarily limiting the practice of medicine. ME EQUIPMENT should not arbitrarily prevent off-label use that does not present a HAZARD, e.g. preventing the use of ME EQUIPMENT for a PATIENT population because efficacy data does not exist. In such a case, using a protective measure in the ME EQUIPMENT is more appropriate, e.g. a warning message or pop-up window on the display.

The USABILITY ENGINEERING PROCESS helps discover which actions are “readily predictable.”

Definition 3.11 – USABILITY

The time needed to become acquainted with the ME EQUIPMENT and its operation is called “learnability” (ISO 9241-11:1998, Table B.2 [5]). Freedom from discomfort, and positive attitude towards the use of the ME EQUIPMENT is called “satisfaction” (ISO 9241-11:1998, definition 3.4 [5]).

NOTE How easy it is to remember the operational details of ME EQUIPMENT can be thought of as “memorizability” [10].

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

To gauge if ME EQUIPMENT exhibits adequate USABILITY, specifications for the following influencing factors are required:

- OPERATOR;
- task/goals; and
- conditions and setting in which the OPERATOR interacts with the ME EQUIPMENT.

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.

Some OPERATOR-EQUIPMENT INTERFACES 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 OPERATOR is using the ME EQUIPMENT in an emergency or stressful situation, is fatigued, or uses the ME EQUIPMENT only rarely.

Definition 3.13 – USABILITY ENGINEERING FILE

The USABILITY ENGINEERING FILE can be 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.

Subclause 4.1 – Conditions for application to ME EQUIPMENT

This collateral standard specifies requirements addressing particular RISKS associated with USABILITY. When these requirements are complied with, the RESIDUAL RISKS associated with USABILITY are presumed to be acceptable unless there is objective evidence to the contrary. This follows from 4.2 of the General Standard, which states “Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.”

The criteria for judging risk acceptability are established by the USABILITY VALIDATION plan, which specifies the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS.

Subclause 4.2 – RISK MANAGEMENT PROCESS for ME EQUIPMENT

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 1.3.4 in Figure E.1). Examples of task related requirements are:

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

Context of use:

The context of use can have a significant impact on **USABILITY** of **ME EQUIPMENT**. For safety reasons the context of use needs to be analyzed and considered by the **MANUFACTURER**. When **ME EQUIPMENT** is used as part of a **MEDICAL ELECTRICAL SYSTEM**, context of use needs to consider the attributes of the other elements of the system.

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

- spatial context:
 - architecture: in-house, in town, types of building, e.g.: hospital (ward, OT, ICU), theatre, cinema, home;
 - outside;
 - technological settings (airplane, ship, ambulance, car);
 - smoothness and inclination of floor;
 - emergency location;
- social context:
 - organization;
 - shift work (requirement to receive/forward inputs/outputs for **ME EQUIPMENT**);
 - presence of: unattended children; untrained and/or curious adults;
 - responsibility (shared, alone);
- technological context:
 - other technical devices which require operation;
 - other technical devices which constitute a way of handling;
 - other technical devices which will be affected by the operating of this **ME EQUIPMENT**;
 - effect of other devices on this **ME EQUIPMENT**;
- hygienic context:
 - requirements for cleanliness, sterile conditions;
 - facilities for cleaning;
 - facilities for waste disposal;
- physical context:
 - climate: altitude, ambient pressure, temperature, rain, snow, wind, light;
 - acceleration, movement of frame of reference (car, ship, etc.);
 - daytime;
 - light;
- activity context:
 - distractions;
 - other tasks which can interfere with the operation of the **ME EQUIPMENT**;
 - surprise/startle effect;
 - strain and stress;
 - influence on the working environment;
 - if the **ME EQUIPMENT** alters the working environment (e.g. general lighting during minimal invasive surgery) to which other devices have been adapted, the **USABILITY** of these other devices could be deteriorated, e.g. the visibility of a monitor.

Subclause 5.1 – ACCOMPANYING DOCUMENTS

It is important for the RESPONSIBLE ORGANIZATION and OPERATOR to have a good understanding of the operation of ME EQUIPMENT. A good mental model of ME EQUIPMENT helps provide a greater degree of safety as the OPERATOR will better understand the ME EQUIPMENT's benefits and limitations, which can reduce USE ERROR, improve error mitigation and aid in troubleshooting.

Subclause 5.2 – TRAINING and materials for TRAINING

Modern ME EQUIPMENT is often complex with multiple functions. To help ensure safe use, specific TRAINING is often required. Any TRAINING materials provided with the ME EQUIPMENT should consider the OPERATOR 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 employed by the MANUFACTURER can provide these materials.

Clause 6 – USE ERROR and USABILITY

This collateral standard introduces 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 ME EQUIPMENT are the result of oversight or carelessness on the part of the OPERATOR of the ME EQUIPMENT. Much more commonly, USE ERRORS are the direct result of poor human interface design. This predisposes the OPERATOR to make an incorrect or unintended act or omission. The concept of USABILITY has been added to this clause because Clause 6 deals with requirements for the USABILITY ENGINEERING PROCESS to address the RISK of USE ERRORS.

Subclause 6.1 – Safety for the PATIENT, OPERATOR and other persons

As ME EQUIPMENT become more complicated, USE ERRORS and accidents are inevitable (see D.1.3). Much of the ME EQUIPMENT available on the market today are non-intuitive, difficult to learn and use. As healthcare evolves, less educated OPERATORS and the PATIENTS themselves are now using ME EQUIPMENT. In the past, the OPERATOR of ME EQUIPMENT was often technologically skilled and was able to cope with ambiguous, difficult to use OPERATOR-EQUIPMENT INTERFACE that was needed to operate ME EQUIPMENT. The design of usable ME EQUIPMENT is a difficult, often unpredictable, endeavour, yet many organizations treat it as it were just “common sense”. The design of the OPERATOR-EQUIPMENT INTERFACE to achieve adequate USABILITY requires a very different skill set than that of the technical implementation of that interface. The design of the OPERATOR-EQUIPMENT INTERFACE should be operator-centric and needs a multidisciplinary team approach to its design. This team can include actual OPERATORS, engineers, user-interface specialists, cognitive psychologists, multimedia programmers, USABILITY engineers, marketing and training personnel. See D.1.1.

