Automatic Identification Technologies for UDI: Bar Code & RFID

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AIM North America Healthcare Committee
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Two related FDA initiatives

- **UDI: Unique Device Identification (*now*)**
  - Medical devices
  - Patient care, diagnostic or treatment devices

- **SNI: Standardized Numeric Identification (*near future*)**
  - Prescription drugs
  - Pharmaceuticals
  - Biologics
  - Vaccines

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UDI & SNI products have usage commonality

- Medical devices, pharmaceuticals and biologics are dispensed in the hospital and *all are used at the patient bedside*
- All will use AIDC data carriers and need a common reader technology to enter that data into the patient Electronic Health Record (EHR)

Display form of a Unique Device Identifier

- **From *Final Rule* § 801.40(a)**
- "… The UDI must be presented in two forms:
  (1) Easily readable plain-text, and
  (2) Automatic identification and data capture (AIDC) technology
- Note the form of AIDC technology is *not* specified!

Why require AIDC?

- Automated product identification
- Automation of inventory control & tracking
- Ease and accuracy of inputting UDI data for product validation against GUDID product database
- Automated data entry into patient Electronic Healthcare Record
- Simplify recall processing by identifying only the recalled product lot or serial numbers

UDI: Unique Device Identification

- **Per FDA *Final Rule* as of September 24, 2013, requirements are by device Class**
  - Class I: Device Identifier (DI) ONLY
  - Class II and III: Device Identifier (DI) + Production Identifier (PI)
    - DI + PI (Lot/Batch and/or Exp Date and/or Prod Date, etc.)
    - DI + PI (Serial Number)
    - DI + PI (Lot/Batch and/or Exp Date and/or Serial Number, etc.)

  As a result, unserialized medical devices are not necessarily "uniquely labeled", just accurately identified
- **Phased Implementation**
  - Class III (2014), Class II (2015), and then Class I

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Can the NHRIC be used as a UDI Device Identifier?

- National Health Related Items Code (NHRIC)
- Originally conceived as an "*NDC for non-pharmaceuticals*"
- NHRICs and medical NDC labeler codes are rescinded as of the UDI compliance dates for each Class
  - May no longer appear on the device, device label or package

UDI implementation has 3 parts

1. Reformat your existing data according to standards of using a Issuing Agency that is accredited by the FDA
2. Encode the data into a AIDC format: Example using GS1-128:

3. Register your UDI in the FDA GUDID via one of two proposed methods

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Issuing Agencies support UDI encoding

- Under the ISO (International Standards Organization) specification on unique identification, ISO/IEC 15459-2
  - "An *Issuing Agency* is an FDA-accredited organization that operates a system for assignment of UDIs according to the final rule."
- Three Issuing Agencies are currently accredited by FDA for UDI:
  - GS1, HIBCC and ICCBBA

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Issuing Agencies for UDI encoding in AIDC

GS1 *or* HIBCC *or* ISBT 128

ICCBBA is a nongovernmental organization in official relations with the World Health Organization

- Each has a system for encoding medical devices'
  - Device Identifiers
  - Production Identifiers (may have multiple fields)
- Each assigns Enterprise Identifiers, which are intended to be concatenated with Product Identifiers

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Each uses proven AIDC technologies

- GS1-128
- GS1 Data Bar
- GS1 Data Matrix
- RFID EPC Gen 2 UHF Tag

- Code 128 and Code 39
- Data Matrix, QR Code, Aztec Code
- RFID ISO 18000-6c UHF Gen 2 tag

- *ISBT128*
- Data Matrix
- RFID ISO 18000-3 mode 1 HF tag

AIDC standards for UDI

International AIDC standards exist and are well documented

- For data structures; example:
  - GS1 General Specifications
  - ANSI/HIBC 2.3 Supplier Labeling Standard
  - ICCBBA *ISBT128* Technical Specification
- For encoding in bar code (*www.iso.org*); examples:
  - ISO/IEC 15417 Code 128 bar code symbology specification
  - ISO/IEC 16022 Data Matrix bar code symbology specification
  - ISO/IEC 16388 Code 39 bar code symbology specifications

