BRITISH STANDARD

BS ISO 15223-2:2010

Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied

Part 2: Symbol development, selection and validation

ICS 01.080.20; 11.040.01

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

British Standards Documents Document Sharing Hub

Full document details: BS ISO 15223-2:2010

National foreword

This British Standard is the UK implementation of ISO 15223-2:2010.

The UK participation in its preparation was entrusted to Technical Committee CH/210/3, General terminology and symbols for Medical Devices.

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.

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2010

© BSI 2010

ISBN 978 0 580 57532 7

Amendments/corrigenda issued since publication

Date	Comments

Documents
Document Sharing Hub

Full document details: BS ISO 15223-2:2010

INTERNATIONAL STANDARD

ISO 15223-2

First edition
2010-01-15

Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied —

Part 2: Symbol development, selection and validation

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux —

Partie 2: Développement, sélection et validation de symboles

Reference number
ISO 15223-2:2010(E)

Documents
Document Sharing Hub

© ISO 2010

Full document details: BS ISO 15223-2:2010

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

COPYRIGHT PROTECTED DOCUMENT

© ISO 2010

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

© ISO 2010 – All rights reserved

Documents
Document Sharing Hub

Full document details: BS ISO 15223-2:2010

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Principles for identification and development of new symbols 3
4.1 Identifying the need for a symbol 3
4.2 Symbols with horizontal applications 3
4.3 Symbols for use within a restricted range of device types 3

5 Process for selecting and validating symbols for inclusion in ISO 15223-1 3
5.1 General 3
5.2 Initial evaluation 4
5.3 Second evaluation 4

6 Classification of risk 7

7 Concept development 7
7.1 Existence of other symbols 7
7.2 Symbol design 8

8 Evaluation 8
8.1 Testing early symbol concepts 8
8.2 Comprehension testing 9
8.3 Memory testing 9
8.4 Usability testing 9

9 Acceptance criteria 10
9.1 General 10
9.2 Symbols with no to low safety relevance 10
9.3 Symbols with moderate to high safety relevance 10

Annex A (normative) **Information to be provided during the symbol development process for adoption of a symbol into ISO 15223-1** 11

Annex B (normative) **ISO/TC 145/SC 3 proposal for graphical symbols** 12

Annex C (normative) **IEC/SC 3C proposal for graphical symbol form** 14

Bibliography 16

© ISO 2010 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 15223-2:2010

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 15223-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO 15223-2, together with ISO 15223-1:2007, cancels and replaces ISO 15223:2000, which has been technically revised.

ISO 15223 consists of the following parts, under the general title *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*:

— *Part 1: General requirements*

— *Part 2: Symbol development, selection and validation*

© ISO 2010 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 15223-2:2010

Introduction

The ISO 15223 series of International Standards addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices. As such, in most regulatory domains the symbols are required to be presented with the device. The information can be required to be presented on the device itself, as part of the label or provided with the device.

Many countries require that their own language be used to present textual information with medical devices. This presents problems to device manufacturers and users. Faced with the requirement to produce labelling in a number of different languages, manufacturers might have to increase the size of the package or label, thus potentially increasing packaging waste, or compressing the information, thus compromising legibility. Users presented with devices labelled in a number of different languages can experience confusion and delay in locating the needed information in an appropriate language. ISO 15223-1 proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings, that are independent of language.

While compiling the symbols presented in ISO 15223-1, it was recognised that a systematic methodology for the development and presentation of symbols was needed. ISO/TC 210 began by formulating a “best practices” document, *Guide to the development and registration of symbols for use in the labelling of medical devices*.

When this guide was circulated to interested parties, a number of regulatory authorities were of the opinion that they would have greater confidence in the use of symbols to replace text if the best practices set out in the Guide were expressed as normative requirements in a standards document. Some of the best practices for symbols development and usage have been translated into normative requirements in ISO 15223.

Much of the information required on a medical device itself, as part of the label, or provided with the device constitutes information for safety within an integrated approach to risk management. As with any risk control measure, the manufacturer needs to verify the effectiveness of the information for safety before it can be accepted. The use of standardized symbols agreed by consensus on an international basis can address the confusion that users can experience when presented with labelling in a number of different languages. However, the proliferation of symbols without control and harmonization is undesirable and detracts from the effectiveness of using symbols to convey information for safety. In addition, some users and regulatory authorities have concerns that the unrestricted use of symbols without validation can represent a hazard.

This part of ISO 15223 includes methods for validating those candidate symbols being proposed for inclusion in ISO 15223-1. It can also be used by manufacturers and regulators for validating symbols for use with medical devices, where suitable symbols are not standardized.

This document has been prepared by ISO/TC 210 to influence the quality of symbols developed for use in labelling by establishing a process that addresses the need to ensure quality of symbols accepted in ISO 15223-1 by:

— establishing need;

— providing guidance on development of symbols;

— carrying out testing to make sure that the candidate symbol is suitable for adoption and use.

When the processes detailed in this part of ISO 15223 have been carried out, the probability of misinterpretation of symbols accepted in ISO 15223-1 is reduced.

© ISO 2010 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 15223-2:2010

Documents
Document Sharing Hub

Full document details: BS ISO 15223-2:2010

INTERNATIONAL STANDARD ISO 15223-2:2010(E)

Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied —

Part 2:
Symbol development, selection and validation

1 Scope

This part of ISO 15223 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

The purpose of this part of ISO 15223 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

If the symbol validation process detailed in this part of ISO 15223 has been complied with, then the residual risks, as defined in ISO 14971 and IEC 62366, associated with the usability of a medical device symbol are presumed to be acceptable, unless there is objective evidence to the contrary.

This part of ISO 15223 is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labelling.

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 9186-1:2007, *Graphical symbols — Test methods — Part 1: Methods for testing comprehensibility*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80416-2, *Basic principles for graphical symbols for use on equipment — Part 2: Form and use of arrows*

IEC 80416-1:2008, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
appropriateness ranking test
procedure for ranking candidate symbols according to their considered appropriateness for representing a particular meaning

© ISO 2010 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 15223-2:2010