Automatic Identification Data Capture (AIDC)

Change Specification

DAPB0108 Amd 1/2022

April 2022

Improving lives with data and technology

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.

Date of publication: 14 April 2022

Contents

1 Overview

Standard number	DAPB0108
Title	Automatic Identification and Data Capture (AIDC)
Release	Amd 1/2022
Type	Information Standard
Definition	DAPB0108 is an information standard developed by GS1 UK and endorsed by NHS via NHS England and NHS Improvement sponsor and NHS Digital SRO. 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. 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: • Serialised Global Trade Item Number (SGTIN) which enables the identification of a specific instance of an item, providing additional granularity for traceability purposes. • 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 • Global Model Number (GMN) to address regulatory requirements[1] for medical devices used in the UK, including in vitro diagnostic medical devices • Radio Frequency Identification (RFID) added to GS1 Data Carriers • Updated information on GS1 Data Carriers, barcode production, barcode quality and compliance (excluding RFID) • Updated diagrams and references to GS1 Standards such as the GS1 Healthcare Global Trade Item Number (GTIN) Allocation Standard • All references to supporting links and guidance, glossary, appendices, governing bodies, and contract dates, updated • Sections updated and re-formatted to align to revised DSAS publication guidance for consistency

[1] 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

2 Helpdesk

2.1 Contact Information

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

Developer	
Organisation	GS1 UK
Email Address	healthcare@gs1uk.org
Phone number	Freephone 0808 178 8799 or 020 7092 3501 (available Mon-Fri 9am-5pm)

2.2 Useful Resources

GS1 UK – 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

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.

3 Guidance by User Group

3.1 Existing Users

Trusts that are already compliant to the original standard, ISB 0108, should review this Change Specification, alongside the Requirements Specification and Implementation Guidance, to ensure all updates are understood and have been implemented as specified.

3.2 New Users

New users looking to implement DAPB0108 AIDC, do not need to review this Change Specification. New users will only need to review and implement the standard based on the information in the Requirements Specification and Implementation Guidance.

4 Statement of all changes to the published Requirements Specification

This table provides a reference by section, from the previous standard, 'ISB 0108: Automatic Identification Data Capture (AIDC) for the NHS in England' to the updated sections of the Requirements Specification for 'DAPB0108: Automatic Identification Data Capture (AIDC)'.

Further details of significant changes are provided in the "Overview of Key Changes to Requirements Specification" section.

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5 Overview of Key Changes to Requirements Specification

The following sections have been amended to update requirement details and references throughout the uplifted 'DAPB0108: Automatic Identification Data Capture (AIDC)' information standard.

Content has been restructured to provide up-to-date usage information in alignment with GS1 Standards. These sections now include references to the GS1 General Specifications which offers further detail and clarity on each fundamental area of GS1 Standards which will enable full compliance to DAPB0108.

5.1 Supporting Information

5.2 Related Standards

Related Standards MUST be used and read alongside this document.

Reference[2]	Title (including links)
Release 21.0.1	GS1 General Specifications
Release 2.5.1	GS1 DataMatrix Guidelines
Release 10.0	GS1 Healthcare GTIN Allocation Rules
Release 3.0.1	GS1 GLN Allocation Rules Standard
Release 1.13	GS1 EPC Tag Data Standard
ISB 0149	NHS Number
DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems
DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems

5.3 Supporting Guidance

Supporting Guidance MAY be used and read alongside this document.

Reference[2]	Title (including links)
ISBT-128	ICCBBA technical standard for the identification, labelling and information processing of medical products of human origin
DCB1077	AIDC for Patient Identification
March 2021	GS1 UK Surgical Instrument Traceability Guidance
Release 2.1	GS1 Healthcare GLN Implementation Guideline
Release 1.1	GS1 Identification of Investigation Products in Clinical Trials Application Standard
Release 1.3	GS1 Logistics Label Guideline

[2] 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.

Reference[2]	Title (including links)
Release 1.0	GS1 Guidelines for the distribution and shipping of medical product of human origin (MHRO)
Release 2.1	GS1 EPC UHF Gen2 Air Interface Protocol Standard
Version 2.0.3	GS1 EPC Class-1 HF RFID Air Interface Protocol Standard

5.4 Requirements

5.4.1 Information Specification

Listed here are the Information Specification requirement items from the current version, DAPB0108, with a status noted as “changed” or “new”, alongside additional details of the amendments.

