Information Standards Board
for Health and Social Care

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Automatic Identification and Data Capture (AIDC) for the NHS in England

Fundamental Information Standard Specification

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Forecast Changes:

Anticipated Change	When
Upon establishment of a clinical safety case, RFID will be brought into scope.	2012

Reviewers:

This document must be reviewed by the following:

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Related Documents:

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
Refer to Section 1.3 and Section 1.4.			

Contents

1 Overview

This product is the Specification for the Fundamental Information Standard: "Automatic Identification and Data Capture (AIDC) for the NHS in England". The specification formally defines the standard and how it should be implemented. The quality criterion for the product is that those responsible for co-ordinating the implementation of information standards in health and social care (including the supplier community) are able to implement the information standard.

1.1 Summary

The table below contains a summary of the information standard.

STANDARD	
Standard Number	ISB 0108
Title	Automatic Identification and Data Capture (AIDC) for the NHS in England
Type	Fundamental
Description	This standard provides the specification and implementation guidance for achieving accurate Automatic Identification and Data Capture (AIDC) using GS1 international code numbering standards. This standard is aimed at individual NHS organisations in England and is a technology *enabling* standard. It should be used as a reference tool by the NHS when procuring, implementing and using AIDC technologies, eg. bar code scanners, printers and assets / document tracking systems. It includes: ▪ How to register an NHS organisation to obtain the GS1 unique organisation prefix. ▪ Code numbering rules (GS1 Keys). ▪ Data carriers. ▪ Producing and verifying bar codes. ▪ Printing bar codes. It is the primary standard in a series of AIDC standards for the NHS in England. As AIDC standards are approved, they will be published here: www.isb.nhs.uk/use/baselines/aidc Out of scope for this Fundamental standard are: ▪ AIDC Operational standards, eg. AIDC for Patient Identification. ▪ Radio Frequency Identification (pending an approved clinical safety case). ▪ Bar coding of blood and blood products tracking. ▪ Scanning of bar codes and system design. ▪ Assets / document tracking across the entire NHS.

Applies to	This standard applies to any NHS setting in England where automatic identification and data capture (AIDC) technologies are used. The users of the standard will be those involved in the **procurement**, **deployment** and **use** of AIDC systems using GS1 standards in the NHS in England, as well as those who are associated with the provision of care to the patient, ie. healthcare professionals. These may include: ▪ IT and informatics personnel. ▪ Finance and procurement. ▪ Departmental directors and managers. ▪ Project managers. ▪ Healthcare professionals. ▪ Administration staff. ▪ Estates.
RELEASE	
Release Number	Amd 145/2010
Title	Initial Standard
Description	The first full specification of the standard.
Stage	Full
Implementation Completion Date	31 May 2012.

1.2 Controlled Documents

Document Reference	Name
Visit the GS1 members website (https://members.gs1uk.org/resources/help_support/Pages/Documentation.aspx) for GS1 specific documents, including user and implementation guidance. Membership required.	
Gateway Ref 7763	Coding for Success (DH, 2007)
Gateway Ref 14782	Review of Coding for Success Implementation (DH, 2010)

1.3 Guidance

Document Reference	Name
v0.1 25-Nov-2009	NHS Reconfiguration Overview (NHS Organisation Data Service) (Request document from www.connectingforhealth.nhs.uk/systemsandservices/data/ods)

1.4 Related Standards

Reference	Title
ISB 0149-01	NHS Number for General Practice
ISB 0149-02	NHS Number for Secondary Care
ISB 0160	Patient Safety Risk Management System - Deployment and Use of Health Software
ISB 0129	Patient Safety Risk Management System - Manufacture of Health Software
ISBT 128	Identification, labelling and information processing of human blood, tissue and organ products.

2 Information Specification

#	Requirement
1.	NHS Trusts deploying and using Automatic Identification and Data Capture (AIDC) systems SHOULD do so in accordance with this "AIDC for the NHS in England" Fundamental Standard.
2.	NHS Trusts wishing to create code numbers for the purposes of AIDC using GS1 standards MUST first register as a member with GS1 to obtain their Unique Organisation Prefix.
3.	When registering as a member with GS1, the NHS Trust SHOULD provide GS1 with their ORGANISATION CODE (CODE OF PROVIDER).
4.	All GS1 code numbers created by NHS Trusts for the purposes of AIDC MUST conform to the rules specified by the GS1 Identification Keys. The specific GS1 Identification Key to be used depends entirely on what is needed to be identified, eg. trade item, service, person, document. (Refer to Section 3.2 of this Specification and the GS1 allocation and application rules outlined in the GS1 General Specification.
5.	All GS1 code numbers created by NHS Trusts for the purposes of AIDC MUST be prefixed by the correct GS1 Application Identifier (AI) for that GS1 Identification Key (ie. 8018 is the AI for the GS1 Identification Key of Global Service Relation Number), followed by a GS1 Unique Organisation Prefix. This is to ensure global uniqueness of the GS1 code numbers.
6.	NHS Trusts SHOULD nominate a responsible person for the allocation and management of GS1 code numbers for the purposes of AIDC in their organisation. This person SHOULD be the GS1 Primary Registrant Member. It is recommended that this person SHOULD be the same person or from within the same team who manage and use the Organisation Data Service (ODS) Codes for their organisation (currently known as the ODS key contact or OC1 contact).
7.	The GS1 Primary Registrant, ODS key contact or OC1 contact SHOULD inform the Organisation Data Service (ODS) – the service responsible for management of ODS Codes / National Administrative Codes - in the event of any of the following NHS organisation changes: Splits; Mergers; Status Change; Renaming; and Closures. This is to ensure management of the GS1 Unique Organisation Prefixes and ODS Codes are handled in the same way, in the event of organisation reconfiguration. NHS Trusts will be subsequently advised by ODS on whether they need to obtain a new GS1 Unique Organisation Prefix or not, how to share or map existing code numbers and how to allocate future code numbers. The ODS will create and maintain the background mapping table (from ODS Codes to GS1 codes) and all GS1 Unique Organisation Prefixes for the NHS along with mappings to the relevant ODS codes will be published on their website[1].

[1] The GS1 code set and mappings to ODS codes will not be published until Q4 2011.

8.	In the event of organisation reconfiguration, ALL subsequent changes to GS1 Unique Organisation Prefixes and code numbers created MUST be reflected by changing the central database that stores the code numbers. It is recommended that the GS1 Primary Registrant SHOULD be the individual responsible for this ensuring this happens.
9.	Upon registering as a member of GS1 and receiving a GS1 Unique Organisation Prefix, each NHS Trust MUST create a local policy for GS1 code numbers for the purposes of AIDC based on this Specification. The policy SHOULD outline the processes for allocation, management and retirement of GS1 code numbers created for local use.
10.	The GS1 Primary Registrant MUST create a database to store ALL GS1 code numbers created locally in their NHS Trust for the purposes of AIDC. Code numbers created for the purposes of AIDC MUST always cross refer to information held on a database.
11.	The GS1 Primary Registrant MUST ensure that all code numbers created using their Unique Organisation Prefix are unique. GS1 code numbers created for the purposes of AIDC MUST NOT be reallocated. They MUST be fully retired and archived to ensure their uniqueness.
12.	GS1 Application Identifiers (AIs) 91 through to 99 are specifically allocated to "Company Internal Information". (Refer to Section 3.10.2. of the GS1 General Specification). These AIs MUST NOT be allocated by local NHS Trusts. AIs for the NHS will be published by the NHS Data Dictionary and MUST be adhered to[2]. See Section 3.2.9 of this Specification for a description of GS1 Application Identifiers.
13.	This AIDC for the NHS in England Fundamental Standard and the GS1 System of Standards MUST NOT be used for the management and tracking of blood products. Blood product tracking in the NHS is addressed by the standard ISBT 128.
14.	When creating code numbers for the purposes of AIDC, NHS Trusts SHOULD use one of the GS1 data carriers as outlined in the AIDC for the NHS in England Fundamental Standard Specification at Section 4.
15.	Use of Radio Frequency Identification (RFID) as a data carrier for the purposes of AIDC SHOULD be done in conjunction with a comprehensive clinical safety assessment. At present RFID is out of scope for this standard, as the clinical safety case for RFID has not been established and approved. It is the responsibility of the deploying NHS Trust to identify, assess, manage and accept any residual risk of RFID deployment and use in an NHS / healthcare setting.
16.	Production and verification of bar code data carriers SHOULD be conducted according to the instructions in Section 5 of this Specification.
17.	Printing of bar code data carriers SHOULD be conducted according to instructions in Section 6 of this Specification.

[2] GS1 Application Identifiers for the NHS will not be published in the NHS Data Dictionary until relevant AIDC Operational information standards have been approved by the ISB.

18.	Users SHOULD refer to the GS1 guidance document "Bar Coding – Getting It Right: Recommendations for best practice by GS1 UK" when producing, verifying and printing GS1-128 and EAN-13 bar codes. For GS1 DataMatrix Symbols, the GS1 guidance document "GS1 DataMatrix: An introduction and technical overview of the most advanced GS1 Application Identifiers compliant symbology" SHOULD be used. (NB: GS1 membership registration required).
19.	Users MUST perform a clinical safety assessment when using this standard in a clinical setting. The assessment should be in accordance with the standards ISB 0160 and ISB 0129 as appropriate.

The key words MUST, SHOULD and MAY are defined in the information standards development methodology. They follow RFC-2119.

