
**Health informatics — Patient
healthcard data —**

**Part 3:
Limited clinical data**

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

Partie 3: Données cliniques limitées



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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 21549-3:2004), which has undergone a minor revision. The following changes have been made.

- Foreword: mention of CEN collaboration is removed.
- Scope: first line is reworded.
- Normative references: references that are not cited normatively are moved to the Bibliography.
- [Clause 5](#): paragraph after [Figure 1](#) is reworded.
- [Subclause 7.1](#): last sentence before [Figure 2](#) is reworded.
- [Clauses 6](#), and [7](#): the figures are renumbered sequentially and references to figures and tables are added.
- [Clause 7](#): the class `ExtendedEmergencyData` is moved from Part 4 to Part 3.
- 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

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 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 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 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;
- 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 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 Limited 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 3: Limited clinical data

1 Scope

This part of ISO 21549 is applicable to situations in which limited clinical data are 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 describes and defines the limited clinical data objects used in or referenced by patient healthcards using UML, plain text and abstract syntax notation (ASN.1).

This part of ISO 21549 specifies the basic structure of the data contained within the data object limited clinical data, but does not specify or mandate particular data sets for storage on devices. In particular the data contained within the data objects in limited clinical data are intended to aid the delivery of emergency care, while being by themselves neither intended, nor fit for purpose, for the total of information provision for the delivery of emergency care.

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*

3 Terms and definitions

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

3.1 confidentiality

property that information is not made available or disclosed to unauthorized individuals, entities or processes

[SOURCE: ISO 7498-2:1989, definition 3.3.16]

3.2 data origin authentication

corroboration that the source of data received is as claimed

[SOURCE: ISO 7498-2:1989, definition 3.3.22]

3.3 linkage

ability to join together two or more entities or parts. It may be physical, electrical or relational

4 Symbols and abbreviated terms

ASN.1 Abstract Syntax Notation version 1

HCP healthcare person

UML Unified Modelling Language

UTC Universal Time Coordinated

5 Basic data object model for a healthcare data card - Patient healthcard 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 in [Figure 1](#).

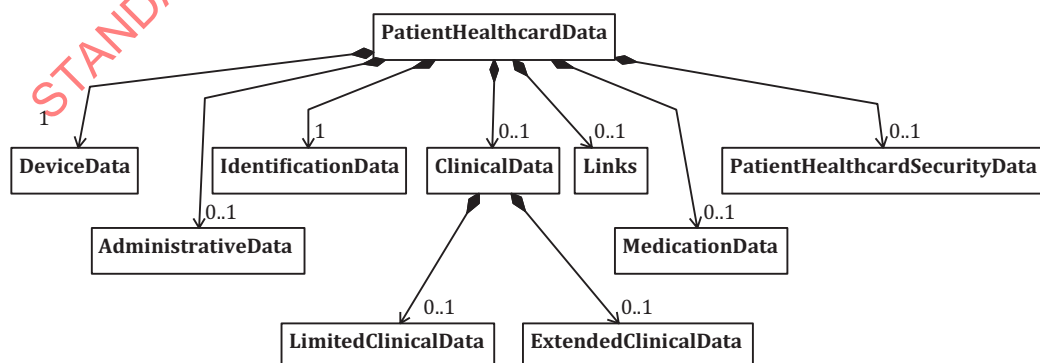


Figure 1 — Patient healthcard data: overall structure

The content of the object LimitedClinicalData are described in [Clauses 6](#) and [7](#). It 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.

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 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.

6.2 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.

6.3 Device and data security attributes

Data stored in data cards used in healthcare 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 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 healthcare professional cards. The rights may be defined at the application level thereby providing application and potential country specificity.

The data object SecurityServices 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 regenerated. This ability also allows exact replication of a data card such as on regeneration after failure.

6.4 Accessory attributes

The data object AccessoryAttributes shall consist of an ordered set of data that is 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.

7 Limited clinical data

7.1 General

The object LimitedClinicalData are specifically divided into four separate data objects, a limited emergency data set, a blood grouping and transfusion record data set, an immunisations received data set and an extended emergency data set. Because of their groupings each of these can have differing security settings including access privileges as determined by the provisions contained within accessory attributes. [Figure 2](#) and [Table 1](#) define the object LimitedClinicalData. The object ExtendedEmergencyData may appear in the object ExtendedClinicalData on the healthcard compliant to ISO 21549-3:2013.

