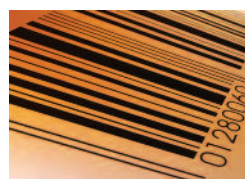




# Barcoding for medical equipment supplied to the NHS and to healthcare equipment resellers

A guidance document for BHTA members



## 2

## Preface

With the desire of the NHS to bring in GS1 standards as quickly as possible across a number of arenas, which started with patient identification, and now include unique device identifiers, it is important that manufacturers and suppliers to the NHS and Local Government are able to respond to the new tender requirements and are able to supply goods with GS1 barcodes attached. Shortly revisions to the Medical Devices Directive will be stepping up the requirements for track and trace processes. Legislation is coming down the line over the next few years across the world for barcoded unique device identifiers and track and trace data.

To assist BHTA members to react to these changing market needs, BHTA and GS1 formed a Working Group to put together a set of Guidelines to help get started with barcoding their equipment. Companies which have introduced barcoding to meet customer requirements have found substantial internal payoffs from improved stock control, faster stocktake, etc. Their customers throughout the supply chain are able to reduce costs significantly and improve efficiency as well.

The volunteers for the Working Group came from across the range of BHTA sectors, from companies large and small, from manufacturers and distributors. The Group was led by Julian Cobbledick (Assistive Partner), Alison Holland (Gordon Ellis), and Barend ter Haar (BES Rehab). The Group had input from representatives from CR Bard, Bartrams, Invacare, Karma Mobility, Mangar, Millbrook, Otto Bock, Patterson Medical, Roma Medical, Scanmobility, Teasdale, Uniscan Walkers. GS1 input was provided by Roger Lamb, Neil Piper, and David Weatherby.

**“Barcoding is an important issue that every company within our industry needs to consider now in line with NHS terms and conditions from 2013. This document provides a comprehensive overview for businesses in a straight-forward, easy to digest format.**

**My sincere thanks to the Working Group for pulling together this timely guide.”**



**Ray Hodgkinson MBE**

Director General BHTA

P.S. The new eProcurement rules for the NHS Mandate the use of barcodes – see

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/344574/NHS\\_eProcurement\\_Strategy.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/344574/NHS_eProcurement_Strategy.pdf)

# Contents

<b>1</b>	<b>Introductory Overview</b>	<b>4</b>			
1.1	The National and International picture	4	3.1.3	Positioning barcodes on packaging and products	14
1.2	Recent UK and International announcements and developments	5	3.2	Software	16
1.2.1	June 10 2011 Simon Burns, Minister of State for Health	5	3.3	Label printers	16
1.2.2	Extracts from 'Raising Our Game' May 2012	5	3.4	Barcode Reader/Scanner	17
1.2.3	US FDA Rule July 2012	6	3.5	Data Carrier print/mark quality	17
1.2.4	In mainland Europe and elsewhere in the world	7	3.6	Number of Marks	18
<b>2</b>	<b>The basics of barcoding – guidance</b>	<b>8</b>	<b>4</b>	<b>Modular items (Kits)</b>	<b>19</b>
2.1	The Unique Device Identifier: the GTIN (Global Trade Item Number)	8	4.1	Non-assembled	19
2.1.1	What data do I need to identify items uniquely?	8	4.2	Aggregated components	19
2.1.2	The anatomy of a GTIN-13	8	<b>5</b>	<b>Customer Specific Articles (Configured Products)</b>	<b>20</b>
2.1.3	Different GTINs for different packaging	8	<b>6</b>	<b>Additional GS1 data</b>	<b>21</b>
2.1.4	Keeping GTINs unique	9	6.1	Location coding for logistics and distribution	21
2.1.5	Informing Customers about my GS1 GTINs and background data	9	<b>7</b>	<b>Barcode reading capabilities within the NHS and loan stores</b>	<b>22</b>
2.1.6	How do I get a GTIN?	9	<b>8</b>	<b>Recommended steps for implementing barcoding of products</b>	<b>22</b>
2.2	Barcode symbology	10	<b>9</b>	<b>Bibliography</b>	<b>23</b>
2.2.1	Barcodes – what do they do?	10	<b>10</b>	<b>Frequently Asked Questions (FAQs) – in no particular order</b>	<b>23</b>
2.2.2	Types of 'data carrier' (barcodes)	10	<b>Appendix A: Joining GS1</b>	<b>25</b>	
2.3	Format/Sequence of encoding different types of GS1 Data	10	<b>Appendix B: Label testing standards</b>	<b>25</b>	
2.3.1	Application Indicators (AIs)	10	B.1	FINAT	25
2.3.2	Batch Number	11	B.2	North American Standards	25
2.3.3	Serial Number	11	<b>Appendix C: GMDN Nomenclature</b>	<b>26</b>	
2.3.4	Expiration Date	11	<b>Appendix D: Case Studies</b>	<b>27</b>	
<b>3</b>	<b>Printing barcodes</b>	<b>12</b>	1.	Barcoding Healthcare Equipment for use in the community	27
3.1	Label design	12	<b>Appendix E: Glossary of Terms</b>	<b>28</b>	
3.1.1	Barcode orientation	12			
3.1.2	A word about Verification of Readability	14			

## 1. Introductory Overview

During 2013 Class 2&3 equipment and items supplied into the NHS and reseller supply chain required a unique barcode to be applied to the items and their packaging, to enable track and trace of the items through the healthcare supply chains. There is a need therefore for manufacturers and suppliers to get the systems into place in time to meet these new requirements. The aim of this document is to provide manufacturers with the basics to get started – a Dummy’s Guide in effect. Employing barcode technology, and the associated database management, also has major financial benefits for manufacturers and their entire supply chain, in controlling and managing stocks of parts and final products. The journey to this point has come both from UK based initiatives (see 1.2 below), as well as from overseas.

For supply into the NHS the requirement is to use the globally recognised standard for uniqueness provided by GS1 – a worldwide based not-for-profit association. The basic principle is that every unique item is assigned a unique device identifier (UDI) called a GTIN (or Global Trade Item Number) within the GS1 system. The item is identified by a barcode printed on its packaging (and, where feasible, indelibly marked on the product itself). The barcode contains the GTIN information which identifies the item: other sections of the barcode can also contain other specific information (such as date of manufacture or serial number).

The NHS has produced a very valuable, and readable, document ISB 0108 *Automatic Identification Data Capture (AIDC) for the NHS in England*, released 31/5/12 and downloadable from [www.isb.nhs.uk](http://www.isb.nhs.uk). There is significant

commonality between that document and this Guide, although this Guide concentrates more on the needs of **suppliers** to the NHS.

### 1.1 The National and International picture

The new NHS Supply Chain Terms and Conditions, took effect from January 2013, and the NHS Terms and Conditions changes in 2014, both include requirements for Medical Devices sold under these agreements to include barcode labelled information carrying the minimum of the GTIN, the date of manufacture and/or use by date, and a batch or serial number.

As can be seen from the abstracts below, the expectation from the NHS is that standardisation of coding will help Trusts to check that they are paying a standardised price for the items they are procuring. However, from the Patient Safety point of view, the current review of the Medical Devices Directive is placing a requirement to be able to track Medical Devices to their point of use, and trace back from the point of use to the sources of the materials used in the construction of the medical device. A further development has been the addition of Match into Track, Trace, and Match, where the patient is matched or identified to the Device. The first steps are in place with current requirements that all hospital patients are tagged with a barcoded wristband which uses a GS1 code carried via a 2D GS1 DataMatrix symbol (details can be found in ISB 1077 – [www.isb.nhs.uk](http://www.isb.nhs.uk)). A further benefit of capturing the Track and Trace information is to help protect against counterfeit products.



