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

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

Reference number
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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).

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 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.

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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.

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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.

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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.

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3.3
data capture
deliberate action that results in the registration of a record into a record keeping system

3.4
care unit
ward
subdivision of an organization where the *subject of care* (3.15) receives the care they need during their stay

3.5
global service relation number[2)]
GSRN
identification key to identify the relationship between an organization offering services and the recipient or provider of services

Note 1 to entry: GSRN are encoded on data carriers with an Application Identifier 8018 for the recipient of a service (Subject of Care) and with an Application Identifier 8017 for the provider of a service (Individual Provider).

3.6
healthcare provider
organization or facility that delivers healthcare to subjects of care

3.7
integrating the healthcare enterprise
IHE®[3)]
initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information

Note 1 to entry: IHE® promotes the coordinated use of established standards to address specific clinical need in support of optimal patient care.

Note 2 to entry: Systems developed in accordance with IHE® communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

3.8
individual provider
person who provides or is a potential provider of a health care service

Note 1 to entry: An individual provider is an individual person and is not considered to be a group of providers.

Note 2 to entry: Not all health care providers are recognized by professional bodies. It is for this reason that 'health care professional' has not been used to describe them. All health care professionals are providers, but not all providers are health care professionals.

3.9
individual provider identification
unique number or code issued for the purpose of identifying an individual provider

3.10
information system
organized collection of hardware, software, supplies, policies, procedures and people that stores, processes and provides access to information

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2) GSRN is the GS1® identifier for service relations and is supplied by the GS1® System. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the service relation identifier named. Equivalent products may be used if they can be shown to lead to the same results.

3) IHE is the registered trademark of the Healthcare Information Management Systems Society. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

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3.11
machine readable code
code, readable by a machine, which contains information used to establish a relationship between a physical object such as a medical product package and data sources such as medical, production, logistical and/or reimbursement coding systems

3.12
record
recorded information, in any form, including data in computer systems, created or received and maintained by an organization or person in the transaction of business or the conduct of affairs and kept as evidence of such activity

3.13
registration
act of giving a record a unique identity in a record keeping system

3.14
service relation instance number
SRIN
attribute to a *global service relation number* (3.5) to identify an instance within a care process

EXAMPLE An identification band, an order sheet, a test-tube, etc.

3.15
subject of care
SoC
person seeking to receive, receiving or having received health care

4 GS1® specifications and ISO deliverables

In this document, automatic identification and data capture (AIDC) refers to selected data carriers which are widely used across many industries, jurisdictions and which are already based on and specified in ISO deliverables. The benefit of this approach is to use the already widely available applications and devices for encoding and reading the different types of data carriers. It should, however, be noted that certain types of data carriers such as data matrix may only be read by image-based scanners.

AIDC solutions should be in accordance with GS1® general specifications, which in-turn are based on ISO deliverables. If the recommendation is followed, then information contained in the data carriers shall be structured and standardized according to the GS1® semantics. The identification key (global service relation number, GSRN) is the identifier for service relations (such as SoC and Individual Providers) and is supplied by the GS1® System of Standards.

5 Data structures and semantics

5.1 Application identifiers

The GS1® item identification system and related encoding standard are complemented by the GS1® maintained application identifiers, hereafter referred to as “GS1® Application Identifiers” or “GS1® AIs”. This document comprises two principal elements that are the key to any encoding system: the data content and the data carrier.

The use of GS1® AIs is subject to the rules established by GS1®.

GS1® maintains a list of over 200 AIs which support various processes with automatic identification and data capture.

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5.2 Global service relation number (GSRN)

The GSRN is the GS1® Identification Key used to identify the relationship between an organization offering services and the recipient or provider of services. The key comprises of a GS1® Company Prefix, Service Reference and Check Digit, with an 18 numeric digits fix length.

Two different AIs are used to distinguish SoC from individual provider as illustrated in Figure 1.

