INTERNATIONAL STANDARD

ISO 15223-1

First 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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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

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

This first edition of ISO 15223-1, together with the proposed part 2 of ISO 15223, cancels and replaces ISO 15223:2000.

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*

The development, selection and validation of symbols are to be the object of a future part currently under development:

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

Introduction

ISO 15223 addresses symbols that may be used to convey 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 device in most regulatory domains. The information may be required on the device itself, as part of the label, or provided with the device. Many countries require that their own language be used to display textual information with medical devices. This raises problems to device manufacturers and users.

Manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This results in a major problem of translation, design and logistics when multiple languages are included on a single label or piece of documentation. Users of medical devices, labelled in a number of different languages, can experience confusion and delay in locating the appropriate language. ISO 15223 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined meanings.

While compiling symbols to present in ISO 15223, ISO/TC 210 came to recognise the need for systematic methodology for the development and presentation of symbols proposed for adoption. This will be the subject of a new International Standard to be developed as ISO 15223-2 on development, selection and validation.

This part of ISO 15223 is primarily intended to be used by manufacturers of medical devices, who market identical products in countries having different language requirements for medical device labelling. This part of ISO 15223 may also be of assistance to:

— distributors of medical devices or other representatives of manufacturers;

— health care providers responsible for training as well as those being trained;

— those responsible for post market vigilance;

— health care regulatory authorities, testing organizations, certification bodies and other organizations responsible for implementing regulations affecting medical devices and having responsibility for post market surveillance.

— consumers or end users of medical devices who draw their supplies from a number of sources and may 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 part of ISO 15223 identifies requirements for the development and use of symbols that may be used to 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 limited to symbols applicable to a broad spectrum of devices that may be marketed globally. These symbols may be used on the device itself or its package or in the associated documentation.

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

IEC 80416-1:2001, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of symbol originals*

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

IEC 80416-3:2002, *Basic principles for graphical symbols for use on equipment — Part 3: Guidelines for the application of graphical symbols*

ISO 80416-4, *Basic principles for graphical symbols for use on equipment — Part 4: Guidelines for the adaptation of graphical symbols for use on screens and displays (icons)*

3 Terms and definitions

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

3.1
characteristic information
mental representation of a property or properties of an object or set of objects

3.2
description
normative text attached to the representation of the symbol original, which defines the purpose, the application and the use of the symbol original

[IEC 80416-1:2001, definition 3.6]

3.3
iconic presentation
pictorial or graphic representation using familiar objects including alphanumeric characters

3.4
label
written, printed or graphic information provided upon the medical device itself

NOTE 1 Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

NOTE 2 Adapted from GHTF/SG1/N043:2005.

3.5
labelling
written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers or

— accompanying a medical device,

related to identification, technical description and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer."

[ISO 13485:2003, definition 3.6]

3.6
symbol concept
diagrammatic representation of a symbol that conveys the essential elements of the symbol but which is not yet formally translated into the format required for a symbol original

3.7
symbol original
drawing of a symbol, prepared in accordance with IEC 80416-1, used for reference or reproduction purposes

NOTE Adapted from IEC 80416-1:2001, definition 3.3.

3.8
symbol used in medical device labelling
an object presented on the label and/or associated documentation of a medical device that communicates characteristic information (see 3.1) without relying on knowledge of the language of a particular nation or people by the supplier or receiver of the information

NOTE The symbol can utilize symbolic or iconic presentation.

3.9
symbolic presentation
abstract pictorial or graphic presentation

3.10
title
unique name by which a symbol is identified and spoken of

[IEC 80416-1:2001, definition 3.5]

4 General requirements

4.1 Proposal for symbols for adoption

Proposals for symbols for adoption into ISO 15223 shall be submitted to the secretariat of ISO/TC 210.