Subclause 6.2.2.1 – ME EQUIPMENT application specification

The ME EQUIPMENT application specification describes the important attributes that are fundamental to the function of the ME EQUIPMENT and its USABILITY. The ME EQUIPMENT application specification is the foundation for defining the USABILITY SPECIFICATION. It is important to design ME EQUIPMENT tailored to the intended OPERATOR(S). Factors that should be considered when developing OPERATOR PROFILE(S) are age, gender, national origin, level of education and occupation. Intended OPERATOR disabilities must be taken into account. For example, ME EQUIPMENT for use by diabetics should consider that they often have poor visual acuity and have a poor sense of touch.

See element 1.1.2.4 in Figure E.1 for an example of an OPERATOR PROFILE.

Subclause 6.2.3 – USABILITY SPECIFICATION

The USE SCENARIOS described in the USABILITY SPECIFICATION are representations of actual tasks that OPERATORS and RESPONSIBLE ORGANIZATION would conceivably perform with the ME EQUIPMENT. They include the end result of the task they are trying to achieve, the reason for performing the tasks, the functional state of the ME EQUIPMENT when a task is initiated and readouts of displays and printouts that the OPERATOR will see while performing the task. USE SCENARIOS should include common routine tasks and rarely used tasks that may be performed in an emergency situation.

Subclause 6.2.4 – USABILITY VERIFICATION

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

- guide the development of parts of the ME EQUIPMENT such as ACCOMPANYING DOCUMENTS and TRAINING, and
- if necessary, make adjustments to the OPERATOR-EQUIPMENT INTERFACE.

USABILITY VERIFICATION is done through a process of observing and collecting data from intended OPERATORS while they interact with either the ME EQUIPMENT or a (high fidelity) ME EQUIPMENT prototype in the intended or simulated environment of use.

USABILITY VERIFICATION tests the OPERATOR-EQUIPMENT INTERFACE whereas USABILITY VALIDATION confirms whether the ME EQUIPMENT meets the USABILITY requirements for a specific application or INTENDED USE. See also the rationale for Subclause 6.2.6 and D.4.7.2.

Subclause 6.2.6 – 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 OPERATOR-EQUIPMENT INTERFACE because unexpected interactions between the ME EQUIPMENT and the OPERATOR might occur that can only be discovered by VALIDATION.

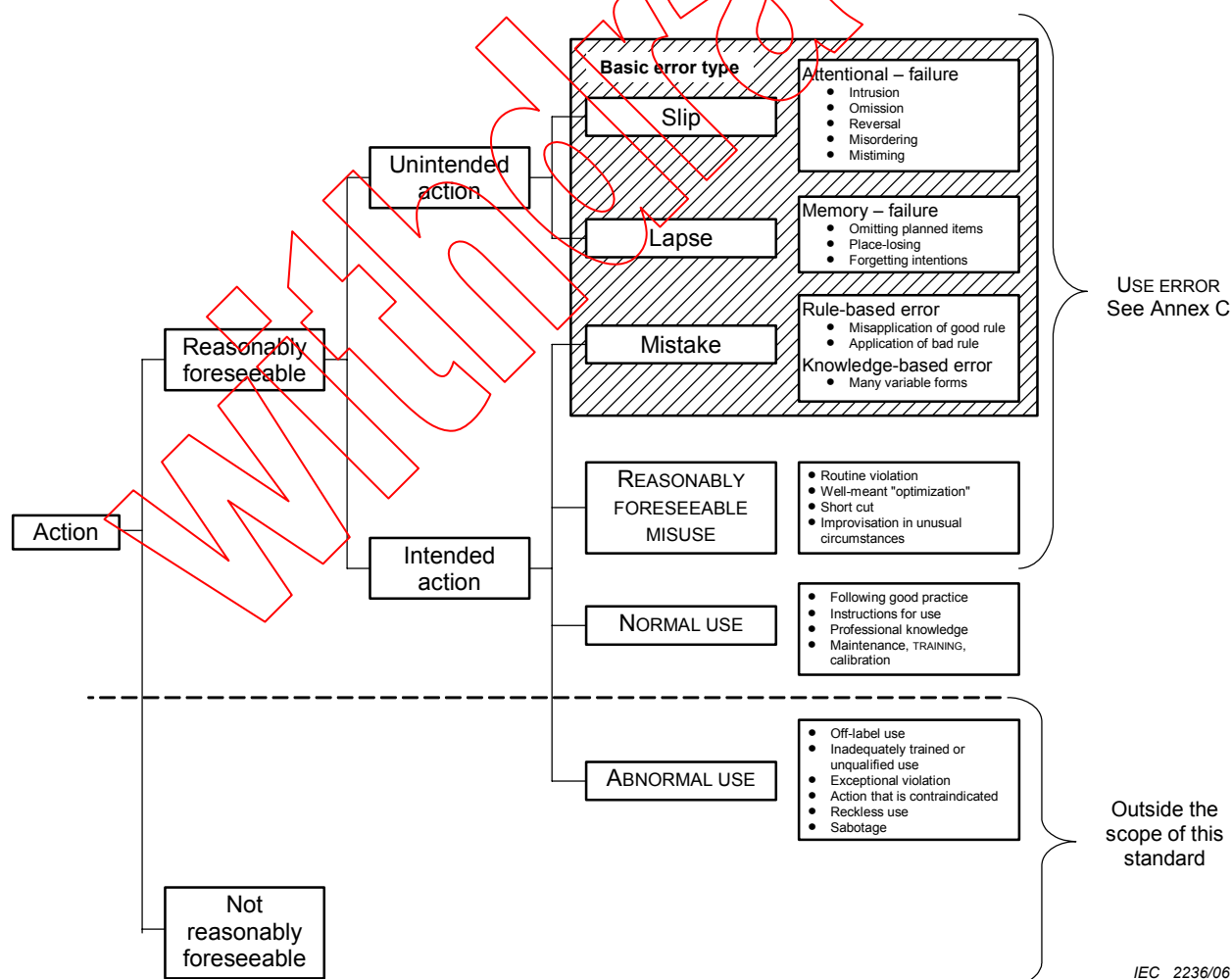
Annex B (informative)

A taxonomy of OPERATOR action

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 [11]).

Slips, lapses, mistakes and REASONABLY FORESEEABLE MISUSE are all considered forms of USE ERROR. In the USABILITY ENGINEERING PROCESS, it is necessary 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. For this standard, the taxonomy of Figure B.1 is used.



