How to transfer UDIs via HL7 v2 in LAW Profile

Idea collection for IICC Meeting

Cornelia Felder, Software Architect
Ralf Herzog, Connectivity Architect

Question from IVD Session

FDA BAA presentation, June 8th 2023

“Is there a possibility to encode the LIDR elements into the software of your analyzers capable of being sent with result messages when interfaced to an LIS or POC Middleware whenever a test is resulted?”

-> as of now the answer is NO

Missing guidance and specifications.

Open points

need to be clarified to move on

- LIDR asks for UID data elements. Is this the same as UDI?
  Is there an aligned view on UDI? (see next slide)

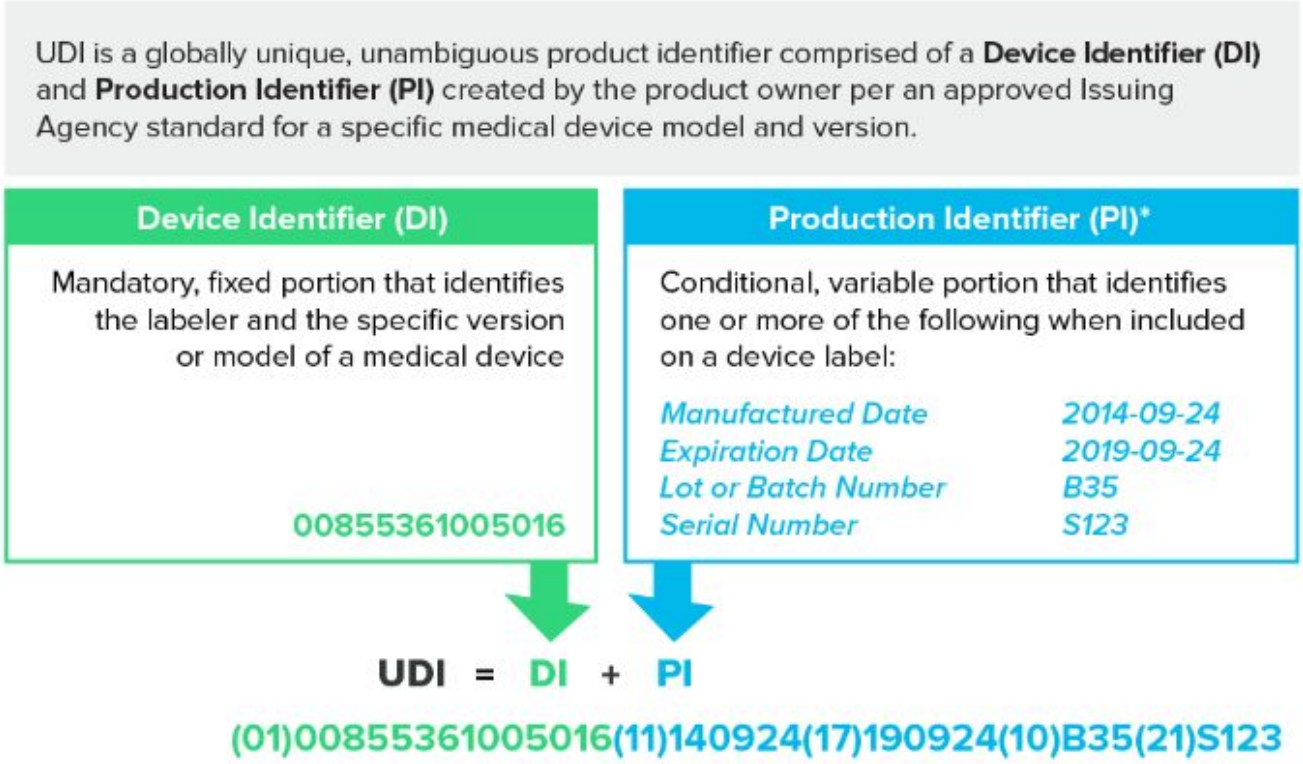
- Shall/can we rely on LIS system's to concatenate the UDI out of different HL7 fields/ components/ subcomponents?

- Shall/can we apply the same pattern for Analyzer UDI and Reagent UDI?

- Can we work on a transitional architecture for LIDR using LIVD files and concatenate the information on LIS level?