Most NHS hospitals have already successfully implemented GS1 standards including: Sherwood Forest Hospitals NHS Foundation Trust, Airedale NHS Trust, Birmingham Children's Hospital NHS Foundation Trust, and Leeds Teaching Hospitals NHS Trust (Bar coding and RFID).

In the USA the FDA is enforcing legislation which Congress passed in 2007 directing the FDA to develop regulations establishing a unique device identification system for medical devices. This has a programme which requires barcoding of track and trace data being required in 2013 for Class 3 devices and some Class 1 devices, 2015 for Class 2 devices, and 2017 for most Class 1 devices (see 1.2.3).

In France the use of GS1 standards for Medical devices was already implemented in 2011. Across the EU full implementation by 2016 is currently scheduled.

## 1.2 Recent UK and International announcements and developments

### 1.2.1 June 10th 2011 Simon Burns, Minister of State for Health

"The use of a single barcode system across the retail sector is what makes supermarket price comparison websites, which help shoppers save money on their groceries, possible.

The NHS cannot afford to continue paying different prices for the same products. By simply using barcodes, NHS procurement will become more efficient as organisations can see how much they are paying for products compared with others. It's a simple idea that could save the NHS millions.

- Most importantly this is a vital opportunity to save money for reinvestment in front-line care at a time when the NHS needs to make efficiency savings.
- The NHS has enormous buying power if it works consistently and GS1 barcoding is a key foundation block to improve it.
- It also has great potential to improve patient safety. Barcoding systems have been shown to reduce medication errors, the risk of wrong-site surgery and the effective tracking and tracing of surgical instruments, equipment and other devices to improve record keeping and reduce error, malfunction and contamination.
- The expectation is that all products should be identifiable by or carry GS1 barcodes by the end of 2012"

### 1.2.2 Extracts from 'Raising Our Game' May 2012

In 2011 the National Audit Office and the subsequent Public Accounts Committee made a number of recommendations to improve NHS procurement. They identified:

- A requirement for Trusts and suppliers to adopt standard bar-coding (GS1), to improve procurement data and enable price comparisons whilst improving stock control and patient safety
- A need for Trusts to make greater use of e-commerce systems to improve management information

Underpinning e-procurement technology is the need for standard coding. Ministers have already stated that we are committed to GS1 as our preferred supply chain standard and the Department is working with industry sectors to

## 6

urge them to adopt the standard. However, Trusts need to ensure they make full use of the coding system by investing in technology such as bar-code readers and insist it is used by all suppliers. A reference guide to support Trusts with this action can be accessed at <http://healthcare.gs1uk.org/>

Trust Chief Executives would like to see price and product comparison systems that allow them to benchmark prices and performance, but they are not sure where to invest. Trust Boards can easily play their part by working with GS1 to introduce standard coding of all products, making price comparison easier.

**Action: Trusts should include the requirement for suppliers to provide GS1 GTINs (Global Trade Item Numbers) and associated data as an integral part of any procurement process. In addition Trusts should make it clear to their suppliers that provision of GS1 data will be evaluated positively in any competitive situation and over time provision of the data will become a mandatory requirement**

During 2012, DH created a dashboard of indicators and measures to help Trust Boards strengthen their accountability for procurement and to ensure the ability to report publicly.

In June 2014 DH published an eProcurement guide that has **mandated** the use of GS1 barcodes by **every** supplier to the NHS.

### 1.2.3 US FDA Rule July 2012

On 3rd July 2012 the U.S. Food and Drug Administration proposed: “that most medical devices distributed in the United States carry a unique device identifier, or UDI. A UDI system has the potential to improve the quality of information in medical device adverse events reports, which will help identify product problems more quickly, better target recalls, and improve patient safety. US FDA have worked closely with industry, the clinical community and patient and consumer groups and conducted four pilot studies in the development of this proposed rule.

“The safety of medical devices is a top priority for the FDA, Congress, industry, and patients“ said FDA Commissioner Margaret A. Hamburg, M.D. “The unique identification system will enhance the flow of information about medical devices, especially adverse events and, as a result, will advance our ability to improve patient safety.”

**With certain exceptions, under the proposed rule, a UDI would include: a device identifier, which is a unique numeric or alphanumeric code specific to a device model; and a production identifier, which includes the current production information for a device.**

US FDA are proposing a risk-based, phased-in approach to implementation, focusing on the highest risk medical devices first and exempting only low-risk devices from some or all of the requirements. US FDA is also proposing to exempt over-the-counter devices sold at retail as these devices generally have Universal Product Codes in place.

A UDI is a unique numeric or alphanumeric code that acts as a key to certain basic identifying information about a device, such as the name of the manufacturer and the type of

device, and may represent certain other information about the device, such as its expiration date and batch or lot number. This information will be contained in a publicly available UDI database, and no identifying patient information will be stored in this device information center.

The proposed rule reflects the considerable input we received from the medical device industry, the clinical community, patients and consumers, and industry experts. To minimize industry costs and expedite implementation, the proposed rule builds upon current standards and systems already in use by some companies. A UDI system can provide multiple benefits, including:

- Allow more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Provide a consistent way to enter information about devices in electronic health records and clinical information systems.
- Provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.”

*For more information, please see:*

*<http://www.fda.gov/UDI> and for the full consultation document*

*[www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001](http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001) which raises important points for consideration*

#### **1.2.4 In mainland Europe and elsewhere in the world**

The current Revision of the Medical Devices Directives in Europe will include a ‘traceability’ requirement, meaning devices will have to carry a unique identifier. Following the PIP (breast implant) scandal, there have been urgent calls for the traceability aspect of the legislation to be brought forward prior to the implementation of the Revision. This legislation will be aligned with that of the United States as part of an initiative to set up a global system for UDI.

UDI programmes are underway in other major markets around the world and will be based on internationally accepted standards which will eventually become a global requirement for devices. To that end, industry must be ready to harness the benefits of UDI, both in terms of supply chain management and patient safety.

**Important Note:**  
**GS1 barcodes satisfy UK, USA, EU and Australian regulations.**

## 8 2 The basics of barcoding – guidance

(It is normal practice to give a product an identifying name or number. The process of barcoding is simply to make the name or number machine readable).

### 2.1 The Unique Device Identifier: the GTIN (Global Trade Item Number)

#### 2.1.1 What data do I need to identify items uniquely?

Unique identification provides an opportunity to differentiate, in a machine readable form, any given item. Such information is rapidly becoming a pre-requisite, when the item's unique reference linked with a batch number (or unique serial number) and expiration date, whereby traceability of all healthcare products from production to delivery to the patient (point of care) is achievable.

Every product you supply should be assigned a 'GTIN'. The purpose of the Global Trade Item Number™ (GTIN™) is to be a unique reference for an item. The GTIN does not need to replace any name or product number you use for the item, but is assigned as a standardised 'cross reference' for use on bar codes.

The GTIN is used for the unique identification of trade items worldwide. GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.

#### 2.1.2 The anatomy of a GTIN-13

The GTIN is made up of three components, the GS1 Company Prefix, the Item Reference, and a Check Digit.

##### GS1 Company Prefix

The GS1 Company Prefix consists of five to

eleven digits depending on the capacity needs of the company.

The first two or three digits constitute the GS1 Prefix allocated by the GS1 Global Office to each GS1 Member Organisation. It does not mean that the item is produced or distributed in the country to which the prefix has been allocated. The GS1 Company Number that follows the GS1 Prefix is allocated by the Member Organisation.

##### Item Reference

The Item Reference is a component of the Global Trade Item Number (GTIN). The unique GTIN is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information. The simplest way to allocate Item References is sequentially, e.g. 0001, 0001, 0002, 0003, etc. The length of the item reference varies according to the length of the company prefix. This will be provided to you within the guidance issued at the point of joining GS1.

##### Check Digit

The Check Digit is the last digit. It is a digit calculated from all the other digits in the GTIN, and is a means by which database software can check that the other digits have been entered correctly, and not transposed, for example.

