Harmonizing Unique Device Identifiers: Issues and Solutions

Background:

Unique Device Identifiers (UDIs) serve important regulatory and supply chain functions for medical devices. They allow for tracking of devices throughout the global supply chain to the patient and provide global visibility to device adverse event reporting and a better means to perform post-market surveillance, thereby enhancing patient safety.

Increasingly, UDI requirements such as Device Identifier triggers (rules requiring creation of a new Device Identifier) are not globally harmonized which is causing a proliferation of Device Identifiers to be created and registered globally. Additional and competing concepts, such as Basic UDI-DI and Master UDI-DI are confounding the problem. Here are some specific issues medical imaging manufacturers experience with UDIs stemming from a lack of harmonization.

Issues:

- Lack of harmonization within jurisdictional UDI databases leading to additional administrative burden
- Rules built into the regional databases that cause creation of new device identifiers when a data element is changed
- Lack of direct "translation" between different Issuing Entities
- Varying definitions of terms and concepts between jurisdictions causes creation of new UDI-DIs to accommodate different rules
- New UDI automatic identification and data capture (AIDC) symbology requirements are emerging in some jurisdictions without regard for the UDI issuing entity standards used in healthcare or the user ability to read certain symbologies across geographies in the global supply chain.
- Requirements for UDI direct marking of devices are not consistently applied across geographies, and some geographies have delayed publishing those requirements until there is a better understanding of direct marking implementation.
- There continues to be a lack of focused education for healthcare delivery organizations. Therefore, healthcare delivery organizations are slow to adopt UDI because their systems are not prepared to consume the UDI-DI proliferation according to the standards used to create UDI.

All of the above-mentioned issues are contradictory to the spirit of UNIQUE Device Identification and potentially hamper the global interoperability of the UDI system. These

issues affect traceability of medical devices, adverse event reporting, global data sharing and transparency, and ultimately result in inefficient processes, higher cost and a decrease of patient safety.

Solutions:

- When implementing UDI Systems, jurisdictions should adhere to the International Medical Device Regulators Forum's (IMDRF) Unique Device Identification guidance document N7: 2013 and associated N48:2019 Unique Device Identifier (UDI) Application Guide.
- Additionally, jurisdictions should implement IMDRF guidance on data elements N53:2019, Use of Data Elements Across IMDRF Jurisdictions.
    - Update data elements in a table
- Support an IMDRF workshop on Unique Device Identification.
- Support updates to N48 and N53, which will add detail to support a globally harmonized approach to the implementation of a UDI system.
- Implement according to UDI Issuing Entities together with relevant IEC and ISO standards.

Annex: Examples of Issues

This section provides some of the specific examples for the issues cited from industry stemming from a lack of harmonization.

Issue #1 - Lack of harmonization within jurisdictional UDI databases leading to additional administrative burden (2 examples provided: Latex and License/Authorization/Registration number)

Grouper	Source	Data Element	Description
Latex	EU	Containing Latex	An indication of whether the device or packaging is labelled as containing natural rubber that comes in contact with humans
Latex	IMDRF	Critical warnings or contraindications	a. [e.g.: Labeled as containing latex? (Yes/No),
Latex	US	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber". Choose Yes/No from the drop down list.
License/Auth./Reg. number	EU	Single Registration Number	The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfill its obligations under Article 29. Issued in accordance with Article 31(2) (MDR) and Article 28(2) (IVDR)

