Using AIMS for UDI Tracking

UDI Background

In 2007, the Food and Drug Administration (FDA) called for the creation of a unique device identification system for medical devices, requiring the devices labels to bear a unique identifier.[1] After five years, in September, 2013 the FDA published a final rule that establishes a Unique Device Identification (UDI) system.[2] The intention of the FDA's UDI system final rule is to provide standard device identification and associated identifying information to support various public health initiatives and most notably to support the FDA's post-market surveillance activities, such as recalls and adverse events.[3]

UDI Overview

In short, the rule requires medical device manufacturers to assign a UDI-compliant code to each of its covered products, to label these products with the code in both human and machine-readable (e.g. barcode, RFID) formats, and to publish additional data on those devices to the FDA's Global UDI Database. The actual UDI number is composed of two data parts: the Device Identifier (DI) number and the Production Identifier (PI) number.

The Device Identifier is the mandatory, fixed portion of a UDI that identifies (1) the labeler and (2) the specific version or model of a device.[4] The device manufacturer does not assign the DI, but rather it comes from an organization accredited by the FDA. Three organizations have been accredited: GS1, Health Industry Business Communications Council (HIBCC), and ICCBBA. Each organization has a unique required format for the DI. (See Table 1)

Table 1: Device Identifier Formats[5]

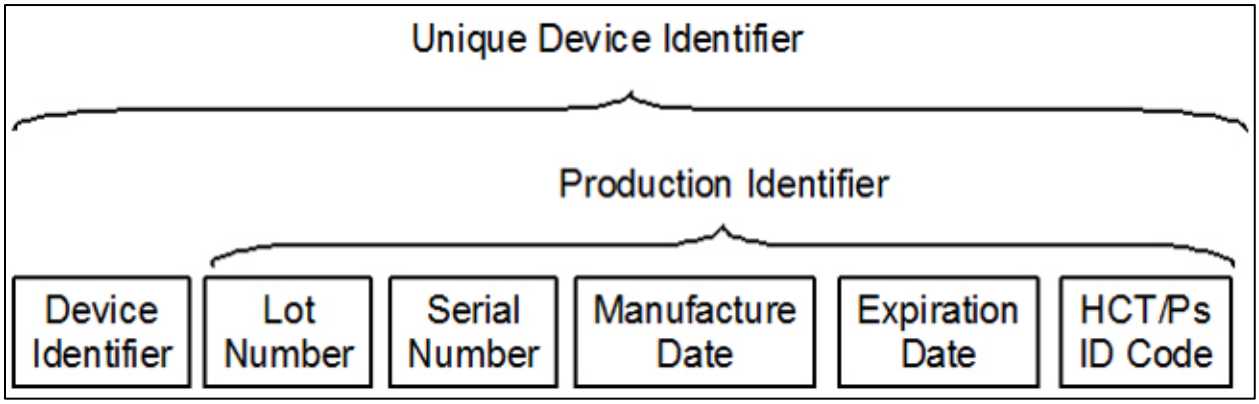
Accredited Agency	Device Identifier Format
GS1	14 numeric characters
HIBCC	6-23 alphanumeric characters
ICCBBA	18 alphanumeric characters

The Production Identifier is a conditional, variable portion of a UDI.[4] If any of the following is included in the label of a device, it must also be included in a PI.

1. Lot or batch number within which a device was manufactured
2. Serial number of a specific device
3. Expiration date of a specific device
4. The date a specific device was manufactured
5. For an HCT/P regulated as a device, the distinct identification code required by 21 CFR § 1271.290 (C)

Figure 1 illustrates the components of a UDI.

Figure 1: The Components of UDI[5]



The FDA determined that a phase-based approach would be the most feasible way to implement UDI. Table 2 provides a timeline for when devices must have UDI numbers applied. It is important to note that any device labeled prior to the compliance dates do not require a UDI.

