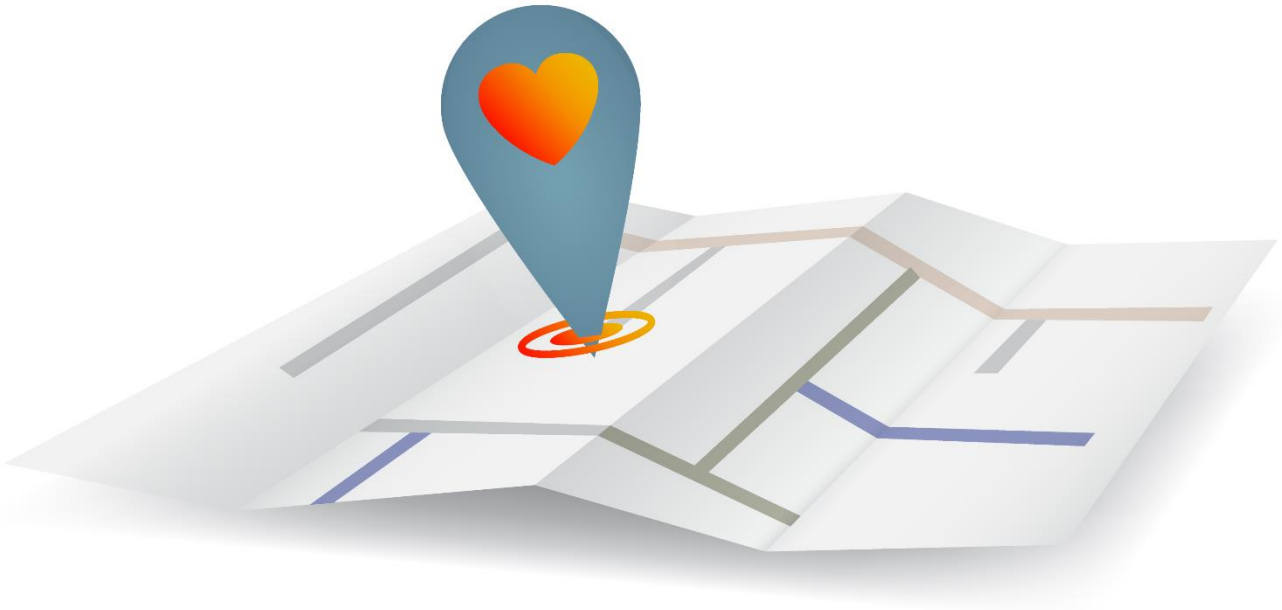

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Reference Architecture for OBJECT LOCATING AND IDENTIFICATION

Concerning the healthcare domain in Denmark

DANISH HEALTH DATA AUTHORITY

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Executive summary

The Danish healthcare sector needs to be much better at avoiding wasting time and resources, and thus money. Although citizens and patients can generally feel safe and secure in the Danish healthcare system, numerous errors still occur which could have been avoided. More effective logistics is an important source of continued efficiency improvement and error correction in the healthcare sector. Throughout the healthcare sector today, healthcare staff spend too much time trying to locate people and objects. Furthermore, too much money is spent stocking goods and equipment; money that we could save if the health services were better at sharing and coordinating.

Streamlining the healthcare sector is, without doubt, a difficult task. By its very nature, the sector will always have a certain degree of disorder: much of what takes place during a normal day in the healthcare sector is inevitably unplanned. Sometimes, even planned activities have to make way for unplanned activities. The people or equipment that ought to be at one location, are suddenly involved in solving a problem at an entirely different location.

Therefore, it is no surprise that automated object locating and identification is essential to ensure more efficient and effective processes in the healthcare sector. If we can rely on our IT systems to help us locate colleagues and vital equipment, it goes without saying that this will make us considerably better at planning, coordinating and using the scarce resources at our disposal.
The technologies that enable automated object locating and identification are developing rapidly and in many different directions. Therefore, it is important that we develop our competences in this area, so that we do not lose our way or get locked into specific technological solutions. Technological development will create new possibilities for a better and more effective and efficient healthcare sector. It is important that we respond to this development in a way that allows us all to develop in the same direction and not diverging directions.

Cross-sector services across Regions and municipalities are becoming an ever greater priority, and this means that equipment and services will be increasingly cross-sectoral in the future. Undoubtedly, this is a development that will gain momentum in the years to come.

This reference architecture has been prepared to provide support for all IT systems in the healthcare domain related to object locating and/or identification. The objective is to set out targets and a framework, so that the various healthcare actors can develop together within this area, and so that they can use each other's solutions and communicate with them.

> As an important element in the reference architecture, we present a model for an integration system which receives and presents identity and location data using established standards. Hereby, the systems that produce location data are decoupled from the systems that use the location data. As a result, reuse will increase and operational problems with integrations will decrease.

Thus, the reference architecture helps provide a common and robust overview of the possibilities for introducing object locating systems, allowing the healthcare sector to tap into the huge potential provided by modern object locating solutions. This is a potential which many other sectors, such as the transport sector and retailers, are already exploiting.

1. Introduction

This reference architecture addresses using the location of an object at a given point in time to support workflows in the healthcare sector. Object identification technologies and object locating technologies have been described in literature. However, there is currently no coherent treatment of the subject in the context of the health domain. This reference architecture lays out an architecture, identifies standards and describes uses for object locating and object identification in the healthcare domain.

1.1 Objective

The technological possibilities to keep track of the location of people and physical objects, whether indoors or outdoors, are reaching maturity and are continuously improving. This opens up for a wide array of possibilities for efficiency improvements throughout society, including in the healthcare sector.

This document describes a *reference architecture for object locating and identification* (in the following referred to as "the reference architecture"). The reference architecture is to serve as a guide and a common framework for projects that involve automatic identification and location. The goal is to make it easier to exchange location-related information and to capitalise more on investments in location-related systems.

The reference architecture is to contribute to achieving our vision and goals for efficiency. Furthermore, the reference architecture is to be robust, so as to ensure that it can cope with future new business requirements and changes in the external environment, see figure 1, section 2.2. This requires using international, approved standards, so that the interdependencies between applications, technologies and external factors are reduced as far as possible. The reference architecture is to ensure a decoupling between applications and their underlying technologies and infrastructure for object locating and identification. To allow for this, applications and underlying technologies must be able to develop independently of each other and without major interdependencies.

The focus of the reference architecture is to describe a generic architecture for the healthcare sector. To describe the value created by the reference architecture, the following usage scenarios have been prepared, see Annex D Usage scenarios for more details[1]:

- Improved inventory management in the home care sector. Easier and more exact inventory management, including recovery of objects on loan.
- Finding staff in the home care sector. Finding the nearest member of staff in order to assign a specific task.
- Planning service tasks at hospitals. Making it easier to find service workers for specific tasks.
- Learning from analyses of location data at hospitals. To optimise transport routes and inventory management.
- Finding citizens with dementia. Getting a notification when a person with dementia leaves a specific area and being able to locate said person again.
- Secondary use of location data nationally. This includes for research and planning, in particular.
- Object locating across authorities. Healthcare equipment on loan: identification, error messages and reclaiming equipment.

Using the reference architecture will provide a number of benefits, including that it will:

- Simplify systems integration, making it easier for systems to "communicate" with each other.
- Facilitate access to, and thus the value of, location data.
- Form a basis for reusing methodologies and software components across systems.
- Provide a conceptual framework for talking about object locating and identification.
- Provide inspiration for new systems or changes to existing systems, so that the data available is exploited to the best possible extent.
- Be included in the requirements in connection with procurement of IT solutions.

[1] The usage scenarios are not exhaustive for all uses in the health area; rather they are meant as illustrative examples. There will likely be many different kinds of usage scenarios which can include object locating and localisation data.

1.2 Reference architecture as method and product

In this document, the meaning of the concept, a reference architecture describes the required common framework for a number of IT systems within a specific domain, based on thoroughly tested solutions. The possibilities for using the reference architecture in part or in full depend e.g. on whether the objective is to develop new IT solutions or to refurbish existing solutions. Similarly, the possibilities can be affected by whether there are dependencies on existing solutions and organisations.

The problems with IT systems that deal with the same or overlapping information but are developed without the ability to exchange such information, are well known. The main problem often stems from a lack of knowledge about the systems with which the system will have to be able to exchange information (in the long-term). Often, the required integrations cannot be predicted, e.g. in connection with mergers of organisations.

> If IT systems are integrated with no governance of the integration process, the task becomes increasingly complicated with each system that is added. Two systems with separate definitions and interpretations of reality can be difficult to integrate; when you have five, or even ten systems, the difficulty of the task increases significant.

The solution to these challenges is standardisation, i.e. to use common, precise definitions of terms, workflows and events; to use common technical protocols to couple systems and common or coordinated workflows in the maintenance and operation of the systems. Such standardisation is the primary focus of this reference architecture.

Another problem with interrelated systems developed without coordination is that functionalities are repeated in several systems. This redundancy means that hours are spent developing and maintaining the systems which could otherwise have been saved. Furthermore, it results in unnecessarily complex integrations and makes understanding, use and administration of the systems more difficult. This reference architecture identifies the components which should be reused across systems.

A reference architecture should be defined:

- Broadly enough to cover all relevant, future systems. The reference architecture will be supplemented by current usage scenarios and the more long-term visions for the solution. Usage scenarios can be annexed throughout the lifespan of the reference architecture. As far as possible, the usage scenarios will relate to the healthcare sector but could also relate to other sectors.

- Detailed enough to achieve the desired integration possibilities without limiting the systems more than necessary. Therefore, decisions regarding standards, interfaces, operating processes etc. which must be taken to achieve the goals of the reference architecture will be in focus in the reference architecture, while all other decisions will be down to the individual systems.

1.3 The drafting process

In 2014, Danish Regions Health IT (RSI) published a reference architecture for object locating and identification [REGREF], in the following referred to as the *Danish Regions' reference architecture*, as part of their common guide for digital solutions in the healthcare sector 2014-2016 [RGONPEJL]. All five Regions have participated in the preparation of the Danish Regions' reference architecture with the Danish Regions Health IT (RSI) as the process coordinator.

As part of the 2015 budget agreement, the government and Danish Regions agreed to make the *Danish Regions' reference architecture* national, so that it covers all providers in the healthcare domain throughout Denmark. Thus, the Danish Health Data Authority established a working group with representatives from municipalities, Regions and the Ministry of Health. The nationalisation follows the guidelines described in *Tillæg til Standarder og referencearkitekturer vedr. sundheds-it området* (addendum to Standards and reference architectures for healthcare IT)[PRCSSTAND]. The work of the working group is addressed by the Danish Health Data Authority's advisory committee on standards and IT architecture [RUSA] with reference to the National Board of eHealth [NTNLBEST], just as it has been reviewed through a public consultation process in Denmark.

1.4 Reading instructions

The primary target group of this reference architecture is persons involved in the development of systems for locating of equipment and people in the healthcare domain, including decision makers and IT developers. In a wider context, the reference architecture is also targeted at people working in communication, organisation and development in the healthcare domain.
This document keeps to general terminology and aims to provide a so-called logical[2] overview of an IT architecture for managing object locating and identification.

> The key terms of this reference architecture are ***object locating*** and ***identification***, i.e. being able to identify people or objects, and being able to detect their location.

In practice, object locating will cover both these aspects, as automated object locating without identification would rarely make sense.

This document operates with **principles** (P) and **recommendations** (R):

- **Principles** must be adhered to as much as possible, as they are a prerequisite for integration across systems and across different actors.
- **Recommendations** should preferably be followed, because they generally focus on quality, optimization and use of well-proven standards.

The bullet points under principles and recommendations include examples of possible implications of the principle or recommendation in question.

Text highlighted by square brackets [] is reference to a source. Sources are listed in References.

Below is a brief description of the content of each main chapter.

1.4.1 Chapter 2 Vision and goals

This chapter describes the objective of the reference architecture and delineates the reference architecture from the overall systems complex. This chapter describes the context envisioned for the reference architecture.

[2] By *logical* architecture is meant an implementation-independent definition of the architecture, often grouping related physical entities according to their purpose and structure. (Paraphrased from TOGAF [TOGAF]).

1.4.2 Chapter 3 Framework and principles

This chapter describes the scope of the basic requirements of the reference architecture as well as the principles and the decisions underlying the development of the IT architecture.

1.4.3 Chapter 4 Architecture

This chapter describes the elements included in a solution for managing object locating and identification. Furthermore, the chapter describes the principles for managing solutions.

1.4.4 Chapter 5 Recommendations for system architecture

This chapter describes the structure of the system architecture, including recommendations and principles for this. The chapter is aimed at solutions architects.

1.4.5 Chapter 6 References

Used in both the main document and in annexes.

1.4.6 Annexes

Annex A: Key capabilities checklist for solutions - a guide for solution architectures that require that solutions need to be in compliance with the reference architecture. The list can also be used as a checklist for reviewing system architectures.

Annex B: Wish list for future versions of the reference architecture - lists focus areas that could imply that the architecture should be revised.

Annex C: Glossary - describes the most important terminology used in the document.

Annex D: Usage scenarios - provided as examples of applications of technologies and data within object locating and identification.

1.5 Management and maintenance

This reference architecture sets out an architecture, principles and recommendations for compliance in connection with procurement and development of solutions at state, Regional and municipal levels, see Annex A: Key capabilities checklist for solutions. Furthermore, the reference architecture plays a role in standards management, in that it identifies a number of standards as described in *Tillæg til Standarder og referencearkitekturer vedr. sundhedsområdet* (addendum to Standards and reference architectures for healthcare IT) [PRCSSTAND].

This document will be updated according to the governance model for national healthcare IT [PRCSSTAND], which has been adopted by the National Board of eHealth [NTNLBEST]. The Danish Health Data Authority is responsible for ongoing revisions of the document (updates, editing, additions and corrections).

Changes are registered in the document's revision log (see above). Furthermore, Annex B contains a Wish list for future versions of the reference architecture, and this can be used to specify future versions.

1.6 Background documents

This section provides suggestions for background documentation that is recommended as background reading for more detail on the area or aspects thereof.

As an introduction to device identifiers, it is recommended to read *UDI Guidance* [UDIGUIDE], published by the International Medical Device Regulators Forum [IMDRF]. UDI is short for Unique Device Identification. The IMDRF has broad participation, e.g. from Europe, the US, Japan, China and Brazil. The *UDI Guidance* document is targeted at government authorities and describes a framework for developing UDI systems. The US FDA has come a long way in this regard, including with establishing national UDI databases (UDID). The US database is called the Global Unique Identification Database (GUDID) [GUDID] and contains product information about medical device products. The EU is expected to follow this lead. Furthermore, it is expected that Denmark will be affected by developments in the EU. The GS1 [GS1], ICCBBA [ICCBBA] and HIBCC [HIBCC] standardisation organisations are also UDI compliant.

For an overview of GS1 and its standards, visit the GS1 website [GS1]. Read about the use of Global Location Numbers (GLN) at the GS1 website [GLNOVERB]. Rules for allocation are in the *GLN Allocation Rules (printable version) Standard* on the GS1 website [GLNNR]. A guide for implementing and using GLN in the healthcare sector has been prepared [GLNSUND].

For *in-depth knowledge* about how to create GS1 identifiers, see [GS1GENSPEC], which e.g. describes how to create GLN, GTIN, GRAI, GIAI, and GSRN. For more about the HIBCC *HIBC Supplier Labelling Standard* [HIBCC] and the ICCBBA *ISBT 128* [ICCBBA] see the websites of the respective organisations. Furthermore, this document also identifies which GS1 standards have been transferred to ISO standards.

For a description of *governance* with regard to standards and architecture in the healthcare domain, see the Danish Health Data Authority website [PRCSSTAND]. The site also has a description of how to set standards [PRCSSTAND], and of the National Board of eHealth and the Danish Health Data Authority's advisory committee on standards and IT architecture [RUSA].

2. Vision and goals

The vision of the reference architecture is to contribute to establishing a common direction for developments in the area, while also communicating a clear message. The vision:

> This reference architecture must enable efficient introduction of robust applications for object locating and identification.