License/Auth./Reg. number	IMDRF	License and/or marketing authorization or registration number	
License/Auth./Reg. number	US	FDA Listing Number	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f). Enter all relevant listing numbers that enable the labeler to commercially distribute the given version or model of device. Listing number is optional for HCT/P devices with a BLA premarket number.
License/Auth./Reg. number	US	FDA Premarket Submission Number Supplement Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the Submission types are: 510(k), De Novo, PMA, PDP, HDE, BLA, and NDA. Supplement Number: Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP. Enter current FDA Premarket Submission Number(s). Each DI record represents a version or model of a device. For each DI record, you must submit the premarket authorization number (if the model or version was originally approved in a PMA, HDE, BLA, or NDA supplement) and the supplement number through which you originally obtained approval or clearance or were granted classification for the version or model identified in the DI record, as required by 830.310(b)(11). FDA Premarket Numbers should be verified with the corresponding FDA premarket database to make sure the Number is consistent with the device record. Device records should be updated with additional numbers in the future, as needed. FDA Premarket Supplement number is collected as a separate field. Example: De Novo #123456 should be entered as 'DEN123456.' Example: PMA # P190010/S46 should be entered as 'P190010' in the 'FDA Premarket Submission Number' field and '46' in the 'FDA Premarket Supplement Number' field.

Issue #2 - Rules built into the regional databases that cause creation of new device identifiers when a data element is changed

	FDA	GS1	EU	IMDRF	KR
Change in the Issuing Agency (e.g., GS1 or HIBCC)	X				
Change in the Device Count (quantity)	X	X	X	X	
Change in the Brand Name (this is the "family" name for a product)	X	X	X	X	X
Change in the version or model number on the device label or accompanying packaging used to identify a category or design of a device.	X		X	X	
Change in the device classification of a kit (e.g., Class III to Class II)	X				
Change in the Single Use status of a device or accessory	X		X	X	
Change in the Latex Content (i.e., required to be labeled as containing Latex)	X				
Change in the MRI Safety Status	X				
Change in the Device Packaged as Sterile Status (i.e., device/accessory is packaged sterile or if a device/accessory requires sterilization prior to use)	X		X	X	
Change in the product form, fit or function or intended use		X	X		
Change in the dimensional or gross weight		X			
Addition/Removal of a certification mark		X			
Time Critical or promotional product		X			
Price on Pack		X			
Change in packaging configuration		X			X
Critical Warnings or Contra-indications			X	X	X
Change in the Basic UDI-DI			X		
Change in the Clinical Size				X	
Change in manufacturing company					X
Change in license owner					X

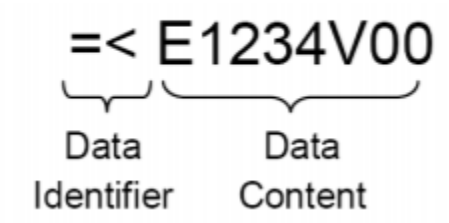
Issue #3 - Lack of direct "translation" between different Issuing Entities. The 3 issuing entities include GS1, HIBC and ICCBBA. The Formats for each issuing entity vary and are not directly translatable. For example:

GS1 – Global Trade Identification Number: GTINs may be eight, 12, 13, or 14 digits long, and each of these four numbering structures are constructed in a similar fashion, combining Company Prefix, Item Reference and a calculated Check Digit (GTIN-14 adds another component- the Indicator Digit, which can be 1-8). GTIN-8s will be encoded in an EAN-8 barcode. GTIN-12s may be shown in UPC-A, ITF-14, or GS1-128 barcodes. GTIN-13s may be encoded in EAN-13, ITF-14 or GS1-128 barcodes, and GTIN-14s may be encoded in ITF-14 or GS1-128 barcodes. The choice of barcode will depend on the application; for example, items to be sold at a retail establishment could be marked with EAN-8, EAN-13, UPC-A or UPC-E barcodes.

HIBC - The HIBC LIC Primary Data Structure format encodes a "+" identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single-digit Check Character (C).

ICCBBA - Data structures generally comprise two elements: • Data identifier: a two or three-character code that identifies the data structure)and • Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys the unit is A, RhD positive).

Figure 1 Data Structure



Data characters are the individual ASCII characters that make up the data content. Some information may be conveyed at different levels of detail in different data structures.

For example, the volume of a blood product may be conveyed in two data structures:

- Product Code [Data Structure 003] as part of the Final Volume attribute group (e.g., equal to or greater than 200 mL to less than 400 mL) or
- Dimensions [Data Structure 029] as a specific value (e.g., 223 mL).

