List of Titles

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, instructions 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.

Particular care should 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.*

List of Titles

American National Standard ANSI/AAMI/ISO 15225:2000

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

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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.

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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

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

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

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 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).

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 C are for information only.

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

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.

American National Standard **ANSI/AAMI/ISO 15225:2000**

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

1 Scope

This European Standard specifies requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate cooperation and exchange of regulatory data on an international level between interested parties such as: Regulatory Authorities, Manufacturers, Suppliers, Health Care Providers, and End Users.

NOTE 1—This European Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases utilizing the nomenclature system described herein.

The requirements contained in this standard are applicable to the development and maintenance of a European nomenclature for medical device identification.

NOTE 2—This European Standard will not include the nomenclature itself. The nomenclature will be supplied as a separate document.

NOTE 3—It is intended to complement the specific requirements of the EC Directives on medical devices in the context of specifying means by which common identification can be achieved between bodies required to exchange data in conformity with the requirements of the Directives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this European Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1087:1990, *Terminology—Vocabulary*.

ISO/IEC 8859-1:1998, *Information processing—8-bit single-byte coded graphic character sets*.

ISO/IEC 2382-1:1993, *Information technology—Vocabulary—Part 1: Fundamental terms*.

ISO 2382-4:1987, *Information processing systems—Vocabulary—Part 4: Organization of data*.

ISO/IEC 2382-17:1996, *Information technology—Vocabulary—Part 17: Databases*.

NOTE—Other documents which may be useful for the understanding of this standard are listed in the Bibliography.

3 Definitions

For the purposes of this standard, the following definitions apply:

NOTE—Many terms are used in this document which have their basis in regulatory statutes. Examples of these words are “medical device,” “custom made medical device” and “manufacturer.” These terms are defined in the respective jurisdictions where the nomenclature will be used. There is no attempt to define these terms in this document because of potential conflicts with the legal definitions of the respective jurisdiction. This standard has been crafted so as to transcend and avoid substantive conflict of different definitions of these terms.

3.1 character: A member of a set of elements used for the organization, control or representation of data [ISO/IEC 8859-1:1998].

3.2 concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087:1990].

3.3 device category: No definition available.

NOTE—4.2 contains a description of the term “device category.”

3.4 device type: No definition available.

NOTE—4.4 contains a description of the term “device type.”

3.5 file: A named set of records stored or processed as a unit [ISO/IEC 2382-1:1993].

3.6 foreign key: In a relation, one or a group of attributes that corresponds to a primary key in another relation [ISO/IEC 2382-17:1996].

3.7 generic device group: No definition available.

NOTE—4.3 contains a description of the term “generic device group.”

3.8 identifier: One or more characters used to identify or name a data element and possibly to indicate certain properties of that data element [ISO 2382-4:1987].

3.9 name: Designation of an object by a linguistic expression [ISO 1087:1990].

3.10 nomenclature: System of terms which is elaborated according to pre-established naming rules [ISO 1087:1990].

3.11 preferred term: Term recommended by an authoritative body [ISO 1087:1990].

3.12 primary key: A key that unambiguously identifies one record [ISO/IEC 2382-17:1996].

3.13 relational structure: A structure of data that are arranged as relations [ISO/IEC 2382-17:1996].

3.14 secondary key: A key that is not a primary key, but for which an index is maintained and that may identify more than one record [ISO/IEC 2382-17:1996].

3.15 synonyms: Different terms that refer to the same entity [ISO/IEC 2382-17:1996].

3.16 template term: Base concept which occurs in more than two preferred terms.

3.17 term: Designation of a defined concept in a special language by a linguistic expression [ISO 1087:1990].

3.18 control body: Organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the global medical device nomenclature.

3.19 custom made device: Any device specifically made in accordance with a duly qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for sole use of a particular patient.

NOTE—See Council Directive 93/42/EEC concerning medical devices.

3.20 device intended for clinical investigation: Any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of annex X [of Council Directive 93/42/EEC] in an adequate human clinical environment.

NOTE—See Council Directive 93/42/EEC concerning medical devices.

3.21 gate keeper: Organization which maintains and issues the global medical device nomenclature accountable to the control body.

3.22 manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

NOTE—See Council Directive 93/42/EEC concerning medical devices.

3.23 medical device; device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE—See Council Directive 93/42/EEC concerning medical devices.

