Health Informatics - Automatic identification and data capture marking and labelling - Subject of care and individual provider identification (ISO 18530:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18530:2021 sisaldab Euroopa standardi EN ISO 18530:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18530:2021 consists of the English text of the European standard EN ISO 18530:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 10.02.2021.	Date of Availability of the European standard is 10.02.2021.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 35.240.80

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 18530

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Supersedes CEN ISO/TS 18530:2015

English Version

Health Informatics - Automatic identification and data capture marking and labelling - Subject of care and individual provider identification (ISO 18530:2021)

Informatique de santé - Marquage et étiquetage à l'aide de l'identification et de la saisie automatiques des données - Identification du sujet des soins et du prestataire considéré (ISO 18530:2021)

Medizinische Informatik - Automatische Identifikation und Datenerfassungskennzeichnung und -beschriftung - Identifikation von Behandelten und individuellen Anbietern (ISO 18530:2021)

This European Standard was approved by CEN on 11 June 2020.

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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 18530:2021 E

European foreword

This document (EN ISO 18530:2021) 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 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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

This document supersedes CEN ISO/TS 18530:2015.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 18530:2021 has been approved by CEN as EN ISO 18530:2021 without any modification.

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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).

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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.

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, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition cancels and replaces ISO/TS 18530:2014, which has been technically revised.

The main changes compared to the previous edition are as follows:

— new definitions added;

— use case and UML diagrams updated;

— bibliography expanded.

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

The delivery of healthcare relies heavily on the ability to uniquely and accurately identify people when they attend for care, i.e. the Subject of Care (SoC), as well as, when they provide care, i.e. the Individual Provider.

Health informatics, supporting healthcare delivery, requires a clear specification to identify the SoC and the Individual Provider so that they are correctly associated with the health information contained within a healthcare application. This has led to the need to capture and share information across different systems and healthcare applications.

Data carriers, such as barcodes and Radio Frequency Identification (RFID), commonly referred to as Automatic Identification and Data Capture (AIDC), have amplified the importance of defining the identifier data structures for the SoC and Individual Provider to prevent ambiguity when information is being captured. AIDC provides a wide spectrum of solutions, in particular, regarding optical carriers (such as barcodes). Furthermore, the semantics of data carried is defined by a number of organizations (also named "issuing agencies"), some of them having commercial activities, others nation-wide missions, as well as, standard development organizations. This document focuses on the use of the GS1® System of Standards[1)] since a considerable majority of supplies in healthcare around the world are identified in accordance to this multisectorial and global system of standards. Interoperability is easier to secure once a single system of standards is used in the healthcare setting.

Interoperability, where information is shared and used by different information systems, requires a common SoC and Individual Provider identification semantic to ensure that shared information is consistent and unambiguous. The same SoC and Individual Provider are accurately identified, referenced and cross-referenced in each system. Effective data capture systems and information sharing is the key to improving the care of SoCs and delivery by Individual Providers in terms of conformance, accuracy and integrity of the health data.

In hospitals, a SoC (as in-patient) usually experiences a large number of care instances. Examples of these instances include: prescriptions and medicinal product administration, laboratory testing of SoC bio-samples and subsequent analysis and reporting. Each of these instances requires accurate reconciliation of the instance and delivery to the SoC. Healthcare providers (i.e. organizations that deliver healthcare to the SoC) have introduced AIDC technology based barcodes to help capture the SoC's identity, as well as, identification of other related items such as biology samples, so that manual key entry can be replaced by AIDC. In the complex hospital environment with many care instances, the need for uniqueness of identifications is generally recognized, since this avoids identification conflicts, overlaps, uncertainty and risks.

The use of AIDC in the context of chronic care reinforces the need for standards. The SoC in the chronic care instance is not always in the same fixed location where a single technology is available. AIDC can therefore be interoperable with a variety of technologies, solutions and devices. This will enable a continuum of care.

As out-patients, SoCs may be self-medicating. A SoC undergoing treatment for chronic conditions, in particular, should administer and record their medication according to a prescribed treatment plan. This treatment plan can be very prescriptive, on an as-needed basis, or be preventive in nature to avoid dangerous clinical outcomes.

There is also a need to manage and clinically monitor the treatment plan for the SoC for safety and stock purposes. AIDC enables capture of the SoC's identification, medicinal product, administration event, recording of relevant data about the medicinal product administered and other data such as batch number, expiration information and amount used. This should be done for in-patients as well as out-patients. This same data capture can be used to efficiently manage and replenish stock.

1) GS1 is a registered trademark. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

Benefits from unique SoC Identification in AIDC can be documented from the following three examples:

— Patient, as well as, data can travel outside a provider's environment: Following a devastating tornado in Joplin, Missouri, USA, in 2011, 183 SoCs from St John's Hospital had to be swiftly evacuated to other regional hospitals. Under such “chaotic” conditions, a patient identifier that is truly unique would prevent replacing identification bands immediately for every SoC admitted to a different hospital.

— For regional referral laboratories, especially those performing blood bank testing: positively identifying SoCs and linking them to previous records, is essential for patient safety. Two different SoC with the same name, hospitalized at two different facilities using identical patient identification numbering schemes (perhaps because they use the same IT system), could lead to serious errors.

— A provider uses two identifiers for the management of care processes: the “patient identification” and the “case identification”. One provider organized the number banks for the two identifiers in such a way, that data collision was excluded. After years of use of that solution, number banks started overlapping without anyone noticing, until two SoCs were having the same numbers, one of “patient identification”, the other for “care identification”. A mismatch with serious incident occurred.

Health informatics — Automatic identification and data capture marking and labelling — Subject of care and individual provider identification

1 Scope

This document outlines the standards needed to identify and label the Subject of Care (SoC) and the Individual Provider on objects such as identification (wrist) bands, identification tags or other objects, to enable automatic data capture using data carriers in the care delivery process.

It provides for a unique SoC identification that can be used for other purposes, such as recording the identity of the SoC in individual health records.

This document serves as a reference for any organization which plans to implement or improve Automatic Identification and Data Capture (AIDC) in their delivery of care process. It is based on the use of the GS1® system of standards. Other solutions, such as using other identification systems (for example, systems based on ISBT 128), are possible but not addressed by this document.

This document describes good practices to reduce/avoid variation and workarounds which challenge the efficiency of AIDC at the point of care and compromise patient safety[5][6].

This document specifies how to manage identifiers in the AIDC process, and completes the information found in ISO/TS 22220 and ISO/TS 27527.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
application identifier
AI
GS1® prefix that defines the meaning and purpose of the data element that follows, as defined in ISO/IEC 15418 and GS1® General Specifications

[SOURCE: ISO/IEC 19762:2016, 01.01.82]

3.2
automatic identification and data capture
AIDC
methods or technologies for automatically identifying objects, collecting data about them, and entering that data directly into computer systems, eliminating manual entry

Note 1 to entry: The methods or technologies typically considered as part of AIDC include barcodes, which can be linear or 2-dimensional symbols, and Radio Frequency Identification (RFID) tags/chips.