Singapore Standards Council

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TECHNICAL REFERENCE

Medical devices –

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

Published by

Enterprise Singapore

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		Name
Convenor	:	Dr Christian Gert Bluechel
Secretary	:	Mr Kevin Tan
Members	:	Mr Peter Haywood
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		Mr Watson Ong
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		Prof Tong Yen Wah

The organisations in which the experts of the National Mirror Working Group are involved are:

Advent Access Pte Ltd
AWAK Technologies Pte Ltd
Kidney Dialysis Foundation
National University of Singapore
Temasek Polytechnic
The Institution of Engineers, Singapore

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National Foreword

This Technical Reference was prepared by the National Mirror Working Group on IEC SC62D MT20 appointed by the Technical Committee on Medical Devices under the direction of the Biomedical and Health Standards Committee.

This standard is identical with IEC/TR 62366-2:2016, “Medical devices – Part 2: Guidance on the application of usability engineering to medical devices”, published by the International Electrotechnical Commission.

Attention is drawn to the following:

1. Where appropriate, the words “International Standard” shall be read as “Singapore Standard”.

2. The reference to International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
IEC 62366-1	SS IEC 62366-1
IEC TR 62366-2	TR IEC/TR 62366-2
IEC 60601-1	SS IEC 60601-1
IEC 60601-1-6	SS IEC 60601-1-6
IEC 60601-1-8	SS IEC 60601-1-8
IEC 60601-1-11	SS IEC 60601-1-11
ISO 13485	SS ISO 13485
ISO 14971	SS ISO 14971

3. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

Attention is drawn to the possibility that some of the elements of this Technical Reference may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

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1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*

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MEDICAL DEVICES –

Part 2: Guidance on the 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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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).