

## 5 Parsing the ISBT 128 UDI to Extract the Data Items Required by 45 CFR Part 170

The approved formats for an ISBT 128 UDI are specified in the FDA document “UDI formats by FDA-Accredited Issuing Agency.” The relevant table is reproduced below. The ISBT 128 UDI is based on ISBT 128 data structures that contain data identifiers. ISBT 128 data identifiers correspond to the FDA UDI data delimiters. (Note: The example human readable bar coded information was updated to utilize current dates and a more relevant Product Description Code.)

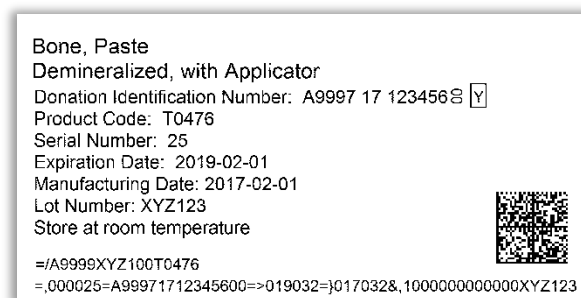
**Table 5 ISBT 128 UDI for Medical Devices Containing HCT/P**

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI (Device Identifier)	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Distinct Identification Code (Donation Identification Number)	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		<i>Maximum Base UDI for HCT/Ps</i>	<i>Alphanumeric</i>	79	67

Example of Human Readable Bar Coded Information:

=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,100000000000XYZ123

**Figure 5 Example Label with 2-D Symbol**

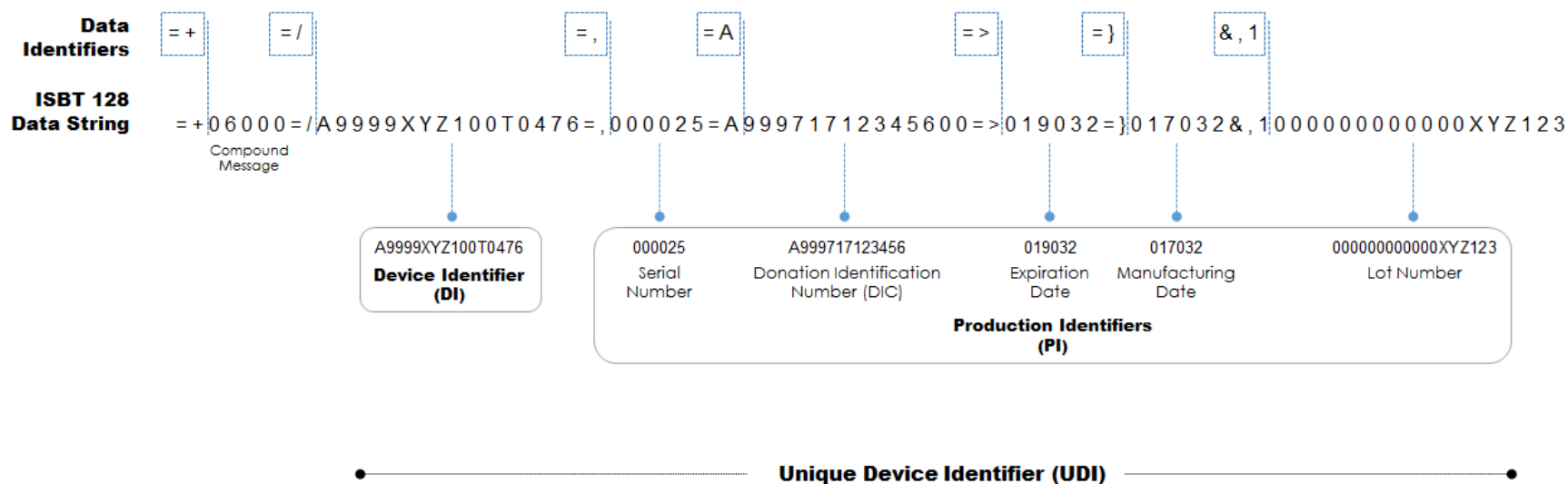


It is recommended that the ISBT 128 UDI be encoded within an ISBT 128 Compound Message in a 2-D Data Matrix code. However, the Standard does permit the use of Code 128 linear bar codes for compound messages.

When the UDI is encoded in a Data Matrix code the full UDI will be received as a single input string. An example is:

=+06000=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

**Figure 6 Parsing of an ISBT 128 UDI**



The initial “=” character indicates that this is an ISBT 128 data string. Elements of the message are divided either by the “=” or the “&” character.

The first element (=+06000) indicates that this is a compound message and the content can be interpreted in accordance with Section 4.1.

The second element is the Device Identifier (DI). This is identified by the data identifier “=/” and the 16 data characters following this data identifier comprise the device identifier (A9999XYZ100T0476) as specified in 45 CFR Part 170.

The remaining elements are the production identifiers and may appear in any order. They are each identified by a data identifier. The Donation Identification Number [referred to as the distinct identification code required by 21 CFR 1271.290(c)] and the serial number are mandatory PIs. The other PIs are optional within the ISBT 128 Standard.

In the above example the third element is the Product Divisions Code (Serial Number PI). It is identified by the data identifier “=,” and has six data characters (000025). This is the “serial number of a specific device” as specified in 45 CFR Part 170.

The fourth element is the Donation Identification Number (Distinct Identification Code PI). It is identified by the data identifier “=” followed by any alpha/numeric character. The “=” character is followed by 15 data characters, but only the first 13 of these are the Donation Identification Number. The last two characters are flag characters and should be ignored. Thus, in the example, the data characters A999717123456 form the Donation Identification Number. This is the distinct identification code required by 21 CFR 1271.290(c) as specified in 45 CFR Part 170.

The fifth element is the Expiration Date PI. This is identified by the data identifier “=>” and has six data characters. These are presented in an YYYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 019032 refers to 1 Feb 2019.





The sixth element is the Manufacturing Date PI. This is identified by the data identifier “=)” and has six data characters. These are presented in an YYYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 017032 refers to 1 Feb 2017. This is the date of manufacture as specified in 45 CFR Part 170.

The seventh element is the Lot Number PI. This is identified by the data identifier “&,1” and the 18 data characters following this data identifier (000000000000XYZ123) are the lot or batch number as specified in 45 CFR Part 170.

*(Note: If non-UDI data structures are included in the message, they appear after the PIs.)*

If the UDI is presented as linear barcodes, each element shall be carried in an individual Code 128 linear code and will be identified by its data identifiers. The compound message data structure is not used in this situation. See Figure 7.

**Figure 7 Example Label with Multiple Linear Bar Codes**

<b>Tendon</b>	Generis Tissue Bank
With Suture	Anytown, USA 99999-9999
Frozen	Store at -80 C or colder
Sterilized with Radiation	
Product Code: T0480	
Device Identifier (DI): A9999004344T0480	 =/A9999004344T0480
DIN: A9997 17 123456 Ⓢ ☐	 =A99971712345600
Serial Number: 000005	 =.000005
Exp. Date: 2018-01-20	 =>018020