Where DAPB0108 items have been changed, these can be cross-referenced with the ISB 0108 items, listed further below.

#	DAPB0108 Requirements	Status	Details
General			
1.	DABP0108 SHOULD be used as a reference tool by the NHS when procuring, implementing, and using AIDC technologies such as barcode encoding software, scanners, and printers.	Changed	Previously ISB 0108 item 1
2.	GS1 General Specifications section headings and numbers have been provided throughout this document and MUST be referenced to meet compliance to each relevant section of DAPB0108.	New	
3.	DAPB0108 and GS1 Standards MUST NOT be used for the management and tracking of blood products or other biological medical product of human origin (MHRO) as this is addressed by the ICCBBA technical standard ISBT-128.	Changed	Previously ISB 0108 item 13
4.	Users MUST perform a clinical safety assessment when using this standard in a clinical setting, in accordance with the NHS Digital information standards DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems, and DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems, to identify and acceptably manage clinical safety risk associated with solution / system design, context of use and human factors.	Changed	Previously ISB 0108 item 19
GS1 Identification (prefix management and data requirements)			
5.	All members SHOULD manage their prefixes and allocate GTINs and GLNs through the dedicated GS1 UK member portal, MyNumberbank.	New	
6.	A GCP is unique to the member whom it is licenced to, therefore Trusts MUST notify GS1 UK of any legal status changes as a result of an acquisition, merger, partial purchase, split or “spin-off”, within one year of that change to facilitate a smooth transition.	Changed	Previously ISB 0108 item 7
7.	GS1 Identification Keys and attributes MUST adhere to the data formats shown in Section 7, in line with the “Application Standards” and “Application Identifier Definition” sections referenced in the GS1 General Specifications.	Changed	Previously ISB 0108 item 4
8.	If using 96-bit RFID tags, GS1 Identification Keys and attributes MUST also adhere to the data formats referenced in the “EPC Binary Coding Schemes” section of the GS1 EPC Tag Data Standard (TDS).	New	
9.	All data MUST be encoded with the GS1 Subset of ISO/IEC 646 (equivalent to ASCII table 256), as per the GS1 AI encodable character set 82 table, shown in Appendix 2. Space characters are invalid and MUST NOT be encoded.	New	

10.	GS1 Application Identifiers (AI) MUST be used when encoding GS1 Identification Keys and any supplementary attribute data to GS1 Data Carriers, as outlined in Section 7, in line with the “Application Identifier Definition” sections referenced in the GS1 General Specifications.	Changed	Previously ISB 0108 item 5
11.	GS1 Identification Keys MUST adhere to the usage and allocation rules outlined in Section 7, in line with the “Application Standards” sections referenced in the GS1 General Specifications, which also include the GS1 Healthcare GTIN Allocation Rules Standard and GLN Allocation Rules Standard.	Changed	Previously ISB 0108 item 4 and 11
12.	All data MUST adhere to the complete invalid pairs and mandatory pairs of element strings tables explained in Section 7, in line with the “Data Relationships” section referenced in the GS1 General Specifications.	New	
GS1 Data Carriers (barcode production and management)			
13.	GS1 barcodes MUST include all technical characteristics and requirements such as start sequence characters and quiet zones, as outlined in Section 8, in line with the “Data Carriers” sections referenced in the GS1 General Specifications (and the GS1 DataMatrix Guidelines if the GS1 DataMatrix is being adopted).	Changed	Previously ISB 0108 item 18
14.	If RFID is to be adopted, the GS1 EPC Tag Data Standards (TDS) MUST be referenced to meet compliance to DAPB0108. The full suite of GS1 Standards which complement the TDS such as the EPC/RFID Air Interface protocols SHOULD be referenced at GS1 RFID Standards homepage.	Changed	Previously ISB 0108 item 15
15.	When structuring data in concatenated barcodes, AIs with fixed length data content SHOULD be placed at the beginning and AIs with variable lengths SHOULD be placed at the end.	New	
16.	If more than one variable length or non-predefined length AI is placed in a single barcode, a Function 1 (FNC1) separator character MUST be used if followed by another element string. No FNC1 is needed at the end of the last data item in a string.	New	
17.	Symbol Placement MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules, such as for General Distribution or Logistics Labels, shown in the "Symbol Placement Guidelines" section referenced in the GS1 General Specifications.	New	
18.	Multiple Barcode Management MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules, including the rules applicable to regulated healthcare items that are required to be scanned at both retail pharmacy and non-retail pharmacy/bedside, shown in the "Multiple Barcode Management Practices" section referenced in the GS1 General Specifications.	New	
19.	The use of Human Readable Interpretation (HRI) MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules including guidance for use in healthcare, shown in the "Human Readable Interpretation (HRI) rules" section referenced in the GS1 General Specifications. Exceptions MAY occur only when local regulatory or legal requirements mandate otherwise.	New	

