SLOVENSKI STANDARD
SIST EN 12435:2006

01-april-2006

Nadomeǵ a:
SIST ENV 12435:2003

Zdravstvena informatika – Prikaz rezultatov meritev v medicinskih znanostih

Health informatics - Expression of results of measurements in health sciences

Medizinische Informatik - Darstellung der Ergebnisse von Messungen in den Gesundheitswissenschaften

Informatique de santé - Expression des résultats de mesure dans le domaine de la santé

Ta slovenski standard je istoveten z: **EN 12435:2006**

ICS:

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

SIST EN 12435:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12435

January 2006

ICS 11.020; 35.240.70

Supersedes ENV 12435:1999

English Version

Health informatics - Expression of results of measurements in health sciences

Informatique de santé - Expression des résultats de mesure dans le domaine de la santé

Medizinische Informatik - Darstellung der Ergebnisse von Messungen in den Gesundhetswissenschaften

This European Standard was approved by CEN on 14 December 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 12435:2006: E

Contents

Foreword

This document (EN 12435:2006) has been prepared by Technical Committee CEN/ TC 251 "Health informatics", the secretariat of which is held by NEN.

This document falls under mandate BC/CEN/03/ 255/97/23 of the European Commission and the European Free Trade Association.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2006, and conflicting national standards shall be withdrawn at the latest by July 2006.

This document supersedes ENV 12435:1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

Results of measurements on the human or animal body, and its environment are essential in the health sciences. The disciplines involved in measurement often use different ways of expressing their results. Conventions within user groups are not universally applicable. The situation is further complicated by differences in the ways they are expressed in national legislation and in local administration. From the many available conventions, a consensus must therefore be reached on how to express the results of measurements on the body and its environment, particularly for exchange between information systems.

Universal principles for the expression of measurements have been laid down by Technical Committee 12 of the International Organization for Standardization in its series of standards ISO 31 and ISO 1000, which implement the International System of Units (SI) defined by the General Conference on Weights and Measures. Those principles have been applied to biological systems and certain units have been added by the International Council on Radiological Protection, International Council on Standardization in Haematology, the International Federation of Clinical Chemistry, the International Union of Biochemistry and Molecular Biology, the International Union of Pure and Applied Chemistry and the World Health Organization. Implementation of this EN will provide wider comprehension and interaction between countries and specialities.

The main normative provisions of this European standard are expressed in Clauses 5, 6 and 7. They include the following aspects of the performance of a device or system related to the result of a measurement:

— the selection of kind-of-quantity and the unit in which to express it in accordance with the provisions of Clause 5

— where reported, the uncertainty of the value in accordance with the provisions of Annex D

— for the purposes of display, printing, transmission and storage, the elements of the results of measurement in accordance with the provisions of Clause 7.

1 Scope

This document is intended for use by parties to the design, development, acquisition, use and monitoring of health-care related information and information systems. It provides a list of units of measurement to be used in representing values of measurable quantities in health sciences.

The International System of Units forms the basis for this EN. Units with their associated kinds-of-quantity are arranged in order of dimension in Tables 1, 2 and 4 (Clause 5), and in Annex A.

Different kinds-of-quantity may apply to a given combination of component(s) and system. Often the different quantities are interconvertible and examples of such interconvertibility are given in Annex C.

Tables of conversion factors (Annex A) are provided from units in current use to SI units or their multiples.

To represent the result of a measurement (Clause 6), this EN addresses requirements for the following:

— relational operator (Clause 4)

— numerical value (Subclause 6.1)

— uncertainty of measurement (Subclause 6.2; Annex D)

— unit of measurement (Clause 5).

This EN covers the requirements for representation of these data elements in displayed and printed form, and provides an approach for support of languages in non-Roman alphabets (Clause 7).

The scope of this standard is limited to textual representation. Support is not provided for the display or printing of images or graphs.

This standard does not cover the requirements for expression of the results of measurements in speech, speech synthesis or handwriting. It does not cover the form and syntax of requests for clinical measurements, nor detailed aspects of data transmission. It refers the user to other CEN standards that address the detailed specification of the interchange format. It does not address the syntax for recording of natural-language statements about quantities, such as those used in recording information about drugs dispensed or about treatment of patients. It does not cover the units of financial quantities, which are covered by ISO 4217.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31-11:1992, *Quantities and units – Part 11: Mathematical signs and symbols for use in the physical sciences and technology.*

3 Definitions, abbreviations and acronyms

3.1 Definitions

3.1.1
base kind-of-quantity
one of the kinds-of-quantity that, in a system of kinds-of-quantity, are conventionally accepted as functionally independent of one another (after VIM)

3.1.2
base unit
unit of measurement of a base kind-of-quantity in a given system of kinds-of-quantity (after VIM)

3.1.3
character
member of a set of elements used for the organization, control or representation of information (after ISO 10 646-1)

3.1.4
coded character
character in its coded representation (after ISO 10 646-1)

3.1.5
coherent unit
derived unit of measurement that may be expressed as a product of powers of base units with the proportionality factor one (VIM)

3.1.6
component
definable part of a system (ENV 1614)

NOTE In analytical chemistry, component is sometimes called constituent or analyte.

