



## **LUC UOU Explained Talk Track**

(Slide 1): Welcome to the AHRMM Learning UDI Community. This presentation is intended to explain the history behind the introduction of the Unit of Use (also known as the “UOU”). This novel concept is not commonly used in industries outside of healthcare. We will review the actual language in the original FDA documents. We will also recommend best practices for medical device manufacturers in the creation of the Unit of Use for their products. By understanding the need for this identifier, medical device manufacturers should be able to load more accurate information into the Global UDI Database (also known as the GUDID) so that the UOU can help improve both patient safety and the overall healthcare supply chain.

(Slide 2): The language shown on this slide is taken directly from the FDA documents creating the Unique Device Identification program. It states that when the lowest packaged level of a product contains more than one device, an unmarked “unit of use” identifier should be created.

(Slide 3): This graphic is taken from an FDA guidance document released in June 2014. It attempts to describe the correct application of the UOU identifier. This presentation provides additional context and information explaining this concept in greater detail.

(Slide 4): The device identifier (or “DI” for short) is a concept common to many industries. While the physical form of the DI appears to be the same in industries such as retailers and grocers, the primary purpose for the DI is not the same. For retailers, the use of the DI is centered on the barcode scanners used at the checkout counter. In healthcare, the use of the DI will be centered on the patient.

In healthcare, we intend to find uses for the DI beyond the smooth flow of commerce. We are also attempting to use these identifiers as part of a patient-centered approach. We eventually plan to incorporate this identifier into the patient’s electronic health record. The DI will also support many other related activities that will enhance the overall safe and effective use of medical devices in healthcare.

(Slide 5): The FDA intends for UDI to serve as critical infrastructure for a host of patient-centered activity. This graphic is taken from an actual FDA document and shows how UDI will clearly serve as the unifying center for areas such as device registries, longitudinal studies, safety monitoring, and much more. To achieve these lofty goals, it will be important to adapt the standards from a retail-centered packaging focus to accommodate this new, patient-centered approach.

(Slide 6): We need to clearly differentiate the tracking of the packaged product which is common to supply chain activity from tracking the products which may be contained within those packages. When there are multiple devices contained in the lowest packaged level, there may be a need for clinicians to track the use of individual items on specific patients. The FDA created the UOU concept to cover this precise need.

(Slide 7): This diagram is meant to show the various packaging levels for a product while at the same time showing the unpackaged, unmarked unit of use identifier. This medical device comes in two packaging levels. However, the lowest package level is a sealed tray containing twenty-five individual syringes. The FDA requires manufacturers to identify the individual products with an unmarked UOU DI. These individual syringes are unmarked and unpackaged. At the same time, there may be a need to identify the use of these individual syringes separate from the lowest packaged level. Without the UOU DI, there would be no way to record this information in a standardized manner.

(Slide 8): While this may seem like a simple concept, there is a lot of confusion with this concept. There is no precedent for it in other industries. The term “unit of use” may seem to imply that it is the same as the lowest



packaged level, but this is NOT the case. In most supply chains, you are not able to distribute product in any form lower than the lowest package level. This is especially true for items which are packaged as sterile. These items are no longer considered sterile once the package is opened. In healthcare, there may be clinical reasons why we need to track the individual items below their lowest packaged level. The UOU DI allows us to differentiate between the individual device and the grouping at the lowest packaged level.

(Slide 9): The novel nature of this concept has resulted in confusion regarding the creation and implementation of the unit of use identifier. As an unmarked identifier, there is no physical barcode to scan. In order to use the UOU DI, it may be necessary to create alternative mechanisms that are not needed for the scanning of packaged product—for example, using shelf tags to represent the UOU DI. We also don't have a clear template of these procedures from other industries. Additionally, some manufacturers may have loaded data to GUDID inconsistently. The UOU DI may be missing entirely or contain dummy numbers and/or data. We also have some examples where the UOU DI is confused with the lowest packaged level.

(Slide 10): 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 medical device manufacturers. 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 11): In order to provide more detailed guidance, the issuing agencies have provided additional information in the appendix. We have provided slides from both the HIBCC and GS1 US. Please refer to your respective issuing agency if you require further assistance.



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# Unit of Use (UOU) Explained

Why it Exists and  
Best Practices for Creation



# FDA Definition of “Unit of Use”

A virtual identifier assigned to an individual medical device when a Unique Device Identifier (UDI) is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device.



