SLOVENSKI STANDARD
SIST ENV 12611:2003

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Medicinska informatika – Kategorijska struktura sistemov konceptov – Medicinske naprave

Medical informatics - Categorial structure of systems of concepts - Medical devices

Medizinische Informatik - Kategoriale Struktur von Begriffssystemen - Medizinische Geräte

Informatique de santé - Structure catégorielle de systemes de concepts - Dispositifs médicaux

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST ENV 12611:2003 **en**

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Medical informatics - Categorial structure of systems of concepts - Medical Devices

Informatique de santé - Structure catégorielle de systèmes de concepts - Dispositifs médicaux

Medizinische Informatik - Kategoriale Struktur von Begriffssystemen - Medizinische Geräte

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CEN

European Committee for Standardization
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Contents

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Medical Informatics", the secretariat of which is held by IBN.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

0 Introduction

0.1 Medical devices and medical device groups

For the purpose of this prestandard medical devices are defined as in the Medical Device Directive, 93/42/EEC. They include almost any article apart from medicinal products which are used on human beings for medical purposes. Thus medical devices comprise a very large variety of articles such as: electrocardiographs, ventilators, lasers, x-ray equipment, syringes, catheters, dental materials and hearing aids.

The millions of actual physical medical device items in use around the world are not considered in this standard; only medical device groups as explained below.

Medical devices can be described at different levels of abstraction (shown in figure 1), as done in the proposed standard "prEN xxxx Nomenclature - Specification for a Nomenclature System for Medical Devices for the purpose of Regulatory Data Exchange" from CEN/TC257/SC1.

The lowest level of abstraction in the standard proposed by CEN/TC257/SC1 is medical device type (3.12). This level only covers one particular kind of medical device produced by a given manufacturer and with a particular identification assigned by the manufacturer. An example is an electrocardiograph from company ABCD, model xyz. There are more than 500 000 different medical device types.

The next level of abstraction is medical device group (3.10). This level ranges from medical device type to medical device category, and it covers a set of medical device types with similar functions. An example is "electrocardiograph". There are up to 10 000 different medical device groups. A medical device group is designated by a term, or more frequently by a terminological phrase (3.18).

The highest level of abstraction is the medical device category (3.9). Each medical device category covers many related medical device groups. An example is electro-medical/mechanical devices. A medical device group may belong to more than one medical device category. There are in general 10 to 20 medical device categories. 12 medical device categories are defined in the standard proposed by CEN/TC257/SC1 (see annex B).

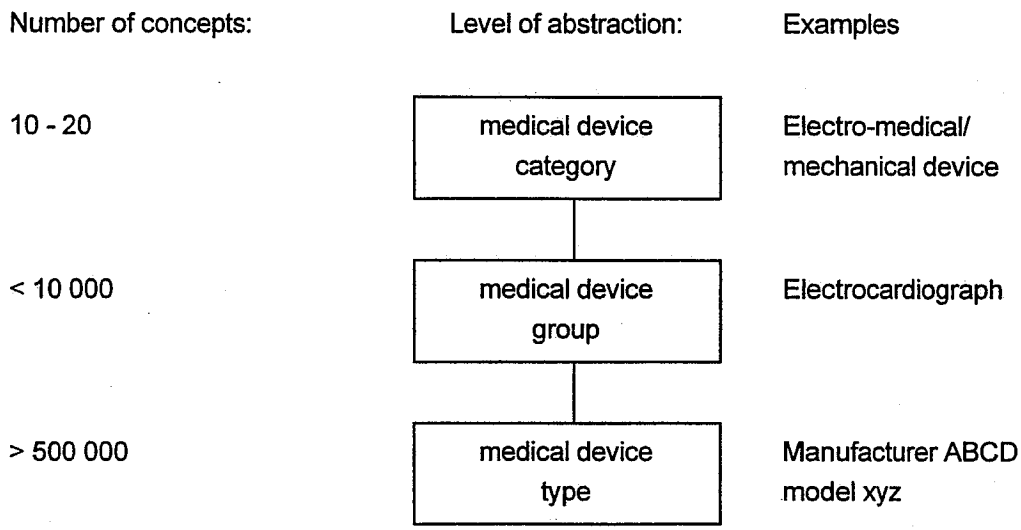

Figure 1 Levels of abstraction for medical devices according to prEN xxxx from CEN/TC251/SC1.