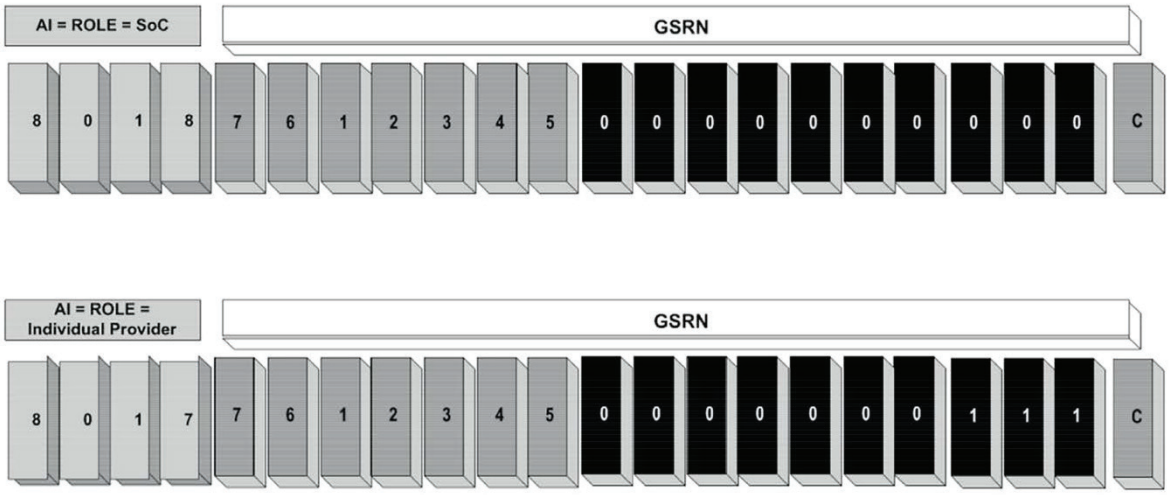

Figure 1 — Global service relation number (GSRN)

5.3 Service relation instance number (SRIN)

The SRIN is an attribute to the GSRN which allows distinguishing different encounters during the same episode, or the reuse of the same GSRN in different episodes. SRIN is a 10 numeric digits variable length filed. AI 8019 shall only be used in conjunction with AI 8017 or 8018; Figure 2 illustrates the combination for a SoC.

Figure 2 — Service relation instance number (SRIN)

For the purpose of this document, for conformance with ISBT 128, the SRIN shall be used as a fixed length string with the first two digits (NN) reserved for the ISBT 128 location code (Table RT018); the selection of the remaining eight (8) digits is left to the discretion of the user and may be incremental.

6 SoC and Individual Provider identification as a recognized priority

6.1 General

The World Health Organization (WHO) and the Joint Commission International (JCI) have developed a list of priority solutions to enhance patient (meaning SoC) safety. Among the list of solutions WHO and JCI recommended is the use of AIDC technology (when the technical framework permits). Among the "Nine patient safety solutions"[1] given by WHO, the second solution[2] addresses patient (SoC) identification and the use of “barcodes” to reduce the risk of identification errors. Other solutions (communication during patient hand-over; performance of correct procedures at correct body site; assuring medication accuracy at transitions in care) require security of a patient’s (SoC’s) identification.

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Annex A illustrates how SoC and Individual Provider identification should be enabled for different types of healthcare care use cases. If used, the Annex A explains the type of care and how AIDC can be implemented as a good practice in different use cases. The following use cases (UC) are included:

— UC 01 to 04 covers the typical overall SoC flow through a hospital (see Figure A.1);

— UC 05 to 11 describes specific care instances that might arise within a hospital environment (see Figure A.2);

— UC 12 to 19 looks at machine readable coding in complex point of care environments (see Figures A.3 and A.4);

— UC 20 to 24 looks at machine readable coding in the blood transfusion processes (see Figures A.4 and A.5);

— UC 25 to 27 describes machine readable coding for chronic outpatients (see Figure A.6);

— UC 28 to 30 examines the need to integrate nationwide SoC and Individual Provider identification (see Figure A.7).

The textual presentation of the use cases is completed with UML diagrams where, in particular, data capture is positioned; instructions are included in the "good practice" section.

In each of the use cases, there is requirement to provide unambiguous data qualifiers to distinguish between the SoC, the Individual Provider and the product for data capture. Without qualifiers, it is impossible to guarantee that the captured information (or data) is what was intended. There is also the possibility of duplication of identity. This is avoided by using a standardized globally unique identification.

6.2 Supported processes

Annex A provides examples of a series of processes that are supported by capturing SoC identifier, SRIN and Individual Provider identification. Table 1 (based on the examples found in Annex A) provides an overview so that implementers can evaluate their needs and the appropriate solution to adopt.

