INTERNATIONAL STANDARD

ISO 15223-2

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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

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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*

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.

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

3.2
associative strength test
procedure for comparing the strength of an association between a candidate symbol and several possible meanings

3.3
characteristic information
information that represents the property or properties of a symbol

3.4
comprehension test
procedure for quantifying the degree of understanding by the target group of the candidate symbol

NOTE Adapted from ISO 9186-1:2007, definition 3.1.

3.5
description
normative text that defines the purpose, the application and the use of the symbol

NOTE Adapted from IEC 80416-1:2008, definition 3.2.

3.6
symbol concept
diagrammatic representation of a candidate symbol which conveys the essential elements of the symbol but which has not yet been produced as a symbol original on a pattern template

3.7
symbol original
drawing of a graphical symbol, including the corner markings, prepared in accordance with IEC 80416-1 and, where appropriate, ISO 80416-2

NOTE Adapted from IEC 80416-1:2008, definition 3.8.

3.8
symbol used in medical device labelling
graphic representation appearing on the label and/or associated documentation of a medical device which communicates characteristic information without the supplier or receiver of the information relying on knowledge of the language of a particular nation or people

NOTE The symbol can be an abstract pictorial or graphic representation, or one that uses familiar objects including alphanumeric characters.

3.9
title
unique name by which a graphical symbol is identified and spoken of

NOTE Adapted from IEC 80416-1:2008, definition 3.9.

3.10
target group
user population characterized by such factors as age, gender, education, occupation, cultural background, experience and training, and physical ability when relevant

3.11
usability
characteristic of the symbol which establishes effectiveness, efficiency, ease of user learning and user satisfaction

NOTE Adapted from IEC 62366 [10].

4 Principles for identification and development of new symbols

4.1 Identifying the need for a symbol

When identifying the need for a symbol, the following elements shall be considered:

a) the benefits derived from using a symbol;

b) the intended target group:

— their training and knowledge of, and experience with, the medical device(s) where the candidate symbol is intended to be used;

— their general medical knowledge.

4.2 Symbols with horizontal applications

The development of symbols with horizontal applications to a wide range of medical devices in a number of geographic or regulatory areas should be encouraged when there is a clear and significant need for a symbol. This is particularly true when these symbols are used to meet regulatory requirements. Such symbols shall be considered prime candidates for inclusion in ISO 15223-1.

4.3 Symbols for use within a restricted range of device types

The development of symbols for use within a restricted range of device types or within specific geographic or regulatory areas should be encouraged only if the need is clear and significant. The process of identifying the need should take account of the target group and the arrangements foreseen for publicizing the new symbols. Such symbols can be prime candidates for inclusion in standards for particular kinds of medical devices. However, they are not prime candidates for inclusion in ISO 15223-1. When, in the opinion of ISO/TC 210, there is sufficient international interest in a particular symbol of this type, the symbol may be included in ISO 15223-1 and any geographic or other limitations on its use shall be indicated.

5 Process for selecting and validating symbols for inclusion in ISO 15223-1

5.1 General

Symbols presented to ISO/TC 210 for inclusion in ISO 15223-1 shall be developed, selected and validated using the process described in this clause.

Proposals for symbols to be included in ISO 15223-1 shall be submitted to ISO/TC 210/WG 3 via the ISO/TC 210 Secretariat at: symbolsinfo@aami.org. Any person or group may propose a symbol.

NOTE 1 A schematic representation of the process for developing, selecting and validating symbols as outlined in this International Standard is shown in Figure 1.

NOTE 2 Within the symbol development process, it is necessary to submit the candidate symbol either to ISO/TC 145/SC 3 for approval for registration in ISO 7000 [1], or to IEC/SC 3C for approval for registration in IEC 60417-DB [6].

NOTE 3 If an entirely new symbol or partly developed concept is presented for consideration, they can be submitted for advice to ISO/TC 210/WG 3 (before the initial evaluation as described in 5.2), with as much of the information contained in Annex A as is available.

5.2 Initial evaluation

Symbols shall be submitted to ISO/TC 210/WG 3 with at least the information required by a) to g) of Annex A for initial evaluation. If the symbol is an existing symbol or based on existing symbology, relevant parts of the requirements in Annex A may be provided by reference to published documents.

NOTE The information in h) and i) of Annex A is not considered essential for the initial evaluation. However, if any testing or registration has already been carried out, this information should be made available to ISO/TC 210/WG 3 at this time.

ISO/TC 210/WG 3 will undertake an initial evaluation and provide an assessment of the symbol proposal, an opinion as to whether further development of the symbol is recommended, and if recommended, advice on whether symbol registration should be sought via ISO/TC 145/SC 3 or IEC/SC 3C.

If the outcome of the initial evaluation is to further develop the symbol, the proposer will be informed and may proceed according to 5.3.

If the outcome of the initial evaluation is to not further develop the symbol, the proposer will be informed and provided with an explanation of the decision.

5.3 Second evaluation

If the initial evaluation recommends further development of the symbol, the candidate symbol will need to be submitted to international symbol registrars and the relevant safety tests outlined in Clauses 8 and 9 will need to be undertaken. To pursue acceptance of the candidate symbol in ISO 15223-1, the proposer has the option of first submitting the candidate symbol, through ISO/TC 210/WG3, to the international registrars, and then carrying out the relevant safety tests (Option 1 below) or, inversely, of first carrying out the relevant safety tests and then submitting, through ISO/TC 210/WG 3, the candidate symbol to the international registrars (Option 2).

