THE SOCIETY FOR LIFE SCIENCE PROFESSIONA

New Bar Code for Small Healthcare Items

ISPE Meeting – May 25th 2004

Romaco
EXCELLENCE THROUGH INNOVATION

Contents

- *The FDA rule*
- *Unit Dose Bar Code*
- *The EAN•UCC solution*
- *EAN•UCC and GTIN*
- *The Types of RSS Bar Code*
- *The Composite Component*
- *The Complete Code*
- *Examples*
- *The HIBCC Proposals*
- *RSS Bar Code V Data Matrix Code*
- *Laetus 2D-COSI 8x0*

The FDA rule

U.S. Food and Drug Administration

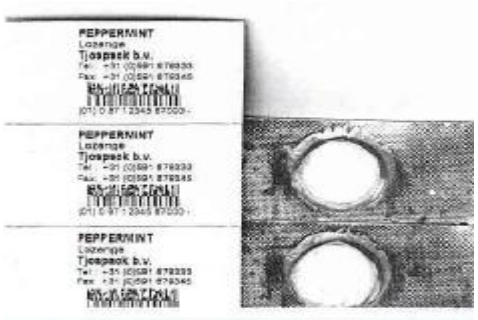
- On December 3, 2001 FDA announced a proposed rule requiring that the National Drug Code (NDC) be bar-coded on all pharmaceutical and biological products,
- “Unit-dose packaging" means a method of packaging a product into a non-reusable container designed to hold a single dosage unit intended for administration directly from that container.
- The FDA announcement stated that it was also examining the requirement for lot number and expiry (expiration) date.
- It must be stated that FDA do not specify which barcode symbology is to be used. The advantage a of well introduced linear symbols and the existing EAN•UCC system was mentioned.

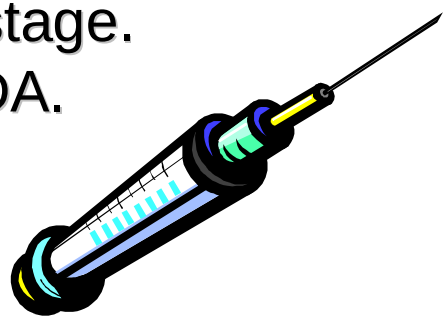
FDA Comments (extract)

- Which medical products should carry a bar code?
  - The bar code should be present for each individual dose that goes to the patient.
- Bar coding is needed in hospitals and health-systems for the following reasons:
  - Ensuring the accuracy of medication identification
  - Ensuring the accuracy of the medication administration process
  - Improving efficiencies within the medication distribution system in hospitals
  - Reducing the number or medication errors
  - Improving the efficiency of the supply system, including ordering, receipt, storage and dispensing, billing, administration documentation and tracking of drug products

Unit Dose barcodes

- Within the area of very small healthcare items, the unit dose items dispensed to the patient at the hospital bedside have a high importance for correct product identification.
- The lack of possibilities for automatic identification leads to high manual effort and potential errors during medication, documentation or at the stock control stage. This was an area of concern for the FDA.





About EAN.UCC

Uniform Code Council, Inc.®
The Global Language of Business®

- The Uniform Code Council (UCC) in the USA promote standard product identification and electronic commerce. The UCC is an industry service organisation working in 23 industry sectors in the USA.
- The UCC is a ‘not for profit company’. As a member organization of EAN International, the UCC together with EAN International, co-manage the EAN•UCC System and the EAN•UCC Global Standards Management Process (GSMP).
- The RSS and Composite Component specifications are in the public domain. Their purpose is to increase healthcare supply chain efficiencies, and reduce medication errors. The majorities of global pharmaceutical companies are UCC members and use the global EAN•UCC system.

About EAN.UCC and GTIN

- For longer than the last 25 years therefore the EAN•UCC system was used to encode the American National Drug Code (NDC) number inside the overall Global Trade Item Number (GTIN).
- Also included in the GTIN is the data structures for lot number and expiration date. The GTIN system is accepted and recognised globally.
- The EAN•UCC system of product and process identification is the one used by global pharmaceutical and healthcare manufacturers.
- So it was no surprise that since the 1970s when the National Drug Code was created by regulation, the NDC was incorporated in the GTIN by the global EAN•UCC system.