3.1.7
derived kind-of-quantity
kind-of-quantity defined, in a system of kinds-of-quantity, as a function of base kinds-of-quantity of that system (after VIM)

3.1.8
derived unit
unit of measurement of a derived kind-of-quantity in a given system of kinds-of-quantity (after VIM)

3.1.9
dimension of quantity
expression that represents a quantity in a system of quantities as the product of powers of factors that represent the base kinds-of-quantity of the system (after VIM)

NOTE The use of this term is explained in Annex B.

3.1.10
entity
that which can be individually described and considered

[ISO 8402:1994]

NOTE 1 The word unit is used for this concept in statistics and in counting for what is counted, which may be, for instance, physical objects, physical particles, repetitive operations or repetitive processes, or any combination of such (detected, for instance, by pattern recognition).

NOTE 2 The concept is called element in set theory, in which a collection of elements constitute a set:

element - set

In this context, a component may be considered as a set of entities:

entity - component

NOTE 3 An entity, in contrast to a unit of measurement, constitutes part of the specification of a component (on the left side of the equation in Subclause 4.2) and not part of the unit of measurement (on the right side of the equation). The entity thus forms part of the specification of the measurable quantity. Some examples of such measurable quantities based on counting are given in Subclause 5.6.5.

3.1.11
factor prefix
prefix word or symbol for attachment to the name or symbol of a unit in order to form units that are multiples or submultiples of that unit

NOTE Factor prefixes provide a series to allow submultiples and multiples of SI units in the range 10-24 to 1024.

3.1.12
graphic character
character in its visible representation

[ISO 10 646-1]

3.1.13
interchange
transfer of character-coded data from one user to another, using telecommunication means or interchangeable carriers (after ISO 10 646-1)

3.1.14
International System of Units (SI)
coherent system of units adopted and recommended by the General Conference on Weights and Measures (VIM)

3.1.15
kind-of-quantity
element of information common to a set of mutually comparable measurable quantities and necessary for the definition of a measurable quantity, along with a system and often a component

NOTE 1 The definition of this concept is under discussion in ISO/TC12.

NOTE 2 The unqualified word quantity is also widely used for this concept, which VIM calls quantity in a general sense.

NOTE 3 A kind-of-quantity can be designated by a name or a symbol, but cannot be measured.

EXAMPLES:

— pressure p

— substance concentration c

— length l

3.1.16
measurable quantity
attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively (VIM)

NOTE 1 Phenomenon, body or substance correspond to the concepts of system and component as used in clinical laboratory sciences. Qualitatively refers to the need to define a quantity before it can be measured.

NOTE 2 A measurable quantity is defined by several elements of information, here called kind-of-quantity, component and system.

EXAMPLES:

— pressure (kind-of-quantity) of air (component) in surgical theatre of hospital X at 1995-05-01 10:00 (system)

— substance concentration (kind-of-quantity) of dioxygen (component) in blood of John Smith (born at place X on 1950-01-1) at time 1995-05-01 10:00 (system)

— length (kind-of-quantity) of John Smith (born at place X on 1950-01-1) at time 1995-05-01 10:00 (system)

3.1.17
measurement
set of operations having the object of determining a value of a quantity (VIM)

3.1.18
numerical value
quotient of the value of a quantity and the unit used in its expression (after VIM)

3.1.19
octet
ordered sequence of eight bits considered as an entity (after ISO 10 646-1)

3.1.20
off-system unit
unit of measurement that does not belong to a given system of units (VIM)

3.1.21
quantity
see kind-of-quantity and measurable quantity.

3.1.22
result of measurement
value attributed to a measurable quantity obtained by measurement (after VIM)

NOTE For the purposes of this ENV, result is taken to include the relational operator (Subclauses 4.1 and 4.3) and a measurable value of uncertainty (Annex D).