4 Principle of structure

4.1 General

The nomenclature is structured in three stages as shown in Figure 1. These stages differ in the breadth of the sets of devices represented by the terms defined within each stage. All medical devices can be classified within each stage. The stages have a relational structure (3.13) in the following order:

a) device category (see 4.2);

b) generic device group (see 4.3); and

c) device type (see 4.4).

NOTE—Attention is drawn to the difference between “product category,” as used in the EU Directives on medical devices, and “device category” as used in this standard. The former represents a small group of closely related devices. The latter represents a broader based grouping (see 4.2).

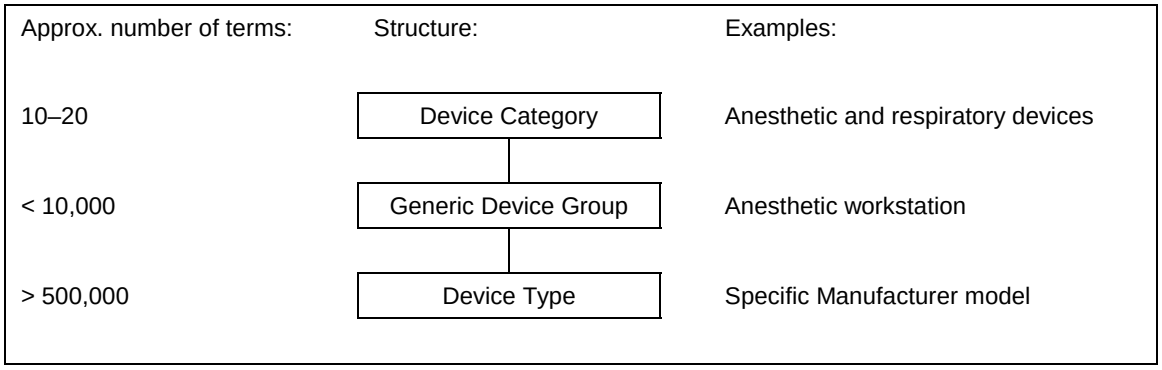

Figure 1—General structure for the nomenclature

4.2 Device category

Individual categories have broad usage definitions that represent disparate devices having common areas of intended use or common technology. Device category has the largest number of devices covered by each stored term (3.17).

For data organization device category includes the record holding a device category term (3.17) and associated data such as its code and other attributes.

NOTE—5.1 specifies requirements for device categories.

4.3 Generic device group

The generic device group contains sets of devices having the same or similar intended uses or commonality of technology. Sets of devices are grouped together for the purpose of device vigilance reporting, or other purposes where sets of essentially similar devices from different sources need to be collected. Potentially, any device attribute (for example: implant/non-implant, sterile/non-sterile) can be used as a means of arranging associated data.

For data organization the generic device group includes the record holding a device group term (3.17). The device group term (3.17) can include the following:

a) preferred term (3.11);

b) template term (3.16 and 5.2.4); and

c) synonym (3.15);

and associated data as follows:

d) code;

e) definition;

f) for synonyms, code of the generic device group record holding the preferred term or template term; and

g) for templates, the template specifier.

NOTE—5.2 specifies requirements for generic device groups and annex B gives examples of generic device groups.

4.4 Device type

The device type contains individual medical devices including devices intended for clinical investigation (3.20) and custom-made devices (3.19) or set of medical devices including variants which may be produced. Device types contain sufficient characteristics in common for the manufacturer to establish a make and model. Device type has the smallest number of devices covered by each stored term (3.17).

For data organization device type includes the record holding the device type designation and its associated data such as its code and other attributes.

Names to be stored are drawn from the manufacturer's (3.22) documentation.

NOTE—5.3 specifies requirements for device types.

5 Requirements

5.1 Device category

Device category shall be selected from the appropriate term(s) listed in annex A.

NOTE—At present the list is not exhaustive and a small number of Device Categories may need to be added.

5.2 Generic device group

NOTE—See annex B for examples of the generation of Generic Device Groups terms.

5.2.1 General

NOTE—A generic device group can be a member of more than one device category.

The nomenclature shall be constructed using preferred terms (3.11), template terms and synonyms (3.15) as appropriate. All terms shall be given in the singular form. The reference version of the preferred terms and template terms in the generic device group data file shall be in English.

5.2.2 Abbreviations and acronyms

Abbreviations and acronyms, other than symbols for units, used as a term, or as part of a term, shall be given in capitals.

Abbreviations used in preferred terms and template terms shall be expanded in the assigned definition. An abbreviation used as a synonym, or part thereof, shall be expanded within the term after the given abbreviation.

5.2.3 Preferred terms

A preferred term shall represent a set of device types that perform similar or equivalent functions or have characteristics in common.