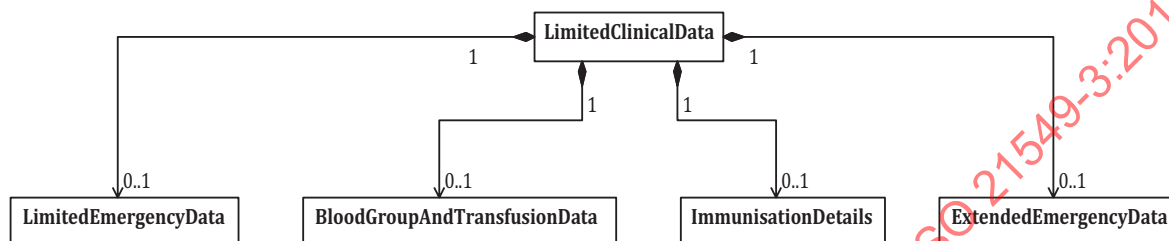


Figure 2 — Structure of LimitedClinicalData

Table 1 — Specification of individual entities within the object LimitedClinicalData

Object name	Data Type	Multiplicity	Comments
LimitedEmergencyData	Class	0..1	This class holds the emergency medical record of the record person.
BloodGroupingAndTransfusionData	Class	0..1	This class holds the blood group and records appertaining to any blood products received by the record person.
ImmunisationDetails	Class	0..1	This class holds the immunization records in relation to the record person.
ExtendedEmergencyData	Class	0..1	This class holds the national or regional extension of limited emergency data.

7.2 The limited emergency data set

An object LimitedEmergencyData shall consist of a set of data consisting of the object EmergencyDataBitMap, a sequence of booleans, within which the status “true” shall indicate the presence of the condition in the record person, or in the case of a medication that the record person may be taking this medication, plus the optional element AccessoryAttributes. This object is intended to convey the majority of the fixed clinical data set defined within the draft International emergency health record in addition to data normally communicated by patient carried warning cards and “Medic Alert” tokens. [Figure 3](#) and [Table 2](#) define the object LimitedEmergencyData.

LimitedEmergencyData
+emergencyDataBitMap : EmergencyDataBitMap [1]
+accessoryAttributes : AccessoryAttributes [0..1]

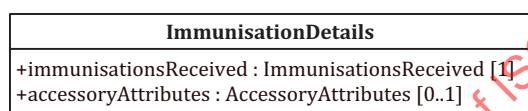
Figure 3 — Structure of LimitedEmergencyData

Table 2 — Specification of individual entities within the object LimitedEmergencyData

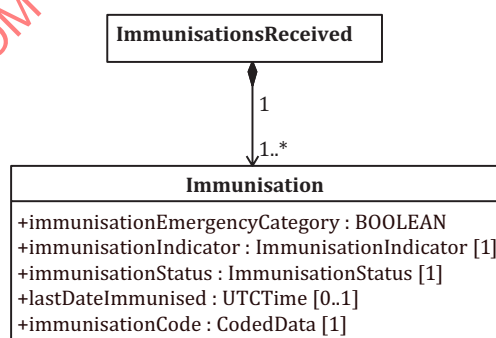
Object name	Data Type	Multiplicity	Comments
emergencyDataBitMap	EmergencyDataBitMap	1	Sequence of Booleans.
accessoryAttributes	AccessoryAttributes	0..1	An object that incorporates data that determines authentication and authorization in particular.

7.3 Immunization details

The immunization record contained within Immunization Details is intended to provide a record of immunisations received by the record person and is deliberately separate from other coded clinical data in order that it can be attributed differing security status. It is normal practice that this type of information would be accorded the same level of security status as the Limited Emergency Data. [Figure 4](#) and [Table 3](#) define the object ImmunisationDetails. [Figure 5](#) and [Tables 4](#) and [5](#) define the objects ImmunisationsReceived and Immunization.

**Figure 4 — Structure of ImmunisationDetails****Table 3 — Specification of individual entities within the object ImmunisationDetails**

Object name	Data Type	Multiplicity	Comments
immunisationsReceived	ImmunisationsReceived	1	A list of the Immunisations received.
accessoryAttributes	AccessoryAttributes	0..1	An object that incorporates data that determines authentication and authorization in particular.

**Figure 5 — Structure of ImmunisationsReceived****Table 4 — Specification of individual entities within the object ImmunisationsReceived**

Object name	Data Type	Multiplicity	Comments
Immunization	Class	1..*	Immunization received.

Table 5 — Specification of individual entities within the object Immunization

Object name	Data Type	Multiplicity	Comments
immunisationEmergencyCategory	BOOLEAN		
immunisationIndicator	ImmunisationIndicator	1	Never(0), One or more(1), Unknown(2), Adverse reaction(3).
immunisationStatus	ImmunisationStatus	1	Unspecified(0), First dose(1), Second dose(2), Third dose(3), Completed course(4), Booster(5).
lastDateImmunised	UTCTime	0..1	
immunisationCode	CodedData	1	The actual coded data meaning of the immunization.

