Harmonization Pattern for Unique Device Identifiers

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Preamble

The FDA has introduced a formal Unique Device Identifier (UDI) specification, see http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc for the Issuer specific element formats. The purpose of this Harmonization Pattern is to describe a consistent pattern to be followed in the construction of HL7 specifications to ensure maximum interoperability between those HL7 specifications which include UDIs.

Element	Description	Data Type	Cardinality	Notes
UDI and Contained Elements				
UDI	FDA Unique Device Identifier	Identifier/Code	1..1	The value is the Human Readable Form of the UDI. An FDA UDI OID is available for reference where required.
Elements Contained Within A UDI				
di	Device Identifier	Code	1..1	The value is a string. Issuer OIDs are available to identify which Device Identifier code system.
manufacture	Manufacture Date	Timestamp	0..1	The value is an Issuer specific string containing the date, often without century, and optionally with the hour.
expiration	Expiry Date	Timestamp	0..1	The value is an Issuer specific string containing the date, often without century, and optionally with the hour.
lot	Lot Number	String	0..1	The value is an alphanumeric string.
serial	Serial Number	String	0..1	The value is an alphanumeric string.
din	Donation Identification Number	Identifier	0..1	The value is a string. An ICCBBA DIN OID is available for reference where required, but is not required when the specific data element is scoped to ICCBBA DINs.

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

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 for FDA UDIs, and another string component to carry the UDI human readable string. The UDI will be stored as an Identifier when that is the purpose of the data collection, as a globally unique Id for the device, and as a code when the intent is to capture the type of device without a requirement for global uniqueness.

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.

<u>**Overview**</u>

The purpose of this pattern is to provide a standardized (and safe) way of expressing Unique Device Identifiers (UDIs) for exchange in HL7 v2 segments, V3 Documents and Messages, and FHIR resources.

UDI: When exchanging UDIs the entire Human Readable Form of the string may be exchanged in a unique identifier data type If as a unique identifier then the identifier root shall be the OID assigned to UDI, for example for FDA UDIs the root shall be 2.16.840.1.113883.3.3719, and the extension shall be the Human Readable Form appropriate for the style of content. The content style can be determined from the leading characters of the content:

UDIs beginning with: '{' are in the GS1 Exchange Format (note not the GS1 Human Readable Format);
'0-9' are a GS1 DI (containing only the DI value, no PI or GS1 AI);
'+' are in the HIBCC Human Readable style;
'=' or '&' are in the ICCBBA Human Readable style.

The unadulterated UDI string should be the exchange standard. The exchange of UDI sub-elements is not required or desired when the full UDI string is available. If the component data elements are included along with the full UDI string, a practice which is strongly discouraged, then the data elements must match the content of the UDI string. Also, recipient applications are advised to parse the UDI string and compare the individual data elements, as a validation.

Caution: The UDI may contain personally identifying information in the form of the **serial number** which may be used to link to other information on a patient. Standard practise for exchanging potentially identifying content should be exercised when exchanging UDIs which contain a **serial number**. See the guidance below:

Guidance

When exchanging UDI, the following guidance applies:

If there is a UDI:
Regardless of content, transmit the unadulterated, string form of the UDI
If privacy is a concern then notify recipient applications that the content contain PII and HIPAA-compliant procedures should be followed before parsing the UDI string into individual data elements.
If there is no UDI:
Transmit all available elements as elements.
If privacy is a concern then notify recipient application that the content contain PII and HIPAA-compliant procedures should be followed.

For Labelers – parties who are populating the GUDID database
Labelers are responsible for populating the GUDID database. The reference definitional information, the DI, PI and such other information as required to populate the GUDID database, shall be transmitted as elements.

For Implementers:
For some UDI issuing systems, such as the FDA-UDI in the United States, there is a database, eg. GUDID, where the DI can be validated, in real or near-real time. Implementations should consider their requirements as to validation of the DI against such systems as a part of the input validation process.

In those circumstances where the exchange of elements is warranted the following applies:

di: When exchanging Device Identifiers (DI) the root shall be the OID, or standards' appropriate corollary to the OID, assigned to DI and the extension shall be the Human Readable Form of the content. For example, for DIs the root shall be:

      GS1 DIs: 2.51.1.1
      HIBCC DIs: 1.0.15961.10.816
      ICCBBA DIs: 2.16.840.1.113883.6.18.1.17 for Blood containers and 2.16.840.1.113883.6.18.1.34 otherwise.

manufacture: The user system will convert the date and optional hour from the Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

expiration: The user system will convert the date and optional hour from the Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

lot: The user system will extract the contents of the field from the Human Readable Form as a simple string data type.

serial: The user system will extract the contents of the field from the Human Readable Form as a simple string data type.

din: When exchanging Donation Identification Numbers (DIN) the root shall be the OID assigned to DIN and the extension shall be the Human Readable Form of the content. For example, for DINs the root shall be:

      ICCBBA DINs: 2.16.840.1.113883.6.18.2.1

Note: Alpha and alphanumeric fields may contain characters which must be escaped for proper handling with any given serialization.

FHIR

In FHIR there are elements for each of the current UDI elements except for Donor Identification Number which must be sent as an extension.

