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WHITE PAPER

UDI LABELING
OVERVIEW

Introduction

UDI: the new medical device labeling system

The Food and Drug Administration's Unique Device Identification (UDI) System is a new rule that has been created to ensure that medical device manufacturers label their devices so that the health care community, regulators, and the public can better identify medical devices during shipping, in storage, and at point-of-use. Unique device identifiers, according to the final UDI rule, must appear on labels for various classes of devices, product packaging, and in certain cases the medical devices themselves. Along with the UDI rule, the FDA has created the Global Unique Device Identification Database (GUDID) in which the medical device manufacturer will register each UDI so that any member of the public may look up a UDI to retrieve device and manufacturer information.

Required UDI Label Elements

Under the final UDI rule, every UDI must be presented in two forms: human-readable plain text, and encoded with Automatic Identification and Data Capture (AIDC) technology. The UDI is the combination of two numeric or alpha numeric sequences: the Device Identifier, and the Product Identifier. What is the purpose of each of these identifiers?

- **Device Identifier**

A device identifier is a fixed portion of the UDI that identifies the labeler and the specific version or model of a device. According to the FDA:

"The labeler is the person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; in most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.[1]"

- **Production Identifier**

A conditional, variable portion of the UDI that identifies one or more of the following when included on the label of a device:

  - Lot or batch number Serial number

  - Expiration date

  - Date manufactured

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[1] https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

      o   Distinct identification code required by 18 C.F.R. §1271.290(c) human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Format and anatomy of a UDI Label

A compliant UDI label must have:

- Brand name of the device.

- GMDN Description: The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products managed by the GMDN Agency. GMDN describing information can be found at www.gmdnagency.com

- Size – if versions of the device come in more than one size, the size of the device within the packaging must be shown.

- Catalog number of device.

- Device Count – Quantity of devices within labeled packaging

- Production Identifier: Lot Number of device

- For Single Use – If the medical device is intended to be use once, it must be shown.

- Production Identifier: Expiration Date – All dates on UDI labels must be in the YYYY-MM-DD format

- Storage and Handling Information – If the medical device has an expiration or use by date, or must be handled with certain precautions (for instance, kept dry) that must be illustrated on the UDI label.

- Labeler Name and Physical Address

- Support Contact Information: Telephone number or e-mail the end-user or FDA can use to contact the manufacturer and/or labeler of the medical device.

- Unique Device Identifier (Device Identifier + Product Identifier)

Scope of UDI Final Rule[2]

What does UDI entail?

The transition to the final UDI rule is a significant task that is requiring medical device manufacturers to develop new practices in order to remain compliant with the new FDA regulation.

In order to comply with the final UDI rule, a medical device manufacturer must include on their label both the Device Identification number and the Product Number. The combination of these two numbers, with AIDC technology, creates the Unique Device Identifier. The UDI is then registered with the Global Unique Device Identification Database (GUDID), a newly developed public database built by the FDA which catalogs every medical device with a unique identifier.

According to the FDA:

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.[3]

The UDI rule stipulates that the UDI be shown in both plain text (readable numbers) and in an Automatic Identification and Data Capture (AIDC) code that can be read by a data capture device such as a barcode scanner. Most AIDC technology comes in the form of a linear barcode, but it is not uncommon or prohibited for a medical device manufacturer to use 2D barcodes or Radio Frequency Identification (RFID) as the AIDC component of their UDI.

The UDI Final rule begins to come into effect September 2014, however all UDI rule changes happen gradually, over a six-year span, which culminates with the final deadline in 2020.

Benefits of UDI Label Changes

Increased Safety, Ease of Identification, Global Security

When fully implemented, the UDI system will increase patient safety, device security, and improve identification from manufacturing site to point of use. According to the FDA[4] there are numerous benefits to the UDI labeling change. The UDI rule will allow for:

- **Better Reporting, Review and Analysis**
  - The final UDI rule will allow healthcare professionals to easily identify medical devices, recognize those devices during review and analysis, and report problematic devices more quickly, and with fewer errors.