3.1.23
scale
set of possible values that may be attributed to a quantity of a certain kind (after ENV 1614)

NOTE In instrumentation, scale also means the ordered set of marks … forming part of the display on a measuring instrument (VIM).

3.1.24
symbol
representation of a concept by letters, numerals, pictograms or any combination thereof (after ISO 1087:1990)

3.1.25
system
demarcated arrangement of a set of elements and a set of relationships between these elements (ENV 1614)

3.1.26
systematic name
name consistent with the principles of a nomenclature (ENV 1614)

3.1.27
uncertainty of measurement
parameter that is associated with the result of a measurement and that characterizes the dispersion of the values attributable to the quantity measured (after VIM)

3.1.28
unit of measurement
measurable quantity, defined and adopted by convention, with which other quantities of the same dimension are compared in order to express their magnitudes relative to that quantity (after VIM)

NOTE The word unit is also used in statistics and in counting for what is here called entity (Subclause 3.1.10).

3.1.29
value of quantity
magnitude of a measurable quantity generally expressed as a number multiplied by a unit of measurement (after VIM)

3.2 Abbreviations, initialisms and acronyms

BIPM	International Bureau of Weights and Measures = Bureau International des Poids et Mesures
CEN	European Committee for Standardization = Comité Européen de Normalisation = Europäisches Komitee für Normung
CGPM	General Conference on Weights and Measures = Conférence Générale des Poids et Mesures
CQU	IUPAC Commission on Quantities and Units in Clinical Chemistry and IFCC Committee on Quantities and Units
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport

ENV	European Prestandard = Prénorme Européenne = Europäisches Vornorm
EU	European Union
ICRP	International Council on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
ICSH	International Council on Standardization in Haematology
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry
ISO	International Organization for Standardization
IUBMB	International Union of Biochemistry and Molecular Biology
IUPAC	International Union of Pure and Applied Chemistry
IUPAC-CT	IUPAC Commission on Toxicology
IUPAP	International Union of Pure and Applied Physics
OIML	International Organization for Legal Metrology
OSI	Open Systems Interconnection
SEPCR	European Society for Clinical Respiratory Physiology
SI	International System of Units
VIM	International vocabulary of basic and general terms in metrology (Clause 2)
WHA	World Health Assembly
WHO	World Health Organization
WMO	World Meteorological Organization

4 Elements of data in a measurable quantity and its result

4.1 A measurement can be expressed in a logical statement, which includes the following possible elements:

— system

— component

— kind-of-quantity

— relational operator

— numerical value

— unit of measurement

— uncertainty.

4.2 In symbolic language

$$q = \{q\} \cdot [q] \pm \{uc\} \cdot [q]$$

where q is any measurable quantity (designated by a kind-of-quantity, a system and any component), [q] is a unit of measurement of the quantity q and {q} is its numerical value in that unit, {uc} is the numerical value of combined uncertainty in that same unit.

EXAMPLE

Blood (venous; fasting patient) – Glucose; substance concentration

$= 4{,}9 \text{ mmol L}^{-1} \pm 0{,}2 \text{ mmol L}^{-1}$ where the quantity after the ± is combined standard uncertainty

4.3 The relation sometimes requires other relational operators than equals (=), such as < (is less than), > (is more than), ≤ (is less than or equal to), ≥ (is more than or equal to), ≈ (is approximately equal to) or ≠ (is not equal to) (ISO 31-11: 1992, Clause 3).

NOTE ENV 1614 "Medical informatics – Messages for the exchange of laboratory information" concentrates on the elements of information on the left of the relational operator. This ENV complements that work and concentrates on the right of the relational operator.

5 Units for reporting information in health sciences

5.1 Representation of results of measurements

In the representation of results of measurements, the unitary expressions shall include any of the following:

— SI units (Clauses 5.1 to 5.3)

— units formed from SI units by use of prefix symbols (Clause 5.4)

— certain off-system units (Clause 5.5)

— certain dimensionless units (Clause 5.6).

5.1.1 Annex A provides conversion factors with which algorithms can be designed to convert other units in local use and Annex C provides some criteria for conversion between kinds-of-quantity.

5.1.2 Table 1 lists SI base units each with its associated base kind-of-quantity. Definitions of the SI base units are given in Annex A. Number of entities is sometimes also treated as base and has the coherent SI unit `one'. For the choice of kilogram (with a prefix) as a base unit see Clause 5.4.6.

Table 1 —Base kinds-of-quantity, base units and their dimensional symbols in the International System of Units (SI). The base kinds-of-quantity are in the sequence used by CGPM and in Annex A. Entries begin with the references (Ref.) to that annex.

