

Section 2.7:

Numbering and Symbol Marking for Very Small Healthcare Items

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2.7.1 Introduction

The Reduced Space Symbology[®] (RSS), EAN.UCC System Composite Symbology[®], and Data Matrix (see Section 5.5 and Section 5.6) were specially developed for applications where traditional bar codes symbols were limited or not available. The EAN.UCC System currently limits use of these symbologies to very small healthcare items. This application guideline has been globally agreed.

Very small healthcare items are an application for which there exists no encoding method with traditional EAN.UCC bar code standards. Product identification for unit-of-use items and unit dose items dispensed at bedside is extremely important. The lack of automatic identification of pharmaceuticals and medical-surgical items leads to high manual effort and errors during administration, documentation, and stocking or inventory.

The following guidelines provide the current best practice for use and application of RSS, Composite Symbology, and Data Matrix symbologies in healthcare applications with limited space marking requirements.

2.7.2 Scope

2.7.2.1 Purpose

These guidelines provide a foundation for the implementation of RSS-14[®] Stacked, RSS Limited[®], RSS-14[®] Stacked Omnidirectional, Composite, and Data Matrix Symbologies in healthcare. They provide:

- Application requirements for RSS-14 Stacked, RSS Limited, RSS-14 Stacked Omnidirectional, Composite Component[®], and Data Matrix Symbologies.
- Methods for evaluating RSS-14 Stacked, RSS Limited, RSS-14 Stacked Omnidirectional, Composite Component, and Data Matrix readability and scannability.

2.7.2.2 Applicability

These guidelines are only for healthcare items. They apply to the appropriate use of RSS-14[®] Stacked, RSS Limited[™], RSS-14 Stacked Omnidirectional, Composite Component[®], and Data Matrix on healthcare items that are too small for other EAN.UCC System linear symbologies. The majority of uses for Reduced Space Symbology[®] (RSS) will be on very small items, such as vials, ampoules, very small bottles, and blister packs. The majority of uses for Data Matrix will be on very small items with limited printing area and medical-surgical items that lack a traditionally printable surface or area.

2.7.2.3 Who Should Use These Guidelines

These guidelines are written for the entire healthcare supply chain, from the label printer to the healthcare provider and everyone in between. They provide sufficient information to implement this technology, assuming that the hardware and software being used supports the RSS, EAN.UCC Composite Symbology, and Data Matrix Symbologies according to *ITS/99-001:1999*, *ITS/99-002:1999*, and *ISO/IEC 16022*.

2.7.3 References

The standards listed below are referenced in these guidelines. The relevant provisions contained in the referenced specifications constitute provisions of these guidelines.

ITS/99-001:1999	International Symbology Specification Reduced Space Symbology® (RSS)
ITS/99-002:1999	International Symbology Specification EAN.UCC Composite Symbology®
ISO/IEC 16022	Information Technology – International Symbology Specification – Data Matrix
ISO/IEC 15416	Information technology – Automatic identification and data capture techniques – Bar code print quality test specification – Linear symbols
ISO/IEC 15415	Information Technology – Automatic identification and data capture techniques – Bar code print quality test specification – 2D symbols
ISO 1073-2	Alphanumeric character sets for optical recognition – Part 2: Character set OCR-B – Shapes and dimensions of the printed image

2.7.4 Definitions

Terms and definitions

The terms and definitions provided here and those from the Glossary (see [Section 8](#)) apply to these guidelines:

bar height	The dimension of a bar (line) measured from its top to its bottom.
bar width	The thickness of a bar (line) measured from one of its edges to the other.
Bar Width Reduction/Increase	The uniform reduction/increase of each bar code symbol in the Film Master or digital image file to correct for anticipated bar growth/shrinkage in the imaging or printing process.
very small healthcare items	All kinds of very small pharmaceutical and medical products, mainly unit-of-use items and unit dose items, but also very small packages.
selective Bar Height Reduction	The uniform Bar Height Reduction of a bar code symbol in the Film Master or digital bar code file to correct for anticipated bar growth in the imaging or printing process.
direct part marking	Any method of directly marking (as opposed to applying) the part or surface. Sometimes abbreviated as DPM.

Abbreviations

2D	Two-dimensional
CC	Composite Component®
RSS	Reduced Space Symbology®
GTIN™	Global Trade Item Number™
YYMMDD	Expression of date – Year Year/Month Month/Date Date

2.7.5 Marking Requirements

RSS-14® Stacked, RSS Limited® and RSS-14 Stacked Omnidirectional have been developed for small unit healthcare packages and are designed to encode the Global Trade Item Number™ (GTIN™). The optional Composite Component® can contain additional data elements that refer to that particular item. Data Matrix shall encode GTINs and can contain additional elements that refer to that particular item.

RSS-14 Stacked has the first priority to be used for identification of very small healthcare items. RSS Limited, RSS-14 Stacked Omnidirectional, or Data Matrix shall be used in exceptional cases for certain application requirements. The RSS Limited can be used if the item needs a relatively long but limited height symbol. RSS-14 Stacked Omnidirectional is designed for omnidirectional scanning environments.

In general, all participants of the healthcare supply chain shall be able to read and process all of these variants of RSS symbols.

Data Matrix should be used where printing area is .375 in. (9.525mm) square or smaller or where the marking area will preclude the application of ink (et al) thus requiring the symbol to be applied by means of direct part marking.

Marking & Reading (Scanning Requirements)

Symbology	Print Area Available	Print Density	Scanner Technology Required
RSS Stacked	12.7 mm x 6.35 mm (0.5 in. x 0.25 in.)	≥ 6.7 mil	Laser or Imaging Scanner
RSS Limited	12.7 mm x 6.35 mm (0.5 in. x 0.25 in.)	≥ 6.7 mil	Laser or Imaging Scanner
RSS Stacked Omnidirectional	12.7 mm x 25.4 mm (0.5 in. x 1.0 in.)	≥ 8.0 mil	Retail Style Slot Scanner
Data Matrix	9.525 mm (.375 in.) square	≥10.05 mil	Imaging Scanner

Note: Data Matrix is not intended for general retail scanning.

2.7.5.1 Mandatory Data Elements

Item level marking shall contain the Global Trade Item Number™ (GTIN™) in the RSS-14® Stacked Symbol (or in the RSS Limited™, RSS-14 Stacked Omnidirectional, or Data Matrix Symbol depending on the application requirements previously described).

2.7.5.2 Optional Data Elements

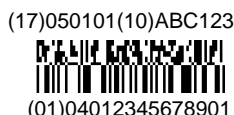
An item may also contain a symbol encoding secondary attribute data. It is recommended to adopt the expiry date and the lot number in the encoded data. Expiry date and lot number must, legally, be expressed minimally in Human Readable Interpretation on the label or package. Automatic handling (scanning and electronic delivery) of this data facilitates many maintenance and documentation duties. Within the Composite Component® and Data Matrix, the secondary information is structured according to the rules of the UCC/EAN 128 Bar Code Symbol Application Identifier (AI) concept.

Neither Composite Component nor Data Matrix is omnidirectionally scannable using a retail style slot scanner and, therefore, neither is suitable for retail applications. Nevertheless, the automatic handling of secondary data offers several possibilities and benefits that may become important even in retail applications (e.g., scanning of best before or expiry dates, lot numbers in case of recalls).

Example¹: RSS-14® Stacked Composite Symbol, Global Trade Item Number™ (GTIN™) in RSS-14 Stacked, AIs (17) expiry date, and (10) lot number in Composite Component A



Example: RSS Limited™ Composite Symbol, GTIN in RSS Limited, AIs (17) expiry date, and (10) lot number in Composite Component A



Example: RSS-14 Stacked Omnidirectional Composite Symbol, GTIN in RSS-14 Stacked Omnidirectional, AIs (17) expiry date, and (10) lot number in Composite Component A



Example: Data Matrix Symbol, GTIN, AIs (17) expiry date, and (10) lot number

¹ Please note that all symbol examples shown in these guidelines are for illustration purposes and do not correspond to the metrics described elsewhere.

(17) 050101 (10) ABC123



(01) 04012345678901

2.7.6 Data Representation

2.7.6.1 Syntax

2.7.6.1.1 Mandatory GTIN™

The data syntax for the mandatory Global Trade Item Number™ (GTIN™) is:

- A two-digit Application Identifier (AI) (01) indicating a GTIN
- A GTIN

As the RSS-14® Stacked, RSS Limited™ and RSS-14 Stacked Omnidirectional always exclusively contain a GTIN, the AI (01) indicating a GTIN is not encoded in these RSS symbols. It must be noted that for Data Matrix, FNC1 (Function Code 1) must be encoded first to indicate a symbol within the EAN.UCC System.

