List of Titles

American National Standard

ANSI/AAMI/ISO 15223:2000

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

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

American National Standard

ANSI/AAMI/ISO 15223:2000
(Revision of AAMI/ISO TIR 15223:1999)

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

Approved 13 March 2000 by
Association for the Advancement of Medical Instrumentation

Approved 12 October 2000 by
American National Standards Institute

Abstract: This American National Standard 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.

Keywords: symbols, graphical symbols, medical devices, medical equipment, packaging, labeling, labels

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AAMI Standard

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by International designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI, therefore this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI VP20:1994	Major technical variations
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-15:2000 [1]	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x [1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 200x [1]	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:200x [1]	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:200x [1]	ANSI/AAMI/ISO 14971:2000	Identical

International designation	U.S. designation	Equivalency
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR 15844:1998	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO 15223, Second edition, 2000-04-15 as an American National Standard was initiated by the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices, which also serves as a U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Symbols and Nomenclature for Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 3), cochaired by Charles B. Sidebottom of Medtronic, Inc., and formerly cochaired by Richard B. Farb of Baxter Healthcare, played an active role in developing the ISO standard. Mr. Farb was also the former convener of the responsible ISO working group, ISO/TC 210/WG 3, *Symbols and nomenclature for medical devices*. Mr. Farb was replaced as convener by Leighton Hansel of Abbott Laboratories in May 2000.

At the time this document was approved, the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices had the following members:

Chair:	Robert C. Flink
Members:	Robert C. Flink, Medtronic, Inc.
	Richard B. Farb, Baxter Healthcare Corporation
	Leighton Hansel, Abbott Laboratories
	Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.
	Harvey Rudolph, PhD, Underwriters Laboratories, Inc.
	Kimberly A. Trautman, U.S. Food and Drug Administration
Alternate:	Charles B. Sidebottom, Medtronic, Inc.

At the time this document was approved, the **AAMI Symbols and Nomenclature for Medical Devices Working Group** had the following members:

Cochairs:	Richard B. Farb
	Charles B. Sidebottom
Members:	Robert G. Britain, NEMA
	James Carpenter, Hill Rom Company
	Richard B. Farb, Baxter Healthcare Corporation
	Christine M. Flahive, Chris Flahive Associates
	Nancy George, MS, BS, Software Quality Management, Inc.
	Leighton Hansel, Abbott Laboratories
	Leigh Hayward, Boston Scientific Corp.
	David Himes, Quinton Instrument Company
	Sandra A. Lee, RN, Steris Corporation
	Gordon Leichter, Getinge/Castle, Inc.
	David M. Link, Expertech Associates
	Joseph A. Mertis, Allegiance Healthcare Corp.
	Dale Munday, Spacelabs Medical, Inc.
	Kay Sachs-Campbell, Guidant Corp.
	Bruce Schullo, Griffith Micro Science, Inc.
	Eileen Schweighardt, Becton Dickinson & Company
	Charles B. Sidebottom, Medtronic, Inc.
	Forest Tabor, Zimmer, Inc.
	Richard C. Thorne, Pharmaceutical Delivery Systems
Alternates:	Gretel Lumley, Zymed, Inc.
	Paul S. Malchesky, Steris Corporation
	Mike Rahn, Griffith Micro Science, Inc.
	Mark N. Smith, Getinge/Castle, Inc.
	Byron Tart, U.S. Food and Drug Administration

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI Adoption of ISO 15223:2000

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this international standard.

ISO 15223:2000 was developed by ISO Technical Committee 210 Quality management and corresponding general aspects for medical devices, to fill a need for an international document on symbols for medical devices.

U.S. participation in ISO/TC 210 is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation on behalf of the American National Standards Institute. The United States made a considerable contribution to this international standard.

AAMI encourages its committees to harmonize their work with international documents as much as possible. Upon review of ISO 15223, the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices and the AAMI Symbols and Nomenclature for Medical Devices Working Group decided to adopt ISO 15223 verbatim as a revision of AAMI/ISO TIR 15223:1999.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI that gives the corresponding U.S. designation and the level of equivalency to the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page viii, this American National Standard is identical to ISO 15223:2000.

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 nongovernmental, 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 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 health care purposes, seek to minimize costs of labeling by reducing or rationalizing labeling 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 labeled 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 labeling 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.