UDI Explanation:

See https://www.greenlight.guru/blog/udi-medical-devices



GS1 Format (Application Identifiers)

GS1 offers the HRI (Human Readable Interpretation) format with GS1 defined Application Identifiers to identify the different parts of a UDI:

- **DI**
  “(01)” - Global Trade Item Number (GTIN)

  PI
- **“(21)”** - Serial number
- **“(240)”** - Additional product identification assigned by the manufacturer
- **“(10)”** - Batch or lot number
- **“(17)”** - Expiration date
- **…** - 519 different Applications Identifiers are currently defined by GS1

See: https://www.gs1.org/standards/barcodes/application-identifiers

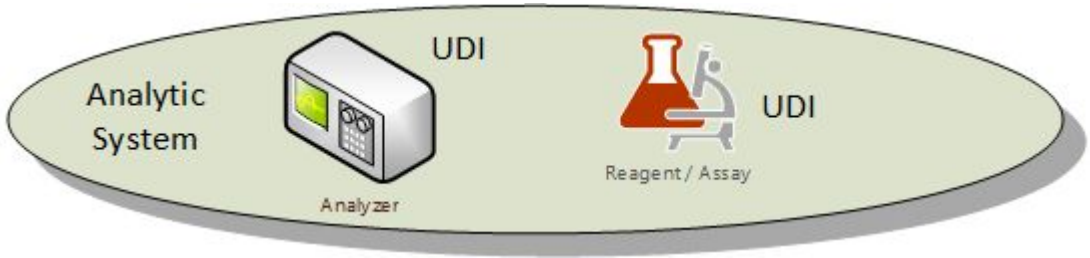
UDI's involved:

UDI = DI & PI (DI:

Simple 1:1 example

Analyzer UDI

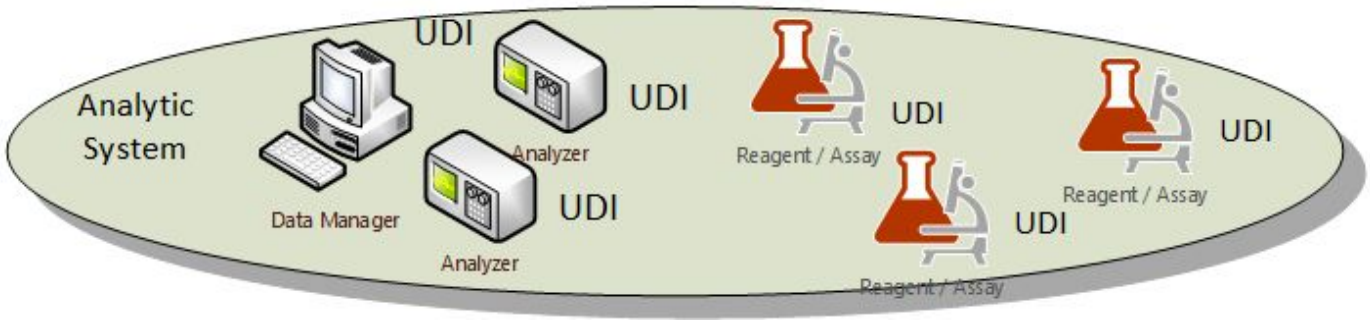
Reagent UDI



More complex example

Multiple Analyzer UDI's

Multiple Reagent UDI's



HL7 Cross Paradigm IG: UDI Pattern, Release 2

Conformance requirements:

1. Systems SHALL transmit the UDI value, SHALL do so using 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)

Example using PRT-10 out of the mentioned IG:

`|{01}00643169001763{21}21A11F4855^^2.16.840.1.113883.3.3719^ISO|`

(artificial example similar to GS1 with not correct Application Identifiers (should be "**`(01)`**" instead of "**`{01}`**" and "**`(21)`**" instead of "**`{21}`**" where a GTIN (Application Identifier "**`(01)`**") and a Serial Number (Application Identifier "**`(21)`**") is transmitted in One Field.

IHE LAW Definitions

Table C.7-21: Element OBX-18 Equipment Instance Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R R O	50	First repeat: Model Second repeat: Serial number Subsequent repeats: Vendor/site defined
Namespace ID (IS)	R R O	20	First Repeat: Manufacturer Second Repeat: Manufacturer Subsequent repeats: Vendor/site defined
Universal ID (ST)	O X	199	First Repeat: UID Subsequent repeats: Not supported
Universal ID Type (ID)	O X	6	First Repeat: ISO Subsequent repeats: Not supported

IHE LAW Definition

OBX-18 is repeatable in v2.5.1. The first instance is mandatory and will be used to carry the instrument model, manufacturer, and optional UDI information.