The 14-digit GTIN is structured as follows:

- A one-digit Indicator (value from 0 to 9). However, only 0 to 8 can be used as 9 is the variable measure prefix. The RSS Limited is restricted to the GTIN with Indicator value 0 or 1.
- The EAN.UCC Company Prefix (or the UCC Company Prefix)
- The Item Reference (designated by the holder of the EAN.UCC Company Prefix (or the UCC Company Prefix))
- A Check Digit (calculated from the first 13 digits of the GTIN)

2.7.6.1.2 Optional Data

Any optional data shall be contained in the 2D Composite Component® or following the Global Trade Item Number™ (GTIN™) in a Data Matrix Symbol. The data syntax for each of the optional data fields is:

- A two- to four-digit Application Identifier (AI) to indicate data type and field size
- The data indicated by the AI. This may be a fixed or variable length field, depending on the AI.

Multiple AI data elements may be concatenated in a single 2D Composite Component message or in a Data Matrix Symbol. Note that if a Data Matrix Symbol is used, the optional data must follow the GTIN information.

All AIs of pre-defined length² should precede the variable field AIs for the most efficient encoding. The FNC1 (Function Code 1) separator character shall separate variable length AI fields.

In healthcare applications, the following AI elements should be used because this data is legally required and implies certain liabilities:

² See [Section 7.9.2](#)

Expiry (Expiration) Date:

The data syntax for the expiry date is n2 + n6:

- A two-digit AI (17) indicating the maximum durability date
- A fixed length field of six digits indicating expiry date as YYMMDD

Lot/Batch Number:

The data syntax for the lot number is n2 + an..20:

- A two-digit AI (10) indicating lot number
- A variable length field of up to 20 alphanumeric characters of lot number data

2.7.6.2 Symbol Metrics

2.7.6.2.1 RSS & Data Matrix

2.7.6.2.1.1 X-Dimension (Module Size) and Symbol Height (Y Dimension)

Symbol(s) Specified	X-Dimension mm (inches)			Minimum Symbol Height for Given X mm (inches)			Quiet Zone		*Minimum Quality Specification
	Minimum	Target	Maximum	For Minimum X-dimension	For Target X-dimension	For Maximum X-dimension	Left	Right	
RSS-14® Stacked	0.170 (0.0067 in.)	0.20 (0.008 in.)	0.41 (0.016 in.)	2.21 (0.087 in.)	2.64 (0.104 in.)	5.28 (0.208 in.)	Not Applicable	Not Applicable	1.5/06/670
RSS Limited™	0.170 (0.0067 in.)	0.20 (0.008 in.)	0.41 (0.016 in.)	1.70 (0.067 in.)	2.03 (0.080 in.)	4.07 (0.160 in.)	Not Applicable	Not Applicable	1.5/06/670
RSS-14 Stacked Omnidirectional	0.170 (0.0067 in.)	0.20 (0.008 in.)	0.41 (0.016 in.)	11.73 (0.4623 in.)	13.8 (0.552 in.)	28.51 (1.104 in.)	Not Applicable	Not Applicable	1.5/06/670
Data Matrix	0.255 (0.01005 in.)	0.3 (0.012 in.)	0.615 (0.024 in.)	Entirely dependent on quantity of data encoded			Symbol must be surrounded by a 1X Quiet Zone		1.5/06/670

* See [Section 2.7.7](#) for full details on minimum quality specifications.

2.7.6.2.1.2 Symbol Size

2.7.6.2.1.2.1 RSS-14® Stacked

This symbol is, at minimum, 50X (50 modules) wide by 13X (13 modules) high. The top row is 5X (5 modules) high and the bottom row is 7X (7 modules) high. The separator pattern between rows is, at minimum, 1X (1 module) high. No Quiet Zones are required. The adjacent background colour can be the same as the guard bar, light on the left and dark on the right side of the symbol respectively.

2.7.6.2.1.2.2 RSS Limited™

This symbol is 74X (74 modules) wide by a minimum of 10X (10 modules) high. No Quiet Zones are required. The adjacent background colour can be the same as the guard bar, light on the left and dark on the right side of the symbol respectively.

2.7.6.2.1.2.3 RSS-14[®] Stacked Omnidirectional

This symbol is, at minimum, 50X (50 modules) wide by 69X (69 modules) high. Each is 33X (33 modules) high minimum, with a 3X (3 modules) high separator pattern between the two rows. No Quiet Zones are required. The adjacent background colour can be the same as the guard bar, light on the left and dark on the right side of the symbol respectively.

