Medical devices—Part 2: Guidance on the application of usability engineering to medical devices
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Abstract: This 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 as defined in ANSI/AAMI/IEC 62366-1:2015.

Keywords: human factors engineering, ergonomics, human factors, usability
AAMI Technical Information Report

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.
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Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

General

TASK ANALYSIS

FUNCTION ANALYSIS

Identify and analyse known problems

Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Identify and describe HAZARD-RELATED USE SCENARIOS

Define USE SCENARIOS

USE SCENARIOS as they relate to RISK MANAGEMENT

Identify HAZARD-RELATED USE SCENARIOS

Methods to define and analyse HAZARD-RELATED USE SCENARIOS

Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION

General

Selection of the HAZARD-RELATED USE SCENARIOS based on SEVERITY

Selection of HAZARD-RELATED USE SCENARIOS based on other circumstances

Establish USER INTERFACE SPECIFICATION

Development of the USER INTERFACE SPECIFICATION

ACCOMPANYING DOCUMENTATION and training

Develop concept sketches

Review USER INTERFACE REQUIREMENTS and constraints

Develop conceptual model(s)

Design software USER INTERFACES (if applicable)

Design hardware USER INTERFACES (if applicable)

Design materials necessary for training and training

Develop detailed designs

Verify the design of the USER INTERFACE

Perform FORMATIVE EVALUATIONS

Conduct multiple FORMATIVE EVALUATIONS

Recommended methods for FORMATIVE EVALUATION
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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

The adoption of IEC TR62366-2 as an American National Standard was initiated by the AAMI Human Factors Engineering Committee (HE). AAMI HE functions as a U.S. sub-Technical Advisory Group to the relevant work in the International Electrotechnical Commission (IEC). U.S. representatives from AAMI HE played a very active part in developing the IEC standard.

At the time this document was published, the AAMI Human Factors Engineering Committee had the following members:

Cochairs:
Mary Beth Privitera, University of Cincinnati
Dr. Molly Story, Sanofi

Members:
Tor Alden, HS Design Inc
Araya Amsalu, Hill-Rom Holdings
Michael Appel, Northeast Georgia Medical Center
Dr. Janey Barnes, User-View Inc
Nancy Bayer, Smiths Medical
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April Jones, LivaNova PLC
Mike Kasamanian, Human Factors Consulting Services Inc
Dr. Michael Lau, Insight Product Development
Lee Leichter, P/L Biomedical
Melissa Lemke, Agilis Consulting Group LLC
Dr. Dana Lowry, National Institute of Standards & Technology
Megha Mahadevan-Shah, Cardinal Health (MP&S)
Barb Majchrowski, Draeger Medical Systems Inc
Dr. Jennifer Martin, The University of Nottingham
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Shawn O'Connell, B Braun of America Inc
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Rob Radwin, University of Wisconsin
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Sara Waxberg, Eli Lilly & Company
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Chris Neon, Cook Inc
Dr. Arathi Sethumadhavan, Medtronic Inc Campus
Jane Smith, GFK
Joan Spear, B Braun of America Inc
Matthew Trachtenberg, Becton Dickinson & Company
Tom Varricchione, Ximedica
Tracy Weldon, Hayward Health
Julia Yeh, Amgen Inc

Alternates:

NOTE — Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.
Background of AAMI adoption of IEC TR62366-2:2016

As indicated in the foreword to the main body of this document (page x), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by IEC Technical Committee 62, Electrical equipment in medical practice, Subcommittee 62A, Common aspects of electrical equipment used in medical devices, to specify a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. This guidance document can be helpful for those implementing a usability engineering process (human factors engineering) as defined in ANSI/AAMI/IEC 62366-1. It applies to all medical devices, including those used by laypersons and/or healthcare professionals.

U.S. participation in IEC/SC62A is organized through the U.S. Technical Advisory Group to IEC/SC62A, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI/IEC TIR62366-2 was registered by the American National Standards Institute (ANSI) on 24 July 2016.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other IEC standards. See the Glossary of Equivalent Standards for a list of IEC standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the recommended practice. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

"May" is used to indicate that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr, Suite 301, Arlington, VA 22203-1633.

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.

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5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

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.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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.

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

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<th>Report on voting</th>
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<td>62A/1015/DTR</td>
<td>62A/1040A/RVC</td>
</tr>
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</table>

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.
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

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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.