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Medicinska informatika – Prikaz meritvenih rezultatov v medicinskih znanostih

Medical informatics - Expression of the results of measurements in health sciences

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Medical Informatics - Expression of results of measurements in health sciences

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the 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 ENV will provide wider comprehension and interaction between countries and specialities.

The main normative provisions of this European Prestandard 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 European Prestandard (ENV) 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 ENV. 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 ENV 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 ENV 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 Prestandard is limited to textual representation. Support is not provided for the display or printing of images or graphs.

This Prestandard 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

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

ENV 1068:1993. Medical informatics - Healthcare information interchange - Registration of coding schemes.

ENV 1613:1994. Medical informatics - Messages for the exchange of laboratory information.

ENV 1614:1994. Medical informatics – Structure for nomenclature, classification and coding of properties in clinical laboratory sciences

ISO 31:1992. Quantities and units. Geneva: ISO.

Pt 0. General principles.

Pts 1–10, 12–13 (specific disciplines)

Pt 11. Mathematical signs and symbols for use in the physical sciences and technology.

ISO 1000:1992. SI units and recommendations for the use of their multiples and of certain other units. Geneva: ISO.

ISO 1087: 1990. Terminology – Vocabulary. Geneva: ISO.

ISO 3534-1:1993. Statistics - Vocabulary and symbols - Pt 1: Probability and general statistical terms. Geneva: ISO.

ISO 4217:1990. Codes for the representation of currencies and funds. Geneva: ISO.

ISO 5428:1984. Greek alphabet coded character set for bibliographic information interchange. Geneva: ISO.

ISO 8402:1994. Quality management and quality assurance — Vocablary. Geneva: ISO.

ISO 8824:1990. Open Systems Interconnection - Specification for Abstract Syntax Notation One (ASN.1). Geneva: ISO.

ISO 8859:1987. Information processing - Registration of graphics character subrepertoires - Eight-bit single byte coded graphic character sets. Part 1 : Latin alphabet No 1.

ISO 8879:1986. Information processing — Text and office systems — Standard Generalized Markup Language (SGML). Geneva: ISO.

ISO 9070:1991. Information technology — SGML support facilities — SGML Document Interchange Format (SDIF). Geneva: ISO.

ISO/IEC 9541:1991. Information interchange - Font information interchange. Geneva: ISO.

ISO 9735:1988. Electronic data interchange for administration, commerce and transport (EDIFACT) - Application level syntax rules (amended and reprinted 1990). Geneva: ISO.

ISO 10 037:1991. Information technology — SGML and text-entry systems — Guidelines for SGML syntax-directed editing systems. Geneva: ISO.

ISO/IEC 10 646-1:1993. Information technology. Universal multiple-octet coded character set (UCS). Pt 1. Architecture and basic multilingual plane. Geneva: ISO.

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 $\in$ set

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

entity $\in$ 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 10^{24}.

3.1.12 **graphic character**: character in its visible representation (after 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. *Qualitativel* 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

$$q = \{q\}\cdot[q] \pm \{\ _{c}\}\cdot[q]$$

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, $\{\ _{c}\}$ is the numerical value of combined uncertainty in that same unit.

EXAMPLE:

☐ Blood(venous; fasting patient)—Glucose; substance concentration
= 4,9 mmol L^{-1} ± 0,2 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: The Prestandard 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 concentrated on the right of the relational operator.

5 Units for reporting information in health sciences

5.0.1 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).

5.0.2 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 Base units of SI

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	
A.102	luminous intensity	I_v	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 × 5 s^{-1} = (2 Pa·s)·(5 s^{-1}) = 10 Pa.

NOTE 1: The multiplication sign × 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

5.3.1 **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 k
= 0,9·10^{-30} k

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 lms = 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 *Φ* being distinguished here by subscripts.

Ref.	Kind of quantity	Unit			Definition in SI-base units
	Name	Symbol	Name	symbol	
A.1	plane angle	*α*, *β*, *γ*, *ϑ*	radian	rad	m m^{-1} = 1
A.1	solid angle	*Ω*	steradian	sr	m^2 m^{-2} = 1
A.20	number rate | of regular events; frequency	*f*, *ν*	hertz	Hz	s^{-1}
A.20	radioactivity	*A*	becquerel	Bq	s^{-1}
A.44	massic energy | of ionizing radiation absorbed; absorbed dose		gray	Gy	m^2 s^{-2}
A.44	effective massic energy | of ionizin radiation	*H*	sievert	Sv	m^2 s^{-2}
A.48	force	*F*	newton	N	kg m s^{-2}
A.50	pressure	*p*	pascal	Pa	kg m^{-1} s^{-2}
A.51	energy	*E*, Q_e	joule	J	kg m^2 s^{-2}
A.58	energy rate; power	*P*, $Φ_e$	watt	W	kg m^2 s^{-3}
A.61	electrical charge	*Q*	coulomb	C	A s
A.72	magnetic induction; magnetic flux density	*B*	tesla	T	kg A^{-1} s^{-2} = kg C^{-1} s^{-1}

A.74	magnetic flux	Φ_m	weber	Wb	Wb kg m² A⁻¹ s⁻² = kg m² C⁻¹ s⁻¹
A.76	electric potential difference	*U*, *V*	volt	V	kg m² A⁻¹ s⁻³ = kg m² C⁻¹ s⁻²
A.78	mutual inductance	*L*	henry	H	kg m² A⁻² s⁻² = kg m² C⁻²
A.80	electrical conductance	*G*	siemens	S	A² s³ k ⁻¹ m⁻² = s C² k ⁻¹ m⁻²
A.81	electric resistance	*R*	ohm	Ω	kg m² A⁻² s⁻³ = kg m² C⁻² s⁻¹
A.85	electrical capacitance	*C*	farad	F	A² s⁴ k ⁻¹ m⁻² = C² s² k ⁻¹ m⁻²
A.87	Celsius temperature	*t*, ϑ	degree	C	K
A.102	li ht rate; luminous flux	Φ_v	lumen	lm	cd sr
A.103	areic li ht rate | of incident radiation; illuminance	M_v	lux	lx	cd sr m⁻²
A.119	catalytic activity	*z*	katal	kat	mol s⁻¹

Table 3. SI prefixes denoting decimal factors, 10^n. $m = 3n$. The origins of the prefixes are indicated as an aid for memorization: Da, Danish; Es, Spanish; Gr, Greek; It, Italian; La, Latin; No Norwegian.

Name	Symbol	*n*	*m*	Mnemonic
yotta	Y	24	8	La octo (8)
zetta	Z	21	7	La septem (7)
exa	E	18	6	Gr hexa (6)
peta	P	15	5	Gr penta (5)
tera	T	12	4	Gr (monster)
giga	G	9	3	Gr gigas (giant)
mega	M	6	2	Gr megas (great)
kilo	k	3	1	Gr chilioi (1000)
hecto	h	2		Gr hekaton (100)
deca	da	1		Gr deka (10)
deci	d	-1		La decem (10)
centi	c	-2		La centum (100)
milli	m	-3	-1	La mille (1000)
micro	µ	-6	-2	Gr mikros (small)
nano	n	-9	-3	La nanus (dwarf)
pico	p	-12	-4	Es pico, It piccolo (small)
femto	f	-15	-5	Da, No femten (15)
atto	a	-18	-6	Da, No atten (18)
zepto	z	-21	-7	La septem (7)
yocto	y	-24	-8	La octo (8)