SLOVENSKI STANDARD
SIST EN ISO 21549-4:2014

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Nadomešča:
SIST EN ISO 21549-4:2007

Zdravstvena informatika - Podatki o pacientu na zdravstveni kartici - 4. del: Razširjeni klinični podatki (ISO 21549-4:2014)

Health informatics - Patient healthcard data - Part 4: Extended clinical data (ISO 21549-4:2014)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 4: Erweiterter Datensatz der klinischen Daten (ISO 21549-4:2014)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 4: Données cliniques étendues (ISO 21549-4:2014)

Ta slovenski standard je istoveten z: **EN ISO 21549-4:2014**

ICS:

35.240.15	Identifikacijske kartice in sorodne naprave	Identification cards and related devices
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 21549-4:2014 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21549-4

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ICS 35.240.80

Supersedes EN ISO 21549-4:2006

English Version

Health informatics - Patient healthcard data - Part 4: Extended clinical data (ISO 21549-4:2014)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 4: Données cliniques étendues (ISO 21549-4:2014)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 21549-4:2014) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2014, and conflicting national standards shall be withdrawn at the latest by August 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21549-4:2006.

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Endorsement notice

The text of ISO 21549-4:2014 has been approved by CEN as EN ISO 21549-4:2014 without any modification.

INTERNATIONAL STANDARD

ISO 21549-4

Second edition
2014-02-15

Health informatics — Patient healthcard data —

Part 4: Extended clinical data

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

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

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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*

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 caries 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).

