LUC UOU Examples Talk Track

(Slide 1): Welcome to the AHRMM Learning UDI Community. This presentation is intended to provide more information on potential use cases for the Unit of Use (also known as the "UOU") identifier. This novel concept is not commonly used in industries outside of healthcare. For a detailed explanation on why the UOU was created and how it should be structured, please refer to the companion presentation, "UOU Explained".

(Slide 2): To minimize confusion and foster a standardized approach towards the creation and use of the UOU DI, AHRMM organized a task force to study this issue. This group included stakeholders from across healthcare. It included representation from the FDA, hospitals, clinicians, industry groups, issuing agencies, and medical device manufacturers. They have suggested the following best practices for the UOU.

First, all discrete individual items should be identified, even if they are packaged in larger multiples. For example, if you manufacture syringes in pharmacy trays, you should identify individual syringes within the lowest packaging level as well as at the tray or case level. Second, wherever possible, encourage the development of standard enumeration practices with logical sequences. If your policies permit, it may be beneficial to standardize around the use of specific identifiers related to specific packaging levels. Given the diversity of medical devices, this may not always be possible. We recommend you formulate a logical sequence that works best for your organization. Once those identifiers have been created, it is important to provide the full data (including UOU DI) to all trading partners. You should clearly indicate which DI are marked and which are not. You should also clearly indicate the net content for all products. Finally, it is very important to clearly indicate the unit of use whenever it differs from the lowest packaged level.

(Slide 3): To illustrate how the UOU might be used, we have selected a few potential examples. The first product example is an allergist tray.

(Slide 4): The allergist tray groups multiple syringes together for allergy testing. Clinicians prefer not to unwrap individual syringes when performing these tests. There are 25 identical syringes in the tray without any labels. There are also similar trays available for the pharmacy. This allergist tray is BD catalog number 305535.

(Slide 5): The product hierarchy for this allergist tray has three levels, but only two of these levels have packaging with printed barcodes. All three levels have device identifiers, or DI, assigned to them. The individual syringe is assigned an unmarked unit of use DI. There are 25 syringes in each tray with a printed barcode on the tray. Each case of this allergist tray features a printed barcode and contains 40 trays for a total of 1000 syringes in the full case.

(Slide 6): Slides 6 and 7 are screenshots from the FDA's Global UDI Database, or GUDID for short.

(Slide 7): This slide clearly shows all three levels and the DI for each level. We can also see the unmarked UOU DI.

(Slide 8): Our next example is a Microtainer.

(Slide 9): The microtainer is a device used for capillary blood collection. It is often used on neonates, small children, and elderly patients. Clinicians typically apply a patient specific label directly to the product for identification purposes. At the same time, clinicians also want to be able to see clearly whether there is sampled blood in the tube. CLSI requirements dictate that the lot number and expiration of the tube must be printed on the tube. With so many existing requirements, there is little opportunity for a legible barcode to be printed directly on the microtainer. This microtainer is BD catalog number 365974.

(Slide 10): The product hierarchy for the microtainer has three levels, but only two of these levels have packaging with printed barcodes. This is very similar to the previous allergist tray example. The individual microtainer is assigned an unmarked UOU DI. The shelf pack for this product contains 50 tubes and has a printed barcode on the box. There are four shelf packs contained in a case of 200 tubes with a printed barcode on the case label.

(Slide 11): The next example differs from the previous two examples. For both the allergist tray and the microtainer, all of the products contained in the case were identical to each other. In Vitro Diagnostic, or IVD kits, contain items that are not all identical. This different use case requires a different potential solution.

(Slide 12): IVD kits are moderately complex DNA tests that can generally be performed in about 45 minutes. A single kit can perform 24 separate tests. There are multiple different components in the kit, not 24 separate tests.

(Slide 13): There is only a single DI on the outer carton for the IVD kit as shown here.

(Slide 14): This leads to some uncertainty over the proper usage of the DI. When our task force reviewed IVD kits, we had many outstanding questions.

Today, there is a single DI at the kit level. Should there be an additional UOU DI assigned by the manufacturer in order to account for each of the 24 separate tests contained in the larger kit?

One concern with this approach is that it may confuse clinicians. They may think that the UOU DI is a supply chain unit of measure and attempt to reorder based on the UOU DI instead of the kit level DI. As a larger team, we felt that we didn't have enough experience with IVD kits or DI to be able to make a solid recommendation either for or against this proposed solution.

(Slide 15): Our task force closed our work with these general findings about the UOU DI. Because the products provided for our examples all came from BD and BD uses the GS1 Global Trade Item Number (or GTIN) as their issuing agency, these recommendations are from a BD perspective and center on the GTIN.

BD has standardized their GTIN allocation. They typically assign DI down to the lowest unit of measure possible (Base Unit). BD generally assigns a package indicator digit of zero ("0") as the Base Unit. Some products do not have labels and do not have UDI on the label.

