

# Automatic Identification Data Capture (AIDC)

## Implementation Guidance DAPB0108 Amd 1/2022

April 2022

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# Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a change to an existing information standard for publication under [section 250 of the Health and Social Care Act 2012](#).

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB).

This information standard comprises the following documents:

- Change Specification
- Implementation Guidance
- Requirements Specification.

An Information Standards Notice (DAPB0108 Amd 1/2022) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled copies of these documents can be found on the [NHS Digital website](#). Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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# Contents

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<b>1</b>	<b>Supporting Information</b>	<b>4</b>
1.1	Related Standards	4
1.2	Supporting Guidance	4
<b>2</b>	<b>Overview</b>	<b>5</b>
<b>3</b>	<b>Timescales / Plan</b>	<b>7</b>
<b>4</b>	<b>Helpdesk</b>	<b>8</b>
4.1	Contact Information	8
4.2	Useful Resources	8
<b>5</b>	<b>Implementation Guidance by User Group</b>	<b>9</b>
5.1	All Users	9
5.2	Existing Users	9
5.3	New Users	10
<b>6</b>	<b>Technical Guidance</b>	<b>10</b>
6.1	Encoding Data – GS1 Data Formats	10
6.2	Production and Printing – GS1 Data Carriers	11
6.3	Reading and Decoding	11
6.4	Quality and Compliance	12

# 1 Supporting Information

## 1.1 Related Standards

Related Standards MUST be used and read alongside this document.

Reference <sup>1</sup>	Title (including links)
Release 21.0.1	<a href="#">GS1 General Specifications</a>
Release 2.5.1	<a href="#">GS1 DataMatrix Guidelines</a>
Release 10.0	<a href="#">GS1 Healthcare GTIN Allocation Rules</a>
Release 3.0.1	<a href="#">GS1 GLN Allocation Rules Standard</a>
Release 1.13	<a href="#">GS1 EPC Tag Data Standard</a>
ISB 0149	<a href="#">NHS Number</a>
DCB0160	<a href="#">Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems</a>
DCB0129	<a href="#">Clinical Risk Management: its Application in the Manufacture of Health IT Systems</a>

## 1.2 Supporting Guidance

Supporting Guidance MAY be used and read alongside this document.

Reference <sup>1</sup>	Title (including links)
ISBT-128	<a href="#">ICCBBA technical standard for the identification, labelling and information processing of medical products of human origin</a>
DCB1077	<a href="#">AIDC for Patient Identification</a>
March 2021	<a href="#">GS1 UK Surgical Instrument Traceability Guidance</a>
Release 2.1	<a href="#">GS1 Healthcare GLN Implementation Guideline</a>
Release 1.1	<a href="#">GS1 Identification of Investigation Products in Clinical Trials Application Standard</a>
Release 1.3	<a href="#">GS1 Logistics Label Guideline</a>
Release 1.0	<a href="#">GS1 Guidelines for the distribution and shipping of medical product of human origin (MHRO)</a>
Release 2.1	<a href="#">GS1 EPC UHF Gen2 Air Interface Protocol Standard</a>
Version 2.0.3	<a href="#">GS1 EPC Class-1 HF RFID Air Interface Protocol Standard</a>

<sup>1</sup> GS1 General Specifications and GS1 Standards documents are updated regularly, so whilst release/version numbers or date references have been provided here, the link provided will always direct users to the most recent version of the document.