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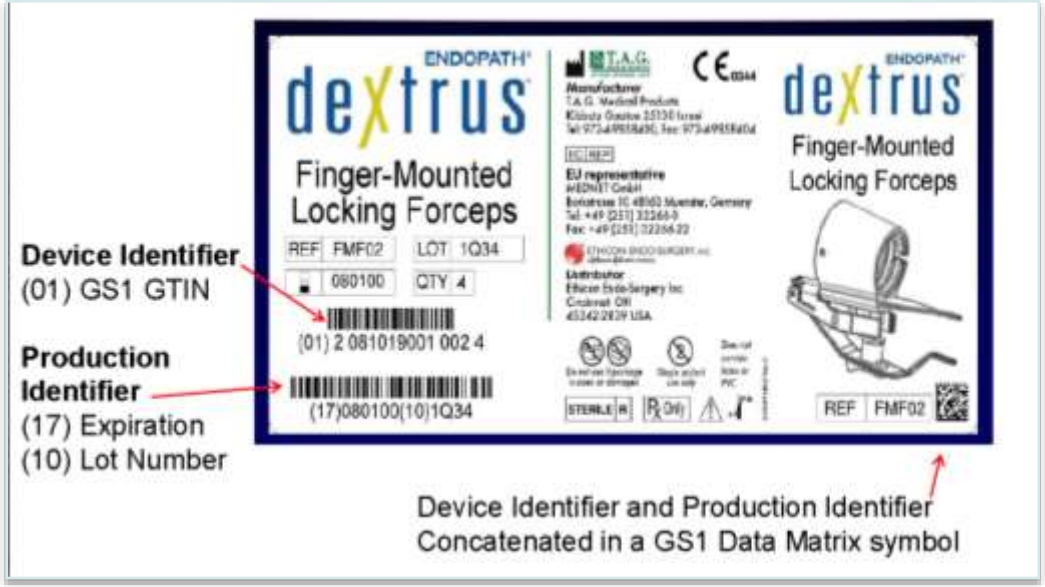
UDI example with 1D and 2-D bar codes