2.1 Conformance Criteria

#	Conformance Criteria
1	All NHS Trusts SHOULD have registered with GS1 and obtained a GS1 Unique Organisation Prefix by 1 February 2012.
2	A named person SHOULD be identified in each NHS Trust with primary responsibility for GS1 registration and allocation and management of the GS1 code numbers created from the GS1 Unique Organisation Prefix.
3	From 1 February 2012, all NHS Trusts SHOULD be able to demonstrate compliance with the Automatic Identification and Data Capture (AIDC) for the NHS in England Fundamental Standard for all new AIDC systems procured, deployed and used by the Trust.
4	From 1 September 2012, where there is a local business and safety case to do so, all NHS Trusts SHOULD have established a clear migration plan to ensure existing AIDC systems adhere to the AIDC for the NHS in England Fundamental Standard by 2 September 2013.
5	A clinical safety risk assessment SHOULD have been conducted by each NHS organisation prior to the deployment and use of AIDC technology in an NHS / healthcare setting. The clinical safety assessment SHOULD be in line with the standard: ISB-0160: Patient Safety Risk Management for the Deployment and Use of Health Software.
6	There are no clinical safety near misses or serious untoward incidents (SUIs) reported as a direct result of AIDC standards.
7	There are no clinical safety near misses or serious untoward incidents (SUIs) reported as a direct result of concurrent coding systems for GS1 codes and ODS codes.
8	From Q4 2011, all NHS Trusts have a background mapping of their ODS code to their GS1 Unique Organisation Prefix which is publicly available via the ODS website.

3 GS1 Code Numbering Standards

The following section provides an introduction to GS1 code numbering standards, ie. the GS1 Unique Organisation Prefix and the GS1 Identification Keys, their purpose, the range available, potential uses and concept of operation.

3.1 GS1 Unique Organisation Prefix

Before any NHS organisation can start to use the GS1 code numbering standards, they will need to register with GS1 as a member, in order to obtain their **GS1 Unique Organisation Prefix**. The Department of Health has purchased membership in advance for each NHS organisation until February 2012 (with a view to extending this for a further 5 years). Refer to Appendix 1 for guidance on how to register an NHS organisation with GS1.

By obtaining a GS1 Unique Organisation Prefix, this entitles the registered NHS organisation to create any and all of the GS1 Identification Keys (see next section). The GS1 Unique Organisation Prefix is unique to the particular user licensed to use it and the user is responsible for ensuring the keys created from that prefix are also unique. The length of the GS1 Unique Organisation Prefix depends on the numbering capacity that the user needs - the shorter the prefix, the more of each Key the user can create.

For further information regarding the GS1 Unique Organisation Prefix, refer to Section 7.6.

3.2 GS1 Identification Keys

To identify something, you need to start with a unique number. GS1 calls these numbers “Keys”. The GS1 Identification Key you need depends on what you want to identify, whether it’s a product, a container, or a person, for example.

Keys are globally unique in the sense that each value is used once only within each key type. Therefore, all GS1 Identification Keys are unique and unambiguous within their intended areas of application, which are shown in the following table.

What you need to identify	Healthcare Examples	GS1 Identification Key Required
Products or services that are traded	NHS manufactured and re-packaged medicines.	GTIN (Global Trade Item Number) – see section 3.2.1
People	Individual patients, employees	(GSRN) Global Service Relation Number – see section 3.2.2

Parties and locations	NHS organisations, outpatient clinic reception, desk 2 in room 10 floor 3, etc.	GLN (Global Location Number) – see section 3.2.3 and section 3.2.4
Documents	Medical documents	GDTI (Global Document Type Identifier) – see section 3.2.5
Logistics units	Pallets, containers, roll cages used in healthcare	SSCC (Serial Shipping Container Code) – see section 3.2.6
Assets such as important equipment	Surgical instruments, medical devices / equipment, eg. IV pumps	GIAI (Global Individual Asset Identifier) – see section 3.2.7
Returnable equipment used for transporting goods	Pallet bases, crates, totes used in healthcare	GRAI (Global Returnable Asset Identifier) – see section 3.2.8

Generally speaking, each GS1 Identification Key is associated with a concept in the real world. The Keys may then be used on the item, in an electronic record or file, in a database, in an electronic message, or in any other data context. Thus, the GS1 Identification Keys can be used to link database information to the physical entity unambiguously. GS1 Identification Keys, and other data attributes, are associated with an Application Identifier (AI) code which is used by bar code readers to interpret the information held in the bar code.

Each AIDC Operational information standard will fully specify the mandatory GS1 Identification Key which MUST be used with that standard. Only one GS1 Identification Key will be permitted for each AIDC Operational information standard.

3.2.1 GTIN – Global Trade Identification Number

The GTIN is the GS1 Identification Key used to identify products and services and helps automate the way they are traded and managed. GTINs can be assigned to any item that may be priced, ordered or invoiced at any point in any supply chain. They are used to recognise the product or service and then to retrieve pre-defined information about the item from a database. GTINs can be read from a GS1 bar code symbol or RFID tag, exchanged in a GS1 eCom message or accessed from the Global Data Synchronisation (GDS) Network. Each different level of packaging has its own GTIN.

GTIN are 8 digits, 12 digits, 13 digits or 14 digits in length:

- **GTIN-8** - Shown in EAN-8 bar codes.
- **GTIN-12** - Shown in a UPC-E and UPC-A bar codes
- **GTIN-13** - Shown in EAN-13 bar codes

- **GTIN-14** - Shown in ITF, GS1-128, GS1 DataBar and GS1 DataMatrix bar codes.

With the exception of ITF the barcodes used to represent a GTIN-14 can accommodate additional attribute information – see Figure 1.

At present GS1 DataBar is not currently used or recommended for use within the healthcare sector however for completeness it is mentioned here due its capability to use application identifiers for encoding attribute information.

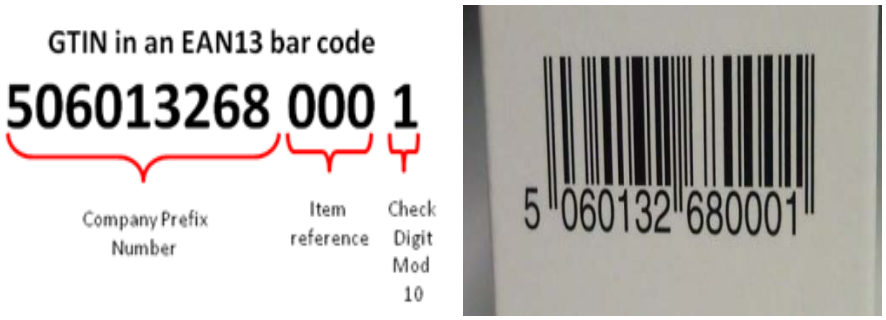


Figure 1 - An example of an EAN-13 bar code used would be as above used typically on pharmaceutical products used within robotic dispensing systems that could also be dispensed or sold over the counter (OTC).

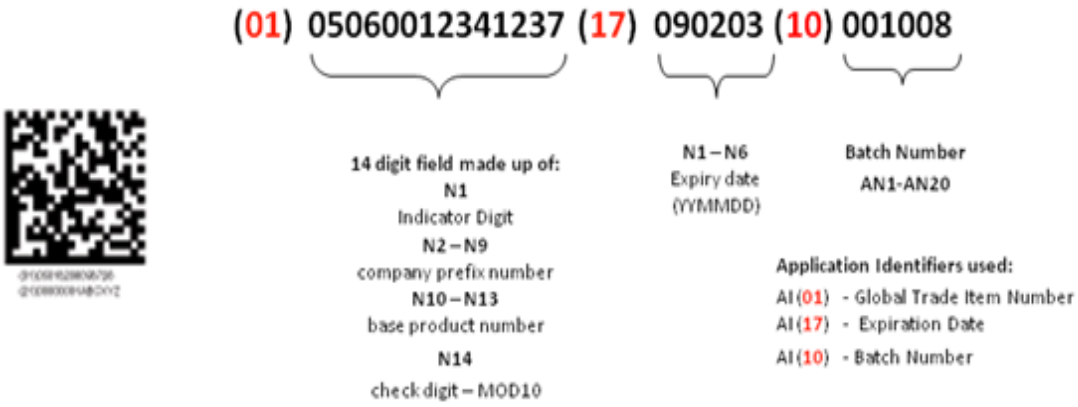


Figure 2 - An example above of a GS1 DataMatrix using a GTIN-14 with attribute information allowing additional information about the product to be encoded within the bar code.

3.2.2 GSRN – Global Service Relation Number

The GSRN is the GS1 Identification Key used to identify the recipient of services in the context of a service relationship. The GSRN is normally assigned by the service provider and may be bar coded using Application Identifier (8018). The GSRN is used to identify patients, doctors, nurses and other hospital staff. The GSRN is written into a bar code on the patient wrist band and can be encoded into identity and access badges for staff. The GSRN is constructed as Figure 3 below:

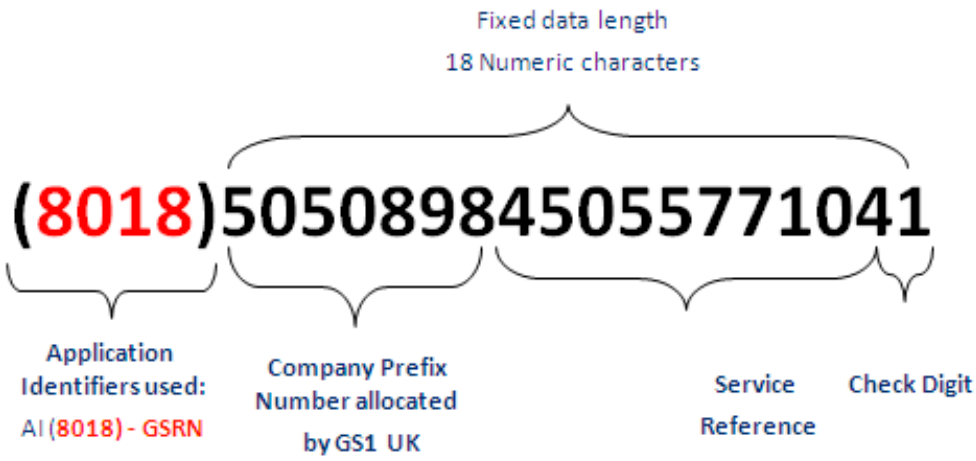


Figure 3

3.2.3 GLN – Global Location Number

As the name implies, the GLN is the GS1 Identification Key for locations. This could mean a building like a warehouse, store or factory or somewhere more specific, like a delivery bay or even a shelf. In addition GLNs are used to identify functions such as the buying department or accounts department as well as entire companies or operating divisions. In healthcare GLNs are used not only for such supply chain and departmental locations but also to identify, for example, wards, nurses' stations and bed bays.