## 2 Overview

<b>Standard number</b>	DAPB0108
<b>Title</b>	Automatic Identification and Data Capture (AIDC)
<b>Release</b>	Amd 1/2022
<b>Type</b>	Information Standard
<b>Definition</b>	<p>DAPB0108 is an information standard developed by GS1 UK and endorsed by NHS via NHS England and NHS Improvement sponsor and NHS Digital SRO.</p> <p>GS1 UK have worked with NHS Digital to update the above NHS standard that applies to NHS settings in England where Automatic Identification and Data Capture (AIDC) technologies (i.e. barcodes and RFID tags) are used as enablers to improve patient safety, ensure greater clinical effectiveness and drive operational efficiencies.</p> <p>As the previous version, ISB 0108, was last published in 2011, there are a number of GS1 Standards and NHS changes which require alignment. This release includes the following updates:</p> <ul style="list-style-type: none"> <li>• Serialised Global Trade Item Number (SGTIN) which enables the identification of a specific instance of an item, providing additional granularity for traceability purposes.</li> <li>• Service Relation Instance Number (SRIN) which enables the identification of specific episodes of care and is an extension to the Global Service Relation Number (GSRN), defined for use by DCB1077: AIDC for Patient Identification</li> <li>• Global Model Number (GMN) to address regulatory requirements<sup>2</sup> for medical devices used in the UK, including in vitro diagnostic medical devices</li> <li>• Radio Frequency Identification (RFID) added to GS1 Data Carriers</li> <li>• Updated information on GS1 Data Carriers, barcode production, barcode quality and compliance (excluding RFID)</li> <li>• Updated diagrams and references to GS1 Standards such as the GS1 Healthcare Global Trade Item Number (GTIN) Allocation Standard</li> <li>• All references to supporting links and guidance, glossary, appendices, governing bodies, and contract dates, updated</li> <li>• Sections updated and re-formatted to align to revised DSAS publication guidance for consistency</li> </ul>
<b>Background</b>	<p>GS1 UK is one of 115 member organisations, with over 56,000 members across various sectors including NHS organisations, striving towards the adoption of GS1 Standards. With multi-year partnership agreements established with healthcare governing bodies across each of the UK nations, both regulatory and business needs throughout NHS Trusts in England and the healthcare sector, can be addressed through the adoption of GS1 Standards across various health systems.</p> <p>GS1 Standards for AIDC technologies and applications are developed and maintained collaboratively by industry users worldwide, enabling organisations to use a common language to identify, capture and share information for traceability and interoperability. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically at point of sale.</p>

<sup>2</sup> UK government guidance on regulating medical devices in the UK can be found at <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain>

	<p>The introduction of the <a href="#">Medicines and Medical Devices Act (MMDA)</a> in February 2021 has enabled the UK to have more authority over how it regulates medicines and medical devices by encouraging the use of existing industry standards such as GS1 Standards. This includes the Medical Device Register (MDR) developed by the <a href="#">Medicines and Healthcare products Regulatory Agency (MHRA)</a>, which ensures that every medical device used in the UK is certified and registered in a central registry with a unique identifier and key information, in a standardised format.</p>
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### 3 Timescales / Plan

The adoption of DAPB0108 enables the use of Automatic Identification and Data Capture (AIDC) technology with GS1 Standards, on a voluntary basis – therefore no compliance deadline has been set.

However, the adoption of DAPB0108 ultimately enables improved data quality through standardisation, allowing information to be exchanged seamlessly between systems and organisations to support the delivery of greater patient safety improvements, enhance clinical effectiveness, and reduce unwarranted clinical variation. By enabling improved data accuracy for Trust records, increased operational efficiencies can be achieved, reducing administrative burdens with tasks such as inventory and asset management or patient level costings, and releasing more time back to patient care<sup>3</sup>.

Additionally, GS1 Standards support initiatives such as the Medical Device Information System (MDIS), which is currently being developed by NHS Digital, as well as compliance to the [Medicines and Healthcare products Regulatory Agency \(MHRA\) Medical Device Register \(MDR\)](#) as legislated by the [Medicines and Medical Devices Act \(MMDA\)](#) in February 2021.

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<sup>3</sup> GS1 UKs Healthcare Case Studies with NHS Trusts and providers can be found at <https://healthcare.gs1uk.org/cases/>

## 4 Helpdesk

### 4.1 Contact Information

For further information and support on the DAPB0108: AIDC information standard, please note the following details:

<b>Developer</b>	
<b>Organisation</b>	GS1 UK
<b>Email Address</b>	<a href="mailto:healthcare@gs1uk.org">healthcare@gs1uk.org</a>
<b>Phone number</b>	Freephone 0808 178 8799 or 020 7092 3501 (available Mon-Fri 9am-5pm)

### 4.2 Useful Resources

#### **GS1 UK** – [www.gs1uk.org](http://www.gs1uk.org)

Visit the GS1 UK webpage to access further information and support on GS1 Standards, including training resources available to GS1 UK members, as well as key member and industry events and news.

