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First edition
2010-01-15

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

Part 2: Symbol development, selection and validation

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

Partie 2: Développement, sélection et validation de symboles

Reference number
ISO 15223-2:2010(E)

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Published in Switzerland

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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 15223-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO 15223-2, together with ISO 15223-1:2007, cancels and replaces ISO 15223:2000, which has been technically revised.

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*

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Introduction

The ISO 15223 series of International Standards addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices. As such, in most regulatory domains the symbols are required to be presented with the device. The information can be required to be presented on the device itself, as part of the label or provided with the device.

Many countries require that their own language be used to present textual information with medical devices. This presents problems to device manufacturers and users. Faced with the requirement to produce labelling in a number of different languages, manufacturers might have to increase the size of the package or label, thus potentially increasing packaging waste, or compressing the information, thus compromising legibility. Users presented with devices labelled in a number of different languages can experience confusion and delay in locating the needed information in an appropriate language. ISO 15223-1 proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings, that are independent of language.

While compiling the symbols presented in ISO 15223-1, it was recognised that a systematic methodology for the development and presentation of symbols was needed. ISO/TC 210 began by formulating a “best practices” document, *Guide to the development and registration of symbols for use in the labelling of medical devices*.

When this guide was circulated to interested parties, a number of regulatory authorities were of the opinion that they would have greater confidence in the use of symbols to replace text if the best practices set out in the Guide were expressed as normative requirements in a standards document. Some of the best practices for symbols development and usage have been translated into normative requirements in ISO 15223.

Much of the information required on a medical device itself, as part of the label, or provided with the device constitutes information for safety within an integrated approach to risk management. As with any risk control measure, the manufacturer needs to verify the effectiveness of the information for safety before it can be accepted. The use of standardized symbols agreed by consensus on an international basis can address the confusion that users can experience when presented with labelling in a number of different languages. However, the proliferation of symbols without control and harmonization is undesirable and detracts from the effectiveness of using symbols to convey information for safety. In addition, some users and regulatory authorities have concerns that the unrestricted use of symbols without validation can represent a hazard.

This part of ISO 15223 includes methods for validating those candidate symbols being proposed for inclusion in ISO 15223-1. It can also be used by manufacturers and regulators for validating symbols for use with medical devices, where suitable symbols are not standardized.

This document has been prepared by ISO/TC 210 to influence the quality of symbols developed for use in labelling by establishing a process that addresses the need to ensure quality of symbols accepted in ISO 15223-1 by:

— establishing need;

— providing guidance on development of symbols;

— carrying out testing to make sure that the candidate symbol is suitable for adoption and use.

When the processes detailed in this part of ISO 15223 have been carried out, the probability of misinterpretation of symbols accepted in ISO 15223-1 is reduced.

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