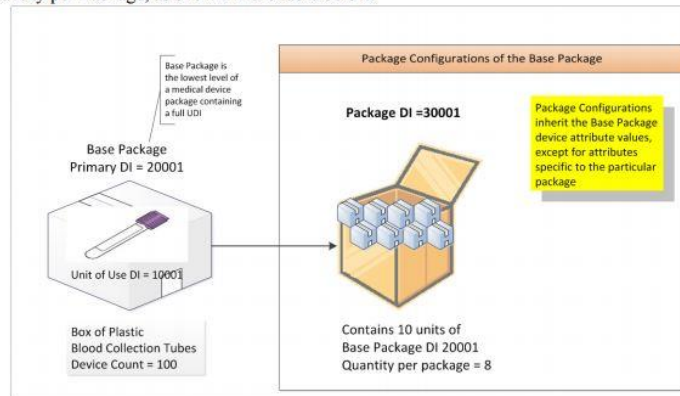
# FDA Graphic

EXAMPLE 1: UNIT OF USE DI + ONE PACKAGE LEVEL

The figure below provides a package configuration example for GUDID where the medical device has Unit of Use DI Number and one package level.

- Box of 100 single use blood collection tubes with the *Primary DI* 20001 and *Device Count* = 100.
  - Note that the tubes themselves do not have the DI on them as they fall under the general exception for individual single use device under 801.30(a)(3). Each tube however, gets a virtual *Unit of Use DI* assigned, and in this case, 10001.
- Case of 8 boxes (800 total), with *Package DI* 30001 (contains 8 of Primary DI 20001), *Quantity per Package* = 8.
- *Package Discontinue Date* is blank, therefore system auto-populates *Package Status* to “In Commercial Distribution.”

Package 30001 inherits all attribute values of base package 20001, except for the attributes specific to 30001 such as Quantity per Package, as shown in the table below.



**Base Package**

Primary Device Identifier	Device Count	Unit of Use DI
20001	100	10001

**Package DI**

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
30001	8	20001	Case		In Commercial Distribution