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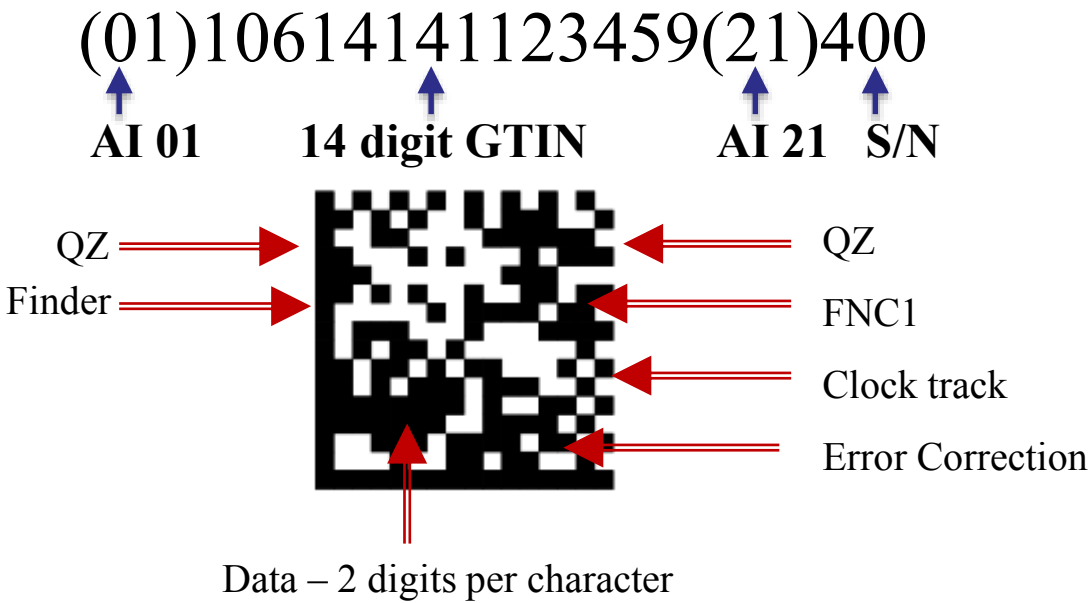
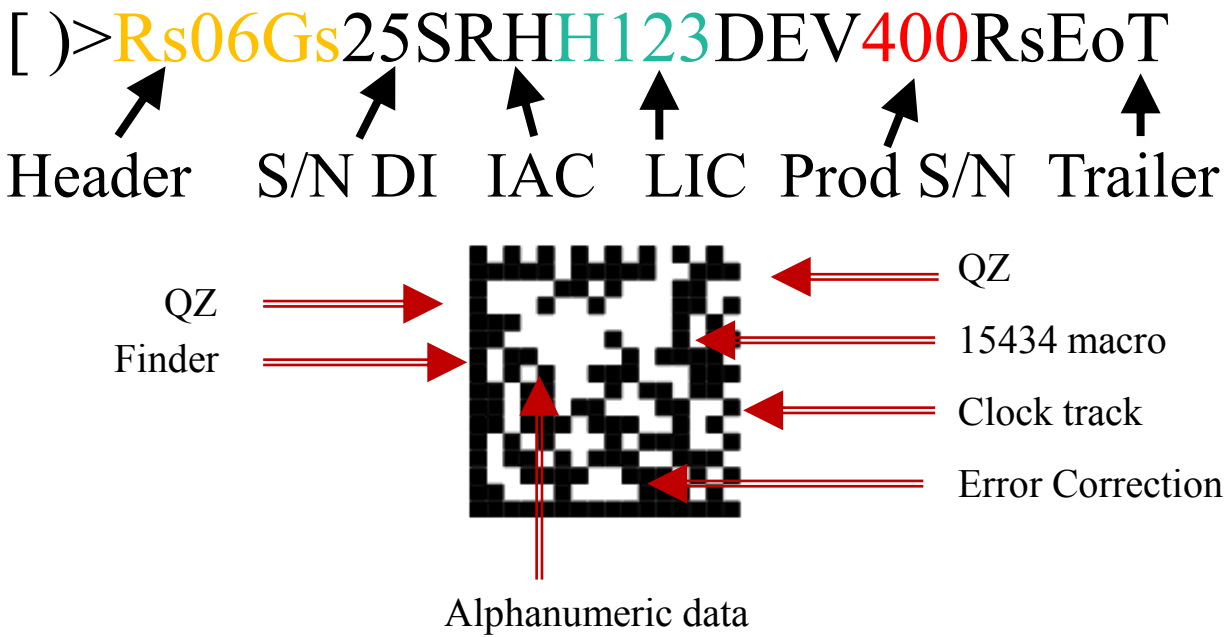
Why use Data Matrix?

- Much less package space than C128
  - All UDI data is in a single symbol
- ISO standard bar code proven in DoD and commercial use worldwide
  - Error correcting design allows data recovery from damaged symbols
- One reader supports GS1, HIBCC, *ISBT128*, SNI at bedside
- Can be direct marked on devices as alternative or supplement to printing on a label or package

Example of GS1 data encoded in GS1 Data Matrix



Example of HIBCC data encoded in a Data Matrix

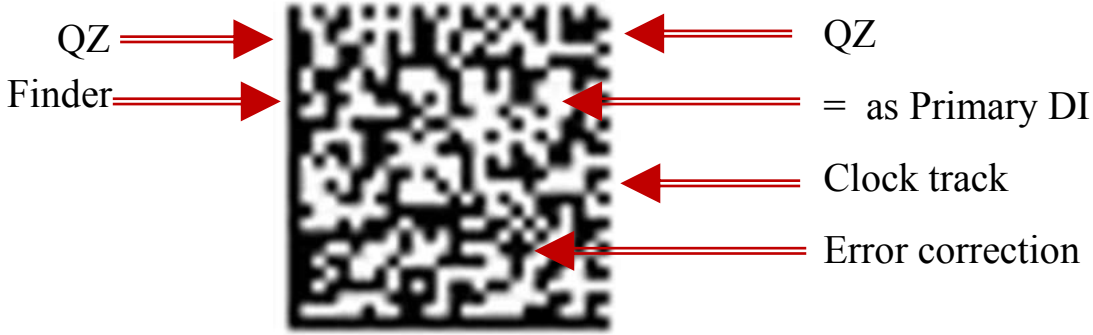


Example of *ISBT128* data encoded in Data Matrix

(Device: Strip of demineralized bone matrix)

