UDI Impact on Healthcare Facilities

What You Should Know About the FDA's Unique Device Identifier Initiative

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Introduction

The Food and Drug Administration (FDA) released a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use on Sept. 24, 2013. With some exceptions, this final rule requires device labelers to include a unique device identifier (UDI) on devices that will be reprocessed, including device labels and packages.[1]

What is the definition of a device labeler? A labeler is:

- "Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label
- Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler."[2]

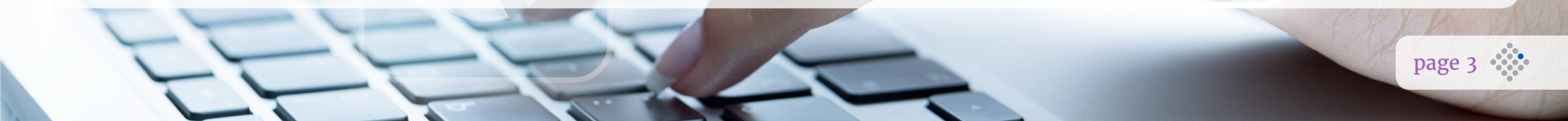
As manufacturers and device labelers adopt UDI standards, medical devices such as surgical instrumentation will come with UDI labeling and marking. The challenge for hospitals will be how to handle this data. This eBook is designed to provide an overview of important information related to the UDI initiative for hospitals and surgery centers.

THE ISSUES DRIVING UDI EFFORTS

Medical devices play an important role in the diagnosis, treatment, and management of so many health-related conditions, and at the same time, are diverse in nature and longevity of use. For example, a medical device may be permanently implanted or temporarily attached to patients and could have imbedded software or emit radiation. In some cases, they may be reused on multiple patients. Consequently, the tracking of devices over long periods of time is needed, but is also unfortunately extremely challenging in today's global healthcare market.

The UDI initiative evolved out of the fact that there is no system that can collect on-going data on medical devices and link individual patients to a specific device to which they have had exposure. These difficulties are directly related to the lack of a standard for unique device identification. Without a robust surveillance system, it is extremely difficult or impossible to:

- Analyze device specific clinical outcomes needed to measure quality and longtime safety of particular medical devices
- Effectively manage adverse events
- Impact overall transparency of post-market surveillance of medical devices[3]



What Is UDI?

A UDI is a unique numeric or alphanumeric code that consists of two parts:

- A device identifier (DI): a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device
- A production identifier (PI): a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - The lot or batch number within which a device was manufactured
  - The serial number of a specific device
  - The expiration date of a specific device
  - The date a specific device was manufactured
  - The distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device[4]

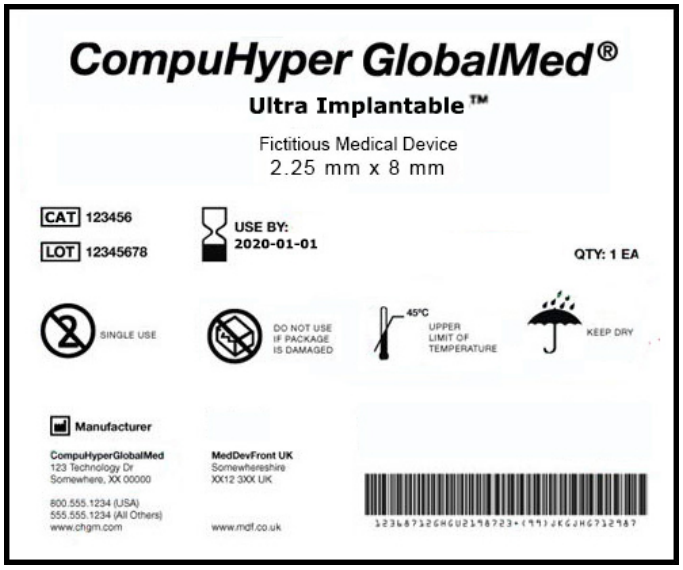
UDI DATA CARRIERS

A UDI label must provide information in plain text, also known as human readable information (HRI), and automatic identification and data capture (AIDC) technology. The AIDC component is in the form of a barcode, also referred to as the data carrier. There are linear versions of barcodes and 2D data matrix barcodes. 2D data matrix barcodes are capable of encoding a great amount of data in a small space, and require only one scan to capture all data elements. For these reasons, a 2D data matrix barcode is typically used for direct marking of surgical instruments and devices.