7.4 Blood grouping and transfusion record

The blood group and transfusion record is intended to be a separate data object from the rest of the patient data set in order that it can be attributed differing security privileges in the same fashion as the Emergency and Immunization record. It is intended to record, where known, the record person's blood group and carry data regarding any blood products they may have received. [Figure 6](#) and [Table 6](#) define the object BloodGroupingAndTransfusionData. [Figure 7](#) and [Table 7](#) define the object BloodGrouping. [Figure 8](#) and [Table 8](#) define the object BloodTransfusionData.

BloodGroupingAndTransfusionData
+bloodGrouping : BloodGrouping [0..1] +bloodTransfusionData : BloodTransfusionData [0..1] +accessoryAttributes : AccessoryAttributes [0..1]

Figure 6 — Structure of BloodGroupingAndTransfusionData**Table 6 — Specification of individual entities within the object BloodGroupingAndTransfusionData**

Object name	Data Type	Multiplicity	Comments
bloodGrouping	BloodGrouping	0..1	Holds data on Blood Group of Record Person.
bloodTransfusion Data	BloodTransfusion Data	0..1	Holds data on blood products received by Record Person.
accessoryAttributes	AccessoryAttributes	0..1	An object that incorporates data that determines authentication and authorization in particular.

BloodGrouping
+bloodGroup : BloodGroup [1] +rhesusFactor : RhesusFactor [1] +dateLastBloodGrouping : UTCTime [1] +bloodGroupFreeText : OCTET STRING (SIZE(1..30)) [0..1]

Figure 7 — Structure of BloodGrouping

Table 7 — Specification of individual entities within the object BloodGrouping

Object name	Data Type	Multiplicity	Comments
bloodGroup	BloodGroup	1	Contains data recording the blood group.
rhesusFactor	RhesusFactor	1	Contains data recording the rhesus factor.
dateLastBloodGrouping	UTCTime	0..1	Contains the date of the last blood grouping.
bloodGroupFreeText	OCTET STRING (SIZE(1..30))	0..1	Allows free text entry describing blood grouping.

BloodTransfusionData
+bloodTransfusionIndicator : BloodTransfusionIndicator [1] +lastBloodTransfusionDate : UTCTime [0..1] +bloodProductGiven : CodedData [0..1]

Figure 8 — Structure of BloodTransfusionData**Table 8 — Specification of individual entities within the object BloodTransfusionData**

Object name	Data Type	Multiplicity	Comments
bloodTransfusionIndicator	BloodTransfusionIndicator	1	0 = Never, 1 = Once, 2 = More than once.
lastBloodTransfusionDate	UTCTime	0..1	Contains the recorded date of the last blood transfusion.
bloodProductGiven	CodedData	0..1	Records the type of blood product given using the structure of Coded Data.

7.5 The extended emergency data set

An optional object ExtendedEmergencyData shall carry information supplemental to the object LimitedEmergencyData. This information contains coded clinical data that may be needed in an emergency. This object may be used as a national or regional extension of limited emergency data. [Figure 9](#) and [Table 9](#) define the object ExtendedEmergencyData. [Table 10](#) defines the object EmergencyItem.

ExtendedEmergencyData
+emergencyItems : EmergencyItem [1..*] +accessoryAttributes : AccessoryAttributes [0..1]

Figure 9 — Structure of ExtendedEmergencyData

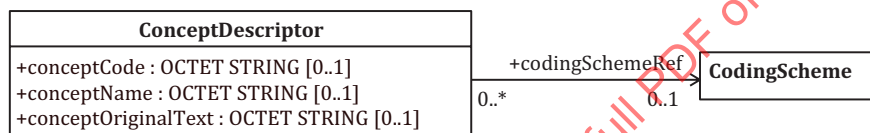
Table 9 — Specification of individual entities within the object ExtendedEmergencyData

Object name	Data Type	Multiplicity	Comments
emergencyItems	EmergencyItem	1..*	This is a list of the coded descriptors of procedures, patient problems or diagnoses.
accessoryAttributes	AccessoryAttributes	0..1	An object that incorporates data that determines authentication and authorization in particular.

Table 10 — The specification of individual entities within the object EmergencyItem

Object name	Data Type	Multiplicity	Comments
emergencyItem	ConceptDescriptor	1	This is a coded descriptor of procedure, patient problem or diagnose.
onsetDateTime	UTCTime	0..1	This is date and time of procedure, patient problem or diagnose.

An object ConceptDescriptor describes an emergency item. The definition of this object is derived from the definition of the data type CD.CV in ISO 21090. [Figure 10](#) and [Table 11](#) define the object ConceptDescriptor.

**Figure 10 — Structure of ConceptDescriptor****Table 11 — Specification of individual entities within the object ConceptDescriptor**

Object name	Data Type	Multiplicity	Comments
conceptCode	OCTET STRING	0..1	This is a concept code
conceptName	OCTET STRING	0..1	This is a concept name
conceptOriginalText	OCTET STRING	0..1	This is an original text used for coding