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Figure B.1 – Summary of the taxonomy of OPERATOR action

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

Annex C (informative)

Examples of USE ERRORS, ABNORMAL USE and design flaws potentially leading to USE ERRORS

C.1 Background

The following USE ERRORS and ABNORMAL USE examples are based on adverse event reports collected by several regulatory authorities [9]. 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 ACCOMPANYING DOCUMENTS of the medical devices involved.

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

The list of design flaws was extracted from Clause D.7 of ISO 14971:2000.

C.2 USE ERRORS

- OPERATOR confuses two buttons and presses the wrong button.
- OPERATOR misinterprets the icon and selects the wrong function.
- OPERATOR enters incorrect sequence and fails to initiate infusion.
- OPERATOR fails to detect a dangerous increase in heart rate because the ALARM LIMIT is mistakenly set too high and OPERATOR is over-reliant on ALARM SYSTEM.
- OPERATOR 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.
- 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.
- OPERATOR is under time pressure and uses a shortcut on excessively lengthy instructions, procedures, pre-use checklist, etc, thereby abbreviating them.

C.3 ABNORMAL USE

The following are abbreviated descriptions of events that occurred despite proper ACCOMPANYING DOCUMENTS, proper design, and proper TRAINING, and were determined to be beyond any reasonable means of RISK CONTROL by the MANUFACTURER.

- Deliberate, premeditated violation of instructions, procedures, pre-use checklist, calibration, or maintenance, etc., as specified in the ACCOMPANYING DOCUMENTS.
- Failure to stop using an X-ray tube after having ignored the warning light that indicates it is overheating. The X-ray equipment subsequently stops operating or fails and that delays or prevents completion of a therapeutic procedure.
- Use of ME EQUIPMENT prior to completing installation or the initial performance checks as specified by the ACCOMPANYING DOCUMENTS.
- Deliberate failure to conduct prescribed device checks prior to each use as defined by the ACCOMPANYING DOCUMENTS.
- Continued use of ME EQUIPMENT beyond the prescribed maintenance interval as clearly defined in the ACCOMPANYING DOCUMENTS as a result of RESPONSIBLE ORGANIZATION'S failure to arrange for maintenance.
- Contrary to the instructions for use, the ME EQUIPMENT was not sterilized prior to implantation.
- Use of electrosurgical device on a pacemaker PATIENT while deliberately ignoring the clear warning in the instructions for use to take proper precautions, resulting in the need to re-program the pacemaker or explant the device. A pacemaker programmer is not available.
- PATIENT harmed because RESPONSIBLE ORGANIZATION had not ensured that the OPERATOR was adequately trained. The ME EQUIPMENT is working in accordance to 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 h in duration. Finding no other pump available, the clinician decides to use the pump in a paediatric extra-corporeal membrane oxygenation (ECMO) procedure that can last several days. The pump fails due to fatigue cracking and the PATIENT bleeds to death.
- A centrifugal pump is made from material that is known to be incompatible with alcohol. The OPERATOR cleans the pump with alcohol despite the product warnings in the ACCOMPANYING DOCUMENTS and clear and prominent warning on the pump that alcohol is not to be used.
- Contrary to clearly perceivable warnings, the RESPONSIBLE ORGANIZATION or OPERATOR removes the safety interlock on a medical laser.
- Contrary to clearly perceivable warnings, filter removed and intentionally not replaced resulting in particulate contamination and subsequent ME EQUIPMENT failure.
- Use of an automated analyzer regardless of obvious warnings on the screen that calibration is to be verified.
- Pacemaker PATIENT placed into MRI system with the knowledge of the physician that use of MRI is contraindicated.
- OPERATOR 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 condition.
- 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.

C.4 Design flaws

Mapping in this context is the manner in which controls and/or displayed information are linked to each other and to ME EQUIPMENT functions and states. In some cases, mapping can be positional, such as grouping together controls or displays that are related to the same function. In other cases, mapping can deal with the direction or sequence of control operation(s), or the semantic/symbolic relationship between controls/displays and related functions. Some mappings are intuitive, based upon general experience (e.g. moving a lever up to increase a quantity). Others are based upon established conventions (e.g. flow controls turned clockwise to reduce flow on a gas machine).

Poor mapping – This would be any mapping that either is counter-intuitive and/or hard-to-remember. For example, an arbitrary sequence of button pushes necessary for setting parameters in an infusion pump would be counter-intuitive and difficult-to-remember. However, it probably would not contradict an established convention (see “controversial” mapping, below).

Controversial mapping – This is any mapping that contradicts an established convention. An obvious example would be the use of the colour green as a warning indicator. Another would be the flow control on a gas machine requiring a clockwise turn of the knob to increase flow.

The following is a list of design flaws that can lead to USE ERROR.

- complex or confusing control system;
- ambiguous or unclear ME EQUIPMENT 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.

Annex D (informative)

Guidance on the USABILITY ENGINEERING PROCESS

D.1 Introduction to USABILITY ENGINEERING PROCESS

D.1.1 General

This annex is introductory guidance to the application of the USABILITY ENGINEERING PROCESS needed to fulfil OPERATOR-EQUIPMENT INTERFACE design requirements in the development of ME EQUIPMENT, including hardware, software, and documentation. This annex is derived from ANSI/AAMI HE 74:2001 [8].

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 OPERATOR-EQUIPMENT INTERFACE includes all aspects of ME EQUIPMENT with which OPERATORS interact when operating the ME EQUIPMENT. Instructions for use and ME EQUIPMENT labelling are integral parts of the OPERATOR-EQUIPMENT INTERFACE. OPERATORS are considered to include maintainers, cleaners, and other service personnel who handle the ME EQUIPMENT. An OPERATOR can be a caregiver (e.g. person who operates 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. family members).

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 ME EQUIPMENT, 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 ME EQUIPMENT industry.

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 ME EQUIPMENT, which range from simple digital thermometers to complex imaging systems, and which can be used in hospitals, clinics or the home by various professionals and laypersons.

As such, it is impossible to prescribe a single set of USABILITY ENGINEERING methods that will be optimal for all design projects. Instead, this document describes a USABILITY ENGINEERING PROCESS that requires additional shaping and scaling to suit practitioners, experience and style as well as project specifications. The document's ultimate goal is to ensure that MANUFACTURERS approach OPERATOR-EQUIPMENT INTERFACE design in a rigorous, effective manner.

