LEARNING UDI COMMUNITY

AHRMM
Advancing Health Care through
Supply Chain Excellence

Unique Device Identification (UDI) Barcode Scanning at the Point of Care Work Group Report

WWW.AHRMM.ORG/LUC

BACKGROUND:

The health care field has long struggled with disparate data sources and lack of data standardization, with each party to the supply chain— manufacturers, distributors, group purchasing organizations (GPOs), and providers—speaking their own language when it comes to device identification. The use of different device identifiers has jeopardized patient safety as it limits the ability for health care stakeholders to accurately identify and track recalled devices and device-related adverse events.

Furthermore, as health systems and hospitals seek to align with the Patient Protection and Affordable Care Act (ACA) and payment reforms, they need accurate and timely data on how products used in patient care impact clinical and financial outcomes. Lack of standardization in device identification has been a major roadblock to these efforts.

On September 24, 2013, the U.S. Food and Drug Administration's (FDA) issued the final Unique Device Identifier (UDI) rule intended to adequately identify medical devices through their manufacturing, distribution and use[1].

The UDI/CQO Connection:

The Association for Health Care Resource & Materials Management (AHRMM), a professional membership group of the American Hospital Association (AHA), is the leading organization for the health care supply chain field.

The AHRMM Cost, Quality, and Outcomes (CQO) Movement was launched in 2013 to advance the role of health care supply chain in delivering higher quality care at a more affordable cost and in a manner that delivers the highest value to patients. The CQO Movement explores the inter-relationships between cost, quality and outcomes as opposed to the more historic view in which these factors were considered separately, often by different functions within the hospital environment (e.g., clinical, financial). The CQO Movement encompasses all activities designed to support both better health and patient care across the entire patient journey.

UDI ANATOMY 101

A UDI consists of two parts:

1. **A *Device Identifier (UDI-DI)***, which is the mandatory, fixed portion of a UDI that corresponds to the model or version of a device.

2. **A *Production Identifier (UDI-PI)***, which is the variable portion of a UDI that identifies one or more of the following when included on the label of a device: lot/batch number, serial number, expiration date, manufacturing date and donor identification number.

Use of device UDIs has the potential to impact CQO in a variety of ways, from better recall tracking and adverse event reporting, to improved charge capture and billing. But the full value of UDI can only be achieved if health care provider organizations can capture UDI data from products and use it within their internal health information technology (HIT) systems (e.g. clinical, financial, supply chain).

[1] For more information on the FDA's UDI requirements, visit https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system

The Opportunities and Challenges of Barcode Scanning:

52% of providers are not scanning the manufacturers' UDIs at the point of care.

Because barcode scanning at the point of use improves product data capture accuracy and efficiency, compared with manual data entry, it has become a health care field best practice. Health care providers have been working to capture device UDI data via barcode scanning so that it populates their electronic health record (EHR) system. That way, the patient record includes complete data on all UDI labeled products used during the continuum of care.

In addition to improving patient care and safety, scanning at the point of use helps health care provider organizations meet Promoting Interoperability (PI) requirements[2].

While UDI capture in the EHR is the goal, health care providers have voiced a number of challenges with barcode scanning. Common problems include the inability to identify the correct barcode to scan on a product's packaging, barcodes failing to scan and lack of HIT system integration.

The AHRMM LUC UDI Barcode Scanning Survey:

The AHRMM Learning UDI Community (LUC), as a health care collaborative effort, is designed to address issues impacting the implementation and use of UDI by developing a common understanding and approach to UDI adoption within the health care setting.

52% cited multiple barcodes on product packaging as a barrier to UDI scanning.

To better understand the barriers to UDI scanning at the point of care, AHRMM conducted the Barcode at the Point of Care Survey. AHRMM, the Association of periOperative Registered Nurses (AORN), Healthcare Purchasing News (HPN), and a number of group purchasing organizations (GPOs) and manufacturers distributed the survey, capturing a wide net of provider participants. Over 400 individuals across a wide range of hospitals and health care organizations, ranging in size from <100 beds to over 1,000 beds, completed the survey, which was administered August 2018.

