SLOVENSKI STANDARD
oSIST prEN ISO 21549-5:2023

01-julij-2023

Zdravstvena informatika - Podatki o pacientu na zdravstveni kartici - 5. del: Identifikacijski podatki (ISO/FDIS 21549-5:2023)

Health informatics - Patient healthcard data - Part 5: Identification data (ISO/FDIS 21549 -5:2023)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 5: Identifikationsdaten (ISO/FDIS 21549-5:2023)

Informatique de santé - Données relatives aux cartes de santé des patients Partie 5: Données d'identification (ISO/FDIS 21549-5:2023)

Ta slovenski standard je istoveten z: **prEN ISO 21549-5**

ICS:

35.240.15	Identifikacijske kartice. Čipne kartice. Biometrija	Identification cards. Chip cards. Biometrics
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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FINAL DRAFT

INTERNATIONAL STANDARD

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ISO/TC **215**

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Health informatics — Patient healthcard data —

Part 5:
Identification data

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

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Foreword

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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 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).

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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.

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

— normative references have been updated;

— errors have been corrected 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.

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 can require linkage to external parties responsible for their own domains which are not within the scope of this 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.

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Medication data 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.

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

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

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Health informatics — Patient healthcard data —

Part 5:
Identification data

1 Scope

This 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 (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 document).

The following topics are therefore beyond the scope of this 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/IEC 5218, *Information technology — Codes for the representation of human sexes*

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

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 <u>https://www.iso.org/obp</u>

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

3.1
identification data
data that provide for the unique identification of the cardholder to whom the records relate

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

5 Identification data objects

5.1 Identification objects and data structure

For the identification of the cardholder, information about the following objects is needed:

— person;

— address;

— telephone;

— miscellaneous.

The structure of the identification information is derived from the LDS set used for machine-readable travel documents (see ISO/IEC 7501-1). No separate objects are introduced for healthcare. The following paragraph contains the table with the definitions of the identification data set.

5.2 Definition of the identification data set

Table 1 shows the definition of identification data according to the ASN.1 basic notation and basic encoding described in ISO/IEC 8824-1 and ISO/IEC 8825-1, respectively. The corresponding ASN.1 definition is given in Annex A. In the ASN.1 definition the ASN.1 data type UTF8String (see ISO/IEC 10646) is used for the coding of alphanumeric data elements. Since the UTF8 encoding uses 1 to 6 bytes for each character, the number of storage bytes which should be provided by the card may be greater than the denoted length in characters. The use of UTF8 should be restricted to a limited international character set, since it does not make sense to provide each country with any unfamiliar character set of another country. The formation of this international character set as a subset of the UCS has to be discussed. Figure 1 shows the UML class diagram. Figure 2 shows the CRT Template of Identification data with an embedded NET.

In case of discrepancies between the definitions and the module in Annex A, Annex A shall takes precedence.