IMPLEMENTATION REALITY SESSION
Unique Device Identification (UDI)
Introductory Session – AIDC

30th GS1 Healthcare Conference – Beijing
Wednesday - 26 October 2016
UDI Implementation “Reality”...

Our Panel...

- **GS1 AIDC UDI Basics**
  - Chuck Biss - GS1 Global Office
  - Senior Director, AIDC Healthcare

- **UDI Regulatory Considerations**
  - Jackie Rae Elkin - Medtronic, Inc.
  - Global Process Owner - Standard Product Identification - Global Regulatory Operations …also our Q&A Moderator

- **UDI AIDC Implementation Experiences**
  - Tom Werthwine – Johnson & Johnson Supply Chain
  - Director, Industry Standards

- **UDI AIDC Implementation Experiences**
  - Stan Malinowski - Medtronic, Inc.
  - UDI Lead for GS1 Standards and Marking
To start, UDI & AIDC...

- UDI’s purpose
- GS1 standards supporting UDI requirements
  - “Translation” of GS1 AIDC to UDI

Chuck Biss
GS1 Global Office
Senior Director AIDC Healthcare
chuck.biss@gs1.org
UDI purpose...

Objective...

A common, **worldwide system for product identification** should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.
UDI system...The AIDC “bits”...

UDI/UDID - System

UDI
- DI
  * Device Identifier (static data)
- PI
  * Production Identifier (dynamic data)

UDID (database)
- Static Data Elements
  - DI = primary access key
  - ...
  - ...

AIDC
- Machine – readable Data Carrier
  - Linear Bar Code
  - 2D Bar Code
  - RFID
  - ...

© GS1 2015
UDI & the GS1 system...

UDI in GS1 identification (identify) terms...

Unambiguous identification of a specific medical device... in two (2) parts:

- **Device Identifier (DI)** – ID of the “generic” medical device (GS1 GTIN)
- **Production Identifier (PI)** – “control” numbers or data used in a mfg. process – (GS1 AI’s - lot/batch, serial number, expiry, etc.)

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
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<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td>(If applicable)</td>
<td>• Expiration Date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>• Lot/Batch AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>• Serial Number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

*Production Identifier data will vary by medical device type and manufacturer current practice.*

DI + PI = UDI

GTIN or GTIN + Al(s) = UDI
UDI in GS1 allocation (identify) terms...

**Allocation** - Some common reasons for a change are: Quantity, pack sterility change, re-labeling of an original device, languages, certification marks, etc.

**Packaging Levels** – A unique UDI s/b on each applicable packaging level as defined by regulation. Logistics items are exempt.

**Always** refer to local UDI regulations & GS1 GTIN Allocation Rules for details.

**Placement** – Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.
UDI & the GS1 system...

UDI in GS1 Data Carrier (capture) terms...

- Any ISO compliant machine-readable Data Carrier which contains the UDI is allowed, 1D/Linear & 2D/Matrix bar code symbols, RFID.
- “Direct Marking” in US FDA terms is not necessarily “direct PART marking”...

All data carriers are for illustration only, not to scale and not in proportional size to one another.
Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information.
UDI requirements may vary by geography - please refer to regional UDI regulations.
UDI label – an example from B.Braun...

H.E.L.P. Acetate Buffer pH 4.85

Device Identifier (DI)
“Static” portion
GTIN (product identifier)

Production Identifier (PI)
“Dynamic” portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format
UDI / GS1 AIDC - the “snapshot”…

Available online at:
http://www.gs1.org/healthcare/udi
&
UDI Implementation

To continue, regulatory...

• UDI Regulatory Considerations
  - the principles, global considerations, the nuances...