D.1.2 The benefits of USABILITY ENGINEERING

The primary goal of a USABILITY ENGINEERING program tailored to medical devices should be making devices 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 equipment, and nuclear power systems. An integrated and structured USABILITY ENGINEERING program can help medical device developers make their devices safer and easier to use.

D.1.3 Avoiding design-induced error

Device-related errors usually result from multiple inter-related factors. Adverse event reports confirm that the device itself often contributes to USE ERRORS, most commonly due to OPERATOR-EQUIPMENT 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 OPERATORS, 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 OPERATOR activation of adjacent controls. A thorough understanding of the 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 device interaction problems, for example, the possibility of incorrect, perhaps dangerous tubing connections due to common physical fit and appearance. USABILITY tests using 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	OPERATOR presses the wrong button
Two icons on a software screen look too similar	OPERATOR misinterprets the icon and selects the wrong function
An OPERATOR-EQUIPMENT INTERFACE requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion	OPERATOR enters incorrect sequence and fails to initiate infusion
Infusion pump displays misleading “Open Door-Reset” message when there is air in the infusion line	OPERATOR repeatedly opens the door and presses the reset key instead of clearing air from the infusion line
OPERATOR-adjusted high and low ALARM LIMITS on a heart-rate monitor are not continuously displayed	OPERATOR fails to detect a dangerous increase in heart rate because ALARM LIMIT is set too high and OPERATOR is over-reliant on ALARM SYSTEM
Typical OPERATOR-applied force exceeds breaking strength of catheter connector	OPERATOR cracks catheter connector when tightening

D.1.4 Improving USABILITY

Medical device OPERATORS (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 devices intended for PATIENTS (e.g. home glucose monitors for diabetics), ease of use can affect whether the PATIENT will be able to use the device at all. Medical device MANUFACTURERS will be well served by investing the necessary resources to improve USABILITY. From a business standpoint, the potential payoffs of investing in improved USABILITY can include:

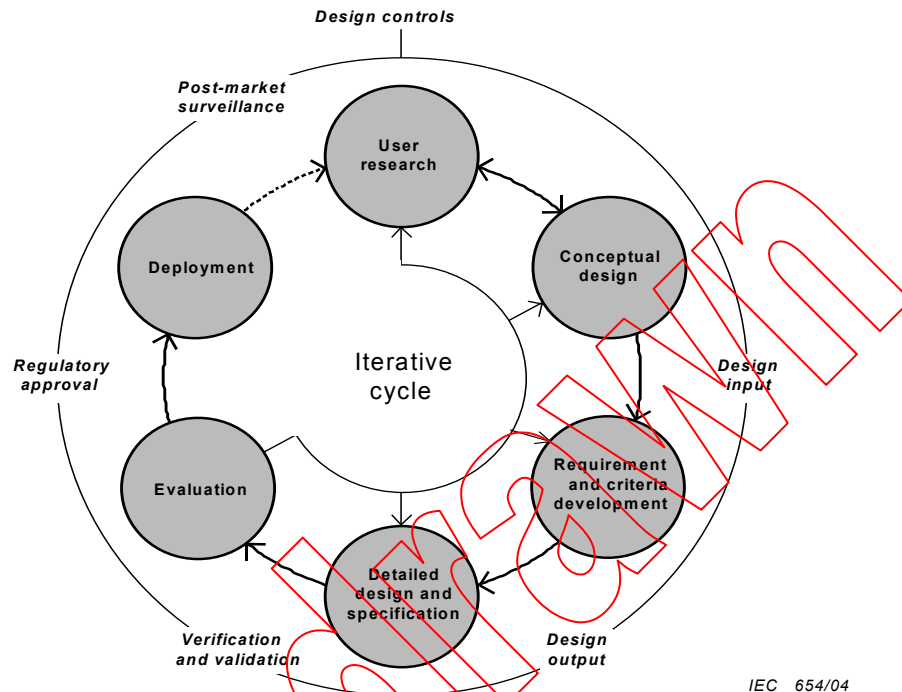
- faster time to market (by avoiding OPERATOR-EQUIPMENT INTERFACE problems late in the development cycle);
- simpler OPERATOR manuals and related learning tools;
- improved marketing through credible claims about a device's USABILITY and associated gains in OPERATOR productivity;
- increased sales (due to increased customer satisfaction);
- reduced TRAINING and support requirements;
- extended market life;
- clearer compliance with regulatory requirements;
- reduced exposure to liability claims; and
- increased OPERATOR 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 will invariably include 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) will vary with each development effort.



NOTE 1 Input from OPERATORS 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 standard.

Figure D.1 – An OPERATOR-EQUIPMENT INTERFACE design cycle

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

Design-cycle element	Subclause of this Collateral Standard
Conceptual design	4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT
Requirement and criteria development	6.2.2.1 ME EQUIPMENT application specification 6.2.2.2 PRIMARY OPERATING FUNCTIONS 6.2.3 USABILITY SPECIFICATION
Detailed design and specification	4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT
Evaluation	6.2.4 USABILITY VERIFICATION 6.2.5 USABILITY VALIDATION plan 6.2.6 USABILITY VALIDATION 4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT

For each step in the cycle, the USABILITY ENGINEERING team uses evidence, judgement, and experience to determine the appropriate USABILITY ENGINEERING activities and effort. Thus, a fundamental goal of this annex is to provide guidance on how to make decisions about the nature and magnitude of USABILITY ENGINEERING activities.

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 an OPERATOR performs when interacting with a device (i.e. task analysis) can be equally appropriate during early conceptualization of a new device, when developing specific 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 will go through many such cycles. With regard to medical devices, 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 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 device evaluation, issues raised by design VERIFICATION activities (i.e. ascertaining whether device design meets previously established design requirements) frequently lead to design changes. Similarly, issues raised during design VALIDATION activities (i.e. ascertaining whether the device adequately addresses established OPERATOR needs) can also precipitate subsequent modifications in design requirements or even in device conceptualization.

The description of the USABILITY ENGINEERING PROCESS as a step-wise cycle can give the misleading impression that OPERATOR-EQUIPMENT 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), 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 OPERATOR-driven design conceptualization (the two connected, upper-right steps). Whether one is considering a revolutionary new device or evolutionary modifications of an existing device, design conceptualization can be driven not only by OPERATOR 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 device design changes that impact OPERATOR-EQUIPMENT 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 OPERATOR research

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

OPERATOR 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 OPERATORS will interact with the device in the actual use environment. This understanding can only come from OPERATOR input and observation. Formal OPERATOR testing, in an actual or simulated setting, is commonly an integral part of the medical device development PROCESS.

