

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



Medical devices – Application of usability engineering to medical devices

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

IEC 62366:2007

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
INTRODUCTION TO THE AMENDMENT	7
1 * Scope	8
2 Normative references	8
3 Terms and definitions	8
4 * Principles.....	12
4.1 General requirements.....	12
4.1.1 * USABILITY ENGINEERING PROCESS	12
4.1.2 RESIDUAL RISK.....	12
4.1.3 Information for SAFETY	13
4.2 * USABILITY ENGINEERING FILE	13
4.3 Scaling of the USABILITY ENGINEERING effort.....	13
5 * USABILITY ENGINEERING PROCESS.....	14
5.1 * Application specification.....	14
5.2 * Frequently used functions.....	14
5.3 Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY	14
5.3.1 Identification of characteristics related to SAFETY.....	14
5.3.2 * Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS.....	15
5.4 PRIMARY OPERATING FUNCTIONS.....	15
5.5 * USABILITY SPECIFICATION.....	16
5.6 USABILITY VALIDATION plan.....	16
5.7 * USER INTERFACE design and implementation.....	17
5.8 * USABILITY VERIFICATION.....	17
5.9 * USABILITY VALIDATION.....	18
5.10 * USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)	18
6 * ACCOMPANYING DOCUMENT	18
7 * Training and materials for training.....	19
Annex A (informative) General guidance and rationale.....	20
Annex B (informative) Categories of USER action.....	32
Annex C (informative) Examples of USE ERRORS, ABNORMAL USE and possible causes.....	34
Annex D (informative) Guidance on the USABILITY ENGINEERING PROCESS.....	37
ANNEX E (informative) Questions that can be used to identify MEDICAL DEVICE characteristics associated with USABILITY that could impact on SAFETY.....	61
ANNEX F (informative) Examples of possible USABILITY related HAZARDOUS SITUATIONS.....	65
Annex G (informative) USABILITY goals: Illustrative example for a home parenteral infusion pump	68
ANNEX H (informative) Sample USABILITY SPECIFICATION and its inputs	78
Annex I (informative) Recommended reading list	88
Annex J (informative) Reference to the essential principles	96
Annex K (normative) Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)	97

Bibliography.....	99
Index of defined terms	101
Figure A.1 – A comparison of the RISK MANAGEMENT PROCESS (ISO 14971:2007) and the USABILITY ENGINEERING PROCESS (IEC 62366)	25
Figure B.1 – Categories of foreseeable USER action	33
Figure D.1 – A USER INTERFACE design cycle	40
Figure D.2 – Bubble diagram of the conceptual model of a physiological monitor	53
Figure F.1 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	66
Table D.1 – Sample of design flaws and associated USE ERRORS	38
Table D.2 – Mapping of Figure D.1 to the subclauses of this International Standard	40
Table D.3 – Examples of USER INTERFACE requirements	43
Table D.4 – Typical deliverables	48
Table D.5 – Examples of objective USABILITY goals	51
Table D.6 – Examples of subjective USABILITY goals	51
Table D.7 – Examples of USER INTERFACE modelling techniques	54
Table D.8 – Characteristics of a typical USABILITY testing effort	54
Table F.1 – Glossary of relevant RISK MANAGEMENT terms	65
Table F.2 – Examples of HARM due to USABILITY related HAZARDS	66
Table G.1 – Power on/off	71
Table G.2 – Program pump	71
Table G.3 – Start/stop infusion	72
Table G.4 – Monitor infusion status	73
Table G.5 – Install and change set	73
Table G.6 – Priming	74
Table G.7 – Respond to and inactivate ALARM SIGNALS ^a	74
Table G.8 – Lockouts	75
Table G.9 – Power management	75
Table G.10 – Preventative and routine maintenance	76
Table G.11 – Basic operation	77
Table G.12 – Advanced functions	77
Table J.1 – Correspondence between this document and the essential principles	96

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

This publication has been prepared for user convenience.

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

It is published as double logo standard.

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

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

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

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

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INTRODUCTION

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

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

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

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

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INTRODUCTION TO THE AMENDMENT

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

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MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

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

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

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

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

2 Normative references

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

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

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

3 Terms and definitions

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

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

3.1

ABNORMAL USE

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

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

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

3.2

ACCOMPANYING DOCUMENT

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

[ISO 14971:2007, definition 2.1, modified]

3.3

ALARM LIMIT

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

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

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

3.4

ALARM OFF

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

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

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

3.5

ALARM SIGNAL

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

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

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

3.6

ALARM SYSTEM

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

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

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

3.7

CORRECT USE

NORMAL USE without USE ERROR

3.8

EFFECTIVENESS

measure of accuracy and completeness with which USERS achieve specified goals

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

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

3.9

EFFICIENCY

EFFECTIVENESS in relation to the resources expended

3.10

INFORMATION SIGNAL

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

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

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

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

3.11

MEDICAL DEVICE

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

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

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

[ISO 13485:2003, definition 3.7]

3.12

*** NORMAL USE**

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

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

NOTE 1 USE ERROR can occur in NORMAL USE.

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

3.13

*** PATIENT**

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

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

3.14

*** PRIMARY OPERATING FUNCTION**

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

3.15

REMINDER SIGNAL

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

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

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