Table 2: Compliance Dates for Implementation of UDI[6]

Class of Device	UDI Placement	Compliance Date
Class III	Labels and packages of devices, including software-only products.	September 24, 2014
Life-supporting or life-sustaining	Labels and packages of devices, including software only products. Direct marking of devices.	September 24, 2015

Class III	Direct marking of devices.	September 24, 2016
Class II	Labels and packages of devices, including software-only products.	September 24, 2016
Class II	Direct marking of devices	September 24, 2018
Class I	Labels and packages of devices without existing barcodes and UPC. Includes software-only products.	September 24, 2018
All medical devices	Labels and packages of devices.	September 24, 2018
All medical devices	Direct marking of devices	September 24, 2020

The Journal of Clinical Engineering detailed each device class below:

- Class III devices have a high potential risk because they are new or they support or sustain human life. Examples include pacemakers, replacement heat valves, and high-energy defibrillators.[7]
- Implantable, life-sustaining or life-supporting non-class III devices have a compliance date of September 24, 2015.[7]
- Class II medical devices have a lower potential risk compared to Class III devices. Examples include x-ray machines, infusion pumps, and electronic stethoscopes.[7]
- Class I medical devices are considered to present the least amount of risk. Examples include surgical gloves and manual stethoscopes.[7]

UDI Implementation & The Healthcare Technology Management (HTM) Community

Full implementation and adoption of the UDI system by all stakeholders should prove especially beneficial for the HTM community in a number of ways. [The system] will allow for the streamlined ability to track and monitor the whereabouts of medical products – which could help minimize the number of malfunctioning devices mistakenly put back into use before appropriate evaluation, and avoid situations where products are used past their expiration dates.[8] It will also provide knowledge of the exact details of device life spans and simplify the process of addressing device recalls or corrective actions.

Within the HTM community, there is still a large amount of uncertainty concerning UDI implementation in practice. It is expected with UDI implementation that a large amount of resources will be needed in the beginning and that systematic changes to the way people identify and manage devices will take place. However, since no one institution is the same, it will be essential to understand what the

implementation plan is going to look like, how it will affect the organization, and develop starting points for success and utilization.

Data Integrity and UDI

Special consideration will need to be given to the process of upholding the data integrity in your organization. It will be paramount for devices to be cataloged and scanned at every stage of the delivery process; from initial ordering and receipt, to direct patient involvement and, if an adverse event or malfunction occurs, through the clinical engineering analysis and testing of this device.[8] The importance of this continuous data logging cannot be overstated, as it directly correlates to efficient device tracking and more effective monitoring of device performance.

UDI and AIMS

AIMS has historically been among the first CMMS vendors to incorporate regulatory requirements in our software, and we expect the same here. AIMS Version 2.5.9.0 will be released with UDI fields prior to the September 24, 2016 Class II Compliance Date. The UDI fields will be created to capture and track the UDI information associated with equipment in AIMS. The UDI fields in AIMS will have the ability to hold the full UDI including the Device Identifier assigned by the issuing agencies and the Production Identifier numbers. Unlike other CMMS vendors, with AIMS, Clinical Engineering departments will be able to track their existing equipment as well as their new equipment in one database.

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[1] Karen Conway, *UDI: Not just for manufacturers anymore*, Health Technology Management, http://www.healthmgttech.com/udi-not-just-for-manufacturers-anymore (Sep. 25, 2015).
[2] 78 FR 58785 (September 24, 2013). UDI Final Rule.
[3] Jay Crowley, Amy Fowler, *What you Need to Know About the FDA's UDI System Final Rule,* http://www.duvalfdalaw.com/resources/documents/client-alerts/bsi-udi-white-paper.pdf (July, 2014).
[4] Food and Drug Administration, *Unique Device Identifier System: Frequently Asked Question, Vol. 1.* http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm410439.pdf (August 20, 2014).
[5] Dan O'Leary, *A Guide to Device, Label, and Package Requirements of the UDI Rule,* Med Device Online, http://www.meddeviceonline.com/doc/a-guide-to-udi-device-label-and-package-requirements-0002 (November 24, 2014).
[6] Richard Vincins, *Understanding the US FDA'S Unique Device Identification (UDI) Regulation: Who needs to comply, deadlines for compliance and how the program works,* http://www.emergogroup.com/resources/articles/white-paper-usa-udi#Form (June 10, 2014).
[7] Cedric Brown, Anchal Kaushiva, Loretta Chi "Fundamentals of Unique Device Identification," *Journal of Clinical Engineering* 40:1 (January-March 2015): 35-36.
[8] Cedric Brown, Anchal Kaushiva, "Incorporating Unique Device Identification Into Your Hospital," *Journal of Clinical Engineering* 40:2 (April-June 2015): 87-89.