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

Part 1: General requirements

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

Partie 1: Exigences générales

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition cancels and replaces the second edition (ISO 15223-1:2012), which has been technically revised with the following principal revisions:

— Clause 2, updated the title of ISO 7000 and added the "date of release" for each of the registered symbols to Table 1;

— symbol 5.1.1, modified the requirement related to the placement of the manufacturer's name and address on IVD labels;

— symbol 5.1.2, modified the requirement related to the placement of name and address of the authorized representative in the European Union on IVD labels;

— symbol 5.4.3, added the information used to indicate an instruction to consult an electronic instructions for use (eIFU);

— symbol 5.4.5, added the reference to ISO 7000, symbol 2725, "Contains or presence of";

— symbol 5.5.5, modified the description of the symbol and the requirement regarding use with IVD;

— A.15, added the examples of the placement of the eIFU indicator.

A list of all parts in the ISO 15223 series can be found on the ISO website.

NOTE Future symbols intended to appear in this document are to be validated in accordance with ISO 15223-2.

This corrected version of ISO 15223-1:2016 incorporates the following correction:

— in A.9, the graphical symbol of NOTE 2 has been corrected.

Introduction

This document addresses the presentation of certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required to appear with the medical device in most regulatory domains. The information can be required to appear on the medical device itself, as part of the label, or provided with the medical device.

Many countries require that their own language be used to display textual information with medical devices. At the same time, manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This can cause problems in relation to translation, design and logistics when multiple languages are included on a single label or piece of documentation. For example, users of medical devices labelled in a number of different languages can experience confusion and delay in locating the appropriate language.

This document proposes solutions to these problems through the use of internationally recognized symbols with precisely defined descriptions.

While compiling symbols to be included in this document, ISO/TC 210 recognized the need for systematic methodology for the selection, development and validation of symbols proposed for adoption. This is the subject of ISO 15223-2.

This document is primarily intended to be used by manufacturers of medical devices who market identical products in countries where there are different language requirements for medical device labelling. It can also be of assistance to

— distributors of medical devices or other representatives of manufacturers,

— healthcare providers responsible for training, as well as those being trained,

— those responsible for post-market vigilance,

— healthcare regulatory authorities, testing organizations, certification bodies and other organizations which are responsible for implementing regulations affecting medical devices and which have responsibility for post-market surveillance, and

— consumers or end users of medical devices who draw their supplies from a number of sources and can have varied language capabilities.

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

Part 1: General requirements

1 Scope

This document identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document.

This document is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging or in the associated documentation. The requirements of this document are not intended to apply to symbols specified in other standards.

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.

ISO 7000[1)], *Graphical symbols for use on equipment — Registered symbols*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
characteristic information
information that represents the property or properties of a symbol

1) The collection of ISO 7000 graphical symbols and additional information concerning their use are available at https://www.iso.org/obp/ui/#search. Each symbol in the database has a "registration date". These dates are given in the ISO Registration Number column in Table 1.

3.2
description
normative text which defines the purpose, application and use of the symbol

[SOURCE: IEC 80416-1:2008, 3.2]

3.3
label
written, printed or graphic information provided upon the medical device itself

[SOURCE: GHTF/SG1/N43:2005]

3.4
labelling
information supplied by the manufacturer that is provided for, associated with, or affixed to, a medical device or any of its containers or wrappers

Note 1 to entry: This information relates to the identification, technical *description* (3.2) and use of the medical device, but excludes shipping documents.

Note 2 to entry: Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer".

3.5
symbol used in medical device labelling
graphical representation appearing on the *label* (3.3) and/or associated documentation of a medical device that communicates *characteristic information* (3.1) without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The symbol can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters.

3.6
title
unique name by which a graphical symbol is identified and spoken of

[SOURCE: IEC 80416-1:2008, 3.9]

4 General requirements

4.1 Proposal of symbols for adoption

Symbols proposed for adoption in this document shall be validated in accordance with ISO 15223-2.

Any symbol proposed for adoption in this document shall be applicable to a range of medical devices and have global or regional applicability.

4.2 Requirements for usage

When risk management shows it to be appropriate for symbols to be used to convey information essential for proper use on the medical device, its packaging or in associated documentation, the symbols given in Table 1 may be used.

Symbols that are registered in ISO 7000 shall comply with the graphical representation in ISO 7000, especially with respect to relative dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE 1 ISO and IEC jointly maintain an online database of graphical symbols for use on equipment, which contains the complete set of graphical symbols included in ISO 7000 and IEC 60417 available at https://www.iso.org/obp/ui/#search. This online collection shows each graphical symbol and identifies it by a reference number and a title (in English and French). The graphical symbols are available in different formats (e.g. AI, DWG, EPS) and some additional data as applicable is provided. Various search and navigation facilities allow for easy retrieval of graphical symbols.

As part of risk management, the manufacturer should determine the appropriate size for the symbol to be legible for its intended function.

NOTE 2 This document does not specify colours or minimum size for the symbols in Table 1, nor does it specify the relative size of symbols and that of indicated information.

It is important that symbols be used properly. Guidance on appropriate use of the general prohibition symbol and the negation symbol is given in Annex B.

Before symbols are used, the manufacturer shall carry out a risk assessment that indicates that the use of the symbol does not introduce an unacceptable risk.

NOTE 3 Additional information regarding risk assessment can be found in ISO 14971.

Symbols may be used without accompanying text. Where regulations require accompanying text, the title of the symbol given in this document should be considered sufficient. All dates and times presented in association with symbols shall use the conventions set out in ISO 8601.

4.3 Other symbols

Other standards specify additional symbols that are applicable to particular kinds or groups of medical devices or to particular situations. Examples of sources for such symbols are identified in the Bibliography. This listing is not exhaustive.

5 Symbols

When appropriate, information essential for proper use shall be indicated on the medical device, its packaging, or in the associated documentation by using the corresponding symbols given in Table 1.

A manufacturer may use any appropriate symbol regardless of category.

NOTE Table 1 has been organized into symbol categories for ease of use. The category into which a symbol is grouped does not have any significance as far as usage is concerned. The order of appearance of symbols and the categories in which they are placed are not prioritized. Examples of the use of symbols can be found in Annex A.

Table 1 — Symbols to convey information essential for proper use

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1 Manufacture							
5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC and 98/79/EC.	This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol.	NOTE 1 This symbol is used to indicate information that is required in Europe.[b] NOTE 2 The full definition of "manufacturer" is given in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. NOTE 3 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 4 Guidance on the requirements for EU Directive 98/79/EC is given in ISO 18113-1, ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5. NOTE 5 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. NOTE 6 The relative size of the symbol and the size of the name and address are not specified.			3082 2011-10-02

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.2 EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.	NOTE 1 This symbol is used to indicate information that is required in the European Community. NOTE 2 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 3 Guidance on the requirements for EU Directive 98/79/EC is given in ISO 18113-1, ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5. NOTE 4 The relative size of the symbol and the size of the name and address are not specified.			N/A

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	NOTE The relative size of the symbol and the size of the date are not specified.		In Europe:[b] — the date could be a year, year and month, or year, month and day, as required in the relevant EU Directive; — this symbol may be used to identify the month and year of manufacture for active implantable medical devices, or the year of manufacture for active medical devices where no use-by date is given, as required by the appropriate EU Directive.	2497 2004-01-15