Symbols being proposed shall be presented following the dimensional criteria and design principles set out in ISO/IEC 80416 series. Where the presentation is symbolic, alphanumeric characters shall not be part of the symbol. Alphanumeric characters may be used when appropriate and relevant in a symbol with iconic presentation.

Symbols presented for advice on acceptability or procedural details, may be presented as symbol concept (see 3.6). Symbols presented for formal adoption shall be symbol originals (see 3.7). When a symbol is presented for advice or adoption, the details set out in Annex B shall be provided.

Any symbol proposed for adoption into this part of ISO 15223 shall be applicable to a range of devices and have global applicability. Other standards specify additional symbols that are applicable to particular kinds or groups of devices or to particular situations. Examples of such sources are identified in the Bibliography. This listing is not exhaustive.

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, on its package or in associated documentation, the symbols given in Table 1 may be used.

In use, the graphical representation of symbols shall comply with that shown in this part of ISO 15223, especially with respect to dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE 1 ISO and IEC jointly maintain an on-line database of Graphical Symbols for Use on Equipment, which contains the complete set of graphical symbols included in ISO 7000 [2] and IEC 60417 [8,9]. 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 access this database is available through the ISO Store [12], the IEC Web Store [13] or by contacting your local National Standards Body.

The symbols and associated information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary.

NOTE 2 Colours and minimum dimensions are not specified in this part of ISO 15223.

It is important that symbols are used properly and guidance on appropriate use of the general prohibition symbol is given in Annex D.

Before symbols are used the manufacturer shall ensure that no additional risk is thereby incurred. Alternatively, appropriate measures to control the risk shall be adopted.

NOTE 3 Additional information regarding risk management can be found in ISO 14971 [4].

All dates and times presented in association with symbols shall use the conventions set out in ISO 8601.

5 Symbols

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

Examples can be found in Annex A.

Table 1 — Symbols to convey information essential for proper use

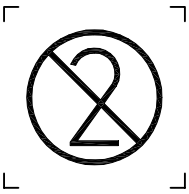
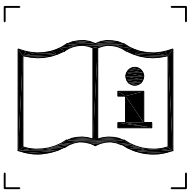
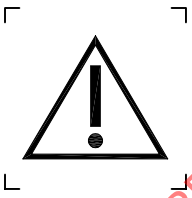
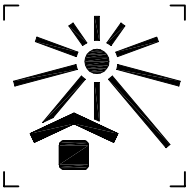
No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.1		Biological risks	ISO 7000-0659 (DB 2004-01)
5.2		Do not re-use	ISO 7000-1051 (DB 2004-01)
5.3		Consult instructions for use NOTE This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device. See also symbol 5.4.	ISO 7000-1641 (DB 2004-01)
5.4		Caution, consult accompanying documents NOTE 1 This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself. See also symbol 5.3. NOTE 2 The symbol A or B in ISO 7000-0434 ("Caution") may also be used.	ISO 7000-0434 (DB 2004-01)
5.5		Fragile, handle with care	ISO 7000-0621 (DB 2004-01)
5.6		Keep away from sunlight NOTE The symbol may also mean “Keep away from heat“ as referenced in ISO 7000:1989.	ISO 7000-0624 (DB 2004-01)

Table 1 (*continued*)