GLNs are often used in communications, especially electronic communications, such as orders or advance shipping notes, to identify relevant locations like where goods should be delivered and where the invoice should be sent.

GLNs can also be represented as bar codes or carried in RFID tags. These can be placed on items being moved through a supply chain to indicate the intended delivery point or can be placed on physical locations themselves to verify that a correct point has been reached.

The GLN is always 13 digits long.

Six different application identifiers are used to identify locations and these are detailed below:

Application identifier	Name	Format
410	Deliver to GLN	n3 + n13
411	Invoice to GLN	n3 + n13
412	Purchased from GLN	n3 + n13
413	Deliver for/forward to GLN	n3 + n13
414	Identification of physical location	n3 + n13
415	GLN of the invoicing party	n3 + n13

An example of a GLN encoded in a GS1-128 bar code is as Figure 4 below:

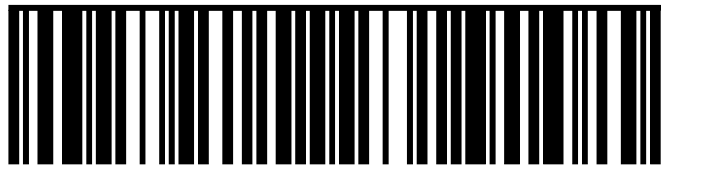


Figure 4

3.2.4 GLN Extensions

Global Location Numbers may also have an optional extension component using the Application Identifier (254). Although optional, when used AI (254) must be in conjunction with AI (414) Identification of a physical location and can be encoded using an EPC tag or GS1-128 symbol.

The GLN Extension will not be communicated with trading partners except by mutual agreement and has been developed in expectation that it will be an important business requirement with the EPC Network.

Locations that currently have a GLN may also use an optional GLN Extension component to distinguish unique locations (storage slots, door locations, bin storage, shelves, peg holes, rack, cabinet, computer/communication bays, etc.). However, a company may choose to assign a unique GLN, without an Extension component, as a way to identify these locations.

3.2.5 GDTI – Global Document Type Identifier

The GDTI is the Identification Key for a document type combined with an optional serial number and used to access database information that is required for document control purposes. The GDTI is assigned for the life time of the document type and may be bar coded using Application Identifier (253). An example of GDTI use is to add a GS1-128 bar code or RFID tag to medical records to enable automated tracking of the records around the hospital. The GDTI is constructed as Figure 5 below:

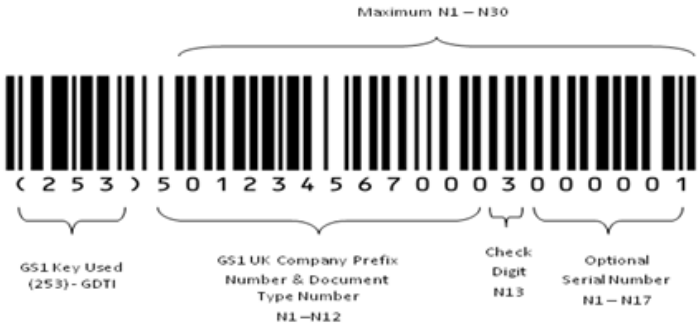


Figure 5

3.2.6 SSCC – Serial Shipping Container Code

The SSCC is the GS1 Identification Key for logistics items. It can identify an item of any composition established for transport and/or storage which needs to be managed through the supply chain. The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. It is denoted by the Application Identifier (00).

The SSCC is used to uniquely identify packages with their contents such as pallet loads and filled containers and is referenced in documentation giving notice of what will be delivered. The SSCC enables a logistics unit to be directly linked to the relevant delivery information so that it can be received and put away efficiently and so that proof of delivery can be established effectively. The SSCC is constructed as Figure 6 below and is used within a GS1-128 bar code when printed.

Figure 6

An extension digit can be any value from 0 to 9.

3.2.7 GIAI – Global Individual Asset Identifier

The GIAI is the GS1 Identification Key for individual assets. These might include things like manufacturing plant, office equipment, medical devices, surgical instruments, components and spare parts, but could be anything an organisation owns and needs to manage.

GIAIs are often shown as bar codes on the items themselves and make asset management easier helping for example to keep the history of an item's use and maintenance, record its whereabouts, determine its ownership and confirm its warranty status. GIAIs are used in a diverse range of healthcare applications such as tracking the life-cycle history of surgical instruments or identifying medical assets such as IV pumps.

The GIAI is assigned by the owner of the asset and may be bar coded using Application Identifier (8004) as Figure 7 below:

Figure 7

3.2.8 GRAI – Global Returnable Asset Identifier

The GRAI is the GS1 Identification Key for types of reusable package or transport equipment. It is used to enable tracking as well as recording of all relevant data associated with the individual asset or asset reference. The GRAI is assigned for the life time of the asset and may be bar coded using Application Identifier (8003).

Identification of these items helps to manage returnable assets by tracking where they have been sent, determining whether they have been returned, monitoring what they have been used for and recording the history of their maintenance.

The GRAI can be used in healthcare to identify roll cages, trolleys, gas cylinders, etc. and is constructed as Figure 8 below:

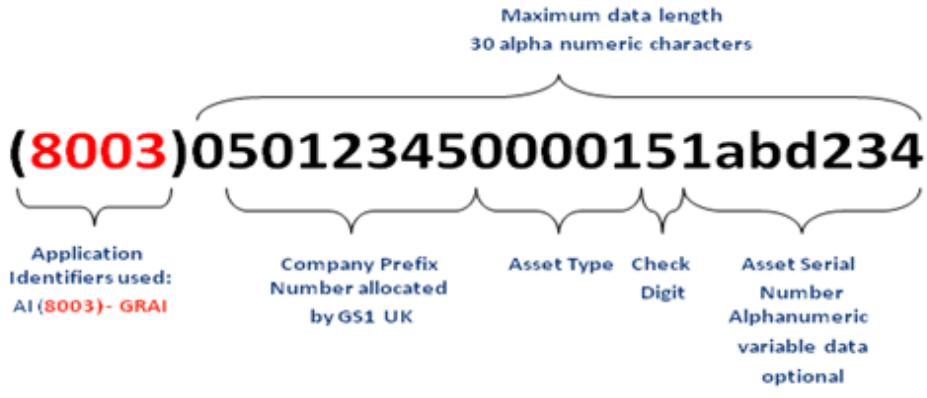


Figure 8

3.2.9 Application Identifiers

As explained earlier, GS1 Identification Keys are used for unambiguous identification of something in the real world. The intention is that the minimum data is carried in physical data carriers attached to the object being identified. Instead, the GS1 Identification Keys are expected to find information about the identified object in a database.

However, the GS1 system also allows attributes to be carried in bar codes or RFID tags. Ideally, this supplementary data will only encode information that cannot be looked up in a database by reference to the key. This could happen if data is needed when connection to a database is not available or when the key identifies a class of objects but the supplementary data relates to a batch or individual instance of the object

GS1 Identification Keys and Supplementary Data are both identified using numeric Application Identifiers (AIs). An AI is a short numeric prefix which identifies the type of data that follows.

Key Concepts:

- There are approximately 100 AIs.
- Each AI is a two, three, or four digit numeric prefix in front of the data to tell what the data means. For example, the AI for SSCC is (00) and for GTIN it is (01).
- GS1-128, GS1 DataBar, GS1 DataMatrix and Composite Component can carry AIs and their corresponding data.
- More than one AI can be carried in one bar code. When this happens, AIs with a fixed length data content (e.g., SSCC has a fixed length of 18 digits) are placed at the beginning and AI with variable lengths are placed at the end. If more than one variable length AI is placed in one bar code, then a special "function" character is used to tell the scanner system when one ends and the other one starts.
- When AIs appear in the text beside the bar code they are surrounded by brackets (eg. GTIN (01) 10614141000019).
- Seven AIs are used for the Keys (GTIN, GLN, SSCC, GRAI, GIAI, GDTI, GSRN).
- 45 AIs are trade item attributes like variable count, net weight, lot number, and expiry date.
- 28 AIs are logistic unit attributes like count of trade items contained, gross weight, gross volume, routing code.
- One AI denotes the GLN Extension.
- The balance are used for special purposes like Shipment Identification, Consignment Identification, Couponing, Refund Receipts, Electronic Serial Identification for Cellular Mobile Telephones, Internal Use, Payment Slips, and Customer Specified Articles.

4 GS1 Data Carriers

4.1 Scope

The following section describes the range of data carriers which are permitted for use with the GS1 Identification Keys, their specific characteristics and concept of operation. Each subsequent AIDC Operational information standard will fully specify the data carriers which MUST, SHOULD, MAY or MUST NOT be used. In some cases, a single data carrier will be mandated, in other cases, more than one data carrier may be permitted. The pros, cons and risks for each will be outlined in order to help NHS organisations decide.

It is important to note that the code numbers (GS1 Identification Keys) are defined independently of the data carrier in which they are embedded.

GS1 Identification Keys and attributes can be used with a range of data carriers, most commonly bar codes but also Radio Frequency Identification (RFID) tags. It is important to note that the GS1 Identification Keys are defined independently of the bar code or RFID tag in which they are embedded. In other words, the GS1 standard data has the same meaning, regardless of the technology in which it is carried.

However, whilst RFID is a key in scope data carrier for the GS1 System of Standards, the clinical safety risk of deploying and using RFID in a hospital / healthcare setting has not yet been fully established. Therefore, **RFID is considered to be an out of scope data carrier for the "AIDC for the NHS in England" Fundamental information standard at present.** Upon establishing an approved clinical safety case for the use of RFID as an AIDC data carrier in the NHS in England, a Change will be made to this Fundamental standard to bring RFID into scope. As such, individual NHS organisations will be responsible and accountable for the clinical safety risk assessment and management of RFID deployment and use for the purposes of AIDC.

The current version of this specification includes three data carriers, of which all fall into the "bar code" category. Additional data carriers will be added as they have been established through development of the AIDC Operational standards.