2.7.6.2.1.2.4 Composite Component[®]

The X-dimension shall be nominally the same as the X-dimension of the associated primary Reduced Space Symbology[®] (RSS) linear symbol. The overall dimensions of the Composite Component[®] depend on the data content. See *International Symbology Specification EAN.UCC Composite Symbology* for details on calculating the dimension of a specific Composite Component Symbol and the allowed tolerances between the linear and the Composite Component.

2.7.6.2.1.2.5 Data Matrix

The X-dimension shall be nominally 1.5X as the X-dimension of a like Reduced Space Symbology[®] (RSS) linear symbol. The overall dimensions of the Data Matrix Symbol depend on the data content. See *ISO/IEC 16022 Information Technology - International Symbology Specification - Data Matrix* for details on calculating the dimensions of a specific Data Matrix Symbol.

2.7.6.3 Human Readable Interpretation

2.7.6.3.1 RSS

2.7.6.3.1.1 Location

The Global Trade Item Number[™] (GTIN[™]) shall be printed in human-readable form underneath the symbol.

Example: RSS-14[®] Stacked Symbol containing the GTIN



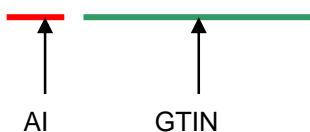
2.7.6.3.1.2 Font

A clearly legible font shall be used for the human-readable digits (e.g., OCR-B as defined in *ISO 1073-2*). Reasonable alternative type fonts and character sizes are acceptable provided the interpretation is clearly legible. The font should be suitable and compatible with other printed materials. When necessary, the font used shall be in accordance with applicable government laws and regulations.

2.7.6.3.1.3 Format

The Global Trade Item Number[™] (GTIN[™]) shall be printed as a single 14-digit number preceded by the corresponding Application Identifier (AI) (01) enclosed in parentheses. Although the AI (01) is not encoded in the Reduced Space Symbology[®] (RSS), it shall be printed to ensure the consistent and unambiguous interpretation of data in the case of a Composite Component[®] Symbol. The parentheses are not part of the data and are not encoded in the bar code symbol.

(01)04012345678901



2.7.6.3.1.4 Data Overflow

There will be instances where there is insufficient space on the very small healthcare item for the Reduced Space Symbology® (RSS) Symbol and the human readable Global Trade Item Number™ (GTIN™). When this situation occurs and this information is already printed on the label because of government mandates or by trade practice, then, at the supplier’s discretion and in accordance with applicable government regulations, the identification number’s Human Readable Interpretation requirement can be waived.

For a consistent representation of the GTIN printed independently from the symbology, the EAN.UCC System data title should be used. For example:

AI	Full Title	Data Title
01	Global Trade Item Number	GTIN

2.7.6.3.2 Composite Component®

2.7.6.3.2.1 Location

If there is sufficient space to print the Human Readable Interpretation of the Composite Component®, it shall be printed above the symbol in proper sequence of the Application Identifiers (AIs) (the Reduced Space Symbology® (RSS) Human Readable Interpretation is printed below). The data shall be printed from top to bottom and left to right. A single AI with accompanying data shall be displayed on one line and not broken into two lines.

Example: RSS-14® Stacked Composite Symbol - Global Trade Item Number™ (GTIN™) printed below RSS-14 Stacked, AIs (17) expiry date and (10) lot number printed above the Composite Component in one single line.



Example: RSS-14 Stacked Composite Symbol – GTIN printed below RSS-14 Stacked, AIs (17) expiry date and (10) lot number printed above the Composite Component from top to bottom and left to right.

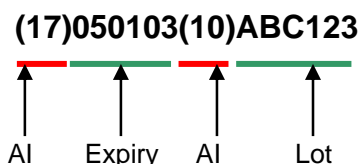


2.7.6.3.2.2 Font

The font should be suitable and compatible with other printed materials and the Reduced Space Symbology® (RSS) Human Readable Interpretation. The font size should be scaled for easy legibility. The font used shall be in accordance with applicable government laws and regulations.

2.7.6.3.2.3 Format

The data should be printed with the preceding Application Identifiers (AIs) enclosed in parentheses. The order of the data should be the same as encoded in the Composite Component® according to the rules in the *General EAN.UCC Specifications*. The parentheses are not part of the data and are not encoded in the bar code symbol, though the AIs are.



