INTERNATIONAL STANDARD

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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.

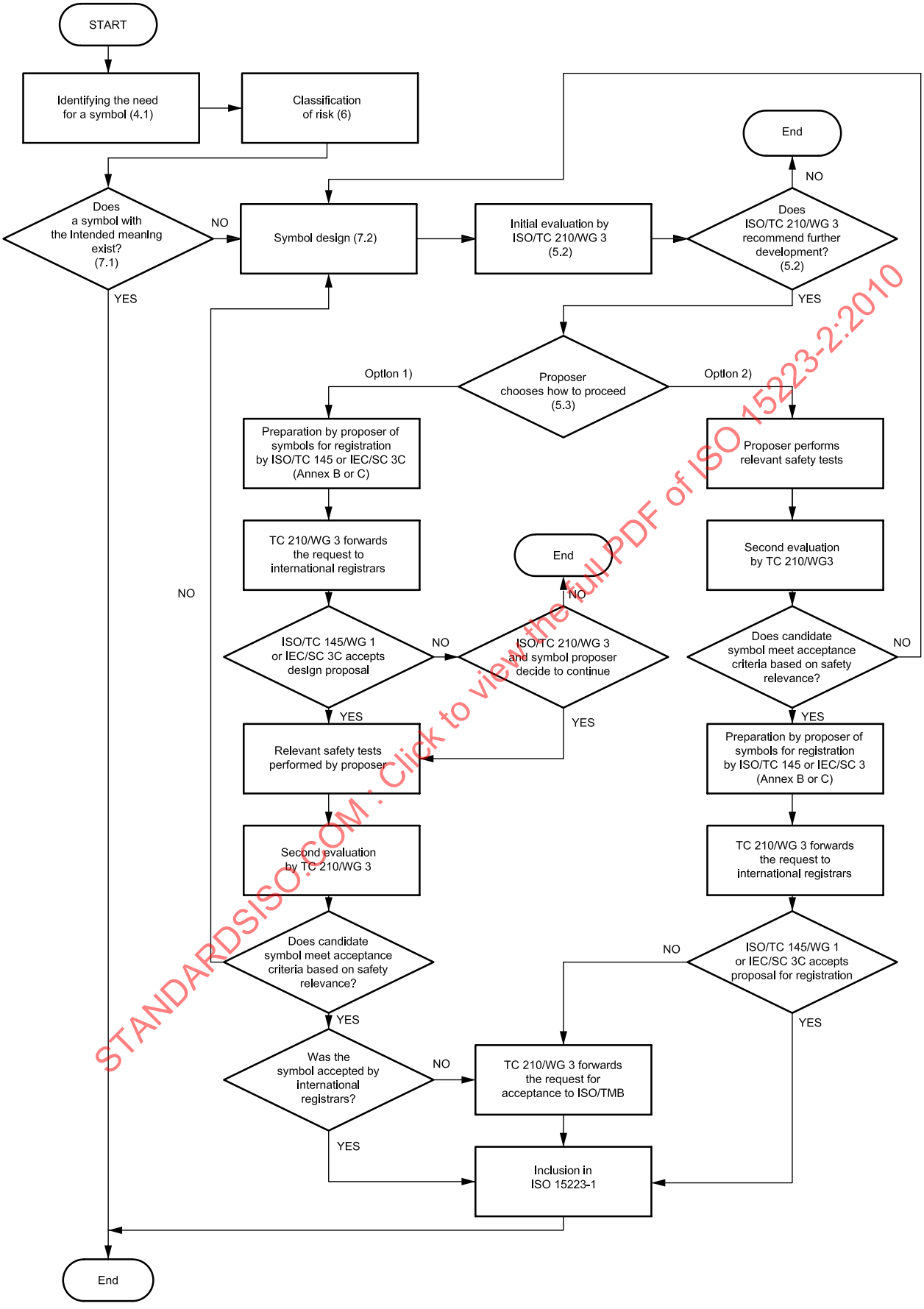


Figure 1 — Overview of the symbol development process

6 Classification of risk

A risk analysis evaluating the substitution of text with a symbol shall be performed.