- GS1 DataMatrix Symbology (2D bar code).
- GS1-128 (1D / linear bar code).
- EAN-13 (1D / linear bar code).

4.2 GS1 DataMatrix Symbology

Full specification details of the GS1 DataMatrix Symbology can be found in the document "GS1 DataMatrix Introduction and Technical Overview".

GS1 DataMatrix is a two-dimensional symbology which can encode large amounts of data in a small space, but can only be read by camera scanners. GS1 DataMatrix uses a special start combination to differentiate the GS1 DataMatrix symbol from the other Data Matrix ECC 200 symbols.

This is achieved by using the Function 1 Symbol Character (FNC1) in the first position of the encoded data. This instructs scanners to process the information according to the GS1 System Rules. GS1 DataMatrix is increasingly the symbol of choice for many in healthcare due to its size and resilience to damage.

Key features of GS1 DataMatrix are:

- A matrix bar code (2 Dimensional) based on ISO/IEC 16022:2006[3].
- Omni directional scanning.
- Maximum Error Correction – ECC200 can withstand typically up to 25% damage to the bar code and still allow for successful scanning.
- Uses ASCII encodation scheme.
- Can only be read by 2D imager / camera / vision systems.
- Can be printed in square or rectangular formats.*
- Can be printed dark on light or light on dark.
- Uses a "L" Shaped finder pattern – **See Figure 9.**
- The opposite corner to the centre of the "L" finder pattern is always the colour of the background (commonly white unless the image is printed light on dark) indicating an ECC200 symbol – **See Figures 10 and 11.**
- The quiet zone is one module width and is used as the quiet zone on all four sides, as with other bar codes do not print in this area.
- Can encode a maximum of 2335 alphanumeric characters or 3116 numeric digits.

* Square format is usually used as it has a larger range of sizes and is the only format available for symbols encoding large amounts of data.

Figure 9 above.

Because GS1 DataMatrix requires camera based scanners it is currently specified for healthcare items not crossing Point of Sale (POS systems / electronic tills) and direct part marking.

[3] ISO/IEC 16022:2006 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

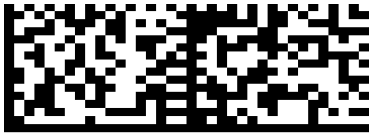


Figure 10 – The above are examples of both square and rectangular formats of the GS1 DataMatrix printed dark on light.

Figure 11 – Example above of GS1 DataMatrix printed light on dark.

4.3 GS1-128

The GS1-128 bar code is a subset of the more general Code 128 Bar Code symbology, it is used to encode element strings using application identifiers. Use of the Function 1 Symbol character (FNC1) in Code 128 symbols in the first character position following the start character has been reserved exclusively for the GS1 system. This instructs scanners to process the information according to the GS1 System Rules. The GS1-128 bar code was previously referred to as a EAN-128 or UCC/EAN-128 bar code.

The GS1-128 bar code is made up as follows reading from left to right (refer to Figure 12 below).

- Left Quiet Zone

A Start Character (A, B, or C)	The Double Character
The Function 1 Symbol Character (FNC1)	Start Pattern

- Data (including the Application Identifier represented in character set A, B, or C)
- A Symbol Check Character
- The Stop Character
- Right Quiet Zone

The data characters represented in the symbol are shown in Human Readable underneath or above the symbol.

Figure 12

Code Sets A, B and C (see A Start Character in Figure 12 above) are as follows and define which code is used initially:

Code set A includes all of the standard upper case alphanumeric characters and punctuation characters together with the symbology elements (eg. characters with ASCII values from 00 to 95) and seven special characters.

Code set B includes all of the standard upper case alphanumeric characters and punctuation characters together with the lowercase alphabetic characters (eg. ASCII characters 32 to 127 inclusive) and seven special characters.

Code set C includes the set of 100 digit pairs from 00 to 99 inclusive, as well as three special characters. This allows numeric data to be encoded as two data digits per symbol character. The data characters are represented in the symbol are shown in Human Readable Interpretation (HRI) underneath or above the symbol. See Figure 13 below.

Characteristics of the GS1-128 symbology are:

- Limited to 165mm wide (the bar code can be printed wider than this but laser scanners are unable to decode any bar code greater than this width).
- 48 alphanumeric character capacity.

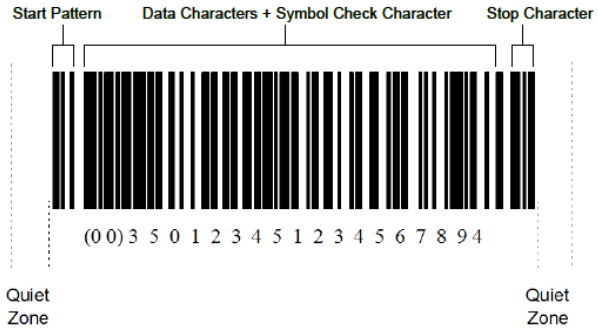


Figure 13

4.4 EAN-13

The EAN-13 bar code is the UK's most common form of product bar code. It can only encode a 13 digit GTIN; it cannot carry other GS1 Identification Keys or any attributes. It is used in retail outlets and in distribution and is common on branded pharmaceutical products

Figure 14 (above)

4.5 Radio Frequency Identification (RFID)

Radio Frequency Identification (RFID) is currently out of scope for this AIDC Fundamental Standard, until the Clinical Safety Case for the use of RFID in NHS organisations has been established and approved.

5 Bar Code Production and Verification

5.1 Choosing the right carrier

The GS1-128 bar code can encode any GS1 information and can be read by almost any bar code reader. This makes it a good choice for many healthcare applications, especially where bar code readers are already deployed.

The GS1 DataMatrix bar code can also encode any GS1 information and has the added benefits of being very small, being able to hold a large amount of data and having the ability to be read even when it has suffered damage. However it requires camera based scanners and is relatively slow to read. Healthcare is increasingly adopting GS1 DataMatrix and this is likely to be the bar code of choice for many applications.

EAN-13 bar codes identify products (trade items) and are therefore likely to be useful in handling products such as food, clothing, office stationery, etc. They will also be found on pharmacy products where the batch number and/or use by date only need to be printed in human readable form.

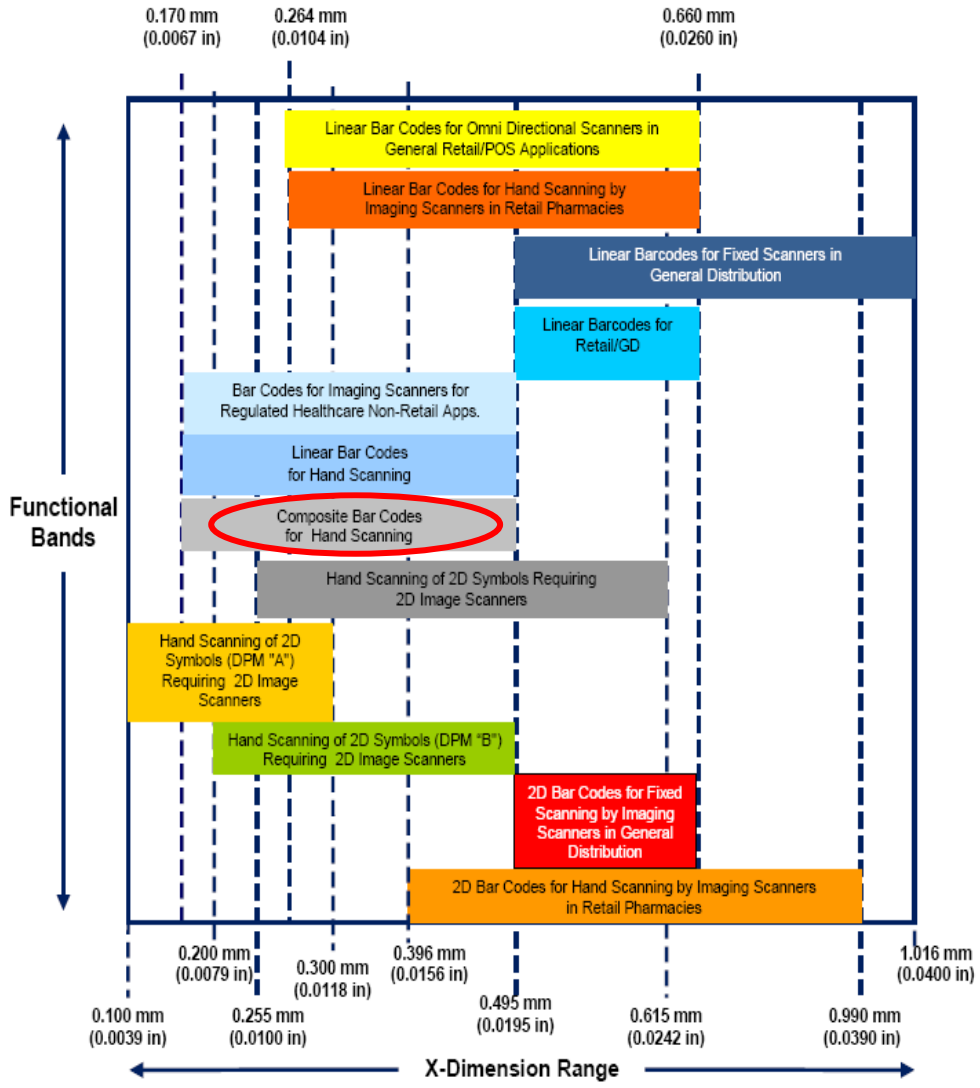
RFID tags are most appropriate where high levels of automation are required, where it is difficult to position a bar code or where many items need to be read at the same time. RFID readers are more expensive than bar code readers and the tags themselves are likely to cost around 50p each depending on their encapsulation and method of attachment method. However, the use of RFID as a data carrier is currently out of scope for this Fundamental Standard and therefore the remainder of this Specification will focus on bar codes only.