20.	When indicating an element string in the non-HRI text section of a barcode label, the data titles outlined for each GS1 Identification Key and attribute in Section 7 and referenced in the “GS1 Application Identifier Definitions” section of the GS1 General Specifications SHOULD be used.	New	
21.	To choose the correct GS1 Data Carrier for the required application, the “Application Standards” section of the GS1 General Specifications MUST be referenced.	Changed	Previously ISB 0108 item 14
22.	To ensure GS1 Data Carriers are able to function optimally and consistently in the required scan environment, the size and minimum quality specifications defined by the “GS1 Symbol Specifications Tables” section of the GS1 General Specifications MUST be adhered to.	New	
Data Carrier Quality and Compliance (validation and verification processes)			
23.	The accurate printing of barcodes is fundamental to successful scanning. Therefore, barcode production MUST include robust validation and verification practices as a standard part of the process.	New	
24.	Barcode validation is carried out on a soft copy barcode sample, which MAY be a photo, scan, or image file of the barcode label, wristband sample, or simply the barcode itself. Whatever the file type, soft copy samples MUST be a high-quality image, without blurring, pixilation, or any type of distortion. All barcode samples SHOULD pass validation before a physical sample is produced and sent in for verification.	New	
25.	Barcode verification MUST be carried out on a physical sample of the barcode label or wristband sample, in its final configuration. If any part of the barcode production process is altered, such as a change to the print technique or equipment, material/substrate type, or any re-design or re-configuration of the barcode label, a new physical sample SHOULD be re-submitted for verification.	New	
26.	If an RFID tag is also barcoded, the barcode validation and verification process MUST be followed, meaning a soft copy sample of the barcode SHOULD be submitted for validation first, ahead of sending any physical sample.	New	

Listed here are the Information Specification requirement items from the previous version, ISB 0108, with a status noted as “changed” or “deleted”, alongside additional details of the amendments.

Where ISB0108 items have been changed, these can be cross-referenced with the DAPB0108 items, listed above.

#	ISB 0108 Requirements	Status	Details
1.	NHS Trusts deploying and using Automatic Identification and Data Capture (AIDC) systems SHOULD do so in accordance with this “AIDC” Fundamental Standard.	Changed	Refer to DABP0108 item 1
~~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.~~	Deleted	No longer applicable

#	ISB 0108 Requirements	Status	Details
~~3.~~	~~When registering as a member with GS1, the NHS Trust SHOULD provide GS1 with their ORGANISATION CODE (CODE OF PROVIDER).~~	Deleted	No longer applicable
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.	Changed	Refer to DABP0108 item 7 and 11
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.	Changed	Refer to DABP0108 item 10
~~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).~~	Deleted	No longer applicable
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.	Changed	Refer to DABP0108 item 6
~~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.~~	Deleted	No longer applicable
~~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.~~	Deleted	No longer applicable

