

STN	Zdravotnícka informatika Údaje na zdravotnej karte pacienta Časť 7: Údaje o liečbe (ISO 21549-7: 2016)	STN EN ISO 21549-7 84 8018
------------	---	--

Health informatics - Patient healthcard data - Part 7: Medication data (ISO 21549-7:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/17

Obsahuje: EN ISO 21549-7:2016, ISO 21549-7:2016

Oznámením tejto normy sa ruší
STN EN ISO 21549-7 (84 8018) z decembra 2007

124915

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 21549-7

December 2016

ICS 35.240.80

Supersedes EN ISO 21549-7:2007

English Version

**Health informatics - Patient healthcard data - Part 7:
Medication data (ISO 21549-7:2016)**

Informatique de santé - Données relatives aux cartes
de santé des patients - Partie 7: Données de médication
(ISO 21549-7:2016)

Medizinische Informatik - Patientendaten auf Karten
im Gesundheitswesen - Teil 7: Medikationsdaten (ISO
21549-7:2016)

This European Standard was approved by CEN on 12 December 2016.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 21549-7:2016) 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 June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.

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 21549-7:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21549-7:2016 has been approved by CEN as EN ISO 21549-7:2016 without any modification.

Health informatics — Patient healthcard data —

Part 7: Medication data

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

Partie 7: Données de médication



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Abbreviated terms	5
5 Basic data object model for a healthcare data card	6
5.1 Patient healthcard data object structure	6
5.2 Basic data objects for referencing	6
5.2.1 Overview	6
5.2.2 Coded data	6
5.3 Device and data security attributes	7
5.4 Accessory attributes	7
6 Functional requirements on card information for prescriptions	7
6.1 Overview of supported uses	7
6.2 Carry a prescription from prescriber to the dispenser	7
6.2.1 General	7
6.2.2 Prescription set	8
6.2.3 Who	8
6.2.4 What	8
6.2.5 Times	9
6.2.6 How	9
6.3 Card information on dispensed prescriptions	9
6.4 Medication notes	9
7 Medication data	10
7.1 General	10
7.2 "MedicationNotes" class	11
7.2.1 General	11
7.2.2 "MedicationHistory" class	12
7.2.3 "MedicationRelevantCharacteristics" class	13
7.2.4 "KnownMedicationRisks" class	14
7.3 "MedicationPrescriptions" class	15
7.4 "MedicationsDispensed" data object	23
7.5 MedicationReferences	30
Annex A (normative) ASN.1 data definitions	32
Annex B (informative) Example of medication notes	48
Bibliography	50

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21549-7:2007), which has been technically revised with the following changes:

- medication notes definition in [Clause 1](#) is modified;
- the list of definitions in [Clause 3](#) is shortened and several definitions are corrected and clarified;
- the list of abbreviation in [Clause 4](#) is shortened;
- an explanation is added in [5.1](#) why MedicationData is modelled as a direct child of the PatientHealthcardData;
- “healthcare person” in [6.2.3](#) is replaced by “healthcare professional”;
- “factor of the quantity” in [6.2.4](#) is replaced by “quantity units”;
- “medication history” in [6.4](#) is changed to “medication notes” in the title and an explanation of a major use is modified;
- in [Clause 7](#), all the names of attributes in the tables are harmonized with the class diagrams. The term “data object” is replaced by “class”. Additional comments are included in the tables. For implementer's convenience, the fragments of ASN.1 definitions are gathered together in the new [Annex A](#);
- explanation of MedicationNotes in [7.2.1](#) is modified;
- comments in [Table 3](#) are modified;
- comments in [Table 4](#) are modified;
- comments in [Table 5](#) are modified;
- Example in 7.2.5 is moved to informative [Annex B](#);

