Medical devices

Part 1: Application of usability engineering to medical devices
National foreword


The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical 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.

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Medical devices - Part 1: Application of usability engineering to medical devices
(IEC 62366-1:2015)

This European Standard was approved by CENELEC on 2015-03-31. 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 CEN-CENELEC Management Centre or to any CENELEC member.

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Foreword


The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2015-12-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-03-31

This document supersedes EN 62366:2008.

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Endorsement notice

The text of the International Standard IEC 62366-1:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Note</th>
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<td>IEC 60601-1-11</td>
<td>NOTE</td>
<td>EN 60601-1-11.</td>
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(normative)

Normative references to international publications with their corresponding European publications

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 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<table>
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<th>Publication</th>
<th>Year</th>
<th>Title</th>
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<tr>
<td>ISO 14971</td>
<td>2007</td>
<td>Medical devices - Application of risk management to medical devices</td>
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICES –

Part 1: 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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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.

International Standard IEC 62366-1 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 ISO technical committee 210: Quality management and corresponding general aspects for MEDICAL DEVICES.

It is published as double logo standard.

This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014).

Part 1 has been updated to include contemporary concepts of USABILITY ENGINEERING, while also streamlining the process. It strengthens links to ISO 14971:2007 and the related methods of RISK MANAGEMENT as applied to SAFETY related aspects of medical device user interfaces. Part 2 contains tutorial information to assist manufacturers in complying with Part 1, as well as offering more detailed descriptions of USABILITY ENGINEERING methods that can be applied
more generally to MEDICAL DEVICES that go beyond safety-related aspects of MEDICAL DEVICE
USER INTERFACES.

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

<table>
<thead>
<tr>
<th>FDIS</th>
<th>Report on voting</th>
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<tr>
<td>62A/977/FDIS</td>
<td>62A/988/RVD</td>
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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 26 P-members
out of 26 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.

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

A list of all parts of the IEC 62366 series, published under the general title Medical devices,
can be found on the IEC website.

The committee has decided that the contents of this publication 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 and Member Bodies 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 (HUMAN FACTORS ENGINEERING) PROCESS are non-intuitive, difficult to learn and difficult to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. The design of the USER INTERFACE to achieve adequate USABILITY requires a different PROCESS and skill set than that of the technical implementation of the USER INTERFACE.

The USABILITY ENGINEERING PROCESS is intended to identify and minimise USE ERRORS and thereby reduce use-associated RISKS. Some, but not all, forms of incorrect use are suited to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.4.

This International Standard describes a USABILITY ENGINEERING PROCESS to provide acceptable RISK related to USABILITY of a MEDICAL DEVICE. 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.

This International Standard strictly focuses on applying the USABILITY ENGINEERING PROCESS to optimize MEDICAL DEVICE USABILITY as it relates to SAFETY. The companion technical report (IEC 62366-21) is comprehensive and has a broader focus. It focuses not only on USABILITY as it relates to SAFETY, but also on how USABILITY relates to attributes such as TASK accuracy, completeness and EFFICIENCY, and USER satisfaction.

NOTE SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or loss or degradation of clinical functionality.

MANUFACTURERS can choose to implement a USABILITY ENGINEERING program focused narrowly on SAFETY or more broadly on SAFETY and other attributes, such as those cited above. A broader focus might also be useful to address specific USABILITY ENGINEERING expectations, such as the need to confirm that USERS can successfully perform non-SAFETY-related TASKS. A MANUFACTURER might also implement a broader program to realize the commercial benefits of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

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1 IEC 62366-2, Medical devices – Part 2: Guidance on the application of usability engineering to medical devices (in preparation).
MEDICAL DEVICES –

Part 1: Application of usability engineering to medical devices

1 Scope

This part of IEC 62366 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS 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 1 SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or loss or degradation of clinical functionality.

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2, which addresses not only SAFETY but also aspects of USABILITY not related to SAFETY.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with, then the USABILITY of a MEDICAL DEVICE as it relates to SAFETY is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 3 Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.

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 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography beginning on page 46.

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 49.

3.1 * ABNORMAL USE

conscious, intentional act or intentional omission of an act that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER

EXAMPLES Reckless use or sabotage or intentional disregard of information for SAFETY are such acts.

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2 IEC 62366-2, Medical devices – Part 2: Guidance on the application of usability engineering to medical devices (in preparation).