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Guidance on error and warning messages for software used in radiotherapy

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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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.

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- withdrawn,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.

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.

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*

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