The Danish healthcare sector could be much better at avoiding wasting time and resources, and thus money. Although citizens and patients can generally feel safe and secure in the Danish healthcare system, numerous errors still occur which could have been avoided. More effective logistics is an important source of continued efficiency improvement, and improvement in general, in the healthcare sector. Throughout the healthcare sector today, healthcare staff spend too much time trying to locate people and objects. Furthermore, we spend too much money stocking goods and equipment; money that we could save if the health services were better at sharing and coordinating.

Streamlining the healthcare sector is, without doubt, a difficult task. By its very nature, the sector will always have a certain degree of disorder. Much of what takes place during a normal day in the healthcare sector is inevitably unplanned. Many planned activities have to make way for unplanned activities. The people or equipment that ought to be at one location, are suddenly involved in solving a problem at an entirely different location. Therefore, it is no surprise that automated object locating and identification is pivotal in ensuring more efficient and effective processes in the healthcare sector. If we can rely on our IT systems to help us locate colleagues and vital equipment, it goes without saying that this will make us considerably better at planning, coordinating and using the scarce resources at our disposal.

The technologies that enable automated object locating and identification are developing rapidly and in many different directions. Therefore, it is important that we develop our competences in this area, so that we do not lose our way or get locked into specific technological solutions. Technological development will create new possibilities for a better and more effective and efficient healthcare sector. It is important that we respond to this development in a way that allows us all to develop in the same direction and not diverging directions.

The aim of this reference architecture is to contribute to revealing the potential of automated object locating and identification for the health services. Furthermore, it is to help ensure that IT systems and applications which make use of object locating and identification are developed with a view to efficiency and long-term relevance, e.g. through ensuring a decoupling of the application layer and the technologies used. The reference architecture will also help ensure interoperability across healthcare sector providers.

2.1 Perspectives and objectives

The perspectives for automated object locating and identification include: Higher productivity, greater safety and security, lower costs, shorter treatments and increased patient and healthcare staff satisfaction.

Some of the more obvious examples of what can be achieved through the introduction of automatic object locating and identification include:

- Improved quality and safety for citizens/patients through quicker response times achieved through using knowledge about the current location of staff.
- Increased safety for citizens through automatic alarm notifications in risk situations and through validation of decisions.
- A perceived increase in service levels for citizens/patients and their relatives as a consequence of smoother processes and assistance in finding people and locations.
- A reduction in the time spent by healthcare staff searching for people and equipment.
- Less time wasted due to more precise coordination of workflows and increased situation awareness.
- Continuous optimisation of workflows through analyses of actual workflows.
- Quicker identification of people and objects by IT systems.
- Full automation of certain tasks such as inventory monitoring.
- Reduction of decentralised storage capacities, due to a better overview of current inventories.
- Fewer costs of equipment through more effective and efficient use and less waste/obsolescence.

In addition to this, the introduction of automatic object locating and identification in daily routines is likely to lead to new ideas for other uses, and this will contribute to creating better health for everyone for the same investment as well as more satisfied citizens/patients and healthcare staff.

2.2 Context

The reference architecture is part of, and is influenced by, a large number of constantly evolving factors in a complex interaction of people, workflows, IT systems and infrastructure. See Figure 1 below for an outline.

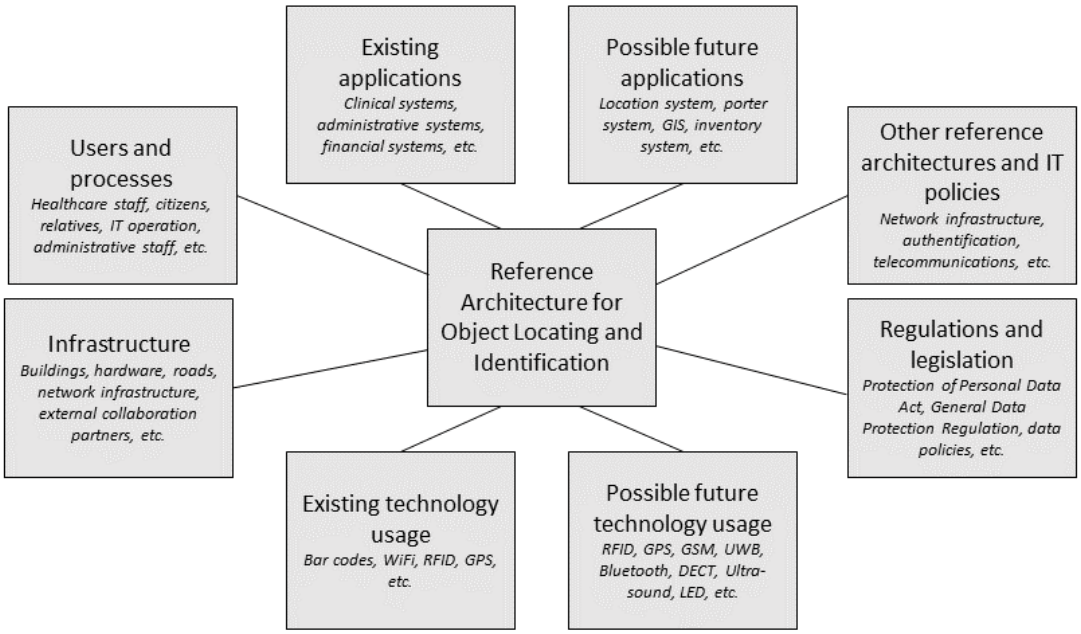


Figure 1: Systems and other factors affecting the reference architecture.

The surrounding infrastructure, such as buildings, roads, hardware and other objects, is crucial for how accurately objects (equipment, people) can be located and for the type of processes that can be established.

Existing legislation, regulations, standards, policies and procedures for data processing, communication, security, etc. are likewise aspects of importance for the reference architecture.

2.3 Trends

The demand for, and thus the benefits of, being able to locate objects across sectors in the Danish healthcare system are still in a nascent phase. Citizens discharged from hospital and transferred to the municipal homecare service are only rarely provided with disability equipment by the hospital.

As telemedicine becomes ever more widespread, requiring hospitals and the municipal homecare service (and possibly other actors) to be able to receive data/alarm notifications from medical devices, the need to be able to locate devices across sector borders will naturally increase. Furthermore, typically, the acquisition cost of such devices will be relatively high.

As described above, technological development allows for lower costs of identifying individual objects, and this is a trend that is likely to continue. There are initiatives to pave the way for exploiting this potential in the EU and internationally. For example, the EU is in the process of introducing directives and guidelines concerning the healthcare domain, which will set the framework for developments, see Annex B, by identifying standards (UDI) [UDIGUIDE] and by facilitating centralised product databases. Similar databases have been established, and are being populated, by the US FDA [GUDID].

2.4 Scope

This reference architecture addresses situations in which there is a correlation between location and identity. In some situations, however, scenarios that use either identity or location can benefit from the methodologies of the reference architecture.
Many technologies for object locating and identification can also collect other types of information. For example, there are sensors which, in addition to RFID technology, can collect information about such things as temperature, motion or humidity and which can perform actual biochemical analyses. Furthermore, there are ID tags which offer simple user interfaces with buttons, feedback, etc. It cannot be predicted which types of data will be collectable in the future. Therefore, it is important that the reference architecture can accommodate such technologies.

2.4.1 Examples that *are* covered by the reference architecture

- **Locating of hospital beds:** The current location of all beds can be determined using Wi-Fi tags in order to optimise processes relating e.g. to transporting, cleaning and preparing beds. *This example is covered by the reference architecture, as the identity and location of beds can be collected automatically.*
- **Locating of staff:** All staff carry a passive RFID tag that can be read by an RFID reader which is typically placed in door openings. On the basis of this, all staff can search for a specific colleague, or e.g. a colleague with certain competences, via a smartphone app. *The reference architecture covers this example, as the identity and location of staff can be collected automatically.*
- **Receipt of goods:** Goods can have been provided with RFID tags by the supplier. Upon receipt, the goods pass through a special gate and the RFID tag is automatically read. When placed in storage, and when later retrieved from storage, the RFID tags on the goods are scanned again. *The reference architecture covers this example, as the identity and location of goods can be collected automatically.*
- **Disability equipment on loan:** Disability equipment is provided with RFID tags by the supplier. On receipt, the RFID tags are registered. When placed in storage, and later when retrieved from storage, the RFID tags on the disability equipment are scanned again. Finally, the tags can be scanned when disability equipment is handed over to citizens. *The reference architecture covers this example, as the identity and location of the device are collected automatically.*
- **Admission cards for buildings:** A person runs his or her ID card through a card reader at the entrance door. *This example is covered by the reference architecture, as the identity as well as the location of the person in question are registered, the latter implicitly because the location of the card reader is known.*
- **Automatic identification of citizens and pharmaceuticals in matching with their administration:** In connection with administration of pharmaceuticals, both the citizen and the pharmaceutical container are registered using an automatic reader to ensure that the right pharmaceutical is dispensed. *Although this is not the primary objective, the location is registered implicitly. For example, a registration is made that the pharmaceutical was given at a specific hospital or in the patient's home. The example therefore falls under the framework of the reference architecture.*

2.4.2 Examples that *are not* covered by the reference architecture

- **Motion sensors in rooms:** An infrared sensor registers the movement of people in a room. *A motion sensor does not register the identity of the person moving about the room and, hence, is not covered by the reference architecture.*
- **Manual entry of measurement data:** Staff carry out manual entry of identity data and measurement data such as temperature and stress level. This could also include information about the location of the person in question. *This does not fall within the scope of the reference architecture, as the information is not registered automatically.*
- **Temperature sensors in a room:** A temperature sensor registers the temperature in a room. Because the temperature sensor is stationary, there *is no registration of mobility information, and the example does therefore not fall within the scope of the reference architecture.*

3. Framework and basic principles

This chapter describes the framework and basic principles upon which the reference architecture is built.

3.1 Legislation and regulations

The legislation listed below must be complied with when developing solutions within object locating and identification:

- The Danish Processing of Personal Data Act (*persondataloven*)
- The Danish Health Services Act (*sundhedsloven*)
- The Danish Medicines Act and the Danish Medical Devices Act (*lægemiddelloven and lov om medicinsk udstyr*)
- The Danish Social Services Act (*serviceloven*)
- Employment law regulations on control measures

The Danish Health Services Act and the Danish Social Services Act generally cover the applications that fall under the scope of this reference architecture. With regard to pharmaceuticals and medical devices, special regulations for good distribution practices (GDP) and traceability apply in certain situations. This chapter does not go into detail about how to interpret the legislation in the individual situation, since this would depend on the individual use-case situation. However, compliance with relevant legislation must always be ensured in connection with change projects and tenders.

With regard to the Danish Processing of Personal Data Act [PERSLOV], many relevant scenarios involve the registration of personal data for persons who are in contact with the healthcare system and/or healthcare staff. These scenarios are therefore covered by the rules in the Danish Processing of Personal Data Act for processing personal data. Alone the fact that the identity of people is registered makes the scenarios subject to the Act. For more, see the guidelines on the Danish Data Protection Agency website.

Framework and policies for managing data that can identify individuals are being continuously developed.

This includes the general Regulation of the European Parliament and of the Council on data protection, which has entered into force and will take effect from 25 May 2018. We assess that the reference architecture is not in conflict with the wording of this regulation. However, since the authoritative interpretation of the regulation has not yet been determined, the reference architecture may have to be adjusted, see Annex B, point 1. Annex B lists a number of initiatives that

could lead to a re-evaluation of this reference architecture. The user should therefore treat the text below as focus areas.

Of special relevance for the *locating of citizens with dementia* usage scenario, see Annex D, is the Act to amend the Danish Health Act and the Act on Authorisation of Healthcare Professionals and on Professional Healthcare (*Lov om ændring af sundhedsloven og lov om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed*) [SALOV] concerning the use of personal alarm systems and person locating/Track & Trace systems at hospitals, detaining citizens, etc. As follow up to the Act, the Danish Health Data Authority has prepared a guidance document [PATREG] on how to report patient data to the national patient registry.

In connection with implementation of projects related to personal data, note the following:

- What needs to be assessed and secured is the use of information, not the systems themselves.
- The objective must be objective and proportional. By proportional is meant that the least intervening solution meeting the objective should be chosen. For example, you are not allowed to Track & Trace all staff groups if you only need to Track & Trace individual members of staff.
- You have a duty to inform the person you have registered that you are collecting information about him or her, which information this is, and what it will be used for. For staff, this might be simple enough, however for uses that affect patients and/or relatives it may be more complicated to implement.
- You must obtain consent from the person you register. For staff, this might be simple enough, however for uses that affect patients and/or relatives it may be more complicated to implement.
- Individuals must be able to gain knowledge about what has been registered about them.
- The person who has been registered is entitled to have incorrect data corrected/deleted.
- Special rules apply if video monitoring is involved, including, not least, with regard to what interpretation of the meaning of 'consent'.
- Processing of information in the system may be subject to notification if the information is confidential. In most situations, this will not be the case for Track & Trace, however you should assess each situation individually, as information about illnesses is generally considered sensitive personal data.
- It may be necessary to provide information that automatic object locating and identification are taking place through sign-posting. To the extent that the employee can be located and his or her movement can be monitored, there is a requirement that you inform the employee in advance about this.

3.2 The concept 'Location'

The concept 'location' and related concepts such as place, position, positioning, and physical location are used in many different contexts. In this *Danish* reference architecture, we use the terms as they are described in the following report: *Begrebsmodellering af stedbegrebet i hospitalssammenhæng* (concept model for the concept 'place' in a Danish hospital context) [BGRBSTED, section 4.2.1][3]. This reference architecture is targeted at people involved in the development of the area of object locating and identification. As the title of the report suggests, focus is on hospitals. However, we assess that the concepts about locating are described to be applicable to the healthcare domain in general. Nonetheless, there can be uses for which the descriptions in the report must be compared with other concept descriptions. Concepts concerning 'location' have been described or are applied in the documents and systems below. The list is for reference when working with specific applications.

- ISA Core Vocabularies, Core Location Vocabulary [ISACORE]
- SNOMED CT , a comprehensive clinical terminology that also contains concepts defining locations, physical objects, and diagnoses, including a number of other terms from the healthcare sector in Denmark [SNOMED CT]
- *Fælles sprog III – KL (common language III - Local Government Denmark)*, also includes the location term (not exhaustive) [SPROGIII]
- Sundhedsvæsenets begrebsbase (database containing central concepts for the Danish healthcare sector) [NBS]
- The OIO standard for 'Organisation, [OIOORG]
- Sundhedsvæsenets Organisationsregister SOR (the Danish Register of Health Organisations) contains SOR locations [SOR]
- The GS1 standard GLN has four application areas [GS1GENSPEC]. "Physical locations" are used to refer to physical locations such as rooms or parts of rooms, and this falls within the scope of this reference architecture. However ”Legal entities”, ”functions”, and ”Routing keys” fall outside the scope of this reference architecture.
- GLN numbers (aka. EAN) to identify billing addresses. In this document, this is understood as a logical/organisational location and not a physical location.

[3] This report has been translated without a reference to an English terminology.

3.3 Decoupling

The following section describes a general principle for decoupling.

P: Decoupling
Applications which use locating data must be decupled from the systems that produce the locating data via a standardised integration layer.

This is the primary goal of the reference architecture: to avoid a future scenario in which several applications have implemented their own integrations for each individual locating system. The integration layer is described in Chapter 4 Architecture.

3.4 Interoperability

This section describes the considerations about interoperability that object locating and identification give rise to.

Through the EIF [EIF], the EU has developed a framework to support interoperability. The EIF has been profiled for national use in the healthcare domain in Denmark [TILSTNDARK]. Internationally, standardisation organisations such as GS1, ISO and others are working to establish and develop common standards for object identification and location.

The Danish Framework for coherent healthcare IT[TILSTNDARK], which translates the EU EIF [EIF] into a Danish context, provides an overview of the elements that lead to successful interoperability in work with object locating and identification in the healthcare sector. These frameworks are not described in this document, however reference is made to the documents mentioned above. Certain capabilities of solutions from the frameworks are described in the checklist in Annex A. See Annex A: Key capabilities checklist for solutions.

3.4.1 Communication between organisations

This section describes the principles for digital communication between organisations.

P:track-out
It is vital that information can be sent to external actors about the object locating.

The movement and status of goods in the healthcare sector may be relevant for the supplier, e.g. so that the supplier can receive information about when a product has been received or is out of stock.

P:track-in
It must be possible to receive information from external actors about the movement of objects.