The risk analysis shall pay particular attention to the following:

a) the severity of harm that is likely to occur if the intended meaning of the symbol is misunderstood;

b) the risk(s) associated with the presence on the medical device label of text and its translation into multiple languages;

c) the possibility that the language of the user might not be present on the label.

As part of the risk analysis, the information associated with the candidate symbol shall be classified as one of the following:

d) no to low safety relevance.

EXAMPLE 1 Catalogue number (ISO 15223-1:2007, symbol 5.15); Fragile, handle with care (ISO 15223-1:2007, symbol 5.5).

e) moderate to high safety relevance.

EXAMPLE 2 Do not resterilize (ISO 15223-1:2007, symbol 5.25); Use by date (ISO 15223-1:2007, symbol 5.12).

NOTE 1 When considering the possible consequences of a misunderstanding, those proposing a new symbol need to focus on the typical use of the candidate symbol. Subclause 4.2 of ISO 15223-1:2007 requires that a manufacturer determine that no additional risk is incurred by use of a symbol in that part of ISO 15223 in a particular situation, or that appropriate strategies to control the risk are adopted.

NOTE 2 Additional information regarding risk analysis is available in ISO 14971 [4].

The results of the risk analysis shall be documented in the proposal for the adoption of a symbol into ISO 15223-1 [see a) of Annex A].

NOTE 3 Any user of this part of ISO 15223 can carry out the additional testing required to support a moderate to high safety relevance classification if they feel it is appropriate. It is not a requirement of this part of ISO 15223 that the results of any secondary testing be communicated to ISO/TC 210/WG 3 via the ISO/TC 210 Secretariat.

7 Concept development

7.1 Existence of other symbols

During the symbol development process, existing symbol sources shall be reviewed to establish whether symbol(s) that address the need identified in 4.1 already exist. This review should include at least ISO 15223-1, ISO 7000 [1], ISO 7010 [2], IEC 60417-DB [6], IEC/TR 60878 [7] and EN 980 [9].

NOTE 1 Existing basic design elements can be used as the basis for new symbols.

Standards produced by technical committees with expertise in the areas of technology relevant to the proposed new symbol(s) should also be reviewed.

NOTE 2 The IEC/ISO database can be an aid in identifying existing symbols with overlapping meaning, and should be consulted early in the development process.

7.2 Symbol design

This stage involves both the generation of trial designs and the collection of design elements in use.

Symbols considered for initial assessment of suitability need only exist in concept form. However, once trial designs have been selected for further testing, a more formal design, following the methods of IEC 80416-1, is advisable. The basic pattern to guide design symbol graphics appears in B.2.

It is useful to agree on a title and description before committing designs to paper. Useful guidance on design issues is set out in ISO/TR 7239 [3]. Principles for the application of arrows in symbols are found in ISO 80416-2.

In addition, IEC 80416-3 [8] provides guidelines on the application of symbols in order to maintain visual clarity and overall consistency when such symbols are applied. This includes such important concepts as the proper way to use the general prohibition symbol (see Annex D of ISO 15223-1:2007).

Care should be taken to avoid ambiguity or confusion arising from changes in orientation of the symbol design. If the meaning of the symbol is dependent on orientation, for example where arrows identify specific directions, this shall be stated in the description.

Consideration shall also be given to the legibility of the symbol, for example when reproduced in a small print size or when positioned near other, possibly related, symbols.

8 Evaluation

8.1 Testing early symbol concepts

When developing a new symbol where no prior model exists, evaluation should result in a progressive reduction of multiple concepts to a preferred candidate symbol.

At the initial stage, there can be more versions of a symbol than can reasonably be tested for comprehension. The most appropriate candidates for further testing may be selected using a comprehensibility judgement test. A comprehensibility judgement test is intended to answer the question: “Which of these symbols best represents a given meaning?”

