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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices – Application of usability engineering to medical devices

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

FOREWORD

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It is published as double logo standard.

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

FDIS	Report of voting
62A/574/FDIS	62A/579/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 20 P-members out of 20 having cast a vote.

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

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

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

The requirements are followed by means to assess compliance.

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

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- withdrawn;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.

INTRODUCTION

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

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

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

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

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

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

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

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

2 Normative references

The following referenced documents 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.

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

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

3 Terms and definitions

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

NOTE An index of defined terms is found beginning on page 98.

3.1
ABNORMAL USE
intentional act or intentional omission of an act by the RESPONSIBLE ORGANIZATION or USER of a MEDICAL DEVICE as a result of conduct that is beyond any further reasonable means of RISK CONTROL by the MANUFACTURER

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

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

3.2
ACCOMPANYING DOCUMENT
document accompanying a MEDICAL DEVICE and containing information for those accountable for the installation, use and maintenance of the MEDICAL DEVICE or the USER, particularly regarding SAFETY

[ISO 14971:2007, definition 2.1, modified]

3.3
ALARM LIMIT
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

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

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

3.4
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

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

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

3.5
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

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

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

3.6
ALARM SYSTEM
parts of the MEDICAL DEVICE that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

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

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

3.7
CORRECT USE
NORMAL USE without USE ERROR

3.8
EFFECTIVENESS
measure of accuracy and completeness with which USERS achieve specified goals

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

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

3.9
EFFICIENCY
EFFECTIVENESS in relation to the resources expended

3.10
INFORMATION SIGNAL
any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

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

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

3.11
MEDICAL DEVICE
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

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

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

[ISO 13485:2003, definition 3.7]

3.12
*** NORMAL USE**
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

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

NOTE 1 USE ERROR can occur in NORMAL USE.

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

3.13
*** PATIENT**
living being (person) undergoing a medical, surgical or dental procedure

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

3.14
*** PRIMARY OPERATING FUNCTION**
function that involves USER interaction that is either frequently used or related to the SAFETY of the MEDICAL DEVICE

3.15
REMINDER SIGNAL
periodic signal that reminds the USER that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

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

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

3.16
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE or combination of MEDICAL DEVICES

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

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

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

3.17
*** USABILITY**
characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction

3.18
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

3.19
*** USABILITY ENGINEERING FILE**
set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

3.20
USABILITY SPECIFICATION
documentation defining the USER INTERFACE requirements related to USABILITY

3.21
USE ERROR
act or omission of an act that results in a different MEDICAL DEVICE response than intended by the MANUFACTURER or expected by the USER

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

NOTE 2 See also Annex B and D.1.3.

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

3.22
USE SCENARIO
specified sequence of events and tasks as performed by a specified USER in a specified environment

3.23
*** USER**
person using, i.e. operating or handling, the MEDICAL DEVICE

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

NOTE 2 PATIENTS or other laypersons can be USERS.

3.24
*** USER INTERFACE**
means by which the USER and the MEDICAL DEVICE interact

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

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

3.25
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

3.26
VALIDATION
confirmation, through the provision of OBJECTIVE EVIDENCE, that the requirements for a specific INTENDED USE or application have been fulfilled

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

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

[ISO 9000:2000, definition 3.8.5]

4 * Principles

4.1 General requirements

4.1.1 * USABILITY ENGINEERING PROCESS

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

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

NOTE See also D.3.1.

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

4.1.2 RESIDUAL RISK

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

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

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

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

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

4.1.3 Information for SAFETY

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

EXAMPLE 1 Warnings or limitation of use in the ACCOMPANYING DOCUMENT

EXAMPLE 2 Markings

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

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

a) inherent SAFETY by design;

b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS, e.g. ALARM SYSTEMS;

c) information for SAFETY, e.g. warnings in the instructions for use, display of a monitored variable, training and materials for training, maintenance details.

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

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

4.2 * USABILITY ENGINEERING FILE

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

EXAMPLE 1 MANUFACTURER'S product design file

EXAMPLE 2 RISK MANAGEMENT FILE

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

4.3 Scaling of the USABILITY ENGINEERING effort

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

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

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

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

5 * USABILITY ENGINEERING PROCESS

5.1 * Application specification

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