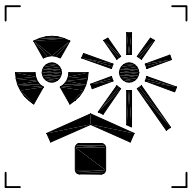
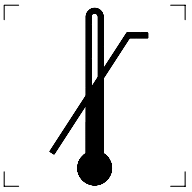
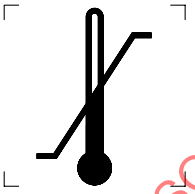
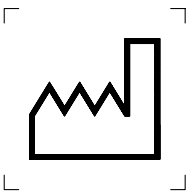
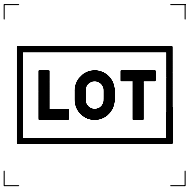
No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.7		Protect from heat and radioactive sources NOTE The symbol may also mean keep away from sunlight and radioactive sources.	ISO 7000-0615 (DB 2004-01)
5.8		Keep away from rain NOTE This symbol may also be “Keep dry“ as referenced in ISO 7000:1989.	ISO 7000-0626 (DB 2004-01)
5.9		Lower limit of temperature NOTE The lower limit of temperature should be indicated adjacent to the lower horizontal line.	ISO 7000-0534 (DB 2004-01)
5.10		Upper limit of temperature NOTE The upper limit of temperature should be indicated adjacent to the upper horizontal line.	ISO 7000-0533 (DB 2004-01)
5.11		Temperature limitation NOTE Upper and lower limits of temperature should be indicated adjacent to the upper and lower horizontal lines.	ISO 7000-0632 (DB 2004-01)
5.12		Use by date NOTE The symbol is accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown. The date could be a year, year and month, or year, month and day, as appropriate.	ISO 7000-2607 (DB 2004-01)
5.13		Date of manufacture NOTE This symbol is accompanied by the date that the device was manufactured. The date could be a year, year and month, or year, month and day, as appropriate.	ISO 7000-2497 (DB 2004-01)
5.14		Batch code NOTE This symbol should be accompanied by the batch code relevant to the device bearing the symbol.	ISO 7000-2492 (DB 2004-01)

Table 1 (*continued*)

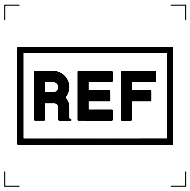
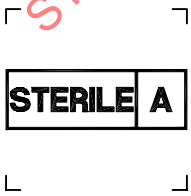
No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.15		Catalogue number NOTE This symbol should be accompanied by the catalogue number relevant to the device bearing the symbol.	ISO 7000-2493 (DB 2004-01)
5.16		Serial number NOTE This symbol should be accompanied by the serial number relevant to the device bearing the symbol.	ISO 7000-2498 (DB 2004-01)
5.17		Control	ISO 7000-2494 (DB 2004-01)
5.18		Negative control	ISO 7000-2495 (DB 2004-01)
5.19		Positive control	ISO 7000-2496 (DB 2004-01)
5.20		Sterile	ISO 7000-2499 (DB 2004-01)
5.21		Sterilized using aseptic processing techniques	ISO 7000-2500 (DB 2004-01)
5.22		Sterilized using ethylene oxide	ISO 7000-2501 (DB 2004-01)

Table 1 (*continued*)

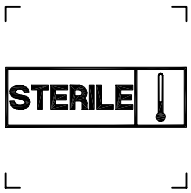
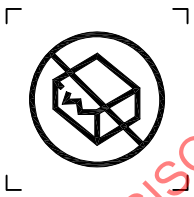
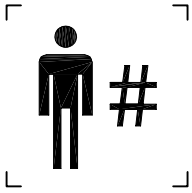
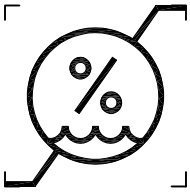
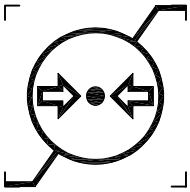
No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.23		Sterilized using irradiation	ISO 7000-2502 (DB 2004-01)
5.24		Sterilized using steam or dry heat	ISO 7000-2503 (DB 2004-01)
5.25		Do not resterilize	ISO 7000-2608 (DB 2004-01)
5.26		Non-sterile	ISO 7000-2609 (DB 2004-01)
5.27		Do not use if package is damaged NOTE Synonym for "Do not use if package is damaged" is "Do not use if the product sterilization barrier or its packaging is compromised".	ISO 7000-2606 (DB 2004-01)
5.28		*In vitro* diagnostic medical device NOTE This symbol should only be used to identify *in vitro* diagnostic medical devices and not to specify that the device is for “In Vitro Use“.	—
5.29		Patient number	ISO 7000-2610 (DB 2004-01)