- [Figures 7](#) and [8](#) are merged. Class “Prescriber” is defined as an attribute. The attribute “qualification” is replaced by the attribute “qualifier” having datatype “CodedData”. The attribute “medicinalProduct” is renamed as “prescribedMedicinalProduct”. The class “MedicinalProduct” is renamed as “PrescribedMedicinalProduct”. The class “ManufacturedMedicinalProduct” is renamed as “PrescribedManufacturedMedicinalProduct”. The class “MagistralMedicinalProduct” is renamed as “PrescribedMagistralMedicinalProduct”. Datatype of the attribute “strength” is replaced by “Strength”, the definition of this new datatype is added. Datatype of the attribute “quantityOfMedicinalProduct” is replaced by “Quantity”. Datatype of the attribute “amountOfIngredient” is replaced by “Amount”. The class “AmountOfIngredient” is replaced by the class “Amount”;
- [Figures 17](#) and [18](#) are merged. Class “Dispenser” is defined as an attribute. The attribute “dispensedMedicinalCode” is replaced by the attribute “dispensedMedicinalProduct” having new datatype “DispensedMedicinalProduct”. This new datatype is a generalization of the classes “DispensedManufacturedMedicinalProduct” and “DispensedMagistralMedicinalProduct”. The attributes “strength”, “form”, manufacturerOfMedicinalProduct” are moved from the class “ActualDispensedItem” to the class “DispensedManufacturedMedicinalProduct”. The attributes “batchIdentifier”, “genericSubstitution” are moved from the class “DispensingInformation” to the class “DispensedManufacturedMedicinalProduct”. Datatype of the attribute “quantityDispensed” is replaced by “QuantityToDispense”, so the class “QuantityDispensed” becomes unused and is deleted. The attributes “magistralMedicinalProductName” and “dispensedQuantity” are added to the class “DispensedMagistralMedicinalProduct”. The attribute “nameOfIngredient” is deleted from the class “DispensedIngredient”. Datatype of the attribute “quantityOfIngredient” is replaced by “Amount”. The attribute “nameOfContainerOrApplicationAid” is deleted from the class “DispensedContainerOrApplicationAid”;
- Figures 26 and 27 are merged;
- new ASN.1 definition is added in [Annex A](#).

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

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 Professional" 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, medication and linkage data.

Device data is defined to include

- identification of the device itself, and
- 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 the following:

- complementary person(s) related data;
- identification of the funding of health care, 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), and
- related actions planned requested or performed.

Medication data may include

- a record of medications purchased by the patient for self administration,
- copies of prescriptions including the authority to dispense records of dispensed medications,

- records of medications dispensed by a pharmacist to the patient, and
- pointers to other systems that contain information that hold medication data, either medication history or prescribed medicines, (or both) and in the case of prescribed medicines, the authority to dispense.

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.

Patient Data Cards may offer facilities to

- communicate prescription information from one healthcare professional to another healthcare professional such as to a healthcare agent or healthcare organization, and
- provide indexes and/or authority to access prescription information held other than on the patient data card.

Health informatics — Patient healthcard data —

Part 7: Medication data

1 Scope

This document applies 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 document specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data sets for storage on devices.

The purpose of this document is for cards to provide information to other health professionals and to the patient or its non-professional caregiver.

It can also be used to carry a new prescription from the prescriber to the dispenser/pharmacy in the design of its sets.

Medication data include the following four components:

- **medication notes:** additional information related to medication and the safe use of medicines by the patient such as medication history, sensitivities and allergies;
- **medication prescriptions:** to carry a new prescription from the prescriber to the dispenser/pharmacy;
- **medication dispensed:** the records of medications dispensed for the patient;
- **medication references:** pointers to other systems that contain information that makes up medication prescription and the authority to dispense.

The following topics are beyond the scope of this document:

- 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 the data takes for use outside the data card, or the way in which such data is visibly represented on the data card or elsewhere.

NOTE Not only does the definition of “medicinal products” differ from country to country, but also the same name can relate to entirely different products in some countries. Therefore, it is important to consider the safety of the patient when the card is used across borders.

This document describes and defines the Medication data objects used within or referenced by patient-held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

This document does not describe nor define the common objects defined within ISO 21549-2, even though they are referenced and utilized within this document.

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 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN