

Secretariat: ANSI

**Health informatics — Patient healthcard data — Part 5: Identification data**

iTech STANDARD PREVIEW

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ISO/FDIS 21549-5

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*A model manuscript of a draft International Standard (known as "The Rice Model") is available at*



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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~~document 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](http://www.iso.org/directives)).

~~Attention is drawn~~ISO draws attention to the possibility that ~~some of the~~elements~~implementation~~ of this document may ~~be involve~~the subject of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). 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 -).~~

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Medical informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 21549-5:2015), of which ~~has been~~ technically revised.

it constitutes a minor revision. The ~~main~~ changes are as follows:

- ~~updated~~ normative references have been updated;
- errors have been corrected ~~errors~~ in Annex A.

A list of all parts in the ISO 21549 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## 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 funding institutions and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems. Administrative data objects may can require linkage to external parties responsible for their own domains which are not within the scope of this ~~part of ISO 21549 document~~. For instance, cross-border reimbursement of healthcare services are usually regulated by law and intergovernmental agreements which are not subject to standardization.

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 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" contains 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 are defined to include:

- unique identification of the device holder (and not information of other persons).

Administrative data can 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;
- identification of other persons as a part of the insurance contract (e.g. a family contract);
- 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;

— related actions planned requested or performed.

Medication data ~~may~~can include:

— a record of medications received or taken by the patient;

— copies of prescriptions including the authority to dispense records of dispensed medication;

— records of medication bought by the patient;

— pointers to other systems that contain information that makes up an electronic prescription and the authority to dispense.

~~Because~~As 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~~modelling technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

This ~~part of ISO 21549~~document describes and defines the basic structure of the identification data objects held on healthcare data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

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

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# Health informatics — Patient healthcard — Part 5: Identification data)

## 1 Scope

This ~~part of ISO 21549 document~~ describes and defines the basic structure of the identification data objects held on healthcare data cards, but ~~it~~ does not specify particular data sets for storage on devices.

~~This document does not apply to~~ 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):

- ~~— security functions and related services that are likely to be specified by users for data cards depending on their specific application, e.g. confidentiality protection, data integrity protection and authentication of persons and devices related to these functions;~~
- ~~— access control services;~~
- ~~— 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 document).~~

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

- ~~— physical or logical solutions for the practical functioning of particular types of data card;~~
- ~~— the forms that 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3166-1, IEC 5218, Information technology — Codes for the representation of names of countries and their subdivisions — Part 1: Country codes~~  
~~human sexes~~

~~ISO 8601, Date and time — Representations for information interchange — Part 1: Basic rules~~

~~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/IEC 5218, Information technology — Codes for the representation of human sexes~~

~~ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation~~

~~ISO/IEC 8825-1, Information technology — ASN.1 encoding rules — Part 1: Specification of Basic Encoding Rules (BER), Canonical Encoding Rules (CER) and Distinguished Encoding Rules (DER)~~

~~ISO/IEC 10646, Information technology — Universal Coded Character Set (UCS)~~

## 8.3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1 identification data

data that provide for the unique identification of the cardholder to whom the records relate

~~[SOURCE: ISO 21549-1, modified — shortened]text of the definition~~

## 10.4 Symbols and abbreviated terms

~~ASN.1 — Abstract Syntax Notation One~~

~~CRT — Cardholder Related Template~~

~~ICAO — International Civil Aviation Organization~~

~~L — Length (ASN.1)~~

~~LDS — Logical Data Structure of machine-readable travel documents~~

~~N — Numeric~~

~~NET — National Extensions Template~~

~~UCS — Universal Multiple-Octet Coded Character Set~~

~~UML — Unified Modelling Language~~

~~UTF8 — UCS Transformation Format 8~~

ASN.1    Abstract syntax notation one

CRT    Cardholder related template

ICAO    International civil aviation organization

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