GLOBAL UDI DATABASE (GUDID)

Under the UDI final rule, the labeler of each medical device labeled with a unique device identifier (UDI) must submit information concerning that device to the GUDID, unless subject to an exception or alternative.

The GUDID contains ONLY the device identifier (DI), which serves as the primary key to obtain device information in the database.[5]



This is a fictitious example of what a unique device identifier (UDI) would look like on a medical device label. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, bar code, and details about the item.[6]

UDI Accredited Organizations and Formats

In today's world, patients can interface with healthcare related devices and procedures inside and outside of their country of residence. Therefore, ideally the UDI system needs to be adopted at a global level. Fundamental concepts that need to be agreed upon between countries in order for the concept to be effective include:

- The UDI and UDI carrier should be based on global standards
- A UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority
- National or local identification numbers should NOT be a substitute for UDI
- Regulatory Authorities should not specify how to modify these standards
- The UDI Database core elements should not be modified
- The UDI Database should use the HL7 SPL for data exchange[7]

To support these concepts, the FDA has accredited three international organizations as unique device identifier issuing agencies:

- GS1
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Banking Automation (ICCBBA)

Each issuing agency has a unique (UDI) format that was reviewed and approved by the FDA as part of the process for accrediting issuing agencies. Any changes to the format of the UDI by an issuing agency must be approved by the FDA before implementation.

It is important for device manufacturers and labelers to use an FDA accredited label format when labeling medical devices prior to distribution. It's equally important for software applications that capture UDI data to be designed to read accredited formats.

When Does UDI Go into Effect?

The final rule for labelers was issued by the FDA on September 24, 2013. The system is being implemented over several years according to the current schedule below with several different requirement due dates for each class or device type.

Class III: Implantable, life-supporting or life-sustaining devices	Labeling Requirements Data Submission Requirements Date Format Requirements	September 24, 2014
	Direct Marking Requirements	September 24, 2014
Devices licensed under the public health service act	Labeling Requirements Data Submission Requirements Date Format Requirements	September 24, 2015
	Direct Marking Requirements	September 24, 2015
Class II	Labeling Requirements Data Submission Requirements Date Format Requirements	September 24, 2016
	Direct Marking Requirements	September 24, 2018
Class I and devices not classified as Class 1, Class II, or Class III that are required to be UDI labeled	Labeling Requirements Data Submission Requirements Date Format Requirements	September 24, 2020
	Direct Marking Requirements	September 24, 2022

Note: This schedule is valid as of the date this document was published.

Common Questions

Q: WHAT DEVICE CLASS DO SURGICAL INSTRUMENTS FALL INTO FOR COMPLIANCE?

A: There are only a small percentage of surgical instruments/devices that are Class II devices. Most stainless steel instruments are Class I medical devices.

Q: WHAT ARE THE DECIDING FACTORS AS TO WHETHER OR NOT A DEVICE NEEDS TO RECEIVE A DIRECT MARK?

A: According to the FDA's 21 CFR 801.45 § 801.45, a device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself *if the device is intended to be used more than once and intended to be reprocessed before each use*.

One of the common misconceptions about UDI is that these rules place regulation on hospitals. It's important to remember that this regulation creates requirements for the device manufacturers which, in turn, impacts hospitals.

Anticipated Benefits of UDI

The big picture for the UDI initiative offers multiple benefits for healthcare facilities and patients. Specifically, by having the capability to precisely identify medical devices by serial number, batch/lot number, or expiration date throughout the global supply chain, the UDI initiative will allow healthcare professionals to:

- Access more accurate reporting related to adverse events so that problem devices can be identified and corrected more quickly
- Manage medical device recalls effectively
- Reduce medical errors by easy access to important information about a device
- Provide a tool for anti-counterfeiting strategies
- Capture product data to populate EHRs for device traceability to patients
- Improve supply chain and inventory processes[8]

From a patient perspective, a fully implemented UDI system would allow patients to access information related to an implanted device they may have received or allow them to research devices that may be part of a suggested treatment.

The Impact of UDI

What does all this mean for hospitals and surgery centers?