This report contains key findings from the survey; perspectives from manufacturers; best practices for providers, suppliers, and HIT vendors (e.g. Enterprise Resource Planning, Electronic Health Record) for overcoming current obstacles to UDI adoption and use.

KEY FINDINGS:

Which Barcode to Scan?

According to those surveyed, two of the most common barriers to UDI scanning at the point of care are related to the inability to identify which barcode on product packaging contains the UDI.

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[2] For full PI requirements, visit the CMS website: www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2019ProgramRequirementsMedicare.html

Some product packaging has multiple barcodes and each barcode can contain different information.

Clinicians and others find it challenging to determine which barcode to scan in order to capture the product's UDI data. In some cases, the clinician must scan more than one barcode to capture all the data needed to populate the EHR and/or manually document additional information not contained within the barcodes.

Among survey respondents, 52 percent cited multiple barcodes on product packaging as a barrier to UDI scanning, while 22 percent said the barcode containing UDI information is not easily identifiable (see Appendix A).

48%
say unreadable barcodes are a barrier to successful UDI capture.

Barcode Breakdowns:

Those health care providers surveyed also reported issues with the barcodes themselves. Two of the most common challenges in this category were barcodes that could not be read, with 48 percent of respondents citing this as a barrier, and stacked/separated barcodes on product packaging, with 47 percent of those surveyed reporting this problem.

What Providers Are (Aren't) Scanning:

Half of survey respondents (50 percent) stated they are not scanning medical/surgical supplies into the EHR. This leaves a significant gap in terms of consistent and accurate UDI capture. Manual entry of the UDI significantly increases the risk of documentation errors that could negatively impact patient safety. Extrapolation of manual data input accuracy tests suggests that an error will occur in every 3-5 devices keyed into the EHR system. These errors could impact the ability to accurately report adverse events, identify recalled product and cause other patient safety-related issues.

50/50
split between those providers scanning medical/surgical supplies in to the EHR and those that are not.

For those health care organizations scanning UDI at the point of care, respondents reported a very low rate of scanning for non-sterile, hospital-sterilized implants (e.g. inside sterile trays). This is because the product packaging is removed prior to the products being sterilized and delivered to the OR.

Preferred Barcode Format:

Health care providers were questioned on their preferences for a barcode format, with proposed formats including linear concatenated and two-dimensional (2D) Data Matrix. Of those respondents currently scanning barcodes at the point of care, 43 percent said they preferred linear concatenated barcodes, while 90 percent said they would support 2D Data Matrix as the UDI standard (see Appendix A).

90%
would support 2D Data Matrix as the barcode standard.

Over half of those currently scanning (52 percent) said their software/scanner would support 2D Data Matrix barcodes. Among the remaining respondents, 37 percent said they were unsure if

they had the technology in place to support 2D Data Matrix, and 11 percent said their software/scanner was incapable of reading the 2D Data Matrix format.

Barcode Placement and Identification:

Because a main challenge is finding the barcode containing the UDI on product packaging, survey respondents were asked if there was a desired location for placing the barcode containing the UDI and accompanying identifiers. Over half of respondents (59 percent) said the front of the package is the preferred location.

Those surveyed were also asked if it would be helpful for manufacturers to print an icon that represents UDI or the word "UDI" next to the barcode to help clinicians identify it. The vast majority (86 percent) agreed that this would be helpful for identifying the correct barcode at the point of use.

86%
say a UDI icon or the word "UDI" next to the barcode would make it easier to identify at the point of care.

HIT Integration: Making the Connections:

Lack of IT integration cited as a main challenge to UDI capture.

Many health care organizations are working to establish their ERP system as the "source of truth" for supply related data, including the UDI-DI data. The UDI-DI is subsequently fed into the EHR where it is matched with the UDI-PI when the product is scanned at the point of care.