Efforts to get to know OPERATORS 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 OPERATOR preferences (e.g. focus groups) are unacceptable substitutes for appropriately designed USABILITY ENGINEERING testing and evaluation. However, marketing groups can facilitate relationships between prospective OPERATORS, 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 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 device.

During the earliest phases of design, it is important to define OPERATOR needs as clearly and specifically as possible, an often difficult task. OPERATORS can have difficulty articulating their needs precisely and sometimes don't really know what they need. The results of focus groups and OPERATOR 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 OPERATOR needs prior to design.

D.2.5 Design requirement/ criteria development

The development of design criteria/requirements can begin once OPERATOR needs and the consequent concept of the device have been well defined. The design criteria/requirements define the intended operating conditions, OPERATOR characteristics, functions, and potential HAZARDS of the device. Typically, the design criteria/requirements, the embodiment of the design input, undergo substantial revision and refinement as the 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 OPERATOR needs, technical and manufacturing constraints and market realities. The USABILITY ENGINEERING team concurrently interprets OPERATOR 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 OPERATOR-EQUIPMENT 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 will meet its intended OPERATOR needs. Thus, as the design PROCESS proceeds, rigorous statements of desired 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 OPERATOR-EQUIPMENT 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 OPERATOR-EQUIPMENT INTERFACE requirements

Category	Example
General	Make sure read-only displays differ visually from displays that allow OPERATORS to edit data.
	Read-only text will be displayed in black text on white background display while text that can be edited will be white text on black background display.
List boxes	Selected item in list box is highlighted by reverse video.
	Must be long enough to view four choices without scrolling.
	All menus have a title.
Menus	Menu items are left-justified.
	The upper left corner of the screen shall be reserved for the ALARM OFF indicator.
Displays	The luminance of the display will be greater than 35 cd/m ² . Contrast will not be less than 7:1.
Control devices	Control panel buttons will be 1,5 cm square with centre to centre spacing of 2 cm.
	The keyboard will be 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 device design can there be assurance that the design is technically sound and also meets the OPERATOR'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 OPERATOR'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 check points 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 OPERATOR involvement.

ME EQUIPMENT markings and ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and as such should undergo the same rigorous evaluation as other OPERATOR-EQUIPMENT 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 device implementation and deployment. This step includes manufacturing, marketing, sales, regulatory clearance, and OPERATOR TRAINING. Design transfer refers to the use of final design specifications to manufacture (and obtain approval to sell) the 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 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 OPERATOR feedback brings the USABILITY ENGINEERING aspects of medical device design full circle. The result is revised device designs as well as ideas for new devices that address the issues raised.

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

D.2.9.1 Design concept development and OPERATOR 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 of 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.2.9.2 Design criteria/requirement development

Through research, USABILITY ENGINEERING personnel determined that the units 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.2.9.3 Design evaluation

OPERATOR input and observation on early prototypes detected problems such as misplacement of electrode pads and unnecessary defibrillation. People were timed doing 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 device on or not fully connecting the electrodes.

D.2.9.4 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 [9]. Twelve-year old children can use commercial AEDs successfully nearly as quickly as emergency medical personnel: 90 s for the children verses 67 s for the professionally trained adults [31].

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 will differ depending on the type of 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 design efforts. More specifically, there should be a recognized USABILITY ENGINEERING leader who is empowered by management and is able to work productively and pragmatically with related disciplines while still pursuing OPERATOR-EQUIPMENT 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 medical devices, such as on-line help, **OPERATOR** manuals, and quick reference guides;
- are responsible for developing courses and material for **TRAINING**;
- can communicate with engineers and developers on a technical level;
- can build (or manage the building of) computer-based **OPERATOR-EQUIPMENT INTERFACE** prototypes;
- can effectively communicate with the relevant **OPERATOR** 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, **EFFECTIVENESS**, and **USABILITY**.

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

- developing a new device, rather than making minor changes to an existing design;
- developing a device involving extensive or complex **OPERATOR** interactions, as opposed to a simple device involving simple **OPERATOR** interactions;
- developing a 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 **OPERATORS**, as opposed to one with which people are experienced.

Conversely, if a product requires limited **OPERATOR** interaction, then substantially less **USABILITY ENGINEERING** work can be warranted. When initiating an evolutionary development effort (i.e. modifying or updating an existing 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 an **ME EQUIPMENT'S ALARM SYSTEM** and no changes in the types of **OPERATORS** and **USE SCENARIOS**, it would be justifiable to verify that aspect of the new 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 devices perform a new medical function, combine functions from separate devices or automate previously manual functions. The inherent complexity of new **ME EQUIPMENT** can require a relatively large-scale **USABILITY ENGINEERING** effort. Generally, the **USABILITY ENGINEERING** effort in products with new technology will be much more substantial than the effort involved in device modification – from the initial research, to conceptualization, through final **VALIDATION**. Also, there will typically be relatively little existing data (e.g. adverse events or hazard analysis information) from which to establish baseline conditions.

D.3.2.2 Case study: Designing minor modifications of a simple device

Consider minor modifications to the design of a simple device involving established technology, such as a syringe pump. In addition to the requisite task of creating an actual OPERATOR-EQUIPMENT INTERFACE design, a responsive USABILITY ENGINEERING program might also include the following activities:

- conduct structured interviews (individual or group) with representative OPERATORS regarding the MANUFACTURER'S current device, as well as several competing 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 USABILITY test to validate the refined near-final design.

Notice that the primary theme of these activities is early and continued involvement of representative OPERATORS, although the actual number of OPERATORS involved can be limited, at least in the case of a simple device.

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

Consider the development of a contrast medium injection system for CAT 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 device performance characteristics, OPERATOR 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 devices should be considered. At this stage, the USABILITY ENGINEERING practitioner or team should have a detailed specification of the OPERATOR-EQUIPMENT INTERFACE requirements and a preliminary step-by-step summary of the procedures that will be carried out.
- Determine allocations of functions between OPERATORS and ME EQUIPMENT 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 OPERATORS 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 controlled and what form of information is to be provided at each stage of the various PROCESSES.