Table 1 — Overview of supported processes

Usage Requirements	SoC identifier	SRIN	Individual Provider Identification
SoC and Individual Provider Identification as a recognized priority	X		X
Machine readable coding for clinical purpose (point of care)	X	X	X
Machine readable coding in complex point of care environments	X	X	X
Machine readable coding to avoid workarounds	X	X	X
Machine readable coding in the blood transfusion processes	X	X	X
Machine readable coding for chronic outpatient	X	X	X
Machine readable coding by integrating nationwide SoC identification	X	X	X

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7 The purpose of globally unique identification

7.1 SoC identification and data processing

When GSRN is used in data processing, solutions have been developed by IHE® International as Master Patient Indexes (MPI), which secure uniqueness of the identification in a defined environment and associates defined demographics to a SoC identifier. MPI should be interconnected by using IHE® tools so that heterogenic identifications are linked together by using the associated demographics. The use of GSRN, as described in this document, does not impact data processing and the use of IHE® tools, since IHE's ®MPI are conceived to address situations where SoC are identified with **any** identifier.

GSRN are fixed length 18 digits numeric keys according GS1® General Specifications[8]. In a GS1® DataMatrix, the SoC GSRN shall be headed by a GS1® AI 8018.

7.2 Implementation challenges

Modern CIS require the use of a SoC identifier and an Individual Provider identification so that processes can be captured with scanning technologies. Some implementation challenges have been noticed, such as the following:

— Acceptance by Individual Provider: To prevent AIDC technologies consuming the Individual Provider's time, it is important to associate these professionals to the implementation steps, including working ergonomic, graphic user interfaces, etc. A benefit of AIDC should be the reduction of administrative work (manual key entries in the nursing files, reordering of consumed products, etc.). Furthermore, it is important that any implementation requires scanning **prior** care processes, so that alerts are issued to prevent errors (scanning after care process would be too late to avoid error). Some processes require even two data captures: one prior to the care process (checking adequacy) and one after the care process (confirming end of process). An example for this double step is the administration of cytostatics[3].

— CIS data-field limitations: the length of the Individual Provider identification and the SoC identifier, when using GSRN, is 18 numeric digits. The optional SRIN for a SoC is a numeric field of up to 10 digits. The CIS is frequently not able to work with such data fields. It is important that healthcare providers and vendors collaborate to understand the value and the flexibility of the solution so that CIS support evolutions for the benefit of efficiencies (reducing manual key entries for documentation processes) and patient safety (combating workarounds[5],[6], checks ahead of care processes, etc.). It is recommended to add appropriate reference in the future call for tender. As an intermediary (temporary) solution, a middleware (e.g. in the form a web service) can be developed or found on the market, to link SoC's GSRN, SRIN, as well as, Individual Provider identification (GSRN) to the existing CIS.

7.3 Symbol placement on identification bands

Barcoding technologies have addressed SoC identifiers on identification bands for years. Therefore, the following experiences should be leveraged:

— Linear/2-dimensional barcodes: linear barcodes are frequently too long to be easily read on identification bands (i.e. because of the curve of the band around the limb). Therefore, DataMatrix is recommended for carrying GSRN and when possible SRIN.

— Two data carriers on the identification band may be necessary for a transition period, since some software may not be able to handle long identification keys. It is a common situation which adds to the potential risk that the two identifiers (the long and the short) do not point to the same SoC. Therefore, such a situation should only be considered for limited periods of time.

— Ease of finding the data carrier: industry experience demonstrates that (because of the limb's curve) the identification band is not always in the same position, thus the data carrier not always visible. The same DataMatrix should be printed optimally 4 times along the identification band. Scanner devices shall be programmed not to read the same DataMatrix more than once. The presence of

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SRIN as an attribute to GSRN provides the benefit that the scanner analyses if the DataMatrix is the same or not. Results of reading more than once the GSRN and SRIN shall be rejected by the scanner.

— Ease of reading the data carrier: industry experience demonstrates that the DataMatrix should always be printed in the middle of the identification band or label (not on its side). This avoids truncations and overlaps, which burden Individual Providers and thus could influence their process conformance.

— In neonatality, it is usual to affix more than one identification band on young babies (e.g. one on the arm, one on the leg). The use of GSRN and SRIN is compatible with this situation, and the CIS should be able to validate that two SRIN are used on identification bands at the same time, for such particular situations.

7.4 Individual Provider identification

Individual Providers do not carry the same type of identification bands as SoC. Individual Provider identification is frequently stored on cards such as identity cards, which allow computer login, room access, etc. Individual Provider identification may be carried in RFID chips, which are defined by software vendors and the solutions implemented by the healthcare provider.