The preferred term shall be unambiguous and comprise the following:

a) base concept; followed by

b) if appropriate, one or more qualifiers separated from the base concept by a comma.

NOTE 1—More specific classification can be achieved by addition of further qualifiers.

The base concept shall be the primary listing basis.

Unambiguous qualifiers shall be used.

NOTE 2—Ambiguous qualifiers include phrases such as “sundries,” “others,” “appliances,” “miscellaneous,” and “various.”

The preferred term “unclassified” shall be available.

NOTE 3—This is to permit preliminary classification when no appropriate existing term is available.

Trade names shall not be used as preferred terms.

Preferred terms shall be assigned a definition of not more than 700 characters.

5.2.4 Template terms

A template term shall be used when more than two preferred terms are formed using the same base concept.

The template term shall be formed from the common base concept followed by the qualifier <specify>.

Template terms shall not be used as synonyms.

Template terms shall be assigned a definition of not more than 700 characters.

5.2.5 Synonyms

Synonyms shall be linked to either:

a) the preferred term; or

b) the template term.

NOTE—Synonyms are an aid to locating the appropriate preferred term.

Synonyms shall not be linked to other synonyms.

5.3 Device type

The nomenclature shall be constructed using either:

a) the information included by the manufacturer in the declaration of conformity appropriate to the affixture of the CE mark; or

b) the information provided to the competent authority in respect of a custom-made device or a device intended for clinical investigation.

The device type designator shall comprise the following:

a) the name of the device as given in the information provided by the manufacturer; and

b) the name of the manufacturer or equivalent responsible person.

A device type shall not be a member of more than one device group.

Device types shall be designated under a generic device group in accordance with the primary intended use as specified by the manufacturer.

6 Data file dictionary

6.1 General

This part of the Standard is provided for information system designers implementing the nomenclature within a database. It provides the minimum requirements for the data fields needed to hold the nomenclature system. Each stage in the data structure is represented by a data file for which the requirements in 6.2 to 6.4 apply.

Further data fields may be added to all data files depending on the requirements of the end user of the database system in question. In systems having more than one natural language version of the terms in the same data file, the primary keys shall be qualified by a unique code for the different languages.

NOTE—This is to maintain their unambiguity.

The character set for transmissions shall be the Latin alphabet No. 1 as specified in ISO/IEC 8859-1:1998.

6.2 Device category data file

The minimum number of fields shall be as specified in Table 1.

Table 1—Requirements for device category data file

Identifier	Data category and format	Comments
code	numeric, 2 digits	Primary key
term	alphanumeric, 60 characters	Primary key
definition	alphanumeric, 18 x 70 characters	

NOTE 1—The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

NOTE 2—Data for this data file are given in annex A (normative).

NOTE 3—When information is exchanged and records in the data files described in Table 1 are part of this information, then only the code of the relevant records needs to be transmitted.

6.3 Generic device group data file

The data field code shall be assigned an incremental sequential cardinal number starting from the value 10000. After a new record is added to the data file, the code shall be incremented by one (1). A record with code set to zero (nil) and the term “Unclassified,” or its equivalent in other languages, shall always be present in the data file. The “Unclassified” record shall have the data fields synonym code and template specifier set to zero (nil) (see Table 2). The generic device group data file shall be as specified in Table 2.

Table 2—Requirements for generic device group data file

Identifier	Data category and format	Comments
code	numeric, 5 digits	Primary key
term	alphanumeric, 60 characters	Primary key
synonym code	numeric, 5 digits	If not equal to zero (nil) then this device group is a synonym where the numeric value is the code of the preferred term or template.
template specifier	numeric, 2 digits	If not equal to zero (nil) then this device group is a template. The numeric value represents how many characters from the term are to be used for looking up (listing) the matching preferred term base concept.
definition	alphanumeric, max 10 x 70 characters	See 5.2 of this standard.
NOTE—Annex C gives example of device group records.		

NOTE 1—The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

NOTE 2—There is no foreign key in this data file relating it to the Device category data file since there is a many-to-many relation between these two data files. The system designer should apply the method(s) available in the database tool to achieve this many-to-many relation, the most common method being a data file holding as foreign keys the codes of both the device category and generic device group records.

The code of the Generic Device group’s records, where the synonym code or the template specifier is not zero (nil), shall not be used as a foreign key in related data files.

NOTE 3—These records may not be available in all natural language versions of the nomenclature system and in such cases no relation will exist (see annex C).

