

Health informatics — Electronic healthcare record communication —

Part 2: Domain term list

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National foreword

This Draft for Development is the English language version of ENV 13606-2:2000.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature due to the limited duration of the European Prestandard. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that the UK experience can be reported to the European organization responsible for its conversion into a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its three-year life. The commencement of the review period will be notified by an announcement in *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee IST/35, Health Informatics, at 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Summary of pages

This document comprises a front cover, an inside front cover, the ENV title page, pages 2 to 59 and a back cover.

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Health informatics - Electronic healthcare record communication - Part 2: Domain term list

This European Prestandard (ENV) was approved by CEN on 29 July 1999 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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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.

This is Part 3 of a multipart standard on *Electronic Healthcare Record Communication*. The multipart standard consists of the following parts:

- Part 1: Extended architecture
- Part 2: Domain term list
- Part 3: Distribution rules
- Part 4: Messages for the exchange of information

This Prestandard was drafted using the conventions of the ISO/IEC directive part 3.

Annexes A, B, C, E, F are normative.
Annexes D and G are informative.

Introduction

For the convenience of the reader, the following conventions have been used within this document:

- architecture constructs generic to the overall standard are shown with initial capitalisation: class names are shown in normal font and attributes are shown in **bold** font;
- constructs and formalisms specific to this part of ENV 13606 are shown in *italics*.

The definitions of terms used within the document are given in Clause 3 of this part of ENV 13606.

The principal normative provisions are given in Clause 4 of this part of ENV 13606. These make reference to normative tables that are given in Annexes A, B, C, E and F and to the informative tables given in Annex D.

Requirements for conformance to this part of ENV 13606 are given in Clause 5.

A fuller description of the measures defined here is provided in Annex G (Informative). Readers unfamiliar with this part of ENV 13606 are strongly recommended to read this first.

Health informatics - Electronic healthcare record communication - Part 2: Domain term list

1 Scope

1.1 General

The Domain Termlist part of ENV 13606 provides a set of measures to support various degrees of interoperability of the EHCRs created on different systems or by different teams on the same system. These measures aim to enhance the likelihood that EHCR entries can be accessed or communicated in a way that:

- supports the visual interpretation of original entries by the end-user of a recipient system;
- facilitates record navigation;
- enables a limited level of amalgamation of received data sufficient to permit the generation of longitudinal views; and
- allows for a limited degree of automated processing, e.g. information retrieval.

These are intended to complement the communication of structural organisation within record entries provided by the architecture (Part 1) and message (Part 4) provisions of ENV 13606.

The real world of health and health care is made up of individual *clinical situations* (see Clause 3), which are described by an EHCR author as *clinical statements*. Within an EHCR system each *clinical statement* will be expressed as an *elementary healthcare record entry*. This will usually combine a set of clinical concepts (perhaps a core concept with some qualification e.g. site, laterality) with a set of contextual information (much of which may also be represented through qualification e.g. certainty, negation). Significant meaning may be conveyed through these qualifiers, but there is no consistent means of assuring that such detailed meaning will be reproducibly communicated between dissimilar systems.

The measures in this part of ENV 13606 are intended to provide a high-level and coarse-grained “shadow” representation of intended meaning that can be applied in a consistent manner even though a wide diversity will (quite properly) continue to exist in the way clinical details are actually recorded within EHCR entries. The coarse-grained annotations on Clusters and Data Items attempts to summarise the most important aspects of this detail, primarily to reduce the risk of serious misinterpretation.

It is not appropriate for this work to attempt a complete and rigorous “mirror” of the detailed clinical entries themselves. It is therefore important to appreciate that these measures are not considered sufficient to assure the safe automatic processing of EHCR data from heterogeneous sources for clinical decision making. Nevertheless, a measure is provided as a framework to build fine-grained coding systems supporting more advanced levels of interoperability in particular communities of users. The common framework will assist to avoid unnecessary diversity and will facilitate a future convergence of the local coding systems.

These proposals are presented as a set of seven measures. The measures are complementary, applied to different classes or parts of a Record Component hierarchy, and offer different degrees of interoperability. Each of these measures is defined within Clause 4 (Provisions) and Annexes A (Normative), B (Normative), C (Normative), D (Informative), E (Normative) and F (Normative) of this part of ENV 13606, and is explained in more detail in Annex G (Informative).

1.2 Target groups of this document

This document is applicable to:

- a) developers of standards on interchange formats for messages involving clinical information;
- b) developers of EHCR architecture standards,
- c) developers of categorial structures and terminological systems on sub-domains where clinical information need to be covered,
- d) information modellers and knowledge engineers building models for record systems,
- e) developers of information systems which need to handle an explicit system of clinical concepts for internal organisation, data warehouse management and middleware services,
- f) developers of mark-up standards for the representation of healthcare documents.

