Harmonization Pattern for Unique Device Identifiers – R3

**March 14 2016**

# Preamble

In April 2013 the International Medical Device Regulators Forum IMDRF UDI Working Group published ‘UDI System for Medical Devices (Version 2.0)’, the basal specification for Unique Device Identifiers (UDI. The US FDA has produced a implementation guide[[1]](#footnote-1) for Unique Device Identifiers (UDI) which implements the IMDRF specification for the United States and provides requirements and timing for use of UDI with different classes of medical devices. Other jurisdictions are expected produce similar IMDRF implementation guides for UDI use in other regulatory regions. This document describes how to use and exchange UDIs within HL7 standards in general. It also provides a limited amount of guidance specific to the FDA specification

This Harmonization Pattern has two objectives:

1. To describe how UDI carriers and their component elements should be referenced in different HL7 data transport standards to ensure consistent representation of UDI information and to better allow conversion of UDI information when translating between standards
2. To provide additional guidance around best practices for representing UDI information that applies to many implementation environments and which maximizes system interoperability.

## UDI Background

The following table describes the data elements that will be addressed by this specification – both the UDI carrier itself as well as the standard device-related elements that can be conveyed within a UDI carrier:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **UDI and Contained Elements** | | | | |
| **Element** | **Description** | **Data Type** | **Cardinality** | **Notes** |
| UDI | Unique Device Identifier | Identifier/Code | 1..1 | The full UDI carrier - either the Human Readable Form [[2]](#footnote-2)(HRF) representation of the barcode as printed on the packaging of the device or Automatic Identification and Data Capture (AIDC) representation.  An additional OID or URL is needed to identify the authoritative source for UDI generation within the jurisdiction. All UDIs are globally unique within a single namespace. However, for ease of implementation, separate OIDs and URIs are provided for each managing jurisdiction. This allows a recipient of a UDI to know which database will contain the UDI-associated metadata. For UDIs of devices managed in the U.S. by the FDA, the values are: 2.16.840.1.113883.3.3719 or http://hl7.org/fhir/NamingSystem/fda-udi  Note: Recognizing a UDI as being assigned by the FDA as opposed to another issuing authority cannot be done by merely looking at the UDI carrier. Typically a jurisdictional OID or URL will be used with the UDI carrier which corresponds to the jurisdiction and UDI repository. For example: products with UDIs provided in the US will use the FDA UDI OID or URL and will have their DIs registered in the GUDID database. |
| **Elements Contained Within A UDI** | | | | |
| Di | Device Identifier | Code | 1..1 | The value is a string. This is the actual identification component. Issuer OIDs and URLs are available to identify which Device Identifier system makes the identifier globally unique.  The current OIDs are:  GS1 DIs: 2.51.1.1  HIBCC DIs: 1.0.15961.10.816  ICCBBA DIs for blood containers:  2.16.840.1.113883.6.18.1.17  ICCBBA DIs for other devices:  2.16.840.1.113883.6.18.1.34  Possible URIs are: To be confirmed  GS1 DIs:   http://hl7.org/fhir/NamingSystem/gs1-di  HIBCC DIs:  http://hl7.org/fhir/NamingSystem/hibcc-di  ICCBBA DIs for blood containers:  http://hl7.org/fhir/NamingSystem/iccbba-blood-di  ICCBA DIs for other devices:  <http://hl7.org/fhir/NamingSystem/iccbba-other-di> |
| Manufacture | Manufacture Date | Timestamp | 0..1 | The value is an Issuer-specific string containing the date, often without century, and optionally with the hour.  The date must be converted to a full date string (possibly with hour) based on Issuer-specific rules. |
| Expiration | Expiration Date | Timestamp | 0..1 | The value is an Issuer-specific string containing the date, often without century, and optionally with the hour.  The date must be converted to a full date string (possibly with hour) based on Issuer-specific rules. |
| Lot | Lot Number | String | 0..1 | The value is a string. |
| Serial | Serial Number | String | 0..1 | The value is a string. |
| DIN  Also known as  DIC | Donation Identification Number  Distinct Identification Code | Identifier | 0..1 | The value is a string.  If the content is from an ICCBBA-encoded UDI, the OID and URI for use are:  2.16.840.1.113883.6.18.2.1 and http://hl7.org/fhir/NamingSystem/iccbba-din  GS1 and HIBCC formatted UDIs do not currently convey the DIN element. |