The movement of the delivery trucks of external actors could be relevant information, e.g. in order to monitor the movement and predict the arrival of deliveries.

P:metadata-out
It must be possible to send information to external actors about objects.

If blood products are labelled e.g. via ID tags by the hospital and sent to external actors, these actors will probably need information about the blood product in question in addition to what can be provided via the ID tag.

Delivery trucks that run between healthcare providers and external service providers will probably be equipped with ID tags. The external service provider may need to be able to read these tags and identify the unique truck to which the tag refers.

P:metadata-in
It must be possible to receive information about objects.

Recipients of goods labelled with barcodes or RFID tags need to be able to translate the codes/RFID into a description of the product in question. For example, if the hospital receives a drug, the hospital must be able to translate the barcode into information about the name of the drug, the name of the supplier, etc.

3.5 Methods of identification

P:Use global standards for methods of identification Global standards for identification must be used to identify objects that need to be exchanged between organisations and other actors in the healthcare sector.

Local or domain-specific identification methods may replace this principle, e.g. the use of CPR (the Danish Civil Registration System) for identification of people.

Today, the US FDA and the EU recognise three organisations that offer codes for unique device identification, UDI [UDIGUIDE]. The US FDA and the EU allow for a scenario of several supplier organisations within the UDI field. Below is a description of the three primary providers of global identification in the healthcare sector.

3.5.1 GS1

GS1 [GS1] develops standards that support the exchange of products across borders and sectors. Health is one of the focus areas of the organisation, and GS1's standards are used by healthcare organisations in many countries.

GS1 is an international, non-profit organisation.

GS1 has a number of standards relevant for traceability and object identification in the healthcare domain.

Danish Regions uses GS1 standards to identify locations and selected objects.

3.5.2 HIBCC

The Health Industry Business Communications Council [HIBCC] issues IDs for use specifically in the healthcare sector and for teaching purposes.

The HIBCC is an industry-sponsored, non-profit organisation.

3.5.3 ICCBBA

ICCBBA [ICCBBA] develops and maintains the ISBT 128 standard, which is used for identification of medical products of human origin (blood, cells, tissue, breastmilk, etc.). The ICCBBA ensures international governance in the area.

3.6 Data exchange

3.6.1 EPCIS

The following section describes a general principle for using EPCIS [EPCIS] in interfaces.

P:Establish EPCIS interfaces
Communication between actors in the reference architecture must be established through EPCIS interfaces.

3.7 Security

This section describes principles concerning protection of information against unauthorised access by persons or systems. The ISO 27001 standard is the basis for the security principles. The stated principles are a part of the reference architecture because they merit special attention, however any system developed on the basis of the reference architecture should comply with the requirements in ISO 27001.

Reference architectures and standards exist for the Danish healthcare sector which describe how to maintain the required data integrity and how to manage personal data in specific contexts. Ensure compliance with the recommendations and principles in *Referencearkitektur for informationssikkerhed* (reference architecture for information security) [REFINF].

P: unauthorised-data access
Data about identifiable objects, persons or groups of objects/persons must only be accessible to users authorised to access the data.

- Civil registration numbers (CPR numbers) can be abused and must be protected from falling into the hands of unauthorised persons.
- Health data about patients obtained from sensors can contain information that must not be viewed by unauthorised persons.
- Information on the movements of people must not be viewed by unauthorised persons.
- The location of pharmaceuticals must not be viewed by unauthorised persons.

P:unauthorised-connection
Unauthorised persons must not be able to submit false data to the system.

It is crucial for the use of, and confidence in, the system that the reported data is credible, not least because a number of security systems may be based on this data. For example, it must not be possible to simulate ID tags for staff by listening in on the communication between the tag

and the reader. Nor must it be possible to submit false sensor data from a patient equipped with a tag that submits measurement data to the system.

P:unauthorised-disablement
Unauthorised persons must not be able to disable the system.

- A person accidentally shuts down the system.
- A person maliciously shuts down the system.
- A person maliciously overloads the system (denial-of-service attack or similar).

P:auditing
It must be possible to determine from the source of data and who uses data.

It must be possible to see which systems send data into the system, and what data is being sent, so that possible errors can be detected.

It must be possible to see what types of data an application uses, so that a response can be made if it turns out the system uses data that was not intended for the system.

4. Architecture

The reference architecture decouples applications and object locating systems by inserting an integration system between the two. The integration system is based on the EPCIS standard from EPCGlobal.

4.1 Existing architecture

Track & Trace technologies and applications are often connected via direct integration between the hardware and the applications using the data.

4.2 Target architecture

In order to be able to reuse identity and locating events in several applications, the goal is to establish an architecture in which the individual locating event can be distributed in due time and independently of whether the sender and the recipient know each other.

4.3 A layered architecture

The overall architecture for object locating and identification can be divided into five logical architecture layers, see figure 2.

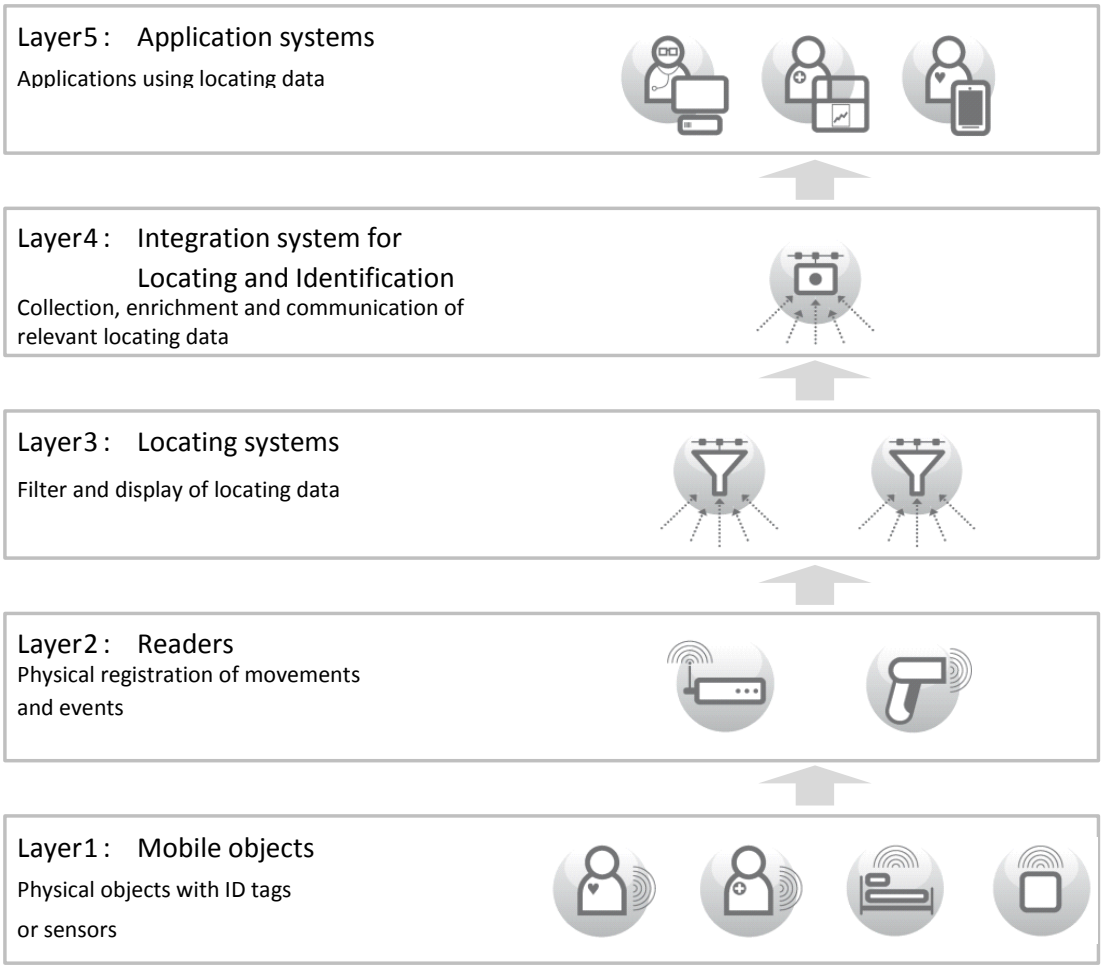


Figure 2: The reference architecture is a layered architecture in which the primary dataflow is from the bottom and up.

The bottom layer has persons, mobile inventory and equipment, goods, etc. These will typically be equipped with an ID tag. These objects are Tracked & Traced in Layer 2 by various types of hardware unit, typically via wireless communication. The IDs, positions and other data read are corrected for errors, duplicates and similar in Layer 3. This often takes place at local level in the software that controls the readers. However, it can also take place at central level in connection with the transfer of data to Layer 4.

In Layer 4, the integration system for object locating and identification (in the following referred to as the integration system) is responsible for collecting, enriching and communicating the relevant data to Layer 5, where applications will typically display the data for end users, trading partners or similar.

Below is a description of a number of principal decisions which, together, shape the reference architecture.

The next chapter describes and elaborates on the individual layer as well as on how the reference architecture is used in the individual layer.

4.4 General Principles

This chapter describes a number of decisions of a cross-sectorial and general nature.

4.4.1 Separation of data capture from applications

A key requirement of the reference architecture is that applications and object locating systems must be decoupled, see [P:decoupling], so as to reduce or avoid interdependency among the systems. This is achieved by introducing an integration system for decoupling.

However, there is a conflicting interest, i.e. the need to be able to connect easily and quickly a simple system for automatic data registration, e.g. to connect a barcode reader to a PC in order to avoid having to enter data manually.

Applications should moreover be allowed to pull data directly from other organisations, even in the case of location data. If several systems use the same externally derived data, it is recommendable to display this data as a single service. For example, this can be achieved by integrating the data in the integration system.

P:indirect-access
The applications may only access the location data via the integration system.
However, this does not necessarily apply to externally derived location data or simple object locating systems in which data is only usable in one specific context.

An important question when establishing IT systems is whether to establish the whole future system at once or whether it should be developed incrementally. Trying to establish the whole system at once means having to predict all future needs and therefore risk making the system unnecessarily complex. If you take the incremental approach, you develop only the part of the system for which there is a current need, which means there will be an ongoing need to adjust the design.

This reference architecture seeks to strike a balance between these two approaches: The overall framework has been designed and validated with regard to all of the identified scenarios and types of technology. At the same time, only the specific functionalities and data for which there is a topical and real need are included. Additional functionalities and data can be added at a later stage if relevant.

P:dynamic
The reference architecture outlines an overall framework, while the details will have to be developed over time as needs arise.

This principle means that certain functionalities and interfaces must be defined as minimally as possible, allowing for possible later expansion. It also means that it must be possible to expand the integration system with new services.

P:new-services
The integration system must be expandable with new services over time as needs evolve.

New services could be new functionalities or the display of existing functionalities in new ways.

4.4.2 Humans involved in all critical decisions

Many processes can be driven by information about the location of the units involved. However, for a number of reasons, critical decisions should always involve a human assessment:

- Positioning will be subject to some degree of uncertainty regardless of the technology used.
- It is important to document who makes critical decisions.
- An IT system cannot identify "exceptions to the rule", e.g. when a patient merely looks into the wrong room.

Therefore, as a general principle, critical decisions should always be made by humans:

P:decisions
Locating solutions must make it easy to make and to document decisions, but locating solutions must not generally be allowed to make critical decisions on their own.

For example, the system should not decide that a patient is in the recovery room based on the fact that the patient's bed or wrist band is in the recovery room. The system should only make it much easier for staff to decide and document this.

4.5 Standards

Interfaces based on standards can reduce the costs of integration between systems considerably.

Even if systems use a standard, the integration task will be considerable. Only relatively simple standards can be considered as plug-and-play solutions. This is because many standards offer several alternative possibilities for exchanging the same type of information and because they often omit to specify a number of details.

For the communication between different organisations, using a standard rather than a proprietary interface can often be an advantage.

The value achieved by basing an interface on a standard are assessed from case to case and in the context of how proliferate and suitable the relevant standard is.

4.5.1 Application of standards between Layers 4 and 5

Layer 5 will consist of ordinary applications such as electronic patient records (EHR) and external systems which are dependent on location data, e.g. from a supplier of goods. For the latter, in particular, there may be a requirement to display data via a relevant standard. In order to ensure the architecture remains as simple as possible, the same interface must be used for all applications in Layer 5. A benefit of this will be that the integration system can more easily be replaced.

The relevant interface in EPCGlobal is called EPCIS Query Interface. Note that, despite the name, this interface displays location data via pull and push.

P:interface-layer4
The interface which Layer 4 displays for Layer 5 must be based on the EPCIS Query Interface.

If selected data is used in many applications, it may be relevant to develop a simpler, proprietary interface as a supplement to this standards-based interface. However, this interface must still be implemented on top of the standardised interface, so that the integration system can still be replaced if desired.

4.5.2 Application of standards between Layers 3 and 4

In the long term, the number of object locating systems is expected to be considerably lower than the number of applications. Thus, the number of integrations between Layers 3 and 4 will be considerably lower than between Layers 4 and 5.

At present, only barcode and RFID systems are expected to make a standards-based interface available. For other technologies, such as Wi-Fi positioning, no standards have been established at this level.

If a object locating system displays both standards-based and proprietary interfaces, the standards-based interfaces should be used, because this will ease the introduction of future object locating systems using the same standard.

P:interface-layer3
Standards-based interfaces should be used between Layer 3 and Layer 4.
Proprietary interfaces may be used, thus only allowing for performance and business concerns.

4.5.3 Application of standards between Layers 2 and 3

Readers and associated software are often procured as a total solution and the interface is usually proprietary. The reference architecture does not exclude such solutions and, therefore, has no requirements regarding this interface.

The aim is to describe standardised methods for integration with selected technologies between Layers 2 and 3 within the framework of collaboration on the reference architecture.

P:interface-layer2
Proprietary interfaces may be used between Layer 2 and Layer 3.
If there is a standards-based interface, this should be used rather than a proprietary interface.

4.5.4 Application of standards between Layers 1 and 2

The protocol between ID tag and reader is in some situations determined by which ID tags are received from external sources, e.g. barcodes and RFID tags on goods. In situations in which these goods have to be registered, the relevant standards will have to be supported. A common solution to this is to buy readers that support several protocols (multi-protocol readers). Many barcode readers support the most popular barcode standards.

It will be an advantage if all readers using the same technology can read all of the organisation's own ID tags in order to accommodate future, as yet unforeseen needs.

If standards exist, these should be used because future demands for managing ID tags from external sources can then more likely be met. The specific protocols to be used should be decided in connection with procurement and testing of the individual object locating system.

R:interface-layer1
The organisation's own ID tags should use as few protocols as possible. A standardised protocol should be used if available.

4.6 Identify

4.6.1 IDs without meaningful information

Unauthorised persons must not be able to read or falsify information on ID tags. This applies in particular to ID tags worn by people, whereas it is less important in other situations, e.g. in connection with labelling of goods such as clothes or plastic gloves.

In situations in which the highest degree of security is desired, communication between the ID tag and the reader should be secured using encryption. For extra security, and as the only security in situations in which encryption is not desirable or possible, the ID on the ID tag must not contain meaningful information such as a civil registration number or name.

Thus, there is a distinction between the real ID of the object, e.g. a civil registration number, and the pseudo ID, which is the ID that is saved on the ID tag. These are often termed GID (Genuine ID) and PID (Pseudo ID).

This decoupling between the ID of the tag and the ID of the physical object moreover provides the option of producing the tags in advance, before they are linked to the physical objects, and this makes it easier to allocate replacement tags.

P:surrogate-id
Unauthorised persons must not be able to use a PID to deduce a GID or in some other way identify the object carrying the ID tag. This means that the PID must be a surrogate ID.

4.6.2 EPCs are used for PIDs

In connection with integration of data from several object locating systems, including data from other organisations, global unique identification is required for all objects which need to be Tracked & Traced.

Actors are expected to have a global unique GS1 company prefix and an associated governance model for use of prefixes.

Such an ID is a fundamental element in the EPCGlobal standards and is called the EPC (Electronic Product Code). EPCs are hierarchical in structure, e.g. EPC:ID. RM:wifi:1234 (slightly simplified), which make them globally unique while still easy to manage at a local level.