5.2 Bar Code Production

GS1 DataMatrix and GS1-128 bar codes are typically printed on demand. Direct thermal, thermal transfer, laser, ion deposition, ink jet and mechanical matrix printing can all be successful but it is important that the printing / marking equipment are properly adjusted and serviced regularly. Typical problems with thermal transfer, direct thermal, ink jet printers arise from misaligned, worn print heads, blocked nozzles, inappropriate media or choice of unacceptable colours. Colour choice for bar code printing is very important and colours should be chosen very carefully. Typically the bar code colour should be as dark as possible ideally black (but blue, green are acceptable) and the background colour should ideally be white (but red, yellow and orange are acceptable).

When printing / marking using bar codes it is important to adhere to the guidelines in Figure 15 (next page) detailing minimum and maximum dimensions that can be used within specific application areas. For example for Direct Part Marking using dot peening an x dimension range of 0.2mm to 0.495mm is recommended, shown outlined in red.

Figure 15 (below)



GS1 DataMatrix Direct Part Marking "**A**" created by DPM marking technologies such as laser or chemical etching and GS1 DataMatrix Direct Part Marking "**B**" created by DPM marking technologies such as dot peen. Due to the marking technologies and characteristics of reading they each have varied ranges of X-Dimensions and different quality criteria recommended and may require different reading equipment

5.3 Symbol Marking Options:

Substrate / Technology	Paper	Corrugated	Glass	Plastic	Metal
Inkjet	Yes	Yes	Yes	Yes	Yes
Laser Etch	For specific colours *or* specific finishing	For specific colours *or* specific finishing	under certain conditions	If contrast can be achieved *or* specific finishing	Painted *or* oxidised
Thermal transfer (on-demand)	Useful for adhesive labels	No	No	Plastic films	No
YAG Laser	Coloured background *or* specific finishing	Coloured background *or* specific finishing	No	Yes	Yes
Ink Jet (on-demand)	Yes	Yes	No	No	No
Direct Part Marking	Film transfer	Film transfer	No	Yes	Yes

Figure 16 (above)

5.4 Laser Etch

Laser etch – or laser engraving – uses precisely controlled lasers to engrave or mark the bar code on the product. A computer controlling a series of mirrors and lenses focuses the laser to burn or etch the bar code. The process allows a product to be directly and permanently marked but is only suitable for “laserable” materials.

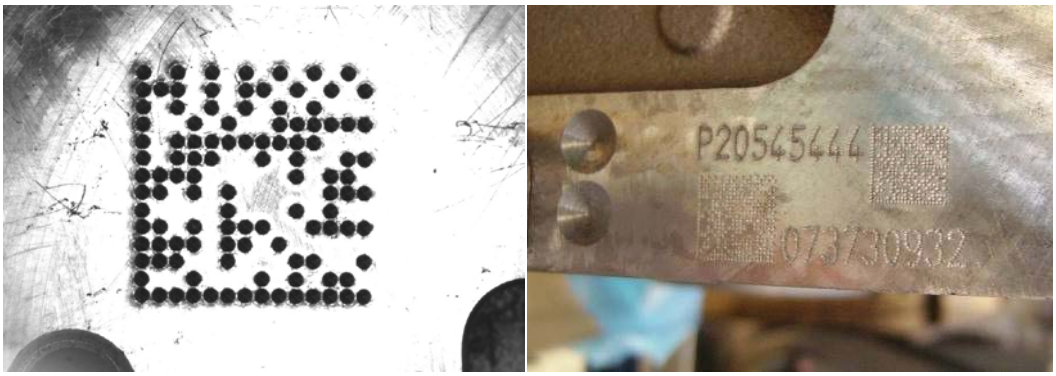
The power of the laser needs to be set based on the volume printing required as well as the speed of printing. The power must be adapted to substrates and commonly ranges from 10 to 100 watts.

Figure 17 - Example: A GS1 DataMatrix printed using Laser:

5.5 Direct Part Marking (Dot-Peening)

The technology is used to directly mark the material and is particular suitable for solid materials (metals, plastics, wood, etc.) It can be used for all the information to be marked on the item (text, date, logo, etc.) as well as the GS1 DataMatrix symbol. A small head – normally made from a very strong material such as tungsten – is computer controlled to make a defined series of identical punch marks in the surface of the substrate. The depth of marking can be carefully controlled to ensure all indents are identical making this technique particularly suited for printing GS1 DataMatrix directly on items made of metal or other material with very hard flat surfaces.

Figure 18 - Example: A GS1 DataMatrix printed using Direct Part Marking:



5.6 Verification

The accurate printing of bar codes is fundamental to successful scanning.

Bar code scanning provides no indication of bar code quality as it gives no information about the symbol other than whether it can be scanned or not by that particular scanner. Scanners look for sufficient contrast between the bars and spaces and decode the different widths of bars and spaces into data that is sent to the software for processing.

The GS1 General Specifications describe a process for the production of bar codes that should result in scannable symbols, but a verification procedure needs to be followed to provide more information about symbol quality.

Staff need to be trained in the use of verification equipment, and must always check symbols visually before using a verifier that meets the requirements of ISO/ IEC 15426-1:2006[4] to provide detailed information. Each symbol must be checked to see that the bars are the correct height, and that no horizontal lines or spaces cut through the symbol. Any marks crossing the bars and spaces of a symbol will reduce its effective height and make it very difficult to scan.

[4] ISO/IEC 15426-1:2006 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 1: Linear symbols

The position of the bar code on the packaging will need to be checked to see that it meets the GS1 General Specifications. Any final labelling or wrapping should also be examined to ensure that the bar codes remain visible and scannable.

When checking symbol quality, you should attempt to simulate the final, filled product or package. If for example a white background is printed on to a clear substrate, check the colour of the contents of the item. If it is not possible to simulate the contents, verify the bar code twice, once over a black background and next over a white background. The worse of the two grades will provide information about the worst possibility.

Having checked that the bar codes are in the correct position and are not shortened in height (truncated), you can use verification equipment to obtain an overall grade for each symbol. Verifiers that meet the international requirements will measure and grade the following seven parameters of the code:

- The symbol contrast (a measure of the contrast difference between the dark bars and the paler background).
- The minimum reflectance (a check that the bars appear dark enough in relation to the spaces).
- The minimum edge contrast (a measure of the least difference in contrast between an adjacent bar and space). This will be a low grade if the bar code is unlikely to be read when it is scanned.
- Modulation (a ratio of the minimum edge contrast to the symbol contrast). This grade will be low if positive bar gain has increased the width of the bars causing a narrowing of the spaces between them.
- Defects (which may be light voids within dark bars or dark spots in the spaces between the bars).
- Decode (an indication that the symbol will decode successfully if it conforms to the specifications, notably in respect of character encodation, check digits and light margins).
- Decodeability (an indication of the accuracy of widths and positions of the bars and spaces).

All of these criteria are measured separately and the grade given to the bar code is the lowest score for any one of these measurements.

All of these characteristics can be measured by verification equipment which meets the requirements of ISO/IEC 15426-1, which incorporates the CEN (Comité European de Normalisation, the European Standards Committee) standards. These standards are compatible with those from ANSI (the American National Standards Institute).

This standard applies to all the bar codes used by the GS1 System, and provides a basis for agreeing with trading partners the quality of symbols that will be accepted. The verifier should ideally be used to check each symbol being tested ten times, using different paths through the symbol.

Higher grades mean that the bar code in question is closer to the ideal than lower scoring symbols, but there may still be some faults that will prevent it from being decoded successfully by all scanners.

The aim is to produce bar codes with grades 4 or A, although this will be difficult with some printing processes and materials. All bar codes must be grade 1.5 or C or above, except for ITF-14 symbols printed on to fibreboard, when grade 0.5 or D is acceptable. In general, higher quality bar codes can be expected to scan more easily and quickly than lower quality bar codes of the same size. Bar codes of similar sizes, with no reduction in height (truncation), and high print quality contribute to fast, effortless scanning.

6 Bar Code Printing

Virtually all consumer units (products that will be sold at a retail point of sale) and very many traded units (the outer cases for the consumer units) will be sold in packaging that is printed with the appropriate bar code.

The image of the bar code that is included in the artwork will need to be adjusted to take account of the spread of ink. This is necessary because direct contact printed bars in bar codes print wider than the actual width of bars on the printing plate. The difference between the width of the bar as it is printed and the specified width on the printing plate is called print gain.

Each bar on the printing plate needs to be reduced in width by the average print gain and this is known as bar width reduction.

All widths of bar have the same bar width reduction so that the spaces on the printing plate will be wider than they will be when they are printed. This adjustment in the width of the bars can be determined by the use of the printability gauges. Many printers will be able to offer advice about the use of the printability gauges and will obtain images that have been correctly adjusted for the particular printing process being used.

Different printing techniques have different tolerances for printing accuracy and different print gains so it is important to check what these are before choosing a particular size of bar code. The choice of substrate used in the printing process will also affect the size of the bar code that can be accurately printed.

If possible, when using flexographic printing, the bars should run parallel to the press web direction. If the bars are required to be perpendicular to the press direction, try to avoid distorting the symbol for the plate roll circumference. This lack of distortion will alter the overall width of the symbol, but will provide dimensional integrity.

When using either silk screen or rotogravure printing processes, the symbol must be aligned parallel to the cell structure on the screen or gravure plate cylinder to provide the smoothest bar edge possible.

6.1 Printing Bar Codes on Demand

Printing bar codes on demand is necessary when including variable information, such as expiry dates, in GS1-128 bar codes for traded units. Some users will want to print bar coded labels on demand for some consumer units, especially when these items are not contained in pre-printed packaging. On demand printing techniques include direct thermal, thermal transfer, laser, ion deposition, ink jet and mechanical matrix.

First of all check that your label design software is compatible with the printer hardware you are planning to use, and that the printer resolution is adequate for the bar codes you are printing. In general this means that your printer must have a resolution of at least 8 dots per mm (approximately 200 dots per inch) as it has to use a whole number of dots to make up the width of the narrowest bars required.

