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**Health informatics — Patient healthcard  
data —**

**Part 2:  
Common objects**

*Informatique de santé — Données relatives aux cartes de santé des  
patients —*  
*(Partie 2: Objets communs)*

ISO 21549-2:2004

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 21549-2 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

- *Part 1: General structure*
- *Part 2: Common objects*
- *Part 3: Limited clinical data*
- *Part 4: Extended clinical data*
- *Part 5: Identification data*
- *Part 6: Administrative data*
- *Part 7: Electronic prescription (medication data)*
- *Part 8: Links*

At the time of publication of this part of ISO 21549, some of these parts were in preparation.

This work is being carried out by ISO/TC 215 in collaboration with CEN/TC 251, *Medical informatics*, under the Vienna Agreement, with ISO having the lead role. This new series of International Standards is intended to replace the European Prestandard ENV 12018 ratified by CEN in 1997.

## Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical records, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions may be automated and data exchange carried out at a number of sites using patient-transportable computer-readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases and support systems has led to the development and use of "healthcare person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized into three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card *de facto* has to contain device data and identification data and may in addition contain administrative and clinical data.

Device data is defined to include:

- identification of the device itself;
- identification of the functions and functioning capabilities of the device.

Identification data may include:

- unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include:

- complementary person-related data;
- identification of the funding of healthcare, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefits;
- other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include:

- items that provide information about health and health events;
- their appraisal and labelling by a healthcare person (HCP);
- related actions planned, requested or performed.

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Because a data card essentially provides specific answers to definite queries, whilst at the same time there is a need to optimize the use of memory by avoiding redundancies, a “high-level” object-modelling technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

Data in the four categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore, it has been considered inadequate to provide a simple list of items carried by healthcare data cards without applying a generic organization, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed. Several such objects may also share attributes.

This part of ISO 21549 describes and defines the common data objects used in or referenced by patient-held health data cards using UML, plain text and abstract syntax notation (ASN.1).

These data objects are utilized in all forms of healthcare data cards, and are used to construct compound data objects as defined in Parts 3 to 8 of ISO 21549.

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# Health informatics — Patient healthcard data —

## Part 2: Common objects

### 1 Scope

This part of ISO 21549 establishes a common framework for the content and the structure of common objects used to construct or referenced by other data-object data held on patient healthcare data cards.

It is applicable to situations in which such data are recorded on or transported by patient healthcards whose physical dimensions are compliant with those of ID-1 cards as defined by ISO/IEC 7810.

This part of ISO 21549 specifies the basic structure of the data, but does not specify or mandate particular data-sets for storage on devices.

The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549 (although its structures can accommodate suitable data objects specified elsewhere):

- the encoding of free text data;
- security functions and related services which are likely to be specified by users for data cards, depending on their specific application, for example confidentiality protection, data integrity protection, and authentication of persons and devices related to these functions;
- access control services which may depend on active use of some data card classes such as microprocessor cards;
- the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it in accordance with this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

- physical or logical solutions for the practical functioning of particular types of data card;
- how the message is processed further “downstream” of the interface between two systems;
- the form which data take for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

### 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.

ENV 1068:1993, *Medical informatics — Healthcare information interchange — Registration of coding schemes*

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 7498-2:1989, *Information processing systems — Open systems interconnection — Basis reference model — Part 2: Security architecture*

ISO/IEC 7810, *Identification cards — Physical characteristics*

ISO/IEC 9798-1:1997, *Information technology — Security techniques — Entity authentication — Part 1: General*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

##### **country**

code that identifies the country of origin of the device issuer

NOTE This may not necessarily be the same as the nationality of the device holder.