Systems that do not use EPCs must be mapped to/from EPCs by the integration system.

R:epc-pid
EPCs must be used as the only PIDs in Layers 4 and 5.
If another ID is used in Layer 3 and lower layers, this is to be mapped to EPCs when transferred to Layer 4.

4.7 Division of responsibilities

This section describes the responsibilities of the different parts of the solution.

4.7.1 The mapping of identity takes place in Layer 5

In principle, Layer 4 can display IDs for Layer 5 as PIDs, GIDs or both. The EPCIS standard specifies that these be displayed as EPCs, i.e. as PIDs. In other words, Layer 5 is responsible for translating PIDs to GIDs.

To simplify the mapping process, an identity service should be established, which all applications can use to translate between PIDs and GIDs, provided the user has the required rights.

Often, additional services will be established in Layer 5 for specific purposes, such as locating of patients. It would be natural that these services encapsulate the mapping of IDs for systems such as electronic patient records (EHR).

P:id-mapping
A general service (identity service) must be established to provide mappings between PIDs and GIDs across people, equipment, goods, etc.

4.7.2 Allocation of PIDs in Layer 4 or lower

Often, locating solutions include specialised software for writing data on ID tags. In some cases, these can also generate PIDs.

The same software can be used across a number of locating solutions which use the same technology.

Linking of PIDs and GIDs should be subject to the same single governance model through methods and technologies.

P:pid-allocation
Generating new PIDs can take place in the individual object locating system or outside of the individual object locating system.
Linking of PIDs and GIDs takes place using one or more purpose-made tools.

4.7.3 Business logic in Layer 5

The integration system is not a general data integration platform. The system is targeted at integration of location data. Information outside this scope is therefore the responsibility of Layer 5.

P:business-logic
All business logic, i.e. information about treatments, diseases, logistics processes, workflows, etc. belong in Layer 5. So does information about physical objects such as patients, staff, equipment, goods, etc.

4.7.4 Business logic in Layer 4

Interpretation of the current position and movement pattern of physical objects, including comparing information from different object locating systems, is advanced logistics and should only be implemented in one location. This will ensure consistency while avoiding having to maintain the logic several times.

P:position-logic
All logic about positions, such as current position, registration of movements, recognition of "same location", belong in Layer 4.
The only information in Layer 4 about physical objects such as patients, staff, equipment, goods, etc. is information about their type, identity, physical position/movement and any sensory data.
Change of state, sensory data, alarms etc. are passed on to Layer 5 without interpretation.

The type of object is necessary information because there may be different rights and different logics linked to different object types.

4.7.5 Exchange of metadata with external actors in Layer 5

As a consequence of [P:business logic], the integration system is not responsible for exchanging data on goods, patients, equipment, etc. with external actors. Events belonging to the business processes are therefore exchanged in Layer 5, e.g. in a logistics system or similar, while the exchange of information about objects (PIDs) and their locations takes place in the integration system.

P:data-exchange
Data on objects, e.g. goods, are exchanged directly between applications in Layer 5 and the external actors.
Data about locations, event types and PIDs are exchanged via services in Layer 4.

4.7.6 Historical data in Layer 5

Historical location data can be pulled from the integration system, e.g. for analysis purposes. However, only data that has been automatically registered is collected in the integration system - manually entered data is not. Furthermore, only location data is stored in the integration system. General data about the objects, which is typically relevant in an analysis context, is not available in the integration system. Finally, the integration system will be optimised for a large number of transactions (OLTP) and not for data analysis (OLAP).

Actual OLAP/warehouse functionality therefore belongs in Layer 5. For example, such a system can periodically pull the relevant data from the integration system in Layer 4 and combine this data with data from other systems.

However, location events are stored briefly in the integration system, Layer 4, partly in order to support polling, which is required by EPCIS, and partly to ensure persistence in connection with failure. Events may also be saved in log files. This data must be deleted periodically, either manually or automatically.

The period for which location events and logs are stored depends on the current needs of the applications. In this context, the requirement in the Processing of Personal Data Act for consent from people who are Tracked & Traced, as well as the principle of proportionality between means and end, must be considered. See section 3.1. on legislation and regulations.

P:historical-data
Business intelligence belongs in Layer 5.
Location events and logs are stored briefly in the integration system.

4.8 Administration

4.8.1 Administration via supplied tools

Often, locating solutions include customized software for administration and configuration of the solution. These tools will therefore often be more suitable than a general solution developed for a number of different positioning technologies.

However, some software products contain functionalities for administration and configuration of readers and ID tags from multiple suppliers but aimed a specific technology such as RFID. Such functionalities should therefore be considered in connection with the procurement of specific products but they are not a part of the architecture.

P:administration-tools
Administration of locating solutions takes place through tools supplied with the locating solution or tools selected for the purpose. The integration system does not offer centralised administration across positioning technologies.

4.8.2 Interfaces for centralised monitoring

Locating solutions often include tools to monitor the functioning of readers, the battery status of ID tags, that parts of the system are not being overloaded, and similar.

Such data should be displayed via interfaces which make it possible to monitor the solution from centralised monitoring tools such as Tivoli, Orion, etc. However, attractive locating solutions may exist which do not do this.

P:monitoring-tools
Non-trivial locating solutions must include the option of monitoring the health of the solution. Locating solutions should display interfaces for monitoring.

4.9 Locating

4.9.1 Identification of places in Layer 5

Named localities are sufficient to meet the needs, although there are a few exceptions. In special scenarios, e.g. scenarios in which there is a need to picture detailed movements in a map, it may be necessary to forward coordinate data to one or more applications.

There are a number of standards for geographic coordinates. However, none of these are directly supported by EPCIS. The need for coordinates can therefore only be supported through expansion of the definitions of the EPCIS standard.

P:locations
As a general rule locations are stated using named localities. If geographic coordinates are necessary, these are displayed by the integration system as a supplement to the named coordinates.

4.9.2 Central location database and service

It is important that all location-related systems use the same localities. To ensure this, a central location database is established so that this data is maintained in one location. A service and interface are displayed through which to access and maintain data. Furthermore, synchronisation mechanisms are established to keep the location database up-to-date with other data sources with information about locations.

P:location-service
A common database of all localities are established which is accessed and maintained via a service (locating service).

4.9.3 Global Location Number

A GLN provides a unique and unambiguous identification of physical, operational and legal units, i.e. of sender, recipient, buyer, seller, supplier/manufacturer, issuer, location of delivery, location of payment, stores and internal departments, etc.

The issue of GLN is coordinated by GS1 and is globally unique. Localities referred to via a GLN can be identified across actors, businesses and systems.

R:locations-identified-with-GLN
We recommend giving all localities a unique Global Location Number, so that they can be used across systems.

4.9.4 Identification of locations in Layer 3 or 4

When using named localities, some object locating systems, typically RTLS systems [RTLS], need to translate coordinates into localities. This task can be performed at either Layer 3 or Layer 4. It is important that the list of localities does not have to be maintained in several locations.

P:mapping-of-position
Positioning of physical objects in a specific room, i.e. translating coordinates into named localities, can take place in Layer 3 or 4. If it is done in Layer 3 (i.e. typically because there are already functionalities for this in the object locating system) then the localities must automatically be pulled into the object locating system from the object locating service.

4.10 Filtering

4.10.1 Explicit filtering

Many positioning technologies submit events at a high frequency. This results in a substantial number of events, which could provide challenges with regard to scaling and constitute a burden on the network. Furthermore many of the events will probably not be required in all usage scenarios.

To avoid this, the amount of data should be reduced and, preferably, at local level, i.e. as close as possible to the reader. This can be achieved partly by reducing the frequency by which location events are sent and partly by filtering out events that are irrelevant. For example, there is no reason to send many events telling that a person has not moved or that the number of goods in a storage facility is unchanged. However, it is essential that applications know as accurately as possible which events they can expect to receive because changes in this pattern can be complicated for the applications to manage.

P:explicite-filtering
The integration system and object locating systems are allowed to filter out irrelevant events. However, events defined as *critical* by even a single actor must never be filtered out.
Which events are supplied from the integration system to the applications must be explicitly documented, including which events are critical and which events have been filtered out by the integration system or any of the underlying object locating systems.

4.10.2 Filtering at local level

Exactly how filtering is to take place depends on the usage scenarios to be supported at a specific time; thus filtering must be configurable.

P:local-filtering
The object locating systems must be configurable to the effect that location events are submitted only periodically or when certain values are registered. Filtering should be achievable at local level, i.e. as close as possible to the reader.

4.11 Error management

4.11.1 Correction of errors in the integration system

Erroneous registrations, such as inaccurate positioning, can have enormous consequences in the applications. Therefore, it is important that these systems are aware of erroneous registrations.

Some of the errors can be corrected in Layer 3 and some cannot be corrected until Layer 4, in which more information is available, e.g. information on how hospital beds can move.

The same data can therefore be displayed with several qualities and an indication of the quality of the registered data is therefore an important part of the interface between Layers 4 and 5.

P:correction-infrastructure
Error correction can take place at Layer 3 and/or Layer 4.
The correctness of the resulting location data must be clearly specified so that the applications can manage this data correctly.

4.11.2 Errors must be correctible in Layer 5

Layer 5 will inevitably receive some erroneous registrations. These can be due to human error or inaccurate sensors. Such error events can entail a number of consequences in the affected applications; consequences that can only be corrected in the applications in question. Thus, it is important that a functionality for error correction exists.

For example, the position of a hospital bed can lead to the bed being registered as "being cleaned". If this is due to an erroneous registration in the positioning system, there must be a way to correct the status of the bed.

P:correction-applications
Each application in Layer 5 must implement a user interface or an automatic process through which the implications of the faulty event can be rectified.

4.12 Event-based communication

As a consequence of [P:delay], it must be possible to forward events to applications immediately after they have been received, i.e. without the application having to explicitly poll data.

P:delay
The integration system must be able to forward incoming events with minimal latency, i.e. without polling.

Event-based databases collect an entire or a partial data set of location events and the event data that can be deduced from the location event. On the basis of the business procedures described in the process database, it is possible to collect events at different abstraction layers. The basic event contains only time, location and object. Extended events are defined as events where time, location and object are enriched with a business event originating from the process database's known business procedures. On the basis of the business event, the extended event can be used to automatize the instigation of the next step in complex processes.

For privacy and proportionality reasons, it is important that event registration is based on valid business needs. We therefore recommend minimising event registration on the basis of the framework for registration of a given object type. Capture of data on patients cannot take place at the same level, as e.g. the location of dispatches in a pneumatic tube system. All designs of event registration must be based on local business needs and take account of privacy rights.

Therefore, exchange of events between actors must only be established such that there is still a proportional correlation between method and consideration for the registered object or person.

4.13 Integrity

4.13.1 Manipulation of communication

The networks that are used to communicate between subsystems, whether these are cabled or wireless, often themselves provide some degree of protection against unauthorised access to data. However, the network itself cannot be expected to provide the required protection. Furthermore, since data can be sensitive, it may therefore be necessary to ensure additional protection.

P:integrity
The transfer of sensitive data must be encryptable.

4.14 Logging

As stated under [P:auditing] it should be possible to register which object locating systems produce data and, then, which applications consume this data. Periodic reviews (i.e. automatic reviews) of these log events can assist in detecting security issues, faulty allocation of rights, etc.

Which systems produce data can be registered at low cost as a part of ensuring the persistence of location events.

Registration of who uses the individual event data will lead to considerably larger overheads. The type of queries performed by the applications can be registered instead.

P:audit-logging
The integration system must log data about which systems produce location data and which systems make queries, including data about the type of query.

5. Recommendations for system architecture

This chapter describes reference architecture recommendations for building a system architecture to support usage scenarios that include object identification and location. Note that the recommendations in the chapter are based on experience rather than analyses, initially from the reference architecture of the Regions [REGREF], supplemented with the experience gained by the Regions based on precisely this reference architecture. .

The usage scenarios in which data is exchanged between various healthcare actors are referred to as external usage scenarios. This may be in connection with Track & Trace implants or recalls of medicine in which the usage scenario involves several actors. In external usage scenarios, the interfaces should be well described to ensure that several software suppliers can exchange data without problems. Therefore, the following will include recommendations on well documented and well tested standards for data exchange.

Communication between actors in the healthcare sector can be based on many-to-many communication or via Global databases shared between several current or future actors, see figure below. The advantage of Global databases is that data entry is only in one location and only in one format. The advantage for users of data is that there is only one location to retrieve data, only one data format to manage and that data is produced by the data owners so the best possible data quality is obtained. However, such a system should have built-in mechanisms to ensure that data is only shared between actors who have agreed to exchange data.

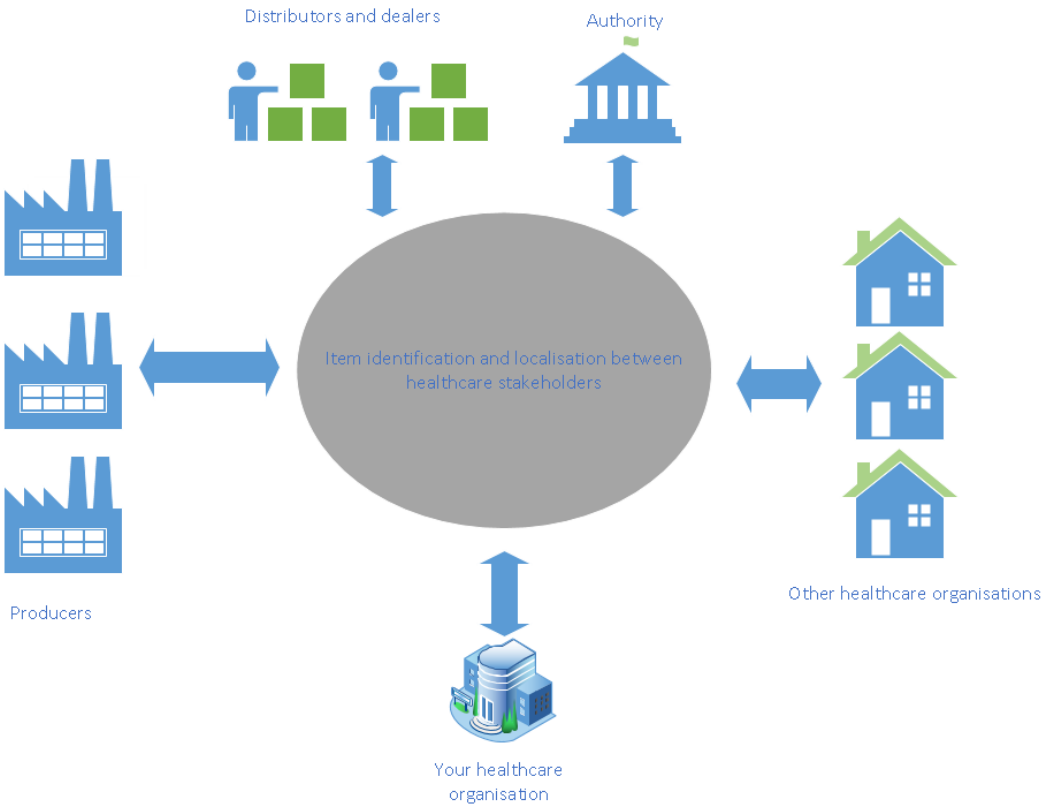


Figure 3: Chart of the need for exchange of data between various healthcare actors

Furthermore, a number of usage scenarios will take place within the actors' own organisation. This may be optimisation of hospital bed flow, staff location, optimisation of flows of goods and staff in home care, etc.