#### 2.1.3 Different GTINs for different packaging

The unique reference will be an identifier of the product in its specific packaged state. If the product is supplied in different packaged states, it should have a GTIN for each packaging level.

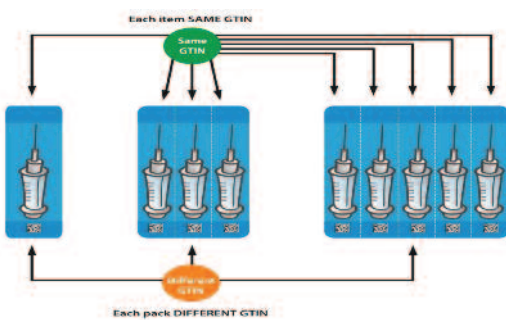


For instance, ACME Products Ltd catalogues a unique item ‘Box of 20 Sticking Plasters’. It is supplied to small retailers as **Single pack of 20 sticking plasters**, and supplied to national pharmacies as **Box of 50 Single packs of 20 sticking plasters**.

Each pack contains numbers of the same individual item. However the GTIN will be different for each of the two packaging levels.

It is essential that each different packaging level (e.g. Unit of Use, Shipper, Case, etc) be assigned a different Global Trade Item Number (GTIN). The example below shows otherwise identical pre-filled syringes in packs of one, three, and five.

The GTIN for each individual item is the same independent of any higher packing levels or use as part of a larger Healthcare Kit. Each grouping (the pack of one, three and five below) requires a separate GTIN.



### 2.1.4 Keeping GTINs unique

Integrity of GTINs throughout the item’s lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies, and other supply chain stakeholders. A change to one aspect, characteristic, variant, or formulation of a trade item will require the allocation of a new GTIN.

Brand Owners who hold the specifications of a healthcare item must allocate and maintain properly their GTINs to enable trading partners to distinguish products effectively for regulatory, supply chain and patient safety concerns. See Healthcare GTIN Allocation Rules at [http://www.gs1.org/docs/gsm/healthcare/GS1\\_Healthcare\\_GTIN\\_Allocation\\_Rules.pdf](http://www.gs1.org/docs/gsm/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)

### 2.1.5 Informing Customers about my GS1 GTINs and background data

A number of actions are vital to ensure that GTINs are accurately communicated within the Supply Chain.

When a new GTIN is assigned to a trade item, it is essential that the Brand Owner provide the detailed information to trading partners about the item’s characteristics. It is essential that the information associated with a GTIN is accurate and communicated in a timely manner. This is particularly essential for items scanned in Healthcare Supply Chains where the absence of accurate data may have safety, product availability, and/or regulatory conformance implications.

Organisations can lodge their GTINs with independent databases such as GS1’s TrueSource database or the BHTA healthcare specific equivalent [www.healthhubcodebank.org](http://www.healthhubcodebank.org) (which will ensure uniqueness and integrity of the GTIN Allocation rules have been applied). This may involve fees.

### 2.1.6 How do I get a GTIN?

To be able to allocate GS1 GTINs, an organisation needs to join GS1 as a member (See Appendix A). This entails a joining fee and an annual subscription. Upon joining, GS1 Member Organisations receive a GS1 Company Prefix and full documentation on how to allocate GTINs to their product.

## 2.2 Barcode symbology

### 2.2.1 Barcodes – what do they do?

On traded products, the barcode's primary purpose is to identify the product to which it is attached.

The familiar pattern of the barcode symbol can also contain a great deal of other information about date of manufacture, use-by date, serial number, pack quantity, amongst others.

The information is translated into a barcode symbol by computer software and printed on a printer that can print the barcode font.

The information carried in the barcode symbol is read back by a scanner and passed to a computer software database for interpretation. The computer program can then use the information for whatever purpose is required (e.g. inventory systems, track and trace, stock control, location and recall, order/invoice).

### 2.2.2 Types of 'data carrier' (barcodes)

A data carrier is a means of storing data in a machine readable form, such as in a barcode. There are many types of barcodes, however GS1 standard barcodes have now been adopted for use in the NHS. GS1 standard barcodes are also predominantly used at retail points of sale. The GS1 DataMatrix barcode is a GS1 implementation specification for the use of the Data Matrix bar code. Similarly the GS1-128 bar code is a special form of the generic Code 128 bar code.

Choosing an appropriate barcode symbol will largely depend on factors such as inner and outer level of packaging used for the item, and the extent of information required about the product:

- Does the customer require a date of manufacture, or a Use-by date to be included in the barcode data?

- Does the product have a batch number and/or serial number?
- Is the product a single unit?
- Is the product one of a multipack that will be used or traded independently of other items in the multipack?

There are different types of data carrier. Linear (1- Dimensional) barcodes are widely used in the retail world. However, GS1 DataMatrix (2- Dimensional) barcodes are increasingly being used because they carry more data in a smaller space, and are a requirement already within the NHS for patient identity tags. Both types of data carriers can carry the same data.

## 2.3 Format/Sequence of encoding different types of GS1 Data

Each block or segment of GS1 data is encoded in a standardised way. Different types of data are identified by **Application Indicators (AIs)**. Special additional characters need to be inserted for symbology indicators, character sets, and data separators. Generally, fixed length data precede variable length data. Please consult GS1 UK or your Solution provider before encoding this data.

There are also recommendations for displaying Human Readable data on the label.

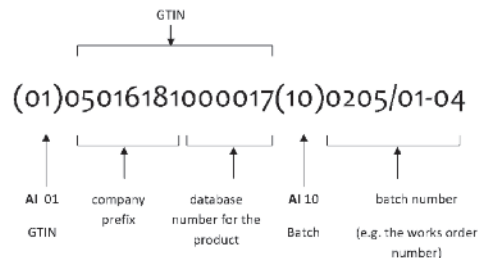
### 2.3.1 Application Indicators (AIs)

Key elements of AIs are:

- There are approximately 100.
- 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 a 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 barcode. When this happens, AIs with a fixed length data content are placed at the beginning and AIs with variable lengths are placed at the end. If more than one variable length AI is placed in one barcode, then a special “function” character is used to tell the scanner system when one ends and another one starts.
- When AIs appear in the text beside the barcode they are surrounded by brackets (e.g. 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



### 2.3.3 Serial Number

A Serial Number (Application Identifier (21)) is typically used on medical devices that are created as specific individual items (e.g. wheelchairs, pacemakers, MRI scanners).

### 2.3.4 Expiration Date

An Expiration Date (Application Identifier (17)) is often referred to as expiry date or maximum durability date and indicates the limit of consumption or use of a product (e.g. for pharmaceutical products it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). All dates are encoded as a fixed length six numeric character with the structure YYMMDD where:

- YY = the tens and units of the year (e.g. 2013 = 13).
- MM = the number of the month (e.g. January = 01).
- DD = the number of the day of the relevant month (e.g. second day = 02).

### 2.3.2 Batch Number

A Batch Number (Application Identifier (10)) is typically assigned at the point of manufacture using, for example, a production lot number, a shift number, a machine number, a time, or an internal production code. The data is alphanumeric and length is variable up to 20 characters (avoid using special characters such as “/” where possible).

*There are many GS1 publications available for download, and information and guidance on all aspects of barcoding is provided on the GS1 website*

*Guidance on GTIN numbering can be found in the GS1 publication ‘Bar Coding - Getting it Right’ - Number Allocation on p6, and Appendix 2 p39, downloadable from the GS1 website*

### 3 Printing barcodes

Barcodes can easily be printed onto adhesive labels, to be applied to the product packaging. This is a particularly convenient way to produce barcodes when information in the barcode is of a changing nature – for example batch numbers, date of manufacture, serial number, etc. Where only the GTIN is required it is feasible to have the barcode pre-printed onto the product packaging.

