INTERNATIONAL STANDARD

ISO 15223-1

Second edition
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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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Contents

Page

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 15223-1 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 15223-1:2007) and EN 980:2008, which have been technically revised. It also incorporates the amendment ISO 15223-1:2007/Amd.1:2008.

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*

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

Introduction

This part of ISO 15223 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 part of ISO 15223 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined descriptions.

While compiling symbols to be included in this part of ISO 15223, 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 part of ISO 15223 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.

This part of ISO 15223 constitutes a technical revision of both ISO 15223-1:2007 and EN 980:2008, combining the symbols and requirements of both standards for the first time. There has been a steady convergence of the symbol requirements in ISO 15223-1 and EN 980 over recent years, with many of the previous differences between the standards resolved. This part of ISO 15223 represents a significant advance in the safe and effective use of symbols to transcend language, giving manufacturers, regulators and others a single set of global symbols for use with medical devices.

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

Part 1:
General requirements

1 Scope

This part of ISO 15223 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 part of ISO 15223.

This part of ISO 15223 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 part of ISO 15223 are not intended to apply to symbols specified in other standards.

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 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

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.

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

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

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

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

NOTE Adapted from 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 This information relates to the identification, technical description and use of the medical device, but excludes shipping documents.

NOTE 2 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 and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

NOTE 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

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

4 General requirements

4.1 Proposal of symbols for adoption

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

Any symbol proposed for adoption in this part of ISO 15223 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. In that database, each graphical symbol is identified by a reference number and contains a title (in English and French), a graphical representation in GIF and vectorized PDF format, and some additional data as applicable. Various search and navigation facilities allow for easy retrieval of graphical symbols. Information on how to subscribe in order to access this database is available through the ISO Store, the IEC Web Store or by contacting your local national standards body.

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 part of ISO 15223 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 part of ISO 15223 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

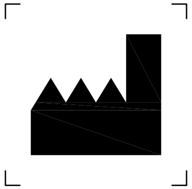
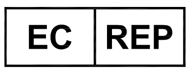
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.1 Manufacture							
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 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. According to EU Directive 98/79/EC, the address is not required with the symbol on an IVD medical device's immediate container, as specified in ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5, except when the immediate container is also the outer container.	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 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. NOTE 5 The relative size of the symbol and the size of the name and address are not specified.			3082
5.1.2 	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. The address is not required with the symbol on an *in vitro* diagnostic medical device's immediate container, as specified in ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5, except when the immediate container is also the outer container.	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 The relative size of the symbol and the size of the name and address are not specified.			

Table 1 (*continued*)

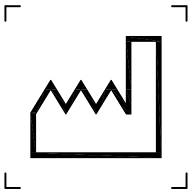
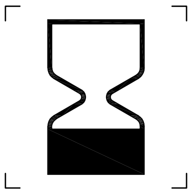
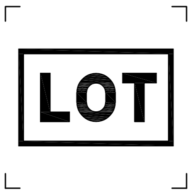
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.1.3 	Date of manufacture	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate 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 1 The relative size of the symbol and the size of the date are not specified. NOTE 2 This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacture can be combined in one symbol.		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
5.1.4 	Use-by date	Indicates the date after which the medical device is not to be used.	This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date 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 1 For example, June 2002 is expressed as 2002-06. NOTE 2 The relative size of the symbol and the size of the date are not specified. NOTE 3 Synonym for "use-by date" is "use by". NOTE 4 For some medical devices (e.g. IVDs), this date is only valid when the medical device is unopened.		In Europe[b]: — the date could be a year, year and month, or year, month and day, as required by the relevant EU Directive; — this symbol can be used to identify the time limit for implanting an active implantable medical device safely as required by EU Directive 90/385/EEC.	2607
5.1.5 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	NOTE 1 The relative size of the symbol and the size of the batch code are not specified. NOTE 2 Synonyms for "batch code" are "lot number" and "batch number".			2492

Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.1.6 	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	The manufacturer's catalogue number shall be adjacent to the symbol.	NOTE 1 The relative size of the symbol and the size of the catalogue number are not specified. NOTE 2 Synonyms for "catalogue number" are "reference number" and "reorder number".	In Europe[b], the manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this part of ISO 15223.		2493
5.1.7 	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.	NOTE The relative size of the symbol and the size of the serial number are not specified.	In Europe[b], the manufacturer's serial number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this part of ISO 15223.		2498
5.2 Sterility							
5.2.1 	Sterile	Indicates a medical device that has been subjected to a sterilization process.		NOTE Use of this symbol precludes the use of symbols 5.2.2 to 5.2.5.	In Europe[b], this symbol is restricted to use on terminally sterilized medical devices (4.1 of EN 556-1:2001 applies, including its associated note).		2499