Although in theory this flow of data from the ERP to the EHR may improve the accuracy and efficiency of populating product information in the patient record, survey respondents cited lack of IT integration as a main challenge to point of care UDI capture.

Manufacturer Support:

The survey also assessed whether health care providers knew how to obtain support from manufacturers when they experienced issues with barcode scanning. Most respondents (64 percent) said they did not know how to contact manufacturers for resolution of barcode or related data issues.

Health care providers were also asked whether suppliers were knowledgeable about UDI/barcodes in general, they responded with a 50/50 split on whether manufacturers were knowledgeable in this area.

64%
of providers don't know how to contact manufacturers with barcode or data issues.

THE MANUFACTURER PERSPECTIVE

Because the survey was focused on health care providers and their perspectives on the situation, the Learning UDI work group felt it was important to also garner insights from manufacturers on the challenges they face when making changes to product packaging, including barcodes. Manufacturers do not format and place barcodes in an arbitrary manner, conversely most have long-established processes and systems in place that dictate the number of barcodes and their placement on product labels. Furthermore, a packaging change is not

a "flip of a switch" process, but rather a complex series of procedures involving many key stakeholders (internal and external) and has regulatory ramifications.

MULTIPLE BARCODES

With over half of providers surveyed (52 percent) citing multiple barcodes on product packaging as a barrier to UDI scanning, it is important to understand what drives manufacturers to place multiple barcodes on their products. Here are a few reasons for this practice.

- **Customer demand:** Some manufacturers place both 2D Data Matrix and concatenated or stacked linear barcodes containing the UDI on packages because of customer limitations in reading one type of barcode or the other.
- **Inventory management:** Some manufacturers have set up their inventory management systems in a way that uses internal manufacturing barcodes on the package to manage product flow.
- **Diagnostics products:** Disposable products that are used in conjunction with a piece of diagnostic equipment generally have two barcodes – one containing the UDI and a second barcode that the machine scans to confirm the disposable product's compatibility with the machine.
- **Products manufactured by a third party:** Some medical device companies rely on third parties to manufacturer their products and this contract manufacturer might place an additional barcode on the product for any variety of reasons (e.g. to support internal processes, distribution, etc.).
- **Implant labels:** Manufacturers of implants may provide multiple labels to their customers to facilitate manual documentation for different purposes (e.g. patient record, charge capture) when the provider organization does not have a scanning system in place.

Barcode and Other Packaging Changes:

Those health care providers surveyed voiced their preferences for a single barcode containing the UDI on the front of packaging. They also indicated growing support for the 2D Data Matrix format. When asked if they could deliver this, manufacturers offered insights into what these changes would entail for them.

- Multiple stakeholders: Any change to product packaging and labeling requires the involvement of many groups throughout a manufacturer's operations, including labeling, engineering, packaging, legal, regulatory, planners/buyers, warehouse, etc. If the product is sold in multiple countries, then overseas affiliates must also be involved in the change.
- Complex processes: From the time a decision is made to change packaging to the point where that new packaging is at the point of care can take months and even years. The manufacturer must document all the steps in its systems. Here is a snapshot of the typical process:

1. Secure time on the labeling group's schedule so a designer can create the new label (amidst all their other priorities and responsibilities related to normal lifecycle management changes and new product introductions).
2. Once the labeling group has designed the new label, route it through all the necessary stakeholders (as cited above) to secure their feedback, make changes, and finalize the design.
3. Submit the change to the regulatory bodies of the markets impacted (e.g. FDA). If the product is sold in multiple countries, the manufacturer will need to route the change through regulators for each country and all will have to agree to the change.
4. Once all approvals have been secured, the manufacturer must have a printer create the artwork/new printing plates. Depending upon the extent of the change, the company might also have to change equipment on its packaging line. For example, a different barcode format may necessitate the purchase and installation of new capital equipment (e.g. printers, lasers) on the production line.
5. In the case where a manufacturer adds a UDI icon the manufacturer will also have to change the product's insert – adding a description of this identifier. This insert too must be routed through the same extensive review process as the label.