The ISO/TC 210 Secretariat will keep the proposer informed of the progress of the submission.

Option 1):

1) The proposer shall prepare the documentation required for submission to either ISO/TC 145/SC 3 or IEC/SC 3C, as recommended by ISO/TC 210/WG 3, in accordance with Annex B or Annex C, as appropriate[1)] , and submit the registration documentation and the information required in a) to g) of Annex A to the ISO/TC 210 Secretariat. If the candidate symbol is already registered, the proposer shall prepare and submit the information required in a) to h) of Annex A to the ISO/TC 210 Secretariat.

   NOTE This option does not require the proposer to carry out the tests described in Clauses 8 and 9 before submitting the registration documentation to the ISO/TC 210 Secretariat.

2) If not already registered, the ISO/TC 210 Secretariat will submit the candidate symbol to ISO/TC 145/SC 3 or IEC/SC 3C, as appropriate, for registration.

3) If, after assessment by ISO/TC 145/SC 3 or IEC/SC 3C, the candidate symbol is approved for registration, the proposer shall carry out the tests described in Clauses 8 and 9 and submit the information requested in i) of Annex A to ISO/TC 210/WG 3 via the ISO/TC 210 Secretariat.

1) As the requirements are different for submission to ISO/TC 145/SC 3 and IEC/SC 3C, two annexes are needed, one for each procedure.

4) If, after assessment by ISO/TC 145/SC 3 or IEC/SC 3C (even after redesigned proposals have been considered), the candidate symbol is not considered to be suitable for registration, ISO/TC 210/WG 3 shall ask the proposer whether to proceed with the symbol development process. If the proposer decides to proceed, the proposer shall then carry out the tests described in Clauses 8 and 9 and submit the test results and the information required in i) of Annex A to ISO/TC 210/WG 3 via the ISO/TC 210 Secretariat.

5) ISO/TC 210/WG 3 will then undertake a second evaluation and, considering the test results from Clauses 8 and 9 and the additional information provided, decide whether the candidate symbol meets the acceptance criteria based on safety relevance.

6) If the candidate symbol does not meet the acceptance criteria based on safety relevance, the proposer will be informed and provided with an explanation of the decision by ISO/TC 210/WG 3. The proposer may redesign the symbol and resubmit the proposal via the ISO/TC 210 Secretariat.

7) If the candidate symbol is considered to be suitable for inclusion in ISO 15223-1, it will be submitted for adoption in ISO 15223-1 through normal voting procedures in ISO/TC 210.

8) If accepted through normal voting procedures in ISO/TC 210 and registered by ISO/TC 145/SC 3 or IEC/SC 3C, the adopted symbol is published in ISO 15223-1.

9) If accepted through normal voting procedures in ISO/TC 210 but not registered by ISO/TC 145/SC 3 or IEC/SC 3C and the difference of opinion between either ISO/TC 145/SC 3 or IEC/SC 3C and ISO/TC 210/WG 3 cannot be resolved, the ISO/TC 210 Secretariat shall make a request to the ISO Technical Management Board for permission to publish without registration.

Option 2):

1) The proposer shall prepare the documentation required for submission to either ISO/TC 145/SC 3 or IEC/SC 3C, as recommended by ISO/TC 210/WG 3 in accordance with Annex B or Annex C, as appropriate. The proposer shall also carry out the tests described in Clauses 8 and 9 and submit the test results, the registration documentation and the information given in a) to g) and i) of Annex A to the ISO/TC 210 Secretariat. If the candidate symbol is already registered, the proposer shall prepare and submit the information required in a) to i) of Annex A to the ISO/TC 210 Secretariat.

2) ISO/TC 210/WG 3 will then undertake a second evaluation, and considering the test results from Clauses 8 and 9 and the additional information provided, decide whether the candidate symbol meets the acceptance criteria based on safety relevance.

3) If the candidate symbol does not meet the acceptance criteria based on safety relevance, the proposer will be informed and provided with an explanation of the decision by ISO/TC 210/WG 3. The proposer may redesign the symbol and resubmit the proposal via the ISO/TC 210 Secretariat.

4) If the candidate symbol is considered suitable for inclusion in ISO 15223-1 and if not already registered, the ISO/TC 210 Secretariat will submit the candidate symbol to ISO/TC 145/SC 3 or IEC/SC 3C, as appropriate, for registration.

5) If after assessment by ISO/TC 145/SC 3 or IEC/SC 3C, the candidate symbol is approved for registration, it will be submitted for adoption into ISO 15223-1 through normal voting procedures in ISO/TC 210.

6) If accepted through normal voting procedures in ISO/TC 210 and registered by ISO/TC 145/SC 3 or IEC/SC 3C, the adopted symbol is published in ISO 15223-1.

7) If, after assessment by ISO/TC 145/SC 3 or IEC/SC 3C (even after redesigned proposals have been considered) the candidate symbol is not approved for registration and the difference of opinion between either ISO/TC 145/SC 3 or IEC/SC 3C and ISO/TC 210/WG 3 cannot be resolved, the ISO/TC 210 Secretariat shall make a request to the ISO Technical Management Board for permission to publish without registration after the candidate symbol has been accepted through normal voting procedures in ISO/TC 210.