- Conduct a complete RISK ANALYSIS that incorporates USE ERROR and develop design solutions to prevent or mitigate the RISKS identified. A prudent assumption is that every predictable USE ERROR will be made by some OPERATORS some of the time. This analysis should be updated throughout the development PROCESS.
- Conduct a full-scale design and development effort, using the design and evaluation techniques described in Clause D.5 and D.6. These include modelling, performing task analyses, prototyping, and conducting USABILITY tests. Using iterative design and simulation can prevent costly retrofits later. Low-fidelity models are typically used during concept and early development work to examine alternative design concepts. As development progresses, prototypes of increasing fidelity facilitate cost-effective design evaluation.
- In this injection system example, one might initially create static screen simulations of the OPERATOR-EQUIPMENT INTERFACE and rough physical mock-ups of the injector and the syringes. Early stage evaluation might include hypothetical walk-throughs with OPERATORS in the environment defined in the INTENDED USE. However, as the designs of the various components become more refined and the prototypes more realistic, VERIFICATION research should progress to more objective USABILITY testing.

Here, a technician might be given a series of tasks to perform on a touch screen prototype and/or a working mock-up of the injector. The results of all evaluations should be incorporated into the next design iteration, so that errors are eliminated and OPERATORS require less instruction.

- Computerized prototypes are especially valuable for testing alternative OPERATOR-EQUIPMENT INTERFACE designs prior to the production of operational models. It is normally preferred to use rapid prototyping tools for OPERATOR-EQUIPMENT INTERFACES implemented in software. The faster that prototypes can be created and modified, the more likely it is that OPERATOR test results will have a real impact on the product's design.
- Once high-fidelity prototypes or early production models are available, VALIDATION tests are performed to assure that the device meets the OPERATORS' and PATIENTS' needs. At this point, OPERATORS should be able to safely and efficiently proceed through each required step: filling the disposable syringe, placing it on the injector, choosing the injection protocol on the screen control unit, activating and monitoring the injection, etc.

D.3.3 Documenting the USABILITY ENGINEERING activities

USABILITY ENGINEERING documentation should precisely state the requirements to be met and should be written in a language and manner most useful to the specification's end-users, who are often engineers and software developers.

USABILITY ENGINEERING should be incorporated into existing design control PROCESSES and addressed within the specification, design, documentation, and RISK MANAGEMENT PROCESSES as appropriate. Documentation should be generated and maintained in accordance with applicable standards such as ISO 13485 [6] and ISO 14971.

Early in a project, a USABILITY ENGINEERING plan should be initiated and recorded. The plan should be updated as needed throughout the project. A typical USABILITY ENGINEERING plan might include:

- scope;
- fundamental OPERATOR-EQUIPMENT INTERFACE design approaches;
- planned USABILITY ENGINEERING analyses and studies;
- OPERATOR-EQUIPMENT INTERFACE design PROCESS and planned use of USABILITY ENGINEERING tools and techniques (e.g. observational studies, USABILITY testing, design reviews);
- use of national, international or corporate human-machine interface standards and guidelines (e.g. ANSI/AAMI HE 48 [7]);
- a method for tracking and resolving USABILITY ENGINEERING issues;
- USABILITY ENGINEERING deliverables (see Table D.4);
- schedule and milestones;
- personnel and required resources.

Table D.4 – Typical deliverables

Design control component	USABILITY ENGINEERING PROCESS step	Example deliverables
Design conceptualization	OPERATOR research	USABILITY ENGINEERING plan, OPERATOR PROFILES, task analysis, description of use environment USABILITY ENGINEERING analysis of precursor, fielded ME EQUIPMENT
	Design concept development	USABILITY requirements (goals) USE SCENARIOS, storyboards
Design input	Design criteria/requirement development	USE ERROR analysis USABILITY SPECIFICATION
Design output	Device design/refinement	OPERATOR-EQUIPMENT INTERFACE models, prototypes OPERATOR-EQUIPMENT INTERFACE design specifications
		USABILITY VALIDATION Plan
Design VERIFICATION and VALIDATION	Design evaluation	USABILITY testing report
	Device implementation and deployment	USABILITY ENGINEERING inputs to design change requests

D.4 The USABILITY ENGINEERING PROCESS

D.4.1 A systematic approach

D.4.1.1 Introduction

The USABILITY ENGINEERING PROCESS recognizes that every medical device is an element of a larger complex. At a minimum, such complexes include the physical environment where the device is used, the device OPERATORS, the PATIENT and other devices or ancillary equipment. A thorough understanding of the complex of which the device is one element is integral to the USABILITY ENGINEERING PROCESS. The relationships among elements, first considered early in the design PROCESS, are essential to plan subsequent USABILITY ENGINEERING efforts, especially design evaluation.

Early in the USABILITY ENGINEERING PROCESS, the various elements of the complex that will be considered in the design should be defined. Broader definitions of the complex tend to produce devices that better meet actual needs. Also, broader descriptions are more likely to produce devices that are revolutionary, as opposed to evolutionary. However, in many design projects, broad definitions can be impractical or unnecessary.

Fundamentally, the USABILITY ENGINEERING PROCESS is an OPERATOR-centred PROCESS. That is, it is driven by OPERATORS' actual needs and is based on the premise that the OPERATOR is always a critical element of the system. At a minimum, research should evaluate how a person uses, or might use, a device in a specific clinical setting (e.g. doctor's office, at home,

or in an emergency department). Research should also evaluate the anticipated environments of use, such as where a caregiver administers treatment, where the device is maintained, where support personnel interact with a device (e.g. a transporter in an elevator), or where the PATIENT uses the device.

A concerted effort should be made to consider as many use environments as possible. It is important to consider that the range of use environments typically expands during the product's life span. By anticipating additional use environments, MANUFACTURERS can reduce the need for expensive redesign, enhance marketability, and yield substantial long-term savings. For example, many devices designed for hospital use are now being used in the home as well, often without the MANUFACTURER'S knowledge or intent. When devices are used in ways that fall outside the scope of the original design, safety and USABILITY can be seriously compromised.

D.4.1.2 USABILITY ENGINEERING research

D.4.1.2.1 Overview

USABILITY ENGINEERING research generally addresses one or more of the following concerns.

D.4.1.2.2 Function

What function(s) does the device perform (e.g. how does this device augment the caregiver's abilities to care for the PATIENT)?

D.4.1.2.3 OPERATORS

Who will use the device and/or its data (both directly and indirectly)? This includes the cultural, sociological, educational, and experiential characteristics of the potential OPERATORS. If the device is to be used by a team of OPERATORS, then issues include effects on team function and team TRAINING.