Proposed Best Practices for UDI Scanning

Based on the above complex processes and the survey's finding, it is imperative for device manufacturers, health care providers and HIT vendors to collaboratively address these issues because no one party can overcome these challenges. In accordance with the survey findings, the Learning UDI Barcodes at the Point of Care Work Group recommends the following leading practices for UDI scanning.

Recommendations for Manufacturers

- Review internal processes and accrediting agency guidelines for alternatives to putting multiple barcodes on a package. Utilize qualifiers[3] where applicable as an alternative to additional barcodes. Per FDA draft guidance, qualifiers should follow the UDI.
- If multiple barcodes are unavoidable, health care providers request manufacturers use the International Organization of Standards (ISO) symbol for UDI to assist caregivers in determining which barcode contains UDI information. Approval of this voluntary ISO symbol (assigned #15223) for use when multiple barcodes are present on the label is slated for the end of 2019.
- Perform appropriate testing on barcodes to ensure they meet all requirements before placing them into production.
- The Primary Device Identifier field in the FDA's Global UDI Database (GUDID) should include the DI for the lowest packaged item that bears the UDI. If the Primary Device

[3] GS1 standards use the term "Application Identifier"

Identifier represents a single device multi-pack, and the single devices do not include a UDI or a barcode on the package, then assign a Unit of Use DI to the individual items and record this Unit of Use DI in the Unit of Use DI field in GUDID. The Unit of Use DI does not appear on the label but is an identifier that clinical staff and Supply Chain use to account for a single device when the UDI is labeled on a higher level of packaging. Clinical staff and Supply Chain obtain the Unit of Use DI information from the FDA's AccessGUDID portal or the manufacturer (see Appendix C).

- Have a formal process for handling customer questions and issues related to UDIs, barcodes and GUDID inquiries. Populate the "customer contact" field in the GUDID with the information necessary to trigger that process. Avoid putting an individual as the contact given the challenge of keeping this information current. Ensure all call center staff members are trained to escalate the customer issue to the qualified person(s) for assessment and correction, if applicable.
- Develop a formal process to correct and update the GUDID as quickly as possible.
- Create multi-disciplinary teams representing sales, operations and compliance and conduct site visits to gain a clear understanding of how customers are using the UDI and its impact on clinical workflow and patient safety.
- Print only the UDI for that specific unit of measure on the package (e.g. don't put the "each" and the "box" codes on an "each" package).
- Standardize to a single issuing agency[4] (IA) to avoid having both a GS1 and a Health Industry Business Communications Council (HIBCC) UDI on the same product label.

Recommendations for Health Care Providers

- Ensure all stakeholders understand the importance of point of care barcode scanning and how manual entry leads to documentation errors which pose a patient safety risk.
- Train staff on scanning techniques for dealing with multiple barcode packaging:
    - Scan the barcode adjacent to the human readable component of the UDI to identify the correct barcode. GS1 barcodes containing the UDI typically start with an (01) and HIBCC barcodes start with "+" followed by a letter (see Appendix A for sample barcodes).
    - Have a formal process for inputting UDI information into the EHR in the event of a barcode scanning failure. Make sure the process includes retaining the packaging of the failed barcode for diagnosis and follow up.
- Develop the internal capability to test and diagnose barcode issues, as well as a formal process for escalating those issues to the manufacturer and the FDA. Make sure scanners are programmed to read both 2D Data Matrix and linear barcodes.
- Educate manufacturers and others within the health care field that the health care supply chain extends into the patient record, outcomes research databases and impacts billing

[4] An FDA-accredited issuing agency (IA) is an organization that operates a system for assignment of UDIs according to the UDI Rule. FDA has accredited three issuing agencies – GS1, HIBCC and ICCBBA.

and compliance requirements. Invite them to come onsite and follow their product through the entire supply chain and clinical workflow process. Challenge them to work with providers to develop mutually beneficial solutions.