An 8 dpmm printer will be able to print bar codes whose x-dimensions are 0.25 mm, 0.375 mm, and 0.50 mm. A 12 dpmm printer (approximately 300 dots per inch) will be able to print bars with x-dimensions of 0.25 mm, 0.333 mm, 0.416 mm, 0.50 mm and so on.

All on demand printers, whether they are direct thermal, thermal transfer, dot matrix, ink jet or laser, will print better bar codes with well defined edges if they are printing the bar codes in picket fence orientation. This means that the bars go in the same direction as the substrate when it passes through the printer.

Printing in picket fence orientation means that the width of the bar code can be no wider than the print head.

If it is necessary to print a bar code which would be wider than the print head, then it must be printed in ladder orientation. This means that any failure in the print head elements will cause white lines to appear across the bar code. These faults in effect reduce the height of the bar code and make it more difficult to scan.

Matching the label stock with the technique being used is also important, as poor quality paper can create dust which can cause the print heads to burn out sooner than expected. It is also necessary to match thermal transfer ribbons to the equipment being used and ensure that the correct pressures are being used with the print heads. The incorrect choice of ribbon and paper may be workable, but the machinery is likely to require much higher maintenance costs and require much more frequent servicing. It is highly recommended to use validated combinations of ribbons and labels, and to use verification equipment to check the print quality.

Direct thermal printing may be appropriate for some products, and the correct label stock must be sourced. Bear in mind that these labels remain heat sensitive and may be inappropriate if goods are kept in direct sunlight or if the labels are heated in any subsequent process.

6.2 Printing GS1 128 Bar Codes

These bar codes are often printed on demand, so the operator of the equipment needs to be aware of certain requirements.

6.2.1 Function 1

GS1-128 symbols are a subset of Code 128 and they require a special symbol character (a pattern of three bars and three spaces) called Function 1 to be used as part of the start pattern. If the Function 1 character is not correctly included as part of the start pattern the symbol will not meet the requirements of the GS1 System.

6.2.2 Choosing the correct character set

There is a choice of character sets to help users minimise the space taken up by these bar codes. Use character set C to print pairs of digits using one symbol character (a pattern of three bars and three spaces) rather than two symbol characters whenever possible. If single letters or numbers are required use character sets B or A.

6.2.3 Concatenation

Concatenation is an effective means for encoding several element strings in a single bar code and should be used to save label space and optimise scanning operations.

The element strings may appear in any order in a GS1-128 bar code.

The best practice is to put data of fixed length before any variable data to minimise the length of the bar code. If a variable length field is followed by another element string, it must be terminated by the Function 1 character. When a variable length field appears at the end of a GS1-128 bar code it does not need to be terminated by the Function 1 character.

If the SSCC is used, it must always appear in the lowest bar code on the label. The SSCC can be alone or concatenated with other data in the same bar code. Concatenation cannot be used with the SSCC on standard A6 labels because the bar code would be too wide for the label.

6.2.4 Choosing the correct size

GS1-128 bar codes can vary in size according to how well they can be printed. The maximum width for the x-dimension (the width of the narrowest bars and spaces) is 1.016 mm and the minimum x-dimension is 0.495 mm when these bar codes are used on trade item groupings. Users must choose an x-dimension that can be reproduced by their on demand printing equipment.

The x-dimension must be a multiple of the size of the smallest line that can be printed, and if an 8 dpmm (200 dpi) printer is used, the x-dimensions can be 0.50 mm, 0.625 mm, 0.75 mm, 0.875 mm and 1.00 mm.

If using labels, an x-dimension of 0.50 mm will be acceptable, provided the printed bar codes, when verified, meet the minimum grade required.

If printing these GS1-128 bar codes directly onto fibreboard outercases an x-dimension of 1.00 mm is recommended, but verifiers must still be used to check that the bar codes meet the minimum grade required. Further information about verification is provided earlier in Section 5.6.

6.2.5 Height of bars

Whichever x-dimension is chosen, the height of the bars must be at least 32 mm.

6.2.6 Keeping adequate light margins

The light margins on each side of a symbol which has an x-dimension of 1 mm are 10 mm. The light margin is always equal to 10 times the x-dimension, but when the x-dimension is 0.50 mm it is recommended that the light margins are at least 7 mm on each side.

6.2.7 When are brackets required around application identifiers?

Brackets are used around each application identifier (AI) in the data printed below the bar code. This makes it easier for people to read the AI and the data it denotes. The brackets are not encoded into the GS1-128 bar code itself.

6.2.8 Determining the length of a GS1-128 bar code

GS1-128 bar codes will vary in length depending on the types of information they carry so it is important to check that the intended length of the bar code, with the necessary light margins to the left and right, is no longer than 165 mm.

Each symbol character (except the stop character) has a width of 11 mm if an x-dimension of 1 mm is chosen, and each symbol must include four symbol characters to begin and complete the bar code.

For example, how long will a GS1-128 bar code be that includes a GTIN and an expiry date? The data required in the bar code is all numeric so character set C will be chosen.

The data required in the bar code will be as follows:

0105012345678900170606 06.

The bar code begins with Start C and Function 1 characters and ends with a symbol check character and the stop character.

The 24 numbers required in the bar code will be shown by 12 symbol characters in this character set, so the complete symbol will be 16 symbol characters in length.

The width of the bar code (if an x-dimension of 1 mm is chosen) will be:

(16 x 11) mm + 2 mm extra for the stop character + 20 mm for the two light margins

176 + 2 + 20 = 198 mm.

This measurement exceeds the maximum allowed length so the x-dimension must be reduced. If an x-dimension of 0.50 mm is chosen the bar code will be half this length, 99 mm.

If an x-dimension of 0.625 mm is chosen the length will be 123.75 mm, and with an x-dimension of 0.75 mm, the length will be 148.5 mm.

6.2.9 Choosing the correct application identifiers

When providing extra information on a traded unit, most users will encode the GTIN for the product with information such as an expiry date. The GTIN on the item must be preceded by the AI 01, and the extra information denoted by using the AIs as explained in the GS1 General Specifications. The most commonly used AIs and their field lengths are given below.

When labelling pallets, the GS1 logistics label must be used. All the data shown on the label must refer to the contents of the whole pallet. The SSCC is the only compulsory element, and will be the only reference used on pallets of mixed product.

For pallets with uniform contents, any of the AIs listed below can be used. Please remember that you cannot use AIs 01 and 02 together.

AI 01 must only be used when the pallet is also a traded unit, ie. it is ordered and invoiced as a single item. In all other cases, use the AIs 02 and 37 to describe the contents of the pallet.

This is not an exhaustive list of all the application identifiers that can be used on traded units or on pallets. Please consult the GS1 General Specification to find a complete listing of all the AIs.

6.2.10 Common print problems with GS1-128

- Printing Code 128 symbols instead of GS1-128 symbols because the mandatory Function 1 character is not included.
- Encoding the brackets around the application identifiers as data within a GS1-128 bar code. These brackets are only used around the application identifiers in the human readable characters printed below the bar code.
- Printing a GS1-128 symbol wider than 165 mm. This dimension includes the light margins which are not explicitly indicated, so special attention must be given.
- Not showing the application identifiers in brackets below a GS1-128 bar code.
- Not including the application identifiers required to define the data in a GS1-128 bar code.

6.3 Printing GS1 DataMatrix Symbology

The exact choice of software will need to meet the individual business requirements. In general terms the software must be capable of generating a GS1 DataMatrix symbol in full conformance to the ISO/IEC 16022 standard. Often a difficult area is the programming of FNC1 in first position as each software supplier has (or has not) developed its own method.

Please refer to the document "GS1 DataMatrix Introduction and Technical Overview" for full details on how to produce GS1 DataMatrix Symbology.

7 GS1 Background Information

GS1 is an international not-for-profit association with Member Organisations in over 100 countries.

GS1 is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world.

GS1 has over 30 years' experience in global standards offering a range of standards, services and solutions to fundamentally improve efficiency and visibility of supply and demand chains.

GS1 standards are used in multiple sectors and industries.

Retail

GS1 has made a significant contribution to the efficiency of the retail supply chain and the overall growth of the retail industry.

Healthcare

Adopting and implementing GS1 standards enable the effective and efficient roll-out of Automatic Identification and Traceability Systems throughout the Healthcare sector.

Transport and Logistics

Transport and Logistics companies get competitive advantage by applying GS1 standards across their supply chain operations. GS1 also works closely with the World Customs Organisation.

Consumer Electronics

GS1 standards can enable visibility throughout the total life cycle of consumer electronics products.

Defence

7.1 The GS1 System

The GS1 System (formerly the EAN.UCC System) provides global standards for identification, data synchronisation, automatic data capture, and electronic communications in all trade and industry sectors. It enables companies to bar code their products, use radio frequency tags, exchange information electronically, and use scanning and reading systems to track and trace items all the way from production, through distribution and on to the hospital and to the final patient.

Developed in the early 1970s in America by the Uniform Code Council, and extended in the late 1970s for global use by EAN International, the GS1 System is now used by over one million organisations worldwide as the basis for improved supply chain management systems. The system is managed globally by GS1, a non profit making association based in Brussels. GS1 UK is the UK authority for the GS1 System and it was established in 1976 to promote and develop the use of the system for the benefit of British business and the national health service. It now has over 21,000 member companies and hospitals and works closely with other GS1 national organisations to ensure that new developments meet changing business requirements.

7.2 GS1 and ISO standards

GS1 enjoys strong working partnerships and alliances with a variety of trade associations and standards bodies including Aim Global, HL7, ICCBBA, UN/CEFACT and ISO. GS1's working relationship with ISO is a particularly long and active one. A number of GS1 staff members participate actively in ISO standard development committees, or serve as their Chair and/or secretariat. GS1 adopts ISO standards where they meet the needs of its members and also puts forward standards it has developed for adoption by ISO.

Working with GS1 standards means working with ISO-compliant standards, with the added value of services, training and implementation support.

7.3 Funding and Governance

GS1 is governed by a management board composed of key leaders and drivers from multi-nationals, retailers, manufacturers and GS1 Member Organisations. As a result, the GS1 management board has a global, multi-sectorial make-up.

GS1 Member Organisations (MOs) around the world are funded by their local members through annual subscription fees and provision of services.

