Unique Device Identifier (UDI) Labeling

On September 24, 2013, the United States Food and Drug Administration (FDA) released a final rule requiring that most medical devices distributed in the United States carry Unique Device Identifiers (UDI). The UDI system facilitates medical device identification, traceability, and tracking through distribution and use. The rule requires that product information pertaining to the devices be submitted to the FDA's Global Unique Device Identification Database (GUDID).

In addition, the rule also requires that a new, standardized date format be placed on all medical device labels.

Masimo is in the process of updating our Class II product labeling for compliance with GS1 Standards to meet the FDA implementation timeline, which we have posted below (see FAQ question #3).

If you have questions beyond the scope of these FAQs, please contact Customer Service:

> US: customerorders@masimo.com
> Outside US: emeasales@masimo.com

Frequently Asked Questions

1. What is UDI?

A Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters based on a global coding standard that adequately identifies a device at the point of distribution and at the point of use. A UDI is composed of:

> A device identifier, the GTIN (Global Trade Item Number): a mandatory, fixed portion of a UDI identifying the specific version or device model and the labeler of that device; and

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

- The production lot or batch within which a device was manufactured;

- The serial number of a specific device;

- The expiration date of a specific device; and/or

- The date a specific device was manufactured.

Masimo uses **GS1** as our accredited agency for assigning barcodes and barcode structures.

*Please note that any product that is **NOT** classified as a medical device is not required to contain a barcode.*

2. Who has to comply with the UDI regulations?

All medical device companies must comply with the UDI regulations.

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3. What is the implementation timeline for complying with the UDI regulations?

FDA UDI Timeline	Final Rule	Sept. 24, 2014	Sept. 24, 2015	Sept. 24, 2016	Sept. 24, 2018	Sept. 24, 2020
Labels and Packages must contain UDI Dates must be formatted as YYYY-MM-DD Products must be submitted to FDA UDI Database	Final Rule Published Sept. 24, 2013	Class III	Implantable or live sustaining/ supporting	Class II	Class I	
Products intended to be used more than once **must have direct part marking**			Implantable or live sustaining/ supporting	Class III	Class II	Class I

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4. How will Masimo comply with UDI?

Masimo distributes Class II and a few Class I products. Masimo will be compliant with the UDI regulations within the timeframe required by the FDA.

*Please note that any product that is **NOT** classified as a medical device is not required to contain a barcode.*

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5. What will my new label look like?

Below are examples of the current and the new UDI-compliant labels for Masimo sensor products.

Please Note: Depending on the product type, the label will contain one of two dates. For products that have a "Use By" date, it will appear as YYYY-MM-DD beneath the expiration symbol, and will also be encoded as YYMMDD preceded by the application identifier (17) within the GS1 and 2D barcodes. For products that do not have a "Use By" date, the Date of Manufacture will appear as YYYY-MM-DD adjacent to the date of manufacture symbol and also be encoded as YYMMDD preceded by the application identifier (11) within the GS1 and 2D barcodes.
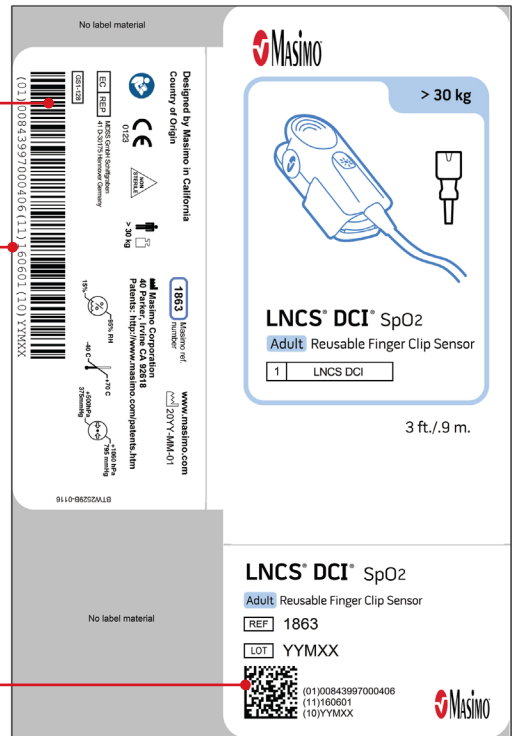
CURRENT

NEW

GS1 1D Linear Barcode

The Use By Date – (17) 190601 has been added to the barcode (see question #5)

GS1 2D Data Matrix Barcode

CURRENT

NEW

GS1 1D Linear Barcode

The Date of Manufacture – (11) 160601 has been added to the barcode (see question #5)

GS1 2D Data Matrix Barcode

6. What is a Global Trade Item Number (GTIN)?

A GTIN is a globally unique GS1 Identification Number used to identify a "trade item." GTINs are assigned by the brand owner (labeler) of the product and are used to identify products as they move through the global supply chain to the end user, such as a hospital. If you are not currently using the GS1 system with GTINs to manage your products, you will need to obtain the GTINs for the products you are purchasing.

For more information about GTINs, please contact GS1 at: https://www.gs1us.org/resources/standards

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7. How Do I Get Product GTINs?

Email Masimo Customer Service:

    US: customerorders@masimo.com
    Outside US: emeasales@masimo.com

Please include your customer ID and the product part number(s) in the email.

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8. I am currently entering or scanning the Masimo LOT and/or REF barcodes on the label. Will I need to change my current process?

Yes. The LOT or REF barcodes on the label will be removed and replaced with text and can no longer be scanned. For LOT information, you will either scan the GS1 barcode or locate it next to the LOT symbol on the label. The REF information can be identified in the corresponding GTIN. For more information on GTINs, see question #6 above.

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9. Will Masimo product numbers change as UDI labeling is implemented?

No, Masimo product numbers will remain the same.

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10. What is the new standardized date format and when does it go into effect?

The UDI rule adopted the standardized date format YYYY-MM-DD on device labels. Dates on labels will be in the new format no later than the date on which the label of the device must bear a UDI. For more information on the implementation timeline, see question #3 above.

11. Will Masimo be providing product information online?

The GUDID is a publicly searchable database that contains the device identification (DI) portion of the UDI for every medical device as well as other required product information. All medical device companies must submit DI information to the GUDID. Masimo has started populating the GUDID and will ensure that all products are added according to or in advance of the UDI implementation timeline.

12. What about existing inventories? Do manufacturers have to re-mark them?

No, there are two exceptions for existing inventories:

> Devices that are in commercial distribution prior to the applicable compliance date do not have to comply with the final rule.

> Devices that are manufactured and labeled prior to the applicable compliance date are also exempt from compliance. However, this exception expires 3 years after the applicable compliance date.

13. Do all devices need to be directly marked with their UDIs?

No. The rule only requires direct marking for reusable medical devices that need to be reprocessed (cleaned/sterilized) before reuse. For more information on the direct marking implementation timeline, see question #3 above.

Additional Resources

For more information on the UDI system, visit Unique Device Identification (UDI) on the FDA website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/

If you have additional questions about how Masimo is complying with UDI regulations, please contact Masimo Customer Service at:

US: customerorders@masimo.com
Outside US: emeasales@masimo.com