#	ISB 0108 Requirements	Status	Details
~~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.~~	Deleted	No longer applicable
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.	Changed	Refer to DABP0108 item 11
~~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. See Section 3.2.9 of this Specification for a description of GS1 Application Identifiers.~~	Deleted	No longer applicable
13.	This AIDC 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.	Changed	Refer to DABP0108 item 3
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 Fundamental Standard Specification at Section 4.	Changed	Refer to DABP0108 item 21
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.	Changed	Refer to DABP0108 item 14
~~16.~~	~~Production and verification of bar code data carriers SHOULD be conducted according to the instructions in Section 5 of this Specification.~~	Deleted	Updated and split
~~17.~~	~~Printing of bar code data carriers SHOULD be conducted according to instructions in Section 6 of this Specification.~~	Deleted	Updated and split
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).	Changed	Refer to DABP0108 item 13 and 14
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.	Changed	Refer to DABP0108 item 4

5.4.2 Conformance Criteria

As each MUST/MUST NOT requirement listed in the DAPB0108 Information Specification needs an equivalent Conformance Criterion to check compliance, the previous ISB 0108 list is no longer applicable. Amendments have been noted below.

#	ISB 0108 Conformance Criteria	Status
~~1~~	~~All NHS Trusts SHOULD have registered with GS1 and obtained a GS1 Unique Organisation Prefix by 1 February 2012.~~	Deleted
~~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.~~	Deleted
~~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.~~	Deleted
~~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.~~	Deleted
~~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.~~	Deleted
~~6~~	~~There are no clinical safety near misses or serious untoward incidents (SUIs) reported as a direct result of AIDC standards.~~	Deleted
~~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.~~	Deleted
~~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.~~	Deleted

#	DAPB0108 Conformance Criteria	Status
General		
2.	The GS1 General Specifications section headings and numbers have been referenced to meet compliance to DAPB0108.	New
3.	DAPB0108 and GS1 Standards have not been used to manage and track blood products or other biological medical products of human origin (MHRO), which is addressed by the ICCBBA technical standard ISBT-128.	New
4.	When using this standard in a clinical setting, users have performed a clinical safety assessment in accordance with the NHS Digital information standards DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems, and DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems.	New
GS1 Identification (prefix management and data requirements)		

#	DAPB0108 Conformance Criteria	Status
6.	In the event of any legal status changes as a result of an acquisition, merger, partial purchase, split or “spin-off”, the Trust has notified GS1 UK within one year of that change.	New
7.	GS1 Identification Keys and attributes adhere to the data formats shown in Section 7, in line with the “Application Standards” and “Application Identifier Definition” sections referenced in the GS1 General Specifications.	New
8.	If using 96-bit RFID tags, GS1 Identification Keys and attributes also adhere to the data formats referenced in the “EPC Binary Coding Schemes” section of the GS1 EPC Tag Data Standard (TDS).	New
9.	All data is encoded with the GS1 Subset of ISO/IEC 646 (equivalent to ASCII table 256), as per the GS1 AI encodable character set 82 table, shown in Appendix 2. Space characters are not encoded.	New
10.	GS1 Application Identifiers (AI) are used when encoding GS1 Identification Keys and any supplementary attribute data to GS1 Data Carriers, as outlined in Section 7, in line with the “Application Identifier Definition” sections referenced in the GS1 General Specifications.	New
11.	GS1 Identification Keys adhere to the usage and allocation rules outlined in Section 7, in line with the “Application Standards” sections referenced in the GS1 General Specifications, which also include the GS1 Healthcare GTIN Allocation Rules Standard and GLN Allocation Rules Standard.	New
12.	All data adheres to the complete invalid pairs and mandatory pairs of element strings tables explained in Section 7, in line with the “Data Relationships” section referenced in the GS1 General Specifications.	New
GS1 Data Carriers (barcode production and management)		
13.	GS1 barcodes include all technical characteristics and requirements such as start sequence characters and quiet zones, as outlined in Section 10, in line with the “Data Carriers” sections referenced in the GS1 General Specifications (and the GS1 DataMatrix Guidelines if the GS1 DataMatrix is being adopted).	New
14.	If RFID is to be adopted, the GS1 EPC Tag Data Standards (TDS) is referenced to meet compliance to DAPB0108.	New
16.	If more than one variable length or non-predefined length AI is placed in a single barcode, a Function 1 (FNC1) separator character is used if followed by another element string.	New
17.	Symbol Placement adheres to the guidance outlined in Section 8, in line with the complete set of application specific rules, such as for General Distribution or Logistics Labels, as shown in the "Symbol Placement Guidelines" section referenced in the GS1 General Specifications.	New
18.	The use of Multiple Barcodes adheres to the guidance outlined in Section 8, in line with the rules applicable to regulated healthcare items that are required to be scanned at both retail pharmacy and non-retail pharmacy/bedside, shown in the "Multiple Barcode Management Practices" section referenced in the GS1 General Specifications.	New
19.	The use of Human Readable Interpretation (HRI) adheres to the guidance outlined in Section 8, in line with the complete set of application specific rules including guidance for use in healthcare, shown in the "Human Readable Interpretation (HRI) rules" section referenced in the GS1 General Specifications.	New
21.	To choose the correct GS1 Data Carrier for the required application, "Application Standards" in section 2 of the GS1 General Specifications is referenced.	New