Table B.2-1: First Instance of Element OBX-18 Equipment Instance Identifier

Sub-Component	Usage	Comment
Entity Identifier	R	Model
Namespace	R	Manufacturer
Universal ID	O	UID when populated
Universal ID Type	O	ISO when populated

The second instance of OBX-18 is also mandatory and will be used to carry the serial number.

Table B.2-2: Second Instance of Element OBX-18 Equipment Instance Identifier

Sub-Component	Usage	Comment
Entity Identifier	R	Serial Number
Namespace	R	Manufacturer
Universal ID	X	
Universal ID Type	X	

ED's email -> both options

OBX Repeat	Entity Identifier	Namespace ID (Manufacturer)	Universal ID	Universal ID Type
1	Example Instrument	Roche	51022222233336	DI
2	1234	Roche	1234	PI

The table was put together with a focus on the Manufacturer information, as can be seen with the First & Second repeats providing Model and Serial Number.
This could be viewed as providing the DI and the PI in the manufacturer's representation.
It would be straightforward to update the LAW specification to state that the Universal ID and Universal ID Type would be populated with DI for the first repeat, and PI for the second repeat.

OBX Repeat	Entity Identifier	Namespace ID (Manufacturer)	Universal ID	Universal ID Type
1	Example Instrument	Roche	(01)51022222233336(21)1234	GSI
2	1234	Roche		

Or, as Conny pointed out the DI and PI could be provided in human readable form just in the first repeat.

Ultimately, it really depends on how the upstream systems would capture and store the DI and PI. I feel this would be good topic for the SHIELD working groups to discuss. I think it impacts both the LIDR and IVD Data Hub working groups. For some instruments, the DI information (UDI) for the kind of instrument may be found in LIDR information if the instrument does not transmit it. In this instance the LIS would need to assemble the UID (DI + PI) from the LAW content and LIDR mapping information. For the Roche instruments, the DI and PI would captured from the LAW communication only. Ultimately the UID would be stored in the IVD Data Hub so we need to understand expectations for getting it there.

LIVD already supports UID for the test, and LAW supports the inventory segment (INV) with a Manufacturer Lot Number. We'll need to review this with working group to align on a strategy for this information too.

IHE LAW - Option I

IHE LAW defines OBX-18 to be used this way:

- First Repetition describes the Model (==> DI part of UDI),
- Second Repetition is the Serial number (==> PI part of UDI),
- Universal ID Type seems to be wrongly defined.

Suggested Format and Place - Option I

The UDI in GS1 Format "(01)08889444561189(21)1234567" would be transferred in OBX-18 **but** split up according to the current definition of OBX-18 where the DI Part of the UDI would be transferred in OBX-18(1)-3 in GS1 Format, while the PI Part (Serial Number) is already in OBX-18(2)-1 as now already defined:

`Option 1a` **|Model^MANUFACTURER^(01)08889444561189^GS1~1234567^MANUFACTURER|**

or alternative version (same place, but different format not using GS1 Application Identifiers, Ed's Example)):

`Option 1b` **|Model^MANUFACTURER^08889444561189^DI~1234567^MANUFACTURER^1234567^PI|**

Pros / Cons:

+ Option 1a Minor Update IHE LAW specification is required (ISO should be removed from the Table B2-1 and some clarification how to do this, but we do **not** change any cardinality etc.)
- Option 1b additional needs 2nd instance of OBX-18(2)-3 and OBX-18(2)-4 needs currently not allowed elements.
+ No duplication of information.
+ Could be used the same way in INV-1 (just placing the DI Part of Reagent/Disposable there while using the already existing fields for LOT, Expiration, etc.)
- UDI would need to be concatenated by the LIS/MW/other receiving System.

Hint: There is a Change Request at HL7 to add the different Issuing Agencies to Table 0301 (Universal ID type). Accepted by OO (Orders and Observations) Working Group, discussion with Vocabulary Working Group open.

Suggested Format and Place - Option I
for Reagents and Consumables

To transfer **reagents** and **consumable identifiers** the INV Segment associated with the test results OBX could be used.

INV-1 - Substance Identifier is a valid place, more precise INV-1-1 (Identifier) or INV-1-4 (Alternate Identifier) (to be able to transfer the Manufacturer defined Identifiers together with UDIs). Alternate Identifier would be needed to be added to INV-1 - if needed, INV-1-3 and INV-1-6 would need to be mandatory to be able to distinguish (INV-1-3 is mandatory).