This prestandard is for the categorial structure of a system of concepts for medical device groups.

0.2 Users and uses of nomenclatures

Nomenclatures and coding systems for medical devices are used by several different parties (see annex E), among which are:

- Clinical engineers/technicians
- Clinical personnel
- Competent authorities/notified bodies/accredited testhouses
- Financing organizations/insurance companies
- Health authorities
- Hospital managers/administrators
- Manufacturers/distributors/service vendors
- Researchers.

Each party has specific needs and they may deal with medical devices at the different levels of abstraction described in 0 1 These parties can be called "end users" or "indirect users".

When nomenclatures for medical device groups are organized (see 0.3) by database designers and system developers, the organization must take into account the needs of the "end users". This prestandard addresses the database designers and developers of nomenclatures, and thus these can be called "direct users" of this prestandard.

Summarizing, the users of this prestandard are:

- Direct users:
  Developers of nomenclatures, coding systems and designers of databases and information systems concerning medical devices.

- Indirect users:
  Users of medical devices and users of information systems dealing with medical device data.

0.3 Organizing medical device nomenclatures

Existing nomenclatures (see annex D) for medical devices operate with up to 10 000 medical device groups. (In different nomenclatures, different terms may be used for the term medical device group). There is no generally recognized way to organize these 10 000 medical device groups and existing nomenclatures imply different ways of organization, particularly concerning small subsets of medical device groups, selected for special uses.

The lack of strong organization can cause problems for users. It may, for instance, be difficult to find the relevant medical device group when registering a new medical device. It may be difficult to maintain a medical device group nomenclature and coding system, and it may be difficult to translate a medical device group nomenclature from one language to another. (See more about user needs in annex E).

This prestandard defines a categorial structure for a system of concepts [prENV 12264] for medical device groups, i.e. it outlines a system of descriptors in this field and provides a generative pattern and combinatorial rules specifying how to combine the descriptors into sensible expressions. (References in [ ] refer to clause 2 or to annex F).

Using a generative pattern, filled with appropriate descriptors, each medical device group may be precisely described within the system of concepts; this instance of generative pattern may be used to generate systematic names or to uniquely identify each medical device group with respect to the others.

For each medical device group, one of the descriptors is the base concept (3.2), i.e. a generic medical device that may be used as superordinate concept to produce a systematic intensional definition. Examples of base concepts are: microscope, pacemaker, syringe, catheter and bandage. (A more comprehensive list of base concepts is given in annex A).

One or more characteristics differentiate a medical device group from its base concept; each characteristic is made up of a semantic link (3.14) followed by a descriptor (associated concept (3.1)).

The semantic link can be considered as a question with the descriptor providing the answer. This is illustrated through the following example:

Base concept (descriptor): equipment

Differentiating characteristic 1:

Semantic link:	has context of use
Descriptor:	surgical field

Differentiating characteristic 2:

Semantic link:	is based on
Descriptor:	laser technique (argon gas)

This medical device group (target concept) is: Lasers, Surgical, Argon [ref. 4, 16-491]

Examples of medical device groups with base concepts and differentiating characteristics are given in annex C.

0.4 Future applications

If all medical device groups (of existing nomenclatures) are described with instances of generative patterns in a common way, a number of possibilities would be available to the user. Among these are:

- A structured and precise "description" of each medical device group facilitating understanding (and translation to other languages).

- The descriptors will permit a large number of search possibilities.

- Different structures of nomenclatures for medical device groups needed for different purposes can be dynamically explored by sorting on patterns of semantic links or descriptors.

- A new device group is "easily placed in the nomenclature" in a structured way, if it first is given its semantic links and descriptors. If this is done according to common rules, all new device groups will be identified in the same way in all existing nomenclatures for medical devices, and thus the differences between the existing nomenclatures will be diminished in future.

- Mapping between different medical device coding systems will be facilitated.