A simple form of a comprehensibility judgement test is the “appropriateness ranking test”. In this test, a sample of the target group places the candidate symbols in order of merit according to their considered appropriateness for representing a particular meaning.

In this method, a sample of the target group is given a meaning that they will be asked to associate with the candidate symbols. The candidate symbols are presented to the sample of the target group for ranking according to their appropriateness for representing that particular meaning. If there are only a few candidate symbols, they can be embedded within a group of similar symbols in order to provide more choice.

The top two or three symbols that best represent the given meaning are selected for further evaluation. Candidate symbols that are rarely selected are eliminated from further consideration.

Clause 7 of ISO 9186-1:2007 describes a more detailed method that may be used for testing the comprehensibility of candidate symbols with either printed material or computer screen presentation, depending on which is most practical.

NOTE In ISO 9186-1, the “comprehensibility test” is described as the “judgement test”, i.e. a procedure for eliciting judgements of the comprehensibility of the candidate symbol.

8.2 Comprehension testing

Comprehension testing quantifies the degree of understanding of candidate symbols by the target group. Comprehension testing is intended to answer the questions: “What do you think this means?” or “What action would you take in response to this symbol?”

A simple form of a comprehension test is the “associative strength test”. A candidate symbol can have more than one interpretation. The associative strength test can be used to show if there is an appropriate association between the candidate symbol and its intended meaning.

In this method, each candidate symbol is presented to a sample of the target group who are asked to rank from low to high the association between the candidate symbol and several possible meanings. It is not advisable to use a symbol with weak association as that symbol is likely to be misinterpreted.

Clause 6 of ISO 9186-1:2007 describes a more detailed method that may be used for testing comprehension of candidate symbols with either printed material or computer screen presentation, depending on which is most practical.

8.3 Memory testing

It is rare that everyone in the target group understands a new symbol's meaning on first exposure. Some learning can be involved. Some symbols are easily learned while others require significant effort to memorize. Once learned, the memory of some symbols is retained better than others.

In memory testing, subjects are taught the meaning of the symbols, then their mastery of the symbols and their meaning is demonstrated. The ease of learning can indicate whether a symbol is intuitive and can be inferred by the time it takes the subject to learn the meaning of the symbol. Retention is then tested after a period of time has elapsed by asking the subjects to recall the meaning of the symbols.

8.4 Usability testing

Usability testing is the method of systematically observing and recording representative subjects' understanding of symbols in the context of use. It might be appropriate to employ usability testing in situations where the symbol:

1) has high safety implications,

2) has a large and varied target group or

3) has implications for the use of the device.

Usability testing should be executed systematically and controlled for sources of bias and unreliability. It can verify that the symbol usability meets the usability objective.

NOTE Context is an important factor in learning and understanding the meaning of symbols. The symbol needs to be assessed in context because the context could have significant effects on the understanding and use of symbols. A given symbol might be meaningless when seen by itself but becomes obvious when seen in the context where it is intended to be used. Likewise, a given symbol on one device may have a different meaning on another product, which could cause confusion.

9 Acceptance criteria

9.1 General

Much of the information required on or with a medical device is information for safety within an integrated approach to risk management. The criticality of that information depends on the nature of its application. For example, the “sterile” symbol (see ISO 15223-1:2007, symbol 5.20) usually conveys a significant safety message because there is a risk of contamination. On the other hand, the date of manufacture (see ISO 15223-1:2007, symbol 5.13) might convey significant information for safety only under particular circumstances.

As with any risk control measure, the effectiveness of a candidate symbol for conveying information for safety shall be validated in accordance with 9.2 or 9.3, as relevant, before it can be accepted in ISO 15223-1.

In the early stages of testing, comparative evaluation is sufficient because the purpose of the testing is to select the best candidates from an initial set of design concepts. Absolute criteria are advisable later in the process to avoid the adoption of a poor symbol merely by virtue of its being tested against even worse alternatives.

