

UDI formats by FDA-Accredited Issuing Agency

[Version 1.3](#): January 27, 2017

FDA has accredited three organizations as [UDI issuing agencies](#): GS1, Health Industry Business Communications Council (HIBCC), and International Council for Commonality in Blood Banking Automation (ICCBBA). Each issuing agency has a unique unique device identifier (UDI) format that was reviewed and approved by FDA as part of the its process for accrediting issuing agencies. Any changes to the format of the UDI by an issuing agency must be approved by FDA before implementation.

This document contains information and links related to the format of the UDI for each FDA-accredited issuing agency. It is intended to provide a broad overview of each issuing agency's technical formats for the device identifier and production identifiers specified in the FDA's UDI rule. For detailed information on issuing agency formats and guidelines for UDIs, contact the [issuing agency](#) directly.

GS1® Issuing Agency¹

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	Device Identifier (DI)	Numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22	20
GS1	(21)	Serial Number	alphanumeric	22	20
GS1		Maximum Base UDI	alphanumeric	76	66
Example of GS1 easily readable plain-text UDI: (01)5102222233336(11)141231(17)150707(10)A213B1(21)1234					

GS1 Sample UDI labels:

[http://www.gs1.org/sites/default/files/docs/healthcare/udi_label_samples - 20150317.pdf](http://www.gs1.org/sites/default/files/docs/healthcare/udi_label_samples_-_20150317.pdf)

¹ <http://www.gs1.org/>

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Health Industry Business Communications Council® (HIBCC) Issuing Agency

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	+	Device Identifier (DI)	Alphanumeric	7 to 24	6 to 23
HIBCC	\$	Lot Number Only	Alphanumeric	19	18
HIBCC	\$\$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	\$\$	Expiration Date followed by Lot Number	Exp Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	\$\$2	Expiration Date followed by Lot Number	Exp Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	\$\$3	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	\$\$4	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	\$\$5	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	\$\$6	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	\$+	Serial Number only	Alphanumeric	20	18
HIBCC	\$\$+7	Serial Number only (alternative option)	Alphanumeric	22	18
HIBCC	\$\$+	Expiration Date followed by Serial Number	Exp Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+2	Expiration Date followed by Serial Number	Exp Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+3	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+4	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDDHH] Serial Number: alphanumeric	12 18	8 18

² <http://www.hibcc.org>

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	\$\$+5	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+6	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number <u>also</u> required and included in main secondary data string	Alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC	/14D	Expiration Date (supplemental to secondary barcode)	Numeric [YYYYMMDD]	12	8
<i>HIBCC</i>		Maximum Base UDI	Alphanumeric	70 to 87	58 to 75
Example of HIBCC easily readable plain-text UDI: +H123PARTNO1234567890120/\$\$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

HIBCC Sample UDI labels:

<http://www.hibcc.org/wp-content/uploads/2016/02/HIBCC-UDI-Label-Examples.pdf>

International Council for Commonality in Blood Banking Automation (ICCBBA)
³
Issuing Agency

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	Device Identifier (DI)	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Distinct Identification Code (Donation Identification Number)	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYYJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYYJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		Maximum Base UDI for HCT/Ps	Alphanumeric	79	67
Example of ICCBBA easily readable plain-text UDI: =/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

³ <http://www.iccbba.org>

<i>Blood Bags Only</i>	Identifying Symbol	Identifier	Data type	Eye Readable Barcode Field Size	Database Field Size
ICCBBA	=)	Device Identifier (DI) for blood containers (bags)	Alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	Alphanumeric	12	10
<i>ICCBBA</i>		<i>Maximum Base UDI for Blood Bags</i>	<i>Alphanumeric</i>	24	20
Example of ICCBBA easily readable plain-text UDI for blood bags only: =)1TE123456A&)RZ12345678					

ICCBBA Sample UDI labels: <https://www.iccbba.org/subject-area/medical-devices/label-examples>

UDI Check Digit Rules

In order to minimize errors and ensure accuracy in data entry and data exchange, DIs are verified by check digit rules designed by Issuing Agencies to validate the integrity of UDI. UDIs submitted through Web client/HL7 SPL submissions are checked based on the issuing agency's guidelines, which are available on their website.

Check digit calculators for FDA-Accredited Issuing Agency:

GS1: [Check digit Rules](#)⁴

ICCBBA: [Lookup Tools](#)⁵

HIBCC: [Modulo 43](#)⁶

⁴ <http://www.gs1us.org/resources/tools/check-digit-calculator>

⁵ <http://www.iccbba.org/lookup-tools>

⁶ <http://www.hibcc.org/wp-content/uploads/2016/01/Mod-43-Check-Character.pdf>

UDI formats by FDA-Accredited Issuing Agency – Document History

Version	Date	Change	Rationale
1.0	May 7, 2014	Original	
1.1	November 3, 2015	Added /14D data delimiter to HIBCC chart	Additional data delimiter added to new HIBC Supplier Labeling Standard (SLS) 2.5
1.2	March 9, 2016	<ol style="list-style-type: none">1. In ICCBBA’s tables changed: “DI” to “Device Identifier (DI)” and “Donation Identification Number” to “Distinct Identification Code (Donation Identification Number)”2. In GS1 and HIBCCA tables, changed “DI” to “Device Identifier (DI)”3. Provided links to examples of labels for accredited IAs	<ol style="list-style-type: none">1. At request of ICCBBA2. For added clarity3. As a resource
1.3	January 27, 2017	Removed an erroneous space in example of HIBCC easily readable plain-text UDI	Typographical error