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American National Standard ANSI/AAMI/ISO 15223:2000

Medical devices—Symbols to be used with medical device labels, labeling, 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:

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

— medical device users 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

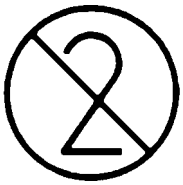
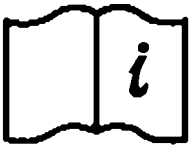
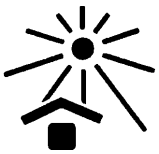
No.	Symbol	Referent
3.1		Biological risk
3.2		Do not re-use
3.3		Consult operating instructions [a)]
3.4		Caution, consult accompanying documents [b) c)]
3.5		Fragile, handle with care
3.6		Keep away from sunlight
3.7		Protect from heat and radioactive sources

Table 1 (continued)

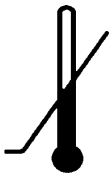
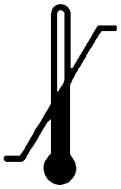
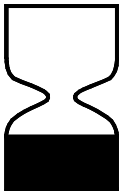
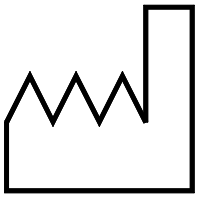
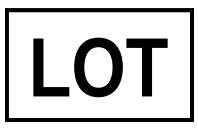
No.	Symbol	Referent
3.8		Keep dry
3.9		Lower limit of temperature
3.10		Upper limit of temperature
3.11		Temperature limitation
3.12		Use by [d]
3.13		Date of manufacture [e]
3.14		Batch code

Table 1 (continued)

No.	Symbol	Referent
3.15		Catalog number
3.16		Serial number
3.17		Control [f]
3.18		Negative control [g]
3.19		Positive control [h]
3.20		Sterile
3.21		Sterilized using aseptic processing techniques

Table 1 (continued)

No.	Symbol	Referent
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 use 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 labeling 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.

Annex A
(informative)

Guidance on the creation and use of symbols to convey information essential for proper use

A.1 Origins of symbols

Within the ISO framework of standards and technical reports, all symbols are to be standardized through Technical Committee ISO/TC 145 and included in ISO 7000. ISO/TC 145 works closely with IEC/TC 3, which has the responsibility for standardization of graphical symbols relating to electrotechnical standardization. Symbols standardized by IEC/TC 3 are published in IEC 60417-1. This mechanism allows for coordination across product and service sectors for a common set of standardized symbols.

New symbols may be proposed to ISO/TC 145 from any ISO technical committee and may subsequently be published in a standard by other technical committees.

Some of the symbols included in this International Standard originated in the medical device sector, while others were already in ISO 7000. ISO/TC 210 has proposed those symbols unique for medical devices and has chosen those from ISO 7000 that may be particularly useful to convey information essential for proper use of medical devices.

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

A.2 Transition period

It is recommended that the symbols proposed as acceptable for wider use in this International Standard 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 sooner. The manufacturer may 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 may 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, which was developed by CEN/TC 52.

A.3 Proposals for additional symbols

Members of the medical device sector are encouraged to propose additional symbols that may have widespread utility in transcending language. Proposals should be submitted to ISO/TC 210 through the national member bodies of ISO.

In making a proposal, the sponsor should provide a formally designed symbol following the principles for creation of graphical symbols contained in ISO 3461-1, as well as a documented definition. The presentation of the symbol should take into account the accepted style of approved and existing symbols. Where such symbols, in the opinion of ISO/TC 210, properly fit the scope of this International Standard, 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 International Standard.

Annex B
(informative)

Bibliography

[1] ISO 780:1997, *Packaging—Pictorial marking for handling of goods.*

[2] ISO 3461-1:1988, *General principles for the creation of graphical symbols—Part 1: Graphical symbols for use on equipment.*

[3] ISO 7000:1989, *Graphical symbols for use on equipment—Index and synopsis.*

[4] ISO 8601:1988, *Data elements and interchange formats—Information interchange—Representation of dates and times.*

[5] IEC 60417-1:1998, *Graphical symbols for use on equipment—Part 1: Overview and application.*

[6] IEC 60601-1:1988, *Medical electrical equipment—Part 1: General requirements for safety.*

[7] EN 71-6:1994, *Safety of toys—Part 6: Graphical symbols for age warning labeling.*

[8] EN 980:1996, *Graphical symbols for use in the labeling of medical devices.*