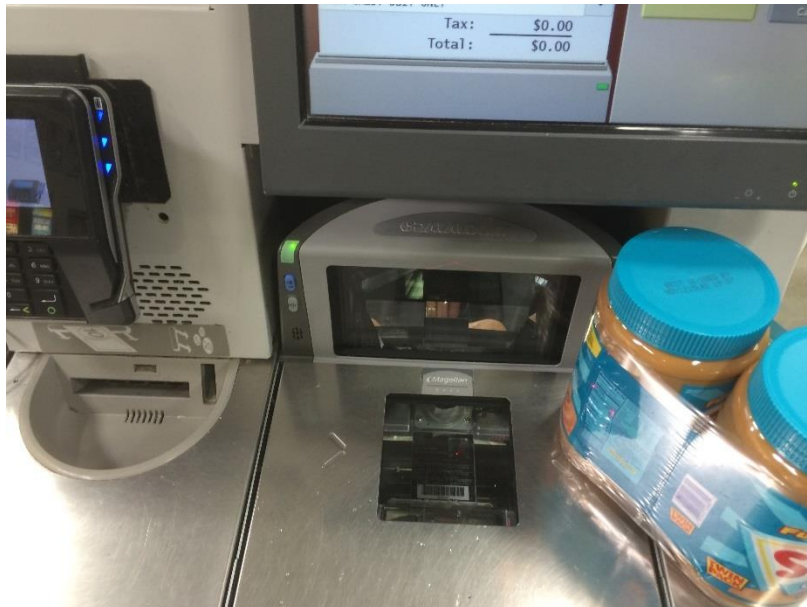


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# Retail vs. Healthcare

**Centered on checkout**

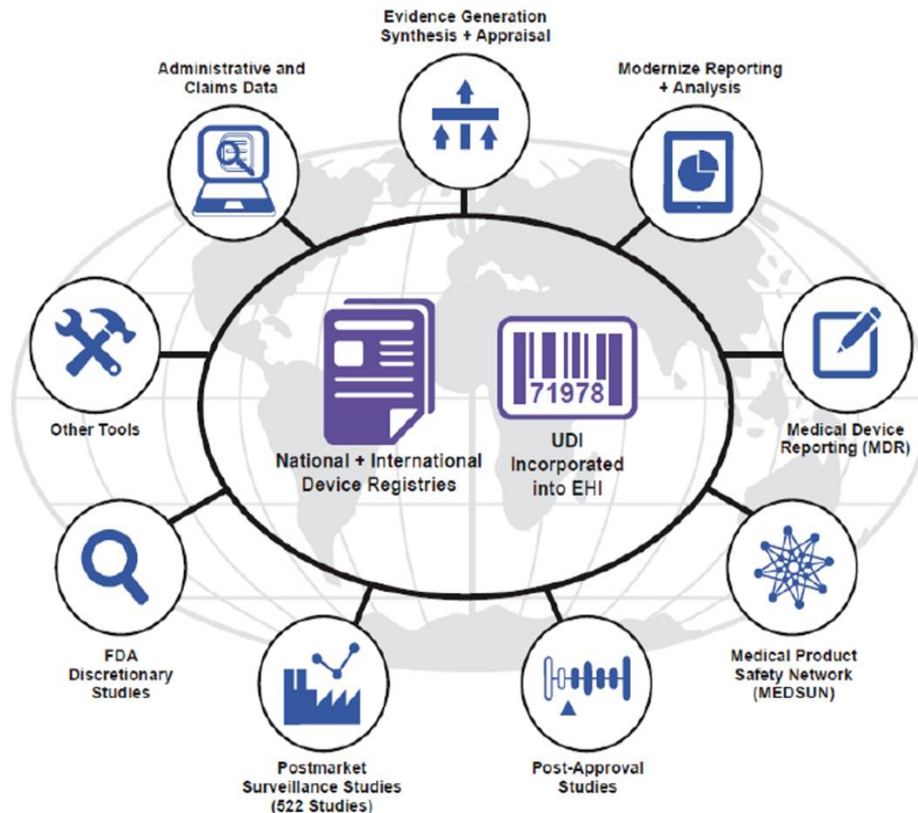


**Centered on the patient**





# Critical infrastructure





# Dual use of UOU

## Supply Chain

- Item Recognition
- Positive inventory control

## Clinical Use

- Tracking to individual patients
- Potential use in electronic health records
- Potential use in recalls





## UOU Package Example



Single Item  
(Unmarked)



Tray of 25  
(Full UDI Marked)



Case of 1000  
(Full UDI Marked)

Unit of Measure (Package Level)	ANSI UOM	Device Identifier (DI)	Qty	Units at Next pkg level	Contains DI Package
Single Item	-	<b>UOU DI (Unmarked)</b>	1	-	-
Tray (Lowest Pkg Level with DI)	TY	<b>Lowest Pkg Level DI (Full UDI Marked)</b>	25	-	No
Case	CA	<b>Case Level DI (Full UDI Marked)</b>	1000	40	Tray



# Lowest packaged level $\neq$ UOU

- Many products used on patients have multiple items in the lowest packaging level
- This concept is not generally used in industries outside healthcare
- There may be **clinical** reasons why we would like to track individual items within these specific packages
- From a **supply chain** perspective, the item cannot be replenished at any level lower than the lowest packaged level



# What are some potential issues with UOU?

- UOU is an unmarked identifier
  - Nothing to scan
  - No physical tie to products
- No clear templates of UOU in other industries
- Data being loaded to GUDID inconsistently
- DI being assigned improperly by labelers
  - Missing UOU entirely in GUDID
  - Dummy numbers or data in GUDID
- UOU being confused with lowest packaged level



# 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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# Appendix

Issuing Agency Examples



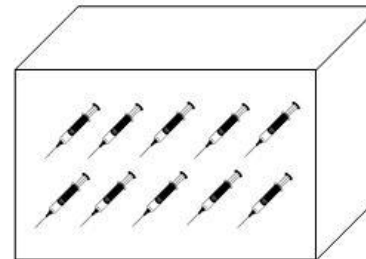
# Health Industry Business Communications Council (HIBCC) example

## HIBCC Unit-of-Use Example

Packaging Level	HIBCC Device Identifier	Quantity	Labeled with UDI?
Single Syringe	A999ABC1230	1	No
Package	A999ABC1231	10	Yes
Case	A999ABC1232	100	Yes