- Include UDI and barcode requirements in contractual agreements (e.g require manufacturers to follow FDA guidelines when publishing data in the GUDID, ensure data includes all units of measure (packaging string) and that barcodes can be easily scanned.) These data points can be used as metrics when selecting manufacturer partners.
- Include the UDI-DI for all levels of packaging in the item masters and/or data warehouse programs. Interfacing of this data ensures availability to scan at the point of use.
- If inaccurate or incomplete data is found in the GUDID, report it to the manufacturer using the "Customer Contact" information populated in the GUDID. Inaccurate information can also be reported to the FDA help desk.
- Work with your software application providers to ensure their software is configured to read all information (including hidden characters) contained within a barcode. It should be able to parse and apply logic to all Qualifiers, including the logic to ignore those Qualifiers used exclusively for internal manufacturing processes. This will prevent the need for health care providers to program each individual scanner.
- Challenge software application providers to collectively improve interoperability within and between systems to fully transact UDI. As well as to develop mechanisms to effectively manage UDI-DI changes.

Recommendations for Software Application Providers: ERP, EHR, Inventory Management and Other Related Third-Party Solution Providers

- Configure software to read all information (including hidden characters) contained within a barcode. Be able to parse and apply logic to all Qualifiers including the logic to ignore those Qualifiers that are for internal manufacturing use only. Make sure the parsing program identifies delimiters (e.g. GS1 FNC1 Group Separator (GS)) after variable length fields.
- Software application provider systems must accommodate UDI-DI, UDI-PI and GUDID data for every level of packaging not just unit of purchase or unit of use. They also should provide functionality for providers to track UDI-DI changes.
- Software applications meet CEHRT (Certified EHR technology) requirements. https://www.healthit.gov/sites/default/files/170%20315%28a%29%2814%29%20Implantable%20Device%20List.pdf Users should verify requirements have been met.
- Software application providers should collectively improve interoperability within and between systems to fully transact UDI.

Recommendations for External Scanner Vendors

- Scanners should function as the input device and read all characters contained in the barcode, including hidden characters. Logic should be applied at the software

application level so that configuration at the scanner level is not required.

- Be sure to include the appropriate configuration barcode images for the various keyboards used in the health care field.

Recommendations for Regulatory Agencies:

- The Office of the National Coordinator for Health Information Technology (ONC) should consider subsidizing the investment in optical scanners that can effectively read 2D Data Matrix to facilitate input of UDI into the EHR and to promote adoption of a 2D Data Matrix standard across health care. This would provide the opportunity for the health care field to maximize their existing investment and realize the benefits of their EHR infrastructure.

CONCLUSION

The ability to capture UDI data at the point of care for documentation in the electronic health record (EHR) is critical to achieving the goals of the FDA's UDI vision, which includes improving patient safety, modernizing device post- market surveillance, and facilitating medical device innovation[5].

Standardized product data is also critical to driving improved Cost, Quality, and Outcomes (CQO) in health care. If health care organizations are to deliver improved patient outcomes at an appropriate cost, they must have accurate and timely product data on which to make decisions.

The ability to capture UDI data is also necessary for hospitals to meet Promoting Interoperability (PI) requirements, while ensuring all members of the patient's care team have access to the complete medical device history throughout the delivery of care. The UDI is the key to providing patient- centered care through the tracking of product use, recalls, and outcomes.

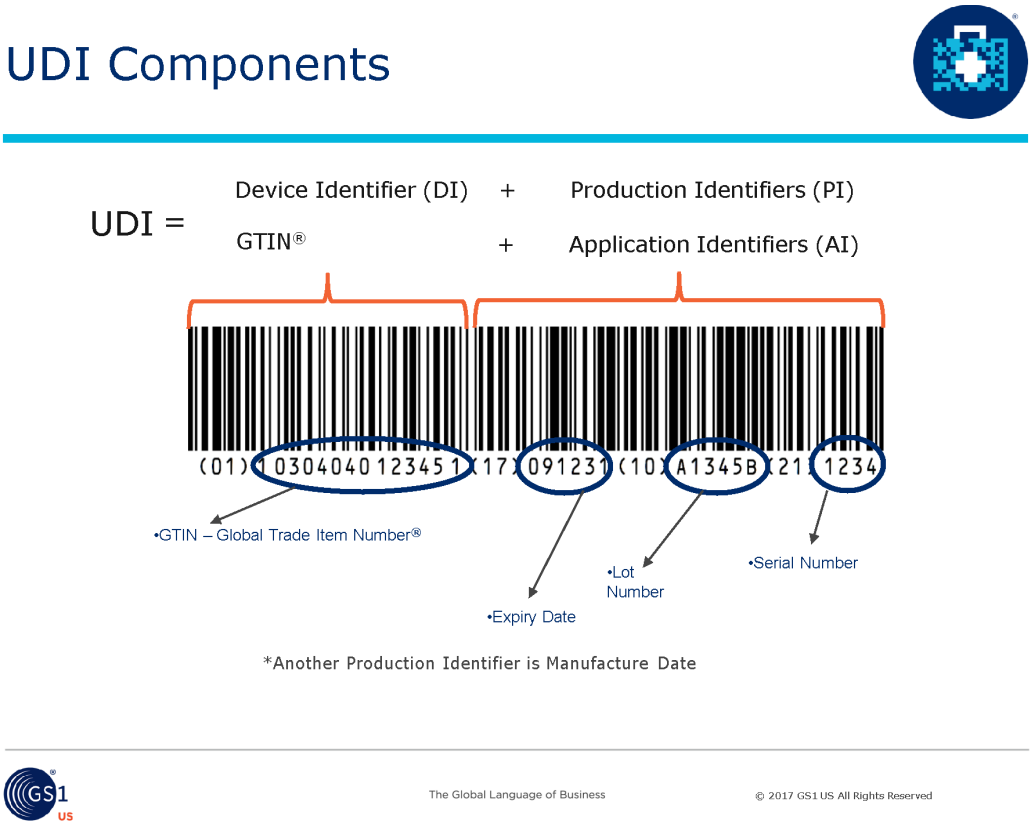
As evidenced in this survey, health care providers are struggling to automatically capture UDI data at the point of care. Manufacturers, providers and HIT system vendors must collaboratively overcome these challenges so that providers can capture and view UDI data in an accurate, easy, and efficient way that does not add to their workload. The solution must be designed so that the provider can focus on their main responsibility –- caring for the patients – with UDI capture as a simple step that does not distract from or disrupt care delivery but provides information about medical devices.

We urge stakeholders to implement the recommended practices in this report. They can also reach out to FDA-accredited issuing agencies (IA), including GS1, HIBCC, and International Council for Commonality in Blood Banking Automation (ICCBBA), for additional resources.

Furthermore, the AHRMM Learning UDI Community (LUC) has a vast repository of guidance documents, white papers, work group reports, and case studies from individual health care

[5] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

organizations with best practices for tackling issues related to UDI implementation.