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[2] https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

[3] http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/globaludidatabasegudid/default.html

[4] http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/globaludidatabasegudid/default.html

- **Reduced Human Error**

  - With easily-read unique identification, health care professionals will more rapidly and precisely identify medical devices, while obtaining vital characteristic information of the device.

- **Better Recordkeeping, and Faster Device Approval**

  - The final UDI rule will provide a clear way to electronically document the use of medical devices in health information records and systems, claim data sources, and registries. More accessible post-market surveillance will support approval of both newly developed devices, and new uses for currently-marketed devices.

- **Improved Recall Management**

  - Unique identifiers will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.

- **Improved International Medical Device Security and Management**

  - The UDI rule will be the beginnings of a foundation for a global, secure distribution chain. Enhanced global stability will help address counterfeiting and diversion, while also helping nations to better prepare for international medical emergencies. UDI will lead to the development of a medical device identification system that is recognized around the world.

<u>**UDI Implementation Timeline**</u>

Compliance Timetable	
UDI Label Requirements Dates 2014-2020	
Compliance Date	**Requirement**
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. 21 C.F.R. § 801.20. Dates on the labels of these devices must be formatted as required by 21 C.F.R. § 801.18. Data for these devices must be submitted to the GUDID database. 21 C.F.R. § 830.300. A 1-year extension of this compliance date may be requested under 21 C.F.R. § 801.55; such a request must be submitted no later than June 23, 2014.

	Class III stand-alone software must provide its UDI as required by 21 C.F.R. § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of Class I, II, and III[5] implantable, life-supporting, and life-sustaining devices must bear a UDI. 21 C.F.R. § 801.20. Dates on the labels of these devices must be formatted as required by 21 C.F.R. § 801.18.
	A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. 21 C.F.R. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by 21 C.F.R. § 801.50(b).
	Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. 21 C.F.R. § 830.300.
3 years after publication of the final rule (September 24, 2016)	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. 21 C.F.R. § 801.45.
	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. 21 C.F.R. § 801.45.
	Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. 21 C.F.R. § 830.300.
5 years after publication of the final rule (September 24,	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be

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http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UCM328694.pdf

2018)	reprocessed before each use. 21 C.F.R. § 801.45.
	The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. 21 C.F.R. § 801.20. Dates on the labels of <u>all</u> devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by 21 C.F.R. § 801.18.
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. 21 C.F.R. § 830.300. Class I stand-alone software must provide its UDI as required by 21 C.F.R. § 801.50(b).
7 years after publication of the final rule (September 24, 2020)	Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. 21 C.F.R. § 801.45.
Compliance dates for all other provisions of the final rule. Except for the provisions listed above, FDA requires full compliance with the final rule as of the effective date, October 24, 2013. 78 F.R. § 58785	
Time Extensions: The request for medical device manufacturers to file extensions for UDI compliance passed on June 24th 2014.	

<u>Accredited Issuing Agencies for Approving UDI Labels</u>

A manufacturer seeking approval for their UDI labels must contact an agency that is accredited by the FDA. The issuing agency gives the manufacturer or labeler format and compliance guidelines to follow, and ultimately approves their UDI.

According to the FDA, "an issuing agency is an FDA-accredited organization that operates a system for assignment of UDIs according to the final rule.[6]" There are multiple issuing agencies with approval from the FDA to grant UDI assignment, with more applying for accreditation. Issuing agencies can be easily found through FDA.gov.

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[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=Members-Only%20Updates#top

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm#agencies

UDI Labeling Exceptions and Alternatives

The FDA allows for medical device manufacturers to file for exemptions from the UDI rule if using UDI is "not technologically feasible, or an alternative would provide for more accurate, precise, or rapid device identification… or would better ensure the safety or effectiveness of the device," according to the FDA exception website[7], where requests for exemptions can be made.

Phasing Out NHRIC and NDC Labeling Codes

Medical device manufacturers, who are still using National Health Related Items Code (NHRIC) and National Drug Code (NDC) numbers for devices should be aware that these codes are being "phased out over a time period that corresponds with the compliance dates for UDI requirements," according to the FDA[8].