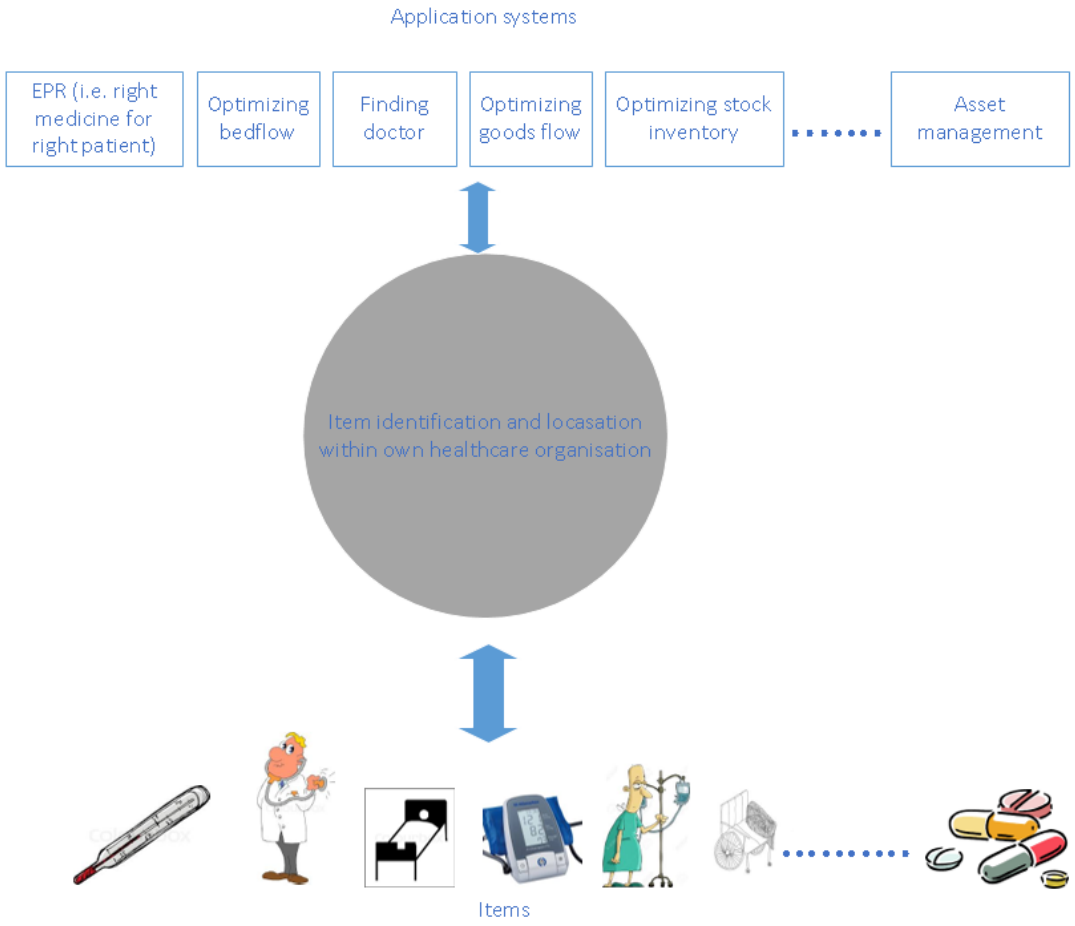


Figure 4: Chart of internal usage scenarios that include object identification and location. The list of objects and applications may be extended.

We recommend sharing some information in both internal and external usage scenarios. The following principles should be applied for the recommended system architecture:

P: Data reuse
Data should be reused to the highest extent possible in order to ensure high data quality. Data should be produced as close to the data source as possible.

P: Reuse of interfaces
In order to reduce development and maintenance costs, the number of interfaces for data exchange should be kept at a minimum.

The principles above should be used together with the architecture principles stated in section 4 as a basis for a proposed system architecture. The overall recommendation is a system architecture, as shown below, consisting of Global databases for external communication, as well as

central internal databases for internal usage scenarios. The following will describe in detail the recommended system architecture.

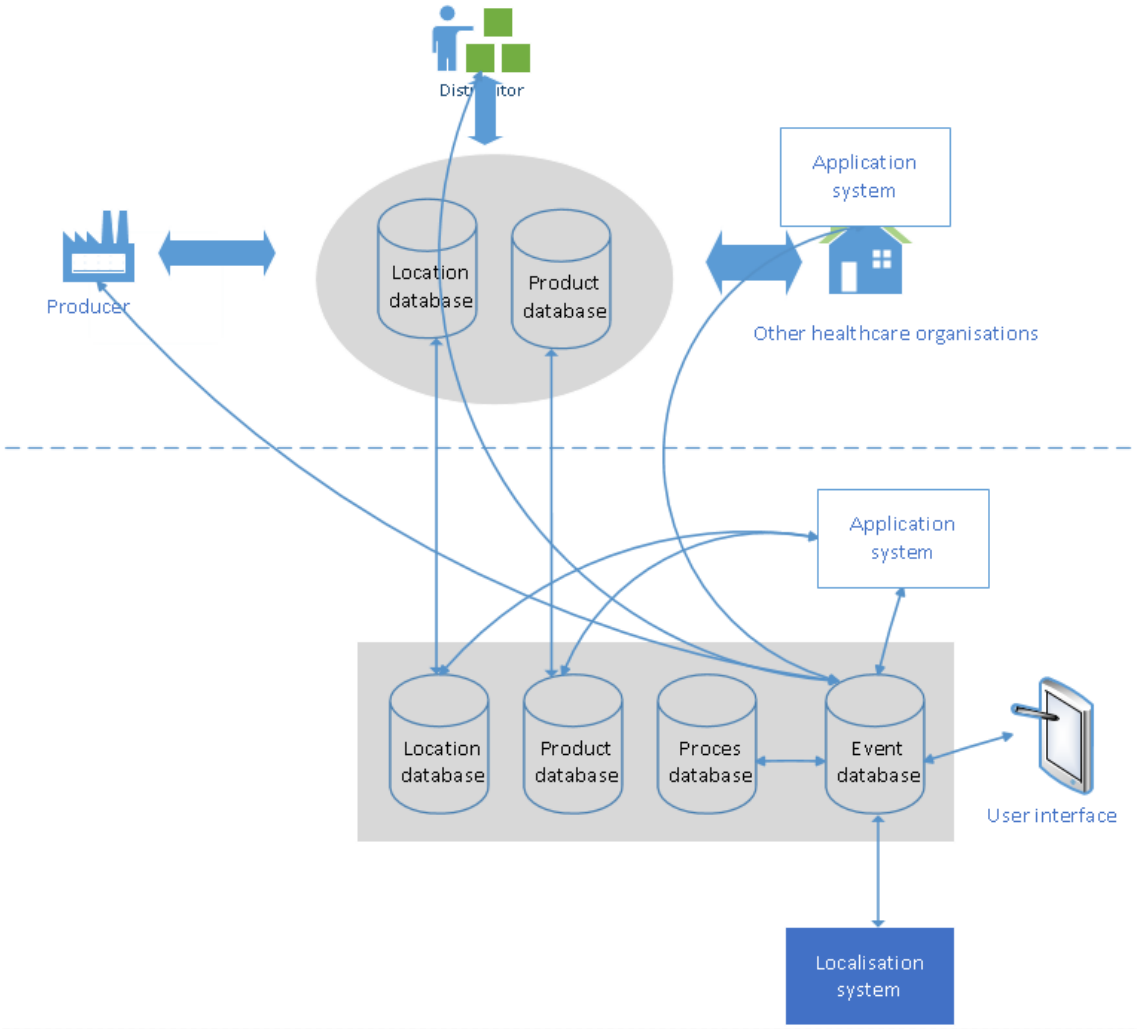


Figure 5: Simple chart of internal and external components and communication flow between the components

5.1 Recommended system architecture between healthcare actors

For external usage scenarios, we recommend a model with Global databases to exchange product master data and location data in order to ensure the best possible data quality and the greatest possible reuse of data.

R: Use Global databases for product data and location data
We recommend using GS1 data pools to exchange product data and location data between healthcare actors. We only recommend sharing data that is necessary for other actors.

R: Transfer of data between own organisation and GS1 data pools
We recommend using GDSN to exchange master data between data pools and own health organisation.

EPCIS is used to indicate where a given object is located, i.e. the connection between the object and location. Currently, there are no national or international databases accessible to the public to exchange EPCIS data, so initially exchange of data must be carried out using many-to-many communication between healthcare providers, producers, dealers and authorities.

R: Indication of objectID and location is exchanged via the EPCIS standard in many-to-many communication
Responsibility for **authentication** and authorisation of actors will have to be agreed by the parties.

We recommend working towards common accessible event databases between relevant actors to streamline the exchange of event data between relevant parties.

5.1.1 Data pools and GDSN recommendations

Global Data Synchronisation Network (GDSN®) [GDSN] is a standard for exchanging master data for products and services, e.g. description of product, dimensions of product, number of units etc. between producers and users. GDSN® is based on synchronisation of data between certified GDSN® data pools that enable producers to update data in one location and provide all users with access to updated and validated data on products via one data entry. For example, NEHTA's National Product Catalogue for hospitals in Australia is based on GDSN.

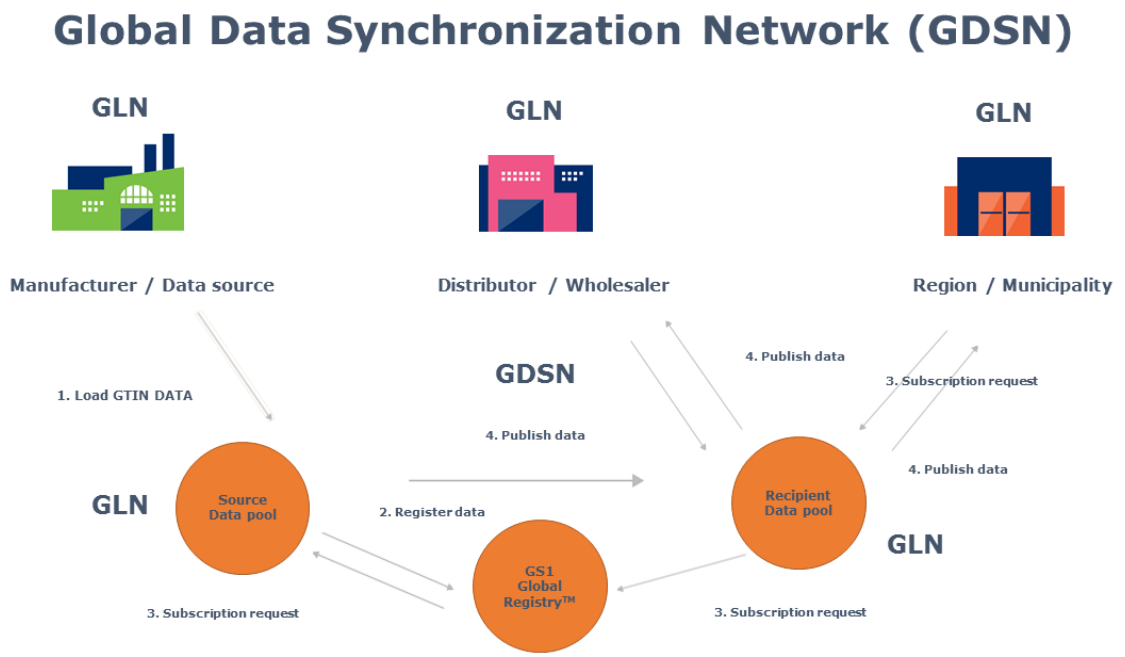


Figure 6: Chart of GDSN dataflow. The figure was made available by GS1 Denmark.

In order to be able to provide support for a given usage scenario, accessibility of relevant product and location master data must be ensured. In order to provide support for a usage scenario within logistics, it may be necessary to know the weight and size of an object. For each usage scenario to be implemented, it is necessary to ensure accessibility of relevant master data. We recommend using as a starting point the usage scenarios already implemented in other countries by selecting relevant master data for the requested usage scenarios. Any addition of attributes relevant in a specific Danish context should be developed collaboratively with GS1.

R: We recommend using as a starting point the instructions in "GDSN_Healthcare_Use_Cases_Guideline", including the product attributes to be exchanged, as described in " GDSN Healthcare Use Cases and Attributes"

5.1.2 EPCIS and recommendations

EPCIS is an ISO standard for event registration. The objective of EPCIS is to enable different systems to generate and exchange data in order to create transparency for events (the so-called "visibility event data") – both within an organisation and between organisations. This exchange of data will enable users to gain a shared knowledge of the movements of physical and digital objects in relevant process contexts in the healthcare sector. Generating standard event data will establish a data basis to support a number of different processes such as traceability, recall, verification, analyses, etc.

Like many other standards, EPCIS only provides interoperability up to a certain point. For example, it defines the basic message format, but does not state precisely which format to use in which situations. This means that EPCIS is a relatively open standard that allows business partners to define their own language.

However, EPCGlobal also defines the Core Business Vocabulary Standard, which is a specific example of such a common language.

R: Core Business Vocabulary is used in connection with data exchange with EPCIS. Usage scenarios which are not covered by Core Business Vocabulary will have to work with GS1 on extending Core Business Vocabulary in order to support all relevant use scenarios.

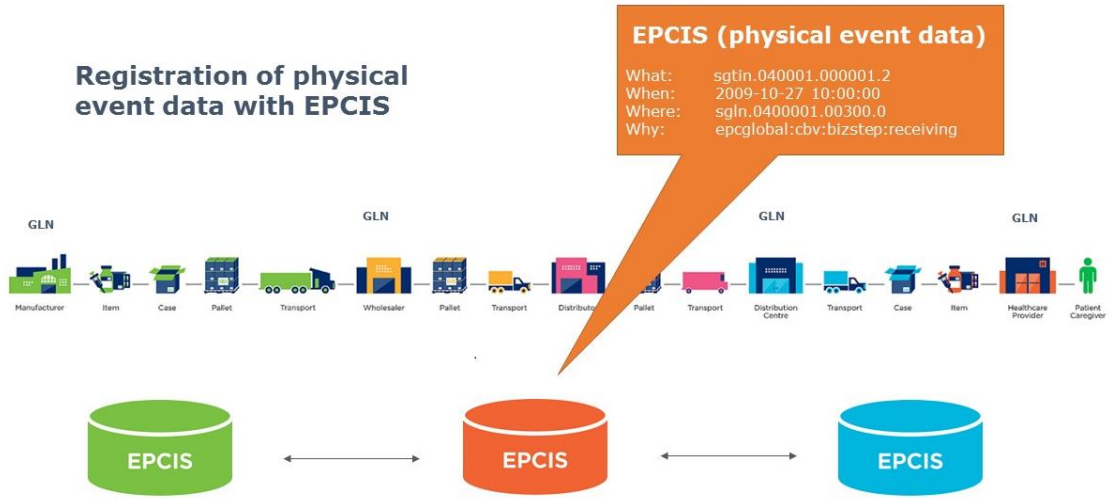


Figure 7: Chart of communication between EPCIS repositories with examples of what is communicated. The figure was made available by GS1 Denmark.

5.1.3 Location and recommendations

Global Location Number (GLN ®) is a globally unique and unambiguous identification key to identify physical, operational and legal units, and it comes under ISO/IEC 6523 "Information technology – Structure for the identification of organizations and organization parts". GLN can be used to identify locations such as reception, delivery point, stock position, lounge, operating theatre, hospital storage, etc. GLN is also used to identify recipients and senders of electronic messages such as e-invoices. GLN is used to identify municipalities, Regions and state authorities in connection with the Electronic Invoicing Act (*lov om elektronisk fakturering*), in which GLN is known as EAN.

A GLN Registry is a database, in which users of GLN numbers can add relevant attributes such as address, postal code, contact person, etc. to a GLN and make this information available to partners. Different GLN Registries can exchange information on GLN numbers with each other via GS1 GLN Service, so that users can receive information on all registered GLN numbers via one data entry.

Public institutions in Denmark can obtain GLN numbers from the Danish Health Data Authority's number series.

R: A GLN is allocated according to the "GLN Healthcare Implementation guide". The recommendation only applies to physical localities, as legal and organisational units are not covered by the reference architecture.

5.1.4 Recommendations regarding object identification

Object identification is central in this reference architecture, and we recommend using GS1 standards for object identification. The following examines the most important standards.

GTIN
Global Trade Item Number (GTIN®) is a globally unique and unambiguous identification key to identify products and services. GTIN follows ISO/IEC 15459 - Part 4: Individual products and product packages. GTIN can be used for all products at all packaging levels, e.g. primary packaging, secondary packaging or tertiary packaging (pallets). GTIN can be used to identify medicines, medical devices and other articles used in the healthcare sector. GTIN is used as a Device Identifier in connection with requirements for UDI (Unique Device Identifiers) for medical devices in the US.

R: We recommend using the instructions in the "GS1 Healthcare GTIN Allocation Rules".

GRAI
Global Returnable Asset Identifier (GRAI®) is a globally unique and unambiguous identification of reusable units such as box pallets, medicine chests, storage boxes.