#### 3.2

##### **data integrity**

the property that data have not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989]

#### 3.3

##### **data object**

collection of data that has a natural grouping and may be identified as a complete entity

#### 3.4

##### **data sub-object**

component of a data object that itself may be identified as a discrete entity

#### 3.5

##### **device holder**

individual transporting a data card which contains a record with the individual identified as the major record person

#### 3.6

##### **entity authentication**

corroboration that an entity is the one claimed

[ISO/IEC 9798-1:1997]

#### 3.7

##### **erasure**

process whereby, after a given point in time, access to a data entity is permanently removed or access permanently denied to all parties

NOTE This may not necessarily involve physical removal from the device, but may merely be the result of altering security such that access is permanently denied to all parties.

#### 3.8

##### **healthcard holder**

individual transporting a healthcare data card which contains a record with the individual identified as the major record person



**3.9****healthcare data card**

machine-readable card, conformant to ISO/IEC 7810, intended for use within the healthcare domain

**3.10****major industry identifier****MII**

code that identifies the sector/industry within which the data card is intended for use

NOTE The designated MII for healthcare is 80.

**3.11****major record identifier**

identifier linked to a primary record relating to a record person in a data card and a given healthcare delivery system

**3.12****record**

collection of data

**3.13****record person**

individual about whom there is an identifiable record containing person-related data

**3.14****security**

combination of confidentiality, integrity and availability

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**4 Symbols and abbreviated terms**

ASN.1	Abstract syntax notation, version 1 <small><a href="https://standards.iteh.ai/catalog/standards/sist/98420887-76bc-44bb-899a-50dd6cc2fb2/iso-21549-2-2004">https://standards.iteh.ai/catalog/standards/sist/98420887-76bc-44bb-899a-50dd6cc2fb2/iso-21549-2-2004</a></small>
EN	European Standard
HCP	Healthcare person
ICC	Integrated-circuit card
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MII	Major industry identifier
UML	Unified modelling language
UTC	Coordinated universal time

**5 Basic data object model for a healthcare data card — Patient healthcard data object structure**

A set of basic data objects has been designed to facilitate the storage of clinical data in a flexible structure, allowing for future application-specific enhancements. These tools should help the implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many types of data card.

The tools consist of a generic data structure based on an object-oriented model represented as a UML class diagram as shown below in Figure 1.

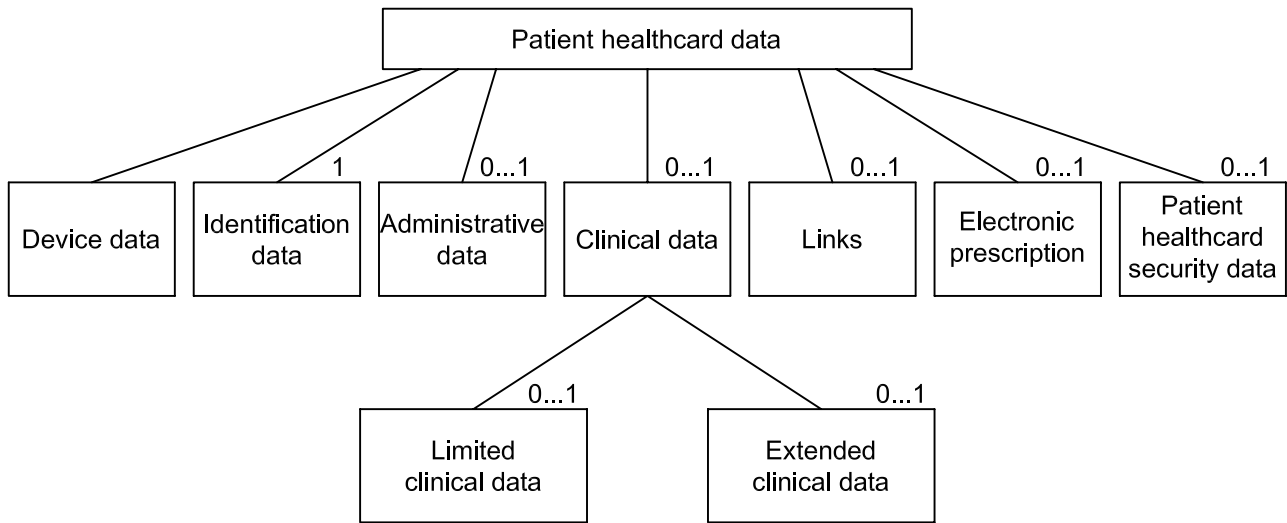


Figure 1 — Patient healthcard data — Overall structure

The content of this object-oriented structure is described below and intrinsically will also require the use of data objects not defined in this part of ISO 21549.