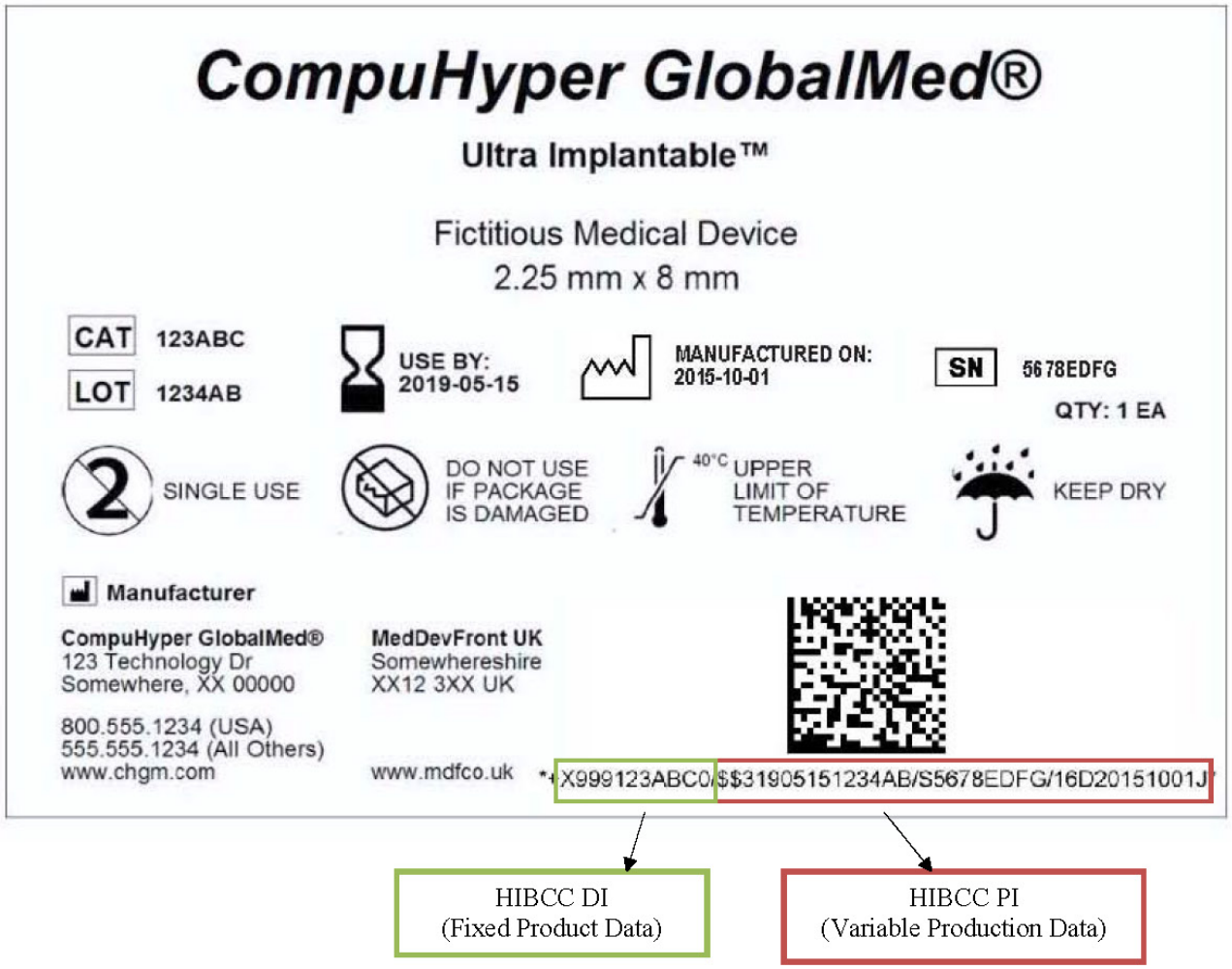


APPENDIX A: EXAMPLES OF BARCODE TYPES

Health Industry Business Communications Council
2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
FAX 602-381-1093
www.hibcc.org