1.3 Topics considered outside the scope of this document

This document is not intended to:

- a) provide value sets to replace original values of either names or content of record components;
- b) represent administrative and organisational context i.e. data about the patient, the professional, and the healthcare organisation, such as names, addresses, identifiers, locations, attestation data: these topics are addressed by other parts of ENV 13606;
- c) regulate how details shall be used either within names or within content of record items: in particular, it is not overlapping with categorial structures defined by CEN ENV 12264;
- d) define precise names for or the content of Record Components;
- e) propose large or exhaustive lists of acceptable names for low-level Record Components (as, for example, provided by LOINC [18]).

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 12264:1997	Medical Informatics — Categorical structure of systems of concepts — Model for representation of semantics
ENV 12381:1996	Medical Informatics — Time standards for healthcare specific problems
ENV 13606-1:2000	Health informatics — Electronic healthcare record communication — part 1: Extended architecture
ENV 13606-4:2000	Health informatics — Electronic healthcare record communication — part 4: Messages for the exchange of information

3 Terms, definitions and abbreviations

For the purposes of this part of ENV 13606, the terms and definitions given in ENV 12264:1997, ENV 13606-1, ENV 13606-4 (some of which are repeated below for convenience) and the following apply.

3.1

situation

phenomenon occurring (or having the potential to occur) at or over a time in a given world context

[ENV 12381]

NOTE. It extends the normal English use of the term to any state or process, including activities.

3.2

clinical situation

situation applied specifically to clinical data and clinical care.

NOTE. *Clinical situations* include the health state of a patient, healthcare actions or any other type of event of healthcare relevance, whether in the past, present or projected for the future. A list of types of *clinical situations* is provided in this document as the “FOCUS Annotation Type” in Annex B, table B.1.

3.3

clinical statement

description of a single *clinical situation*, as intended for representation within a patient’s record by an author.

NOTE. This is, in essence, a logical (virtual) concept; it provides the clinical information content of an *elementary healthcare record entry*. The information within a *clinical statement* is the minimum necessary, but sufficient, to describe the *clinical situation* precisely. It is not possible to define this concept unambiguously, but in practice it will usually reflect a single clinical observation, interpretation or action. This term is therefore not applicable to the whole of a longer clinical discourse, as might be represented by narrative entries, free-text letters etc.

3.4

healthcare record entry

data set, suitably attributed, which forms part of, or a whole, contribution to a healthcare record at one place and time.

3.5

elementary healthcare record entry

elementary entry

healthcare record entry which reflects a single *clinical situation*

NOTE. It is the representation of a single *clinical statement*. If subdivided, it will result in the loss or significant misrepresentation of its original meaning. Architecturally an elementary entry will usually be represented by a single Data Item or a *Cluster* (see Subclause 4.2), possibly with some additional qualifiers. The content type might, for example, be a coded term, a number, a Boolean or a date. Plain text, if a short phrase relating to a single *clinical situation*, might also be an appropriate content type but longer narrative entries would NOT be examples of an *elementary healthcare record entry*, even if they are represented by a single Data Item.

3.6

annotation type

feature of context pertaining to a *clinical statement*

EXAMPLES. Subject of information, life cycle, knowing mode, relevance.

3.7

annotation identifier

annotation

a means to summarise the key contextual information pertaining to a component complex or a *data item*.

NOTE. The *annotations* are added to the record component as a coded value. The Annotation Measure within this part of ENV 13606 provides a means to summarise in a standardised form the key contextual information pertaining to an elementary or compounded entry, primarily to assist in its safe interpretation. A secondary purpose is to facilitate the retrieval of relevant entries by computerised searches.

3.8

categorial structure

reduced system of concepts to describe the organisation of the semantic categories in a particular system of concepts for development, maintenance and application of terminological systems

[ENV 12264:1997, modified]

NOTE. Categorial structure, system of concept, semantic categories were introduced in ENV 12264:1997. Readers unfamiliar with these topics are strongly recommended to refer to that Prestandard before using the Archetype Measure in 4.6, 5.6 and Annex D (informative).

3.9

dissection

systematic representation of a phrase according to a predefined *categorial structure* and using predefined descriptors

3.10

archetype

semantic network to describe the typical relations among the semantic categories evoked by a particular entity

NOTE. Archetypes describe the typical structure of the involved entity. They are different from categorial structures defined in CEN ENV 12264 “Model of Semantics”, that instead describes the mandatory structure of a semantic category for compliant terminological systems (i.e. the part of an archetype that can satisfy a specific purpose), with additional rules for well-formed expressions.

3.11

clinical information

information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional.

[ENV1613]

NOTE Clinical information about a patient may include information about the patient's environment or about related people or animals where this is relevant.

3.12

EHCR extract

EHCR message component representing the entirety of a patient's electronic healthcare record or that part of the record contained within a particular instance of an EHCR message.

[ENV13606-4]

3.13

record component

component

part of an electronic health care record that is identifiable for the purposes of referencing and revision.

[ENV13606-4]

3.14

original component complex

OCC

record component representing an aggregation of other *record components* that is determined by the time and situation in which they were originally added to the EHCR.

[ENV13606-4]

3.15

folder

original component complex used to group *record components* collected and/or recorded during several contacts with a patient.

NOTE. A folder may include information collected and recorded at different times and by different people.

3.16

composition

original component complex that contains a set of *record components* relating to one time and place of care delivery, a single session of recording or a single document included in the EHCR.

EXAMPLES. Consultation note, operation note, discharge summary, vital signs chart, laboratory report.

3.17

headed section

original component complex representing a sub-division within a *composition*, the contents of which have a common theme or are derived through the same healthcare process.

3.18

cluster

original component complex used to aggregate *data items* and/or other *clusters* to represent a compound concept.

EXAMPLES. A blood pressure measurement consisting of systolic and diastolic pressure, a collection or closely related clinical findings, results of a battery of laboratory investigations, a treatment schedule consisting of several individually specified preparations or dosages.

3.19

selected component complex

SCC

record component representing an aggregation of other *record components* that is not determined by the time or situation in which they were originally added to the EHCR.

[ENV13606-4]

NOTE. Selected component complexes are used to provide alternative view or groupings of records. They can represent the record as viewed at a particular time or they can represent groupings of clinically or logically associated record components.

3.20

data item

single unit of data that in a certain context is considered indivisible.

[ENV13606-4]

NOTE 1. The content of data is dependent upon the structure and type of the identified data type.

NOTE 2. The context may mean that this component's content may represent for example either a single clinical statement or a single complex type such as an X-ray report. Its granularity is determined by the context.

3.21

link set item

record component that provides a means of associating two or more other instances of EHCR message component, and specifying the relationship between them.

[ENV13606-4]

NOTE. The link set item is used to convey a collection of one or more link items (defined in accordance with part 1 of ENV 13606) for which both the link source component and relationship are identical.

3.22

component name category

attribute that provides a high level indication of the general nature of the content of a *record component*.

[ENV13606-4]

NOTE 1. These categories are assigned by or derived from the EHCR, depending upon the nature of the data or the process being carried out.

NOTE 2. See this part of ENV 13606 for permissible values, for the different types of record component.

3.23 Abbreviations

The following abbreviations are used in this European Prestandard.

DIM	Domain Information Model
DTD	Document Type Definition
EHCR	Electronic Healthcare Record
ENV	European Prestandard
GMD	General Message Description
GP	General Practitioner
HGMD	Hierarchical General Message Description
ICSI	International Coding Scheme Identifier
IMS	Implementable Message Specification
MIG	Message Implementation Guide
OCC	Original Component Complex
SCC	Selected Component Complex
UID	Unique Identifier
UML	Unified Modelling Language
XML	Extensible Markup Language

4 Provisions

4.1 General

The seven specific measures included within this Clause of the pre-standard are listed below.

- 1) A basic classification of Original Component Complexes.
- 2) A categorisation of names of Compositions and Headed Sections
- 3) A proposal for *Annotation Identifiers* to summarise the essential meaning contained within the lower-order parts of an EHCR hierarchy and the clinical detail within a Data Item.
- 4) A categorisation of the relationship names that may be represented by Link Set Items.
- 5) A framework for the semantic representation of the detail within *clinical statements*.
- 6) A set of tables to provide enumerated lists of terms and codes (“term list”) to be used as value domains for a set of attributes described in part 4 of ENV 13606
- 7) As a support to the implementation of measures 1-3 above, a template for recording local cross-mapping information is also specified.

4.2 Specialisations of Original Component Complex

The abstract class Original Component Complex (OCC) is used within part 1 and part 4 of ENV 13606 to represent the principal aggregation and containment hierarchies within an EHCR for newly acquired clinical facts, interpretations and plans.

This part of ENV 13606 proposes a broad sub-categorisation of the OCC into four specialisations, as shown in Table 1 below.