The FDA also notes that, "if a device is not required to have a UDI on its label, any NHRIC or NDC number assigned to it is rescinded and may no longer be on the device label or package after September 24, 2018." The deadline for requesting the continued use for FDA labeler codes is September 24th 2014, and manufacturers may apply online at the FDA UDI help desk.

Implementation: Leveraging Technology for Accuracy in UDI Labeling

Traditional State of In House Labeling: Thermal Transfer Barcode Printers and Pre-Printed Labels

Until the most recent advances in printing technologies, companies purchased preprinted label templates, printed variable information on-demand, and applied the labels onto their medical device packaging. The traditional state is comprised of two steps.

- **Step 1: Acquire Pre-printed labels**

A medical device manufacturer must develop and approve the label in-house, and procure pre-printed labels from a label provider. The preprinted label is usually a shell that contains static information such as logos, color codes, product image, manufacturer information, etc. The shell is designed to later

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[7]

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm

[8]

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm

accept variable, serialized or lot-specific information printed in a secondary operation at the time of packaging of the device.

Once the stock of pre-printed labels has been received, and the quantity verified, the manufacturer undertakes the responsibility of managing numerous preprinted label stocks, one for each product variation, family or class. There is often a large stock of preprinted labels with static information that is susceptible to obsolescence.

At the time of labeling, the manufacturer's packaging technician must locate the correct preprinted label roll and deliver it with the correct packaging components to the work cell.

- **Step 2: Overprint with barcode printer**

After completing each aspect of step one, the manufacturer must now prepare to use a barcode label printer to print information on the label that is specific to the product and production lot being processed and packaged. The labeler must select the correct pre-printed label roll, install the roll in the correct barcode printer, open the correct label file on the computer running the barcode label software, and then ensure proper thermal transfer overprinting with variable information from the correct label database.

Traditional State Illustration:
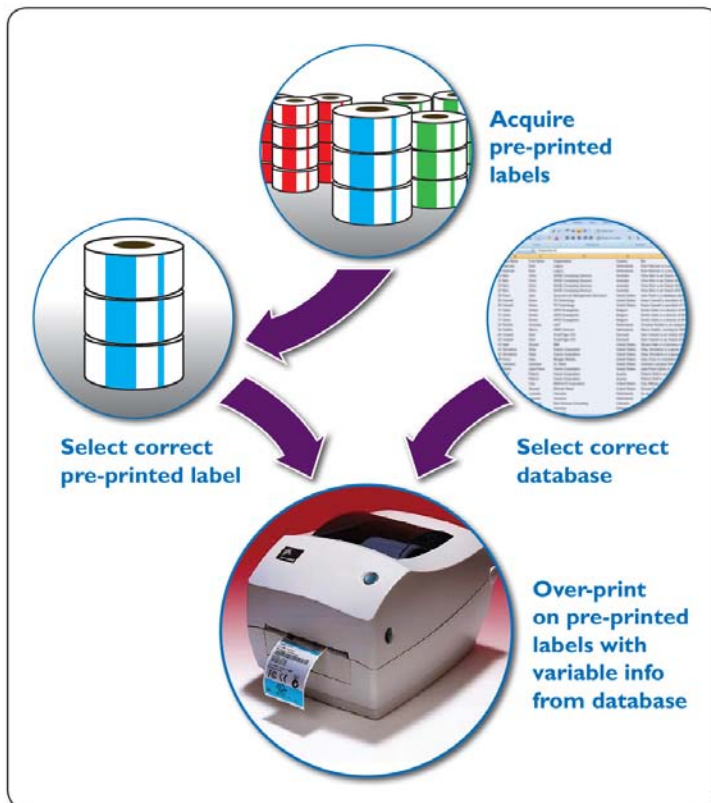
Drawbacks of Traditional State

Although historically ubiquitous throughout the medical device industry, the drawbacks of the traditional state of in-house label printing are more readily seen through the lens of rapidly developing technology. The principal drawbacks are those of human error, waste, and inefficiency.

- **Human Error**

Relying on humans to make calculated, precise decisions 100% of the time carries an inherent risk. Label designers can make errors, printer operators can miss them, and warehouse staff can retrieve incorrect inventory from product shelves. This carries the cost in labor hours of reproduction, as well as the costs of wasted pre-printed labels and packaging materials.