Individual Provider identification is used, not only in the care processes as described in this document but can also be used for rule management (allowing access to information relating to Individual Provider qualifications, functions, etc.), for patient record access and other functionalities at the healthcare provider's discretion.

Individual Provider identification should be defined by the healthcare provider for its staff and the Individual Providers licensed to work in its premises. The use of GSRN should allow larger organizations using the same Individual Provider identification with structured decentralized identification management, by avoiding overlaps and identification errors.

GSRN are fixed length 18 digits numeric keys according to GS1® General Specifications. In a data carrier such as GS1® DataMatrix, the Individual Provider GSRN shall be headed by a GS1® Application Identifier 8017.

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Annex A
(informative)

Examples of use cases (UC)

A.1 The typical hospital care process (UC 01 to 04)

A.1.1 General

The use of machine-readable coding enhances the hospital care delivery at different stages of the care cycle. Typical hospital use-cases reflect interaction between the SoC and Individual Providers along a care pathway. This is simplified, at high level and generic. In reality, each care process may differ from hospital to hospital.

The typical hospital stages are the following:

a) Admissions: the SoC presents at the hospital;

b) Care unit: when the SoC is admitted to the care unit or ward;

c) Surgical: when the SoC undergoes a clinical procedure;

d) Discharge: after the procedure and recovery the SoC is discharged back to the community.

Each of these stages is concerned with the movement of the patient through the care pathway and assuring the identity of the SoC.

A.1.2 Use cases

A.1.2.1 Admission process (UC 01)

The SoC arrives at the admissions department. The SoC provides his/her identity using an identification card or by other means. Other documents such as the referral letter and related insurance details may also be provided. The Admissions Clerk verifies the SoC's identity, the reason for admission as detailed in the referral letter and, registers the SoC for admission. The SoC is issued an identification band and a series of adhesive labels, each detailing the name and appropriate demographics, as well as, the SoC Identifier (GSRN). The identification band is attached to the patient and the labels are placed in a record folder which the SoC brings to the care unit. Alternatively, stickers should be printed "on demand" at point of care

A.1.2.2 At the care unit (UC 02)

The SoC is welcomed, brought to the ward, and prepared for bed; identification of bed as location is captured. Clinical information, i.e. temperature, blood pressure etc., is collected and recorded. Bio samples are collected in a sample tube and sent to the hospital laboratory.

A.1.2.3 Surgical operation (UC 03)

The SoC is prepared for surgical operation. A medicinal product is administered to the SoC and the SoC is brought to the preparation room where anaesthetics are injected. The SoC is wheeled into the operating theatre. After the operation is completed, the SoC is brought to the recovery room. When the SoC is ready, the SoC is returned to the ward.

