
**Health informatics — Patient
healthcard data —**

**Part 4:
Extended clinical data**

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

iTeh STANDARD PREVIEW
Partie 4: Données cliniques étendues
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 21549-4:2006), which has undergone a minor revision. The following changes have been made:

- Foreword: mention of CEN collaboration is removed.
- Scope: first paragraph is reworded.
- Scope: requirements “shall” are replaced by “are” in the third paragraph.
- Normative references: references that are not cited normatively are moved to the Bibliography.
- Terms and definitions, [subclause 3.1](#): the second sentence is removed.
- [Clause 5](#): paragraph after [Figure 1](#) is reworded.
- [Clause 7](#): references to figures and tables are added; the class ExtendedEmergencyData is moved to Part 3.
- [Annexes B](#) and [C](#): requirements “shall” are replaced by “should”.
- [Annex B, subclause B.2](#): syntax errors are corrected.
- Bibliography: created to list all the documents cited that are not in the normative references.

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: Medication data*
- *Part 8: Links*

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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, 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.

The advent of remotely accessible databases 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 standardised data format for interchange.

The person related data carried by a data card can be categorised in 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, clinical, medication and linkage data.

Device data are 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 while 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).

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

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Health informatics — Patient healthcard data —

Part 4: Extended clinical data

1 Scope

This part of ISO 21549 is applicable to situations in which clinical data additional to the limited clinical data defined in ISO 21549-3 is recorded on or transported by patient healthcare data cards compliant with the physical dimensions of ID-1 cards defined by ISO/IEC 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 this part of ISO 21549, data items required for that application are drawn from the list of objects (some of which are extensible) as provided in [Clause 5](#). These are used in conjunction with other data defined in other parts of this International Standard.

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 elsewhere specified).

- 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 initialisation 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21549-1, *Health informatics — Patient healthcard data — Part 1: General structure*

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

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

3 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 21549-1, ISO 21549-2, ISO 21549-3 and the following apply.

3.1 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

[SOURCE: ENV 1613]

3.5 healthcare party

organization or person responsible for the direct or indirect provision of healthcare to an individual, or involved in the provision of healthcare-related services

[SOURCE: ENV 1613]

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

[SOURCE: ENV 13607]

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4 Symbols and abbreviated terms

ASN.1	Abstract Syntax Notation version 1	ISO 21549-4:2014
HCP	Healthcare Person	https://standards.iteh.ai/catalog/standards/sist/5e91a4b8-95f2-4425-a31c-e7ec01baecb0/iso-21549-4-2014
HDC	Healthcare Data Card	
UML	Unified Modelling Language	
UTC	Universal Time Coordinated	

5 Basic data object model for a healthcare data card

5.1 Patient HDC data object structure

A set of basic data objects have 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 an UML class diagram as shown below in [Figure 1](#).

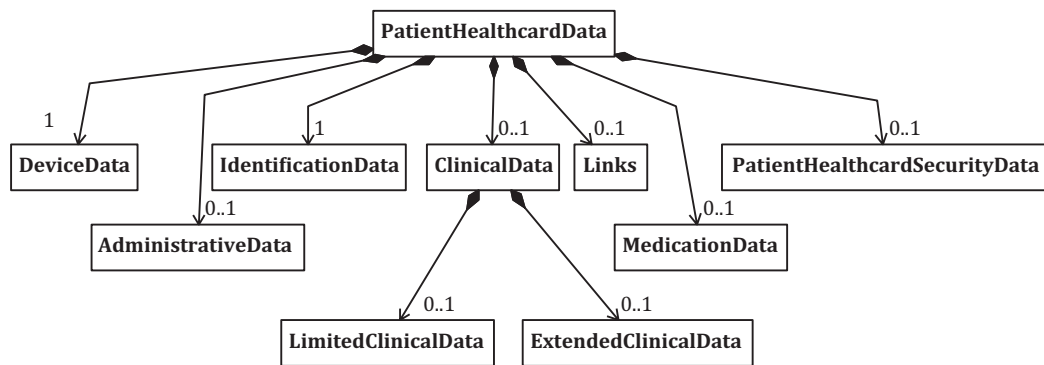


Figure 1 — Patient healthcard data: overall structure

The content of this object-oriented structure described in [Clause 7](#) and [Annex A](#) 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 while 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 of generally useful data type definitions have been made 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 within 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 International Standard.

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 utilizes 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 emphasized that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the data card.

Such access privileges are attributable to specific individuals with respect to discrete data items. These privileges will be defined by application developers and can be controlled by automated systems such as