- **Waste**

In the Traditional State, waste in labeling is produced by excess inventory and human error. When a manufacturer of medical devices purchases pre-printed labels, the minimum orders are typically greater than the immediate need. These labels tie up cash in inventory. When errors are discovered on the pre-printed labels, or changes need to be made, the stock of labels must be scrapped and replaced, resulting in a cost of many hundreds or thousands of dollars. Further, obtaining new labels is time-consuming and can delay product shipments. The turnaround time for an entirely new supply of large quantities of labels can be lengthy, causing breaks in production, and increased man hours to count, inventory and document label stock.

- **Inefficiency**

The inefficiencies in the traditional state are numerous:

- The waiting period to receive labels in house or at the work-cell,

- excessive labor-hours devoted to the documentation and counting of labels,

- the difficulty of procuring and achieving uniformity in labels throughout multiple facilities across continents,

- increased scrap and cost due to obsolescence,

- excess quantity of labels,

- cash tied up in inventory and slower inventory turns, and

- the inability to support LEAN production methodology, such as the processing of work orders just-in-time or in batches of one, or by eliminating changeover time.

On their own each of these contributes to wasted time and money for a medical device manufacturer, and combined, lead to large losses in profit and efficiency.

The Emerging State of UDI Labeling: In-House Digital Color Label Printing

The technology in full color digital label printing, coupled with enterprise-level label design software, has made in-house, digital, color label printing an ideal solution for risk reduction and LEAN production for medical device manufacturers.

Enterprise Label Management System

With one central system of label design and management, and local printing, medical device manufacturers can manage their labeling from any location and ensure that the risk of mislabeling due to human error is eliminated. Labels can be printed in an international language, integrated with major enterprise resource planning (ERP) or product lifecycle management (PLM) systems.

A centrally-managed label management system networks with in-house digital label printers, deployed in work cells across multiple plants globally, to print compliant labels, quickly, on a just-in-time basis. Enterprise-level label management systems ensure security and compliance, and allow for global on-demand printing, all of which reduce cost, risk, and time spent labeling and designing.

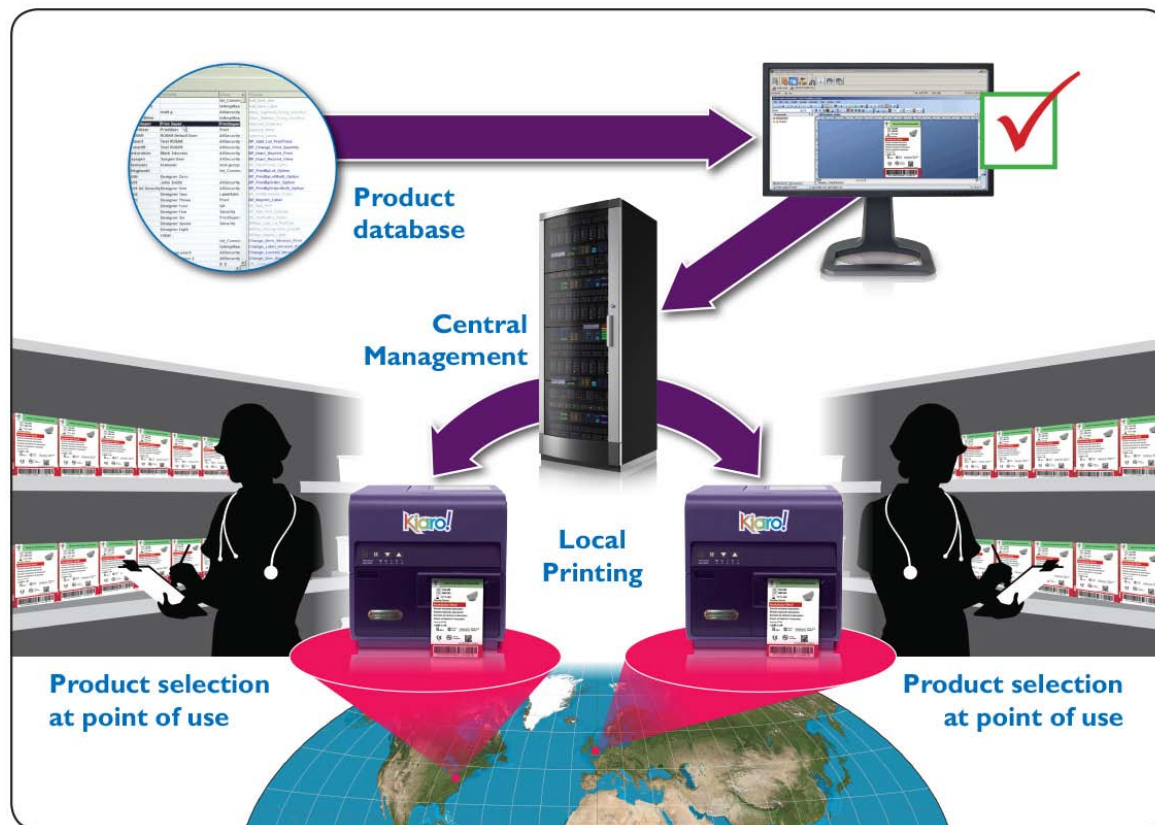### In-Plant Digital Label Printing Process