Every purpose requires a specific modification of the nomenclatures and of the classifications; national regulations and organizations require further modifications. The only way to ensure coherence among the different nomenclature systems is to map each (medical device group) terminological phrase present in each nomenclature to a particular set of descriptors in a thesaurus (a system of descriptors), so that concepts considered as different (by the experts, in the nomenclature) are identified by a unique set of descriptors. In this way it is also possible to build a very large, comprehensive, "master" nomenclature, from which each application can extract its own subset of medical device groups to build a (new) nomenclature and coding system for a specific purpose.

This "master" nomenclature is solely for maintenance in a given Coding Centre, it is not for distribution to users. It may be used by National Coding Centres to produce their own nomenclatures; it may be used also by European Committees to produce their own nomenclatures.

Each country will translate its appropriate selection of concepts; most concepts will have at least an English term.

The computer version can be rearranged or browsed according to different criteria (different order of dimensions/types of characteristics); a preferred one is declared for paper-based representation.

All together, the set of nomenclatures and coding systems is coherent and inter-mappable, especially if the nomenclature level is preserved for transmission and storage of individual data, and classifications are used only on aggregated data for "final" transformations.

0.5 Relations to CEN/TC257/SC1 standards

The concept of medical device group in this prestandard corresponds to the same concept in the proposed (Nomenclature - Specification for a Nomenclature System for medical devices for the purpose of Regulatory Data Exchange) [Ref. 1] from CEN/TC257/SC1. The proposed standard [Ref. 1] generally covers the concepts: medical device type, medical device group and medical device category. This pre-standard supplements it and specifies the requirements for the organization of medical device groups.

0.6 Organization of this prestandard

Clauses 4 to 7 reflect the above outlined categorial structure. Clause 4 defines the target concepts (medical device groups). Clause 5 deals with base concepts. Clause 6 lists semantic links with associated concepts. Clause 7 gives combinatorial rules. Clause 8 describes compliance to the above requirements.

Medical Informatics - Categorial structure of systems of concepts - Medical devices

1 Scope

This European Prestandard specifies the necessary requirements (clauses 5, 6 and 7) for the categorial structure of systems of concepts for medical device groups (clause 4).

This prestandard is meant to be used by organizations involved with the development or maintenance of nomenclatures and coding systems for medical devices, and by designers of databases or information systems involving medical devices.

2 Normative references

This European Prestandard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prENV 12264 Medical Informatics - Categorial Structures of Systems of Concepts - Model for Representation of Semantics (MOSE).

ISO 1087: 1996 Vocabulary of terminology.

3 Definitions

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

3.1 associated concept : *Concept* connected to a *base concept* by a *semantic link*. [prENV 12264]
EXAMPLE: Consider the target concept "Lasers, Surgical, Argon" [ref. 4, 16-491] in a system of concepts about the target category <medical device group>. The associated concept "surgical field" is connected to the base concept "equipment" by the semantic link "has context of use:".

NOTE: A semantic link and an associated concept make up a differentiating characteristic. A base concept followed by one or more differentiating characteristics forms the intensional definition of a subordinate concept (target concept).

3.2 base concept : *Concept* used systematically as a superordinate *concept* in intensional definitions. [prENV 12264]

EXAMPLE: The base concept "equipment" can be used systematically to produce intensional definitions of target concepts in a system of concepts about <medical device groups>.

NOTE: The term "base concept" must not be confused with the term "superordinate concept". Base concepts are labelled globally within a particular system of concepts; a list may be produced. A concept is labelled as "superordinate" only if considered against one or more subordinate concepts. In fact, each base concept will be superordinate to a number of target concepts.

3.3 categorial structure : Reduced system of *concepts* to describe the organization of the semantic categories in a particular system of *concepts*. [prENV 12264]

3.4 concept : Unit of knowledge constructed through combining characteristics. [ISO 1087]

3.5 differentiating criterion : Group of characteristics used as basis for the establishment of systematic subdivisions in a system of *concepts*. [prENV 12264]

EXAMPLE: The differentiating criterion "has context of use: <speciality>" can be used to establish systematic subdivisions in a system of concepts about <medical device groups>.

NOTE: A differentiating criterion may be expressed as a semantic link followed by one or more associated semantic categories or an associated domain.