When the UDI is used as a unique instance identifier, it must contain a Serial Number, and it shall be stored in the **identifier** element. Otherwise, the UDI shall be stored in the **type** element. Note that a UDI may be used in a type element even if it contains a serial number. If the Repository is not identified within the string then default to the FDA OID.

The DI shall be stored in the **type** element with appropriate OID and DI string.

The manufacture date shall be stored in the **manufactureDate** element with the century added as required.

The expiry date shall be stored in the **expiry** element.

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

The serial number shall be stored in the **identifier** element, without a system specified, when privacy is not a concern.

The Donor Identification Number shall be sent as an extension to the Device, for example

```
  <Device>
        <extension url=https://hl7.org/fhir/DonorIdentificationNumber">
           <valueIdentifier>
               <system value="urn:oid: 2.16.840.1.113883.6.18.2.1"/>
               <value value="the actual DIN string"/>
           </valueIdentifier>
         </extension>
        Additional attributes
</Device>
```
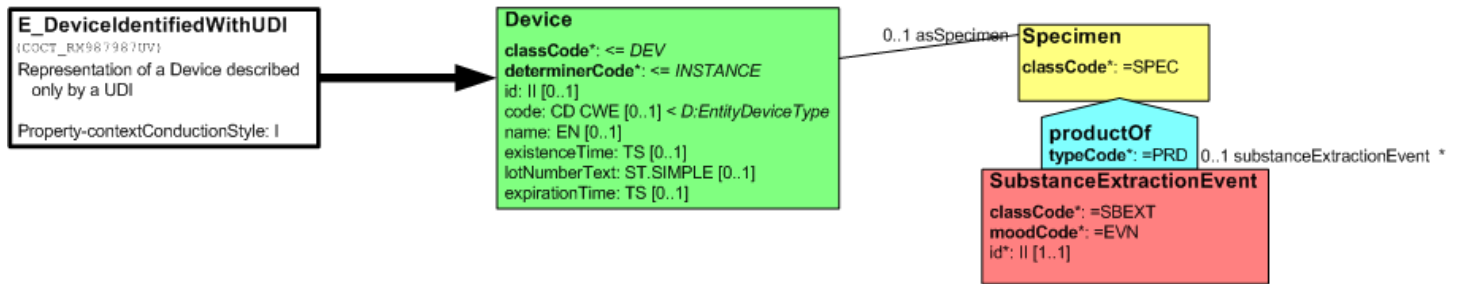
FHIR Examples

In FHIR a 'udi' is stored in the identifier attribute and the FDA UDI OID is the default system.

```
<Device xmlns="http://hl7.org/fhir">
…
   <identifier>
      <system value ="urn:oid:2.16.840.1.113883.3.3719"/>
      < value="{01}0061414999996{17}910304{10}123ABC{21}1234567890"/>
   </identifier>
…
</Device>
```

The same example content as above where no UDI exists and where there are no privacy concerns.

```
<Device xmlns="http://hl7.org/fhir">
…
   <identifier>
      <system value="http://goodcare.org/devices/id"/>
      <value value="345675"/>
   </identifier>
   <identifier>
      <value value="1234567890"/>                 <!—this is the serial number -->
   </identifier>
   <type>
      <coding>
         system value="urn:oid: 2.51.1.1"/>
         <value value="0061414999996"/>
      </coding>
   </type>
   <expiry value = "19910304"/>          <!—Note the addition of the century -->
   <lotNumber value="123ABC"/>
…
</Device>
```

V3

When the UDI is used as a unique instance identifier, it must contain a Serial Number, and it shall be stored in the **Device.id** element. Otherwise, the UDI shall be stored in the **Device.code** element. Note that a UDI may be used in a Device.code element even if it contains a serial number. If the Repository is not identified within the string then default to the FDA OID.

The DI shall be stored in the **Device.code** element with appropriate OID and DI string.
The manufacture date shall be stored in the low value of the **Device.existenceTime** element with the century added as required.
The expiry date shall be stored in the high value of the **Device.expirationTime** element.
The lot shall be stored in the **Device.lotNumberText** element.
The serial number shall be stored in the **Device.name** element when privacy is not a concern.

Add a SubstanceExtractionEvent that means Donor and the id will be the donor number.
The Donor Identification Number shall be stored in the **SubstanceExtractionEvent.id** with the root set to "2.51.1.1" and the extension to the actual Donor Number.

V3 CDA

The UDI is provided in the **participantRole.id** element (II data type) with the FDA OID as the default root.

<u>GS1 UDI example:</u>

```
<participantRole>
…
   <id root="2.16.840.1.113883.3.3719" extension="{01}00643169001763{17}160712{21}21A11F4855">
…
</participantRole>
```

<u>HIBCC UDI example:</u>

```
<participantRole>
…
   <id root="2.16.840.1.113883.3.3719"
         extension="+25PLHH123C123456789+26Q9+Q5+1TL123456789+14D20110101">
…
</participantRole>
```

V2

The UDI shall be stored in the **PRT.10** element as an EI data type with the FDA OID as the default root.

PRT.10: |{01}00643169001763{17}160712{21}21A11F4855^^2.16.840.1.113883.3.3719^ISO|

The required HL7 committees are engaged in defining the required v2 fields for inclusion in 2.8.2.