There are some products (such as the IVD test kits) without discreet individual units inside. BD chose to designate the overall kit as the Base Unit and indicate the proper number of tests provided for these kits.

Higher levels of packaging all contain full UDI on the labels. BD also accounts for the Base Unit and all additional packaging levels in its master data. This strategy complies with the FDA UDI guidelines and allows for clinicians to use the UOU DI and Base Unit data if they voluntarily choose to do so.

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Unit of Use (UOU) Examples

Theory and Potential Practice

Suggested Best Practice

- Discrete individual items should have unique identifiers even if they are packaged in larger multiples.
- Where possible, encourage the development of standard enumeration practices with logical sequences
- Provide full data to all trading partners
  - Clearly indicate which DI are marked
  - Clearly indicate the net content for all products
- Clearly indicate the unit of use whenever it differs from the lowest packaged level

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Allergist Tray Example

BD Allergist Tray

- Syringes in allergy trays are used for allergy testing
- Clinicians prefer not to unwrap each individual syringe and therefore prefer trays
- The individual syringes don't have labels on them
- Similar syringe trays are available for pharmacy
- The example depicted is for Catalog Number **305535**

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BD Allergist Tray: GTIN Assignment

- DI: 00382903055357
  (DI Assigned, unmarked)

Each
1 Each

- DI: 30382903055358
  (Full UDI on Label)

Allergist Tray
25 Each

- DI: 50382903055352
  (Full UDI on Label)

Case
40 Trays of 25
1,000 Each

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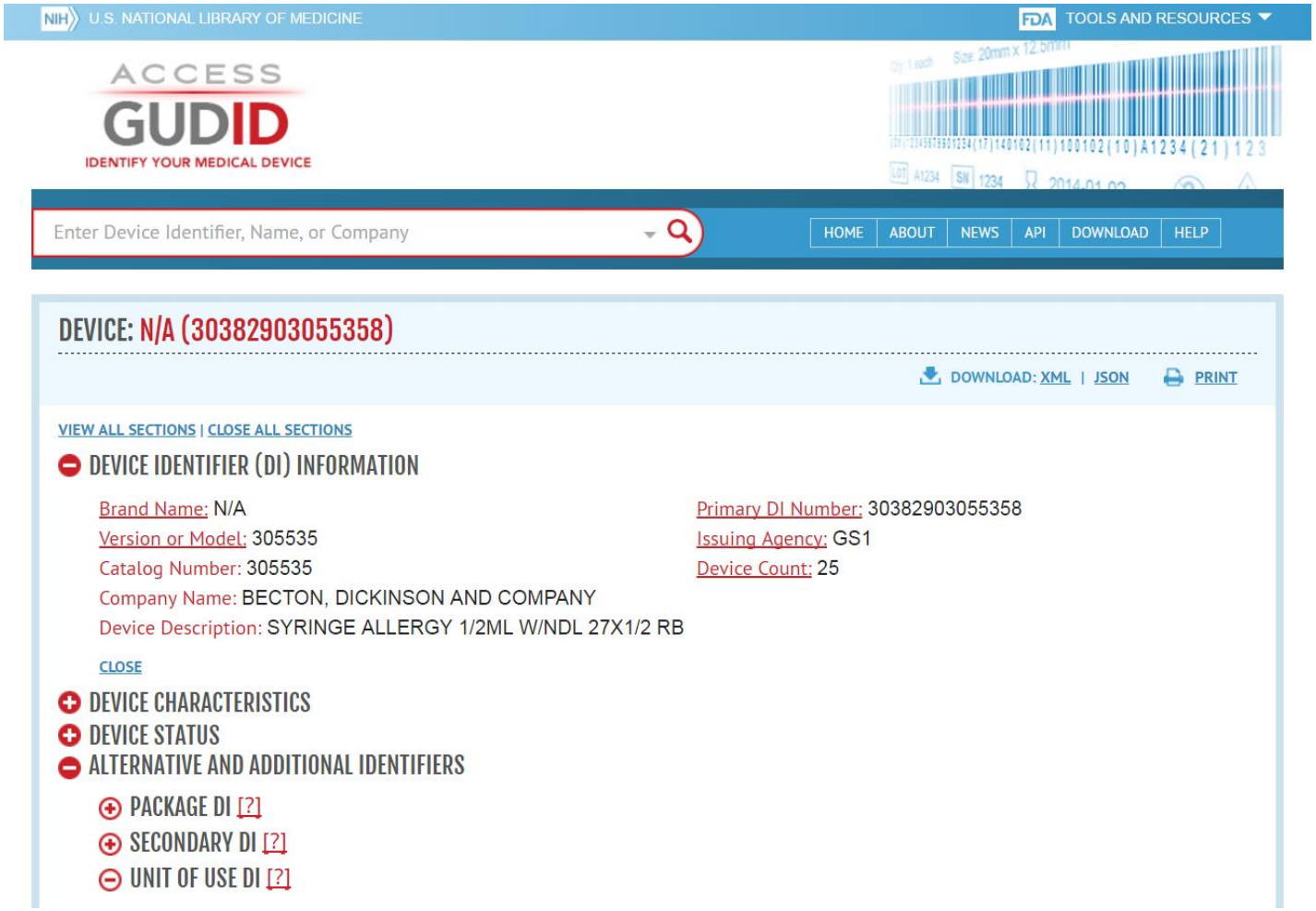
BD Allergist Tray in GUDID