#### **GS1 UK's Healthcare Portal** – <https://healthcare.gs1uk.org>

Head to GS1 UK's Healthcare Portal to see how GS1's global standards for unique identification and AIDC technologies are used within the Healthcare sector to improve patient safety and drive clinical and operational efficiencies.

#### **GS1 Standards** – <https://www.gs1.org/standards>

The GS1 Standards homepage is where users can access the most up-to-date releases of all GS1 Standards and Guidelines documentation and includes a wealth of resources on everything from GS1 Identification Keys to GS1 Data carriers, to sector and application specific guidance, showcasing Standards in Action.

#### **NHS Digital: Standards and Collections** – [www.digital.nhs.uk](http://www.digital.nhs.uk)

Access an alphabetical list of all published Data Alliance Partnership Board (DAPB) standards and collections. The list is updated on a monthly basis, following the approval of new items, and changes, by the DAPB.

## 5 Implementation Guidance by User Group

### 5.1 All Users

The DAPB0108: AIDC for NHS England information standard MUST be reviewed alongside the GS1 General Specifications section headings and numbers<sup>4</sup>, that have been provided throughout the Requirements Specification.

To be compliant with DAPB0108, is to be compliant to any relevant GS1 Standards, which means that the AIDC system or product being procured, deployed, and used, can:

- Utilise GS1 Identification keys for the required data elements based on the functionality and purpose of the system being considered.
- Produce, print, and read GS1 Data Carriers such as barcodes or EPC/RFID tags, in accordance with the specifications provided for the intended application.

Whilst system design and business processes around collections and data flow remain out of scope for DAPB0108, health IT systems may need to be modified to ensure the data format and data carrier requirements specified can be complied with. The safety implications of any such modifications must be considered by manufacturers of health IT systems as well as those involved in the deployment and use of health IT systems. This is outlined in the following related information standards:

- DCB0129: Clinical Risk Management: its application in the Manufacture of Health IT systems
- DCB0160: Clinical Risk Management: its application in the Deployment and use of Health IT systems

### 5.2 Existing Users

Any Trusts that are already compliant to the original standard, ISB 0108, should review the related Change Specification to ensure all changes are understood and if needed, can be implemented as specified.

Whenever any changes are made to barcode or EPC/RFID systems for production and printing, including any changes to materials such as print techniques or label substrate, users should re-confirm compliance to DAPB0108.

Barcode and EPC/RFID tag validation and verification services offered by GS1 UK, are available to all NHS Trusts in England, as part of the GS1 UK membership contract (next renewal March 2024).

Any trusts that are already compliant to the original standard, ISB 0108 should consider the following steps:

1. Review the Change Specification for DAPB0108 on all changes to the existing standard
2. Read the Requirements Specification for DAPB0108
3. Contact GS1UK to confirm that you are using the correct Global Company Prefix/es

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<sup>4</sup> Please refer to section headings where possible, as section numbers may change when the GS1 General Specifications are republished annually.

4. Understand your local position, engage with stakeholders
5. Plan what you need to do and who needs to be involved (including system suppliers)
6. Facilitate required actions, such as any training needed
7. Implement / do
8. Post review and re-evaluate if required

## 5.3 New Users

New users that want to implement the latest standard, DAPB0108 should consider the following steps:

1. Read the Requirements Specification for DAPB0108
2. Contact GS1UK to confirm that you are using the correct Global Company Prefix/es
3. Understand your local position, engage with stakeholders
4. Plan what you need to do and who needs to be involved (including system suppliers)
5. Facilitate required actions, such as any training needed
6. Implement / do
7. Post review and re-evaluate if required

## 6 Technical Guidance

Systems and equipment which produce, print and read GS1 Data Carriers, encoded with GS1 Identification Keys and attributes must be configured in accordance with the guidance set out in the [GS1 General Specifications](#) (which also includes the [GS1 DataMatrix Guidelines](#), the [GS1 EPC Tag Data Standards](#) and the [EPC UHF Gen2 Air Interface Protocol Standard](#)).

### 6.1 Encoding Data – GS1 Data Formats

The encoding structure required for this information standard and used for all GS1 Identification Keys and attribute data, is the subset of International Standard ISO/IEC 646 (equivalent to ASCII table 256), known as the GS1 AI encodable character set 82.