Ref.	Base kind-of-quantity		Base unit		Dimension
	name	symbol	name	symbol	
A.1	number (of entities)	*N*	one	1	1
A.2	length	l	metre	m	L
A.10	mass	m	kilogram	kg	M
A.19	time	t	second	s	T
A.66	electrical current	I	ampere	A	I
A.87	thermodynamic temperature	T, ϑ	kelvin	K	Θ
A.102	luminous intensity	Iv	candela	cd	J
A.107	amount-of-substance	n	mole	mol	N

5.2 Derived coherent units of SI and mathematical operations with units

5.2.1 Most coherent units of derived kinds-of-quantity are represented with **compound units** obtained by multiplication or division or both of the component base units. Such expressions require the mathematical operations of multiplication, division and raising to a power.

EXAMPLE Mole per square metre second (mol m^{-2} s^{-1}) is the SI-coherent compound unit of areic substance rate (Annex A.120).

5.2.2 Multiplication between units shall be represented by either a space, by a half-raised point (·) or by raising to a power.

EXAMPLES The product of pascal and second (called pascal second) is represented as Pa s or Pa · s.

The product of 2 Pa s with 5 s^{-1} is 2 Pa s X 5 s^{-1} = (2 Pa s) · (5 s^{-1}) = 10 Pa.

NOTE 1 The multiplication sign X is not recommended by ISO 31-0 for expression of units.

NOTE 2 The space between a numerical value and a unit also represents multiplication.

NOTE 3 Raising a unit u to a power is usually expressed as `unit squared' ($u^2$), `unit cubed' (u^3) or `unit to the fourth power' ($u^4$). For units of length, the designations `square unit' and `cubic unit' (e.g. square metre and cubic metre) are used as long as the derived quantity can be viewed as an area and a volume, respectively. Otherwise

designations like metre squared and metre cubed are used. In Annex A, only designations like square metre and cubic metre are listed.

5.2.3 **Division** of units shall be represented by multiplication of negative powers (example above) or by a slash (/). Not more than one slash shall be used in one compound unit, unless brackets are used in the expression to avoid ambiguity.

EXAMPLE mol m^{-2} s^{-1} = mol·m^{-2}·s^{-1} = mol/(m^2 s) = (mol/m^2)/s *but not* mol/m^2/s

5.3 Derived coherent units of SI with special names and symbols

Special names or **symbols**, usually both, are allowed for certain derived SI units (Table 2).

5.4 Multiples and submultiples of units: prefix names and symbols

5.4.1 If a system of units is chosen with only one unit for each dimension, there are bound to be some **very large and very small numerical values**, which can be expressed more briefly by use of **powers of 10**, such that numerical values (i.e. the mantissas) can almost always be between 0,1 and 1000 (Subclause 6.1.3).

EXAMPLES

Molar number constant, N_A, ≈ 602 213 670 000 000 000 000 000 mol^{-1}

= 602,213 67·10^{21} mol^{-1}

Rest mass of an electron, m_e ≈ 0,000 000 000 000 000 000 000 000 000 000 9 kg

= 0,9·10^{-30} kg

5.4.2 Instead of using powers of 10 with numerical values, **decimal prefixes** may be attached to SI units. The prefixes

Table 2 — Kinds-of-quantity associated with derived SI units with special names or symbols. The sequence of the list is as in Annex A, to which the references (Ref.) apply, essentially by order of dimension (Table 1) with increasing magnitude of powers of those dimensions, first positive and then negative. The trivial names of some kinds-of-quantity (A.44, equivalent dose) imply also an unnamed generalized component (marked by the modulus sign, |, in the systematic name). Systematic names of electrical and luminous kinds-of-quantity are based on electrical charge (unit C = A s) and quantity of light (unit lm s = cd sr s), respectively. The distinction *electric* and *electrical* is a non-normative mental aid in marking those kinds-of-quantity in which electrical charge forms part of the denominator and numerator, respectively, of the definition. The name and symbol of the katal have been recognized by IUPAC, IFCC, IUBMB and WHO; other units are recognized also by BIPM (1991). The symbols *t*, ϑ and Φ have several meanings in Table 1 and 2, those of □ being distinguished here by subscripts.

Ref. name	Kind-of-quantity		Unit symbol		Definition in SI-base units
	symbol	name			
A.1	plane angle γ, ϑ	α, β,	radian	rad	m m^{-1} = 1
A.1	solid angle	Ω	steradian	sr	m^2 m^{-2} = 1