#	DAPB0108 Conformance Criteria	Status
22.	To ensure GS1 Data Carriers are able to function optimally and consistently in the required scan environment, the size and minimum quality specifications defined by “GS1 Symbol Specifications Tables” in section 5 of the GS1 General Specifications are adhered to.	New
Data Carrier Quality and Compliance (validation and verification processes)		
23.	Barcode production includes robust validation and verification practices as a standard part of the process, to ensure barcodes are printed accurately and scan successfully.	New
24.	Soft copy samples submitted for barcode validation are a high-quality image, without blurring, pixilation, or any type of distortion.	New
25.	Barcode verification is be carried out on a physical sample of the barcode label or wristband sample, in its final configuration.	New
26.	If an RFID tag is also barcoded, the barcode validation and verification process is followed.	New

5.5 GS1 Identification Standards

Previously titled ‘GS1 Code Numbering Standards’, this section includes new content, outlined below.

5.5.1 SGTIN – Serialised Global Trade Item Number

A serial number is an attribute of a Global Trade Item Number (GTIN) and is often referred to as a ‘serialised GTIN’ (SGTIN). It enables a specific instance of a trade item to be identified, providing an extra level of granularity for traceability purposes.

The SGTIN has been included in this update, as it is commonly used throughout the healthcare sector to record the use of specific surgical equipment or medical devices used for patient care and for maintenance purposes.

5.5.2 SRIN – Service Relation Instance Number

A Service Relation Instance Number (SRIN) is an attribute and optional extension of a Global Service Relation Number (GSRN). Where the GSRN identifies the service relationship between a provider, (e.g., caregiver), or a recipient (e.g., patient), the SRIN enables further identification of the service encounter, in relation to the service provider or recipient.

The SRIN has been included in this update, as it is defined for use on patient identity bands by the NHS Digital information standard DCB1077: AIDC for Patient Identification.

5.5.3 GMN – Global Model Number

The Global Model Number (GMN) is a GS1 Identification Key used to identify a product model or family, based on shared attributes as defined by industry or regulation.

Within the healthcare sector, the GMN supports the implementation of Basic UDI-DI[3] requirements for the regulatory database of medical devices, as required by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Medicines and Medical Devices Act (MMDA). The GMN has been included for informative purposes only as its unlikely that an NHS Trust will ever need to assign a GMN.

5.5.4 Data Relationships

GS1 Standards provides application neutral rules for mandatory and invalid combinations of element strings on the same physical entity.

As the healthcare sector requires more and more data to be captured quickly and accurately to deliver greater patient safety and clinical effectiveness, this section has been added to provide an overview on how GS1 identification and attribute data MUST and MUST NOT be used together.

[3] Basic Unique Device Identifier – Device Identifier (Basic UDI-DI), is the main key for medical device records in the UDI regulatory database

5.6 GS1 Data Carriers

The GS1 Data Carriers section, includes the changes outlined below.

5.6.1 Radio Frequency Identification (RFID)

Radio-Frequency Identification (RFID) is a type of automatic identification and data capture (AIDC) technology which uses radio waves to read and obtain information stored on an RFID tag.

In the previous standard ISB 0108, which was published in 2011, RFID was considered out of scope, pending the establishment and approval of a Clinical Safety Case for its use across the NHS in England. Over the years and prior to the update of the current standard to DABP0108, the use of RFID across the healthcare sector has become more widespread due to its ability to enable real-time tracking and management of items that move about.