HIBCC UDI Label Examples

DataMatrix

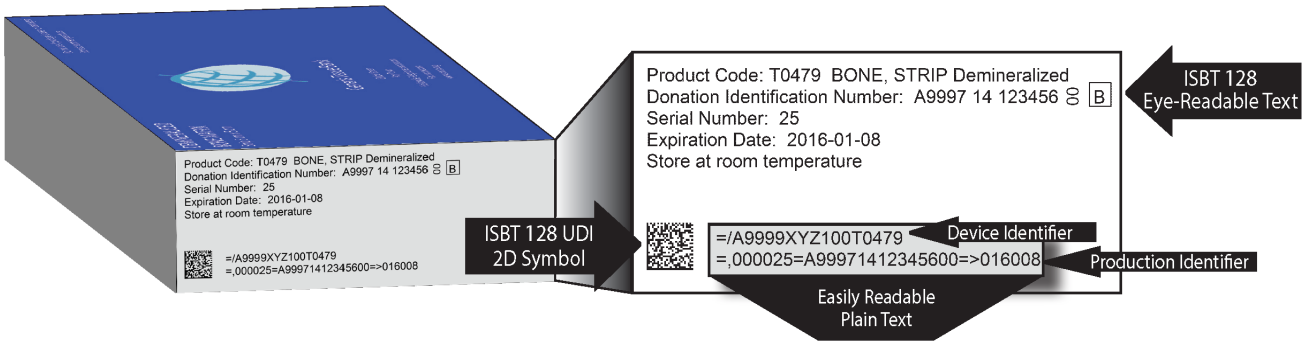


GS1 UDI Label

USING ISBT 128 UNIQUE DEVICE IDENTIFIER ON MEDICAL DEVICES THAT CONTAIN HUMAN TISSUE

ISBT 128 More than Identification

Medical devices containing Human Cells, Tissues, or Cellular and Tissue-Based Products (HCT/P) labeled using ISBT 128 will provide UDI information, including the Donation Identification Number, in a standardized electronically-readable format and in eye-readable text. These illustrations show examples of how the information may be presented. The two-dimensional symbol contains the critical tracking information. Receiving systems should be programmed to scan and interpret this symbol to provide optimal efficiency and accuracy.



Item	Recommended Abbreviation(s)	What it Identifies
Donation Identification Number	DIN	This identifier links the product to its donor (the Distinct Identification Code as required by 21 CFR 1271.290(c)).
Product Code	Prod Code or PC	This code identifies the type of product (e.g., bone powder or a pre-sutured tendon).
Pack Number or Serial Number	Pack or SN	This code uniquely identifies a specific product for a given DIN and Product Code.
Expiration Date	Exp or Exp Date	The date on which the product should no longer be used.
Manufacturing or Production Date	Mnf Date or Prod Date	The date on which the product was made.
Lot Number	Lot No. or LN	This identifier links to a production record of the process or the tissue.
Device Identifier	DI	The FDA UDI Device Identifier (identifies the specific version or model of a device and the labeler of the device).
Production Identifier	PI	The FDA UDI Production Identifier (information that more precisely identifies the device).

GS1 and ICCBBA Joint Guidance recommends use of ISBT 128 on medical devices containing HCT/P.

HIBCC Label

ICCBBA LABEL

APPENDIX B: REGULATORY REQUIREMENTS SUPPORTING UDI

FDA

www.AccessGUDID.gov

ONC

The ONCs requirements for Implantable Devices List CEHRT §170.315(a)(14) can be accessed on HealthIT.gov. (https://www.healthit.gov/sites/default/files/170%20315%28a%29%2814%29%20Implantable%20Device%20List.pdf)

CMS

Promoting Interoperability https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

Single Item
(Unmarked)

Tray of 25
(Full UDI Marked)

Case of 1000
(Full UDI Marked)

Unit of Measure (Package Level)	ANSI UOM	Device Identifier (DI)	Qty	Units at Next pkg level	Contains DI Package
Single Item	-	UOU DI (Unmarked)	1	-	-
Tray (Lowest Pkg Level with DI)	TY	Lowest Pkg Level DI (Full UDI Marked)	25	-	No
Case	CA	Case Level DI (Full UDI Marked)	1000	40	Tray

APPENDIX C

Unit of Use (UoU) Example

Access the Unit of Use Explained webcast and presentation for more information.