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TECHNICAL REPORT

colour inside

Medical devices –
Part 2: Guidance on the application of usability engineering to medical devices

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MEDICAL DEVICES –

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FOREWORD

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IEC 62366-2, which is a technical report, has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and technical committee ISO/TC 210: Quality management and corresponding general aspects for medical devices.

It is published as a double logo standard.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/1015/DTR	62A/1040A/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P-members out of 36 having cast a vote.

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

In this Technical Report, the following print types are used.

– Guidance for the implementation of a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS required by IEC 62366-1:2015 and definitions): roman type.

– *Additional information about USABILITY ENGINEERING best practices: italic type*.

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

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

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

This technical report is to be read in conjunction with IEC 62366-1:2015.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This technical report provides MEDICAL DEVICE MANUFACTURERS with guidance on how to integrate USABILITY ENGINEERING (also called HUMAN FACTORS ENGINEERING) principles and USER INTERFACE design practices into their overall MEDICAL DEVICE development PROCESSES. The technical report recognizes that all MEDICAL DEVICES involving human interaction present opportunities for optimization through the application of USABILITY ENGINEERING and seeks to guide the MEDICAL DEVICE MANUFACTURERS efforts.

This report concerns the quality of USER interactions with MEDICAL DEVICES that are as varied as acquiring information on a display, pressing a physical button or on-screen touch target button, selecting items on a software menu, attaching ACCESSORIES to a MEDICAL DEVICE and interpreting warnings as well as understanding relevant aspects for the proper use of the MEDICAL DEVICE by reading the ACCOMPANYING DOCUMENTATION. USABILITY ENGINEERING programs, if properly implemented, can increase the likelihood that USERS are able to perform such actions correctly and without hindrance.

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 difficult to use. In addition, MEDICAL DEVICES developed without applying USABILITY ENGINEERING or developed with incomplete or inadequate application of USABILITY ENGINEERING can include design shortcomings that can lead to USE ERRORS, particularly with varied USERS and USE ENVIRONMENTS, which can lead to HARM.

As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. While MEDICAL DEVICES become increasingly sophisticated, they can be more likely to induce USE ERRORS. If not properly designed or safeguarded, MEDICAL DEVICES could contribute to HAZARDOUS SITUATIONS and can be a source of HARM. An appropriate-tailored investment in USABILITY ENGINEERING ensures that MEDICAL DEVICES will have acceptable RISK and USABILITY and that design shortcomings are identified and removed from the USER INTERFACE. Accordingly, this technical report emphasizes the importance of designing for USABILITY, with an emphasis placed on ensuring SAFETY.

Ascribing to this report helps MANUFACTURERS respond effectively to regulatory expectations that call for the application of USABILITY ENGINEERING during the MEDICAL DEVICE development PROCESS. It also helps MANUFACTURERS produce MEDICAL DEVICES that have well designed USER INTERFACES that satisfy USERS. As such, it can propel a MANUFACTURER beyond a common sense approach to USER INTERFACE design to an approach that fully embraces USABILITY ENGINEERING as an essential step toward design excellence. Other beneficiaries of this document's guidance include authorities having jurisdiction (AHJ) and MEDICAL DEVICE consumers who share a common interest in safe and effective MEDICAL DEVICES.

The guidance provided in this report applies to all MEDICAL DEVICES, including those used by laypersons and/or healthcare professionals; MEDICAL DEVICES that perform just one function and those that perform many functions; USER INTERFACES in the form of hardware, software, documentation, and packaging; MEDICAL DEVICES that fit in a pocket, sit on a table, ride on a cart, or fill a room; and MEDICAL DEVICES that require no prior operational knowledge or call for training before use. Accordingly, it applies to a pen injector, glucose meter, infusion pump, PATIENT monitor, anaesthesia workstation, and radiation therapy system, just to name a few MEDICAL DEVICES.

MEDICAL DEVICES –

Part 2: Guidance on the application of usability engineering to medical devices

1 Scope and purpose

1.1 Scope

This Part of IEC 62366, which is a Technical Report, contains background information and provides guidance that addresses specific areas that experience suggests can be helpful for those implementing a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS both as defined in IEC 62366-1:2015 *and as supporting goals other than SAFETY*. This technical report is not intended to be used for regulatory purposes. It contains no requirements and only provides guidance and tutorial information.

NOTE 1 SAFETY is freedom from unacceptable RISK, which is described in ISO 14971. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or to loss or degradation of clinical performance.

NOTE 2 The PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE, as it relates to SAFETY is found in IEC 62366-1:2015.

