SS IEC 62366-1:2018+A1:2020

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(ICS 11.040)

SINGAPORE STANDARD

Medical devices

– Part 1 : Application of usability engineering to medical devices

Incorporating Amendment No. 1

Singapore Standards Council

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– Part 1 : Application of usability engineering to medical devices

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The content of this Singapore Standard was approved on 15 November 2018 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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BHSC set up the Technical Committee on Medical Devices to oversee the preparation of this standard. The Technical Committee consists of the following members:

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Secretary	:	Ms Iris Peng	*Singapore Manufacturing Federation – Standards Development Organisation*
Members	:	Ms Chua Chui Khim	*Becton Dickinson Medical (S) Pte Ltd*
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The Technical Committee set up the National Mirror Working Group on IEC SC62D MT20 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

		Name
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Secretary	:	Mr Kevin Tan
Members	:	Mr Peter Haywood
		Dr Ho Teck Tuak
		Mr Watson Ong
		Mr Peh Ruey Feng
		Prof Tong Yen Wah

The organisations in which the experts of the 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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CONTENTS

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on IEC SC62D MT20 set up by the Technical Committee on Medical Devices under the purview of BHSC.

This standard is an identical adoption of IEC 62366-1:2015, “Medical devices – Part 1: Application of usability engineering to medical devices”, including the amendments to this edition, published by the International Electrotechnical Commission.

NOTE 1 – Where appropriate, the words “International Standard” are read as “Singapore Standard”.

NOTE 2 – Reference to International Standards are replaced by applicable Singapore Standards/Technical References.

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

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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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.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 62366-1 edition 1.1 contains the first edition (2015-02) [documents 62A/977/FDIS and 62A/988/RVD] and its corrigendum (2016-07), and its amendment 1 (2020-06) [documents 62A/1386/FDIS and 62A/1397/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

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 14971:2019 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.

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 the base publication and its amendment 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.5.

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 62366-2[1]) 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 performance.

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 advantages of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

INTRODUCTION to Amendment 1

The first edition of IEC 62366-1 was published in 2015. Since its publication, experts working in the field have identified several inaccuracies that warrant correction. In total, 22 issues were identified and presented to the National Committee members of IEC/SC 62A and to the Member Bodies of ISO/TC 210. A majority of the members of both committees that stated a position supported developing this amendment to address the identified issues while making no fundamental changes to the USABILITY ENGINEERING PROCESS as originally conceived in IEC 62366-1:2015.

To assist the USER to implement the USABILITY ENGINEERING PROCESS, the technical report IEC TR 62366-2 is available, which contains tutorial information to assist MANUFACTURERS in complying with this document, as well as more generally to design MEDICAL DEVICES that goes

1 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.

beyond SAFETY-related aspects of USER INTERFACES and offers more detailed descriptions of USABILITY ENGINEERING methods that can be applied.

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 NORMAL USE, i.e., CORRECT USE and USE ERROR. 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 HAZARDS including loss or degradation of clinical performance.

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2[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 56.

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

2 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.