IEC 62366

Edition 1.0 2007-10

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

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