GIAI
Global Individual Asset Identifier (GIAI®) is a globally unique and unambiguous identification key to identify assets such as ultrasound scanners, blood pressure meters, etc.

GSRN
Global Service Relation Number® is a globally unique and unambiguous identification key to identify staff and patients in the healthcare sector. ISO/TS 18530:2014 Health Informatics -- Automatic identification and data capture marking and labelling -- Subject of care and individual provider identification, is based on GSRN®. Staff in the healthcare sector could be nurses and other nursing staff, physicians, orderlies, etc.

R: We recommend using the instructions in the "GS1 General Specifications" when using GRAI, GIAI and GSRN.

Note that it is not necessary to use a specific unique identification type, the individual organisation can choose which one to use. An example is a scalpel. If emphasis is on the fact that the scalpel is one out of many scalpels of a given kind, the scalpel can be given a GTIN. If the scalpel has already been labelled by the producer, it would be obvious to reuse this GTIN. If it is necessary to identify a specific scalpel, a serial number can be added to the GTIN. However, a GIAI can be used instead if the scalpel is already in production and has not been labelled in advance, and it needs to be identified individually.

If focus in on reusing the scalpel, so that it is first used in one operation, then sterilised and used in a new operation, the organisation can choose to use a GRAI. Like GTIN, a GRAI can be a *type* ID or an *individual* ID. In this context, it is not important which identification type is used, but that it lives up to its purpose.

R: Keep up with GS1 maintenance of Best Practice

GS1 continuously updates guidelines on using the standards above. Use should therefore be combined with general orientation towards new descriptions of the way in which the standards are used. Moreover, it is important to keep up with experience from the healthcare sector in other countries and with the way in which other sectors develop the use of identification standards.

5.1.5 EPCIS object identification

When event data is exchanged between healthcare actors, the EPCIS standard is used. This standard is very flexible in terms of object identification, so that several different standards can be supported. EPCIS records objects as EPCs (Electronic Product Codes). EPCs are built on a hierarchical framework making them globally unique, but still easy to administer at local level. A mapping between GS1 object identities and EPC is outlined below:

An EPC object identification uses the following syntax:

```
urn:epc:id:scheme:component1.component2.…
```

in which "scheme" indicates an EPC scheme, and component1, component2 and any subsequent data depends on the stated scheme.

For an sGTIN, it looks as follows:

General syntax:

```
urn:epc:id:sgtin:CompanyPrefix.ItemRefAndIndicator.SerialNumber
```

Example:

```
urn:epc:id:sgtin:0614141.112345.400
```

R: We recommend using the instructions in the ”EPC Tag Data Standard” to map GS1 object identities and EPC object identities.

5.1.6 Object identifiers

Object identifiers ([OID]) are used to identify virtual objects[4]. If the object is an identifier (e.g. GTIN) or a classification, OID is used to indicate semantic information about it. Issuers of the current identifier/classification will thus own an OID, in which relevant information can be added such as versioning, notation forms and description.

Use of OID can take place as follows:

```
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

For example, if identifiers were GTIN and were issued by GS1, the result would be:

```
< GTIN_ID code ="xxx" codeSystem ="2.51.1.1"/>
```

R: We recommend using object identifiers (OID) for the identifications recommended in this reference architecture.

The US Food and Drug Administration (FDA) and Health Level Seven (HL7) recommend using OIDs to specify context for identifiers such as UDIs, GLN and classifications. This means that HL7-CDA uses OID for all relevant objects, e.g. identifiers and classifications, in all documents. GS1 has created OIDs for all organisation identifiers that can be used by everyone according to the same pattern as shown above.

Note that the objects referred to in the title of this report is physical objects, whereas the object in OIDs are virtual objects.

5.2 Recommended system architecture in own organisation

Based on the principle of reusing interfaces, it makes sense to reuse the external interfaces for the internal usage scenarios, but many internal location systems will often have proprietary interfaces.

R: We recommend reusing the same GS1-based interfaces in internal usage scenarios as are used in the external scenarios.

We recommend that the organisation implement its system for object identification and location based on the following system components, and that the organisation reuse the external interfaces as far as possible.

- Applications
- Location database
- Product database
- Event database
- Process database

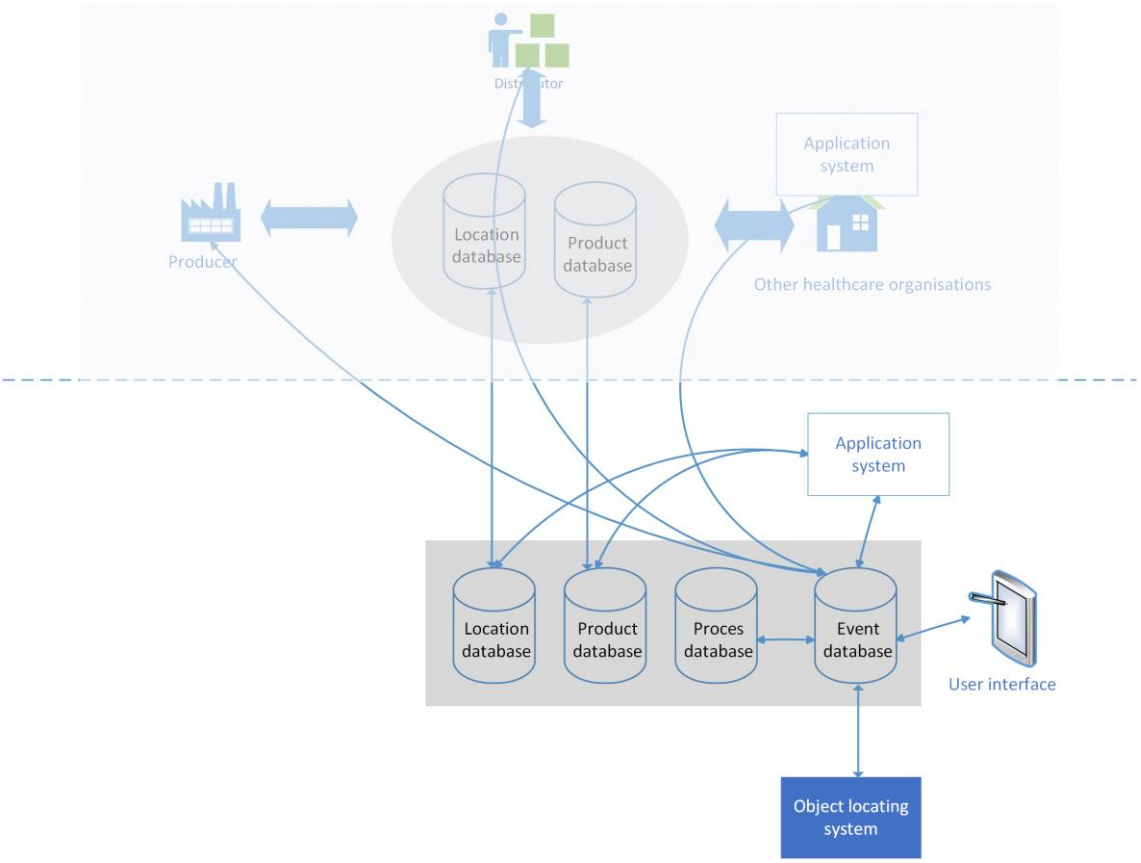


Figure 8: Chart of components for internal applications.

Object locating systems are the software and hardware components that locate an object. An object locating system always consists of a data carrier which is fixed to the object to be located; readers to read the data carrier and thereby locate it; and finally software to pass on data.
This area includes many technologies (barcode, RFID, Wi-Fi, ultrasound, infra-red light) and these technologies rarely use the same object ID, data carrier or communication interfaces to pass on data.

Applications are the systems that receive location data. The business value is added in the applications. This may be a planning tool for service workers that combines the location of orderlies with the location of tasks, or recall of medicine that combines expiration date with the location of the medicine.

External systems are applications outside the organisation. These systems present separate issues regarding security and access to additional data on the objects traced, but otherwise act as internal applications.

The location database stores a unique name for all localities used in the organisation, including relevant localities outside the organisation, and all metadata on the localities. Localities may overlap wholly or partially.

The process database is used to indicate the importance of events. This means that all statements on *what* an object has done refer to process steps in this database. Process steps are defined in the Core Business Vocabulary and may be ”Arriving”, for example.

The event database may contain all registered location events and is used to answer inquiries from applications. This may be "All events on a location between 4pm and 5pm for objects of the type Bed". The event database answers the EPCIS repository.

5.2.1 Interface for applications

The interface displayed for use applications is based on the EPCIS standard of EPCGlobal. The relevant interface is the EPCIS Query Interface which enables simple queries for EPC-based events; both as query-answer via SOAP and as a subscription to a specific query with callback via HTTP.

EPCIS not only displays location data, but also lists the metadata that can be returned regarding these events, e.g. localities and types of objects (e.g. patient, bed, staff).

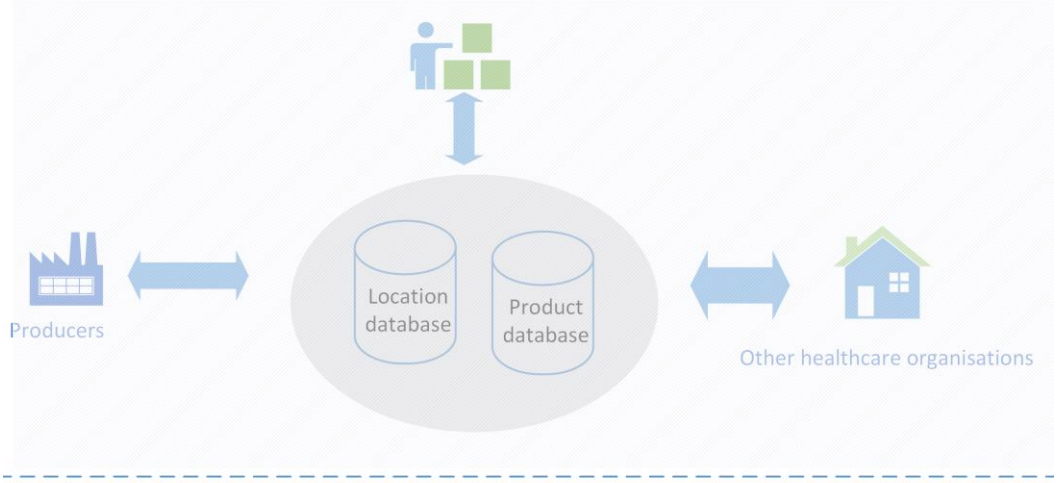
This standard generally allows for simple inquiries that combine selected event attributes, e.g. "all events in areas A, B, C between 12 noon and 1pm". However, own inquires may be added.

EPCIS Query Control Interface is supported via SOAP over HTTP or HTTPS.

EPCIS Query Callback is supported via EPCIS XML over HTTP or HTTPS.

5.3 Proprietary systems

In some cases, it is sensible not to follow the recommendation above. First of all, GS1 only supports a small number of data carriers and few wireless interfaces. For instance, GS1 does not support location via Wi-Fi, ultrasound or infra-red light, and a specific usage scenario may only be feasible with a given technology. Secondly, an actor may be interested in being able to reuse an existing infrastructure such as Wi-Fi combined with mobile phones for location of staff. This may give rise to development of new proprietary systems as shown in the chart below. The proprietary system is characterised by not being able to exchange data directly with other applications, but the entire business value is within the proprietary system. It is not immediately possible for a proprietary system to access central data pools of localities or product data, and if such data is necessary for the usage scenario, it will have to be maintained manually.



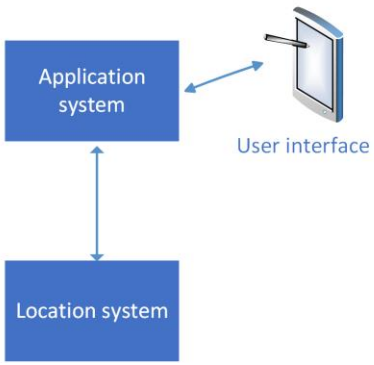


Figure 9: Proprietary systems will not be readily able to exchange data with other systems.

R: In order to facilitate any subsequent integration with other systems, GS1-based standards are recommended for location (GLN) and item identification (GTIN, GRAI etc.) to the extent that this is possible within the proprietary system.

5.4 Heterogeneous system landscape

If location data and object identification from proprietary systems are to be shared with external actors or with other internal applications, we suggest GS1 standards are used.

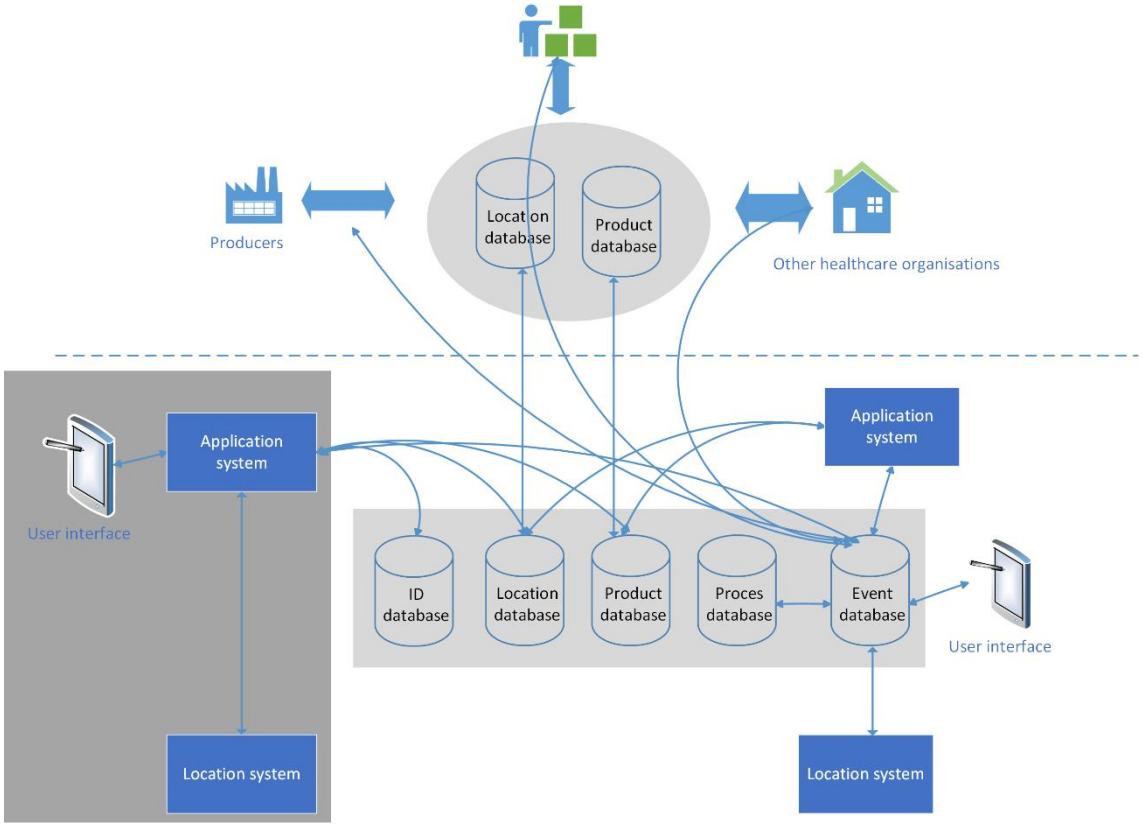


Figure 10: Sharing location data and object identification from proprietary systems with external actors

5.4.1 Mapping of object identifiers

If another object identification term than GS1 (GTIN, GRAI etc.) is used in the proprietary system, mapping between the two terms will be necessary. We suggest an identity database for this. The identity database maps between e.g. MAC addresses and GTIN or GSRN and civil registration numbers.

The identity database contains the relationship between PID and GID as well as any additional information that enables search in and mapping between these. The interfaces for mapping object identification have not been standardised, so this service can be realised via XML or SOAP over HTTPS, for example.

The interface is to be used for:

1. Mapping between PID and GID, and vice versa.
2. User interfaces for maintaining identity relationships must be able to display, add, delete and update all identity data.

5.4.2 Mapping of locations

If a proprietary system uses an object locating system that is not based on GLN but on coordinates, for example, it should also be possible to map between these location terms. This functionality may be built into the location database or created in a separate database. Interfaces for mapping between different location terms have not been standardised, and this service can be realised via XML or SOAP over HTTPS, for example.

The interface is to be used for:

3. Mapping between coordinates and GLN, and vice versa.
4. User interfaces for maintaining identity relationships must be able to display, add, delete and update all location data.

5.4.3 Updating event database

If a proprietary system uses an event database that is not an EPCIS repository with EPCIS Query interface, but other systems use this event database for the proprietary system's event data, we recommend transfer of event data to the general event database via the EPCIS Capture interface.

The interface is to be used for:

5. Transfer of event data from location system to the event database.

R: We recommend using the EPCIS Capture interface to import event data to the event database.

The EPCIS Capture interface is used to capture events from location systems. The interface consists of a single operation (Capture) that transfers a list of location events and does not return an answer.

The EPCIS Capture interface is accessed via XML over HTTPS or HTTP.

The location system ensures that all events are received correctly by the event database by resending events for which an acknowledgement has not been received, see the EPCIS Capture interface.

Although the generic interface for capture of event data is the EPCIS Capture interface, it is still possible to create common components which receive data via other formats. For instance, many locating solutions will have an API that does not live up to the EPCIS Capture interface, and separate interfaces or integration components may be established for these systems.

5.4.4 Integration into proprietary systems

Below is an example of a complete locating solution which in itself contains the same components as shown in section 4.3. This means that it contains subsystems at all layers; user interface, middleware, event database, location database, ID database, readers, ID tags and administration tools, etc.

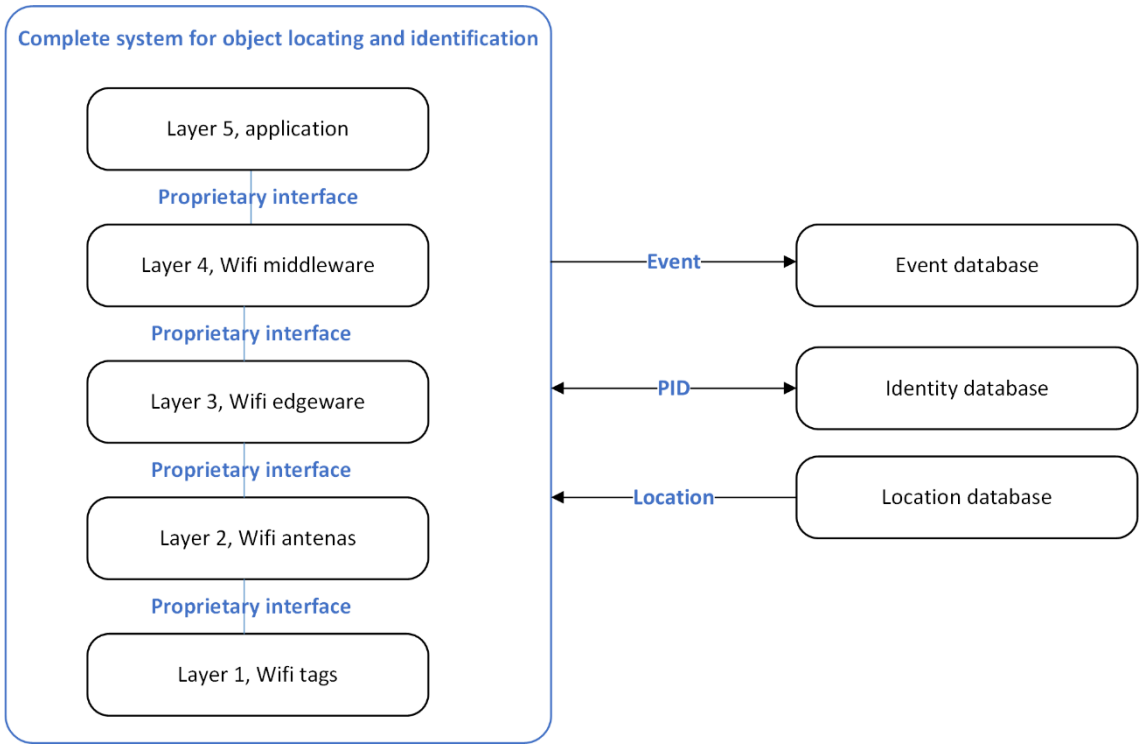


Figure 11: Complete object locating and identification solution

Attempts have been made to show that locations and object identifiers should be mapped to the chosen GS1 standards in order to be able to update the event database with events from the proprietary system. From the event database, other applications (both internal and external) can use event data from the proprietary system.

6. References

This section contains references and supplementary reading that help support the content of the reference architecture. Note that hypertext is used in the table below.

Tabel 1 References

Name	Description	Reference
[BGRBSTED]	*Begrebsmodellering af stedbegrebet i hospitalssammenhæng* (term model for the term 'location' in a hospital context) Report to the Central Denmark Region in connection with the term work that systematises and clarifies terminology for location-related terms and organisational units at a hospital.	DANTERMcentret
[DIGIEFF]	MAKING eHEALTH WORK – National Strategy for Digitisation of the Danish Healthcare Sector 2013-2017	Danish Health Data Authority
[DIGIVLF]	Strategy for Digital Welfare: Empowerment, Flexibility, Efficiency. Common Public-Sector Strategy for Digital Welfare 2013-2020	Agency for Digitisation
[EIF]	European Interoperability Framework 1.0 (EIF 1.0) EU framework to promote interoperability in the European Union.	EU
[EPCGlobal, 2011]	EPCglobal Standards Overview	http://tinyurl.com/6c97vcf
[EPCIS]	EPCIS "The goal of EPCIS is to enable disparate applications to leverage Electronic Product Code (EPC) data via EPC-related data sharing, both within and across enterprises. Ultimately, this sharing is aimed at enabling participants in the EPCglobal Network to gain a shared view of the disposition of EPC-bearing objects within a relevant business context."	GS1
[GDSN]	GS1 Global Data Synchronisation Network® (GDSN) GDSN "enables trading partners to automatically share their business data with each other. This means organisations can have confidence that when one of their suppliers or retailers updates their database, their own database is similarly updated as a result. Everyone has access to the same continuously refreshed data."	GS1
[GLNNR]	GS1 GLN Allocation Rules Rules for allocating GLN numbers	GS1
[GLNOVERB]	GLN Allocation Rules Home GLN overview	GS1

[GLNSUND]	GLN in Healthcare - Implementation Guide GS1 guideline for use of GLN in the healthcare sector.	GS1
[GS1 HCR, 2011]	GS1 Healthcare Reference Book	httsp://ti-nyurl.com/5v584mh
[GS1 HCS, 2011]	GS1 Standards in Healthcare	http://ti-nyurl.com/6462dk9
[GS1]	GS1 Among other things, GS1 provides the standard GTIN, GLN, GRAI, GIAI, GSRN	GS1
[GS1GENSPEC]	GS1 General Specifications "The foundational GS1 standard that defines how identification keys, data attributes and barcodes must be used in business applications"	GS1
[GUDID]	General Unique Device Identification Database (GUDID) "FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labellers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). The public can search and download information from the GUDID"	FDA
[HIBCC]	Health Industry Business Communications Consortium (HIBCC) Provides HIBC Supplier Labelling Standard.	HIBCC
[ICCBBA]	ICCBBA provides the standard ISBT 128 "ICCBBA is an international non-governmental organization (NGO) in official relations with the World Health Organization (WHO) that manages, develops, and licenses ISBT 128; the international information standard for the terminology, coding and labelling of medical products of human origin."	ICCBBA
[IMDRF]	International Medical Device Regulators Forum (IMDRF) The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.	IMDRF
[ISACORE]	Core Location Vocabulary	EU, ISA

	"The Location Core Vocabulary provides a minimum set of classes and properties for describing a location represented as an address, a geographic name, or a geometry."	
[ICT support for logistics, 2010]	Report: *It-understøttelse af patient-, ressource- og transport logistik (*IT support for patient, resource and transport logistics). The New University Hospital in Aarhus (DNU) 2010	Subproject F2-01, IT Main activities, 15.02.2010, The New University Hospital in Aarhus
[NTNLBEST]	The National Board of eHealth	Danish Health Data Authority
[OIOORG]	OIO Organisation Organisation data is part of, and used in, many processes and IT systems. This website provides an overview of some of the most important and relevant specifications if your solution is to be able to handle organisation data.	OIO
[PERSLOV]	The Danish Processing of Personal Data Act (*persondata-loven*) Act on Processing of Personal Data	http://ti-nyurl.com/5vh02a3 http://ti-nyurl.com/6lytan2
[PRCSSTAND]	Process for setting national standards in healthcare	Danish Health Data Authority
[PRIVACY]	COMMISSION RECOMMENDATION of 12 May 2009 on the implementation of privacy and data protection principles in applications supported by radio-frequency identification	EU
[REFINF]	Reference Architecture for information security A reference architecture can work as a common guide that helps security models develop in the same direction.	Danish Health Data Authority
[REGREF]	Reference Architecture for Object Locating and Identification. Danish Regions' reference architecture, published in 2014.	Danish Regions Health IT (RSI)
[RGONPEJL]	The Region's common guides for digitisation of the Danish healthcare sector 2014-2016.	Danish Regions Health IT (RSI)
[RGONSTRAT]	Coherent, efficient and standardised digital solutions 2013-2019	Danish Regions Health IT (RSI)
[RUSA]	The Danish Health Data Authority's advisory committee on standards and IT architecture (RUSA)	Danish Health Data Authority
[SNOMED CT]	SNOMED CT® The National Release Center, NRC, is responsible for communicating the SNOMED CT® health terminology in Denmark.	Danish Health Data Authority
[SOR]	National Health Organisation Register – SOR (*Sundhedsvæsenets Organisationsregister*).	Danish Health Data Authority

	"SOR is a register that contains organisation and address data about the healthcare sector. The register is used by a number of administrative back-end systems in the healthcare sector. SOR contains data about hospitals, the primary sector (physiotherapists, general practitioners, dentists, etc.) and to a lesser degree about the health organisation of municipalities. Degree of coverage of the different data regions varies."	
[SPROGIII]	*Fælles Sprog III* (common language III) "Social and health documentation focusing on citizens. FSIII is a new joint municipal method for documenting and exchanging data in the social and healthcare sector. The objective is to contribute coherence, quality and efficiency in municipal efforts for citizens."	LOCAL GOVERNMENT DENMARK
[NBS]	Term database of the healthcare sector "The term database is prepared by the *Nationale Begrebsarbejde for Sundhedsvæsenet (NBS)* (national conceptual work for the healthcare sector) and contains term systems within key specialist healthcare domains. The term systems and the associated definitions of terms are made available for the Danish healthcare sector and other interested parties."	Danish Health Data Authority
[TILSTNDARK]	*Tillæg til Standarder og referencearkitekturer vedr. sundheds-it området* (addendum to Standards and reference architecture for healthcare IT) Specification of governance and processes for preparation and approval of architecture products. A framework for coherent healthcare IT has been set up here.	Danish Health Data Authority
[UDIGUIDE]	UDI Guidance - Unique Device Identification (UDI) of Medical Devices "This guidance provides a framework for those regulatory authorities that intend to develop their UDI Systems that achieves a globally harmonized approach to the UDI. The framework can be used at a local, national, or global level such that these systems are implemented without Regional or national differences. This guidance is intended to provide a high-level conceptual view of how a global UDI System should work."	IMDRF
[W3C]	World Wide Web Consortium "The World Wide Web Consortium is an international community that develops open standards to ensure the long-term growth of the Web"	W3C
[TOGAF]	**The Open Group Architecture Framework** "The TOGAF® framework is the de facto global standard for Enterprise Architecture. The Open Group Architecture Forum, comprised of more than 200 enterprises, develops and maintains the TOGAF standard and publishes successive versions at regular intervals."	The Open Group

[OID]	Object identifiers "An object identifier (OID) is an extensively used identification mechanism jointly developed by ITU-T and ISO / IEC for naming any type of object, term or "thing" with a globally unambiguous name which requires a persisting name (long life-time). It is not intended to be used for transient naming. OIDs, once allocated, should not be reused for a different object/thing. It is based on a hierarchical name structure based on the "OID tree". This naming structure uses a sequence of names, of which the first name identifies a top-level "node" in the OID tree, and the next provides further identification of arcs leading to sub-nodes beneath the top-level, and so on to any depth. A critical feature of this identification mechanism is that it makes OIDs available to a great many organisations and specifications for their own use (including countries, ITU-T Recommendations, ISO and IEC International Standards, specifications from national, Regional or international organisations, etc.).	http://www.oid-info.com/index.htm
[SALOV]	Act to amend the Danish Health Act and the Act on Authorisation of Healthcare Professionals and on Professional Healthcare (*Lov om ændring af sundhedsloven og lov om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed*) concerning the use of personal alarms and person locating/Track & Trace systems at hospitals, detaining patients etc.	Retsinformation (legal info)
[PATREG]	Registration of patients and *Fællesindhold* *Fællesindhold* describes the different requirements for reporting to the national patient registry (LPR).	Danish Health Data Authority
[REST]	Representational state transfer (REST) or RESTful Web services are one way of providing interoperability between computer systems on the Internet.	Wikipedia
[RTLS]	Real-time locating systems (RTLS) are used to automatically identify and track the location of objects or people in real time, usually within a building or other contained area.	Wikipedia

Annex A: Key capabilities checklist for solutions

If a solution is to comply with this reference architecture, it should be possible to answer the questions in the table below in the affirmative.

Tabel 2 Checklist

Area/aspect[5]	**Check**	**Reference**
Governance	Are you using the latest version of the reference architecture? See the Danish Health Data Authority's website for the latest version	DANISH HEALTH DATA AUTHORITY
Business descriptions	Are you using use cases from the Healthcare guidelines?	Chapter 5
Information	Are you using EPCIS and Core Business Vocabulary in connection with exchange of data between layer 4 and layer 5?	Section 3.6 Chapter 5
Information	Are you using terms for object locating and object as described in *Begrebsmodellering af stedbegrebet i hospitalssammenhæng* (term model for the term 'locating' in a hospital context) – Danish Regions Health IT (RSI) [BGRB-STED, section 4.2.1]?	Section 3.2
Information, application	Do your business logics comply with the 5 logical architecture layers?	Section 4.3
Security	Are you complying with the recommendations in the ISO27000 family of standards for information security?	Section 3.7
Security	Have you carried out a Privacy Impact Assessment, see methods in CEN 16571?	[PRIVACY]
Security	Have you informed your organisation through boards from RFI ISO/IEC 29160 / CEN 16570 about the possibility that RFID will be registered automatically?	[PRIVACY]
Standards	Are you using GLN as identifiers for localities?	Section 4.8.3 Chapter 5
Standards	Are you using GS1 standards for GTIN, GRAI, GIAI, GSRN as identifiers for objects?	Section 3.5 Chapter 5
Standards	Are you using GDSN to exchange master data on products?	Chapter 5
Standards	Are you using EPC to indicate identifier syntax?	Chapter 4
Application (standards)	Are you using OID to indicate the context of identifiers and classifications in interfaces?	Chapter 5

[5] Areas and aspects are described in the Framework for coherent healthcare IT [TILSTNDARK], which provides an overview of the elements that lead to successful interoperability in localisation and item identification work in the healthcare sector.

Annex B: Wish list for future versions of the reference architecture

This annex is a summary of future objects relevant for the reference architecture. The annex can be used to write about aspects expected in the near future such as the EU Medical Device Regulation and the EU Data Protection Regulation. Objects can also be reconsidered in connection with future revisions.

Tabel 3 Wish list

Point	Area	Proposal	Section
1	Legislation	When the authoritative interpretation of the adopted EU Regulation regarding personal data protection, which will enter into force on 25 May 2018, is available, a revision of the reference architecture is likely to take place.	3.6