There is inevitably some expenditure involved in setting up software and printers to print your own barcodes. Alternatively many print firms will print labels to your specification.

#### 3.1 Label design

The first step is to consider the design of the label as it is important to take into account the organisation’s logo, product, and other printed information other than the barcode. Any change incurs cost, so it is important to get this right first time!

The design of the label will also influence the selection of any specialised consumables – adhesive materials, inks used, gloss finish etc, as will the required durability of the label – for example on items that will be cleaned or decontaminated on a frequent basis. Guidelines on labelling can be found in ISB 0108, and some relevant standards are listed in Appendix B.

As an alternative to labelling there is an option to use some form of direct part marking. A barcode is marked directly onto the surface of the device. The barcode to be used on devices might be a linear barcode, but for surgical instruments in NHS should be a 2-dimensional GS1 DataMatrix symbol.

There are different methods of marking devices including electrochemical marking, dot marking, dot peening, laser etching, and laser bonding. In all cases you need specialist marking equipment and so you may need to consult experts who understand the marking technology and data requirements.

#### 3.1.1 Barcode orientation

##### Linear barcodes

Linear barcode symbol orientation is often referred to as being ‘picket fence’, or ‘ladder’:



‘Picket fence’ orientation can be described by thinking of the bars on the symbol as a fence: the bars are parallel with the storage shelf or pallet



‘Ladder’ orientation is the opposite to picket fence: the bars of the symbol can be viewed as a ladder, perpendicular to the storage shelf or pallet

(Note: the printing process can affect clarity of barcode reproduction: better results will often be more consistently achieved if the bars of the symbol follow the printing run – see 3.5)

General principles for successful scanning <b>ORIENTATION</b>	Flat sided item	Curved item
The preferred placement is picket fence orientation	✓	✓
Where complete width of bars will not be visible, ladder orientation is acceptable		✓

- Maximum Error Correction – ECC200 can withstand typically up to 25% damage to the barcode 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 – shown on the left (note: a QR barcode of the type shown on the right with 3 squares in the corners contains marketing links to websites and is not a GS1 DataMatrix barcode):

For full information on label placement and orientation refer to the GS1 specification document ‘*GS1 General Specifications*’ Section 6: *Symbol Placement Guidelines*.

There are also specific guidelines for identifying and tracking cases and pallets. Full details can be found in the GS1 document ‘*Bar Coding – Getting it Right*’, specifically Section 8 (*pallet labels*).



Images courtesy of Wikipedia

**GS1 DataMatrix barcodes**

GS1 DataMatrix is increasingly the symbol of choice for many in healthcare due to its small size and resilience to damage.

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.)

Key features of GS1 DataMatrix are:

- A matrix barcode (2 Dimensional) based on ISO/IEC 16022:2006
- Omni directional scanning.

- 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.
- The quiet zone is one module width and is used as the quiet zone on all four sides: as with other barcodes do not print in this area.
- Can encode a maximum of 2335 alpha-numeric characters or 3116 numeric digits.

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.

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

### 3.1.2 A word about Verification of Readability

Barcodes are designed to make it possible to transfer information about a product accurately and efficiently. A barcode that is poorly printed, or does not conform to the GS1 standards regarding quality, light margins, bar heights, etc, may result in a non-scannable symbol.

Therefore, visual and technical verification of printed barcodes should be an essential part of your procedures, and it is recommended that you carry out some periodic 'verification' of your barcode labels. At the simplest level you should scan your printed barcodes to ensure they are readable. At this time, it is also recommended that you check that the barcode contains the information you expect.

There are verification software packages available. There are also specialists who will check your labels for you. If you out-source the printing of your labels your supplier should carry out verification for you.

Please refer to: GS1 'Bar Coding - Getting It Right', p25. GS1 'General Specifications'  
Note: GS1 UK offers a bar code label validation and verification service. See [www.gs1uk.org](http://www.gs1uk.org) for more information.

### 3.1.3 Positioning barcodes on packaging and products

All equipment and items supplied into the NHS, or any other supply chain, will require a durable barcode to be applied.

The barcode should be easily accessible for successful scanning, and easy to apply at point of manufacture.

For suppliers of products within the NHS, and also other organisations or customers, there are a number of important factors to be taken into

consideration when determining where the barcode should be affixed.

Durability of the product (and its identifying barcode):

- Is the product intended to be used once and thrown away?
  - Is there a decontamination process?
- Is the product intended to be used again
  - Will there be a decontamination process?
  - Will the product require refurbishment, with the likely replacement of worn parts?
- Packaging and shipping requirements:
  - Is the product packaged as a single item, or in a multi-pack requiring an outer packaging layer?
  - Is the surface where the label will be attached flat or curved?

For the GS1 standard specification, see the GS1 publication: '*General Specifications, Section 6.8 Placement Labels Used in General Distribution*'.

Further guidance can be found in GS1 '*Bar Coding - Getting It Right*', p22

#### Positioning on packaging

Best practice recommendations would have the symbol located in the same position on similar shaped products. This generally means toward the base, on the rear face of the product (but not on the base itself).

Ideally the symbol should be at least 5mm away from any packaging seams, folds, or the edge of the package. Wherever possible the symbol should be on a flat surface, or a consistently curved area. Cylindrical products can be a problem: however if the barcode is positioned vertically to the curve ('ladder' orientation, see above) this will aid a successful scan.

**Positioning on the product**

To facilitate handling, scanning and servicing in the warehouse and in the field, the following are recommendations for standardising barcode

positioning for products that are often to be found in loan stores and equipment resellers. (This is not a comprehensive list of medical devices.)

Equipment	Label Position
<p><b>Three/Four legged equipment e.g.:</b></p> <ul style="list-style-type: none"> <li>• Commodes</li> <li>• Walking Frames</li> <li>• Stools</li> <li>• Mobilators</li> <li>• Rollators</li> <li>• Wheelchairs</li> </ul>	<p>Middle of right hand rear leg, inside edge</p>
<p><b>Flat items e.g.:</b></p> <ul style="list-style-type: none"> <li>• Bath Boards</li> <li>• Transfer Boards</li> </ul>	<p>Bottom rear right</p>
<p><b>Cubic e.g.:</b></p> <ul style="list-style-type: none"> <li>• Raised Toilet Seats</li> <li>• Bed Pans</li> <li>• Commode Pots</li> </ul>	<p>Rear right</p>
<p><b>Beds:</b></p> <ul style="list-style-type: none"> <li>• Hydraulic or Electric</li> </ul>	<p>Right hand side foot end, underside of mattress carrier</p>
<p><b>Foam Filled Mattresses and Cushions:</b> (often with washable covers)</p> <ul style="list-style-type: none"> <li>• Foam Mattresses</li> <li>• Cushions</li> </ul>	<p>Consider: Indelible ink - write or print number onto fabric Iron-on labels as per laundry units Right hand side foot end underside of mattress Right hand side rear underside of cushion</p>
<p><b>Hoists/Stand-aids:</b></p> <ul style="list-style-type: none"> <li>• All hydraulic or electric hoists</li> <li>• Stand-aids</li> <li>• Suspended Hoists (Ceiling Track)</li> </ul>	<p>Lower right hand side of mobile main mast Motorised hoist unit</p>
<p><b>Pressure Care Mattresses:</b></p> <ul style="list-style-type: none"> <li>• Mattress &amp; pump unit</li> <li>• Pump unit</li> </ul>	<p>Right hand side foot end of underside of mattress Rear right of pump unit</p>
<p><b>Single legged Equipment e.g.:</b></p> <ul style="list-style-type: none"> <li>• Walking Sticks</li> <li>• Tripod Sticks</li> <li>• Crutches</li> </ul>	<p>Lower right side of main item (not on extender)</p>
<p><b>Soft Fabric Cover Items:</b></p> <ul style="list-style-type: none"> <li>• Cot Sides</li> <li>• Mattresses</li> <li>• Handling belts</li> <li>• Cushions</li> <li>• Slings</li> <li>• Slide Sheets</li> </ul>	<p>Fix label to manufacturer's label and consider swing tags. Consider: Indelible ink - write or print number onto fabric Iron on labels as per laundry units</p>