Note: the data types used above and defined below are for illustration, not a requirement. Each HL7 standard family will use the data types specific and appropriate to that family.

String data will typically be alphanumeric but may contain other symbols. In some HL7 standard serializations, these symbols may need to be escaped as per standard-specific rules (e.g. delimiter escape characters in v2 or ampersands in XML).

Note: non-UDI elements, i.e. elements which are not listed in the table above, may also appear within the UDI carrier.

**Identifier/Code** – a system data type, typically composed of an issuer component and a value component. For example, it may use one string component to carry the OID or URL, and another string component to carry the UDI carrier HRF or AIDC representation (see below). For some standards, when conveyed as an identifier, there may also be a component that identifies the “type” of identifier (in this case, “UDI”). The UDI carrier will be stored as an Identifier when that is the purpose of the data collection, as a globally unique Id for the device, as a code when the intent is to capture the type of device without a requirement for global uniqueness or in a specifically element designated to hold the UDI carrier.

The “type” element should be set to “UDI” where this is supported.

**Timestamp** – a time stamp data type which is capable of carrying the full date, perhaps with the century missing, and optionally the hour included.

**String** – a simple string data type.

**Sample UDI Barcode**



**HRF (Human Readable Format)**

The Human Readable Form is a rendering of the barcode contents, the data not the markup, using only printable ASCII characters. The HRF may be different for each barcode issuer (GS1, HIBCC, ICCBBA, etc.).

**(01)09504000059118(17)141120(10)7654321D(21)10987654d321 (GS1)**

**Examples:**

**(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234 (GS1 HRF – not for exchange)**

**{01}51022222233336{11}141231{17}150707{10}A213B1{21}1234 (GS1 HRF - exchangeable)**

**+51022222233336/$$515187A213B1/S1234/16D20141231R (HIBCC HRF)**

**=/51022222233336=,1234/=A213B1=>015187=}014365 (ICCBBA HRF)**

UDIs beginning with: ‘(‘ are in the GS1 Human Readable Format

‘{‘ are in the GS1 Exchange Format (note not the GS1 Human Readable format);

‘0-9’ is a GS1 DI (containing only the DI value);

‘+‘ are in the HIBCC Human Readable style;

‘=‘ or ‘&’ are in the ICCBBA Human Readable style.

Note: The official GS1 HRF is not safely parseable as separator characters (parentheses) are also permitted as part of component string values. For this reason, instance data is generally transmitted using the GS1 HRF exchangeable syntax (curly braces in the place of the parentheses when used as separators).

**AIDC (Automatic Identification and Data Capture)**

The AIDC format of the barcode contents includes both the data and the markup and may contain unprintable ASCII characters. In the example below the <GS> stands for the unprintable character 29 (hex 1D). The actual standards organizations responsible for barcode standards should be consulted to understand the encoding of information into the various barcode standards.

UDIs beginning with: ‘0-9’ is a GS1 AIDC format;

‘+‘ are in the HIBCC Human Readable style;

‘=‘ or ‘&’ are in the ICCBBA Human Readable style.

The character checked is the first character after the barcode style identification string. In the examples below the barcode style string is the first 3 characters therefore the 4th character is examined.

