INTERNATIONAL STANDARD

**ISO 21549-4**

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# Health informatics — Patient healthcard data —

## Part 4: Extended clinical data

*Informatique de santé — Données relatives aux cartes de santé des patients —*

*Partie 4: Données cliniques élargies*



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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 21549-4 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)*

# 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 record files, 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.

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 in three broad types: i) identification (of the device itself and the individual to whom the data it caries relates), ii) administrative and iii) 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, clinical, medication and linkage 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(s) related data;
- 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 provider (HCP);
- related actions planned requested or performed.

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

This part of ISO 21549 describes and defines the Extended Clinical Data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1)[13].

This part of ISO 21549 does not describe and define the common objects defined in ISO 21549-2, even though they are referenced and utilized within this document.

# Health informatics — Patient healthcard data —

# Part 4: Extended clinical data

## 1 Scope

This part of ISO 21549 is applicable to situations in which such data are recorded on or transported by patient healthcare data cards compliant with the physical dimensions of ID-1 cards defined by ISO 7810.

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

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with ISO 21549, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in Clauses 6 and 7. These shall then be used in conjunction with other data defined in other parts of ISO 21549.



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 according to 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 cards;
- how the message is processed further “downstream” of the interface between two systems;
- the form which data takes 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.

ISO/IEC 7810:2003, *Identification cards — Physical characteristics*

ISO 21549-2:2004-05, *Health informatics — Patient healthcard data — Part 2: Common objects*

ISO 21549-3:2004-05, *Health informatics — Patient healthcard data — Part 3: Limited clinical data*

## 3 Terms and definitions

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

**3.1**
**clinical information**
information about a subject of care, relevant to the health or treatment of that subject of care, which is recorded by or on behalf of a healthcare professional

NOTE 1 Clinical data/information are/is related to the health and healthcare of an individual, collected from or about an individual receiving healthcare services. It includes a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medication prescribed; description of responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health. [ASTM E1769, CPRI]



NOTE 2 Clinical information about a subject of care may include information about the subject of care's environment or about related people where this is relevant.



[EN 14720-1]

**3.2**
**data object**
collection of data, which has a natural grouping and may be identified as a complete entity

**3.3**
**healthcard holder**
individual transporting a healthcare data card that contains a record with the individual identified as the major record person

**3.4**
**healthcare data card**
machine-readable card, conformant to ISO 7810, intended for use within the healthcare domain

**3.5**
**healthcare party**
organization or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE Healthcare parties are a subset of healthcare agents.

[EN 14720-1]

**3.6**
**linkage**
ability to join together two or more entities or parts

NOTE It may be physical, electrical or relational.

**3.7**
**record**
collection of data

**3.8**
**record person**
individual about whom there is an identifiable record containing person-related data

**3.9**
**relaying agent**
party agreed to be acting as an intermediary, communicating messages between the requesting and requested healthcare parties in both directions when direct communication is not possible as the requested healthcare party's identity is not known, being dependent on individual patient's choice

## 4 Symbols and abbreviated terms

ASN.1 Abstract Syntax Notation version 1

EN European Norm

HCP Healthcare person

HDC Healthcare data card

IEC International Electrotechnical Commission

ISO International Organization for Standardization

UML Unified Modelling Language

UTC Coordinated Universal Time



## 5 Basic data object model for a healthcare data card

### 5.1 Patient HDC 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 cards.

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.