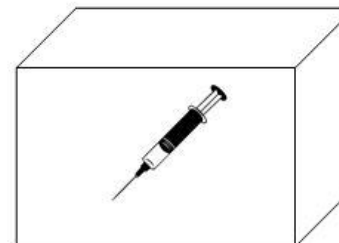
Example 1: 10 Syringes in 1 Package, Not individually packaged or labeled

LIC = A999  
 Product Code = ABC123  
 Unit of Measure = 1  
 Primary DI = A999ABC1231  
 Unit of Use DI = A999ABC1230



Example 2: Single Syringe Individually packaged and labeled with a UDI

LIC = A999  
 Product Code = ABC123  
 Unit of Measure = 0 (single unit)  
 Primary DI = A999ABC1230



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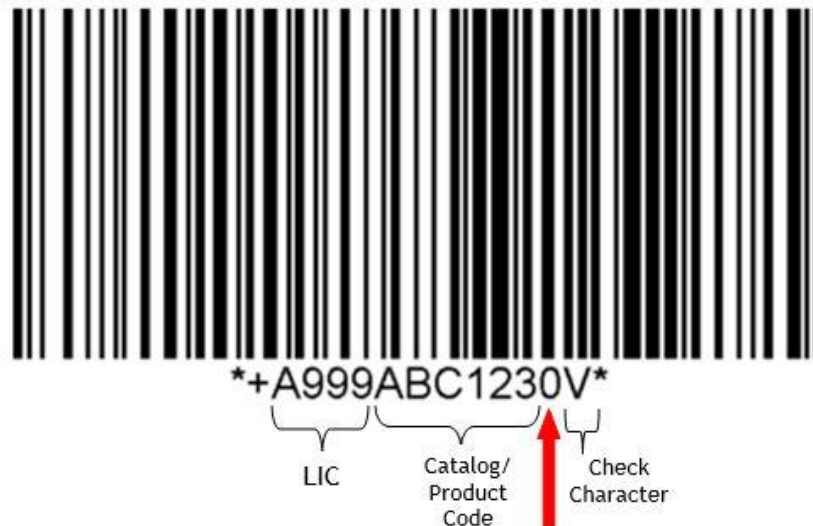




# HIBCC Guide to Understanding Unit of Measure (Packaging Level)

## What is Unit of Measure(Package Level Indicator)?

All HIBC UDIs & Auto-ID symbols contain a Unit of Measure field in the Device Identifier (primary data structure). The Unit of Measure is a number (0-9) assigned by the labeler to indicate package level. The Unit of Measure is always located directly after the Product Code. In the image below, the Unit of Measure is the "0" above the red arrow.





# HIBCC Guide to Understanding Unit of Measure (Packaging Level)

## How Do I Assign a Unit of Measure?

A single unit (i.e. an "each") is always represented by a Unit of Measure of "0". The Unit of Measure "9" is reserved for packages containing variable quantities (i.e. the package quantities are customized). Units of Measure 1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest. The example below shows how to assign the Unit of Measure to different package levels for a device.

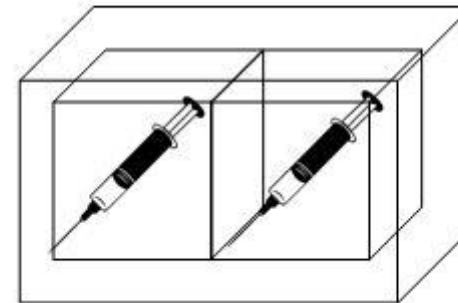
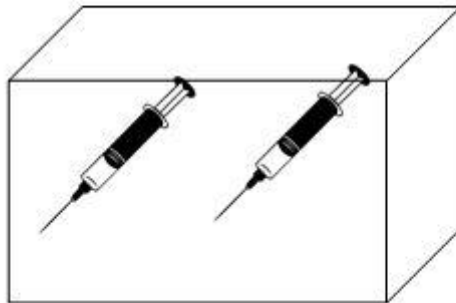






# HIBCC Guide to Understanding Unit of Measure (Packaging Level)

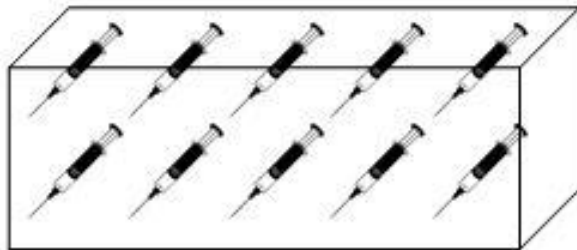
The syringe is also available in sets of two. The images below show two different packaging scenarios for the set of two devices. The Unit of Measure is the same whether the box contains two unpackaged syringes or two individually packaged syringes. The Unit of Measure would be "1" for both scenarios.