GS1 is driven by the mission of delivering local services through Member Organisations but with a global reach. GS1 has 108 Member Organisations serving more than 150 countries around the world.

7.4 Participating in Standards Development

GS1 has a developed a detailed and comprehensive process for the management of standards. This is called the Global Standards Management Process (GSMP).

7.4.1 Global Standards Management Process (GSMP)

The Global Standards Management Process (GSMP) is the global forum for users to bring business needs that require standard based solutions to create a more efficient Supply Chain. Specifically, the GSMP provides a comprehensive set of methods and rules allowing both the GSMP and EPC communities and affected industry groups to submit their needs and lead in the creation of globally agreed standards and guidelines.

7.4.2 What standards are management by GSMP?

GSMP is the global standards management process for six types of standards. They include:

- BarCodes & Identification
- Electronic Product Code (EPC)
- Global Data Synchronization Network (GDSN)
- eCOM (and EANCOM)
- Global Product Classification (GPC)
- Traceability
- Data Accuracy

7.4.3 How do I get involved?

Building standards that improve supply chain efficiency is a collaborative effort among all stakeholders. Member participation is critical in order to make the process work.

Participation is primarily through teleconferences and some physical meetings. The work is performed through Work Requests (WR). Once you become a member of a specific group you will receive invitations to the development team conference calls and have access to the repository for standards development work.

You are able to join as many GSMP Groups that are relevant to your organisation and you are able to resource effectively.

GSMP standards are global and affect multiple sectors. Your level of participation may vary by change request based upon your organisation's needs without affecting your membership standing.

7.4.4 What is the Intellectual Property Policy (IPP)?

The GS1 IP Policy (IPP) sets out the licensing terms for a ratified standard or Specification. The intent of the IPP is to seek to provide royalty-free licensing of the necessary claims of patents owned by participants in the Working Group in regard to the Specification developed by the Working Group. Many patents exist and are being filed today in areas relevant to requirements, process, and specifications.

7.4.5 What is the GSMP Participation Model?

Governance groups aid in the leadership and operation of GSMP. They provide advice to the Working Groups as well as ensure that the GSMP process is followed, work efforts are prioritised, and conflicts are resolved.

Figure 19 (above)

GSMP Working groups bring together users from all industries and from everywhere in the world to develop supply chain standards and implementation guidance.

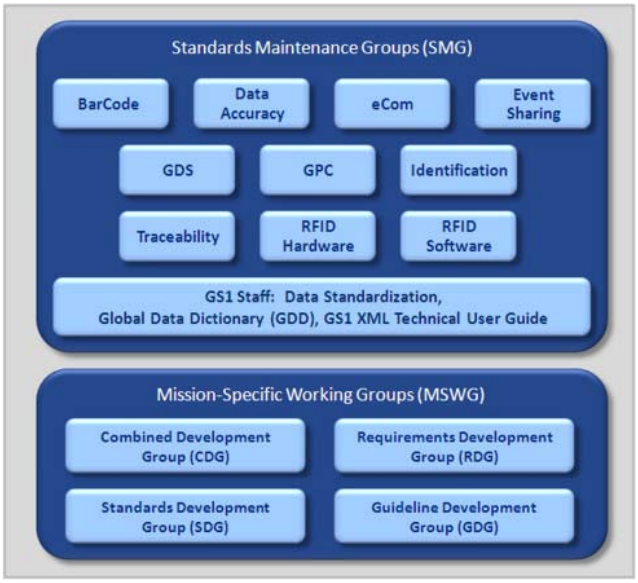


Figure 20 (above)

7.4.6 What is the new GSMP process?

The GSMP provides a comprehensive set of methods and rules allowing the user community and affected industry groups to submit their needs and lead in the creation of globally agreed standards and guidelines. The GSMP Process Consists of Four Key Steps:

Figure 19 (above)

7.5 GS1 Healthcare

GS1 Healthcare is a voluntary, global Healthcare user community bringing together all Healthcare stakeholders: pharmaceutical and medical devices manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies and associations.

The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.

Using GS1 standard identifiers and bar codes for medicines, clinicians, patients, locations, medical devices and consumables promotes the matching of the right care to the right patients and enables recording the full service line costing of procedures and patient care.

7.5.1 GS1 UK Healthcare User Group (HUG)

- The role of GS1 UK HUG is to promote and encourage the development and use of global standards, primarily in automatic identification and data capture (AIDC) technology, to improve patient safety and efficiency.

- GS1 UK HUG aims to become the single most authoritative source where the healthcare industry comes to for advice and help on global AIDC standards.
- The Group's leadership team includes the Association of British Healthcare Industries (ABHI), Association of British Pharmaceutical Industries (ABPI), Mölnlycke Health Care, Smiths Medical, Department of Health, Leeds Teaching Hospitals NHS Trust, NHS Connecting for Health (NHS CFH), National Patient Safety Agency (NPSA) and NHS Supply Chain.

7.6 GS1 Unique Organisation Prefixes – Additional Information

7.6.1 About Unique Organisation Prefixes

Unique Organisation Prefixes are a central component of the GS1 standards. The global uniqueness of the Unique Organisation Prefixes is assured through their issuance from the GS1 numbering bank. These numbers are only available from GS1 upon the user paying a fee for usage of its Unique Organisation Prefix (and thereby becoming a member of the GS1 global community).

The UK Member Organisation of GS1 is GS1 UK. The Unique Organisation Prefixes (formally referred to by GS1 as Company Prefixes) have been procured by NHS Connecting for Health under a formal Agreement with GS1 UK (the initial term being 5 years). The prefixes form the nucleus of all the Unique Organisational Prefixes to be deployed by the NHS.

The Agreement gives CFH and users in the NHS community licence of use of the Unique Organisation Prefixes and free access to the GS1 standards to NHS organisations. Under the terms of this Agreement, licences are renewable annually and provision has been made for users to contract with GS1 UK individually at the best terms commercially available at the time if, in the totally unexpected event, that NHS CFH terminate the Agreement prematurely.

7.6.2 Concept of Operation

A Unique Organisation Prefix is allocated to a user (eg. an NHS Trust) by GS1 UK from its number bank upon instruction by NHS CFH, according to agreed procedures described in Appendix 1. This number is used to uniquely code all entities to be identified by the user according to the application of use.

The Unique Organisation Prefix represents one element of the GS1 standards and is the foundational enabler of AIDC.

Conceptually, the numbers are symbolised by use of a data carrier (eg. a bar code) and automatically captured via a scanning process. The captured data can then be processed by an ICT application or may be transmitted to a third party by EDI or some other communications protocol, eg. XML. (Note that HL7 (out of scope of this submission) based applications are not impacted by this process.)

The construct of the identifier (and there are several types of identifier within the GS1 standards) varies according to its application. For example, NHS locations may be identified by the use of the GLN (Global Location Number); NHS manufactured products by the GTIN (Global Trade Item Number); and services and people e.g. patients, by the GSRN (Global Service Relationship Number).

An identifier should have no meaning but used simply as a key to computer held files storing the required application data.

Each Unique Organisation Prefix as issued by GS1 UK is globally unique. Implementation rules governing the use of the standard in healthcare require that identifiers are never reallocated or reused, ensuring their uniqueness in perpetuity.

There will however be instances where the Unique Organisation Prefix as originally allocated to an entity eg. a hospital, may be required to change and that entity allocated a different Unique Organisation Prefix - for example, when two or more Trusts are consolidated. Specific rules have been defined by GS1 to cover these scenarios which are included in the GTIN Allocation Rules described below.

7.6.3 Healthcare Global Trade Identification Number Allocation Rules

The GS1 GTIN Allocation Rules are a set of guidelines covering the change management of Unique Organisation Prefixes as associated with products (GTINs), as allocated for example by NHS manufacturing or repackaging units to NHS originated medicines. They include guidelines on instances where the Unique Organisation Prefix allocated to an entity, an NHS Trust for example, is caused to change due to a revision to the Trust 'ownership' of that hospital.

http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

8 Known Risks and Issues

This section describes known risks and issue with the information standard. These were reported to the Information Standards Board as part of the standard submission and accepted by the standard Sponsor.

8.1 Risks

Description	Priority (L/M/H)	Progress / Resolution
GS1 is an external company that requires licence funding. What will happen if this central funding ceases?	M	The central funding is used to register each NHS organisation as a member of GS1. GS1 members are allocated a unique company prefix, which thereby allows organisations to create unique code numbers eg. for their products and services, ie. GTINs. Should central funding cease for GS1 membership (currently due to expire February 2012, however, anticipated to be renewed for a further 5 years), each NHS organisation who wishes to continue using GS1 standards would be required to pay for their own membership, which is a relatively small yearly fee. There is no requirement for central licensing costs to continue to use the bar code format. Therefore, there is no dependency here.
What if, in the future, GS1 no longer continued to exist as an organisation?	M	If GS1 ceased to exist as an organisation, the unique company prefixes and code numbering system could still be used in exactly the same way as when the organisation did exist. There is no dependency on GS1 existing as an organisation in order to use the code numbering system. However, there would be a risk that, in the absence of a governing organisation / body who allocated and maintained the unique company prefixes, the code numbers would not be unique internationally. This would only become an issue if the NHS were using the code numbers for, eg. trading with external organisations. Therefore, in the event of GS1 no longer existing (or the NHS deciding to no longer adopt GS1 standards) the NHS would either need to develop an internal coding system or seek to adopt a new external replacement.

At present, the clinical safety implications of deploying Radio Frequency Identification (RFID) in NHS environments is not fully understood as there is no established Clinical Safety Case.	H	The Fundamental Standard is excluding RFID from its scope, ie. RFID will not be a recommended data carrier for use with the AIDC standards, until the RFID Clinical Safety Case has been established and approved by the NHS CFH Clinical Safety Group. In this event, a Change Submission to the Fundamental Standard will be made to ISB. NHS organisations deploying RFID for the purposes of AIDC will be responsible and accountable for RFID safety.
Successful implementation of this standard relies on individual local NHS organisations applying the rules as defined, including ensuring correct allocation and maintenance of local code numbers for assets.	M	Information Specification No's 9, 10 and 11 are the mitigations – see Specification document. To be carried forwards to implementation.