9.2 Symbols with no to low safety relevance

When a symbol is intended to convey information with no to low safety relevance, the preferred candidate may be compared against established symbols to validate its association with the intended meaning. The association with the intended meaning shall be at least as strong as with symbols of comparable safety relevance that have already been accepted in ISO 15223-1.

A simple form of comparison is the “associative strength test”. In this method, the candidate symbol(s) is/are presented to a sample of the target group along with symbols drawn from ISO 15223-1. Those participating in the test are asked to choose an intended meaning for each symbol, from a list of possibilities. As part of the report, the proposer shall indicate which symbols from ISO 15223-1 were chosen for the associative strength test.

NOTE 1 The list of possible meanings should be longer than the list of symbols to avoid arriving at an answer by process of elimination.

NOTE 2 Context is an important factor in understanding the meaning of symbols (see 8.4, Note).

(A) candidate symbol(s) with no to low safety relevance which receive(s) an associative strength score that is at least equal to the score received by the symbols already in ISO 15223-1 can be considered for inclusion in ISO 15223-1.

9.3 Symbols with moderate to high safety relevance

Candidate symbols with moderate to high safety relevance shall undergo comprehension testing (8.2), memory testing (8.3) and usability testing (8.4).

The acceptance criteria for these tests shall be determined by the proposer and shall be based on the results of the risk analysis in Clause 6. This criterion shall be established prior to the start of the testing and shall be documented in the proposal for the adoption of a symbol in ISO 15223-1 [see i) of Annex A].

Annex A
(normative)

Information to be provided during the symbol development process for adoption of a symbol into ISO 15223-1

When proposing a symbol for adoption in ISO 15223-1, the proposer shall provide the following information:

a) identification of the need for the symbol with results of a risk analysis for the replacement of text by a symbol;

b) clear and unambiguous title and description for the symbol;

c) identification of the target group and the device(s) that is/are intended to bear the symbol, and the regulatory domain(s) into which the devices are intended to be marketed;

d) details of existing or candidate symbols with the same or related meaning;

e) identity of the proposer submitting the symbol(s) and contact details to whom correspondence should be addressed;

f) symbol original set out within the basic pattern (see B.2) following the principles of IEC 80416-1:2008, 8.1 to 8.3;

g) identification of any particular considerations such as orientation which can affect legibility, reproduction or understanding;

h) details of any existing registration or submission to an international registrar (ISO/TC 145/SC 3 or IEC/SC 3C);

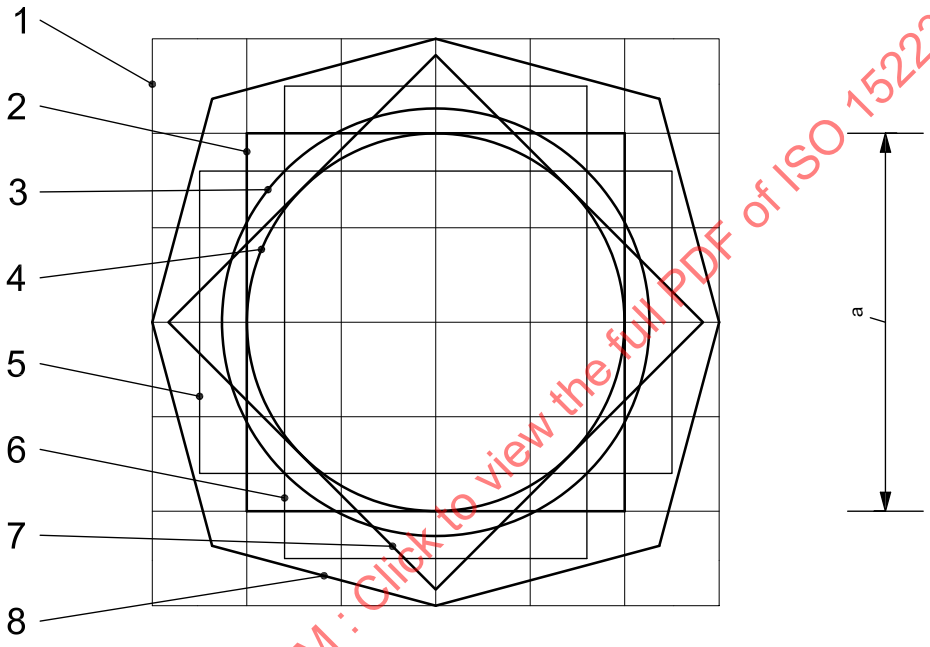
i) details of any evaluation carried out on the use, comprehension or acceptability of the symbol.

