TECHNICAL REPORT

ISO/TR 15223

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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

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 main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 15223, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This document is being published as an ISO Technical Report at this time because it is urgently needed in the marketplace, however it is simultaneously being circulated for adoption as an International Standard. When ISO/TC 210 began work on this item several years ago, the technical committee was incorrectly informed that a document such as this, consisting entirely of symbols, could not be published as an International Standard. It was subsequently learned that publication as a standard was permissible, and given the already wide acceptance of the symbols contained herein, the decision was made to proceed immediately to circulation as a draft International Standard so that an International Standard will replace the Technical Report as soon as possible.

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Introduction

This Technical Report (type 3) considers certain items of information which 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, part of the label of the device on its packaging, or provided with the device in an information document.

These items of information are subject to international harmonization to the end that there is agreement on information to be provided. However, there is no harmonization with regard to 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 which 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 can 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 Technical Report 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 Technical Report identifies symbols and their meanings which may be used to convey information essential to the user and others for safe and effective use of medical devices. The report is primarily intended to be used by the following:

— 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 post market surveillance.

This report 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.

2 Concepts

2.1 General

This Technical Report does not introduce new definitions. The following concepts are provided for guidance. In particular circumstances the legal definitions expressed by relevant statutes should be applied.

2.2 Information essential for proper use

This refers to information which is essential for the safe use of the device for the patient, user or others. It would, for example, include the degree of microbial cleanliness up to and including sterility when this is necessary with regard to the essential purpose. It would also include information which would facilitate traceability in the interest of postmarket surveillance by manufacturers and postmarket vigilance by regulatory authorities. It may include storage and handling instructions.

2.3 Transition period

This refers to a period during which the symbols and the meaning appear in association in order to familiarize distributors, users and others with the symbol.

3 Origins of symbols

Within the ISO framework of standards and technical reports, all symbols are to be standardized through ISO technical committee ISO/TC 145 and are included in ISO 7000. This mechanism allows for across-product coordination and service sectors coordination for a common set of standardized symbols. The symbols may be proposed to ISO/TC 145 from any technical committee and subsequently be used in International Standards published by other technical committees.

Some of the symbols included in this Technical Report originated in the medical device sector, while others were already in ISO 7000. ISO/TC 210 has proposed those unique for medical devices and has chosen those from ISO 7000 which may be particularly useful for medical devices.

One of the origins of symbols for medical devices is EN 980. Each of the symbols from EN 980 has been included in ISO 7000 and this Technical Report. Other symbols have been proposed directly from the medical device sector through ISO/TC 210.

4 Transition period

It is recommended that the symbols proposed as acceptable for wider use in this Technical Report should appear together with the relevant meaning in a language understandable to the end-user. This recommendation may be relaxed for a given market area under the following conditions, whichever applies soonest. The manufacturer can demonstrate that the symbol and its meaning have appeared as recommended for a continuous period as required by the relevant regulatory authority in the market concerned or can satisfactorily demonstrate that 75 % of typical end-users recognize the symbol and can give the meaning without prompting.

“Appear together” in the context of this transition period should be construed as meaning at the same time in association with the same device. This is to allow manufacturers to use symbols on small packaging, while including the wording on other information that is provided with the device.

An example of an appropriate transition period for a consumer market is provided in EN 71-6, developed by CEN/TC 52.

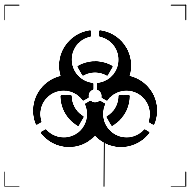
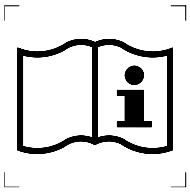
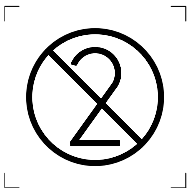
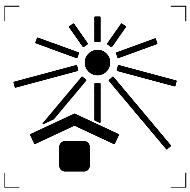
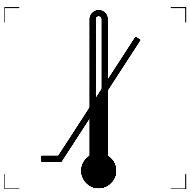
5 Proposals for additional symbols

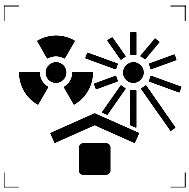
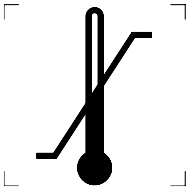
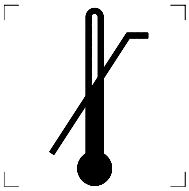
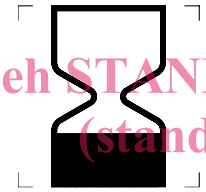
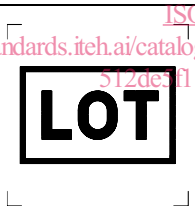
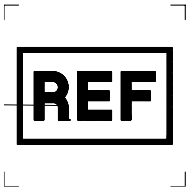
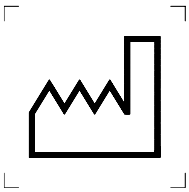
Members of the medical device sector are encouraged to propose additional symbols to ISO/TC 210/WG 3. In making a proposal, the sponsor should provide a formally designed symbol including minimum dimensions as well as a documented definition. Presentation of the symbol should take into account the accepted style norms of approved and existing symbols. Where such symbols, in the opinion of ISO/TC 210, properly fit the scope of this Technical Report, and can be seen as having widespread utility in transcending language, they will be proposed to ISO/TC 145 for inclusion in ISO 7000. Once accepted in this manner, they will be included in the subsequent revision of this Technical Report.

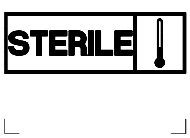
6 Symbols

Recommended symbols are shown in table 1.

Table 1 — Recommended symbols

No.	Symbol	Title
6.1		Biological risk
6.2		Consult instructions for use
6.3		Do not re-use
6.4		Fragile, handle with care
6.5		Caution, consult accompanying documents NOTE The title given is compiled from all of the sources and recommended for use during the transition period (see clause 4).
		Keep away from heat
6.7		Keep dry
6.8		Lower limit of temperature

No.	Symbol	Title
6.9		Protect from heat and radioactive sources
6.10		Temperature limitation
6.11		Upper limit of temperature
6.12		Use by
6.13		Batch code
		Catalogue number
6.15		Control
6.16		Date of manufacture

No.	Symbol	Title
6.17		Negative control
6.18		Positive control
6.19		Sterile
6.20		Serial number
6.21		Sterilized using aseptic processing techniques
		Sterilized using ethylene oxide
6.23		Sterilized using irradiation
6.24		Sterilized using steam or dry heat