

# SVENSK STANDARD

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**Hälsa- och sjukvårdsinformatik – Kommunikation av elektronisk patientjournal –**

**Del 2: Specifikation för utbyte av arketyper (ISO 13606-2:2019)**

**Health informatics – Electronic health record communication –  
Part 2: Archetype interchange specification (ISO 13606-2:2019)**

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Denna standard ersätter SS-EN 13606-2:2007, utgåva 1

The European Standard EN ISO 13606-2:2019 has the status of a Swedish Standard. This document contains the official version of EN ISO 13606-2:2019.

This standard supersedes the SS-EN 13606-2:2007, edition 1

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EUROPEAN STANDARD

**EN ISO 13606-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2019

ICS 35.240.80

Supersedes EN 13606-2:2007

English Version

**Health informatics - Electronic health record  
communication - Part 2: Archetype interchange  
specification (ISO 13606-2:2019)**

Informatique de santé - Communication du dossier  
de santé informatisé - Partie 2: Spécification  
d'échange d'archétype (ISO 13606-2:2019)

Medizinische Informatik - Kommunikation  
von Patientendaten in elektronischer Form  
- Teil 2: Spezifikation für den Austausch  
von Archetypen (ISO 13606-2:2019)

This European Standard was approved by CEN on 2 July 2019.

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## European foreword

This document (EN ISO 13606-2:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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### Endorsement notice

The text of ISO 13606-2:2019 has been approved by CEN as EN ISO 13606-2:2019 without any modification.

## Introduction

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement. In this document dependency upon any of the other parts of this series is explicitly stated where it applies.

Comprehensive, multi-enterprise and longitudinal electronic health records will often in practice be achieved through the joining up of multiple clinical applications, databases (and increasingly devices) that are each tailored to the needs of individual conditions, specialties or enterprises.

This requires that Electronic Health Record (EHR) data from diverse systems be capable of being mapped to and from a single comprehensive representation, which is used to underpin interfaces and messages within a distributed network (federation) of EHR systems and services. This common representation has to be sufficiently generic and rich to represent any conceivable health record data, comprising part or all of an EHR (or a set of EHRs) being communicated.

The approach adopted in the ISO 13606 standards series, underpinned by international research on the EHR, has been to define a rigorous and generic Reference Model that is suitable for all kinds of data and data structures within an EHR, and in which all labelling and context information is an integral part of each construct. An EHR Extract (as defined in ISO 13606-1) will contain all of the names, structure and context required for it to be interpreted faithfully on receipt even if its organisation and the nature of the clinical content have not been “agreed” in advance.

However, the wide-scale sharing of health records, and their meaningful analysis across distributed sites, also requires that a consistent approach is used for the clinical (semantic) data structures that will be communicated via the Reference Model, so that equivalent clinical information is represented consistently. This is necessary in order for clinical applications and analysis tools safely to process EHR data that have come from heterogeneous sources.

### 0.1 Archetypes

The challenge for EHR interoperability is therefore to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this standard series distinguishes a Reference Model, used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

**The Reference Model** is specified as an Open Distributed Processing (ODP) Information Viewpoint model, representing the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. In the 13606 standards series, the Reference Model is defined in Part 1. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this standard series).

**Archetypes** are effectively pre-coordinated combinations of named RECORD\_COMPONENT hierarchies that are agreed within a community in order to ensure semantic interoperability, data consistency and data quality.

For an EHR\_EXTRACT, as defined in ISO 13606-1, an archetype specifies (and effectively constrains) a particular hierarchy of RECORD\_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the datatypes and value ranges that ELEMENT data values can take, and might include other dependency constraints. Archetype instances themselves conform to a formal model, known as an Archetype Model



(which is a constraint model, also specified as an ODP Information Viewpoint Model). Although the Archetype Model is stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions.

Archetypes can be used within EHR systems to govern the EHR data committed to a repository. However, for the purposes of this interoperability standard series, no assumption is made about the use of archetypes within the EHR Provider system whenever this standard series is used for EHR communication. It is assumed that the original EHR data, if not already archetyped, can be mapped to a set of archetypes, if desired, when generating the EHR\_EXTRACT.

The reference model defined in ISO 13606-1 has a property that can be used to specify the archetype to which any RECORD\_COMPONENT within an EHR\_EXTRACT conforms. The class RECORD\_COMPONENT includes an attribute *archetype\_id* to identify the archetype and node to which that RECORD\_COMPONENT conforms.

Part 3 of this standard series includes a set of Reference Archetypes: which are base archetypes that are likely to be specialised further before they are used. Those archetypes are example instances of this Archetype Model.

The Archetype Model specified in this document was originally developed by the openEHR Foundation, which publishes its archetypes using Archetype Definition Language, conforming to this Archetype Model, referenced within [Annex A](#). The Archetype Model has been the subject of collaborative updating to incorporate the requirements and modelling inputs from the Clinical Information Modeling Initiative (CIMI). CIMI is in the process of submitting a modelling language (Archetype Modeling Language, AML) to the Object Management Group. AML also aligns to this Archetype Model.

## 0.2 Archetype datatypes

It should be noted that ISO 13606-1 and ISO 13606-2 use datatypes for different purposes.

Part 1 defines datatypes to represent the properties of the Reference Model, as a profile of ISO 21090, in 5.3. It separately defines in [Clause 7](#) the data types that can be the values of Element, also a subset of ISO 21090. All these datatypes are finally expressed in terms of the so-called “primitive” datatypes (Integer, Real, String, Boolean, Date/Time/Datetime).

Part 2 uses the same set of primitive datatypes to represent the properties of the Archetype Object Model. Additionally, Part 2 defines a set of classes that allow defining constraints over primitive datatypes of Part 1. These constraining classes are shown in [Figure 9](#) of Part 2, as descendants of the C\_PRIMITIVE\_OBJECT class.

