PD CEN ISO/TS 18530:2015

BSI Standards Publication

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

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**National foreword**

This Published Document is the UK implementation of CEN ISO/TS 18530:2015. It is identical to ISO/TS 18530:2014. It supersedes PD ISO/TS 18530:2014 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.



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**Compliance with a British Standard cannot confer immunity from legal obligations.**

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TECHNICAL SPECIFICATION

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# CEN ISO/TS 18530

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English Version

# Health Informatics - Automatic identification and data capture marking and labelling - Subject of care and individual provider identification (ISO/TS 18530:2014)

Informatique de santé - Identification lisible par capture automatique et marquage - Identification des sujets de soins de santé et des professionnels de la santé (ISO/TS 18530:2014)

Medizinische Informatik - Automatische Identifikation und Datenerfassungskennzeichnung und -beschriftung - Identifikation von Behandelten und individuellen Anbietern (ISO/TS 18530:2014)

This Technical Specification (CEN/TS) was approved by CEN on 28 October 2015 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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## European foreword

The text of ISO/TS 18530:2014 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 18530:2015 by Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

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**Endorsement notice**

The text of ISO/TS 18530:2014 has been approved by CEN as CEN ISO/TS 18530:2015 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.

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

# 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 bar codes 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 bar codes). 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 Technical Specification 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 compliance, 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 medication 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. organisations that deliver healthcare to the SoC) have introduced AIDC technologies based bar codes 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, medication, administration event, recording of relevant data about the medication 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. Any trademark used in this document is information given for the convenience of users and does not constitute an endorsement.

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, hospitalised 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 Technical Specification outlines the standards needed to identify and label the Subject of Care (SoC) and the Individual Provider on objects such as 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 may be used for other purposes, such as recording the identity of the SoC in medical health records.

This Technical Specification 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 to be used in conjunction with the GS1[2)] system of standards.

This Technical Specification describes good practices to reduce/avoid variation and workarounds which challenge the efficiency of AIDC at the point of care and compromise patient safety.

This Technical Specification 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

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 22220, *Health informatics — Identification of subjects of health care*

ISO/TS 27527, *Health informatics — Provider identification*

ISO/IEC 15418, *Information technology — Automatic identification and data capture techniques — GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance*

ISO/IEC 16022, *Information technology— Automatic identification and data capture techniques — Data Matrix bar code symbology specification*

## 3 Terms and definitions

**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 19762-1:2008, 01.01.94]

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