Jackie Elkin
Medtronic, Inc.
Global Process Owner - Standard Product Identification
Global Regulatory Operations
PRINCIPLES OF UDI IMPLEMENTATION

October 26, 2016
Medtronic
Further, Together

OUR THERAPIES IMPROVE
THE LIVES OF MORE THAN
2 PEOPLE
EVERY SECOND

EXTENSIVE SCOPE
PROVEN RESULTS

85,000+
EMPLOYEES

7,500+
SCIENTISTS AND ENGINEERS

53,000+
PATENTS

62
MILLION+
LIVES IMPROVED

400+
CLINICAL TRIALS

OUR REACH EXTENDS
AROUND THE WORLD

155+
COUNTRIES

460+
LOCATIONS

80+
MANUFACTURING FACILITIES

50+
RESEARCH AND INNOVATION CENTERS

Medtronic
Further, Together
THE START OF AN ENDURING MISSION

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- To maintain good citizenship as a company.
AGENDA

- IMDRF UDI Guidance
  - UDI System Expectations
  - UDI System Framework
- Comparison of UDI for US / EU / IMDRF
  1) Develop a Standardize System of UDI
  2) Place UDI in HRI & AIDC on Package / Device
- Final Thoughts
UDI ........... The Whole World is Watching
IMDRF
UDI SYSTEM
FRAMEWORK
2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems — such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences..........................


IMDRF Guidance
UDI for Medical Devices
Final Version,
December 9, 2013

http://www.imdrf.org/documents/documents.asp
IMDRF
UDI SYSTEM EXPECTATIONS
THE FUNDAMENTAL CONCEPTS OF A GLOBALLY HARMONIZED UDI SYSTEM INCLUDE:

- the UDI and UDI Carrier are based on **global standards**, 
- a UDI applied to a medical device anywhere in the world should be able to be **used globally and to meet the UDI requirements** of its regulatory authority, 
- national or local identification numbers should **NOT be a substitute for** UDI, 
- regulatory authorities **should not specify the procedure for modifying** these UDI standards 
- the UDI Database (UDID) **core elements should not be modified**, 
- the UDID should use the Health Level Seven **International (HL7) Structured Product Label (SPL) and web based interface for data submission**, 
- every medical device needs to be identified by a **UDI**, unless it is **exempted**
A GLOBALLY HARMONIZED AND CONSISTENT APPROACH TO UDI IS EXPECTED TO PROVIDE:

- **traceability of medical devices**, especially for field safety corrective actions,
- **adequate identification** of medical devices **through distribution and use**,
- **identification** of medical devices in **adverse events**,
- **reduction of medical errors**,
- **documenting and longitudinal capture of data** on medical devices.
COMPARISON OF UDI IMDRF / US / EU
UNIQUE DEVICE IDENTIFICATION SYSTEM

Comprised of 3 Distinct Ideas

1. Development of a standardized system of Unique Device Identifiers (UDI)

2. Placing UDI in human readable and AutoID formats on package, label or device

3. UDID – Register UDI data in UDI Database
DEVELOP A STANDARDIZED SYSTEM OF UDI
- Manufacturer should create and maintain globally unique UDIs on medical devices
- Only the Manufacturer can establish UDI on the device or its packaging
- Globally accepted ISO/IEC coding standards implemented by global organizations such as GS1, HIBCC and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use.
- National or regional regulatory requirements shall not restrict methods of AIDC as this will hinder the establishment of a globally harmonized UDI System.
National/regional regulation for UDI System shall include a robust and transparent mechanism for evaluating and adjudicating requests for UDI exemptions and alternative placements of UDI-DI and UDI-PI.

The employed UDI must meet the requirements of the globally harmonized UDI System to adequately identify a device through its distribution and use.

A change of the label to display or modify a UDI-DI should not (in and of itself) require a premarket submission and/or re-registration. Manufacturers may be requested to notify/inform the Regulator.
The UDI contains two parts: an UDI-DI and UDI-PI.

If a lot number, serial number, software version or expiration date appears on the label, they should be part of the UDI-PI. If there also is a manufacturing date on the label, it does NOT need to be included in the UDI-PI (unless it is the only UDI-PI).

A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI. Shipping containers should be exempted.

When a UDI is not assigned (and labelled) to a device at the level of its unit of use, UoU UDI-DI should be assigned, to associate the use of a device with a patient.
Each component, sub-system or accessory considered a medical device and is commercially available needs a separate UDI unless the components are part of a convenience, medical procedure, IVD kit or configurable medical device system that is marked with its own UDI. **Kits should have their own UDI.**

**Any change in the following Requires a New DI:**
- Brand Name,
- Device version or model,
- Labelled as single use,
- Clinical Size (Volume, Length, Diameter),
- Packaged sterile / need sterilization before use,
- Quantity of devices provided in a package,
- Critical warnings or contraindications: e.g. containing Latex or DEHP.
PLACE UDI HRI & AIDC ON PACKAGE / DEVICE
The **UDI Carrier** (AIDC & HRI of the UDI) **shall be on the label or on the device itself and on all higher levels of device packaging.**

- **In case of significant space constraints** on the Unit of Use package the UDI carrier **may be placed on the next higher package level.**

- The UDI Carrier for single use medical devices of risk class A and B packaged and labeled individually **does not need to be on its package but rather on higher level of packaging e.g. carton.**
No particular AIDC methods should be required by a regulatory authority. Globally accepted AIDC methods based on ISO standards (GS1, HIBCC or ICCBBA) shall be used.

If linear bar codes are used, the UDI-DI and UDI-PI can be concatenated or non-concatenated in two or more bar codes.

In case of RFID, a linear or 2D bar code shall also be provided on the label.

The HRI format shall follow the rules of the UDI code issuing organization.
If there are significant constraints limiting the use of both AIDC and HRI on the label, the **AIDC format shall be favored**.

Medical devices that are reusable and require reprocessing between patients should have a **UDI Carrier on the device itself**. FDA allows HRI.

A single finished medical device made up of multiple parts that have to be assembled **may have the UDI Carrier only on one part**.

Non-prescription medical devices exclusively for **retail Point of Sale (POS) do not need to encode Production Identifiers** in AIDC on the point of sale package.
FINAL THOUGHTS ..................
UDI EVOLUTION AND CHALLENGES

**Prerequisites**
- RIM – Regulatory data & systems
- Global Standards Adoption
- Regulatory Data Migration

**Compliance**
- Multi-year US implementation
- New regulations expected in several countries

**Efficiencies & Benefits**
- Supply Chain efficiencies
- Business opportunities
- Customer Offerings

**How do we …………………….. ?**

Utilize RIM to full potential
- Adoption (enforcement) of principles and policy

Drive continuous improvement?
- Refine & improve UDI processes
- Extend submission capabilities
- Extend team structure to support Geographies

Formalize identification of benefits?
- Benchmarking
- Future state / benefit planning
T H A N K  Y O U !

Jackie Rae Elkin
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LET'S TAKE HEALTHCARE FURTHER, TOGETHER
UDI Implementation

To continue, implementation experiences...

• UDI AIDC Implementation
  - one company’s implementation view to date, good and bad...

Tom Werthwine
Johnson & Johnson Supply Chain
Director, Industry Standards
UDI AIDC Implementation Experience

Tom Werthwine
Director, Industry Standards
Johnson & Johnson Supply Chain

October 2016
Johnson & Johnson - A Global Presence

• Global Leader in Health Care
• More than 275 Operating Companies in 60 Countries
• Selling Products in more than 175 Countries
• Approximately 128,000 Employees Worldwide
The Johnson & Johnson Credo

- Created in 1943
- Drives deep commitment to ethical principles
- Common set of values unifying diverse business
Johnson & Johnson Medical China

• Founded in 1994
• More than 3,500 employees
• Headquartered in Shanghai
• Offices in Beijing, Guangzhou, Wuhan, Nanjing, Jinan, Hangzhou, Chongqing, Chengdu, Shenyang, Xi'an, Tianjin
• Products for minimally invasive and open surgery, electrophysiology diabetes care, orthopedic & infection prevention
• Committed to technology, patient education and physician training
The Challenges

For Johnson & Johnson companies

• A large portfolio of medical devices and in-vitro diagnostics
• A large and complex “make organization” relying on internal and external manufacturers
• Multiple ways to print labelling and a diverse packaging portfolio
• Products that need direct part marking
• A dynamic merger, acquisition, and divestiture program
The Challenges

For Customers

• Many companies adopted the HIBCC bar code standard and some customers use the bar codes
• Some customers use linear only bar code scanners
• Customers new to AIDC have issues with scanning
• Customers adopting UDI want to pre-load GTINs before they received UDI-compliant product
The Process

**Build an Extraordinary team**

- Find the Champions of UDI
- Engage all functions

**Rely on external resources**

**Develop enterprise wide policies**

- GS1 bar codes
- GTINS in one place
- Document specific decisions
Recognize that AIDC in healthcare is an open system.
The Technology

Common mistakes in bar coding

New label designers often select EC200 Datamatrix and Code 128 and not the GS1 versions that use GS1 data carrier identifiers and group separators.