As part of the Scan4Safety (S4S) programme, two demonstrator sites[4] across the NHS in England adopted RFID to improve visibility of assets such beds and medical devices. This enabled staff to access vital equipment wherever and whenever they were needed, whether for patient care or for maintenance purposes, ultimately providing greater patient safety and improving operational efficiency.

RFID has been included in this update as its benefits have been established through the S4S programme[5] and it has been concluded that its deployment is primarily for secondary uses and will therefore have no direct impact on Clinical Safety. Consequently, a Clinical Safety Case Report is not required.

5.6.2 Data Carrier Management

This section has been added to ensure data carriers are applied correctly and can serve their intended purpose. An overview of key guidelines and best practices have been included for the following topics:

- Symbol Placement Guidelines
- Multiple Barcode Management Practices
- Human Readable Interpretation Rules (HRI)

[4] The Scan4Safety (S4S) programme involved six NHS Trusts in England who were competitively chosen by the Department of Health and Social Care (DHSC) to implement GS1 Standards and demonstrate the adoption journey and key benefits.

[5] Following completion of the S4S programme, a report on the accumulated data and insights has been published at https://healthcare.gs1uk.org/scan4safety/

5.7 Barcode Production

This section restructures two sections previously titled ‘Barcode Production and Verification’ and ‘Barcode Printing’, with the changes outlined below.

5.7.1 Choosing the Right Data Carrier

This section remains a crucial part of the Barcode Production topic, however, has been revised to provide more clarity on how to choose the correct data carrier based on the intended use or scan environment, using GS1 Application Standards.

5.7.2 GS1 Application Standards

GS1 Application Standards define a set of requirements and options that enables users to select and produce the most appropriate GS1 Data Carrier for their requirements.

It has been included in this update to explain what a GS1 Application Standard is and to provide an overview of the type of information included, that helps users to choose and produce a GS1 Data Carrier to the correct specifications, for the intended purpose.

5.7.3 GS1 Symbol Specification Tables

GS1 Symbol Specification Tables define the size allowances and minimum quality requirements of GS1 Data Carriers in respect to the intended area of use. Compliance to these specifications enables the symbols to function effectively and consistently within their required scan environment and to global standards.

GS1 Symbol Specification Tables has been included in this update to explain the key physical parameters required to meet compliance to GS1 Standards.

5.7.4 Barcode Printing and Symbol Marking Techniques

This section has been revised to clarify that information has been provided for informative purposes only and is not part of the specification defined by GS1 Standards.

An additional two subsections describing common symbol marking techniques used by NHS Trusts have also been added, with changes also reflected in the updated substrate and marking technologies table:

- Thermal transfer
- Inkjet

5.8 Data Carrier Quality and Compliance

This section restructures two sections previously titled ‘Barcode Production and Verification’ and ‘Barcode Printing’, with the changes outlined below.

5.8.1 Barcode Validation

Barcode Validation is a preliminary review of a barcode image or label, which checks that the correct the barcode symbol type is being used and that the data encoded to it is valid and contains all the required data, including the correct format, for the intended application.

This new section has been added to explain that the validation process precedes the formal verification which provides an overall symbol quality grade of a finished physical sample.

5.8.2 Barcode Verification

This section has been revised to provide more clarity on what the Barcode Verification process involves.

Two new subsections (listed below) have been added, to provide an explanation of the physical print parameters that are graded as well as the GS1 symbol size specifications that are required to meet compliance to GS1 Standards.

- Print Parameters
- GS1 Specifications

5.8.3 RFID tag validation

As RFID has been added to this update of the current standard to DABP0108, this new section has been included to provide information on how RFID tag quality and compliance is checked and what is required to meet compliance to GS1 Standards.

5.8.4 Validation and Verification Support for NHS Trusts

This section has been added as validation and verification support is available to all NHS Trusts in England as part of the renewed membership contract with GS1 UK.

6 Statement of all changes to the published Implementation Guidance

The Implementation Guidance for ‘DAPB0108 Automatic Identification Data Capture (AIDC)’ is a new document, published to support implementation of the updated standard, therefore there are no changes to the document.