=+04035=/A9999XYZ100T7049=,000025=A99971412345600=>016008

Cmpd Msg 35	Device Identifier	S/N	Source Donation ID	Exp Date



Data – 2 digits per symbol character

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Reading mixed Data Matrix symbols

- The type of Data Matrix symbol can be discriminated (under ISO defined rules) from the transmitted reader data stream
  - GS1 symbols have FNC1 with special Symbology Identifier option
  - HIBCC data streams start with a “+”
  - ICCBBA *ISBT128* data streams start with an “=“ or “&”
- For further information on UDI encodation:
  - GS1: http://www.gs1.org/healthcare/udi
  - HIBCC: http://www.hibcc.org/udi-resources/
  - ICCBBA: http://www.iccbba.org/subject-area/medical-device

UDI is enabled by many proven labeling and marking techniques

Let the application drive the marking technology for a high quality mark!

- Thermal Transfer Labels
- Data Plates
- Dot Peen
- Laser Etching
- Chemical Etching
- Silk Screen
- RFID (UHF / HF)
- Direct Thermal Labeling
- Ink Jet (e.g., New DotCode symbology)
- Laser Ablation
- Laser Annealing
- Cast / Forged
- Photo Etch
- Woven/Embroidery

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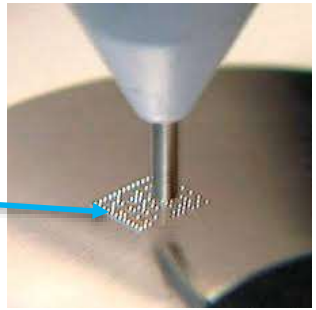
When should direct marking be used?

- Implantable devices, when space permits
- Reusable and sterilizable devices
  - Ex: Surgical instruments

What technologies are used for direct marking?

- Laser etching
- Chemical etching
- Dot peening
- Ink stencil
- Laser polymer fusing
- For further information relevant to UDI, see:



http://aimglobal.site-ym.com/default.asp?page=dpm_faq

http://www.acq.osd.mil/dpap/Docs/uid/direct%20implement.pdf

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Are there quality standards for direct marking?

- Yes, originally developed by AIM for the aerospace and defense products industries
- See:
  - ISO TR 24720:2008 *Guidelines for direct part marking*
  - ISO 28219:2009 *Packaging labeling and DPM with bar code and 2D symbols*

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Why to *use* RFID? – Technical Reasons

- RFID may be used to *augment the bar codes* for locating product
  - Especially useful in locating inventory items quickly, as in an ER or surgical suite or on a crash cart
    - Many specialized UHF RFID-enabled cabinets have been developed to support use of RFID
  - HF RFID has proven ROI in blood bank operations
- Manufacturers need to evaluate potential benefits

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Use of RFID – Business aspects

- RFID adds significant cost
  - Cost per unit product
  - Reader cost
  - How do *you* recover cost and get a positive ROI?
- If you use only RFID, without an accompanying bar code, will everyone in your distribution supply chain be able to read the RFID tag?
  - How will *they* recover cost and get a positive ROI?

AIDC standards are a great information resource

- Printing
  - ISO/IEC 15415 Bar code print quality test specification for two-dimensional symbols
  - ISO/IEC TR 29158 Direct part mark (DPM) quality guideline
- Label performance
  - UL 969
  - IEC 60601-1 3rd Edition
- Encoding data in RFID
  - GS1 EPC Tag Data Standard
  - ISO/IEC 15962 RFID data encoding rules and logical memory functions

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OK, so what do I have to do now?

- Take inventory of what you have today
- Do the “Gap Analysis” for the marking process
- Make a decision on the strategy for the data formats (i.e., which AIDC technology and data format)
- Get the internal resources up to speed and helping (i.e., it is not just a printed label layout change)
- Contact AIM to ask questions and get the information you need

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Five key steps to implement UDI

1) Determine the accredited Issuing Agency to implement UDI in your environment and with your specific products
   - You may need to use more than one, depending on your product mix
2) Reformat your Product Information (PI) data to the format chosen by your organization
3) Mark the product in manufacturing with DI and PI using the AIDC technology implemented by your organization
4) Register the Device / Product with the FDA GUDID Database
5) Ship the Device / Product

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Questions? Contact us:

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