Table 1: Specialisations of the Original Component Complex class

OCC specialisation	Description	Examples of Component Names
<i>Folder</i>	High-level subdivisions of the entire EHCR for a patient, usually grouping entries over long time-spans within one organisation or department, or for a particular health problem	GP Record Inpatient Stay Diabetes Care Record
<i>Composition</i>	A set of record entries relating to one time and place of care delivery; grouped contributions to an aspect of health care activity; composed reports and overviews of clinical progress	Consultation Operation Notes Discharge Summary Vital Signs Chart
<i>Headed Section</i>	Sub-divisions used to group entries with a common theme or derived through a common healthcare process	Past Medical History Presenting Symptoms Examination Findings Treatment Plan
<i>Cluster</i>	Low-level aggregations of elementary entries (Record Items) to represent a compound clinical concept	Heart Sounds Differential White Cell Count Insulin Schedule

This categorisation is intended to assist in the navigation of large complex EHCRs and enables requestors of EHCR extracts to specify an appropriate level of granularity for the Record Component(s) they require. This proposal is also required to support other proposals within this part of ENV 13606.

Every instance of the OCC class within a conformant EHCR shall be related (directly or via a data dictionary) to one of the four specialisations.

The chosen specialisation for each class instance should reflect the overall record information contained by that instance (and implied by its Record Component name).

It is not mandatory to use all of the specialisations within a Record Component hierarchy: some may reasonably be omitted by some EHCR implementations or in selected circumstances. It is important that each specialisations is used consistently to categorise the record information contained by that class.

Every instance value for specialisations shall comply with the containment constraints stated in part 4 of ENV 13606.

4.3 Categories for names of Compositions and Headed Sections

4.3.1 General

The provisions within parts 1 and 4 of ENV 13606 anticipate that Record Components will be named using controlled vocabularies. These will be determined by local enterprises or national and international bodies, and this standard does not provide any such list. This measure provides a set of categories for some Record Component names that can be used to identify or to group similar kinds of record entries. This is primarily to allow EHCR entries or extracts originating from a range of different clinical teams to be processed and handled in a homogeneous fashion for record navigation, for searching, and for high-level aggregation analyses.

The chosen category for each class instance should reflect the overall record information contained by that instance (and implied by its Record Component name). The category might not be applicable to every member of the class in isolation. This measure does not presume whether the information contained is a highly structured set of further Record Components or a set of narrative entries. The categorisation must be applied consistently, so that all equivalent instances are similarly categorised.

The categories provided by this measure apply to Original Component Complexes and to some kinds of Selected Component Complex. They are defined below in relation to the specialisations of OCC defined above.

4.3.2 Folder

No categories are provided for this class.

4.3.3 Composition

The categories provided for this class are given in Table A.1 within Annex A of this part of ENV 13606. It is recognised that instances of *Composition* will occasionally come under more than one category. This proposal therefore permits any instance of *Composition* to be categorised by more than one entry in Table A.1. However, it is strongly advocated that just one category is chosen for each instance.

Some of the entries in Table A.1 refer to views or other aggregations of previously recorded information. In some record systems these may be implemented using the Selected Component Complex (SCC) rather than the Original Component Complex. The table provided here is also an optional categorisation for some instances of SCC, and may be used for this purpose.

4.3.4 Headed section

The categories provided for this class are given in Table A.2 within Annex A of this part of ENV 13606. It is recognised that a significant proportion of *Headed Section* instances will come under more than one category. This proposal therefore permits any instance of *Headed Section* to be categorised by more than one entry in Table A.2. However, it is strongly advocated that usually one and at most three such categories are chosen for each instance.

4.3.5 Cluster

No categories are provided for this class. Two further measures within this pre-standard include members of this class, and are described below.

4.4 Annotation identifiers

4.4.1 General

A nomenclature of the information represented by the detail within *clinical statements* is beyond the scope of this standard. However, the Annotation Measure within this part of ENV 13606 provides a means to summarise in a standardised form the key contextual information pertaining to a Data Item or a *Cluster*, primarily to assist in its safe interpretation. A secondary purpose is to facilitate the retrieval of relevant entries by computerised searches. *Annotations* apply to Data Items and *Clusters* within an EHCR. (Some contextual meaning may be informed by the higher-order nested Record Components, e.g. from *Headed Section* names. This will be relevant at the time of mapping an elementary healthcare record entry to its *Annotations*).

4.4.2 Annotation types and Basic Descriptors

The Annotation Measure is implemented through a set of *Annotation Types*, which represent the key potential features of context that may be represented within any EHCR entry. Each *Annotation Type* is provided with an enumerated list (*Basic Descriptors*) to represent the set of its possible values. The set of *Basic Descriptors* applied to a particular Record Component are its *Annotations*. The *Annotations* are expressly not the means by which original information within EHCR entries should be represented: they provide a parallel and standardised summary representation.