BD Allergist Tray in GUDID (cont'd)

ALTERNATIVE AND ADDITIONAL IDENTIFIERS

PACKAGE DI [?]

Package DI Number	Quantity per Package	Contains DI Package	Package Discontinue Date	Package Status
50382903055352	40	30382903055358		In Commercial Distribution

CLOSE

SECONDARY DI [?]

UNIT OF USE DI [?]

Unit of Use DI Number: 00382903055357

CLOSE

DIRECT MARKING (DM) [?]

Device Subject to Direct Marking (DM), but Exempt: Yes
DM DI Different from Primary DI: No
DM DI Number: None

CLOSE

PRODUCTION IDENTIFIER(S) IN UDI [?]

Lot or Batch Number: Yes
Serial Number: No
Expiration Date: Yes
Manufacturing Date: No
Donation Identification Number: No

CLOSE

CUSTOMER CONTACT [?]

Microtainer Example

BD Microtainer® tube

- Device is used for capillary blood collection
- Often used on neonates, small children, and the elderly
- After blood is drawn, patient's specific label is applied to the product
- Clinicians need to see blood in in container
- Per Clinical and Laboratory Standards Institute (CLSI) requirements, Lot Number and Expiration Date are printed on each tube
- A catalog number and a UDI DI have been assigned
- The example depicted is for Catalog Number **365974**

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BD Microtainer® tube: GTIN Assignment

- DI: 00382903659746

  (DI Assigned, Unmarked)

Each
1 Each

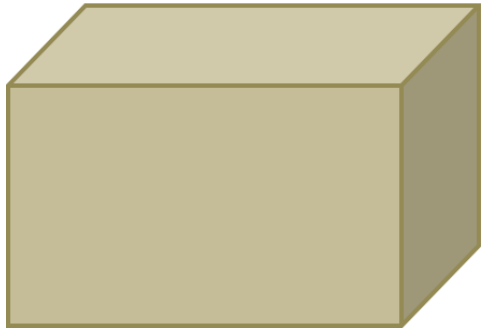
- DI: 30382903659747

  (Full UDI on Label)

Shelf Pack
50 Each

- DI: 50382903659741

  (Full UDI on Label)



Case
200 Each

IVD Tray Example

Note: IVD contains items which are not all the same. This creates a different use case which cannot employ the same logic as the previous examples.

BD Affirm™ VPIII Microbial Identification Tests

- Easy-to-perform moderately-complex DNA probe technology that takes about 45 minutes.
- 1 Kit can be used for 24 Tests
- The Kit contains a variety of components, not 24 discreet tests

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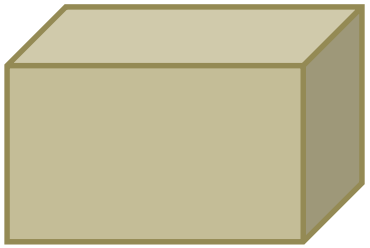
BD Affirm™ VPIII Microbial Identification Tests: GTIN Assignment

- DI: 00382904462529
  (Full UDI on Label)



Kit
Can be used for
24 Tests

IVD and the UOU

- Today, we might potentially assign the UOU DI to represent a single test in the medical records for an individual patient. This UOU DI would be the single DI assigned to the full kit.
- Should we assign an additional DI to represent the individual kit since this particular kit can be used 24 separate times?
- One concern with a separate identifier is that some clinicians might feel that they can order one of the 24 uses of the individual test kit (not possible).
- We have not had enough experience yet with the UOU and IVD to know whether or not this is feasible.

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UOU: GTIN Assignments

- BD generally assigns a GTIN to the lowest unit-of-measure possible (Base Unit)
- Following the GS1 GTIN Allocation Rules, BD typically uses a “0” for the package indicator on the Base Unit
- Some products don’t have labels, and therefore don’t have a UDI on the label
- Some Products (Test Kits) don’t have individual discreet units inside and therefore define the Kit as an Each and note the number of tests that can conducted per kit
- Higher levels of packaging will be fully enumerated with a full UDI
- The Base Unit GTIN is accounted for in our master data
- This strategy is compliant with FDA’s UDI regulation
- Healthcare Providers may use the DI assigned to the Base Unit for EHR or other tracking processes if desired (no obligation)