# HIBCC Guide to Understanding Unit of Measure (Packaging Level)

Finally, the syringe is available in a case of 10. The Unit of Measure for the case of 10 syringes would be "2". It is also fine to skip numbers and assign a higher Unit of Measure if there is a chance that the device will be available in smaller quantities later on.



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# HIBCC Guide to Understanding Unit of Measure (Packaging Level)

Note that the HIBC standard allows labelers to use the same Product/Catalog Number for all package levels of a device (as shown in the example above). The Device Identifier is still unique for each packaging level because each level is assigned a different Unit of Measure, as required for the FDA's UDI rule.

Note: The term "Package Level Indicator" can be used interchangeably with "Unit of Measure".

For additional questions contact HIBCC by email at [info@hibcc.org](mailto:info@hibcc.org)

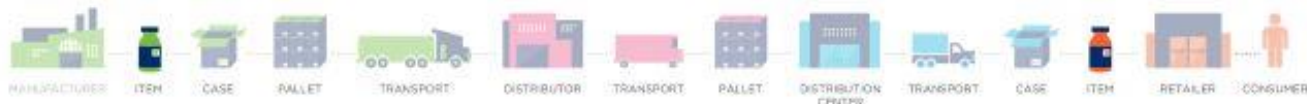
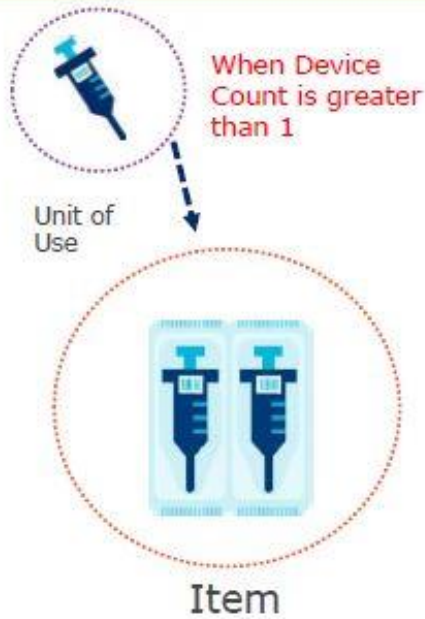




# Trade Item Hierarchy and GTIN<sup>®</sup> Assignment Methods

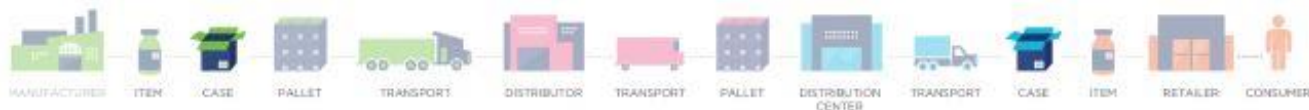
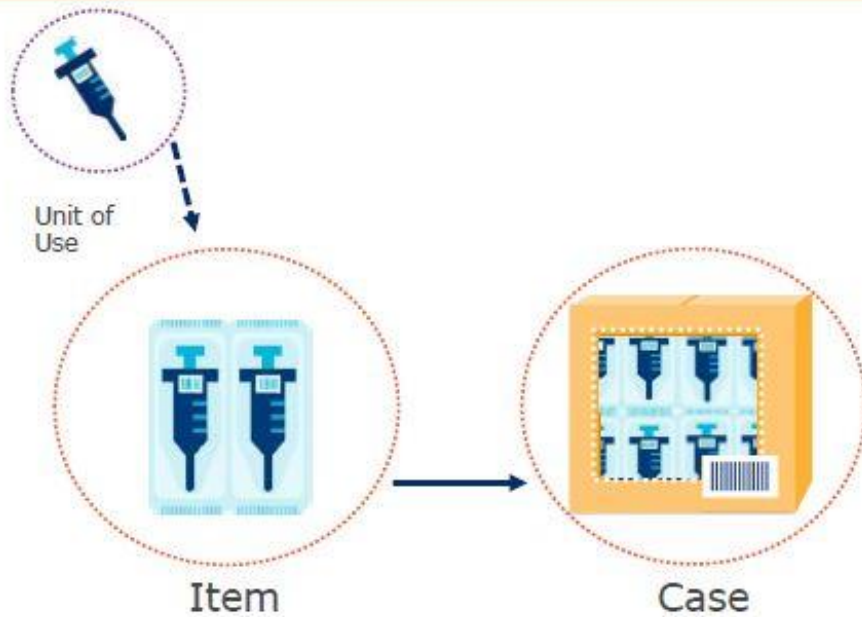