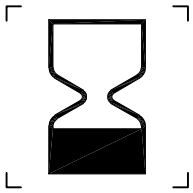
Table 1 (*continued*)

No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.30		Humidity limitation NOTE Humidity limitation should be indicated adjacent to the upper and lower horizontal lines.	ISO 7000-2620 (DB 2004-01)
5.31		Atmospheric pressure limitation NOTE The atmospheric pressure limitations should be indicated adjacent to the upper and lower horizontal lines.	ISO 7000-2621 (DB 2004-01)

Annex A
(informative)

Examples

A.1 Examples of use of the symbol for "Use by date"



2005-09-15

2005-09

A.2 Example of use of the symbol for "Batch code"

ABC123

A.3 Example of the use of the symbol for "Serial number"

ABC123

A.4 Example of use of the symbol for "Catalogue number"

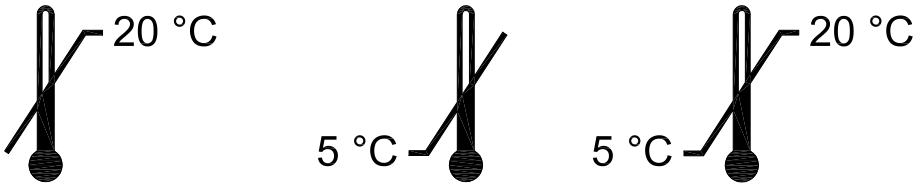
ABC123

A.5 Examples of use of the symbol for "Date of manufacture"

2004-06

2004

A.6 Examples of use of the symbols for temperature limits



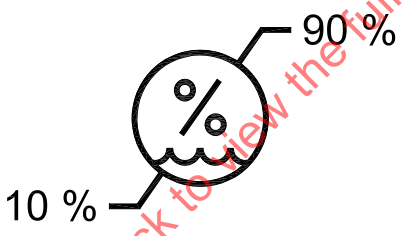
Upper limit of temperature

Lower limit of temperature

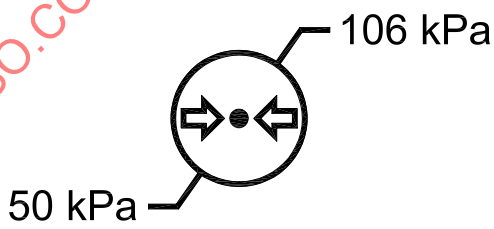
Temperature limitation

A.7 Example of use of the symbol for "Patient number"

A.8 Example of use of the symbol for "Humidity limitation"



A.9 Example of use of the symbol for "Atmospheric pressure limitation"



Annex B
(normative)

Proposal for the adoption of a symbol into ISO 15223-1

When proposing a symbol for adoption into ISO 15223-1, the initiator of the request shall provide the following information;

a) a rationale for the development of the symbol with an assessment of how the use of the symbol to assist safe and effective use with results of risk analysis for the substitution of the symbol for text;

b) clear and unambiguous title (3.10) and description (3.2) for the symbol;

c) identification of the intended users of the device(s) which will bear the symbol;

d) details of existing or proposed symbols in the same or related applications;

e) symbol original (3.7) set out within the basic pattern (Annex C) following the principles of IEC 80416-1:2001, subclauses 7.1 to 7.3;

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

g) details of any evaluation carried out on the use, comprehension or acceptability of the symbol;

h) detail of any existing registration or submission to a gatekeeper (ISO/TC 145 or IEC/SC 3C);

i) proposals for further development including validation;

j) the identity of the organization submitting the symbol(s), the relationship of the organization to ISO/TC 210 and the name and contact details of a person to whom correspondence should be addressed.

If the symbol is an existing symbol or based on existing symbology, elements of the above information can be provided by making reference to published documents.

When an entirely new symbol is presented for consideration or partly developed ideas are submitted for advice, as much of the above information as is available at the time, should be submitted. In addition, the symbol can be presented as a symbol concept (3.6).