Equipment	Label Position
<b>Bath Lifters:</b> All types of actuator or bladder operated bath lifts	Right hand side rear of back rest, near the top
<b>Mattress Variators:</b> <ul style="list-style-type: none"> <li>• Mattress variators actuator or bladder operated</li> <li>• Pillow lifters electrical or manual</li> </ul>	Lower right hand side of base unit
<b>Rails e.g.:</b> <ul style="list-style-type: none"> <li>• Grab Rails</li> <li>• Mop Stick</li> </ul>	Individually packed – on the packaging Unpackaged – inner side Not labelled
<b>Specialist e.g.:</b> <ul style="list-style-type: none"> <li>• Suction Machines</li> </ul>	Alongside manufacturer's information
<b>Bed Rails e.g.:</b> <ul style="list-style-type: none"> <li>• Bed Sticks</li> <li>• Bed Rails</li> <li>• Side Rails</li> </ul>	Right hand side below handle Right hand side of elbow Inside base of side rail at rear on flat surface or on Right hand side of middle of rail
<b>Chair and Bed Raisers e.g.:</b> <ul style="list-style-type: none"> <li>• Langham Type</li> <li>• Morris Type</li> </ul>	Lower outer side of plinth Upper side of inner rail
<b>Miscellaneous e.g.:</b> <ul style="list-style-type: none"> <li>• Specials</li> <li>• Paediatric equipment</li> <li>• Bumpers</li> </ul>	Alongside the manufacturer's label or, if soft, fixed to it
<b>Small Items: (Variable Measure)</b> <ul style="list-style-type: none"> <li>• Cutlery</li> <li>• Wheels</li> <li>• Spare parts</li> <li>• Cups</li> <li>• Legs</li> </ul>	Fixed to external packaging or shelf

© Assistive Partner 2012

### 3.2 Software

You will need to select software to hold the information connected with the data in the barcode. The data will be held in a database and will be used to construct the print file (text, fonts, codes) to be sent to the printer to print the label. Also, to receive the encoded data back from a scanner when scanning takes place, the software will need to know how to store and interpret the

data. Software will also be required to format data which is to be sent electronically to customers. You can use [www.healthhubcodebank.org](http://www.healthhubcodebank.org)

### 3.3 Label printers

Selecting printing equipment which is suitable for your purpose is very important. There are a number of ways to print barcodes. This could



be as simple as onto paper labels via a laser bin printer or as complex as onto a dedicated thermal-transfer label printer with specialist inks, adhesives, and label materials (see Appendix B).

You should take professional advice and consider the following:

- What devices will scan the barcodes as the items move along the supply chain
- Is there a minimum definition (usually dots-per-inch) of print required
- Will the items be recycled or cleaned
- Are you fixing more than one label
- Will the label have a single code or should you consider printing linear and 2D GS1 DataMatrix codes
- Have you carried out preliminary tests before investing in a specific material, hardware, or process

### 3.4 Barcode Reader/Scanner

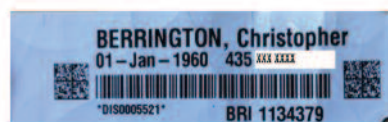
The type of barcode reader (scanner) to be used will affect many of your label and print decisions. Single linear barcodes can be read by laser scanners and by more modern imaging (photographic based) scanners. 2D GS1 DataMatrix barcodes will only work effectively using imaging scanners and cannot be read by laser scanners.

It is likely that many major barcode scanner manufacturers will phase out laser scanners and focus development on imaging scanners and on radio frequency scanners for radio emitting chips (known as RFID or Radio Frequency Identification Devices).

An eye to the future is important as is a clear understanding of your customers' current and future barcode reading capability or limitations. The BHTA working group considers that most customers will be preparing to read barcodes in the future and as such are likely to be using

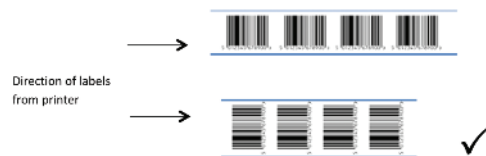
imaging scanners. For that reason (and because more data can be carried, and damaged labels can often still be read) the working group recommends 2D GS1 DataMatrix as the barcode label of choice (perhaps with a linear barcode printed alongside on the same label for a migration period).

For patient identification, the NHS requires the data are encapsulated in a 2D matrix barcode. However, additional linear barcodes and human readable material are allowed. For example:



### 3.5 Data Carrier print/mark quality

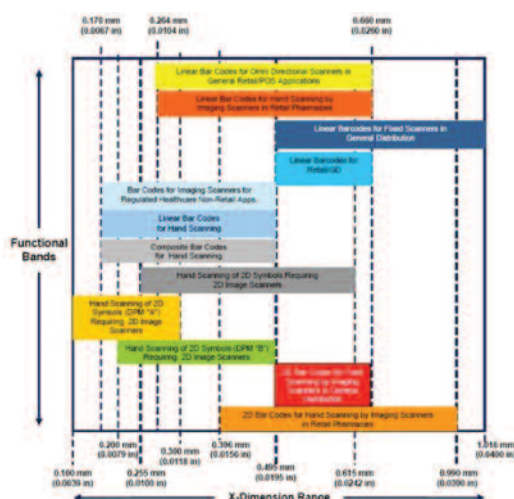
It is important to print barcoded labels to a standard that will enable the barcode to be successfully read at every stage of its distribution journey, and by a variety of scanning devices. The printing process can affect the clarity of barcodes, and in general better results will be more consistently achieved if the bars of the symbol follow the direction of the print run.



Similarly, the choice of substrate – label papers may have gloss, buff, or plain finishes – can affect the ‘spread’ of ink after printing, affecting the scanning quality of the symbol. Different printing techniques have different tolerances for printing accuracy so it is important to check what these are before choosing a particular size of barcode. The type of adhesive is important as the choice will be determined by the type of use or reuse within the supply chain.

The following tables from ISB 0108 give useful guidance:

Technology	Substrate				
	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
Inkjet (on-demand)	Yes	Yes	No	No	No
Direct Part Marking	Film transfer	Film transfer	No	Yes	Yes



Recommended reading: GS1 publication 'Bar Coding – Getting It Right', p44 and ISB 0108

### 3.6 Number of Marks

There must be only one GTIN represented on an item, and a minimum of one symbol visible on each item, either as a label or as a mark on the product itself.

A minimum of one barcode symbol is required by the GS1 standard, however it is generally recommended that for trade items two or more symbols representing the same GTIN are placed on opposite sides; this is particularly relevant for large or bulky items or where packaging may easily be damaged.

## 4 Modular items (Kits)

A modular item (or kit) is one where a fixed set of items are picked for shipment. No real assembly takes place – the components of the kit are typically picked and shipped in separate boxes, or alternatively picked and packed in one box for shipment.

### 4.1 Non-assembled

An example of the first scenario is a bed consisting of a mattress support (platform), a pair of bed ends, and a set of side rails. The customer orders this using a master part number, e.g. 'DELUXE\_BED' and when shipment takes place, three boxes are picked and shipped to the customer with a delivery note showing both the master part number the customer ordered, in addition to the components of the kit, for example:

Line	Part Number	Description	Quantity Shipped
1	DELUXE_BED	Acme Deluxe Bed (Kit)	
	Consisting of:		
	MATT_SUPP1	Deluxe Mattress Support	1
	BED_ENDS	Beds Ends	1
	SIDE_RAILS	Side Rails (Beech)	1

It may be possible for components of the kit to be individually ordered by the customer, for example a replacement set of side rails, therefore both the master part number and the component part numbers might have GTINs allocated. The question then arises as to how the cartons comprising the kit should be labelled. In this scenario it is suggested that the cartons each have a label with the GS1 barcode representing the GTIN of the kit component, and that the GTIN of the kit is shown on the delivery paperwork, ideally with an accompanying barcode.