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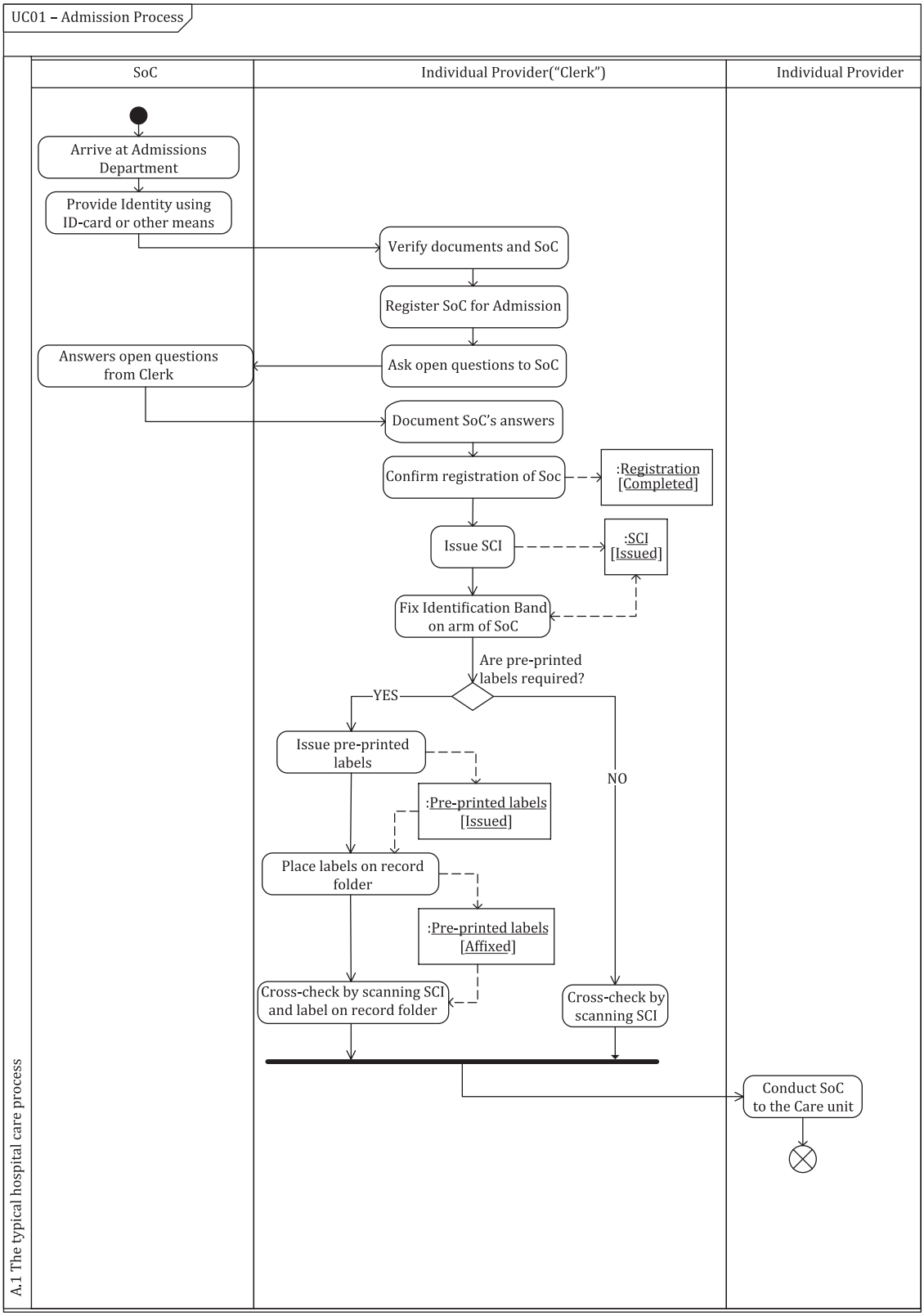
A.1.2.4 Discharge (UC 04)

Once the SoC has recovered, the care pathway is complete. The SoC is transferred to a rehabilitation clinic. A hospital discharge letter is prepared and sent ahead of the arrival SoC at the rehabilitation clinic.