This limited character set is supported by almost all computer systems available globally and includes:

- Alphabetic characters, as lower (e.g., a-z) and upper case (e.g., A-Z)
- Numeric characters (e.g., 0-9)
- Various punctuation symbol characters, with the exception of space characters “ ” which are considered invalid within the GS1 system

For EPC/RFID tags, data content should adhere to the specifications laid out in the [GS1 EPC Tag Data Standards](#). Please note, 96-bit tags have some capacity restrictions with limitations on numeric characters and the number range allowed.

## 6.2 Production and Printing – GS1 Data Carriers

Software of some type will be required to produce GS1 Data Carriers so that the data may be formatted into the required data syntax by the printing device (including EPC/RFID encoders) and configured in accordance with the requirements outlined in the GS1 Symbol Specification Tables and defined by the GS1 Application Standards, for the intended scan environment and application.

Often a difficult area for the production of GS1 barcodes, is the programming of the Function 1 symbol character (FNC1), as each software supplier has (or has not) developed its own method to obtain the correct encoding in the form of codeword 232. It is worth ensuring any software deployed has this feature. The exact choice of software will need to meet the individual business requirements.

For EPC/RFID tags, production software must be capable of conforming to the [GS1 EPC Tag Data Standards](#) and the [EPC UHF Gen2 Air Interface Protocol Standard](#).

## 6.3 Reading and Decoding

Once a barcode symbol is printed (or an EPC/RFID tag is encoded), a reading or scanning device is required to capture the encoded data. The word 'scanning' is normally used to cover two separate processes:

1. The scan: the actual reading of the dark and light areas for barcode symbols; or extraction of the tag content for an EPC/RFID tag
2. The decode: the process of converting barcode symbols or EPC binary string into their equivalent GS1 element strings. Once decoded, the data will be passed to an information system for further processing.

GS1 DataMatrix symbols require scanners that can read in 2-dimensions. Typically, this requires camera or imaging technology, which are also capable of reading EAN-13 and GS1-128 linear barcodes. However, it's worth noting this is a different technology than what is used by laser scanners which can only read linear barcodes.

Scanners can be programmed to recognise a GS1 barcode symbol, due to its decoding system and each symbol's unique start patterns (e.g., for GS1 DataMatrix symbols, the symbol finder pattern and leading FNC1). This is a key security feature which enables the scanner to distinguish between data encoded according to GS1 Standards and any other type of data. This offers system protection and allows GS1 data strings (i.e., GS1 Application Identifiers and the following data) to be correctly interpreted.

The scanner does not normally contain any intelligence but simply transfers the string of characters read from the symbol to the information system for further processing, as determined by individual business requirements.

For EPC/RFID tags, readers must be capable of conforming to the [GS1 EPC Tag Data Standards](#) and the [EPC UHF Gen2 Air Interface Protocol Standard](#).

## 6.4 Quality and Compliance

The primary function of any barcode or EPC/RFID tag, is to carry data from the point at which it is originated, to the point at which the data needs to be captured. Meaning, the accurate printing of barcodes is fundamental to successful scanning.

Therefore, barcode production must also include robust validation and verification practices to ensure quality and compliance checks of the encoded data and printed barcode are a standard part of the production process.

- **Validation** is an informal, preliminary check that reviews the barcode symbol type and the encoded data to ensure both the data carrier and the data structure found is valid and compliant to GS1 Standards for the intended application. Symbol placement and any other visible elements such as HRI are also checked.
- **Verification** measures the physical production quality of the barcode and the encoded data, by providing a grade to indicate the overall symbol quality. This enables a high level of confidence that the symbol will scan in an open environment within its intended area of application, as well as highlights any potential problems with the symbol through diagnostic information provided on verification reports.

As verification is the final, formal step to confirming full compliance to GS1 Standards, samples to be verified must be provided in their finished configuration only. It should be noted that some symbols that fail verification will still be readable by some barcode readers. However, it is important not to confuse scanning with verification. At best, scanning a symbol can be used as a “go/no-go” test of whether a symbol can be read by that particular scanner.

- **EPC/RFID tags** can only be validated (not verified) as it's only the data format of the tag content that is checked for compliance.