Index des termes définis

ALARME ARRETEE 3.4
ANALYSE DU RISQUE ..... ISO 14971:2007, 2.17
APTITUDE A L'UTILISATION 3.17
DANGER ..... ISO 14971:2007, 2.3
DISPOSITIF MEDICAL 3.11
DOCUMENT D'ACCOMPAGNEMENT 3.2
DOMMAGE ..... ISO 14971:2007, 2.2
DOSSIER D'INGENIERIE DE L'APTITUDE A L'UTILISATION 3.19
DOSSIER DE GESTION DES RISQUES ..... ISO 14971:2007, 2.23
EFFICACITE 3.8
ENREGISTREMENT ..... ISO 14971:2007, 2.14
ERREUR D'UTILISATION 3.21
EVALUATION DU RISQUE ..... ISO 14971:2007, 2.21
FABRICANT ..... ISO 14971:2007, 2.8
FONCTION PRINCIPALE DE SERVICE 3.14
GESTION DES RISQUES ..... ISO 14971:2007, 2.22
GRAVITE ..... ISO 14971:2007, 2.25
INGENIERIE DE L'APTITUDE A L'UTILISATION 3.18
INTERFACE UTILISATEUR 3.24
INTERFACE UTILISATEUR DE PROVENANCE INCONNUE ..... (UOUP, *USER INTERFACE OF UNKNOWN PROVENANCE*) 3.27
LIMITE D'ALARME 3.3
MAITRISE DU RISQUE ..... ISO 14971:2007, 2.19
ORGANISME RESPONSABLE 3.16
PATIENT 3.13
PREUVE TANGIBLE ..... ISO 14971:2007, 2.10
PROCESSUS ..... ISO 14971:2007, 2.13
PROFIL DE L'UTILISATEUR 3.25
RENDEMENT 3.9
RISQUE ..... ISO 14971:2007, 2.16
RISQUE RESIDUEL ..... ISO 14971:2007, 2.15
SCENARIO D'UTILISATION 3.22

SECURITE ..... ISO 14971:2007, 2.24
SIGNAL D'ALARME 3.5
SIGNAL DE RAPPEL 3.15
SIGNAL D'INFORMATION 3.10
SITUATION DANGEREUSE ..... ISO 14971:2007, 2.4
SPECIFICATION D'APTITUDE A L'UTILISATION 3.20
SYSTEME D'ALARME 3.6
UTILISATEUR 3.23
UTILISATION ANORMALE 3.1
UTILISATION CORRECTE 3.7
UTILISATION NORMALE 3.12
UTILISATION PREVUE ..... ISO 14971:2007, 2.5
VALIDATION 3.26
VERIFICATION ..... ISO 14971:2007, 2.28

IEC 62366

Edition 1.1 2014-01

FINAL VERSION

VERSION FINALE

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 62366:2007-10+AMD1:2014-01 CSV(EN-FR)

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any medical device declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

This publication has been prepared for user convenience.

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

It is published as double logo standard.

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

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

– Requirements and definitions: roman type.

– *Means to assess compliance: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type

– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The requirements are followed by means to assess compliance.

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

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability 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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

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

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

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

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

INTRODUCTION TO THE AMENDMENT

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

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

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

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

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

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication