
**Health informatics — Patient
healthcard data —**

**Part 2:
Common objects**

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

Partie 2: Objets communs

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 (see 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 (see 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.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

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

This second edition cancels and replaces the first edition (ISO 21549-2:2004), which has undergone a minor revision. The following changes have been made.

- Foreword: mention of CEN collaboration is removed.
- Scope: first paragraph is reworded.
- Normative references: references that are not cited normatively are moved to the Bibliography.
- Terms and definitions: unused terms are removed.
- Symbols and abbreviated terms: unused abbreviated terms are removed.
- [Subclause 6.3.2](#), [Table 2](#): data type of codeIdentifier is corrected to match ASN.1 definition.
- [Clauses 5](#), [6](#), and [7](#): the figures and tables are renumbered sequentially, references to the figures and tables are added.
- Bibliography: dates from the references are removed where not applicable.

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

This part of ISO 21549 provides data structures and definitions for limited clinical data for use within patient-held healthcare data cards.

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. 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 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, prescription 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;
- 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 labeling 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 Modeling 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 within 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 data held on patient healthcare data cards. It is also applicable to common objects referenced by other data objects.

This part of ISO 21549 is applicable to situations in which such data is recorded on or transported by patient healthcards 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, 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 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 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 is 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 21090:2011, *Health informatics — Harmonized data types for information interchange*

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 1 to entry: This may not necessarily be the same as the nationality of the device holder.

3.2

data integrity

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

[SOURCE: 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 themselves identified as the major record person

3.6

entity authentication

corroboration that an entity is the one claimed

[SOURCE: ISO/IEC 9798-1:2010]

3.7

erasure

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

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Note 1 to entry: This may not involve physical removal from the device and 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 themselves identified as the major record person

3.9

healthcare data card

machine readable card conformant to ISO/IEC 7816 intended for use within the healthcare domain

3.10

record

collection of data

3.11

record person

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

3.12

security

combination of confidentiality, integrity and availability