## Item



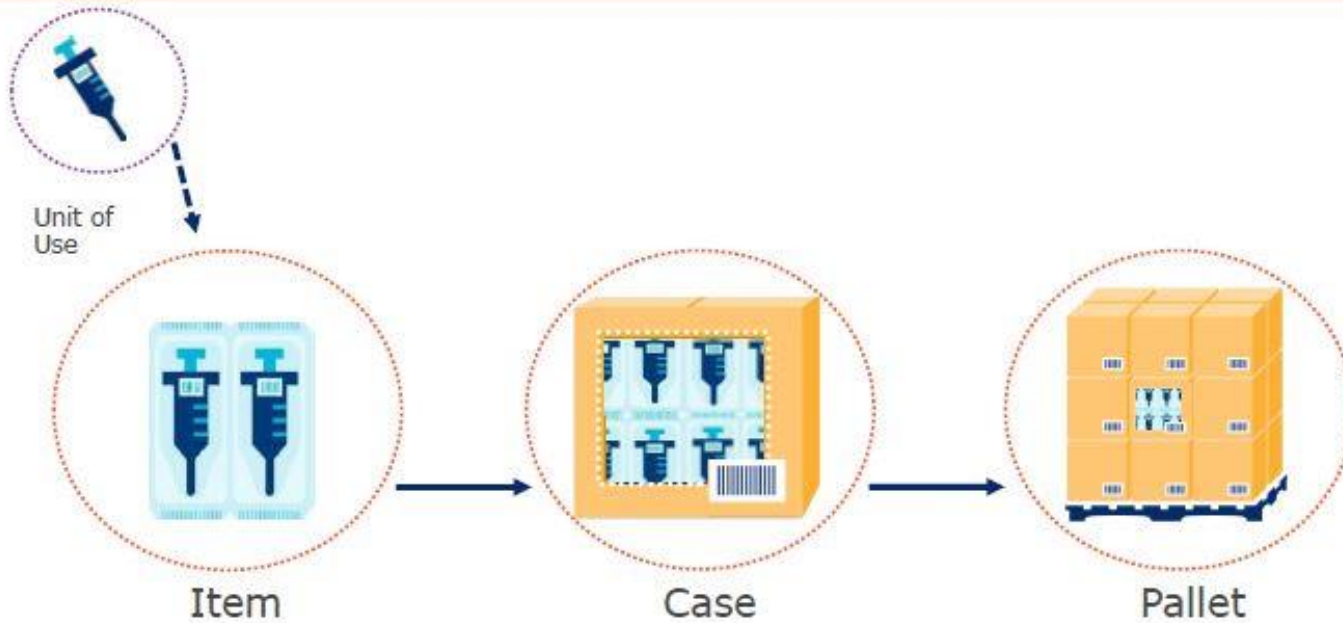


## Case





## Pallet

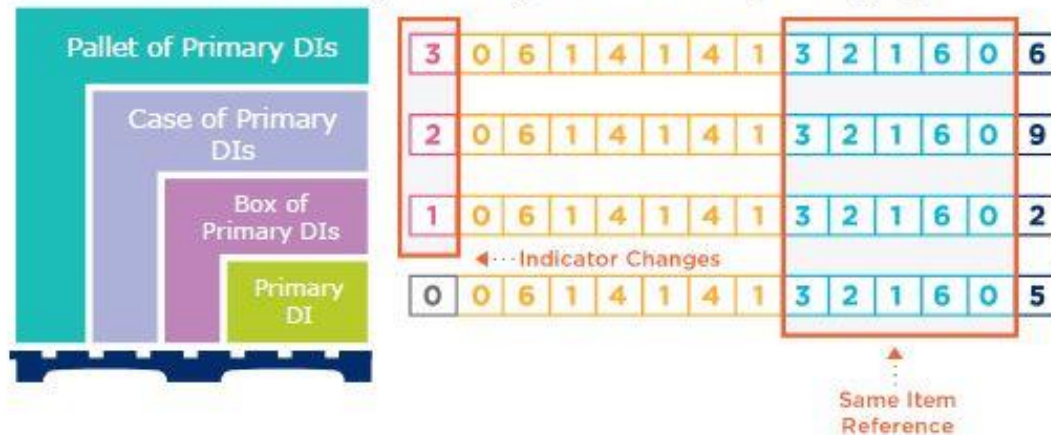




# GTIN<sup>®</sup> Assignment Methods

There are several different options for assignment of GTINs in a hierarchy

Indicator digit for higher levels of packaging







## GTIN Assignment Methods (continued)

There are several different options for assignment of GTINs in a hierarchy

Item reference higher levels of packaging

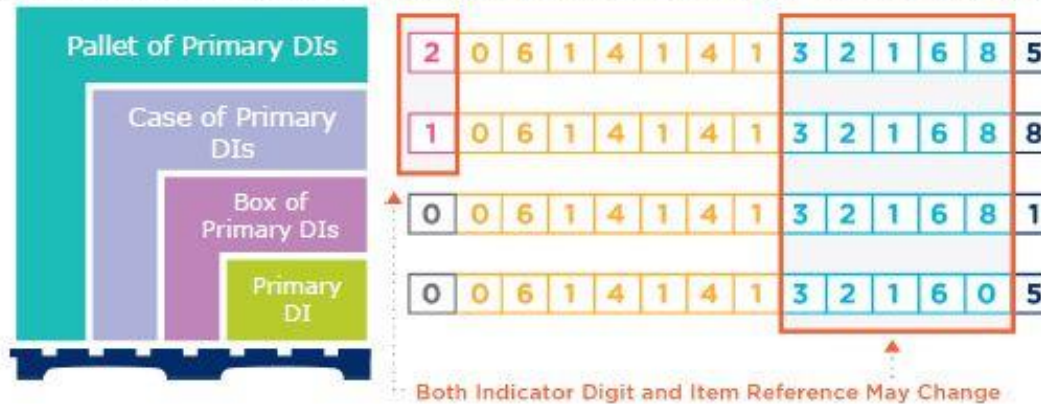




## GTIN Assignment Methods (continued)

There are several different options for assignment of GTINs in a hierarchy