A.1.3 UC 01 to UC 04 process flow



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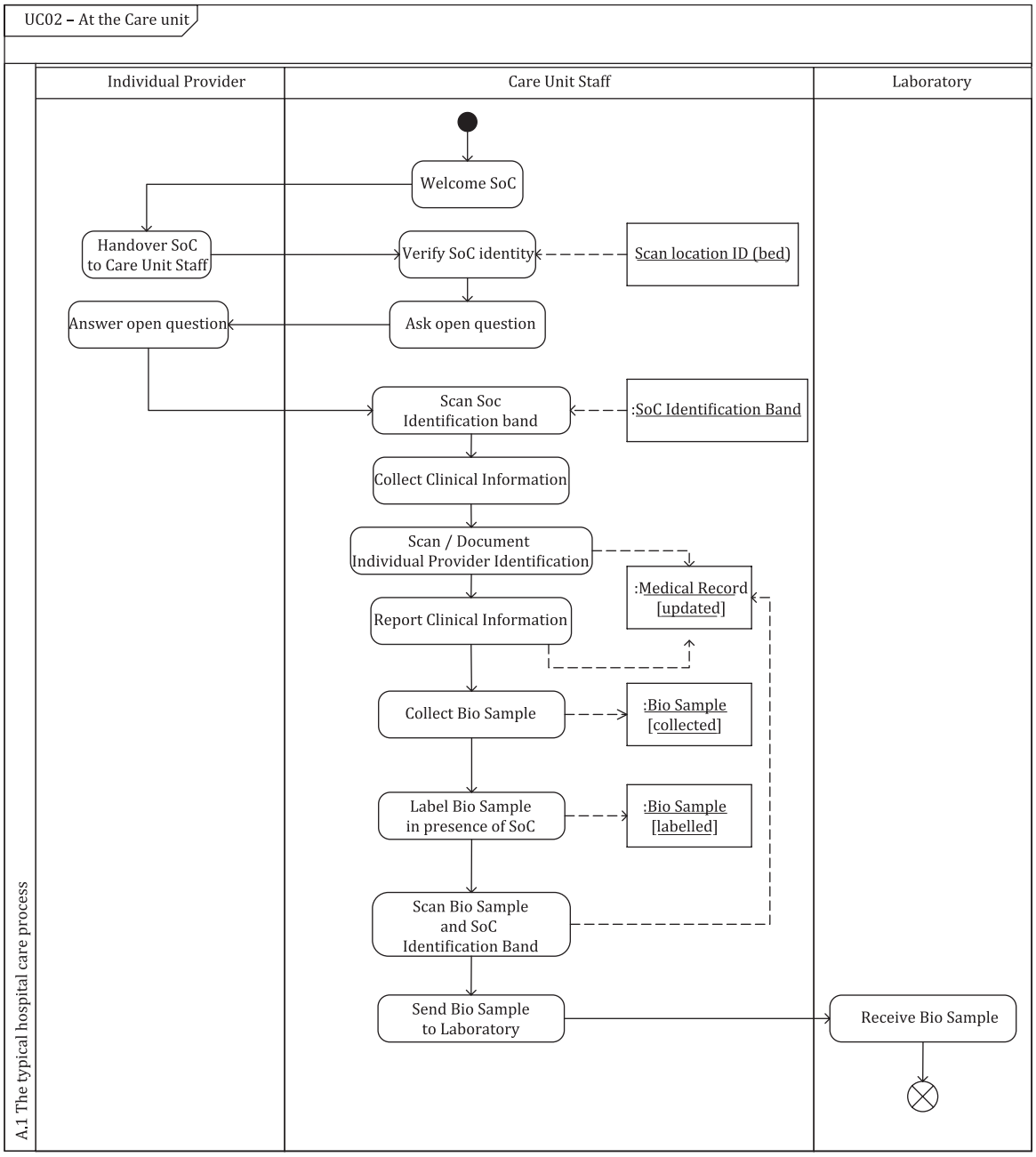

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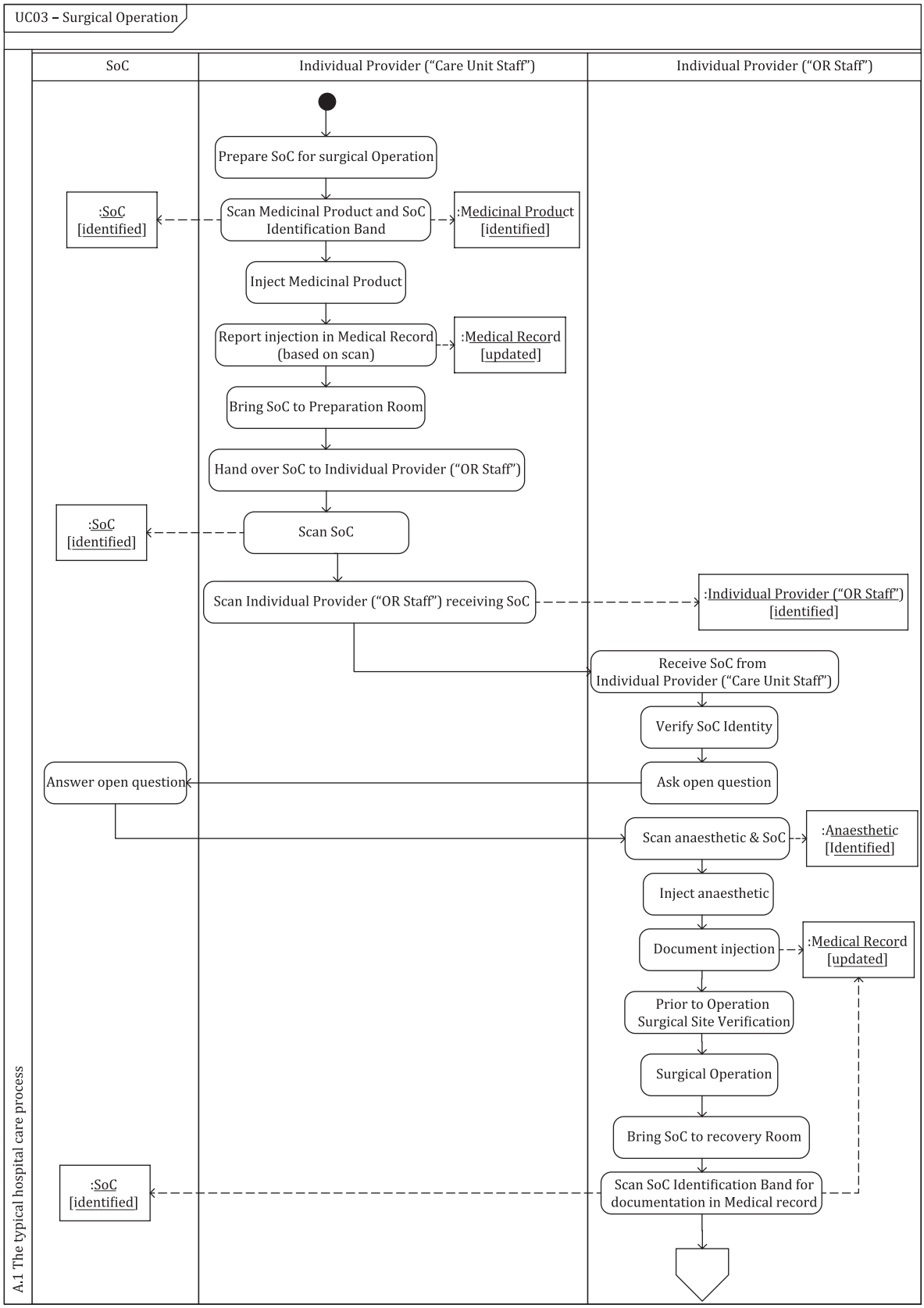