A single Part 1 complex datatype (e.g. PHYSICAL\_QUANTITY) can be constrained by a combination of the constraining classes of the Archetype Object Model, defining constraints on both the complex and primitive datatypes it contains. Thus, Part 1 complex datatypes are treated as classes when defining constraints with Part 2, while Part 1 primitive data types are constrained by the C\_PRIMITIVE\_OBJECT hierarchy.

An example of a PHYSICAL\_QUANTITY archetype can be seen in the example below. In this example, the value on a PHYSICAL\_QUANTITY shall be between 0.0 and 1000.0 and their units shall be UCUM ‘mm[Hg]’ code.

```
PHYSICAL_QUANTITY matches {
  value matches {[0.0..<1000.0]}
  units matches {
    CODED_SIMPLE matches {
      value matches {"mm[Hg]"}
    }
  }
}
```

```

    }
}

```

This example archetype, expressed in terms of the Archetype Object Model, would have the structure shown in [Table 1](#).

**Table 1 — Example structure for representing physical quantity**

Reference Model class, attribute or primitive value	Archetype Model constraining class
PHYSICAL_QUANTITY	C_COMPLEX_OBJECT
value	C_ATTRIBUTE
Real	C_REAL
units	C_ATTRIBUTE
CODED_SIMPLE	C_COMPLEX_OBJECT
value	C_ATTRIBUTE
String	C_STRING

Since the Archetype Object Model is also used to constrain other reference models, as for example the openEHR Reference Model, there will be a need to transform openEHR archetypes to ISO 13606 archetypes, and vice versa. The openEHR Reference Model also uses the same primitive datatypes, but includes a different set of complex datatypes, such as DV\_ORDINAL, or DV\_TEXT<sup>1)</sup>. When transforming an openEHR archetype constraint to an ISO 13606 archetype, it might be necessary to introduce an additional CLUSTER structure to represent the equivalent openEHR sub-components as ELEMENTs.

For example, a representation of an openEHR DV\_ORDINAL in ISO 13606 would have the structure shown in [Table 2](#).

**Table 2 — Example structure for representing an ordinal data value**

openEHR	ISO 13606
DV_ORDINAL	CLUSTER matches { -- DV_ORDINAL
	parts matches {
symbol	ELEMENT matches { -- symbol
	value matches {
DV_CODED_TEXT	CODED_VALUE matches {*}
	}
	}
value	ELEMENT matches { -- value
	value matches {
Integer	INTEGER matches {*}
	}
	}
	}
	}

An example of how the LINK class defined in Part 1 of this standard series can be represented using the Archetype Object Model defined in this document is given in [Annex B](#).

### 0.3 Archetype repositories

1) Please see [http://www.openehr.org/releases/RM/latest/docs/data\\_types/data\\_types.html#\\_text\\_package](http://www.openehr.org/releases/RM/latest/docs/data_types/data_types.html#_text_package) for the specification of this datatype.

The range of archetypes required within a shared EHR community will depend upon its range of clinical activities. The total set needed on a national basis is presently unknown, but there might eventually be several thousand archetypes globally. The ideal sources of knowledge for developing such archetype definitions will be clinical guidelines, care pathways, scientific publications and other embodiments of best practice. However, “de facto” sources of agreed clinical data structures might also include:

- the data schemata (models) of existing clinical systems;
- the lay-out of computer screen forms used by these systems for data entry and for the display of analyses performed;
- data-entry templates, pop-up lists and look-up tables used by these systems;
- shared-care data sets, messages and reports used locally and nationally;
- the structure of forms used for the documentation of clinical consultations or summaries within paper records;
- health information used in secondary data collections;
- the pre-coordinated terms in terminology systems.

Despite this list of *de facto* ways in which clinical data structures are currently represented, these formats are very rarely interoperable without substantial costs. The use of standardised archetypes provides an interoperable way of representing and sharing these specifications, in support of consistent (good quality) health care record-keeping and the semantic interoperability of shared EHRs.

The involvement of national health services, academic organisations and professional bodies in the development of archetypes will enable this approach to contribute to the pursuit of quality evidence-based clinical practice. A key next challenge is to foster communities to build up libraries of archetypes. It is beyond the scope of this document to assert how this work should be advanced, but in several countries so far it would appear that national eHealth programmes are beginning to organise clinical-informatics-vendor teams to develop and operationalise sets of archetypes to meet the needs of specific healthcare domains. In the future regional or national public domain libraries of archetype definitions might be accessed via the Internet, and downloaded for local use within EHR systems. Such usage will also require processes to verify and certify the quality of shared archetypes, which are also beyond the scope of this document but are being taken forward by not for profit organisations such as the open EHR Foundation ([www.openehr.org](http://www.openehr.org)), the Clinical Information Modeling Initiative (CIMI, <http://www.opencimi.org>) the EN13606 Association (<http://www.en13606.org>) and the European Institute for Innovation through Health Data ([www.i-hd.eu](http://www.i-hd.eu)).

#### 0.4 Communicating archetypes

This document specifies, in [Clause 6](#), the requirements for a comprehensive and interoperable archetype representation and defines, in [Clause 7](#), the ODP Information Viewpoint representation for the Archetype Object Model.

This document does not require that any particular model be adopted as the internal architecture of archetype repositories, services or components used to author, store or deploy archetypes in collaboration with EHR services. It does require that these archetypes are capable of being mapped to the Archetype Object Model defined in this document in order to support EHR communication and interoperability within an EHR-sharing community.

A more detailed overview of archetypes can be found here:

<http://www.openehr.org/releases/AM/latest/docs/Overview/Overview.html>