8.2 Issues

Description	Priority (L/M/H)	Progress / Resolution
ISB questioned which body is responsible for the bar code readers and training costs. This needs to be clarified.	L	This will be the NHS organisations who wish to use the solution. It must be locally led by benefits, not mandated from the centre.
There is already an administrative code numbering system in place for NHS locations – the National Administrative Code Service (NACS). This Service is governed by the NHS Organisation Data Service (ODS). There is a current issue in terms of potential conflict between the NACS codes and the GS1 unique organisation prefix. Both parties are fully aware of this issue.	M	The standard specification will include rules around the allocation and maintenance of GS1 unique organisation prefixes, in line with the current policy for NHS organisation codes. The ODS has agreed to support this by holding information mappings between GS1 Unique Organisation Prefix and NACS codes for organisations. This risk is to be carried forwards to the Implementation stage of this standard.

9 Glossary of Terms

Term	Definition
AIDC	Auto Identification and Data Capture
Application Identifier (AI)	The two, three or four digit number that specifies the data that immediately follows it in a GS1-128 bar code. In the case of the NHS Number, the Application Identifier is a Global Service Relation Number (GSRN), with the four digit number 8018.
Bar code or symbol	A graphic code, either printed or photographically reproduced, composed of parallel bars and spaces of various widths (linear bar code, eg. GS1-128) or dots and spaces arranged in an array (2 dimensional bar code, eg. GS1 DataMatrix Symbol).
GDTI	Global Document Type Identifier
GIAI	Global Individual Asset Identifier
GLN	Global Location Number
GRAI	Global Returnable Asset Identifier
GS1	Global Standards - the governing body for GS1 member organisations which administers the GS1 system.
GSRN	Global Service Relation Number – a GS1 Identification Key type (identified as such by the Application Identifier 8010).
GTIN	Global Trade Identification Number
Human readable interpretation	An area beneath the bar code that carries the GS1 number in a human readable form.
Light margins	The clear spaces required to the left and right of any bar code.
Picket fence orientation	Printing a bar code so that the bars are vertical to the base of the product.
Quiet zone	A defined area at the start and end of the bar code.
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
X dimension	The nominal width of the narrowest bars or spaces in a printed bar code.

10 Supporting Information

10.1 Contact Information

For further information about the AIDC information standards for the NHS in England, please contact the following:

Sponsor	
Name	Peter Coates, Commercial Director
Organisation	Department of Health
Email Address	Peter.Coates@dh.gsi.gov.uk
Developer	
Name	Beverley Scott, Senior Clinical Safety Specialist
Organisation	Department of Health Informatics Directorate
Email Address	beverley.scott@nhs.net
AIDC Programme Lead	
Name	Neil Lawrence
Organisation	Department of Health Informatics Directorate
Email Address	neil.lawrence@nhs.net

10.2 Useful resources

http://www.connectingforhealth.nhs.uk/systemsandservices/aidc

www.isb.nhs.uk/use/baselines/aidc

www.gs1uk.org

Appendix 1 – Registration with GS1

Before any NHS organisation can use the GS1 code numbering standards, they will need to register as a member (requires annual renewal). The Department of Health has purchased membership in advance for each NHS organisation until February 2012 (with a view to extending this for a further 5 years).

It is recommended that the person in your organisation who is responsible for information technology or informatics is the primary registrant. Secondary registrants can be added once the primary contact has been validated and the account has been set up – however the primary registrant will need to authorise any secondary registrant. Before registering your organisation, please check with your IT department or contact GS1 UK directly webfeedback@gs1uk.org to confirm that your organisation does not already have a GS1 account.

Instructions for initial (primary) registration:

a. Visit the GS1 UK registration site: http://www.gs1uk.org/Pages/join-gs1uk.aspx

b. Complete the online application form as directed on screen.

c. For “Number of Product Lines”, select “1,000 – 10,000”.

d. For “Turnover / Estimated Turnover (£)”, insert “£1.00”. (The registration form will not accept less than £1.00).

e. For “Industry”, select “Health”.

f. Leave “Company Registration Number” blank.

g. For “VAT Number (EU)”, insert “0”.

h. For “Registered for VAT in the UK or EU?”, select “No”.

i. For “Have you been asked by another business to join GS1 UK?”, select “Yes, by a healthcare body”. Then select the option “CFH scheme”.

j. For “Which products and services do you intend to use?”, select “Creating bar codes”.

k. For “Are you also the billing contact?”, ensure you only select “Yes” if you are the primary registrant for your organisation. (NB: If you state that you are not the billing contact, another section will open up to complete with the billing contact’s details. You will need to obtain these from your organisation. Suggest contacting the information technology or finance department.)

l. After accepting the terms and conditions, click on “Next”. A screen will appear with your “Order Confirmation”. It will list the joining and annual licence fee and ask for a “Payment Type”. Please select “Request an invoice and pay later”.

As you have selected the "CFH scheme" option earlier, GS1 will contact us to validate your membership and notify you upon activation of your account, when you will be able to access "My Numberbank" and create and manage your bar code numbers. **Please note, you will not be billed for the duration of the agreement between the Department of Health and GS1, which at present runs until February 2012.**

Once your organisation has fully registered with GS1, you will be allocated your **Unique Organisation Prefix**. It is this unique number that will become the prefix for all bar code numbers created by your organisation – thus ensuring the bar code numbers are completely exclusive to yourselves. For example, NHS Connecting for Health's unique organisation prefix is "5050898", therefore, all bar code numbers created by NHS CFH begin with "5050898". Further details regarding the GS1 Unique Organisation Prefix can be found earlier in this document at Section 7.6.

There is an online tool called "My Numberbank" which is accessible to all members (primary and secondary) of an organisation's account. The My Numberbank tool can be used to create your organisation's bar code numbers, manage the numbers online and also export the list of numbers into, eg. Microsoft Excel spreadsheets. Whilst this is a useful tool, the Department of Health does not recommend that the NHS use this tool to create and manage its numbers, as the website security is not governed by the NHS. Instead, it is recommended that the primary registrant creates and maintains a database which is stored on their NHS organisation's secure network.

Once your NHS organisation has obtained a unique prefix, you can begin to use the GS1 System of Standards to create bar codes. In this context, the GS1 System of Standards primarily consists of two main aspects: a) GS1 Identification Keys; and b) Data Carriers – see next sections. Each AIDC Operational Standard published by the NHS will include a full specification and user guide, however, this AIDC Fundamental Standard outlines the GS1 Identification Keys and Data Carriers in general terms and should be used as a reference tool alongside each AIDC Operational Standard.

In addition to the documentation accompanying this standard, users should review the GS1 publications listed below, which is only available upon registration (as either a primary or secondary registrant). The documents are available at the following link:

(https://members.gs1uk.org/resources/help_support/Pages/Documentation.aspx)

- GS1System Overview
- GS1 General Specification
- Bar Coding – Getting It Right
- How To Print Bar Code Symbols
- GS1 DataMatrix Introduction and Technical Overview
- Ink Jet Printing GS1 128
- Improving Bar Code Quality
- Barcode Validation and Verification Guide
- How To Choose The Right Scanner

Appendix 2 – Background to AIDC in the NHS in England Standards Development

Automatic identification and data capture (AIDC) is the use of machine-readable codes, eg. bar codes to uniquely identify, quickly and accurately, an item or process. The technology has been in use for decades in many sectors of industry, the most familiar of which is retail, where bar codes on products have been used to improve supply chain efficiency, driving down costs and giving retailers a rich source of information about what shoppers buy.

In February 2007, the Department of Health (DH) published the strategic case for wider adoption of AIDC technologies in healthcare. "Coding for Success: Simple Technology for Safer Patient Care[5]" advised that AIDC technology will become a vital tool in improving patient safety and quality of care, reducing costs and improving efficiency.

Following the publication of Coding for Success, the Department of Health (DH) entered into an agreement with GS1 UK - an international standards body for Auto Identification and Data Capture (AIDC) technologies - for the provision of AIDC codes to the NHS. This agreement followed a statement to Parliament by Lord Hunt (then Minister for Health) and the publishing of the Department of Health's "Coding for Success" report, both of which advocate greater use of AIDC technologies within the health service. The DH provides membership to GS1 for free for all NHS organisations while also funding workshops, a helpdesk, consultancy and expert guidance.

Since this agreement was launched, the DH has been working with GS1 UK to roll out standardised coding solutions into the NHS with great success. Over 300 hospitals are now signed up to using the codes, within 5 main work streams[6].

"Coding for Success" was subsequently reviewed by the DH in 2010 (Review of Coding for Success Implementation[7]), with renewed emphasis on AIDC standardisation across the NHS via the Information Standards Board for Health and Social Care (ISB).

Here, there were two types of standards of concern:

1. Standards for the code numbers themselves, how they are allocated, structured and maintained, ie. the "GS1 Identification Keys" and "Data Carriers". These are the standards developed and owned by the GS1 organisation and are collectively referred to as the GS1 System of Standards. The GS1 System of Standards is not industry specific, although GS1 do provide industry specific guidance to using standards, where relevant. This system includes the unique organisation / company prefix allocation process.

[5] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_066098.pdf
[6] http://www.connectingforhealth.nhs.uk/systemsandservices/aidc
[7] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120722.pdf

2. Standards for how AIDC technologies and code numbering standards should be implemented and used in healthcare. These are information standards which are industry, ie. healthcare specific. They are developed and owned by the NHS and will be submitted for assurance, approval and publication to the Information Standards Board for Health and Social Care (ISB). The purpose of these standards is to ensure safe, consistent and cost effective application of the GS1 system of standards in healthcare.

This AIDC Fundamental information standard falls into the latter (second) category. It is the primary AIDC standard that healthcare organisations must use if deploying AIDC technologies and the GS1 System of Standards in their organisation. As a technology enabling standard, it provides the infrastructure, ie. the fundamental building block for implementing AIDC.