D.4.1.2.4 Context of use

In what clinical use environments will this device operate? What are the characteristics of each of the potential use environments (e.g. home, urgent care centre, hospital ward, operating room, etc.)? What other devices are commonly used in this clinical environment, and how might the use of this device affect the use of these other devices? See also the rationale for 4.2.

D.4.1.2.5 Workload

What are the cognitive and/or physical efforts associated with using the device?

D.4.1.2.6 BASIC SAFETY or ESSENTIAL PERFORMANCE

What attributes of the ME EQUIPMENT could compromise safe use? How will other devices within the system affect BASIC SAFETY or ESSENTIAL PERFORMANCE?

D.4.1.2.7 Use and misuse

What attributes of the ME EQUIPMENT would prevent misuse, provide guidance, and allow for easy and safe correction if misuse occurs?

D.4.2 Case study example: Infusion pumps

Infusion pumps regulate the volume and rate of fluid medication delivered to the PATIENT and notify care providers of events or problems in the PROCESS. Depending on where the system boundaries are drawn, other system elements might include the care providers who use the device, the PATIENT, PATIENT visitors, other PATIENTS, related devices (e.g. tubing sets), other ME EQUIPMENT such as physiological PATIENT monitors, and the physical environment (which is relevant to device design because of issues such as illumination and noise level). If an evolutionary infusion pump is being developed (e.g. one with modified controls, displays, or functions), it can be unnecessary and impractical to define the system this broadly. However, a device that would revolutionize the fluid medication delivery system in hospitals would require thorough examination of all system elements, which could include hospital pharmacy practices, drug labelling, and even drug distribution methods.

Under these circumstances, the boundaries of the system might include the prescribing physician, the pharmacy, the transcriptionist, other hospital personnel (e.g. aides, bioengineers, maintenance personnel, technicians), hospital administrative procedures, the social and cultural environment of the people in the system, and the cultural environment of the hospital. One might even include other device MANUFACTURERS and the services they provide, the PATIENT'S visitors, and drug manufacturers because their products and actions affect or define system elements.

D.4.3 OPERATOR research**D.4.3.1 OPERATOR input**

OPERATOR input is part of an iterative PROCESS that begins in the early design phase and progresses throughout the design cycle. Considering OPERATOR input early in the design PROCESS can prevent costly design errors. OPERATOR involvement should include both OPERATORS and maintainers as well as PATIENTS and PATIENTS' families, when appropriate. Subjective data from OPERATORS should include their ideas on features and appearance, and also feedback on how the device could be made safer, more usable, and more effective. Both positive and negative reactions to the device should be sought. Objective data are generally superior to anecdotal opinions because they facilitate follow-up testing, ensuring design improvement. Examples of objective (i.e. measurable) OPERATOR input include OPERATOR performance problems, issues identified by field or customer service personnel, reported error incidents, and the results of laboratory tests of OPERATOR performance.

A solid understanding of OPERATORS' characteristics, capabilities, needs, and preferences is key to designing for safer and more effective use. There are many ways to obtain this information (see also Clause D.6) including:

- collecting OPERATOR-EQUIPMENT INTERFACE-related information and opinions;
- unobtrusively observing people perform the relevant tasks associated with the device or use a similar device;
- discussing design issues with small groups of OPERATORS with the goal of generating ideas or reaching consensus;
- conducting formal studies of OPERATORS performing relevant tasks under actual or simulated conditions; and
- reviewing USABILITY ENGINEERING technical information.

D.4.3.2 Sampling OPERATORS

OPERATOR research activities should involve people who accurately represent the OPERATOR population. For example, a development team modifying an existing ventilator might gather design input from nurses, respiratory therapists, and physicians who treat ventilated PATIENTS. OPERATOR populations typically vary across multiple dimensions such as age, gender, physical capabilities, experience, expectations, as well as social standing and geographic location. Therefore, by employing appropriate sampling strategies, results from the subject population are likely to generalize to the final OPERATOR population(s). The appropriate number of subjects depends on the objectives of the research as well as the diversity of the OPERATOR population, the complexity of the issues to be addressed, and the desired level of confidence in the findings.

D.4.3.3 Research protocols and informed consent

The goals of the OPERATOR research will dictate the research methods. OPERATOR research can range from broad information-gathering PROCESSES, focused brainstorming, problem-oriented sessions, or more rigorous hypothesis-based approaches. Regardless of the approach, the use of written scripts or other structured guidance documents will assure a uniform PROCESS and enhance resultant data quality. Research protocols are usually desirable and are sometimes a legal requirement. The protocol typically stipulates the rationale for the research, the nature of the subject population, the methods to be employed, and how the resultant data are to be analyzed and interpreted.

Subject consent should be obtained if there is any RISK, if the research makes appreciable time or other demands on the subject or if the results can appear in a peer-reviewed publication.

D.4.4 Design requirement/criteria development

Analysis of OPERATOR input, observation, and research can ascertain OPERATOR needs. Not only is an accurate needs assessment critical to successful design criteria/requirement development, but ultimately it influences commercial success. Establishing OPERATOR-EQUIPMENT INTERFACE design requirements helps place USABILITY ENGINEERING considerations on an equal footing with other engineering considerations because documented goals carry greater weight. Moreover, it helps to focus the design PROCESS, facilitates trade-off decisions involving other disciplines, and establishes criteria for design acceptability.

Initially, design requirements can be in the form of broad and general vision statements but, as the design progresses, requirements become more detailed and specific. Iterative refinement of design requirements permits evolution of the design. Some requirements will be expressed as **USABILITY** goals, such as ease of use and ease of learning (see Table D.5), while others will address more detailed design components such as display brightness, portability, or durability.

The following are examples of detailed **OPERATOR-EQUIPMENT INTERFACE** design requirements.

- The display shall be visible at a distance of 1 m to three people standing side-by-side, with all able to detect colour and read text.
- The ME EQUIPMENT, when being carried, shall have no edges, corners, or protrusions that catch on clothing.
- The ME EQUIPMENT shall be capable of producing an auditory **ALARM SIGNAL** with a sound pressure level adjustable over the range of 45 dBA to 80 dBA as measured 1 m in front of the ME EQUIPMENT.
- The stylus shall activate software controls on the screen when used at an angle between 20° and 90°.