Combination of indicator and item reference higher levels of packaging





## GTIN Assignment Methods (continued): Device Count = 1

Assignment of Device Identification where  
the Primary DI has a device count = 1

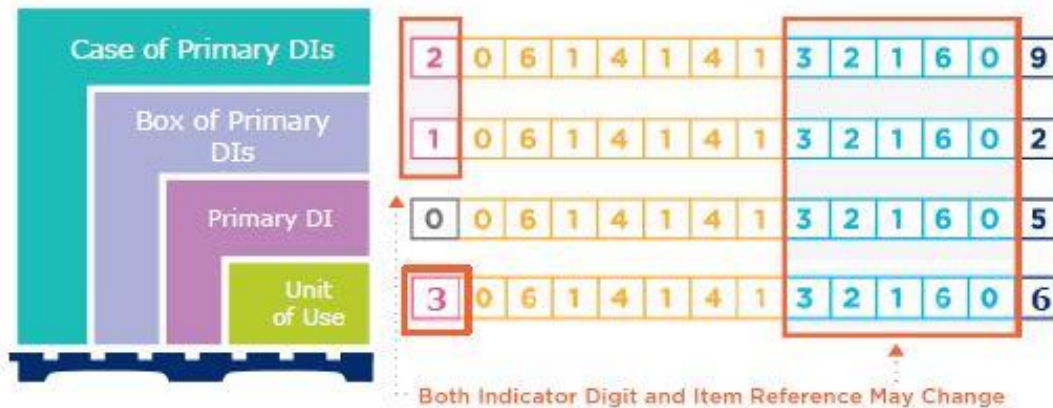


*In this instance the unit of use is the Primary DI*



## GTIN assignment methods (continued): Device Count > 1

Assignment of Device Identification where the Primary DI has a  
device count > 1



*In this instance the unit of use is NOT the Primary DI*