Contains Nonbinding Recommendations

Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 7, 2021.

The draft of this document was issued on July 25, 2016.

For questions about this document regarding CDRH-regulated devices, UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-1853. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1500035 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

Table of Contents

Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This document is intended to assist labelers[1] and FDA-accredited issuing agencies[2] in complying with unique device identifier (UDI) labeling requirements, including by clarifying FDA's interpretation of certain requirements under 21 CFR 801.40. Specifically, this guidance describes the requirements for and FDA's recommendations regarding the form and content of the UDI to help ensure that the UDIs developed under systems for the issuance of UDIs meet the objectives of the Unique Device Identification System Final Rule, 78 FR 58786 (September 24, 2013) (UDI Rule).[3]

Throughout this guidance document, the terms "we," "us," and "our" refer to FDA staff from Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

[1] "Labeler" is defined at 21 CFR 801.3 as (1) 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; and (2) 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] "Issuing agency" is defined at 21 CFR 830.3 as an organization accredited by FDA to operate a system for the issuance of unique device identifiers.

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

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The UDI Rule requires the label and device package[4] of every medical device to bear a UDI, unless an exception or alternative applies (21 CFR 801.20). Additionally, some devices are required to 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 (21 CFR 801.45). The UDI Rule also includes special labeling requirements for stand-alone software regulated as a device (21 CFR 801.50).

The UDI Rule is intended to create a standardized identification system for medical devices that adequately identifies devices through distribution and use. As stated in the preamble to the UDI Rule, this system makes it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use (78 FR 58786).

Under the UDI Rule, each labeler must use one or more systems operated by an FDA-accredited issuing agency to assign UDIs that appear on device labels, on device packages, and, as applicable, on devices themselves as direct markings (21 CFR 801.20, 801.45, and 830.20). In order for there to be an effective identification system, it is essential that the FDA-accredited issuing agencies develop and operate systems for the assignment of UDIs that allow labelers using these systems to be in compliance with UDI labeling requirements.

The UDI must be presented in two forms on the device label and device packages: (1) easily readable plain-text; and (2) automatic identification and data capture (AIDC) technology (21 CFR 801.40(a)). When a device must bear a UDI as a direct marking, the UDI may be provided through either or both easily readable plain-text and AIDC technology forms, or through any alternative technology that will provide the UDI of the device on demand (21 CFR 801.45(c)).

III. Scope

This guidance describes the two forms of a UDI, clarifies the content of the UDI, and addresses use of data delimiters that identify specific data elements within the UDI. The guidance also addresses the recommended order of the data in the easily readable plain-text form of a UDI carrier.

[4] "Label" and "device package" are defined at 21 CFR 801.3.

This guidance does not apply to universal product codes (UPCs).[5] For class I devices, a UPC may serve as the UDI to meet the requirements of 21 CFR 801.20 (21 CFR 801.40(d)). However, a class I device labeler may choose to use a UDI rather than or in addition to a UPC (see 21 CFR 801.35). For more information on UPCs, labelers should contact an issuer of UPCs.[6] Labelers should have proper controls over UPC assignment and use to advance the goals of the UDI system.

IV. Unique Device Identifier (UDI)

"Unique device identifier" is defined as "an identifier that adequately identifies a device through its distribution and use by meeting the requirements of [21 CFR 830.20]" (21 CFR 801.3). A UDI is composed of a device identifier (DI) and a production identifier (PI). "Device identifier" is defined as "a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device" (21 CFR 801.3). "Production identifier" is defined at 21 CFR 801.3 as "a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;
(ii) The serial number of a specific device;
(iii) The expiration date of a specific device;
(iv) The date a specific device was manufactured;
(v) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c) of this chapter."

Under 21 CFR 830.20, a UDI must be issued under a system operated by an FDA-accredited issuing agency[7] and conform to the following international standards incorporated by reference in the UDI Rule in 21 CFR 830.10:

- ISO/IEC 15459-2: Information technology - Unique identifiers--Part 2: Registration procedures;
- ISO/IEC 15459-4: Information technology - Unique identifiers--Part 4: Individual items; and
- ISO/IEC 15459-6: Information technology - Unique identifiers--Part 6: Unique identifier for product groupings.

Additionally, the UDI must only use characters and numbers from the invariant character set of ISO/IEC 646: Information technology - ISO 7-bit coded character set for information interchange.