### 4.2 Aggregated components

An alternative scenario is say, a seating system, where the components are picked and shipped in a single carton. Here it may be that the carton is labelled with a GS1 barcode representing the GTIN of the master part number.

The decisions for each organisation should be driven by what items require tracking and tracing, and for inventory management purposes. In most organisations, processes are already in place: the process of barcoding is simply to make the labels machine readable. It is recommended that all users in the supply chain are guided as to the best practice for recording movements of items.

## 5 Customer Specific Articles (Configured Products)

Some products, for example wheelchairs, have many possible variants (e.g. size, colour, type of wheels). This is often referred to as a configured product. Typically the customer will select the options they want and the product will be assembled or built to order. The particular variant of the product becomes a discrete end item in itself. GS1 refers to this scenario as a **Customer Specific Article**.

Generally, configured products are ordered by specifying a **base article** (such as a generic item, or a model number), and then selecting a series of **options** within a feature. For the manufacturer, processing the order will often utilise configurator software. For example, an order for a SUPER DELUXE wheelchair would invoke the configurator using the base article 'SUPER\_DELUXE'. The sales options for each feature would then be selected from lists. There might, for example, be three possible options for the seat style feature:

POSSIBLE VALUES for: Seat Style:	
Option No.	Description
BHT0004	Sling Seat (Seat To Ground Stand)
BHT0005	Reddell Cushion (Seat To Ground Stand)
BHT0006	Covered Canvas Seat (Fixed 15.75G. Stand)

At the conclusion of the configuration process, a product variant is created which will typically have some unique internal reference or serial number, perhaps containing, as in this example, the sales order number and line:

Variant Number	Description
IU20E134641001	Super Deluxe Power Chair

GS1 refers to this as the **physical item actually produced**.

The supplier needs to be able to identify the actual product produced for its own purposes, and the customer must be readily able to have the same identification information. Two practical solutions to this are presented below:

- A. The supplier may allocate a GTIN-13 to the base article. However, this will not normally be carried by a barcode on a physical article: it exists only for ordering purposes, for example when EDI is employed. Similarly, the supplier can identify options with a GTIN-13 but these should not appear as barcodes on the physical article.

For the physical article actually produced, it is not necessary to pre-allocate GTIN-13 IDs to every possible permutation of the product. Indeed, this will usually be impractical because of the very large number of possible permutations which could run into millions. Instead, GS1 recommends that each variant is assigned a unique GTIN-13 at the time the variant is created. This GTIN can appear on the product and/or its packaging using an appropriate data carrier, for example an EAN-13 barcode or a GS1-128 barcode. It is important to note, however, that the creation of GTINs 'on-demand' implies that the supplier is able to communicate newly created GTINs to the customer in a timely



manner (perhaps as part of the order acknowledgement process) so that the customer is able to use them effectively. In addition to being given a unique GTIN, the article may be allocated a unique serial number, as determined by the manufacturer. Serial numbers can be identified using GS1 Application Identifier (21) and presented using an appropriate data carrier such as a GS1-128 barcode.

and automatically assign it to all configured variants of this product. The GTIN does not of course fully identify the product sold, and it would therefore be absolutely necessary to include the serial number on the barcode if this approach is adopted. Serial numbers can be identified using GS1 Application Identifier (21) and presented using an appropriate data carrier such as a GS1-128 barcode.

B. A practical alternative would be to hold the GTIN at the level of the generic item (the SUPER DELUXE wheelchair in our example),

For further information on the treatment of Customer Specific Articles, refer to section 2.6.11 of GS1 General Specifications.

---

## 6 Additional GS1 data

### 6.1 Location coding for logistics and distribution

Centralised procurement feeding multiple facilities is currently commonplace. Problems arise with multiple delivery points within the facility and tracking of the items delivered. Multiple delivery points or a single goods inwards/warehouse which would 'read' the delivery allowing real-time tracking of purchase orders and location details would allow the accurate distribution within the facility.

Within the families of GS1 codes, there are codes for product locations, known as GLNs. Parts of the NHS require that suppliers apply separate GLN destination barcodes attached to the goods arriving at NHS sites. These codes can specify the location within in a hospital down to a bed in a ward, and could be accompanied by a patient identifier as well. BHTA companies may need to ensure that their labelling facilities are able to provide GLN coding in addition to the product identification described throughout this document.

## 7 Barcode reading capabilities within the NHS and loan stores

Currently NHS Supply Chain sends out goods with barcoded NPC codes: the 220 Trusts, which they supply, have between them at least 1200 linear barcode readers used in their central stores. NHS Supply Chain will in future require that all the items they procure will move to having GTINs and barcodes. (NHS has transition processes to move from NPC to GS1 coding.)

Thus we know that more than half the NHS has the facility to read linear barcodes in their central stores. (Alongside this, 2D GS1 Data Matrix readers must be in use to read the patient identifier tags.) It is also a fact that at least 40% of equipment loan stores presently use barcode readers. There is a mix of laser types and imager types, although almost all new scanners are imager type.

---

## 8 Recommended steps for implementing barcoding of products

- Join GS1 – (see Appendix A)
- Acquire prefix – this is part of the joining process
- Download and digest the documents listed in the Bibliography below
- Assign GTINs to your products and packaging levels
- Decide on your barcode type and the data contained in that
- The barcode detail may include required data, such as batch or serial number, but also additional data to support your business needs
- Decide the print process required, durability, and position of label etc
- Consider what devices will scan the barcodes as the items move along the supply chain
- Pass details regarding your GTINs throughout your supply chain
- Consider depositing data onto [www.healthhubcodebank.org](http://www.healthhubcodebank.org)

---

## 9 Bibliography

23

<http://www.fda.gov/UDI>: for the full FDA consultation document go to:  
[www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001](http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001)

ISB 0108 Automatic Identification Data Capture (AIDC) for the NHS in England, released 31/5/12 and downloadable from:  
[www.isb.nhs.uk/documents/isb-0108/amd-145-2010/01081452010spec.pdf](http://www.isb.nhs.uk/documents/isb-0108/amd-145-2010/01081452010spec.pdf)

ISB 1077 Automatic Identification and Data Capture (AIDC) for Patient Identification:  
[www.isb.nhs.uk/documents/isb-1077/amd-144-2010/10771442010spec.pdf](http://www.isb.nhs.uk/documents/isb-1077/amd-144-2010/10771442010spec.pdf)

<http://www.healthhubcodebank.org/>

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/344574/NHS\\_eProcurement\\_Strategy.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/344574/NHS_eProcurement_Strategy.pdf)

NHS procurement: Raising our game May 2012: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_134376](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_134376)

<http://healthcare.gs1uk.org/>

For GS1: [www.gs1uk.org](http://www.gs1uk.org) Note that the following documents, referenced in this Guide, can only be downloaded by members:

Bar Coding - Getting it Right; GS1 General Specifications; and GS1 DataMatrix Introduction and Technical Overview'.

---

## 10 Frequently Asked Questions (FAQs) – in no particular order

There are many more relevant downloadable guides for members from the GS1 website

**What data do I need to identify items uniquely in machine readable format?** A GTIN will identify an item uniquely, and to be machine readable needs to be in a barcode. See Section 2.1

**What do I do with modular items (kits)?**  
See Section 4

**How do I keep a record of my GTINs?** In a unique database. GS1 also hosts a number bank for recording GTINs, which prevents the allocation of a GTIN to more than one item, and automatically calculates the check digit.

**How do I get my company prefix?** Apply to GS1 – see Appendix A

**What is a GTIN?** See section 2.1.2

## 24

**What are the minimum data I have to include in the barcode?** For the NHS and the proposed revision of the MDD: GTIN, date of manufacture and/or expiry date, and a serial or batch number

**What type of barcode should I use?**  
See Sections 2.2.2 and 3.1.1

**What equipment do I need to create a barcode?** Hardware: computer, barcode printer, and barcode scanner; software; consumables such as labels for on-demand printing

**What is it going to cost?** Membership of GS1 (see Appendix A), hardware (barcode reader(s), printer), software, consumables (labels) – depends on size of operation and degree of sophistication/benefit required

**Why should I – what's the benefit?**  
See Section 1

**What do my customers require?** Barcode reader and software

**I don't have much label space: What is the smallest size code can I use?** See Section 3.5

**Which subcomponents do I have to barcode and how?** See Section 2.3, 4, and 5

**Which customers will be able to use these barcodes?** Currently over half the NHS Trusts and Local Authority equipment loan stores. The NHS is moving to the stage that all of our NHS customers will.

**For reuseable equipment how can I wash the item without damaging the barcode?**  
Ensure appropriate labelling is applied including direct marking – see Section 3.5 and Appendix B

**What are the timescales involved?** Already appearing now in tender documents, and coming out in increasing numbers of procurement T&Cs. Mandated during 2014.

**Where does GMDN fit in?** Being requested by NHS, but is out-with GS1 barcoding. See Appendix C

**Where does GS1 fit in?** The standardisation system selected by the DH and mandated in 2014. It is accepted in USA, EU and Australia.

**Do we still need human readable data on the packaging, and what needs to be visible?**  
For the time being all the data, ideally, and where feasible

**How do we get relevant data into the customer database?** The customer needs to have an appropriately configured database that can receive a configured csv file or similar. This can be provided by 'push through' offered by the supplier, or 'pull back' means, the latter accessed by the customer. Consider using [www.healthhubcodebank.org](http://www.healthhubcodebank.org)

**What track/trace data do I need to keep on my own database?** The means to identify all the materials involved in the manufacture of an item to establish which items need to be recalled due to failures etc, and the details of the customers to whom you have supplied the items from that batch.

**What choices of labelling are there for different materials?** This is an area where you should speak to a label manufacturer. See also table in Section 3.5

**What happens when the same product is sold in different pack quantities (multipacks)?** See section 2.1.3



## Appendix A: Joining GS1

25

To be able to allocate GS1 GTINs an organisation needs to join GS1 as a member. (In the UK go to: <http://www.gs1uk.org/Pages/join-gs1uk.aspx> ). This entails a joining fee and an annual subscription. Upon joining, GS1 Member Organisations receive a GS1 Company Prefix and full documentation on how to allocate GTINs to their product.

There's a one-off joining fee and an annual subscription charge which are outlined below at July 2012 rates. All fees shown are subject to VAT at the standard rate.

Turnover	Joining Fee	Annual Subscription Fee
up to £0.50m	£107	£117
£0.5m to £1m	£119	£129
£1m to £10m	£190	£200
£10m to £50m	£303	£313
£50m to £100m	£327	£1,051
£100m to £250m	£327	£1,386
£250m to £500m	£327	£1,749
£500m to £1bn	£327	£2,203
Over £1bn	£327	£2,602

## Appendix B: Label testing standards

### B.1 FINAT (Fédération Internationale des fabricants et transformateurs d'Adhésifs et Thermocollants sur papiers et autres supports)

FINAT, an international federation headquartered in the Netherlands, has published the FINAT TECHNICAL HANDBOOK – Test Methods 8th Edition, available for purchase at EUR45. This lists a range of test methods for testing the suitability of different aspects of label construction.

### B.2 North American Standards

**CSA (Canadian) C22.2 No 0.15-95 Adhesive Labels Standard**

#### ASTM D 1000:

Thickness  
Adhesion (stainless steel/painted enamel/textured ABS/Polypropylene/polyester powder coated paint)  
Dielectric strength

**ASTM D2979:** Tack

**ASTM G155:** Weatherability

**ASTM B117:** Salt fog resistance

#### Also:

High Service Temperature (up to 145C)

Low Service Temperature (-70C)

Humidity Resistance (30 days 37C 95% humidity)

UV Light Resistance (30 days)

#### Chemical tests (include effect on ink with and without rubbing):

Acetone/Toluene/Isopropyl Alcohol/

Ethanol/Xylene/Methyl ethyl ketone/White

Spirits/SP95 fuel/SP98 fuel/Diesel/Brake

Fluid/Skydrol/Deionised water/Degreaser/50%

Acetic acid/10% hydrochloric acid/

10% sodium hydroxide

**DIN VDE 0472 Part 815:** halogen free materials

## Appendix C: GMDN Nomenclature

The Department of Health is keen that manufacturers provide information of the GMDN codes for the items they provide to the NHS.

The Global Medical Device Nomenclature (GMDN) is a comprehensive system of internationally recognised coded descriptors in the format of preferred terms with definitions used to identify medical devices and related health care products generically.

The main purpose of the GMDN is to provide authorities, health care providers, medical device manufacturers and suppliers, conformity assessment bodies, and other affiliated parties with a single naming system that will support patient safety. The NHS has requested that manufacturers identify their products with GMDN codes.

Information in the form of a code is provided to indicate the generic descriptor within which the device can be identified, by reference to a globally accepted generic medical device nomenclature (the GMDN) so that other particular devices having substantially similar generic features, but coming from another source can be identified, for reasons of data exchange between competent authorities and others, exchange of post-market vigilance information, and inventory purposes.

GMDN codes are not part of the GS1 system of standards and are not included in the barcode symbology. They can be referenced from a database of codes which GMDN holds on behalf of members (see <http://gmdnagency.com/Default.aspx>). The codes for each device are known as a Preferred Terms (P). Uniquely, the GMDN uses Collective Terms (CT) to help users identify the correct P

Term, by a defined medical condition or area of interest.

Information in the form of a 5 digit numeric GMDN Code is cross-referenced to a precisely defined Preferred Term, with which all specific devices having substantially similar generic features, can be identified by type. This is important for reasons of data exchange between healthcare authorities, manufacturers and others, exchange of post-market vigilance information, inventory control, and purchasing.

# Appendix D: Case Studies

## 1. Barcoding Healthcare Equipment For Use In The Community

### Overview:

This example is of an organisation operating from a single warehouse, providing home delivery of healthcare equipment to residents of an English County with a total population of just under 500,000 people. The organisation invested in UNIQUUS® cloud based software from Assistive Partner around five years ago.

### Equipment part marking:

Every item which is likely to be returned, disinfected, and re-issued is marked with an individual ‘asset’ barcode, regardless of item value. Polyvinyl barcode labels are printed using indelible ink. They have proven to stick fast even in high temperature cleaning processes. Labels are fixed at the point of goods receipt from the OEV (Original Equipment Vendor).

### Process:

The organisation has to meet key performance targets for delivery performance. This can vary from four hours to seven days from order. Orders are placed on line by clinicians. Items are picked within the warehouse using wireless barcode scanners. Delivery and installation is carried out by a team of ten mobile technicians. These technicians use mobile barcode scanners which also have GPS tracking and satellite navigation. Customers sign for receipt on the scanner screen and the server is updated in real-time.

### Key objectives achieved:

- Reduced Operations and Administrative Cost
- Increased Inventory Accuracy
- Improved Patient and Customer Service Levels



- Easy to Implement and Use
- Contributed to Increased Profit Margins
- Achieved an Excellent Return on Investment (RoI)

### Key statistical detail:

- Reduced ‘administrative staff to technician’ ratio from 1:2.5 down to 1:5 (saving two headcount)
- Reduced warehouse inventory from >£300,000 to <£240,000
- Reduced incorrect warehouse pick to zero
- Increased technician productivity by 18%
- Achieved 99.9% accuracy of book to physical inventory at annual stock-take
- Achieved over 98% of all key delivery performance targets

### Notes for consideration:

UNIQUUS® is now used by over 12,000 users and 40 organizations in four countries on a 24/7 basis. In 2011 over 1 million inventory items and 400 field technicians were managed through UNIQUUS®. Typically, Assistive Partner clients using barcode scanning and other cloud-based mobile computing tools, achieve >97% inventory accuracy, 15-20% more deliveries, between 10 to 20% inventory reductions, and a 10 to 25% reduction in administrative costs. Competitive and margin pressures in today’s medical equipment market means there’s a need to find ways continually to “do more with less”.

## Appendix E: Glossary of Terms

This glossary provides definitions for the implementation of GS1 Standards.

### A

**AI** Abbreviation for Application Identifier

**AIDC** Abbreviation for Automatic Identification and Data Capture

**Alphanumeric (an)** Describes a character set that contains alphabetic characters (letters) and numeric digits (numbers)

**Application Identifier** The field of two, three, or four numbers at the beginning of an Element String that uniquely defines its format and meaning

**Attribute** A piece of information reflecting a characteristic related to an identification number (e.g. Global Trade Item Number™ (GTIN™),

### B

**Brand owner** The party that is responsible for allocating GS1 System numbering and barcode symbols on a given trade item. The administrator of a GS1 System Company Prefix

### C

**Check digit** A digit calculated from the other digits of an identifier such as a GTIN, used to check that the data has been correctly composed

**Company number** A component of the GS1 Company Prefix. GS1 Member Organisations assign GS1 Company Prefixes to entities that administer the allocation of GS1 System identification numbers. These entities may be, for example, commercial companies, not for profit organisations, governmental agencies,

and business units within organisations. Criteria to qualify for the assignment of a GS1 Company Prefix are set by the GS1 Member Organisations.

**Customer Specific Article** A product, or article, specifically configured from selections of different options

### D

**DH** The Department of Health

### E

**EAN International** EAN International is the former name of GS1

**EAN-13** This is the standard for consumer (retail point of sale), commonly used in the UK and Europe. This barcode translates a 13(or 14) digit EAN/UCC-13 GTIN into bars readable by standard barcode readers.

**EAN-13 Barcode Symbol** A barcode symbol of the EAN/UPC Symbology that encodes GTIN-13 Numbers

**EAN-8 Barcode Symbol** A barcode symbol of the EAN/UPC Symbology that encodes GTIN-8 Numbers

**EDI** Abbreviation for Electronic Data Interchange

**Electronic Message** A composition of Element Strings from scanned data and transaction information assembled for data validation and unambiguous processing in a user application

**Element String** A piece of data defined in structure and meaning, comprising a defining part (prefix or Application Identifier) and a data

part, represented in a GS1 System endorsed data carrier

## F

**Fixed Measure Trade Item** An item always produced in the same pre-defined version (e.g. type, size, weight, contents, design) that may be sold at any point in the supply chain

**Fixed length** Term used to describe a data field in an Element String with an established number of characters

## G

**GLN** Abbreviation for the Global Location Number

**GS1-128 Barcode Symbol** A subset of the Code 128 that is utilised exclusively for GS1 System data structures

**GS1 System** The specifications, standards, and guidelines administered by GS1

**GS1 check digit calculation** A GS1 System algorithm for the calculation of a Check Digit to verify accuracy of data decoded from a barcode symbol

**GS1 company prefix** Part of the international GS1 System data structures consisting of a GS1 Prefix and a Company Number, both of which are allocated by GS1

**GS1 member organisation** A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area) and for managing the correct use of the GS1 System by its member companies

**GS1-128** The GS1-128 barcode is a subset of the more general Code 128 Barcode 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 barcode was previously referred to as a EAN-128 or UCC/EAN-128 barcode. Characteristics of the GS1-128 symbology are:

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

**GS1 DataMatrix ECC200** This is a two dimensional barcode, made up of individual dots or squares. It can hold variable length data, and like conventional barcodes it will hold the GTIN and whatever other data is required for the distribution process

**GTIN™** Abbreviation for the Global Trade Item Number™

**GTIN-12 Data** The 12-digit GS1 System data structure composed of a UPC Company Prefix, Item Reference, and Check Digit

**GTIN-13 number** The GS1 System identification number comprising 13 digits; used to identify trade items

**GTIN-14 number** The GS1 System identification number comprising 14 digits; used to identify trade items

**GTIN-8 number** The GS1 System identification number comprising 8 digits; used to identify trade items and special applications

**Global Location Number** A number that the identifies physical, functional, or legal entities

**Global Trade Item Number™** A Global Trade Item Number™: may be 8, 12, 13, or 14 digits in length

## H

**Human Readable Field** Characters, such as letters and numbers, that can be read by persons, as opposed to symbol characters within barcode symbols, which are read by machines

## I

**Item Reference** The part of the data structure allocated by the user to identify a trade item for a given GS1 Company Prefix

## M

**Magnification** Different sizes of barcode symbols based on a nominal size and a fixed aspect ratio; stated as a per cent or decimal equivalent of a nominal size

## Q

**Quiet Zone** A clear space containing no machine readable marks, which precedes the Start Character of a barcode symbol and follows the Stop Character. Formerly referred to as 'Clear Area' or 'Light Margin'

**Quiet Zone Indicator** A greater than (>) or less than (<) character, printed in the human readable field of the barcode symbol, with the tip aligned with the outer edge of the Quiet Zone

## R

**Retail consumer trade item** The trade item intended to be sold to the end consumer at retail Point-of-Sale. These are identified with unique GTIN-8s, GTIN-12s, GTIN-13s

**RF/RFID** Radio Frequency technology is often considered the technology of the future.

However it is not widely used, and implementation has been slow. It is unlikely to be adopted by health services in the UK in the short or medium term.

## S

**Scanner** An electronic device to read barcode symbols and convert them into electrical signals understandable by a computer device

**Supplier** The party that produces, provides, or furnishes an item or service

**Symbol** The combination of symbol characters and features required by a particular symbology, including Quiet Zone, Start and Stop Characters, data characters, and other auxiliary patterns, which together form a complete scannable entity; an instance of a symbology and a data structure

**Symbol character** A group of bars and spaces in a symbol that is decoded as a single unit. It may represent an individual digit, letter, punctuation mark, control indicator, or multiple data characters

**Symbology** A defined method of representing numeric or alphabetic characters in a barcode; a type of barcode

## T

**Trade Item** Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain

## U

**UPC-A Barcode Symbol** A barcode symbol of the EAN/UPC Symbology that encodes GTIN-12 Identification Numbers



---

**UPC-E Barcode Symbol** A barcode symbol of the EAN/UPC Symbology representing a GTIN-12 Number in six explicitly encoded digits using zero-suppression techniques

**X**

**X-dimension** The specified width of the narrow element in a barcode symbol

## Barcoding for medical equipment supplied to the NHS and to healthcare equipment resellers A guidance document for BHTA members

---

### British Healthcare Trades Association

New Loom House  
Suite 4.06  
101 Back Church Lane  
London  
E1 1LU

Telephone: 020 7702 2141  
Fax: 020 7680 4048  
Email: [bhta@bhta.com](mailto:bhta@bhta.com)  
[www.bhta.com](http://www.bhta.com)

BHTA is a member of the Confederation of British Industry (CBI) – Sectional Member (T/000026043) and of EUROM VI



**August 2014**