**]d2010950400005911817141120107654321D<GS>2110987654d321 (GS1 Data Matrix)**

**]C10151022222233336<GS>111412311715070710A213B1<GS>211234 {GS1 128)**

**]C1+51022222233336/$$515187A213B1/S1234/16D20141231R (HIBCC 128)**

**]C1=/51022222233336=,1234/=A213B1=>015187=}014365 (ICCBBA 128)**

Translating from the AIDC format to the HRF format is contingent on being aware of the issuer standard used to encode it and may, such as with GS1, require a current copy of the specification to be maintained. I.e. the lengths and the values of tags are and the list of valid tags may change with new releases of the GS1 standard.

# General Guidance

**Caution:** The UDI carrier may contain Personally Identifying Information (PII) in the form of the **serial number** or potentially other elements which may be used to link to other information on a patient. Standard practice for exchanging potentially identifying content should be exercised when exchanging UDI carriers which contain a **serial number** or other potentially personally-identifying elements or when communicating un-parsed UDI carriers which may contain such elements.

This section provides instructions for how UDI carriers and their components should be conveyed in various HL7 communication standards. Systems claiming conformance with this specification SHALL convey UDI information as described here when they are aware that they are conveying UDI information. Note that all guidance refers to where elements shall be transmitted if they are included in the instance. The base set of guidance does not assert when the UDI carrier, its constituent values or some combination of those need to be present.

## V2

The HRF or AIDC shall be communicated in either PRT-10 or PRT-22. The HRF is preferred.

PRT-10 is used when the HRF contains the serial number, while PRT-22 is used when it does not.

Note that v2 supports either OIDs or URIs as a means of globally unique identification for identifiers, but only OIDs for code systems.

Within PRT-10, the UDI carrier is sent in component 1 of the EI data type and the OID or URL is sent in component 3, with component 4 identifying whether the OID or URL approach was used.

PRT-10: |{01}00643169001763{17}160712{21}21A11F4855^^2.16.840.1.113883.3.3719^ISO|  
or  
PRT-10: |{01}00643169001763{17}160712{21}21A11F4855^^http://hl7.org/fhir/NamingSystem/fda-udi^URI|

In PRT-22, the both a primary and a secondary code may be transmitted and which components are used depends on whether the value is being conveyed as a primary or secondary code. The UDI string value will go in either component 1 or 4. A code system name, if known, must be sent in either component 3 or 5.

PRT-22: |{01}00643169001763{17}160712^^FDAUDI^^^^^^^^^^^2.16.840.1.113883.3.3719|

Note that v2 escaping techniques will be needed to convey non-printable characters within an AIDC.

The UDI elements shall be conveyed using PRT-16 through PRT-21. These elements are documented in V2.8.2 and later. The correspondence is as follows:

PRT-16 – DI goes into component 1. If known, the OID or URI for the namespace of the DI goes into component 3, with component 4 set to either “ISO” (for OIDs) or “URI”

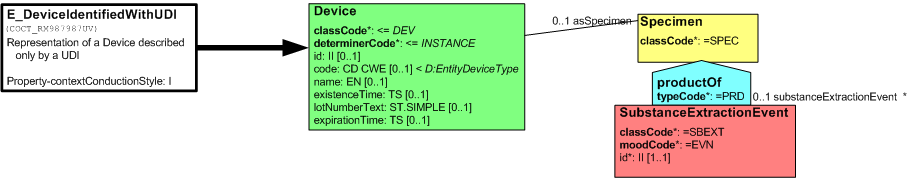
PRT-17 – manufacture is converted to the syntax yyyymmdd[hh]

PRT-18 – expiration is converted to the syntax yyyymmdd[hh]

PRT-19 – lot

PRT-20 – serial

PRT-21 – DIN goes into component 1. If known, the OID or URI for the namespace of the DIN goes into component 3, with component 4 set to either “ISO” (for OIDs) or “URI”V3



***[The above diagram requires updating to convey that the serial number can be represented using an IdentifiedEntity role where the roleCode indicates that it is a sequence or serial number and the serial number value appears in id.extension]***

If the UDI has been parsed and contains a Serial Number or is otherwise known to represent a unique instance identifier, it shall be stored in the **Device.id** element using the “extension” for the UDI and the “root” for the OID. Otherwise, the UDI carrier shall be stored in the **Device.code** element either in the root or one of the translations with the UDI in the “code” element and the OID in the “system” element, with no display value. Because of constraints on valid characters within XML, the AIDC identifier cannot be conveyed in CDA.