NOTE 4—Generic device group codes in the range 1–9999 cannot be used in data transmissions which comply with this Standard. This demands that an official list of generic device groups will never contain records having these code values. Generic device group codes in the range 1–9999 are exclusively reserved for assignment by the end user. These codes are made available for the convenience of end users to store terms outside the scope of this Standard.

6.4 Device type data file

The minimum number of fields shall be as specified in Table 3.

Table 3—Requirements for device type data file

Identifier	Data category and format	Comments
Generic device group code	numeric, 5 digits	Foreign key, represents the link to a generic device group record (preferred term in the nomenclature)
make	alphanumeric, 60 characters	Secondary key, can also act as a foreign key
model	alphanumeric, 60 characters	The make and model represents, when concatenated, the primary key

When concatenated (see Table 3) the contents of the data fields “make” and “model” shall be unique.

NOTE 1—The data field “make” is used to identify the manufacturer on the device label. When appropriate the authorized representative may be identified. A shortened version such as an easily recognizable trade name or alpha-numeric trade mark may be used.

NOTE 2—The data field model should be the name used by the manufacturer to identify the particular type of device. In appropriate circumstances other informative formats such as brand, EAN (European Article Number) or HIBC (Health Industry Bar Code) may be used. This data field should not be confused with the serial number or lot number assigned to the individual device or lots of devices.

NOTE 3—The reasoning for having two data fields representing the primary key is that the model name used by one manufacturer (or even by the same manufacturer when he uses several makes to represent his name) could possibly be used by other manufacturers, thus making it unsuitable for use as a primary key.

NOTE 4—The system designer may find it useful to assign a single (numeric) data field as a more manageable primary key in the database system for this data file.

Annex A
(normative)

Device categories description

Code: 01 Term: Active implantable devices

This category includes devices relying on a source of power other than that directly generated by the human body or by gravity and intended to be totally or partially introduced, surgically or medically, into the human body, or by medical intervention into a natural orifice, and which are intended to remain there after the procedure.

NOTE 1—Examples of devices in this category are: pacemakers, implantable infusion pumps, cochlear implants, and their accessories.

NOTE 2—See active implantable medical device directive.

Code: 02 Term: Anesthetic and respiratory devices

This category includes devices and accessories for supplying, conditioning, monitoring, dispensing, and delivering respiratory, medical and anesthetic gases and vapors for providing and/or controlling respiration and/or anesthesia.

NOTE 3—Examples of devices in this category are: anesthetic work stations, respiratory circuits, ventilators, and their accessories.

Code: 03 Term: Dental devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment, or alleviation of oral, maxillo-facial, and dental disease.

NOTE 4—Examples of devices in this category are: dental hand instruments, impression materials, dental amalgam, dental tools, and their accessories.

Code: 04 Term: Electro mechanical medical devices

This category includes devices where the operation depends upon a source of electrical energy (electromedical) or source of energy other than that directly generated by the patient's body or gravity and which uses this energy to produce its effect or action (mechanical).

NOTE 5—Examples of devices in this category are: EEG, infusion pumps, monitors for hemodialysis, monitors for ECG, spring driven and elastomeric pumps.

Code: 05 Term: Hospital hardware

This category includes devices which are not directly used in diagnosis or examinations, nor have direct influence on the clinical evaluation of the patient's condition, test results, or further treatment.

NOTE 6—Examples of devices in this category are: sterilizers, patient transfer equipment, and disinfectants.

Code: 06 Term: *In vitro* diagnostic devices

This category includes devices which are used for *in vitro* examination of samples from the human body for the purpose of determining physiological or pathological conditions.

NOTE 7—Examples of devices in this category are: blood glucose monitors, bilirubinometers, microbial sensitivity systems, and their accessories.

Code: 07 Term: Non-active implantable devices

This category includes devices other than active implantable devices which are implanted for longer than 30 days.

NOTE 8—Examples of devices in this category are: intrauterine devices, heart valves, bone prostheses, and their accessories.

Code: 08 Term: Ophthalmic and optical devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment, correction, or alleviation of eye diseases and optical malfunctions.

NOTE 9—Examples of devices in this category are: tonometers, intraocular lenses, slit lamps, and their accessories.

Code: 09 Term: Reusable instruments

This category includes devices which are used in surgery or elsewhere and are intended to be cleaned and sterilized for reuse.

NOTE 10—Examples of devices in this category are: retractors, hemostats, drills, saws, and their accessories.

Code: 10 Term: Single use devices

This category includes devices which are intended to be used only once.