This technical report has two main themes:

- information about efficient ways to implement elements required by IEC 62366-1:2015; and
- *additional information, in particular how USABILITY relates to attributes such as TASK EFFICIENCY and USER satisfaction, which can enhance a MEDICAL DEVICE'S commercial success.*

This technical report discusses the business benefits of USABILITY ENGINEERING, the basics of applicable analysis and design techniques, MEDICAL DEVICE USABILITY EVALUATION approaches, efficient ways to address USABILITY ENGINEERING project implementation issues (e.g. integration into a quality management system) and provides a list of useful USABILITY ENGINEERING resources.

This technical report also can be useful for other healthcare products (e.g. drug packaging and drug LABELLING, drug-MEDICAL DEVICE combination products and health IT software).

1.2 Purpose

The intent of this technical report is to provide guidance related to:

- the essential elements of a USABILITY ENGINEERING PROCESS as required by IEC 62366-1:2015, including:
  - USER research techniques,
  - analysis techniques,
  - design techniques, and
  - MEDICAL DEVICE USABILITY EVALUATION approaches (e.g. USABILITY TESTING);
- *the planning and implementation of the USABILITY ENGINEERING PROCESS;*
- *the benefits of applying USABILITY ENGINEERING; and*
- *improve USER satisfaction*.

This technical report is intended to be read in conjunction with IEC 62366-1:2015.

The intended reader for this technical report includes the people or organisations that are involved with *planning, funding, managing, and performing research,* design, evaluation *and regulatory-related activities* (i.e. approbation) related to MEDICAL DEVICES, including, but not limited to:

- company, department, project, and product managers;
- design and engineering professionals (e.g. human factors engineers, industrial designers, technical writers, information designers, software developers, mechanical engineers, electrical engineers, packaging engineers);
- medical researchers and other interested clinicians;
- marketers and other business professionals in the MEDICAL DEVICE industry;
- quality or regulatory staffs of MEDICAL DEVICE MANUFACTURERS (for example, regulatory affairs, RISK MANAGEMENT or quality management roles); and
- writers of product standards.

This technical report is neither intended as the sole source of USABILITY ENGINEERING guidance for MEDICAL DEVICE MANUFACTURERS, nor a complete substitute for human factors expertise. Rather, it is intended to provide readers with a general understanding of how to perform USABILITY ENGINEERING in an economic manner. Readers are advised to supplement the knowledge they gain from this report with knowledge acquired from complementary documents including those specific to the MEDICAL DEVICE of interest. A list of useful USABILITY ENGINEERING resources and further readings is provided in Annex A.

This report does not address detailed USABILITY ENGINEERING design guidance or requirements, such as recommendations on the proper size of text on a computer screen, appropriate ways to arrange a workstation's displays and controls, or characteristics of an appropriate ALARM SIGNAL. Such information can be found in other documents, such as [1][2][3][4][1].

This technical report does not describe a specific set of USABILITY ENGINEERING activities that suit all design projects. Instead, it gives guidance for a general USABILITY ENGINEERING PROCESS requiring further shaping and tailoring to suit a given development project's needs. USABILITY ENGINEERING practice varies widely throughout the world and even within specific countries, companies, and company units. This variation is partly due to the diversity found among USABILITY ENGINEERING practitioners who can have a background in one or more of various professional fields, such as engineering, psychology, or design. Practice differences also exist due to the wide variety of MEDICAL DEVICES, which range from seemingly simple syringes to complex imaging systems, some of which are used in hospitals, clinics, and/or the home by various types of medical professionals as well as laypersons (e.g. PATIENTS and caregivers who take care of PATIENTS, such as a child or spouse).

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 98.

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

1 Numbers in square brackets refer to the Bibliography.

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

3 Terms and definitions

For the purposes of this document, the terms given in IEC 62366-1, ISO 14971, as well as the following apply.

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

3.1
ACCESSORY
additional part for use with MEDICAL DEVICE in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other MEDICAL DEVICE

[SOURCE: IEC 60601-1:2005, 3.3, modified – 'equipment' is replaced by 'MEDICAL DEVICE'] [5]

3.2
ADVERSE EVENT
event associated with a MEDICAL DEVICE that led to death or serious injury of a PATIENT, USER or other person, or that might lead to death or serious injury of a PATIENT, USER or other person if the event recurs

Note 1 to entry: This definition is consistent with guidance in GHTF/SG2/N54/R8:2006. [6]

Note 2 to entry: This definition includes malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

[SOURCE: ISO TS 19218-1:2011, 2.1] [7]

3.3
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

Note 1 to entry: An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

Note 2 to entry: An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, 3.1] [1]

3.4
ALARM LIMIT
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

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

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

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

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

[SOURCE: IEC 60601-1-8:2006, 3.11, modified – 'ME EQUIPMENT or a ME SYSTEM' has been replaced by 'MEDICAL DEVICE'] [1]

3.7
CLOSE CALL
case in which a USER almost commits a USE ERROR while performing a TASK, but recovers in time to avoid making the USE ERROR

EXAMPLE A USER might initially place his or her thumb on the wrong end of an injection pen, but then rotates the pen into the proper position enabling a safe and effective injection.