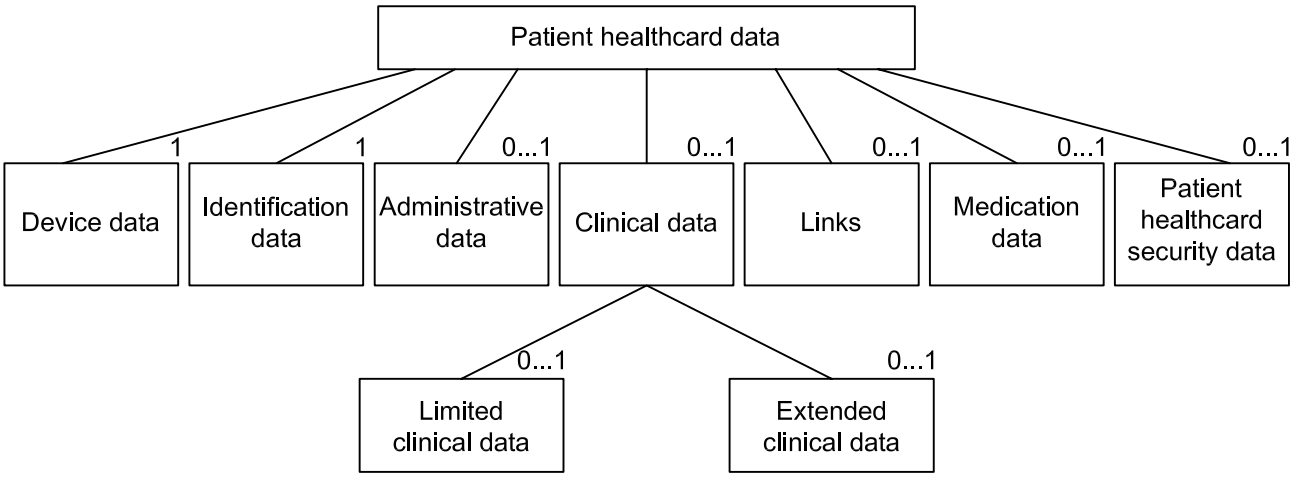


**Figure 1 — Patient healthcard data — overall structure**

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

NOTE 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 part of ISO 21549 allows for 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.



## 5.2 Basic data objects for referencing

### 5.2.1 Overview

A series has been made of generally useful data type definitions that have no intrinsic value in themselves, but which are used to define other objects within this part of ISO 21549. Operations may be performed with these objects in association with other information objects to “add value”. These objects have formal definitions in ISO 21549-2.

### 5.2.2 Coded data

Coded values are understood by reference to the coding scheme to which they apply. The general principle in this part of ISO 21549 is that it is not mandatory to use a particular coding scheme, unless specified within this part of ISO 21549, when such codes act as parameters. One example is the use of ISO 3166-1 for country codes.

When a coding scheme is exclusively specified within this part of ISO 21549 no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may, however, be modified in the future independent of the rest of this part of ISO 21549.

The data object “CodedData” shall be constructed according to the definition contained in ISO 21549-2.

### 5.2.3 Device and data security attributes

Data stored in data cards used in health care may be personally sensitive. For this reason this part of ISO 21549 utilises a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this part of ISO 21549, nor are the mechanisms that make use of these data elements.

It is emphasised that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the data card.

Such rights of “access” are attributable to specific individuals with respect to discrete data items. These rights will be defined by application developers and can be controlled by automated systems such as health care professional cards. The rights may be defined at the application level, thereby providing application and potential country specificity.

The “SecurityServices” data object provides for the storage of data required to deliver these security functions and mechanisms. This data can be “attached” to individual data elements, thereby preserving the original author's security requirements when the data object is transferred between different forms of data card. This mechanism may therefore ensure that in the process of transferring data from active to passive media and then back to active media, the original security requirements are re-generated. This ability also allows exact replication of a data card such as on regeneration after failure.

#### 5.2.4 Accessory attributes

The data object “AccessoryAttributes” shall consist of an ordered set of data that are essential to record an audit trail regarding both the originator of the information and the means via which it arrives to the recipient as defined in ISO 21549-2.

## 6 Functional requirements on card information for extended clinical data

### 6.1 Overview of supported uses



The major consideration in this part of ISO 21549 is for HDC:

- to carry clinical messages (orders, referrals and reports) between the loosely coupled healthcare parties (i.e. parties that aren’t able to establish network connections or do not yet have third trusted party);
- to carry the links and access keys to clinical messages between the tightly coupled healthcare parties (i.e. parties that are able to establish network connection and have third trusted party);
- to carry coded summaries of diagnosis and procedures extending limited clinical data set described in ISO 21549-3. These summaries may be considered as the national or even institutional extensions of limited clinical data.



### 6.2 Clinical message transfer between healthcare parties

HDC designed to transfer clinical messages between healthcare parties shall be considered as a secure data media for a relaying agent. Such HDC may receive clinical messages without a predefined target healthcare party and may also play a role in authenticating the eligibility of the healthcare party to retrieve these clinical data.

## 7 Extended Clinical Data

### 7.1 General

The Extended Clinical Data object is specifically divided into three separate data objects, index of clinical events (class *ClinicalEventDescription*), sequence of mapped clinical messages (class *MappedClinicalMessage*) and extended emergency data (class *ExtendedEmergencyData*). Because of their groupings, each of these can have differing security settings, including access rights as determined by the provisions contained within accessory attributes (class *AccessoryAttributes*).

See Figure 2 and Table 1.