3.6 generative pattern Expression to generate *systematic names* for a subset of *concepts* of a given target semantic category. [prENV 12264]

3.7 medical 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[1)]

3.8 medical device accessory : Article which, while not a device, is required, according to the intended purpose attributed to it by the manufacturer, to enable a *medical device* to be used as specified.

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1) This definition is from the Medical Device Directive, 93/42/EEC.

3.9 medical device category : Set of *medical device groups* comprised of medical devices with common areas of intended use or common technology[1)] .

3.10 medical device group : Set of *medical device types* comprised of medical devices having the same or similar intended uses or commonality of technology[2)].

NOTE: Medical device group covers the range from medical device type to medical device category.

3.11 medical device type : Set of medical devices, identical in material and technical declaration, produced by a given manufacturer[2)].

NOTE: A medical device type is designated by the name of the manufacturer followed by the name given by the manufacturer to the set (i.e. the "model name").

NOTE: The device type, also known as product or product category, contains individual medical devices including devices intended for clinical investigation and costum-made devices or set of medical devices including variants which may be produced. Device types contain sufficient characteristics in common to be subject to a single declaration of conformity for the purpose of affixing the CE mark.

3.12 nomenclature : Set of designators structured according to pre-established rules. [ISO 1087]

NOTE: Terms, names and code values are typical examples of designators.

3.13 semantic link : Unidirectional associative relation from a *base concept*. [prENV 12264]
EXAMPLE: "has context of use:", from the base concept "equipment" to the associated concept "surgical field", in a system of concepts to describe <medical device groups>.

3.14 systematic name : *Terminological phrase* created according to pre-established rules and used as the name for a *target concept*. [prENV 12264]

NOTE: In common practice, a working name is typically used in place of the systematic name. The working name may be either a term or a simpler terminological phrase.

3.15 target concept : *Concept* whose designation is intended to be used in applications. [prENV 12264]
EXAMPLES: "Lasers, Surgical, Argon" [ref.4, 16.481], in a system of concepts to describe the <medical device groups>. The concepts: "laser", "laser, surgical", or "laser, argon" are useful intermediate concepts to organize that system of concepts, but are not considered adequately detailed for typical applications.

3.16 terminology : Set of terms belonging to one special language. [ISO 1087]

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2) The definitions 3.9, 3.10 and 3.11 are fairly similar to the descriptions in [Ref. 1]

3.17 terminological phrase : Phrase containing at least one term and a number of other lexical items, the choice of which being restricted by the term in question. [prENV 12264]
EXAMPLES: "Lasers, Surgical, Argon", "surgical laser, argon", "surgical laser with ionized argon gas".

NOTE: A terminological phrase is usually self-explanatory and may be created or modified by the user according to natural language rules, or permuted for indexing purposes.

4 Target concepts

The target concepts of this European Prestandard are the medical device groups (3.10).
EXAMPLES: medical device groups can be found in the nomenclatures listed in annex D. Examples in this European Prestandard are taken from existing nomenclatures; the source and the respective code are expressed as [source:code]:

Sheets, Operating Room, Reusable [Ref. 4: 15-708]
Ventilators, Home Care, Portable [Ref.4:17-423]

NOTE: Most medical device groups are designated by terminological phrases (3.18); they often consist of an artificial juxtaposition of more elementary terms (representing concepts) separated by commas, in a decreasing order of relevance.

The designation of a medical device group shall permit identification of a base concept (clause 5) and a set of differentiating characteristics, each made of a semantic link followed by an associated concept (clause 6).

The set of descriptors (i.e. base concept and associated concepts) related to a single medical device group shall be unique in a particular system of concepts.

This European Prestandard may also be applied to Medical Device Categories (3.9), accessories, spare parts and to significant components or subsystems useful to describe a medical device group.

5 Base concepts

Base concepts (3.2) are medical devices, without explicit reference to the systematic differentiating characteristics listed in clause 6.
EXAMPLES: "equipment", "kit" (see table A1.1), "prosthesis", "microscope" (see table A1.2), "chair", "scissors" (see table A1.3).

A non-exhaustive normative list of base concepts is provided in annex A1.

Designers of systems of concepts on medical device groups may introduce additional base concepts, harmonized with the ones listed in annex A1.