Because of XML limitations, only the HRF representation can be stored. XML encoding rules prohibit transmission of control codes and there is no appropriate v3 element to transmit an escaped version of the AIDC. Note that a HRF may be used in a Device.code element even if it contains a serial number.

The DI shall be stored in the **Device.code** element in either the root or as a CD.translation with the DI value as the “code” element and the OID conveyed in the “system” element.

The manufacture date shall be stored in the low value of the **Device.existenceTime** element converted to the syntax YYYYMMDD[HH].

The expiry date shall be stored in the high value of the **Device.expirationTime** element converted to the syntax YYYYMMDD[HH].

The lot shall be stored in the **Device.lotNumberText** element.

The Donation Identification Number shall be stored in the “value” element of **SubstanceExtractionEvent.id** with the root set to the OID and the extension to the actual Donation Identification Number.

The **IdentifiedEntity.id** extension element shall be used to store the serial number. The IdentifiedEntity.id root element will generally be omitted although it may be the Issuer OID or URL for the DI.

### V3 Example

<someDevice classCode="DEV" determinerCode="instance">

<id root="2.16.840.1.113883.3.3719" extension="{01}0061414999996{17}910304{10}123ABC{21}1234567890"/>

<code system="2.51.1.1" code="0061414999996"/>

<lotNumberText value="123ABC"/>

<expirationTime value="19910304"/>

<asSpecimen classCode="SPEC">

<substanceExtractionEvent classCode="SBEXT" moodCode="EVN">

<id root="2.16.840.1.113883.6.18.2.1 " extension="the actual DIN string"/>

</substanceExtractionEvent>

</asSpecimen>

<asIdentifiedEntity classCode="IDENT">

<id extension="1234567890"/>

<code system="2.16.840.1.113883.5.111" code="[TBD – SERIAL NUMBER]"/>

</asIdentifiedEntity>

</someDevice>

## V3 CDA

The HRF is provided in the “extension” element of **participantRole.id** with the OID as the root. Because of constraints on valid characters within XML, the AIDC identifier cannot be conveyed in CDA.

Note: The Structured Documents Work Group is continuing to work on identifying how and where to store the individual UDI elements within CDA and CCDA.

GS1 UDI example:

<participantRole>

…

<id root=”2.16.840.1.113883.3.3719” extension=”{01}00643169001763{17}160712{21}21A11F4855”>

…

</participantRole>

HIBCC UDI example:

<participantRole>

…

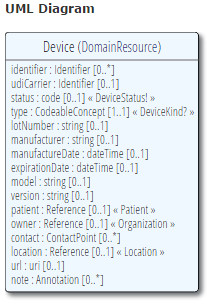
<id root=”2.16.840.1.113883.3.3719”

extension=”+25PLHH123C123456789+26Q9+Q5+1TL123456789+14D20110101”>

…

</participantRole>

## FHIR



The HRF shall be stored in the **udiCarrier** element with the appropriate repository uri as the system. The identifier.type should be set to “UDI”. Because of limitations on character sets in XML and the need to round-trip JSON data through XML, AIDC identifiers cannot be conveyed in FHIR.

The DI shall be stored in the “code” element of one of the Codings of the **type** element with the uri included as the system.

The manufacture date shall be stored in the **manufactureDate** element with the syntax converted to YYYY-MM-DD[THH:MM:SS]. If hour is present, the minutes and seconds should both be set to “00”.

The expiration date shall be stored in the **expiry** element with the syntax converted to YYYY-MM-DD[THH:MM:SS]. If hour is present, the minutes and seconds should both be set to “00”.