2.2.1 Function 1 Symbol Character (FNC1)

By definition in ISO/IEC 16022 GS1 DataMatrix uses a special start sequence to differentiate GS1 DataMatrix from other ISO/IEC Data Matrix symbols. This is achieved by using the Function 1 Symbol Character (FNC1) in the first position of the data encoded. It enables scanners to process the information according to the GS1 System Rules.

The FNC1 (codeword 232) has two separate uses in GS1 DataMatrix:
- Start character: FNC1 is a special, non-printable, character. It is often inserted using a double-byte “Latch to extended ASCII” but this is system dependent.
- Field Separator to separate application identifiers that are not in the predefined list. (See table 2.2.3-1)

⚠️ Important:
- In accordance with ISO/IEC 15424 - Data Carrier Identifiers (including Symbology Identifiers), the Symbology Identifier is the first three characters transmitted by the scanner indicating symbology type. For a GS1 DataMatrix the symbology identifier is Jd2.

Why important?
Used to parse data.
Send GTIN to GTIN field.
Send LOT to LOT field, etc.
The Technology

Collaboration with actual clinical users

Geisinger staff scans new label in OR, warehouse and patient room.
The Rewards

Patient Safety: A Credo Value

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers’ orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers’ orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.
The Rewards

High Quality: A Credo Value

End-to-end visibility of our product through GS1 GTINS (UDI), GLNs and AIDC technology
The Rewards
Supply Chain Efficiency

<table>
<thead>
<tr>
<th>Process</th>
<th>Example</th>
<th>JNJ use</th>
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<tbody>
<tr>
<td>Identify</td>
<td>GTIN = Product</td>
<td>GTINs in product master data; on labels</td>
</tr>
<tr>
<td></td>
<td>GLN = Location</td>
<td>GLN in customer data</td>
</tr>
<tr>
<td>Capture</td>
<td>Bar Code</td>
<td>Bar codes on some product directly; all</td>
</tr>
<tr>
<td></td>
<td>RFID</td>
<td>packaging</td>
</tr>
<tr>
<td>Share</td>
<td>EDI</td>
<td>EDI and GDSN with major customers</td>
</tr>
<tr>
<td></td>
<td>GDSN</td>
<td></td>
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<tr>
<td>Use</td>
<td>Traceability</td>
<td>Visibility for planning, track &amp; trace</td>
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<tr>
<td></td>
<td>POS/POU</td>
<td>and field action</td>
</tr>
<tr>
<td></td>
<td>RA submissions</td>
<td>Market access</td>
</tr>
</tbody>
</table>
The Rewards

“It’s not about the bar code, it’s about the data. . .”

Karen Longe
The Rewards Gained through Cooperation

Use the GS1 International Standards. Manage Device in the same way.

Share core data.

Healthcare is international!

谢谢
UDI Implementation

To continue, implementation experiences...

- UDI AIDC Implementation
  - one company’s implementation view to date, good and bad...

Stan Malinowski
Medtronic, Inc.
UDI Lead for GS1 Standards and Marking
UDI AIDC Implementation Experiences

28th Global GS1 Healthcare Conference

October 20, 2016
Stan Malinowski
Agenda

UDI Approach

• Where to Begin?
• Critical Success Factors
• Program/Project Management
• AIDC in Healthcare
• Data Quality and Management
• Information Publication
Where to Begin?

Get Educated

- UDI Final Rule
- GS1, HIBCC and ICCBBA standards
- IMDRF UDI Guidance
- EU Recommendations and others

Get Engaged

- Medical device industry groups
- Talk to your peers
- Standards organizations
- Implementation workgroups
- Industry projects
- Talk to the agency
Critical Success Factors

Organizational Awareness

- Understand UDI
- Identify beneficial business impact
- Recognize consequence of non-compliance

Organizational Support

- Engage senior leadership
- Secure resources to implement UDI changes
- Prioritize within the business
Establishing the Project

**Scope**
- Define what is in and out of scope
- Minimize scope creep
- Include label and data updates, data management, and equipment

**Schedule**
- Develop schedule based on availability of resources and compliance dates
- Priority by product risk class and impacts

**Resource**
- Establish consistent project management
- Build cross-functional team with company and industry knowledge
- Consider extended team of employees, temporary staff, and consultants

**Budget**
- Secure consensus that UDI compliance requires investment
- Determine available expense and capital budgets to support the project
Understanding the Initiative

**US Regulations**
- UDI
- Labeling
- Conforming amendments

**Global Regulations**
- Regional variation will be challenging
- Define strategy for regional compliance

**Device Labeling**
- Labeling artwork may need new AIDC (Automatic Information and Data Capture) marking
- Space may be an issue due to other regulatory requirements
- Consider options when developing an AIDC policy

**Direct Marking**
- Direct part marking may be required
- Understand the regulation
- Understand your capabilities
- Understand the exemption process when available
Understanding the Initiative

Data Quality
- Information may be unstructured
- Data that may have been for internal use now will reside in an FDA database
- Analyze the current state vs. future state and develop a plan

Data Management
- Creation, processing, storage and publication of data
- New platforms may be required
- Modification to existing data management systems may cause disruption in the business

Data Governance
- Data governance will be needed to control enterprise data
- Keeping the data quality level

Business Process
- Sustainable business processes will enable compliance
- Keeps focus after the project is over
AIDC in Healthcare

Application of UDI

• Multiple device package levels

• Preferred formats for distribution vs. point of use, or by customer

• Content requirements create space challenges

• Label application for inner and outer boxes
AIDC in Healthcare

Application of UDI (Details)

• Printing on primary packaging substrates: inkjet, thermal transfer

• Printing software inconsistencies

• Barcode verification for AIDC quality
  - Process Controls Variables & Process Capability

• Documentation in Device History Record
AIDC Structure is Important

- What’s in our GS1 Barcodes?
- Correct Use of AIM Identifiers
  - JC1 for GS1-128
  - Jd2 for GS1 DataMatrix
- Efficient Use of Application Identifiers - Order Matters
  - UDI application Identifiers
    - (01) GTIN the Device Identifier
    - 1 or more Production Identifiers
      - (17) YYMMDD Use By Date or (11) YYMMDD Manufacturing Date
      - (10) Batch Number and/or (21) Serial Number
Why Data Quality?

- Compliance
- Accuracy
- Efficiency
Definition of Data

What is Product Data?

- Attributes
- Item Level
- Packaging Level
- Compliance and Standards
- “Data Dictionary”
## GTIN Hierarchy

<table>
<thead>
<tr>
<th>Company</th>
<th>Reorder Code</th>
<th>UOM</th>
<th>QOM</th>
<th>GTIN</th>
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<td>9255</td>
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<td>100</td>
<td>30884521021918</td>
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</tbody>
</table>
Infrastructure and Systems

Starting Out...
- Manual interactions
- Un-validated
- Lack of definition

- Disconnections
- Data degradation
- Multiple requirements
Future State

Strategic Approach...
- Defined processes
- Data quality
- Validated interactions
- Model of publication and consumption
Data Publication

Best Practices...

- Global Attribute Spec for all UDI Data
- Scalable for UDI and GDSN publications
- Future applicability OUS
- Other Data Pool applications
Why Data Pool / GDSN for UDI?

**Service**
- Competency for transmitting data
- Attribute definition
- Existing supplier

**Compliance**
- Compliance Reports
- Traceability of submission
- Validation of software

**Advantage**
- One feed to your data pool may serve multiple recipients – take advantage of scale!
- Investigate overlap with other ‘product catalogs’
Take-away

Key Points to Remember

• Understand the initiative – establish project

• UDI value is in the data

• AIDC implementation is different in Healthcare (Structure Matters)

• Data Pool / GDSN for UDI has advantages

• **Start early!**
To conclude... audience questions...