INTERNATIONAL STANDARD

ISO 15223

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

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

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This first edition cancels and replaces ISO/TR 15223:1998.

Annex A of this International Standard is for information only.

Introduction

This International Standard considers certain items of information that may be considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required by laws and regulations of certain political jurisdictions to be presented with the device. This information may be required on the device itself, as part of the label of the device on its packaging, or provided with the device in an information document.

There is a considerable degree of international harmonization of the information to be provided. However, there is no harmonization with regard to the language to be used when presenting this information. This presents potential problems to manufacturers, users and regulatory authorities.

Device manufacturers, desiring to minimize the indirect costs not associated with healthcare purposes, seek to minimize costs of labelling by reducing or rationalizing labelling variants. In the European Union alone, there are thirteen languages that may be required. This presents a major problem of design and logistics. In addition, technical translation can present difficulties in transferring the precise meaning from one language to another.

Users may be presented with devices labelled in a number of different languages. This may cause confusion and delay in locating the appropriate language. It may also create confusion as to precise meanings for multilingual users.

Regulatory authorities may be presented with labelling not in their national language and have difficulty in ascertaining the safety and fitness for use of a device required in emergencies or other exceptional circumstances.

This International Standard proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings that transcend language.

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

1 Scope

This International Standard identifies symbols conventionally used to convey information essential for proper use to the user and others for safe and effective use of medical devices. This International Standard is primarily intended to be used by:

— manufacturers of medical devices who market their products in a number of countries having different language requirements for medical device labelling;

— users of medical devices who draw their supplies from a number of sources and may have varied language capabilities;

— those responsible for postmarket surveillance;

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

This International Standard may also be of assistance to:

— manufacturers having to cope with space limitations on small labels;

— distributors of medical devices or other representatives of manufacturers;

— health care authorities responsible for training as well as those being trained.

NOTE This International Standard deals with a small number of symbols that may be used when appropriate on the device itself, its package or in the accompanying documentation. Many other standards, such as IEC 60601-1, specify additional symbols that are applicable to particular kinds or groups of devices, or to particular situations.

2 Terms and definitions

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

NOTE This International Standard does not introduce new concepts. The following terms and definitions are provided for guidance. In particular circumstances, the legal definitions expressed by relevant statutes should be applied.

2.1
information essential for proper use
information that is essential for the safe use of the device for the patient, user or others

NOTE This information could, for example, include the degree of microbial cleanliness, up to and including sterility, when this is necessary with regard to the essential purpose. It could also include information that would facilitate traceability in the interest of postmarket surveillance by manufacturers and postmarket vigilance by regulatory authorities. It may include storage and handling instructions.

2.2
transition period
period during which a symbol and its referent appear in association in order to familiarize distributors, users and others with the symbol

3 Symbols

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

Table 1 — Symbols to convey information essential for proper use

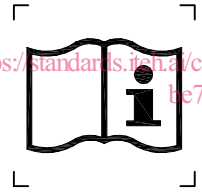
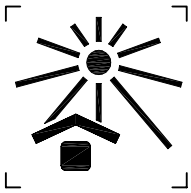
No.	Symbol	Referent
3.1		Biological risk
3.2		Do not re-use
3.3		Consult operating instructions [a]
3.4		Caution, consult accompanying documents [b, c]
3.5		Fragile, handle with care
3.6		Keep away from sunlight

Table 1 (*continued*)

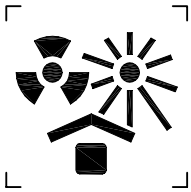
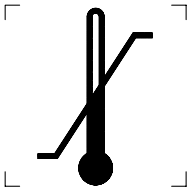
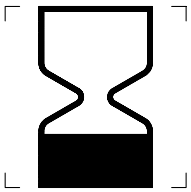
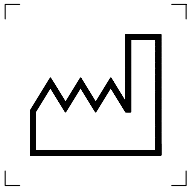
No.	Symbol	Referent
3.7		Protect from heat and radioactive sources
3.8		Keep dry
3.9		Lower limit of temperature
3.10		Upper limit of temperature
3.11		Temperature limitation
3.12		Use by [d]
3.13		Date of manufacture [e]

Table 1 (*continued*)

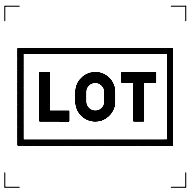
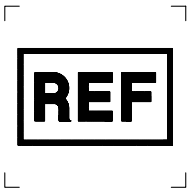
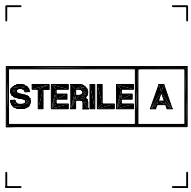
No.	Symbol	Referent
3.14		Batch code
3.15		Catalogue number
3.16		Serial number
3.17		Control [f]
3.18		Negative control [g]
3.19		Positive control [h]
3.20		Sterile

Table 1 (*continued*)

No.	Symbol	Referent
3.21		Sterilized using aseptic processing techniques
3.22		Sterilized using ethylene oxide
3.23		Sterilized using irradiation
3.24		Sterilized using steam or dry heat

[a] This symbol advises the reader to consult the operating instructions for information needed for the proper used of the device. See also symbol 3.4.

[b] 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 3.3.

[c] The referent given is compiled from all of the sources where this symbol appears in conjunction with medical devices. It is recommended that this referent be used during the transition period (see A.2).

[d] 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. See ISO 8601 for date formats.

[e] 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. See ISO 8601 for date formats.

[f] This symbol would appear on the labelling of material that is used as part of the quality control procedure for an *in vitro* diagnostic device.

[g] This is a variant of symbol 3.17 used to indicate a negative control.

[h] This is a variant of symbol 3.17 used to indicate a positive control.