Issue #4 - Varying definitions of terms and concepts between jurisdictions causes creation of new UDI-DIs to accommodate different rules

The term model/brand is of particular concern because these terms differ between jurisdictions. For example, in the US, this term comes from the information found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications,

performance, size, and composition within limits set by the labeler. In the US this is a required term, whereas in the EU, this term is optional, if applicable, and is used to describe the device model, reference, or catalogue number. There are a number of terms that follow this logic of one jurisdiction making the data element mandatory whereas other jurisdictions make the data element as optional (or applicable).

Issue #5 - New UDI automatic identification and data capture (AIDC) symbology requirements are emerging in some jurisdictions without regard for the UDI issuing entity standards used in healthcare or the user ability to read certain symbologies across geographies in the global supply chain.

Radio Frequency Identification (RFID) has become a standard of marking particularly when it comes to direct marking. RFID systems can be broken down by the frequency band within which they operate: low frequency, high frequency, and ultra-high frequency. There are also two broad categories of systems—passive and active RFID

Similarly, there are several barcode technologies which may be used depending on the item being identified. In addition to the endorsed issuing agencies, a medical device may bear a UPC code as a means for complying with UDI – yielding a total of 4 barcode formats available to identify a medical device through the supply chain.

Established Standard:	For Identification of:	Barcode Symbology:
UPC-A or UPC-E	items for sale in the USA and Canada	UPC/EAN
EAN-8 or EAN-13	items for sale worldwide	UPC/EAN
ISBN, ISSN & Bookland	books and periodicals	EAN-13 with UPC/EAN
UCC-128, EAN-128 or SSCC-18	shipping cartons	Code 128
SCC-14	shipping cartons	Interleaved 2 of 5 or Code 128
EAN-14	shipping cartons	Interleaved 2 of 5 or Code 128
SSCC-18	shipping cartons	Code 128
SISAC	serial numbers for serial publications	Code 128
SICI Code	serial numbers for serial publications	Code 128
POSTNET	US mail addresses for the US Post Office	POSTNET
USPS Special Services	US mail return receipts and registered mail	Interleaved 2 of 5 or Code 128
MICR	bank checks	MICR E-13B or CMC-7
LOGMARS	United States Department of Defense standard	Code 39

Issue #6 - Requirements for UDI direct marking of devices are not consistently applied across geographies, and some geographies have delayed publishing those requirements until there is a better understanding of direct marking implementation.

The concept of direct marking is also inconsistent jurisdiction to jurisdiction. Various means of permanent marking may be selected by industry to meet the requirements for direct marking. These may include, but is not limited to a label, indelible label, a placard, etching, etc. The concept of when to direct mark is also not aligned as indicated below:

US	EU	KR
High level disinfection & sterilization	High level Cleaning, High level disinfection & sterilization	Reusable product – this was defined to mean the same as the EU

Issue #7 - There continues to be a lack of focused education for healthcare delivery organizations. Therefore, healthcare delivery organizations are slow to adopt UDI because their systems are not prepared to consume the UDI-DI proliferation according to the standards used to create UDI.

As stated in the IMDRF document **IMDRF/UDI WG/N54 FINAL:2019,** the benefits of UDI strongly rely on effective integration of the UDI to support various regulatory activities during the lifecycle of medical devices[1] and uptake of UDI across the whole healthcare sector.

Those benefits are more likely be achieved when the UDI is recorded in real world electronic health systems (e.g. electronic health records (EHRs), device registries, material management systems, and reimbursement data) and used as part of real world evidence to improve clinical and regulatory decision making.

Due to the issues raised in this paper, these benefits are not able to be effectively utilized by all health care institutions, because the use of the data is not consistent. Of particular interest is the use of the UDI for purchasing as well as traceability and identification for the patient and use. Industry is slow to adopt the use of UDI for the global purchasing processes, and as such a separate reference number is used for purchasing. This hampers the productivity of these institutions to efficiently use UDI as it was intended to be used.

[1] IMDRF COMMON DATA ELEMENTS DOCUMENT (pag.9): http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-rps-common-data-elements.pdf.