2.7.6.3.2.4 Data Overflow

On many packages there will be insufficient space to print both the Human Readable Interpretation for Reduced Space Symbology® (RSS) (Global Trade Item Number™ (GTIN™)) and the Composite Component® information. Printing the RSS (GTIN) or Data Matrix information shall take precedence over the Human Readable Interpretation for the Composite Component or the remainder of data encoded in the Data Matrix Symbol.

The GTIN, expiry date, and lot number are already routinely printed on the label because of government mandates or by trade practice. If there is no space for printing the encoded data above or below the symbol, the data not belonging directly to the symbology should be consistently represented using the EAN.UCC System data titles. For example:

AI	Full Title	Data Title
01	Global Trade Item Number	GTIN
17	Expiration Date	USE BY or EXPIRY
10	Batch or Lot Number	BATCH/LOT

Note: If the RSS Composite Symbol fails to scan, manual input of the data is necessary. As expiry date and lot number should always be part of the information stored in the Composite Symbol and as this information is already printed on the label because of legal requirements, a software solution can be implemented to prompt the user for this data after keying in the GTIN.

2.7.6.3.3 Data Matrix

2.7.6.3.3.1 Location

The Global Trade Item Number™ (GTIN™) shall be printed in human-readable form underneath the symbol.

If there is sufficient space to print the Human Readable Interpretation of the optional attribute data it shall be printed above the symbol in proper sequence of the Application Identifiers (AIs). The data

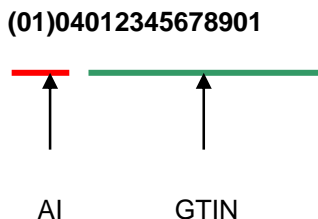
shall be printed from top to bottom and left to right. A single AI with accompanying data shall be displayed on one line and not broken into two lines.

2.7.6.3.3.2 Font

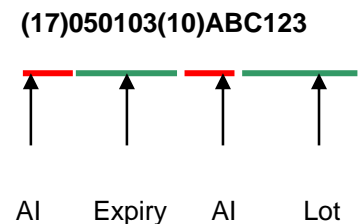
A clearly legible font shall be used for the human-readable digits (e.g., OCR-B as defined in *ISO 1073-2*). Reasonable alternative type fonts and character sizes are acceptable provided the interpretation is clearly legible. The font should be suitable and compatible with other printed materials. When necessary, the font used shall be in accordance with applicable government laws and regulations.

2.7.6.3.3.3 Format

The Global Trade Item Number™ (GTIN™) shall be printed as a single 14-digit number preceded by the corresponding Application Identifier (AI) (01) enclosed in parentheses.



The optional attribute data should be printed with the preceding AIs enclosed in parentheses. The order of the data should be the same as encoded in the Composite Component® according to the rules in the *General EAN.UCC Specifications*. The parentheses are not part of the data and are not encoded in the bar code symbol, though the AIs are.



2.7.7 Print Quality

The minimum print quality grade for RSS-14® Stacked, RSS Limited™ and RSS-14 Stacked Omnidirectional Symbols in healthcare applications shall be a 1.5/6/670 overall symbol grade when measured in accordance with *ISO/IEC 15416*. The measurement of the quality parameters shall be made by a verifier conforming to *ISO/IEC 15416*, using a 0.15 mm (0.006 in.) aperture at a nominal illumination wavelength of 670 nanometres. According to this standard, minimum print quality requirements are shown in the form:

1.5 / 6 / 670

- where 1.5 is the overall symbol quality grade (sometimes expressed as letter grade “C”)
- 6 is the measuring aperture reference number (corresponding to an 0.15 mm or 0.006 in. diameter aperture)
- 670 is the peak response wavelength in nanometres.

For the 2D Composite Component®, ink spread in the direction of the bar y-axis (perpendicular to the bar width or x direction) requires a compensating Bar Width Reduction in the y direction.

2.7.8 Label Location

General principles on placement of bar code labels are described in Section 6 and apply to the label location of Reduced Space Symbology® (RSS)/Composite Symbols.

The majority of uses for RSS will be on very small items with curved surfaces, such as vials, ampoules, and very small bottles. For guidance in locating the RSS/Composite Symbol on curved surfaces, refer to Section 6.2.3.2.