Note 1 to entry: A CLOSE CALL does not include a case in which an initial USE ERROR evokes an ALARM CONDITION, for example, leading the USER to correct the USE ERROR; this is a case of a RISK CONTROL working properly.

3.8
CONCEPTUAL MODEL DIAGRAM
graphical description of the underlying organization and relationships in a USER INTERFACE design.

EXAMPLE A diagram that simply shows labelled circles – perhaps as few as three to five.

3.9
FIDELITY
degree to which a model or SIMULATION reproduces the state and behaviour of a real world object or the perception of a real world object, feature or condition

Note 1 to entry: Low-FIDELITY models share only a limited number of common elements with the actual MEDICAL DEVICE of interest.

Note 2 to entry: High-FIDELITY models share many common elements with the actual MEDICAL DEVICE of interest.

[SOURCE: ISO 16781:2013, 2.4, modified – deleted ', or chosen standard in a measurable or perceivable manner' and added Notes 1 and 2 to entry.] [8]

3.10
FUNCTION ANALYSIS
analysis of MEDICAL DEVICE-related functions that occur to accomplish operational goals and particularly which functions are (or should be) performed automatically by the MEDICAL DEVICE or manually by the USER, or by a combination of both based on their known strengths and weaknesses

3.11
KNOWLEDGE TASK STUDY
a study performed by questioning USERS to understand and interpret important information in the USER INTERFACE that will be applied to make use-related decisions

3.12
LABELLING
written, printed or graphic matter

– affixed to a MEDICAL DEVICE or any of its containers or wrappers, or

– accompanying a MEDICAL DEVICE,

related to identification, technical description, and use of the MEDICAL DEVICE, but excluding shipping documents

Note 1 to entry: For the purposes of this International Standard, the term "marking" as used in ISO 9001 is interpreted to mean "LABELLING".

Note 2 to entry: Some regional and national regulations use the term "LABELLING" more comprehensively to include for example, promotional materials and training.

[SOURCE: ISO 13485:2003[2], 3.6, modified – Deleted existing note, and Note 1 to entry and Note 2 to entry have been added.] [9]

3.13
SIMULATION
conceptualization and use of an abstraction or model that behaves in a way similar to a real MEDICAL DEVICE in its SYSTEM

3.14
TASK ANALYSIS
analysis employed to determine the USER goals and the specific behaviours required of USERS when operating equipment or doing work

Note 1 to entry: The documentation of a TASK ANALYSIS can take a narrative, tabular, or flow chart form.

Note 2 to entry: Example interactions include acquiring information, processing information, making decisions and performing physical actions.

[SOURCE: ISO 9241-5:1998, 3.22, modified – replaced 'people' with 'the USER goals and' and added Notes 1 and 2.] [10]

3.15
USABILITY GOAL
desired quality of a USER-MEDICAL DEVICE interaction

NOTE 1 TO ENTRY: USABILITY GOALS can be expressed in written form, stipulating a particular USABILITY attribute (e.g. TASK compliance rate, TASK speed, learning time, accuracy, visual appeal, comfort) and performance criterion (e.g. number of seconds, USE ERROR rate, average subjective ratings).

NOTE 2 TO ENTRY: USABILITY GOALS can address objective (observable) and subjective (opinion-based) aspects of interaction and can be used as a basis for planning and judging the results of USABILITY TESTS.

3.16
USABILITY SPECIALIST
professional competent on the basis of appropriate education, training, skills or experience to perform USABILITY ENGINEERING activities

Note 1 to entry: A USABILITY SPECIALIST applies knowledge of human characteristics and USABILITY ENGINEERING methods to support the development of safe, effective, usable, and satisfying MEDICAL DEVICES.

3.17
USER INTERFACE REQUIREMENT
testable technical design requirement for a USER INTERFACE characteristic

Note 1 to entry: A USER INTERFACE requirement can be USER INTERFACE design feature or medical device performance level.

Note 2 to entry: A USER INTERFACE REQUIREMENT is typically derived from a USER need.

2 The reference to ISO 13485:2003 was retained to maintain alignment with IEC 62366-1:2015. At the next revision of IEC 62366-1, the references will be updated to the latest edition of ISO 13485.