INTERNATIONAL STANDARD

ISO 3826-2

First edition
2008-08-01

Plastics collapsible containers for human blood and blood components —

Part 2: Graphical symbols for use on labels and instruction leaflets

Poches en plastique souple pour le sang et les composants du sang — Partie 2: Symboles graphiques à utiliser sur les étiquettes et les notices d'utilisation

Reference number
ISO 3826-2:2008(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 3826-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

ISO 3826 consists of the following parts, under the general title *Plastics collapsible containers for human blood and blood components*:

— *Part 1: Conventional containers*

— *Part 2: Graphical symbols for use on labels and instruction leaflets*

— *Part 3: Blood bag systems with integrated features*

Introduction

This part of ISO 3826 has been prepared to:

— reduce the need for multiple translations of words into national languages;

— simplify and rationalize the labelling of blood treatment and transfusion devices which are medical devices used in critical situations, thereby reducing risk of misidentification, promoting safety for the patient and reducing the amount of training required by healthcare personnel;

— promote the movement of blood treatment and transfusion devices across national boundaries;

— support the essential requirements of relevant EU Directives.

The meaning of many of these graphical symbols should be self-evident. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate, the meaning of symbols should be explained in accompanying literature when provided. Annex A provides examples of how the symbols specified in this part of ISO 3826 can be used. These are illustrative only and do not represent the only ways in which requirements of this part of ISO 3826 can be met.

Plastics collapsible containers for human blood and blood components —

Part 2: Graphical symbols for use on labels and instruction leaflets

1 Scope

This part of ISO 3826 addresses symbols that may be used to convey certain items of information related to medical devices dedicated to blood collection processes and storage. 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.

The symbols specified in this part of ISO 3826 do not replace current national regulatory requirements.

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. As other medical devices, blood medical devices, labelled in a number of different languages, can experience confusion and delay in locating the appropriate language. This part of ISO 3826 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined meanings.

This part of ISO 3826 is primarily intended to be used by manufacturers of medical devices dedicated to the blood collection, process storage and distribution, who market identical products in countries having different language requirements for medical device labelling.

This part of ISO 3826 may also be of assistance to different stages of the blood supply chain, e.g.:

— distributors of blood collection devices (manual or automated) or other representatives of manufacturers;

— blood centres and distribution centres to simplify and secure the operating procedures.

The use of these symbols is primarily intended for the medical device rather than the therapeutic product.

This part of ISO 3826 does not specify requirements relating to the size and colour of symbols although the symbols specified have been specially designed so as to be clearly legible when reproduced in the space typically available on the labels of blood treatment and transfusion devices, and also so as to be suitable for on-line printing.

Several of the symbols specified in this part of ISO 3826 may be suitable for application in other areas of medical technology.

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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

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

3.1
basic symbol
graphical representation of a particular object or feature

3.2
compound symbol
graphical representation of a concept formed by the combination of two or more basic symbols

4 Requirements for graphical symbols and their use

4.1 Use of symbols

In use, the graphical representation of symbols shall comply with that given in Table 1 and Table 2, especially with respect to dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE 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 [1] and IEC 60417 [2], [3]. 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 [4], the IEC Web Store [5] or by contacting your local national standards body.

At a distance that takes into account the specifics and size of the product and its packaging, the symbols and associated information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary.

4.2 System of symbols

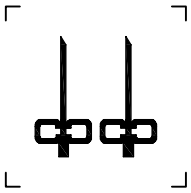
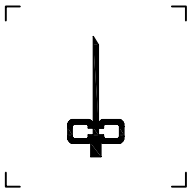
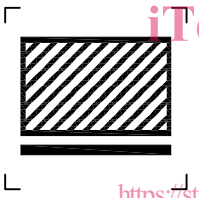
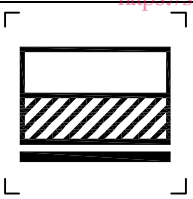
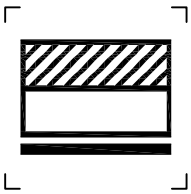
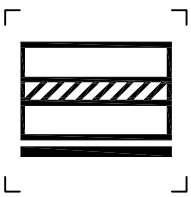
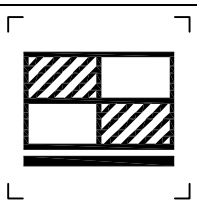
The system of symbols shall comprise basic symbols (see 4.3) that may be combined to form compound symbols (see 4.4).

NOTE Illustrative examples of labels for blood treatment and transfusion medical devices, showing the use of this system of symbols, are given in Annex A.

4.3 Basic symbols

Basic symbols can be used alone, or in combination, to form compound symbols (see 4.4).

Table 1 — Basic symbols to convey information essential for proper use

No.	Symbol	Title and description	ISO 7000 registration number
4.3.1		Blood or blood component container *On medical devices or blood process application: to indicate that the processing or final container is used for the purpose of whole blood or blood component storage.*	ISO 7000-2703
4.3.2		Double needle apheresis protocol *On medical devices or blood process application: to indicate that the medical device is for use by double needle apheresis protocol.*	ISO 7000-2753
4.3.3		Single needle apheresis protocol *On medical devices or blood process application: to indicate that the medical device is for use by single needle apheresis protocol.*	ISO 7000-2754
4.3.4		Whole blood *On medical devices or blood process application: to indicate the presence of whole blood before any stage of processing.*	ISO 7000-2718
4.3.5		Red blood cell concentrate *On medical devices or blood process application: to indicate the presence of red blood cells concentrate obtained after centrifugation of whole blood.*	ISO 7000-2712
4.3.6		Plasma *On medical devices or blood process application: to indicate the presence of plasma obtained after centrifugation of whole blood.*	ISO 7000-2707
4.3.7		Buffy coat *On medical devices or blood process application: to indicate the presence of buffy coat. (Buffy coat is the combination of leukocyte and platelets obtained after centrifugation of whole blood.)*	ISO 7000-2704
4.3.8		Platelets concentrate *On medical devices or blood process application: to indicate the presence of platelets concentrate.*	ISO 7000-2709