An in-house digital color label printer is a high definition photo-quality desktop printer designed to print short-run, on-demand labels. Digital color printers can print on a variety of media substrates for differing durability requirements, at print speeds of up to 8 inches per second.

An in-house digital label printer grants full control of medical device labeling, with on-demand printing for LEAN production. With a color label printer the entire label is controlled in-house, with no reliance on outside printers, no delays in shipping of label stock, no large overhead of label inventory, and minimized changeovers.

Blank labels are loaded in the color label printer, ready to accept full label content on demand from the label management software.

The operator selects the product from the database built into the enterprise management system. The central management system automatically gathers the approved design for the chosen product, and sends the information to the printers, located locally at each manufacturing facility where labels are needed. Only the exact amount of labels needed for that particular production run is printed.

Digital Printing UDI Labels with Label Management Software:

Benefits of In-Plant Digital Color Labeling

A digital color label printer, paired with label management software, allows medical device manufacturers to print entire labels in one pass: barcodes, images including product photos, color logos and branding material, and variable information such as batch code and serialization are all printed at once.

Creating all of the variable static information, with product branding and color code, reduces the risk of human error in every phase of packaging. Label selection is automated through management software, and identification of the correct product on warehouse shelves is simplified with color codes.

- **Design Centrally, Print Globally**

Enterprise level label management software deployed with networked digital label printers allows the manufacturer to design at one central location, and print to label printers located anywhere in the world through simple browser access.

- **Line of Sight Supervision**

Printing color labels with a digital label printer on-site allows for immediate supervision to verify that labels are in-line with regulatory standards. Supervision of labels as they are printed ensures there is no mislabeling, and authorized administrators can revise labels to comply with new regulations or marketing demands. The control of the medical device manufacturer is increased as the reliance of outside print houses to design compliant labels is eliminated.

- **LEAN Process Cost Reduction**

An in-house digital color label printer onsite will reduce cost, by affording medical device manufacturers the opportunity to establish LEAN processes. In-house printing can establish a LEAN workflow by eliminating the risk of storing and reprinting obsolete labels. Without a large inventory of pre-printed labels for human operators to choose from, the risk of human error is reduced, with no chance of selecting incorrect labels from inventory.

- **Additional Safety with Digital Color Printing**

Digital inkjet printers create labels in 1200 DPI (dots-per-inch) which allows medical device manufacturers to develop easy-to-identify color code systems. Medical device manufacturers may find it easier to distinguish product variations with color code cues, and at point-of-use settings staff are able to better identify the correct devices.

With the photo-quality image capability, labelers can accurately represent medical devices on packaging, with the added benefit of incorporating logos and branding on packaging. 1200 DPI printing ensures consistent quality and readability on all label sizes, including small label areas and wraparound label panels.

More UDI Information Resources

The FDA UDI resource center

QuickLabel Systems

Innovatum