

# Medical electrical equipment —

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

ICS 11.040.01

# National foreword

This British Standard is the UK implementation of EN 60601-1-6:2007, incorporating corrigendum March 2010. It is identical with IEC 60601-1-6:2006. It supersedes BS EN 60601-1-6:2004, which will be declared obsolescent and will be withdrawn on publication of the revised BS EN 60601-2 series.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/1, Common aspects of electrical equipment used in medical practice.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a British Standard cannot confer immunity from legal obligations.**

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## Amendments/corrigenda issued since publication

| Date         | Comments                                                                               |
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| 30 June 2008 | Correcting supersession details                                                        |
| 31 July 2010 | Implementation of CENELEC corrigendum March 2010. Date of withdrawal added to Foreword |
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|              |                                                                                        |

**Medical electrical equipment -  
Part 1-6: General requirements  
for basic safety and essential performance -  
Collateral Standard: Usability  
(IEC 60601-1-6:2006)**

Appareils électromédicaux -  
Partie 1-6: Exigences générales  
pour la sécurité de base  
et les performances essentielles -  
Norme collatérale: Aptitude à l'utilisation  
(CEI 60601-1-6:2006)

Medizinische elektrische Geräte -  
Teil 1-6: Allgemeine Festlegungen  
für die Sicherheit einschließlich  
der wesentlichen Leistungsmerkmale -  
Ergänzungsnorm: Gebrauchstauglichkeit  
(IEC 60601-1-6:2006)

This European Standard was approved by CENELEC on 2007-05-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

## CENELEC

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Central Secretariat: rue de Stassart 35, B - 1050 Brussels**

## Foreword

The text of document 62A/550/FDIS, future edition 2 of IEC 60601-1-6, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-6 on 2007-05-01.

The following date was fixed:

- latest date by which the EN has to be implemented  
at national level by publication of an identical  
national standard or by endorsement (dop) 2008-02-01
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 2012-06-01

This European Standard supersedes EN 60601-1-6:2004.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

This EN 60601-1-6 was revised to structurally align it with EN 60601-1:2006 and to implement the decision of IEC SC 62A that the clause numbering structure of collateral standards written to EN 60601-1:2006 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 EN 60601-1:2006.

In the 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: in roman type;
- *test specifications: in 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 NOTES: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the six 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 (\*).

Annexes ZA and ZZ have been added by CENELEC.

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### **Endorsement notice**

The text of the International Standard IEC 60601-1-6:2006 was approved by CENELEC as a European Standard without any modification.

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## 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.

## **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 73.

#### **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]. <sup>1)</sup>

## **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.

<sup>1)</sup> 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<sub>p</sub>, 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.

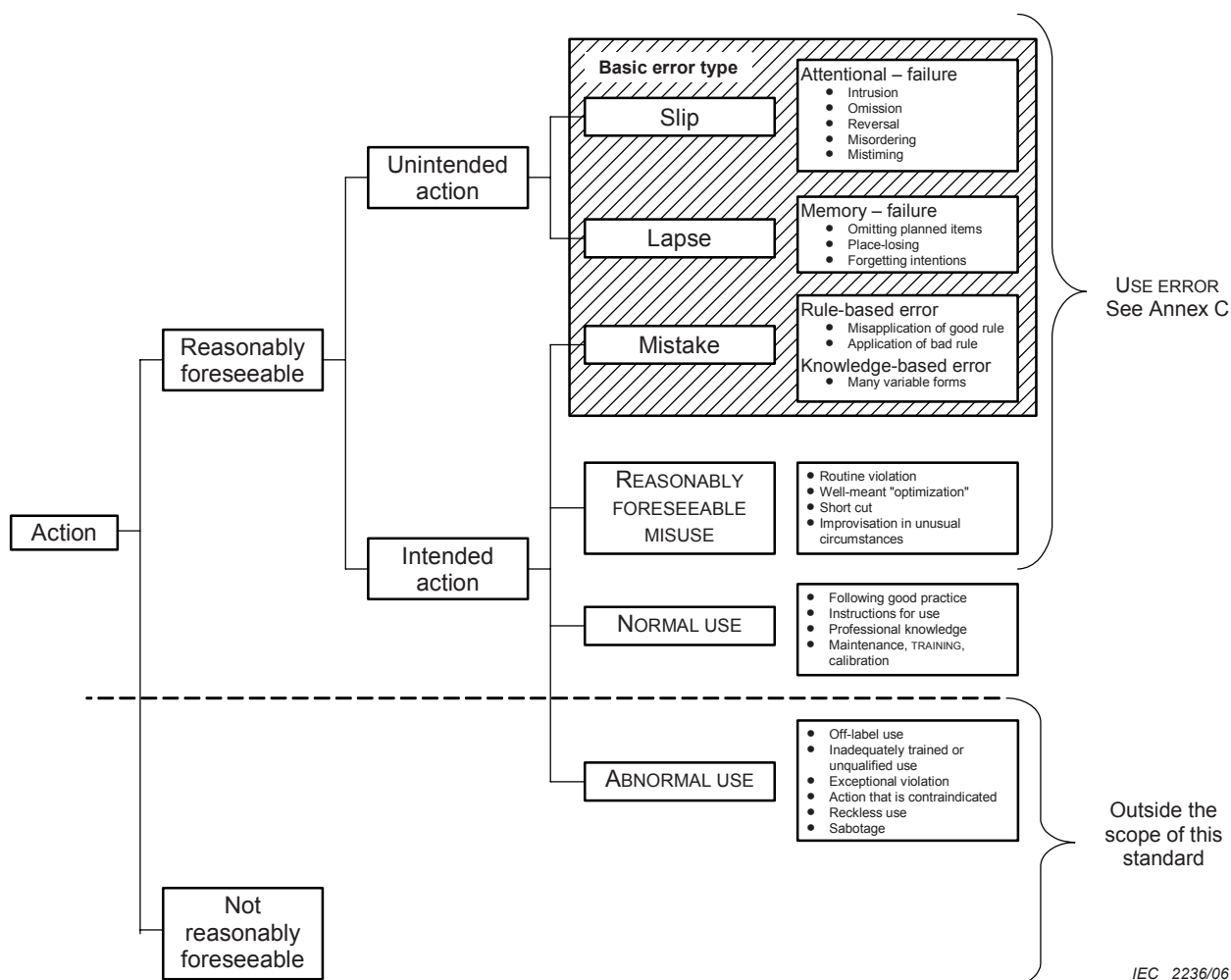


Figure B.1 – Summary of the taxonomy of OPERATOR action

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.