The challenges the UDI initiative presents to hospitals and surgical centers are to find and invest in IT solutions that will allow them to:

- Capture, track, store, retrieve and relay UDI data
- Leverage the new UDI database for information on devices and device recalls
- Take advantage of device labeling and marking changes in a way that promotes patient safety, reduces costs, and improves efficiency

This means UDI data capture will have to be integrated into electronic healthcare record (EHR) systems, as well as other administrative, supply chain, billing, and clinical support applications. Specifically, these systems will need to be able to provide:

- A field to capture UDI information
- Ability to scan, enter, and store UDIs
- Ability to internally transmit UDI information to supply chain and billing systems once a device has been used at the point of care
- Ability to transmit UDI information from EHRs to patients, registries, and payers
- The capability of patients, registries, and payers to access UDI information throughout a universal provider system[9]

Preparing for the impact of the UDI initiative is an on-going process. It will be important for hospital and surgery centers to be aware of the upcoming challenges and timelines associated with UDI in order to make effective purchasing decisions related to IT systems' ability to meet UDI expectations.

IMPACT OF UDI ON CSSDs

As central sterile supply departments (CSSDs) and ORs move from manual to electronic instrument and device management systems, CSSDs will want to invest in software functionality that not only captures FDA accredited UDI label formats, but also provides reporting capabilities related to UDI data.

Additionally, in order to have standardized processes related to reprocessing, CSSDs may want to consider a methodology for marking their "pre" UDI inventory of reusable devices and instruments with an "internal" unique identifier that can also be captured by the asset management software. This way whether an instrument or device came from the manufacturer with a UDI or a unique identifier mark was added later by the hospital, the technician can capture each reprocessing step of an asset in the same manner, and the facility can realize all the safety and efficiency benefits associated with UDI for the majority of their reusable assets.

UDI Preparation Checklist

- Choose an asset management automation solution that can capture an FDA accredited data carrier or barcode (i.e. GS1 and HIBCC formats).
- Invest in scanners capable of reading 2D data matrix barcodes for scanning instruments.
- Choose an asset management automation solution that can link a device to a patient case, and can also retrieve device history easily. This will be important when investigating cases where a surgical site infection is suspected or if there is a device recall of any kind.
- Partner with a vendor that has a solution to mark, track, and manage existing or “pre” UDI instruments and devices.
- Plan and budget for costs associated with marking existing instrument and device inventory. A do-it-yourself approach to instrument marking can extend associated costs out over a longer period but lengthen project completion time. Using a professional service to mark instrument inventory shortens implementation and avoids costs associated with staff learning curves but needs to be included in budget planning.

Early Results of UDI

One of the first facilities to adopt and implement UDI prior to the FDA's regulation was Mercy Healthcare System headquartered in St. Louis, MO. The primary purpose was to create a database that would match patient information from clinical records with UDI-associated data attributes for coronary stents implanted in those patients and to identify obstacles in the process. While there were challenges related to lack of existing software applications to capture full UDI data, the benefits included:

- More effective adverse event reporting and comparative effectiveness research
- More accurate and automated charge capture
- Improved inventory management
- Reduced supply chain inefficiencies
- Reduced days payable outstanding
- Visibility to real-time product usage and automated replenishment[10]

The Pew Charitable Trusts developed a video highlighting the benefits of UDI implementation at Mercy. In the video, Mercy's efforts are discussed by a cardiologist, supply chain executive, and nurse and serve as a model for health care professionals and health systems looking to utilize and benefit from the UDI system.[11]

Summary

Ultimately the success of the UDI initiative is dependent on multiple healthcare stakeholders worldwide adopting key fundamental processes. Once device labelers incorporate labeling requirements into their products, and IT solution providers develop the appropriate software enhancements to accommodate the capture and reporting of UDI data, then it will be up to healthcare facilities to invest in IT systems that allow them to leverage the use of UDI information.

With the FDA's original release date for the UDI final rule being several years ago, and the fact that the labeling requirements are being phased in over 10+ years, the impact of the labeling requirements could easily sneak up on healthcare facilities. Although the initial requirements apply to medical device labelers, the long term implications for healthcare facilities will require planning and preparation. It will be important for the leadership of healthcare facilities, including CSSD, OR, and supply chain managers, to keep up to date on this global initiative as the rollout continues to move forward.

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About Us

Founded in 2001, Censis Technologies, Inc. quickly became the industry leader in surgical asset management by offering highly advanced, web-based software systems focused on maximizing OR efficiency while advancing efficiency, transparency, and regulatory compliance.

With more than 600 organizations utilizing solutions in the Censis portfolio, Censis is committed to partnering with healthcare facilities year after year to enhance patient safety through innovative technology.

To see how surgical asset management can work for you, visit us at www.censis.com/contact-us.

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