NOTE 1 This part of ISO 21549 is solely applicable to patient healthcards containing health data. Data objects containing financial and healthcare reimbursement data are not defined in this International Standard.

NOTE 2 It is possible to take the data objects and recombine them whilst preserving their context-specific tags, and to define new objects while still preserving interoperability.

In addition to the capability of building complex aggregate data objects from simpler building blocks, this International Standard allows associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

## 6 Basic data objects for referencing

### 6.1 Overview

A series of generally useful data type definitions have been made that have no intrinsic value in themselves, but which are used to define other objects in this multi-part standard. Operations may be performed with these objects in association with other information objects to “add value”.

### 6.2 Internal links

#### 6.2.1 General

A number of objects in the data model of this part of ISO 21549 are used mainly as a reference to other objects. One example is the RecordPerson data object that defines the basic identification information of a person to whom records on the device relate. Since this is a part of an aggregate object containing information on all record persons in a sequential order, the pointer may be a simple one-dimensional integer number. This type of pointer has the name RecPersPointer and is used extensively to indicate the record person to whom a certain information object is related.

NOTE This internal link RecPersPointer is especially useful where the healthcard contains records in relation to more than one identifiable individual.

In other situations, constructed objects contain a more general pointer called a RefPointer that is a sequence of tags allowing a reference to any object, including sub-objects that can only be referenced as part of a constructed object, using an application-specific tag and a number of context-specific tags to sufficient depth.

A RefPointer to the name of a healthcare person may contain the following information with the appropriate tags (here represented by their symbolic names):

HealthCarePersons	[7] HealthCarePerson No. 7	[1] HcpName
<i>Application tag</i>	<i>Context level 1</i>	<i>Context level 2</i>

There is also a third possibility that allows the creation of linkages between all objects using the *Linkages* object 5. This is an ordered list of link associations. All entries in this list are a sequential list of other objects, each defined with a RefPointer.

EXAMPLE Link No. 2 may link four objects:

- 1
- 2 RefPointer1 RefPointer2 RefPointer3 RefPointer4
- 3

An example of this process could be the linkage of the following objects as utilized in a patient data card containing clinical data:

Diagnosis	RefPointer1 <a href="http://standards.iteh.ai/standards/ISO-21549-2-2004">ISO 21549-2:2004</a>
MedicationPrescription	RefPointer2 <a href="http://standards.iteh.ai/standards/sist/98420887-76bc-44bb-899a-50ddb6ec2fb2/iso-21549-2-2004">http://standards.iteh.ai/standards/sist/98420887-76bc-44bb-899a-50ddb6ec2fb2/iso-21549-2-2004</a>
MedicationNote	RefPointer3
MedicationDispensed	RefPointer4

This linkage table entry may be pointed to by the ClinRefPointer of each ClinDat object.

NOTE Even though the “Links” object itself is openly available, the linked objects may have restricted access.

The following reference objects may be associated with other information objects defined. This relation is not an aggregation. The reference object is not a part of the information object but stays independent and may be referenced by several objects. The concept used in this part of ISO 21549 is to reference (point at) the appropriate record person as well as a healthcare provider and relevant accessory attributes. These linkages add value to the data and may be used to provide context specificity.

## 6.2.2 The “Links” data object

The “Links” object is used to create internal references or linkages between any other defined data objects stored in the healthcard. It shall be constructed as a sequence of “Link” sub-objects. The data object “Link” shall consist of a sequence of references to other objects in the form of a sequence of “RefPointer” objects. This is pointed to by a “LinkagePointer” object.