About EAN.UCC and GTIN

- With the exception of the United States and Canada, retail products around the world are marked with EAN-8 and EAN-13 digit codes. To sell those products in the U.S. and Canada, manufacturers must re-label with a 12-digit UPC symbol.
- The fact is that the UCC was running out of 12-digit codes and would no longer issue Company Prefixes to companies outside the U.S. and Canada.
- The new EAN•UCC initiative supports a 14-digit GTIN, that will accommodate current UCC-8,UCC-12, EAN-8, EAN-13 and EAN•UCC-14 data structures. The GTIN thus becomes the standard way to uniquely identify products no matter where sourced.

The EAN•UCC solution

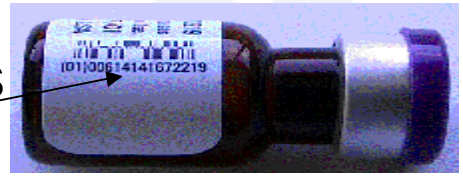
- The UCC developed, patented and placed in the public domain the Reduced Space Symbology and Composite Component in November 1999.
- However the existing EAN•UCC system offered no solution or encoding method for very small healthcare items. So the decision was made by the UCC to make the EAN•UCC system have the NDC embedded in the Reduced Space Symbology (RSS) barcode. This revised specification was issued in 2002.
- The EAN•UCC Composite Component Symbology was developed specifically to identify small items.

RSS 14 Bar Code – The Linear Code

(01) 00614141000012 RSS-14

(01) 00614141000012 RSS-14 Truncated

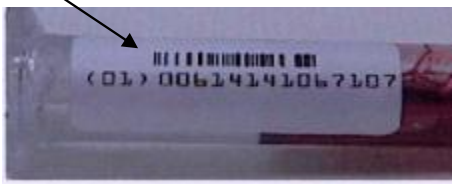
(01) 00614141000012 RSS-14 Stacked, 2ml vials



(01) 00614141000012 RSS-14 Stacked Omnidirectional Produce & healthcare (OTC)

(01) 00614141000012 RSS Expanded

(01) 00614141000012 RSS Limited syringes



(01) 00614141000012 RSS Expanded Stacked Variable Measure

RSS 14 Bar Code – The Linear Code

- RSS-14 - Linear barcode designed to be read by omnidirectional scanners.
- RSS-14 Stacked - Reduced height two row version of RSS-14, cannot be read by omnidirectional scanners.
- RSS Limited – Cannot be read by an omnidirectional scanners.
- RSS-14 Stacked Omnidirectional - Full height two row version of the RSS-14, to be read by an omnidirectional scanner.

(01)20012345678909

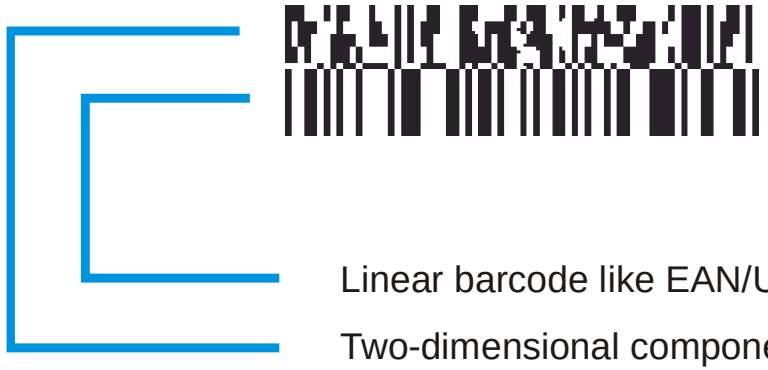
(01)00012345678905

(01)15012345678907

(01)00034567890125

RSS 14 Bar Code – The structure

- The RSS bar code can be used as a linear symbol or with an additional composite symbol.