NOTE 11—Examples of devices in this category are: intravenous infusion sets, condoms, and laparotomy sponges.

Code: 11 Term: Technical aids for disabled persons

This category includes devices specially produced or generally available which compensate for, relieve, prevent, or neutralize an impairment, disability, or handicap.

NOTE 12—Examples of devices in this category are: crutches, artificial limbs, hearing aids, wheelchairs, and their accessories.

Code: 12 Term: Diagnostic and therapeutic radiation devices

This category includes devices which are diagnostic and/or therapeutic and use such modalities as X-rays, magnetic resonance imaging, ultrasound imaging, *in vivo* isotope imaging, and linear accelerators.

NOTE 13—Examples of devices in this category are: X-ray equipment, computed tomography scanners, and their accessories.

Annex B
(informative)

Examples for generation of generic device group terms and synonyms

This informative annex provides examples for the purpose of generating generic device group terms and the updating of the nomenclature.

B.1 Structure of generic device group terms

The preferred term should be of such a character that the nomenclature acquires a functional architecture, bearing in mind the users and use of the device. The qualifier, especially when common to many terms, may be based on the devices' properties or characteristics or field of use by using well established conventions when appropriate.

The general structure of the preferred term is the base concept (singular noun or noun phrase), followed by one or more qualifiers (adjectives or adjectival phrases), delimited or separated by a comma. The base concept is the broadest representation of the generic device group of medical devices that is further described by the qualifiers. The qualifiers, moving from left to right, should be ordered from broader (less specific) to narrower (more specific).

B.2 Examples of generic device group terms

A preferred term should be constructed in the following manner:

Base concept	qualifier	qualifier
Noun or noun phrase	adjective or adjectival phrase	adjective or adjectival phrase

NOTE—The terms used in the examples provided are for illustrative purposes.

Preferred terms, hierarchically structured:

Alarm, enuresis[1)]	not	Enuresis alarm
Circulatory assist unit, ventricular[2)]	not	Ventricular circulatory assist unit

Preferred terms using a qualifier which reflects the "property or characteristic" (principle/method) of the devices to be named by the term:

Suture, nylon

Suture, polyethylene

Suture, polyglyconate

Preferred terms using a qualifier which reflects the "field of use" of the devices to be named by the term:

Dialyzer, apheresis

Dialyzer, bicarbonate

Dialyzer, blood serum/urine

Dialyzer, hemodialysis

Where there are more than two preferred terms having the same base concept, a template should be introduced:

Audiometer, <specify>

Audiometer, Békésy

Audiometer, clinical

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1) Example beginning with a noun.

2) Example beginning with a noun phrase.

Audiometer, impedance

Audiometer, ...

Synonyms:

Dinamap	linked to	Sphygmomanometer, electronic
Heart starter	linked to	Defibrillator
Lucey lamp	linked to	Phototherapy unit

Definition:

Any definition should be written in a manner that makes it comprehensible to all nomenclature users:

Audiometer, <specify>

A device that by using sound stimuli is used to examine hearing-related functions.

Audiometer, phase

A device that is used to determine the minimum perceivable phase difference between tones applied to a patient's left and right ear via a headset. It is used to diagnose nerve damage within the hearing system.

B.3 Abbreviations

Abbreviations used in, or as part of, a synonym or entry term:

TUMT (Trans-Urethral Microwave Thermo therapy)—see Thermo therapy unit.

CPAP unit—Continuous positive airway pressure unit.

B.4 Example of style

The first letter of a device category term or a generic device group term should be in upper case (capital letters). Thereafter, all letters should be reproduced in lower case (small letters).

Capitalized first letter of the base concept:

Defibrillator

Capitalized first letter of the base concept followed by a qualifier in small letters:

Microscope, general purpose

Annex C
(informative)

Examples of generic device group records

C.1 Preferred term

Code	Term	Synonym code	Template specifier	Definition
12345	Dialyzer, serum/urine	0	0	

The synonym code field and template specifier field are both 0, thus indicating that the term is a preferred term.

C.2 Template term

Code	Term	Synonym code	Template specifier	Definition
12346	Dialyzer, <specify>	0	10	

In this case, the template specifier field is set to 10 to indicate that the term is a template term and, at the same time, specify that the first 10 characters from the term field are used to look up the preferred terms that start with the same 10 characters.

C.3 Synonym term

Code	Term	Synonym code	Template specifier	Definition
12347	Serum/urine dialyzer	12345	0	

The synonym code field contains the code of the preferred term (or template term) to use.

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