Table D.5 – Examples of objective and subjective **USABILITY goals**

Objective	Subjective
80 % of OPERATORS shall successfully calibrate the device within 5 min on their first try.	Two thirds of OPERATORS shall prefer the next generation infusion pump to the existing device upon programming a single channel infusion.
After reading the quick reference guide, 90 % of OPERATORS shall be able to configure the display correctly to show two ECG lead traces on the first try.	On average, 80 % of OPERATORS shall rate the monitor's display as 5 or better on a scale of 1 = very hard to read, to 7 = very easy to read.

OPERATOR-EQUIPMENT INTERFACE requirements are ultimately expressed in the form of explicit design specifications that can incorporate subjective or objective performance measures (see Table D.3). Detailed **USABILITY** requirements should be measurable and be based on attributes that are important to **OPERATORS** and safety. To make requirements realistic and credible, performance criteria should be based on the results of benchmark **USABILITY** testing of comparable products, a detailed estimate based on experimentation, or a working hypothesis. However, requirements based on estimates or hypotheses are modified as appropriate during ongoing iterative design and evaluation, and take into consideration **OPERATORS'** actual needs in the environment defined in the **INTENDED USE**.

D.4.5 Device design

D.4.5.1 General guidance

There is no single best method for transitioning from developing **OPERATOR-EQUIPMENT INTERFACE** design requirements to achieving an effective design solution. A great deal depends on the designer or design team's capabilities as well as the type of device. Moreover, **OPERATOR-EQUIPMENT INTERFACE** design has a creative aspect that defies strict definition and control. During the design stage, studies can be needed to make informed decisions about discrete design elements. For example, it can be appropriate to compare cursor positioning devices to select the best one for use in conjunction with an ultrasound workstation. Or one might conduct a comparison study of handgrips on surgical instruments to determine which one is the most comfortable or enables the most precise movement.

D.4.5.2 Structuring an approach to design

The effective design team will commit to a structured approach. Elements typical of such an approach include:

- consideration of several design alternatives. For example, design teams can start with a dozen or more OPERATOR-EQUIPMENT INTERFACE design concept sketches, select as many as five concepts for more detailed consideration, and model and test two or three concepts, before converging on a final, preferred design. The initial consideration of several design alternatives, including some that seem quite radical, is key to innovation, particularly when developing a next-generation device;
- development of simple conceptual models of OPERATOR-EQUIPMENT INTERFACE elements and of OPERATOR-device interactions. Such models give designers a conceptual reference point that ultimately helps to limit design complexity. For example, Figure D.2 demonstrates how an OPERATOR-EQUIPMENT INTERFACE can be modelled at the highest level as five basic elements: three major functions, a menu system, and a set of quick actions;
- prospective application of established design principles and practices (see ANSI/AAMI HE 48 [7]) as appropriate. Preventing a design flaw is easier and more practical than correcting a flaw that was uncovered in a retrospective design evaluation;
- consideration of task frequency, urgency, and criticality as a basis for making human/machine and hardware/software task allocations, as well as display and control organization and layout decisions. These decisions require a thorough understanding of how the device actually will be used;
- giving due weight to OPERATOR-EQUIPMENT INTERFACE quality in any trade-off with other engineering goals;
- construction of OPERATOR-EQUIPMENT INTERFACE models (see D.4.5.3), such as interactive prototypes, to enable realistic USABILITY tests and other evaluations involving OPERATORS;
- use of iterative testing to select a preferred design concept and then to refine it;
- involvement of OPERATORS throughout the design PROCESS.

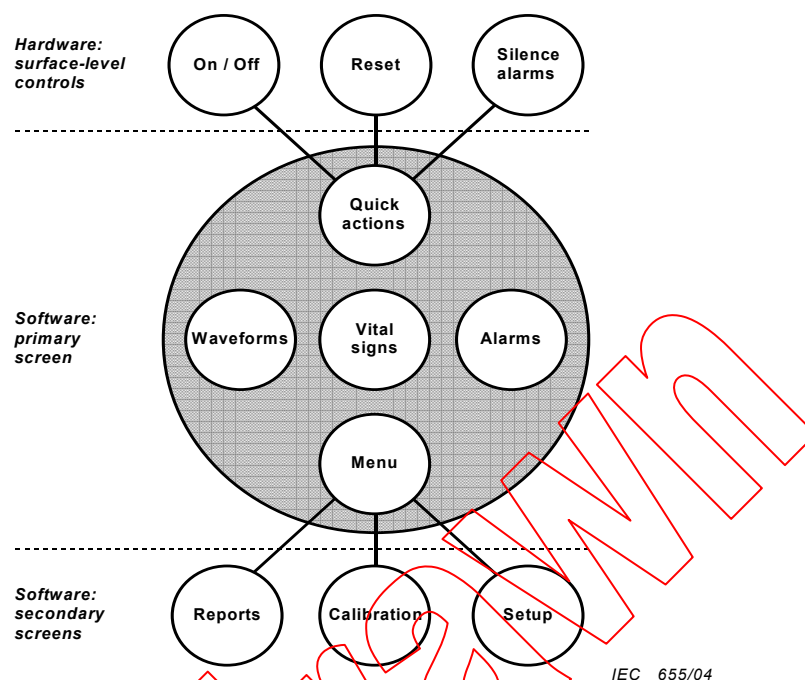


Figure D.2 – Bubble diagram of the conceptual model of a physiological monitor

D.4.5.3 Modelling the OPERATOR-EQUIPMENT INTERFACE

It is valuable to model the OPERATOR-EQUIPMENT INTERFACE at different levels of fidelity during progressive design stages (see Table D.6).

Models should be built early and continuously throughout the design PROCESS as a basis for collecting OPERATOR feedback and evaluating the success of the design. Early in the design PROCESS, sketches, simple block models, or low-fidelity computer-based renderings or interactive simulations (also called prototypes) are usually sufficient. Later in the PROCESS, it can be appropriate to work with refined renderings, appearance or working models, and high-fidelity computer-based simulations.

When modelling a software OPERATOR-EQUIPMENT INTERFACE, it is useful to start with a USABILITY test plan that delineates, among other things, the type of OPERATOR feedback desired (see Table D.7). For example, one can be most interested in how well prospective OPERATORS perform a set of urgent or frequent tasks. In this case, it can be most valuable to develop a partially functional prototype that enables OPERATORS to perform only the tasks of interest.