



BSI Standards Publication

## Medical devices

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

### National foreword

This Published Document is the UK implementation of IEC/TR 62366-2:2016. Together with BS EN 62366-1:2015, it supersedes BS EN 62366:2008+A1:2015 which will be withdrawn on 31 March 2018.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016.

Published by BSI Standards Limited 2016

ISBN 978 0 580 85673 0

ICS 11.040.01

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2016.

### Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

---

# TECHNICAL REPORT



---

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

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

---

ICS 11.040.01

ISBN 978-2-8322-3346-7

**Warning! Make sure that you obtained this publication from an authorized distributor.**

Currently in preview, click buy full version

## CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope and purpose.....	9
1.1 Scope.....	9
1.2 Purpose.....	9
2 Normative references.....	10
3 Terms and definitions.....	11
4 Mapping between the requirements of IEC 62366-1 and the guidance of IEC TR 62366-2.....	14
5 Background and justification of the USABILITY ENGINEERING program.....	14
5.1 How SAFETY relates to USABILITY.....	14
5.2 Reasons to invest in USABILITY ENGINEERING.....	15
6 How to implement a USABILITY ENGINEERING program.....	16
6.1 Effective USABILITY ENGINEERING programs.....	16
6.2 Effective USABILITY ENGINEERING projects and plans.....	16
6.3 Apply an appropriate level of USABILITY ENGINEERING expertise.....	17
6.4 Ensure the necessary resources are available and well timed.....	18
6.5 RISK MANAGEMENT as it relates to USABILITY ENGINEERING.....	18
6.5.1 RISK ANALYSIS.....	18
6.5.2 RISK CONTROL.....	19
6.5.3 Information for SAFETY.....	20
6.5.4 Overall evaluation of RESIDUAL RISK.....	22
6.6 USABILITY ENGINEERING FILE.....	22
6.7 Tailoring the USABILITY ENGINEERING effort.....	23
7 Overview of the USABILITY ENGINEERING PROCESS.....	24
8 Prepare the USE SPECIFICATION.....	27
8.1 Initiate USE SPECIFICATION.....	27
8.2 Analyse the intended USERS, anticipated USER TASKS and intended USE ENVIRONMENTS.....	28
8.2.1 Intended USER.....	28
8.2.2 Anticipated USER TASKS.....	30
8.2.3 Intended USE ENVIRONMENT.....	30
8.3 Finalise the USE SPECIFICATION.....	30
8.4 Recommended methods for developing the USE SPECIFICATION.....	31
8.4.1 General.....	31
8.4.2 Contextual inquiry and observation.....	31
8.4.3 Interview and survey techniques.....	31
8.4.4 Expert reviews.....	32
8.4.5 Advisory panel reviews.....	32
8.4.6 USABILITY TESTS.....	32
9 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS.....	32
9.1 General.....	32
9.2 TASK ANALYSIS.....	33
9.3 FUNCTION ANALYSIS.....	33
9.4 Identify and analyse known problems.....	35

10	Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS .....	35
11	Identify and describe HAZARD-RELATED USE SCENARIOS .....	36
11.1	Define USE SCENARIOS .....	36
11.2	USE SCENARIOS as they relate to RISK MANAGEMENT .....	36
11.3	Identify HAZARD-RELATED USE SCENARIOS .....	37
11.4	Methods to define and analyse HAZARD-RELATED USE SCENARIOS .....	37
12	Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION .....	38
12.1	General .....	38
12.2	Selection of the HAZARD-RELATED USE SCENARIOS based on SEVERITY .....	39
12.3	Selection of HAZARD-RELATED USE SCENARIOS based on other circumstances .....	39
13	Establish USER INTERFACE SPECIFICATION .....	40
13.1	Development of the USER INTERFACE SPECIFICATION .....	40
13.2	ACCOMPANYING DOCUMENTATION and training .....	40
14	Establish USER INTERFACE EVALUATION plan .....	41
14.1	Specify how the USER INTERFACE design will be explored and evaluated .....	41
14.2	FORMATIVE EVALUATION planning .....	42
14.3	SUMMATIVE EVALUATION planning .....	42
14.4	USABILITY TEST planning .....	43
14.5	Example USABILITY TEST protocol and report .....	43
15	Design and implement the USER INTERFACE and training .....	44
15.1	General .....	44
15.2	Develop conceptual model(s) .....	46
15.3	Design software USER INTERFACES (if applicable) .....	47
15.3.1	General .....	47
15.3.2	Review USER INTERFACE REQUIREMENTS and constraints .....	47
15.3.3	Develop software USER INTERFACE structure(s) .....	47
15.3.4	Design wireframes .....	48
15.3.5	Design screen templates .....	48
15.4	Design hardware USER INTERFACES (if applicable) .....	48
15.4.1	General .....	48
15.4.2	Review USER INTERFACE REQUIREMENTS and constraints .....	49
15.4.3	Develop concept sketches .....	49
15.5	Design materials necessary for training and training .....	49
15.5.1	General .....	49
15.5.2	Training materials .....	49
15.5.3	Training .....	51
15.6	Develop detailed designs .....	52
15.7	Verify the design of the USER INTERFACE .....	52
16	Perform FORMATIVE EVALUATIONS .....	52
16.1	Conduct multiple FORMATIVE EVALUATIONS .....	52
16.2	Recommended methods for FORMATIVE EVALUATION .....	53
16.2.1	General .....	53
16.2.2	Conduct heuristic analysis .....	54
16.2.3	Conduct cognitive walkthrough .....	54
16.2.4	Conduct USABILITY TESTS .....	54
16.3	Analysis of FORMATIVE EVALUATION results .....	55
17	Perform SUMMATIVE EVALUATION .....	55
17.1	General .....	55

17.2	Conduct a SUMMATIVE EVALUATION .....	56
17.3	Data collection .....	57
17.3.1	General .....	57
17.3.2	Observational data .....	57
17.3.3	Subjective data .....	58
17.4	Data analysis .....	59
18	Document the USABILITY ENGINEERING project .....	61
19	POST-PRODUCTION review and analysis .....	61
	Annex A (informative) Recommended reading list .....	64
	Annex B (informative) External resources to identify known problems .....	66
B.1	General .....	66
B.2	Austria .....	66
B.3	Germany .....	66
B.4	Sweden .....	67
B.5	Switzerland .....	67
B.6	United Kingdom .....	67
B.7	United States .....	67
	Annex C (informative) Developing USABILITY GOALS for commercial purposes .....	68
C.1	General .....	68
C.2	Objective goals .....	68
C.3	Subjective goals .....	69
	Annex D (informative) USABILITY ENGINEERING project end products .....	71
	Annex E (informative) USABILITY ENGINEERING methods .....	73
E.1	General .....	73
E.2	Advisory panel reviews .....	74
E.3	Brainstorm USE SCENARIOS .....	75
E.4	Cognitive walkthrough .....	75
E.5	Contextual inquiry .....	75
E.6	Day-in-the-life analysis .....	76
E.7	Expert reviews .....	77
E.8	FMEA and FTA .....	77
E.9	Focus groups .....	78
E.10	FUNCTION ANALYSIS .....	78
E.11	Heuristic analysis .....	79
E.12	Observation .....	79
E.13	One-on-one interviews .....	79
E.14	Participatory design .....	80
E.15	PCA analysis .....	80
E.16	SIMULATION .....	82
E.17	Standards reviews .....	82
E.18	Surveys .....	83
E.19	TASK ANALYSIS .....	83
E.20	Time-and-motion studies .....	84
E.21	Workload assessment .....	84
	Annex F (informative) USABILITY ENGINEERING studies in clinical settings .....	85
F.1	General .....	85
F.2	Sample study in the clinical environment .....	85
	Annex G (informative) USER PROFILE .....	87

Annex H (informative) USE ENVIRONMENT descriptions .....	89
Annex I (informative) USER INTERFACE REQUIREMENTS .....	91
Annex J (informative) Model the USER INTERFACE .....	92
J.1 General.....	92
J.2 Develop preliminary prototype(s) .....	92
J.3 Develop a refined prototype.....	92
J.4 Develop a specification prototype .....	93
J.5 Prepare a style guide .....	93
Annex K (informative) USABILITY TEST sample size .....	94
Annex L (informative) Identifying distinct USER groups .....	97
Bibliography .....	98
Index of defined terms .....	101
Figure 1 – Example of a USABILITY ENGINEERING project for a graphical USER INTERFACE .....	26
Figure 2 – Progression of a USER INTERFACE design from multiple concepts to a few concepts to a preferred concept .....	46
Figure 3 – Progression of concepts from multiple concepts to a few concepts to a preferred concept .....	50
Figure E.1 – Sample of a USE ENVIRONMENT within a hospital.....	76
Figure E.2 – Model of USER-MEDICAL DEVICE interaction.....	81
Figure E.3 – Infant manikin used in a neonatal care unit simulator (left), test participant simulating an auto-injector (centre) and an adult manikin used in a surgery SIMULATION (right) .....	82
Figure E.4 – Example hierarchical TASK ANALYSIS.....	84
Figure J.1 – USER INTERFACE designers using prototyping software to build and test a USER INTERFACE.....	93
Figure K.1 – Number of test participants needed in a USABILITY TEST for FORMATIVE EVALUATION .....	95
Table 1 – Mapping between the requirements of IEC 62366-1 and the guidance of IEC TR 62366-2.....	14
Table 2 – Human versus machine capabilities .....	34
Table 3 – Example of five qualitative SEVERITY levels (adapted from Table D.3 of ISO 14971:2007) .....	39
Table 4 – Example outline of a USABILITY TEST protocol.....	44
Table 5 – Example outline of a USABILITY TEST report .....	44
Table 6 – USE ERRORS caused by sample USER INTERFACE design shortcomings.....	55
Table 7 – Sample USE ERRORS and their root causes.....	60
Table D.1 – USABILITY ENGINEERING project end products.....	71
Table E.1 – Recommended application of USABILITY methods .....	74
Table G.1 – Sample USER PROFILE .....	87
Table H.1 – Sample USE ENVIRONMENT .....	89
Table I.1 – Sample USER INTERFACE REQUIREMENTS .....	91
Table K.1 – Cumulative probability of detecting a USABILITY problem .....	96

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## 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.
- 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.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, accept 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, the "state of the art".

IEC TR 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.*