---

[5] A UPC "means the product identifier used to identify an item sold at retail in the United States." 21 CFR 801.3.

[6] Some FDA-accredited issuing agencies issue UPCs. Contact information for FDA-accredited issuing agencies is available at: https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/contact-fda-accredited-issuing-agency.

[7] Available at: https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/udiissuingagencies/default.htm. Should FDA ever act as an issuing agency, a labeler would also be permitted to use UDIs issued under the system operated by FDA. 21 CFR 830.20, 830.200, and 830.210.

It is critical that each FDA-accredited issuing agency develop and operate a system for the assignment of UDIs that is consistent with UDI labeling requirements under 21 CFR Part 801, Subpart B, allowing labelers to confidently use the FDA-accredited issuing agency's system to assign UDIs that meet those requirements.

A. Forms of UDI

The UDI Rule specifies that the UDI on the device label and device packages must be presented in both easily readable plain-text and AIDC technology forms (21 CFR 801.40(a)). In addition, certain devices are required to be directly marked under 21 CFR 801.45. For those devices, the UDI directly marked on the device itself may be provided through either or both easily readable plain-text or AIDC technology, or any alternative technology that will provide the UDI of the device on demand (21 CFR 801.45(c)).

UDIs, particularly when provided through AIDC technology, are intended to allow rapid and accurate data acquisition, recording, and retrieval. The easily readable plain-text form allows healthcare professionals, patients, FDA, and other users of the UDI system to read and enter the UDI into data systems, such as patient records or reports to FDA, without technological assistance. Thus, the easily readable plain-text form may be used as an additional mechanism to capture the UDI if the AIDC form cannot be used.

Figure 1 shows an example of a UDI in both easily readable plain-text and AIDC forms.

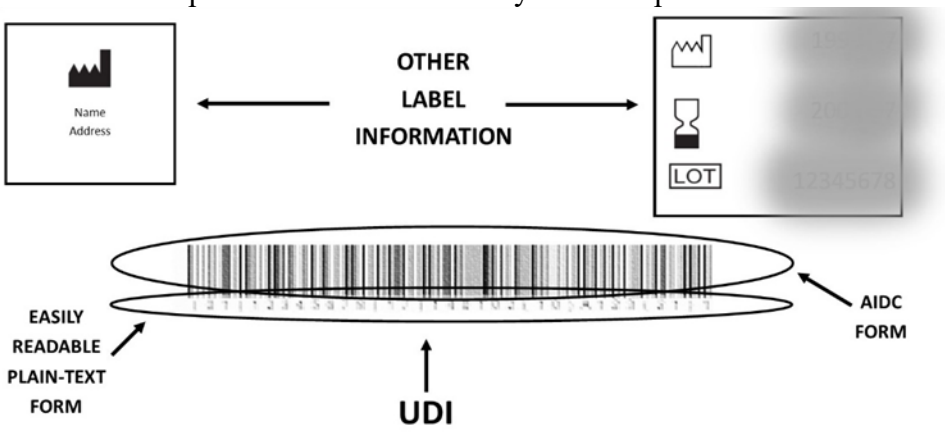

Figure 1. UDI in Easily Readable Plain-Text and AIDC Forms

1. Easily readable plain-text

For purposes of this guidance, "easily readable plain-text" means human-legible interpretation of the UDI data characters. Issuing agencies or other entities may refer to the easily readable plain-text form of the UDI as the human readable interpretation (HRI).[8] The easily readable plain-text form of the UDI must include the DI and, if applicable, PI. It is also important for the easily-readable plain-text form of the UDI to include any data delimiter(s)

[8] See, e.g., UDI N48: Unique Device Identification system (UDI system) Application Guide (March 21, 2019) Available at: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf.

for the DI and PI. If the data delimiters are not included, an individual may not be able to use the easily readable plain-text form of the UDI to identify the device. The easily readable plain-text form of the UDI may be presented as a single line or multiple lines of text, and should be displayed below or near the AIDC technology form of the UDI.

FDA does not prescribe the format for any dates in the PI portion of the UDI and does not require the easily readable plain-text form of the UDI to comply with 21 CFR 801.18 when it includes dates.[9] Labelers should refer to the guidelines of their FDA-accredited issuing agency or contact their FDA-accredited issuing agency with any questions regarding the format of the dates within the UDI.