2	Legislation	Concerning automatic object locating: In 2009, the European Union listed a number of instructions for frameworks for ensuring security and privacy in connection with automatic identification. At the time of writing, these recommendations have not been directly implemented into Danish practice. Future work on the reference architecture should therefore take account of the adoption of such principles in Danish legislation and administrative practice.	3.6
3	Legislation	The European Union is working towards increased use of object locating and identification, and has therefore published "Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (Text with EEA relevance) (2015/C 95/01)". The guidelines point out that the traceability of the origin and destination of products should be ensured for medicinal products. The reference architecture can be updated with rules specific for medicinal products in a later version.	3.6
4	Legislation	The European Union is currently working on object identification, and has published, but not yet adopted, the "REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices (from 2012)". This Regulation obligates Member States to introduce "a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows traceability. However, the UDI system will be implemented gradually and proportionate to the risk class of devices". The reference architecture should be reviewed in connection with the entry into force of the rules in the Regulation on traceability.	3.6
5	Information	This architecture points to a number of identifiers such as UDI, GTIN, GLN. However, many others are used as well, such as central business registration number, civil registration number, SORID, UUID. This means that the number of identifiers is growing and their uses overlap. Therefore, it would be valuable to gain an overview of this trend. The Danish Health Data Authority and the Danish Agency for Digitisation are working on publishing guidelines regarding OIDs under the Digital Strategy 2016-2020. Perhaps these	Chapter 5

		guidelines could be extended with a list of known identifiers and corresponding OIDs and the organisations maintaining these.	
6	Information	National Health Organisation Register – SOR (*Sundhedsvæsenets Organisationsregister*) contains addresses for all the units under a hospital. Localities in this reference architecture are more detailed and therefore not suited for maintenance in SOR. However, they should be maintained in the institutions' own databases, and as suggested here, by using the common standard GLN. GLN covers both organisational units and localities. This could result in a need for mapping the institutions' localities to their units. Therefore, at some point it could be beneficial to register GLN numbers for organisational units in SOR as an alternative to SORID. It is currently unclear what the use should be. However, when cross-disciplinary usage scenarios such as "Object locating across authorities" and "Secondary use of data nationally", see annex D, become more widespread, the need for more detailed information about localities will increase.	
7	Standards	The Agency for Digitisation is working on a replacement for the OIO Org standard named orgDK. This is a Danish profile of organisation ontology under w3.org. The ontology operates with a class for *location*. If it becomes necessary to link GLN locations to GLN organisation units, see point above, and these need to be exchanged, it may make sense to expand orgDK with GLN identifiers for organisational units, so that these are supported in organisation systems such as SOR and the municipalities' support system; Organisation.	
8	Information	Secondary use of data nationally, see annex D. It is likely that location data can be used for process optimisation and management information in the individual institution, but also at national level for planning and research, for example. Currently, no specific uses have been identified. New uses may give rise to reassessment of the architecture.	
9	Governance	It has been suggested to prepare implementation guidelines based on the reference architecture for solutions architects. The guidelines should describe in more detail how requirement specifications can be drawn up for solutions.	
10	Business	During the consultation, KOMBIT and the Capital Region of Denmark suggested that more work needs to be done regarding the usage scenarios. This is partly to clarify the reach of the reference architecture in terms of national usability, e.g. use of the architecture when exchanging equipment between authorities, and partly as use in specific solutions to show the relationship between the suggested system architecture and business requirements.	
11	Standards	During the consultation, the Danish Agency for Data Supply and Efficiency indicated that layer geometry is necessary in order to navigate robots (UGV: Unmanned Ground Vehicle or MIR: Mobile Industrial Robots) to transport objects and equipment around the hospital and between hospital buildings. The reference architecture is not about mobile units (robots), but only about locating objects. The Danish Geodata Agency (now the Danish Agency for Data Sup-	

		ply and Efficiency) has issued material on outdoor and indoor reference networks for the working group. The Danish Geodata Agency is still in the preliminary stages of its work on this area. In the long term, this work may be relevant with regard to location and metadata on a location. The work is currently in an early phase and it is too early to involve the work directly in the reference architecture. However, this should be considered when the reference architecture is revised.	
12	Business	During the consultation, it was noted that there is a need to clarify usage scenarios that cover both indoor and outdoor location. The challenge is that localities will typically not cover all locations sufficiently, as they are only assigned to locations which are already relevant, e.g. addresses, rooms and specific locations in rooms. If a citizen with dementia is to be located, see scenario in annex D, and the citizen can be both outside and inside a building, it is necessary to be able to see all outside positions. The principle in the reference architecture is that *"[location] is generally stated using named localities. If geographic positions are necessary, these will be displayed by the integration system as a supplement to the named coordinates"*, see section 4.8.1. It is too early to say whether this principle will be challenged by specific solutions. However, it may be considered in future revisions of the reference architecture.	4.8
13	Information	During the consultation, Local Government Denmark, KOMBIT and the Agency for Digitisation submitted a request for this reference architecture to describe a link to other public-sector term and information projects on location, place and identities. These projects include *Grunddatamodellen* (the master data model); the national recommendations regarding identifiers; VANDA (Modellering af VanDa - FODS 8.3); and the common public-sector report *"Stedet som nøgle - Referencearkitektur for stedbestemt information version 1.0 (udkast)"* (the location as key – reference architecture for localised information, version 1.0 (draft)". This request should be considered in a future revision of the architecture.	
14	Application, infrastructure	During the consultation, Local Government Denmark and KOMBIT submitted a request for the reference architecture to describe a link to other public-sector reference architecture projects. The municipalities' work towards a more loosely coupled architecture was mentioned in particular, in which events are a key integration pattern. The master data programme was also mentioned. As event messages are also part of the EPCIS standard, we suggest that a future revision of the architecture examines whether there is an overlap in the uses of these messages and the municipal architecture.	

Annex C: Glossary

The material includes a number of words, abbreviations and synonymous that are used in this report essential for understanding this reference architecture.

Tabel 4 Glossary

Term	Description
Application system	A software system using location data. An example of a future application is EHR. The application system can also belong to other organisations, e.g. a supplier.
Physical object	Any physical object that with the addition of appropriate metadata can be uniquely identified.
Object identification	In this context, an object is a physical object that can be identified and located using a technology. For example, a person who carries a nametag with an embedded RFID chip or medical devices with an affixed RFID chip.
EPC Electronic Product Code	A standard for globally unique IDs defined by EPCGlobal, see reference [EPCGlobal, 2011].
EPCGLobal	A joint-venture initiative working on increasing the use of EPC see reference [EPCGlobal, 2011]
EPCIS EPC Information Service	see reference [EPCIS]
GIAI Global Individual Asset Identifier	See reference [GS1] [GS1GENSPEC]
GID *Genuine ID*.	The genuine ID for the object being traced, e.g. a person's civil registration number, as opposed to PID, which is the ID that is stored on the person's ID tag.
GLN Global Location Number	See reference [GLNNR] [GS1GENSPEC]
GRAI Global Returnable Asset Identifier	See reference [GS1] [GS1GENSPEC]
GS1 Global Standards	A standard organisation, see reference [GS1]
GSRN Global Service Relation Number	See reference [GS1] [GS1GENSPEC]
GTIN Global Trade Item Number	See references [GS1] [GS1GENSPEC]

Term	Description
HIBCC Health Industry Business Communications Consortium	See reference [HIBCC]
HTTP Hypertext Transfer Protocol	See reference [W3C]
HTTPS Hypertext Transfer Protocol Secure	See reference [W3C]
Event	Synonym to location event.
ICCBBA International Council for Commonality in Blood Banking Automation	See reference [ICCBBA]
ID tag	An electronic unit or label from which an ID can be read, e.g. using laser or radio waves. Examples of ID tags are barcodes, ID cards with a magnetic strip, RFID tags, Wi-Fi units that transmit IDs.
IMDRF International Medical Device Regulators Forum	See reference [IMDRF]
Integration system for location and identification	A software system that decouples applications from location systems.
Integration system	Synonym to integration system for location and identification.
Logistics (clinical logistics, service logistics).	Logistics in the healthcare sector is specialized into clinical logistics and service logistics: Clinical logistics refers to logistics regarding *patient pathways*: for individual patients and groups of patients, for full pathways and partial pathways, pathway packages etc. Thus the clinical logistics concerns patients and relatives as well as relevant staff. Service logistics refers to the logistical functions and tasks that make the healthcare system (e.g. the hospital) work. The two types of logistics are conditionally dependent and sometimes involve the same actors and resources. Therefore they cannot be separated but, rather, they overlap.
Place	The concept place means that an object can be linked directly to a specific location. A location can be 1, 2 or 3 dimensional and can also be organisational and/or virtual. In practice, by virtue of its description, a location is recognisable and meaningful for the actors who have access to information about the location of an object, e.g. "Dr Hansen is in room 4" or "the nearest infusion pump is in the storage facility". Location can take place on the basis of a positioning that is linked directly to a location via a location database.
Location data	Automatically registered data about the identity and location of physical objects. A collection of location events.

Term	Description
Locating event	A single registration of the identity and location of a number of physical objects at a given time.
Locating solution	The hardware and software which together enable capture of location data. For example, a Wi-Fi installation that can position Wi-Fi units and display these positions for other systems.
Locating-related system	An application system or a locating system.
Locating system	A software system that captures and distributes location data, i.e. the software part of a locating application.
Location	A place which is relevant for locating. This may be a place at or outside a hospital. Examples of localities are "Department Q", "Entrance 3, building 1", "Operating theatre 512", "Rack 31 in storage room 85", "Main pharmacy".
Reader	The piece of hardware that reads an ID tag. Examples of readers are barcode scanners, RFID antennas, Wi-Fi access points.
Organisation	Synonym for the organisation implementing the reference architecture, e.g. Central Region of Denmark.
PID Pseudo ID.	The ID stored on an ID tag, as opposed to GID, which is the genuine ID of the person or object, e.g. civil registration number.
Position	An object's relation to a location or a coordinate. Information that makes it possible to find out where an object is.
Positioning	In this context, the term positioning refers to determining a position in the form of a coordinate, typically through a positioning technology. Different positioning technologies provide coordinates with varying resolution and accuracy.
Real-time	In this context, the term real-time refers to the delay in location information that is acceptable, taking into account purpose and resource consumption. Different scenarios for applications using location information to deliver functionality or service have different requirements for "real-time" in order to be able to deliver relevant value to the healthcare sector.
Reference architecture	Synonymous with the term reference architecture for location and object identification.
REST Representational state transfer	See reference [REST]
RTLS Real-time locating system	See reference [RTLS]
SOAP Simple Object Access Protocol,	See reference [W3C]

Term	Description
Traceability	Traceability is characteristic of data that makes it possible to determine what processing data has gone through. Traceability should *not* be confused with location and has only been included in this glossary for historical reasons. This document does not describe how traceability can be achieved on the basis of location. However, the technologies and methods described in this document can be used in a traceability context.
Master data	Data describing general properties of an object.
Tag	Commonly used name for an electronic ID tag.
UDI Unique Device Identification	A method to ensure unique identification of objects. See reference [UDIGUIDE]
Global database	In this report this refers to, a database available to many different users throughout the world with a set of data that is used and maintained globally for all actors. Alternatively, this could be a database that represents data locally, in which data is replicated from a global database. The FDA's GUDID is an example of such a database, see reference [GUDID]. GDSN is another example of a Global database, see reference [GDSN].

Annex D: Usage scenarios

1. Finding citizens with dementia

Brief description

As society only very reluctantly intervenes in citizens' personal freedom, but sometimes citizens with dementia "go missing". To address this, a number of solutions have been developed, primarily based on GPS technology. These solutions are typically stand-alone solutions without integration to other data-carrying solutions in the homecare sector. GPS technology typically also limits the location potential of these solutions to outdoor location.
Integration into the social care system and into a location term and database linked to local conditions will result in a more accurate location. Moreover, it will be possible to supplement outdoor location with indoor location.

Actor
All staff in assisted living facilities.

Task
The actor is to locate a resident with dementia who has gone missing.

Challenge
Location primarily works outside and is carried out in one IT system, whereas any information about the habits and likes of the citizen is found in another system.

Benefits
Quicker, safer and more relevant location of the citizen.

2. Finding staff in the homecare sector

Brief description

As a manager and colleague, I want to locate either a specific colleague/employee or the nearest colleague/employee with specific competences, perhaps in conjunction with asking whether the relevant colleague/employee can take on a certain new task.

Actor

For example, all managers/staff in the homecare office.

Task

The actor is to locate an employee/colleague who can take on a task.

Challenge

Today, in order to locate a colleague, personnel have to ring the relevant colleague and ask where he/she is. Often personnel have to disturb 5-10 people to make a decision regarding who can take on a task.

Benefits

Automatic location of a person within a reasonable geographic distance and with appropriate competences for a certain new task will save time for the person who is looking for such a person and for the persons who will not be disturbed unnecessarily.

Derived benefits

A more efficient object locating system like this, is likely to improve the overall quality of homecare, as new tasks will be allocated more quickly to an employee, who can then, in turn, be with the citizen more quickly.

3. Improved inventory management in the homecare sector

Brief description
Consumables and similar are stored at central level, at local level and with the individual citizen. Many consumables are bought by citizens themselves and are therefore in principle not under central inventory management.
If the consumables belong to the municipality, sub-optional inventory management will entail inappropriate liquidity management as well as a risk of waste through obsolescence or expiry.

Actor
All staff in the homecare sector.

Task
Consumables are to be transported to the end user.

Challenge
No overview of inventory may result in unnecessary reorders and subsequent unnecessary re-stocking.
If a citizen lacks consumables at home, it may be necessary to drive a long way for refills.

Benefits
Better inventory management and quicker delivery.

4. Secondary use of location data nationally

Brief description

Data is collected at central level and is used for a variety of purposes, e.g. research, payments/invoicing, management information. Currently, location data has not been requested for such purposes. However, it is likely that, as more locations are designated with location data, this data will also be requested.

Actor

Suppliers of data are typically hospitals and municipalities. Recipients of data may be researchers, administrative planners and management in municipalities, Regions and the state. Today, data is reported to national registers at the Regions and the state, see overviews at: The national health registers at the Danish Health Data Authority and The Regions' clinical quality databases at *databasernes fællessekretariat – Regionernes kliniske kvalitetsudviklingsprogram* (the joint secretary of the databases – the Regions' clinical quality-development programme).

Task

Data is to be collected, transformed and displayed in compliance with regulations and legislation.

Challenge

Central collection of data has to be established between authorities.

Benefits

Research and comparison of data may result in exchange of experience, which leads to better quality and process optimisation.

5. Object locating across authorities

Brief description
Authorities do not currently exchange equipment very much. With increasing home monitoring, it is likely that there may be a business case on identifying equipment in order to recover and report that the equipment is faulty.

Actor
Healthcare staff.
Logistics departments.

Task
Healthcare staff are to be able to read a barcode or an ID tag and receive information about who has lent out the equipment. Moreover, they are to be able to request the equipment to be brought back or report that the equipment is faulty.
Lending out equipment is to be registered, solutions are to be established with readers that can scan barcodes and tags as well as look up the person who has borrowed the equipment. The solutions are to function satisfactorily in work situations, e.g. a home carer should have mobile equipment.
The logistics departments are to inspect and coordinate distribution and return of equipment.

Challenge
Establishment of solutions across authorities.

Benefits
It is easy for staff to request for equipment to be returned. Less equipment is lost.

6. Learning from analyses of location data

Brief description

Today, evaluation of the quality of transport routes or changes in stocks requires detailed and expensive measurements. Without the evaluation, there is only a partial picture of what is going on.

Actor

Logistics department. Planners.

Task

Logistics departments are to coordinate and optimise transport routes and react on shortfalls in stocks. Logistics departments are to know where objects are located, whether something is missing and the effect of navigating through certain routes.
Planners need input that enables them to make decisions based on knowledge rather than experience and gut feeling.

Challenge

The ability to procure information leads to high initial costs.

Benefits

It is possible to change behaviour and methods on an informed basis.

7. Planning service tasks at hospitals

Brief description
Today, service tasks at hospitals are carried out through personal contact or fixed patterns. Object locating enables the service staff to plan staffing at the clinic dynamically rather than through fixed routines. The right competences for a task combined with the closest qualified employee to carry out the task provide shorter delivery times and a greater likelihood that the task is carried out successfully.

Actor
Service workers, nurses, physicians, social and healthcare assistants

Task
Find, as quickly as possible, the right employee with the right competences to carry out the task, and allocate tasks to available staff.

Challenge
It may be difficult to offer qualified assistance across organisational borders.

Benefits
Shorter delivery times to carry out tasks with a greater success rate and less risk of incorrect patient care.