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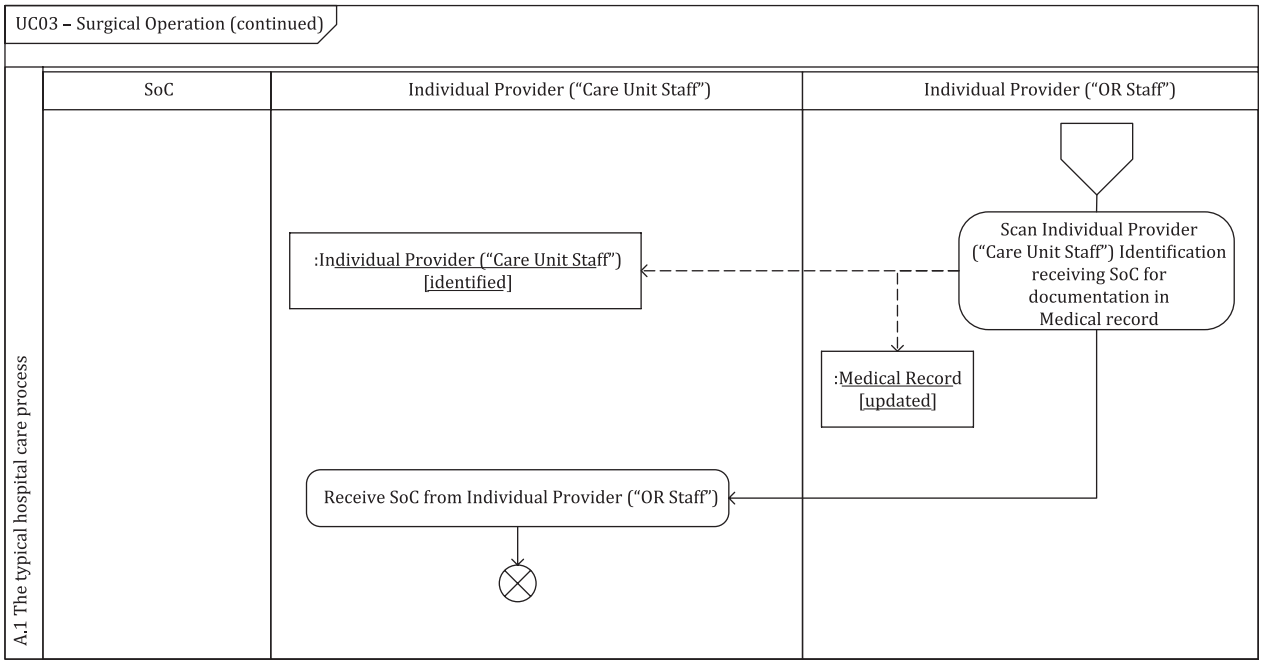

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