Annex B
(normative)

ISO/TC 145/SC 3 proposal for graphical symbols

B.1 ISO/TC 145/SC 3 symbol proposal form

A specimen symbol proposal form is shown in Figure B.1. The most current registration/proposal form may be downloaded from the ISO/TC 145/SC 3 website at www.iso.ch/tc145/sc3.



Key

[a] Nominal size.

Reference	Description
1	Square of 75 mm lateral length, forming the largest horizontal and vertical dimensions of the basic pattern and divided into a grid of 12,5 mm line spacing.
2	Basic square of 50 mm lateral length. This dimension is equal to the nominal size 50 mm of the symbol original.
3	Basic circle of 56,6 mm diameter, having approximately the same surface area as the basic square 2.
4	Circle of 50 mm diameter, being the inscribed circle of the basic square 2.
5, 6	Two rectangles having the same surface area as the basic square 2 and a width of 40 mm and a height of 62,5 mm. They are mutually perpendicular, each drawn to cross symmetrically opposite sides of the basic square 2.
7	Basic square 2 of 50 mm rotated by 45°.
8	Octagon formed by lines at 15° to the outer sides of the grid 1.

NOTE The basic pattern as templates for drawing software can be downloaded for the IEC web site (http://sc3c.iec.ch) and the ISO web site (http://www.iso.ch/tc145/sc3).

Figure B.1 — Basic pattern

B.2 Basic pattern for symbol design

The basic pattern from IEC 80416-1 shall be used as the basis for the creation of a symbol original. It is used as a tool for the design of a symbol original to ensure a balanced visual impression between graphical symbols.

B.3 ISO/TC 145/SC 3 registration process steps

a) TC or SC completes the symbol proposal form that will include EPS file and emails it to http://www.iso.ch/tc145/sc3.

The secretary of ISO/TC 145/SC 3 reviews the symbol proposal form to ensure all required information is filled in. Incomplete forms are sent back to the TC or SC for completion. Completed forms are posted on the ISO/TC 145/SC 3 website for member review.

ISO/TC 145/SC 3 members review symbols for:

— content of required fields;

— compliance to ISO/IEC 80416 guidelines;

— appropriate TC liaison;

— symbol duplication – registered symbol originals with same or similar meaning, or registered symbol with same or similar graphical form.

b) ISO/TC 145/SC 3 comments and the votes on candidate symbol originals are compiled by ISO/TC 145/SC 3 Secretariat. Approved symbol originals are assigned preliminary registration numbers.

c) The TC or SC is notified of preliminary registration numbers, along with comments on disapproved symbols. The TC or SC may submit a revised proposal, starting with a).

d) The TC or SC Secretariat ballots the DIS of approved symbols with preliminary registration numbers through the normal ISO process, and informs ISO/TC 145/SC 3 Secretariat of the results.

e) Registration numbers are assigned by the ISO/TC 145/SC 3 Secretariat to approved symbols. ISO Central Secretariat is informed of the final registration numbers and sent an electronic graphical file of the symbol.

f) The proposing TC or SC secretariat ballots the FDIS with symbols containing final registration numbers through the normal ISO process.