The lot shall be stored in the **lotNumber** element.

The serial number shall be stored in the **identifier** value element without a system specified. The identifier.type should

be set to “SNO”

Note: Order and Observations has not yet determined whether the Device resource will include Devices of Human (or other) Origin (tissue, blood, etc.) and so the need for Donation Identification number is not currently confirmed. If it is supported, then the following may apply:

The Donation Identification Number may be sent as an extension to the Device (example extension used below for demonstration, for example:

<Device>

<extension url=<http://hl7.org/fhir/StructureDefinition/device-donationIdentificationNumber>”>

<valueIdentifier>

<system value=”http://hl7.org/fhir/NamingSystem/iccbba-din”/>

<value value=”the actual DIN string”/>

</valueIdentifier>

</extension>

<!--Additional attributes-->

</Device>

### FHIR Example

<Device xmlns="http://hl7.org/fhir">

…

<identifier>

<type>

<coding>

<system value=”http://hl7.org/fhir/v2/0203”/>

<display value=”Serial Number”/>

<code value=”SNO”/>

</coding>

</type>

<value value="1234567890"/>

</identifier>

<udiCarrier>

<system value=”http://hl7.org/fhir/NamingSystem/fda-udi”/>

<value="{01}0061414999996{17}910304{10}123ABC{21}1234567890"/>

</udiCarrier>

<type>

<coding>

<system value="http://hl7.org/fhir/NamingSystem/gs1-di"/>

<value value="0061414999996"/>

</coding>

</type>

<expiry value = “1991-03-04”/> <!—Note the century + reformatting -->

<lotNumber value=”123ABC”/>

…

</Device>

# Additional Recommendations

This section provides recommended guidance for increased interoperability, but this guidance may not be practical for all systems or appropriate for all use-cases. It presumes that the system creating the instance:

* Is able to convert the raw scanned barcode text to the UDI carrier Human Readable Form (HRF) string
* is able to parse the various forms of UDIs and can extract the various component elements
* is not transmitting in a bandwidth or size-constrained environment or other environment where including both the UDI and its associated component elements would be problematic
* is transmitting in an environment where exposing the UDI components would provide business value

Examples of where these rules may not make sense include instances created by automated devices with limited processing power or complexity as well as general-purpose systems for whom UDI is considered “just another identifier”.

The guidance that follows reflects implementer feedback and should be considered best-practice for systems and implementation guides that fall within the criteria listed above.

Profiles will be defined allowing systems and implementation guides to indicate whether they conform to these additional conformance requirements.

## Conformance requirements:

In accordance with the expressive capability of the HL7 standard being used to convey the instance and any standard-specific requirements (e.g. use of OID vs. URI):

1. Systems SHALL transmit the UDI value, SHALL do so using only the Human Readable Form string (HRF) and SHALL ensure that the OID or URL identifying the UDI assigning system is specified. If the encoding format has both a regular and an exchangeable HRF syntax, the exchangeable syntax SHALL be used. Where a serial number is being conveyed and the intent of the instance is to identify a specific device, the UDI SHALL be included in the element which communicates that intention (if supported by the HL7 standard used)
2. Systems SHALL transmit all components found within the UDI for which data element locations are defined for the HL7 standard used and SHALL ensure that the data present within the components matches the data conveyed within the UDI
3. When conveying the DI and DIN components, the system SHALL ensure that the appropriate OID or URL is declared
4. Where the HL7 standard being used supports both OIDs and URLs (i.e. v2), the system SHALL be capable of recognizing both approaches and recognizing their equivalence.

Paul moves that this UDI proposal be accepted as amended with the cosmetic changes note to be done shortly, Lloyd seconds. Vote: 13/0/1, motion carries.

1. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc> [↑](#footnote-ref-1)
2. Is referred to as ‘Easily readable plain-text in the FDA UDI regulation. [↑](#footnote-ref-2)