PD IEC TR 63183:2019

BSI Standards Publication

Guidance on error and warning messages for software used in radiotherapy

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

National foreword

This Published Document is the UK implementation of IEC TR 63183:2019.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee 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 2020
Published by BSI Standards Limited 2020

ISBN 978 0 580 99921 5

ICS 11.040.60

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 January 2020.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

IEC TR 63183

Edition 1.0 2019-12

TECHNICAL REPORT

colour inside

Guidance on error and warning messages for software used in radiotherapy

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.60

ISBN 978-2-8322-7715-7

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

® Registered trademark of the International Electrotechnical Commission

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 General guidance 8
5 Designing error message displays 8
5.1 Design systems to avoid the errors in the first place 8
5.2 Categorize messages 8
5.3 Consolidate reports and displayed error messages 9
5.4 Summary of main concepts 9
6 Message content usability guidelines 10
6.1 Basic structure 10
6.2 OPERATOR centred 10
6.3 Message clarity 10
6.4 Message action ability 12
6.5 Conciseness 12
6.6 Message specificity 12
6.7 Courteous 13
6.8 Use of error codes 13
7 Guidelines for the development process 13
8 Visual design guidelines 14
Annex A (informative) Checklist 15
Annex B (informative) Examples 16
Bibliography 23
Index of defined terms 24

Figure 1 – Example error message answering what happened, why and what to fix 10
Figure 2 – Example error message with unclear language on how to proceed 11
Figure 3 – Example error message with unfamiliar OPERATOR abbreviations 11
Figure 4 – Example error message implying the system thinks 11
Figure 5 – Example of an unhelpful error message 12
Figure 6 – Example error message showing error code 13
Figure B.1 – Example 1 16
Figure B.2 – Example 2 16
Figure B.3 – Example 3 17
Figure B.4 – Example 4 17
Figure B.5 – Example 5 17
Figure B.6 – Example 6 18
Figure B.7 – Example 7 18
Figure B.8 – Example 8 18
Figure B.9 – Example 9 19
Figure B.10 – Example 10 19

AVA Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

Figure B.11 – Example 11 20
Figure B.12 – Example 12 20
Figure B.13 – Example 13 20
Figure B.14 – Example 14 21
Figure B.15 – Example 15 21
Figure B.16 – Example 16 22
Figure B.17 – Example 17 22
Figure B.18 – Example 18 22

Table 1 – Replacing engineering language with language understandable for operators 10

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

INTERNATIONAL ELECTROTECHNICAL COMMISSION

GUIDANCE ON ERROR AND WARNING MESSAGES FOR SOFTWARE USED IN RADIOTHERAPY

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, 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 TR 63183, which is a Technical Report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Technical Report is based on the following documents:

Draft TR	Report on voting
62C/738/DTR	62C/741/RVDTR

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.

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

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: 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 OF IEC 60601-1, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document 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.

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

INTRODUCTION

This document is intended to be read by persons involved in software development for RADIOTHERAPY and provides guidance on how to write relevant error messages shown to the clinical OPERATORS. This document is meant to provide examples within the RADIOTHERAPY domain and is not meant to replace IEC/ISO standards governing usability (for example, IEC 62366-1:2015). With the advent of more RADIOTHERAPY equipment being computer controlled, there has been a reported increase in the number of treatment delivery errors, some serious, occurring due to misunderstanding of the various error and warning messages shown to the OPERATOR during usage. Mistakes in interpretation are more likely to occur when error messages are written in technical language or are presented to the user without an OPERATOR-friendly explanation.

This problem is compounded by use of the following practices:

– message dialogs are designed from the program's technical point of view and not from the clinical OPERATOR'S point of view;
– message dialogs are optimized for engineering purposes with little input from end USERS;
– insufficient attention and resources are given to applying good practices for usability of message dialogs and careful review by clinical representatives.

In addition, the frequency of messages displayed by the many pieces of RADIOTHERAPY equipment to the OPERATOR can lead to "message overload". This increases the RISK that the OPERATOR will ignore critical information.

This document provides guidance via examples of common mistakes made when writing error messages to be displayed to the OPERATOR.

Documents
Document Sharing Hub

Full document details: PD IEC TR 63183:2019

GUIDANCE ON ERROR AND WARNING MESSAGES FOR SOFTWARE USED IN RADIOTHERAPY

1 Scope

This document, which is a Technical Report, provides guidance on the usage and form of error or warning messages written for software used in RADIOTHERAPY. It does not replace any requirements existing in the safety standards but is meant to be used as a supplement to existing standards on usability by providing specific examples in the field of RADIOTHERAPY.

The two main goals of this document are

1) to present in a concise manner the best practices and design guidelines for good message dialogs, and
2) to illustrate these design guidelines with specific examples from the field of radiation oncology.

This document is intended to be read by the following MANUFACTURERS' employees and representatives:

– engineering department members including: software engineers, RISK managers, quality assurance engineers, technical writers, etc.;
– usability and human factors engineers;
– marketing representatives (product marketing, product managers, business analysts).

Throughout this document, unless specifically called out, these guidelines apply to all categories of messages summarily called error or warning messages (e.g. critical error, warning, system status, informational, routine interlock messages).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-1:—, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*[1]

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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

[1] Fourth edition under preparation. Stage at the time of publication: IEC/AFDIS 60601-2-1:2019

Documents
Document Sharing Hub
Full document details: PD IEC TR 63183:2019