6 Semantic links and associated categories

An appropriate number of semantic links selected from the semantic links described in this clause shall be used, together with the appropriate associated categories (for a non-exhaustive normative list of concepts that belong to each category, and the requirements to introduce additional concepts, see annex A2), to represent systematically medical device groups and to organize development and presentation of a system of concepts on medical device groups.

NOTE: Associated categories are informally described in the present clause; an extensional (non-exhaustive) definition is provided in annex A2.

6.1. Semantic links related to the intended purpose

The first set of semantic links is related to the "intended purpose" of the members of the medical device group.

NOTE: The semantic links below, refer to the *intended* use for which the device is manufactured and (presumably) acquired, and not to the *actual* use or misuse of the device in routine settings.

performs:

It refers to one or more purposes for which the device is produced: the <device function> performed directly by the medical device, the <procedure> or the <care activity> performed by a human that the medical device enables or supports.

EXAMPLES:

Aspirators, Tracheal [Ref.4:10-219]
performs: aspirating (a kind of <device function>)

Individual aerosol therapy devices, ultrasonic [Ref.3: 5003]
performs: aerosol therapy (a kind of <procedure>)

NOTE: This is the most relevant criterion used to cluster medical devices. In fact, a large number of nouns about devices are produced after it: e.g. adapter, calibrator, defibrillator, injector, monitor, regulator, stimulator. Consider also the compound words with: -meter, -scope, -graph, -tome. (Furthermore, see annex A1.2).

has-target:

It refers to one or more associated concepts usually belonging to the following categories: <body component> (including organs and body cavities), <body fluid>, <body function>, <health problem> (including diseases and abnormal body structures), <surgical structure>, <personal role> (including patient and health care staff), <age group>, <environmental component>, <organism>, <material> or <medical device>, which are directly involved in the <device function>, <procedure> or <care activity> performed or assisted by the device.

EXAMPLES:

Aspirators, Tracheal [Ref.4:10-219]
has-target: trachea (a kind of <body component>)
Stools, Anaesthetist's [Ref.4:10-149]
has-target: anaesthetist (a kind of <personal role>)
Environmental Monitors, Atmospheric gas [Ref.4:12-606]
has-target: atmospheric gas (a kind of <environmental component>)
Reagents, Candida Albicans Detection [Ref.4:17-291]
has-target: candida albicans (a kind of <organism>)
Washer, Flexible Endoscope [Ref.4:15-999]
has-target: endoscope(flexible) (a kind of <medical device>)

When the <device function> refers to a <property> of a <body component>, the semantic link "has-target:" should be used, with the <body component> as associated concept and the <property> as its specification. (See also annex A2).

EXAMPLES:

Noninvasive blood pressure monitors [Ref.4:16-173]
has-target: blood(pressure) (a kind of <body component>, specified by a <property>)
Temperature monitors, airway [Ref.4:16-717]
has-target: airway(temperature) (a kind of <body component>, specified by a <property>)

Analogously, when a <body function> and the respective <body component> are present, the latter should be preferred as associated concept, and the <body function> should be used to specify the <body component>.

EXAMPLE:

Ventilators [Ref.4:15-613]
has-target: lung(ventilation) (a kind of <body component>, specified by a <body function>)

has-context-of-use:

It refers to one or more associated concepts, each representing a <speciality> (including generic medical fields) where a device is intended to be used, or a particular <location> where the device is intended to operate (including rooms), or the <position> inside a room or with respect to other devices (including portability features), or the <patient's context>.

EXAMPLES:

Elevators, Neurosurgical [Ref.4:11-507]
has-context-of-use: neurosurgery (a kind of <speciality>)
Ventilators, Home Care, Portable [Ref.4:17-423]
has-context-of-use: patient's home (a kind of <location>)
Casework, Nursing Station [Ref.4:15-899]
has-context-of-use: nursing station (a kind of <location>)
Centrifuges, Tabletop [Ref.4:10-780]
has-context-of-use: tabletop (a kind of <position>)
Spectacle hearing-aids [Ref.6:21 45 09]
has-context-of-use: on spectacles (a kind of <patient's context>)