

**American
National
Standard**

ANSI/AAMI/ISO 15225:2000

**Nomenclature—
Specification for a
nomenclature system for
medical devices for the purpose
of regulatory data exchange**

AAMI

Association for the
Advancement of Medical
Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, disclosures for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Professional judgment must be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.



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Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

Approved 16 October 2000 by
Association for the Advancement of Medical Instrumentation

Approved 01 November 2000 by
American National Standards Institute

Abstract: This American National Standard specifies requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate exchange of regulatory data on an international level between interested parties such as regulatory authorities, manufacturers, suppliers, health care providers, and end users.

Keywords: nomenclature, terminology, vocabulary, device type, character

AAMI Standard

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Published by

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

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Printed in the United States of America

ISBN 1-57020-150-1

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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	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 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical

¹⁾ FDIS approved; being prepared for publication.

International designation	U.S. designation	Equivalency
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO TS 15843:2000	AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical



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Committee representation

Association for the Advancement of Medical Instrumentation

Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO 15225, first edition, 2000-09-15 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) played an active role in developing the ISO standard, and AAMI Working Group cochair Leighton Hansel also serves as convener of ISO/TC 210/WG 3.

At the time this document was balloted, 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.
Leighton Hansel, U.S. Food and Drug Administration
Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.
Harvey Rudolph, PhD, Underwriters Laboratories, Inc.

Alternate: Kimberly A. Trautman, U.S. Food and Drug Administration
Charles B. Sidebottom, Medtronic, Inc.

At the time this document was balloted, the **AAMI Committee on Symbols and Nomenclature for Medical Devices** had the following members:

Cochairs: Leighton Hansel

Members: Charles B. Sidebottom
Robert G. Britain, NEMA

James Carpenter, Hill Rom Company
Christine M. Flahive, Chris Flahive Associates
Nancy George, MS, BS, Software Quality Management, Inc.
Leighton Hansel, U.S. Food and Drug Administration
Leigh Hayward, Boston Scientific Corp.
David Himes, Quinton Instrument Company
Sandra A. Lee, RN, Steris Corp.
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
Charles B. Sidebottom, Medtronic, Inc.
Forest Tabor, Zimmer, Inc.
Richard C. Thorne, Pharmaceutical Delivery Systems
Alternates: Thomas P. Gross, U.S. Food and Drug Administration
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 15225:2000

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 15225:2000 was developed jointly by ISO Technical Committee 210, *Quality management and corresponding general aspects for medical devices*, and CEN Technical Committee 257/SC 1, *Identification, coding, nomenclature and regulatory data sets for medical devices*, to fill a need for an international document on the construction of a nomenclature 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 standard.

AAMI encourages its committees to harmonize their work with international documents as much as possible. Upon review of ISO 15225, 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 15225 verbatim as a new American National Standard.

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

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NOTE—Beginning with the foreword on page ix, this American National Standard is identical to ISO 15225:2000.
or visit www.aami.org.

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 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 15225 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 210, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Throughout the text of this standard, read "... this European Standard ..." to mean "... this International Standard ...". Annex A forms a normative part of this International Standard. Annexes B and G are for information only.

For the purposes of this International Standard, the CEN annexes regarding fulfillment of European Council Directives have been removed.

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Introduction

This European Standard gives rules and guidelines for the construction of a nomenclature system for medical devices in order to enable Competent Authorities, Notified Bodies and manufacturers to meet the requirements of Council Directives on medical devices. It is also intended to assist in the implementation of community sectoral legislation and to facilitate cooperation and exchange of information within the European Community and at international level. It is intended that this assistance and facilitation could be extended to other relevant parties such as Regulatory Bodies and Health Care Providers.

This European Standard also gives the requirements for a minimum data set and relating to this data system its structure. These requirements are provided for system designers setting up databases utilizing the nomenclature system described herein. It is intended that the information covered by this standard should be available in the public domain.

The requirements contained in this standard are applicable to the development and updating of a European Nomenclature for medical devices.

This European Standard provides rules and guidelines for nomenclature design, which will ensure that nomenclatures built upon this standard will be simple to use, rational, applicable by all grades and professions of users and suitable for both computerized systems and printed matter.

In order to avoid the proliferation of nomenclature systems, even though each may be in conformity with this standard, it is desirable that a control body be set up to administer and maintain the European Nomenclature system. This standard has been prepared with the needs of such a body in mind and to provide ease of management at reasonable cost.

It is anticipated that the European Gatekeeper will liaise with other bodies responsible for maintaining nomenclatures in other regulatory environments, with a view to appropriate international harmonization.

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