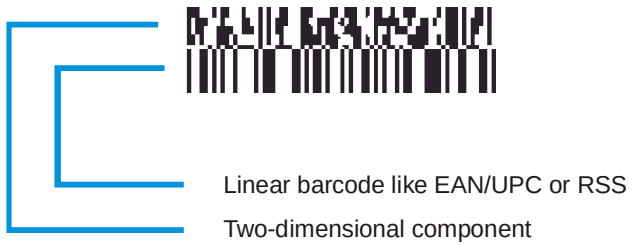


Linear barcode like EAN/UPC or RSS

Two-dimensional component

RSS Bar Code – The Composite Component

- Any item may also contain, if space allows, a Composite Component. At the discretion of the manufacturer, the Composite Component will contain additional information related to the product. It is recommended to use the Composite Component to adopt the expiry date and the lot number, because this is legally required information, at least as human readable information on the Item or package.
- Automatic handling of this data facilitates many maintenance and documentation duties. Within the Composite Component the secondary information is structured according to the rules of the EAN•UCC 128 Application Identifier Concept.



The Composite Component in EAN•UCC

UPC-A Composite

EAN/UCC-128 Composite

(01)03212345678906
(21)A1B2C3D4E5F6G7H8

RSS-14 Composite

(01)03612345678904(11)990102

RSS Limited Composite

(17)050101(10)ABC123

(01)04012345678901

RSS-14 Stacked Composite Composite

(01)03412345678900(17)010200

RSS-14 Stacked Omni

(17)050101(10)ABC123

(01)04012345678901

Examples

Laser Printed Composite code

Screen printed at 600DPI the complete RSS Code

The HIBCC Proposal

- Additionally to the UCC solution the Health Industry Business Communications Council (HIBCC) made its own proposal.
- Recent work by the HIBCC in the USA includes standardised manufacturer, customer, and product identification codes, including the Labeller Identification Code (LIC), Health Industry Number (HIN), and Universal Product Number (UPN) and the Health Industry Bar Code (HIBC) Standards.
- The HIBCC preferred solutions for small healthcare items are PDF417 or the Data Matrix Code.
- Some reasons stated by the HIBCC for the adoption of Data Matrix is because it is a better barcode than RSS. The following page shows the advantages of Data Matrix codes.

RSS Bar codes V Data Matrix codes

- Size - Data Matrix symbols as small as 2 mm can be accurately printed and read. RSS will not fit on all unit-of-use packages.

- Print Quality - Data Matrix can be decoded with as little as 20% contrast. RSS, like all linear barcodes, requires a higher level of print quality and contrast.
- Readability - Data Matrix can be marked directly on any surface including reflective materials such as foil packaging associated with some unit-dose blister packs.
- Error Correction - Data Matrix symbols employ Reed-Solomon error correction. A large proportion of the code (up to 1/3) can be damaged and still decode correctly. RSS has no error-correction capability.

RRS Bar Code Reader 2D-COSI 8x0

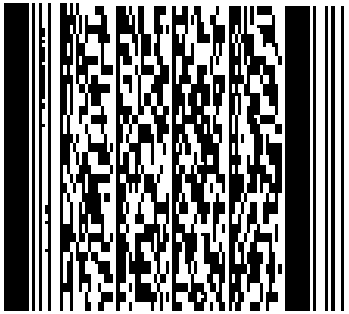
- Due to the requirement to read RSS-14 on blisters, labels and cartons Laetus decided to use the 2D-COSI 8x0 scanner to implement the RSS-14 and additionally the PDF417 symbology decoder.
- With the range of available accessories and the possibility to use this scanner with the standard security system ARGUS 6012 as well as with the new wt technology the 2D-COSI 8x0.

RRS Bar Code Reader 2D-COSI 8x0

- Code readers should support the folowing code symbologies:

- RSS-14, RSS-14 Truncated, RSS-14 Stacked, RSS-14 Stacked Omnidirectional, RSS Limited (each of these RSS-14 version should be able to be read either with or without the additional composite code)

- And PDF417.



Thank you

- Review of the situation today.
- Working together we can achieve the goals of additional patient safety without compromising production efficiency!

- Thank You!