2. AIDC

AIDC is defined at 21 CFR 801.3 as any technology that conveys the UDI or the DI portion of a UDI of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. Therefore, while the UDI Rule does not require the use of a specific form of AIDC or a specific AIDC technology to convey the UDI, the AIDC form of the UDI must be in a format that can be read by a bar code scanner or other AIDC technology (21 CFR 801.3 and 801.40(a)). The labeler should ensure that the AIDC form of the UDI can be reliably read at the points during distribution and use where device identification information is important to capture. Labelers should consult the guidelines of their FDA-accredited issuing agency to determine which forms of AIDC are supported by the issuing agency's UDI system.

When possible, FDA recommends the AIDC form of the UDI be displayed in one segment; however, it may be split into multiple segments. For example, one UDI may be presented in two linear bar codes: one bar code for the DI segment and another bar code for the PI segment. These two bar codes should be in near proximity to each other on the device label, device packages, and, when required, on the device itself.

The labeler may choose to use more than one type of AIDC technology on a single device label, device package, or device (when applicable), to assist users who may be employing different methods of UDI capture technology. For example, a labeler may include a linear (1-D) bar code and data matrix code (2-D) on the device label, both representing the same UDI. In this example, only one easily readable plain-text form of the UDI is required to be on the device label (21 CFR 801.40(a)), and it should be in near proximity to one of the AIDC forms of the UDI.

If a labeler chooses a bar code form of AIDC, the bar code form of the UDI should be tested for print quality. FDA recommends referring to the following standards and technical references for more information on determining the print quality:

[9] The required format for a printed expiration date, date of manufacture, or other date intended to be brought to the attention of the user of the device included on a medical device label is described at 21 CFR 801.18.

- ISO/IEC 15416: Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols;
- ISO/IEC 15415: Information technology -- Automatic identification and data capture techniques -- Bar code symbol print quality test specification – Two-dimensional symbols; and
- ISO/IEC TR 29158: Information technology -- Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline.

21 CFR 801.40(c) specifies that if the AIDC technology form (e.g., RFID technology) used to convey the UDI is not evident upon visual examination of the device label or device package, the device label or device package must disclose the presence of AIDC technology. FDA does not require a specific type of symbol to disclose the presence of AIDC technology that is not evident upon visual examination. However, FDA recommends that labelers consider using symbols that are internationally recognized, where use of such symbols is consistent with 21 CFR 801.15(c).

B. Content of UDI

For purposes of this guidance, we define "UDI carrier" as the means to convey the UDI and potentially non-UDI elements by using easily readable plain-text and/or AIDC forms. UDI carriers may include additional, non-UDI information regarding the device. For example, some FDA-accredited issuing agencies may provide for including non-UDI elements, such as quantity, in the data string within the UDI carrier. However, FDA does not consider such additional non-UDI elements as being part of the UDI. As such, data delimiters for additional non-UDI elements should be different than the DI and PI data delimiters in the UDI.

Under 21 CFR 801.40(b), the easily readable plain-text and AIDC forms of a UDI must include: (1) a device identifier segment; and (2) a production identifier segment that conveys one or more of the identifiers enumerated in the definition of a "production identifier" at 21 CFR 801.3 when included on the device label. The device identifier segment and the production identifier segment cannot include non-UDI elements or data delimiters for non-UDI elements.

The UDI Rule does not require any of the five identifiers comprising a PI to be on the label. However, other regulations may require one or more of the identifiers comprising a PI to be on the label. For example, under 21 CFR 1271.290(c), manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) are required to assign and label HCT/Ps with a distinct identification code. In addition, if the labeler includes any of the identifiers of which a PI is composed on the label, then for all devices required to bear a UDI other than class I devices,[10] the identifier must also be included in the PI segment of the UDI (21 CFR 801.30(d) and 801.40(b)).

[10] FDA's Product Classification database is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

There are some situations where a UDI may comprise a DI only. For example, if a class II device does not include any of the five identifiers of which a PI is composed on the label, then a PI would not be required in the UDI. In addition, the UDI of a class I device is not required to include a PI (21 CFR 801.30(d)). However, the labeler of a class I device may voluntarily include a PI in the UDI.