4.4.3 Annotation of Clusters

Each instance of *Cluster* and each instance of Data Item within an EHCR system shall directly contain (or reference via a data dictionary) the suitable *Annotations*. They shall comprise a set of *Basic Descriptors* taken from those listed in Table B.1 within Annex B of this part of ENV 13606. This set is to be regarded as “frozen” with respect to each versioned Record Component instance, and shall not be varied for different communications purposes.

4.4.4 Reliability of annotations

The *Annotation Type* RELIABILITY OF ANNOTATION is mandatory; the others are optional. It is possible for *Annotations* not to be useful for some Record Components; a minimal representation with only the appropriate value for RELIABILITY OF ANNOTATION would then be applicable.

4.4.5 Coherence of Annotations with the information that is annotated

The meaning communicated through a set of must not conflict with or contradict the information contained within the elementary healthcare record entries being annotated. Moreover, a *Basic Descriptor* applied to an instance of *Cluster* must not conflict with or contradict the *Annotations* of its members.

4.4.6 Exclusion of default and inheritance mechanisms

Default *Basic Descriptor* values are not provided for any of the *Annotation Types*. *Basic Descriptors* do not demonstrate inheritance: in many circumstances the overall contextual meaning applicable to an entry will not also be applicable to each part of that entry. The *Annotations* may, of course, be explicitly repeated at a lower hierarchical level if appropriate.

4.5 Categorisation of Names of Relationships within Link Set Items

None of the earlier measures in this part of ENV 13606 is applicable to the Link Item class. Extensive empirical work is still needed before a definitive and complete nomenclature of Link Item names can be normalised. However, it remains important for local Link Items to be communicated unambiguously between dissimilar EHCR systems.

Table C.1 in Annex C provides a list of values for the attribute Component Name Category for the class Link Set Item, to map locally defined or specialised links implemented within EHCR systems.

4.6 Archetypes and Fine-Grained Descriptors

4.6.1 General

The Annotation Measure, described above, has been provided to allow for a coarse-grained parallel representation of the meaning within *clinical statements*, but cannot assure a precise representation of the detail. However national or local bodies may wish to develop coding systems for the detail that must be recorded about contextual information. These coding systems provide a systematic means by which the semantic context in a *clinical statement* can be consistently represented.

The Archetype Measure, in combination with a set of fine-grained descriptors, provides a framework to generate more coherent coding systems about contextual information and to facilitate their convergence.

It also allows for a limited level of interoperability, independently of the way information is physically structured within EHCR architectures and terminology systems.

According to CEN ENV 12264, information contained within each statement can be described by a *Dissection*, i.e. a set of fine-grained descriptors (single words or short phrases, usually nouns, each naming a unitary concept that belongs to a semantic category) that are combined by semantic links (usually verbs or reflexive verbs) to form a semantic network.

The combination of descriptors and semantic links is regulated by a *Categorial Structure*, that describes how semantic categories and semantic links are related in a particular terminological system.

4.6.2 Table of archetypes

The *Archetypes* provided in Annex D suggest how to construct *Categorial Structures* in a controlled way. Table D.1 of Annex D provides a set of *Archetypes* that may be used primarily to produce a *Categorial Structure* for a local coding system.

The relations presented in an *Archetype* are inherited by the *Archetypes* referring to subordinate clinical situations.

Users can extend or adapt the semantic links and semantic categories provided by the *Archetypes*, as well the related combinatorial rules, documenting the local amendments with explicit references to table D.1.

4.6.3 Fine grained descriptors

Table D.2 of Annex D provides a set of descriptors, organized by semantic category, that may be combined into *Dissections* according to the predefined *Categorial Structure* and thus used to populate a local compositional coding system.

This standard does not dictate whether local coding systems are distributed in a compositional format or consist of a simple list of expressions.

Users can extend or adapt the list of descriptors provided by table D.2, documenting the local amendments with explicit references to table D.2. Names of Semantic Categories in table D.2 can be used as descriptors.

As with the other measures above, the *Dissection* does not replace the original information, but is a complement to this for consistent processing.

4.7 Other enumerated lists

For some particular Attributes described in part 4 of ENV 13606— listed in Table 2 in Subclause 5.7 of this part — , the Value Domain is made of a short enumerated list of values (see Term List - TL in 7.12.5 in part 4 of ENV 13606).

Annex E provides tables with the codes to be used for such Attributes.