ANSI/AAMI/ISO 15223-1:2007,

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

Amendment 1

Approved 18 March 2008 by
Association for the Advancement of Medical Instrumentation

Approved 6 June 2008 by
American National Standards Institute

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
1110 N Glebe Road, Suite 220
Arlington, VA 22201-4795
www.aami.org

© 2008 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq*.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1–57020–317–2

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO 15223-1:2007/Amendment 1:2008 as an amendment to the corresponding American National Standard (ANSI/AAMI/ISO 15223-1:2007) was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, which also functions as a U.S. Technical Advisory Group 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), chaired by Leighton Hansel of Abbott Laboratories and Charles Sidebottom of Medtronic, Inc. played an active part in developing the ISO standard.

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

Cochairs:	Carol L. Herman
	Charles B. Sidebottom, PE
Members:	Leighton W. Hansel, Abbott Laboratories
	Carol L. Herman, U.S. Food and Drug Administration
	Edward R. Kimmelman, BME, JD, Independent Expert
	David Osborn, Philips Medical Systems
	Harvey Rudolph, PhD, Underwriters Laboratories, Inc.
	Charles B. Sidebottom, PE, Medtronic, Inc.
Alternate:	Sherry Liechtweis, Abbott Laboratories
	Ken Slickers, PhD, DABCC, Roche Diagnostics Corp.
	Kimberly A. Trautman, U.S. Food and Drug Administration

At the time this document was published, the committee's **Symbols and Nomenclature for Medical Devices Working Group** had the following members:

Cochairs:	Leighton W. Hansel
	Charles B. Sidebottom, PE
Members:	Krisann M. Anderson, St. Jude Medical, Inc.
	Charles Cogdill, Boston Scientific Corp.
	Rich Eaton, MITA
	Christine M. Flahive, Chris Flahive Associates
	Nancy George, CSQE, CQA, Software Quality Management, Inc.
	Leighton W. Hansel, Abbott Laboratories
	Steve Hellstrom, Hospira Worldwide, Inc.
	Carol L. Herman, U.S. Food and Drug Administration
	Josh Kim, Welch Allyn, Inc.
	Dennis Mertz, Becton Dickinson & Company
	David Osborn, Philips Medical Systems
	Mandy Savino, Covidien
	Charles B. Sidebottom, PE, Medtronic, Inc.
	John G. Smith, Cardinal Health
	Forrest Tabor, Zimmer, Inc.
	Richard C. Thorne, Pharmaceutical Delivery Systems
Alternates:	Richard H. Bean, Zimmer, Inc.
	Tom C. Gorgol, Pharmaceutical Delivery Systems
	Gretel Lumley, Philips Medical Systems
	Patricia A. Melerski, Hospira Worldwide, Inc.
	Kay Sachs-Campbell, Boston Scientific Corp.
	Victoria Wagman, 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 ANSI/AAMI adoption of ISO 15223-1:2007/Amendment 1:2008

As indicated in the foreword to the main body of this document (page v), 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 standard.

ISO 15223-1:2007/Amendment 1:2008 was developed by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and provides new symbols for the safe and proper use of medical devices.

U.S. participation in this ISO TC 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 U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of quality management and corresponding general aspects for medical devices. Upon review of ISO 15223-1/ Amendment 1, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI Symbols and Nomenclature for Medical Devices Working Group decided to adopt it verbatim, as an amendment to ANSI/AAMI/ISO 15223-1:2007.

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, which gives the corresponding U.S. designation and the level of equivalency with 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 comes 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 ISO foreword on page v, this American National Standard Amendment is identical to ISO 15223-1:2007/Amendment 1:2008.

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.

Amendment 1 to ISO 15223-1:2007 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

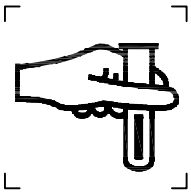
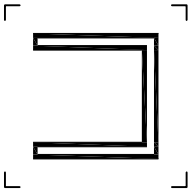
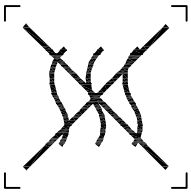
Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied —

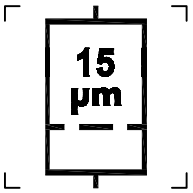
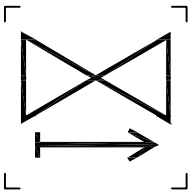
Part 1:
General requirements

AMENDMENT 1

Page 8, Table 1

Add the following symbols to Table 1.

No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.32		Sampling site	ISO 7000-2715
5.33		Fluid path	ISO 7000-2722
5.34		Non-pyrogenic	ISO 7000-2724
5.35		Contains or presence of natural rubber latex NOTE This symbol should be used only when natural rubber latex is a material of construction within the device or the packaging of a device. It is intended to warn those people who may have allergic reactions to certain proteins in natural rubber latex. This symbol should not be used for devices containing "synthetic" rubber.	Derived from ISO 7000-2725

No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.36		Drops per milliliter NOTE On medical devices: to indicate the number of drops per milliliter. The number of drops per milliliter is specified; “20” is shown as an example and should be replaced by the correct number of drops per milliliter.	ISO 7000-2726
5.37		Liquid filter with pore size NOTE On medical devices: to indicate that the infusion or transfusion system contains a liquid filter in various sizes. The nominal pore size of the filter is specified; “15” is shown as an example and should be replaced by the correct pore size.	ISO 7000-2727
5.38		One-way valve	ISO 7000-2728