Open question:

- Lot Information, Expiration Date, Production Date etc. should be transferred in the INV Fields that are used for this currently and the information then can be concatened by the LIS/MW/receiving System (i.e. **Lot Number** in INV-16, **Expiration date** in INV-12) or also in INV-1 separated with GS1 Application Identifiers?
  If in INV-1 than the Identifier component should perhaps be enlarged (current limit of 50).

Suggested Format for INV-1 (Substance Identifier):

```
|ManufacturerId^^99MANUFACTURER^(01)08889444561189^^GS1|
```

Complete example of INV (without Manufacturer ID and using INV-12 for Expiration Date and INV-16 for LotNumber):

```
INV|(01)08889444561189^^GS1|OK^^HL70383|SR^^HL0384|1234||||||
    |20230930235959|||LotNumber
```

Hint: There is a Change Request at HL7 to add the different Issuing Agencies to Table 0301 (Universal ID type). Accepted by OO (Orders and Observations) Working Group, discussion with Vocabulary Working Group open.

Suggested Format and Place - Option II

The UDI in GS1 Format "(01)08889444561189(21)1234567" would be transferred in OBX-18 **and as the already foreseen Universal Identifier.**

|c5800^Roche^(01)51022222233336(21)1234567^GSI~1234567^Roche|

Pros / Cons:

+ Minor update IHE LAW specification required.
- removal of mandatory 2nd repeat would be a major change (as it is not backward compatible), but duplicate information could be avoided.
+ With a removal of 2nd repeat as mandatory, we could allow 2 UDI's if necessary.
+ Repeats can be avoided, as they are rarely used in HL7 and often misunderstood.
+ UDI can be consumed as a whole by LIS/MW/other receiving System.
- Dependence on HL7 tables with Issuing Agencies which currently are only 4 for UDI.
+ same concept for device and reagents can be applied (using GS1 application identifiers)

Suggested Format and Place - for Reagents and Consumables

possibility to use INV-1

Index	Data type	Description	Max. len.	Cardi-nality
INV-1	CE	Substance ID	250	1..1
INV-1-1	ST	Identifier	20	1..1
INV-1-2	ST	Text	199	0..1
INV-1-3	ID	Coding system	12	1..1

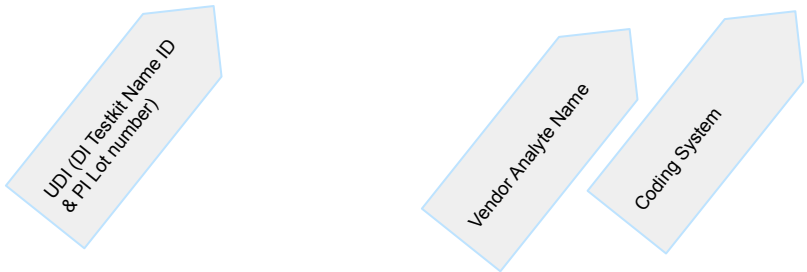
Table 2.2.3-1: Conformance Lengths for Keys/Primary Identifiers

Field	Field Element	Conformance Length (cannot be truncated)
INV-1 Identifier of Substance	CE.1 (ST) Identifier	50

INV1-1 has different max length it the IHE Specs. Should be corrected.

INV-1 can be leveraged, but backwards compatibility has to be guaranteed and descriptive, informative examples will be required. Update IHE LAW specifications.

Interpretation: | **(01)51022227897836(10)45645^**ACTH IVD^**GS1** |



Elements and their naming aligned with LIVD specifications.

Additional notes - meeting 25th July

- This should be discussed in the SHIELD initiative in the context of LIDR.
  as it is not clear what they want from instrument manufacturers.
- The SHIELD audience might not be following such a proposal to make decision, so a proposal in a smaller group should be elaborated and then it can be shared.
- SHIELD is the right place as it should align the industry, subgroup of LIDR and IVD DataHub can answer the questions and work out a proposal which works for the IVD manufacturer, LIS vendors, and other leaders in the industry before it is taken up to IHE, HL7 etc. -- Xavier in the lead to inform Riki and Hang Luu
- CLSI AUTO16 should be on a fast track and the UDI discussion has not to be taken into this currently planned update.

Doing now what patients need next