C. Data delimiters

For the purposes of this guidance, "data delimiter" means a defined data character or set of data characters that identifies specific data elements within an encoded data string represented in the UDI carrier.[11] Data delimiters are used to identify the information that immediately follows them, and data delimiters vary based on the UDI system established by each FDA-accredited issuing agency.[12]

Data delimiters are key to UDI comprehensibility and utility. A data delimiter indicates and distinguishes each data element within the data string represented in the UDI carrier, and inclusion of data delimiters is important for both the easily readable plain-text and AIDC forms of the UDI. Data delimiters allow users to parse the DI and PI in the easily readable plain-text form of the UDI, as well as to verify that the information encoded in the AIDC form of the UDI matches the easily-readable plain text form of the UDI. The data delimiters also enable the UDI to be parsed into electronic systems once scanned. Importantly, data delimiters allow the UDI to be distinguished and captured separately from any non-UDI elements that may be represented in the UDI carrier. In addition, if non-UDI elements are included in the UDI carrier, separate data delimiters for these non-UDI elements should be included. Without appropriate data delimiters to identify non-UDI elements, individuals may not be able to use the easily readable plain-text form of the UDI to identify a device and computer systems may not be able to capture accurately the UDI in AIDC form via an automated process.

---

[11] The term "data delimiter," as used in this guidance, corresponds to the term "qualifier" as used in ISO/IEC 15459-3: Information technology — Automatic identification and data capture techniques — Unique identification —Part 3: Common rules [third edition], and UDI N48: Unique Device Identification system (UDI system) Application Guide (March 21, 2019),-- http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf.

[12] FDA reviewed the UDI format of each issuing agency as part of its process for accrediting issuing agencies under 21 CFR 830.100 and 830.110. The data delimiters used within the UDI formats of FDA-accredited issuing agencies can be found in the UDI Formats by FDA-Accredited Issuing Agency document, available at: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf, on the UDI webpage (www.fda.gov/udi). For more information on encoding data delimiters, labelers should refer to the guidelines of their FDA-accredited issuing agency or contact their FDA-accredited issuing agency.

D. Order of the data represented in the easily readable plain-text form of UDI carrier

In the easily readable plain-text form of the UDI carrier, the UDI should precede any non-UDI elements. The easily readable plain-text form of the UDI should be ordered to specify the DI first, followed by the PI (if any). If there are any non-UDI elements in the UDI carrier, the non-UDI elements should follow the PI that is part of the UDI in the easily readable plain-text form. For example, if the label of a particular device bears an expiration date and quantity, and the labeler wishes to include the quantity in the UDI carrier, the easily readable plain-text of the UDI carrier should display the data delimiter for the DI, followed by the DI; the data delimiter for expiration date, followed by the expiration date PI; and lastly, the data delimiter for quantity, followed by the quantity. While FDA does not prohibit the inclusion of quantity in the UDI carrier, quantity is not considered part of the UDI and the data delimiter for quantity should be different than the DI and PI data delimiters in the UDI. For more information on including certain non-UDI elements in the UDI carrier, labelers should refer to the guidelines of their FDA-accredited issuing agency or contact their FDA-accredited issuing agency.

E. Stand-Alone Software

There are different labeling requirements for stand-alone software depending on whether or not it is distributed in packaged form (21 CFR 801.50). For stand-alone software that is *not* distributed in packaged form, the UDI labeling requirements are met if the UDI is provided through either or both of the following and the version number is conveyed in its PI:

- an easily readable plain-text statement displayed whenever the software is started; or
- an easily readable plain text statement displayed through a menu command (e.g., an "about" command) (21 CFR 801.50(a)).

For stand-alone software that is distributed in packaged form, 21 CFR 801.50(a) does not apply. The stand-alone software must provide its UDI as an easily readable plain-text statement displayed whenever the software is started or through a menu command (21 CFR 801.50(b)). Additionally, the device label and device packages must also bear a UDI in both easily readable plain-text and AIDC forms (21 CFR 801.20(a) and 801.40(a)).[13] As explained above, when the lot or batch within which a device was manufactured is included on the device label, the lot or batch must be included in the PI (21 CFR 801.3 and 801.40(b)). "Software version" is included in the definition of lot or batch at 21 CFR 801.3.[14] Therefore, when a labeler of stand-alone software required to bear a UDI includes a software version on the label, it must be conveyed through the PI (21 CFR 801.3, 801.50(b); see also 78 FR 58794).

[13] See also 78 FR 58804.

[14] "Lot or batch" is defined at 21 CFR 801.3 as "one finished device or more that consists of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits."