

Integrating the Healthcare Enterprise



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**IHE Pharmacy
Technical Framework Supplement**

10

**Uniform Barcode Processing
(UBP)**

15

HL7[®] FHIR[®] STU 3

Using Resources at FMM Level 2-5

Rev. 1.1 – Trial Implementation

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Please verify you have the most recent version of this document. See [here](#) for Trial Implementation and Final Text versions and [here](#) for Public Comment versions.

Foreword

30 This is a supplement to the forthcoming IHE Pharmacy Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on December 4, 2017 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the forthcoming
35 Pharmacy Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/Pharmacy_Public_Comments.

This supplement describes changes to the existing technical framework documents.

“Boxed” instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

40

<i>Amend Section X.X by the following:</i>
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Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

45

General information about IHE can be found at www.ihe.net.

Information about the IHE Pharmacy domain can be found at http://www.ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://www.ihe.net/IHE_Process and
50 <http://www.ihe.net/Profiles>.

The current versions of IHE Pharmacy Technical Framework supplements can be found at http://www.ihe.net/Technical_Frameworks.

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Introduction to this Supplement

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE committee determines that an emerging standard offers significant benefits for the use cases it is attempting to address and has a high likelihood of industry adoption, it may develop IHE profiles and related specifications based on such a standard.

The IHE committee will take care to update and republish the IHE profile in question as the underlying standard evolves. Updates to the profile or its underlying standards may necessitate changes to product implementations and site deployments in order for them to remain interoperable and conformant with the profile in question.

This UBP Profile uses the emerging HL7^{®1} FHIR^{®2} specification. The FHIR release profiled in this supplement is STU 3. HL7 describes the STU (Standard for Trial Use) standardization state at <https://www.hl7.org/fhir/versions.html>.

In addition, HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through 5 (normative ballot ready). The FHIR Maturity Model is described at <http://hl7.org/fhir/versions.html#maturity>.

Key FHIR STU 3 content, such as Resources or ValueSets, used in this profile, and their FMM levels are:

FHIR Resource Name	FMM Level
Medication	FMM 3
Device	FMM 2
Patient	FMM 5
Practitioner	FMM 3
Bundle	FMM 5
OperationOutcome	FMM 5

Scope and introduction

- 115 This supplement provides an interoperability mechanism for systems to request a barcode content to be decoded, for those applications that do not implement the decoding algorithms.

Concretely, this supplement describes the transactions between a system that has a barcode but needs it decoded, and another system that decodes the barcode content.

¹ HL7 is the registered trademark of Health Level Seven International.

² FHIR is the registered trademark of Health Level Seven International.

Introduction

120 The use of barcodes and other automatic identification and data capture (AIDC) in healthcare is increasing. The barcodes contain data that is encoded in a certain way. In order to be able to use that data, software systems need to “understand” the barcode, i.e., decode it.

The decoding is done by algorithms that are described in the specifications of the standards. See for example GS1 barcode specifications.

125 These algorithms are not too complex and can be implemented in many software systems relatively easy.

However, several reasons may exist for a remote decoding of barcodes:

- Algorithms are not implemented in the applications (e.g., legacy apps, apps not compliant with a specific standard or barcode type)
- 130
- Localized barcode syntax e.g., a hospital that implements a specific Application Identifier which must then be implemented in all systems that must scan these barcodes. In this case, it is easier to maintain one algorithm than to update all the systems with the up-to-date algorithm.

135 The need to decode the barcodes remotely creates an interoperability need: Transfer the “original” barcode content for decoding, and getting the decoded content.

This document is aimed to be a description of how to use information retrieved from standard barcodes in various healthcare processes. Some processes where this profile may be relevant are:

- Scanning at the Point of Care also known as ‘bedside scanning’;
 - Traceability of medical devices;
- 140
- Inventory management or generally Supply Chain management.

All these purposes are defined elsewhere – for example the Scanning at the point of care is described in the MMA Profile, and the entire Supply Chain is being defined in an upcoming set of IHE profiles. For the barcode decoding itself, this profile describes the mechanism to request a remote decoding of the content.

145 Besides barcode scanning, this profile is also applicable to other types of Automatic Identification and Data Capture (AIDC), like for example scanning of RFIDs and manual entry of barcodes.

Open Issues and Questions

1. How to handle HL7 v2 messages? Also as a request and a response?
- 150
2. How to handle systems where the barcode reader does not receive the information?

Closed Issues

None

155 **General Introduction**

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of Actors:

160

Actor	Definition
Barcode reader / consumer	Device capable of scanning barcodes. It sends the barcode data for decoding by another system, and receives encoded information, like GTIN, expiry date, batch/lot number from the barcode decoder.
Barcode processor	Receives data from the barcode reader / consumer and sends the decoded barcode content.

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

165

The IHE Uniform Barcode Processing supplement introduces the interoperability mechanisms to decode a raw barcode sequence into a standardized format that can then be exchanged between different IT systems.

Transaction	Definition
Request decoded barcode content [PHARM-4]	The Barcode reader / consumer has scanned the barcode and sends the encoded barcode sequence to the Barcode Processor requesting the decoded barcode information. The barcode processor sends the decoded barcode information as a response to the Barcode reader / consumer as structured information (e.g., GTIN=8712345670012, batch number = 12345, expiry date = 2020-11-12)

170 **Glossary**

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

Glossary Term	Definition
AIDC	Automatic Identification and Data Capture – A technological solution like barcodes and RFIDs that allow information to be captured and entered into IT systems.

Volume 1 – Profiles

175 *Add the following to the IHE Technical Frameworks General Introduction Copyright section:*

The HL7 FHIR standard License can be found at <http://hl7.org/fhir/STU3/license.html>.

Add Section X

180 **X Uniform Barcode Processing (UBP) Profile**

In their daily practice, Healthcare professionals have difficulty ensuring traceability of medical devices and/or pharmaceuticals due to the inability of healthcare ICT systems to communicate with each other in a uniform way. Even when all relevant information for the products is provided by manufacturers captured in a standardized barcode, ICT systems at various stages of the logistical, administrative and care processes cannot communicate product information coming from different barcode systems in a standardized manner. This results in patient risks as well as high inventory cost, waste and out-of-stock situations.

Regulation

190 In the US the FDA issued legislation on the ‘Unique Device Identification’ (UDI) for all medical devices. The accredited organizations that are allowed to provide the UDI are GS1, HIBCC and ICCBBA. This legislation will be issued in the EU as well as other regions, adjusted to the needs and requirements of that region. In opposition to the US UDI legislation, in the EU not only suppliers need to comply, but also healthcare providers. They will be mandated to store the UDI information in their systems in order to fulfill traceability. More details can be found here:

195 <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2017:117:FULL&from=EN>

See video where the benefits of UDI are explained by staff from Mercy Hospital and Medical Center USA: <https://www.youtube.com/watch?v=A3CS8pfTmb4>

The pharmaceutical industry is also moving towards standardization. For example, the EU Industry Associations have adopted GS1 for product identification.

200 http://www.efpia.eu/uploads/Modules/Documents/efpia-gs1-shared-vision-090312_2.pdf

See video on the patient safety by using barcodes on pharmaceuticals by the European Hospital Pharmacist Association, EAHP:

<https://www.youtube.com/watch?list=UUguZ7G2g6CMuBN1C9wdk57Q&t=3&v=Ieiq9kzzEhc>

205 Not all Hospital IT-systems can process the main (bar) coding systems. Interoperability between systems is therefore hindered. This leads to error prone work-around processes in the logistic and care processes. Another challenge is that no standardization is used for the exchange of barcode information. A scanned barcode is sometimes cut off or trimmed to send a smaller amount of characters, resulting in incorrect or missing information at the receiving system.

210 To enable correct registration of used pharmaceuticals and medical devices in the hospital setting, use of standardized information derived from barcodes is crucial. Barcodes are used for the identification of products, locations, persons and documents. The identification can be used throughout the entire supply chain, from manufacturer up and until the patient.

215 The caregiver scans the barcode(s) on the product that are provided by the manufacturer, following the specifications of one of the three standardization bodies: GS1, HIBCC or ICCBBA. Barcodes can be read by all ICT systems used in hospitals that support inventory management, purchase and registration of medical devices and pharmaceuticals.

220 By transforming the information that is stored in the different barcode formats into a standardized format, these ICT systems will be interoperable amongst each other. This way the product data can be transferred from one system to the other leading to patient safety and efficiency in the process of linking the used medical products to patients and inventory.

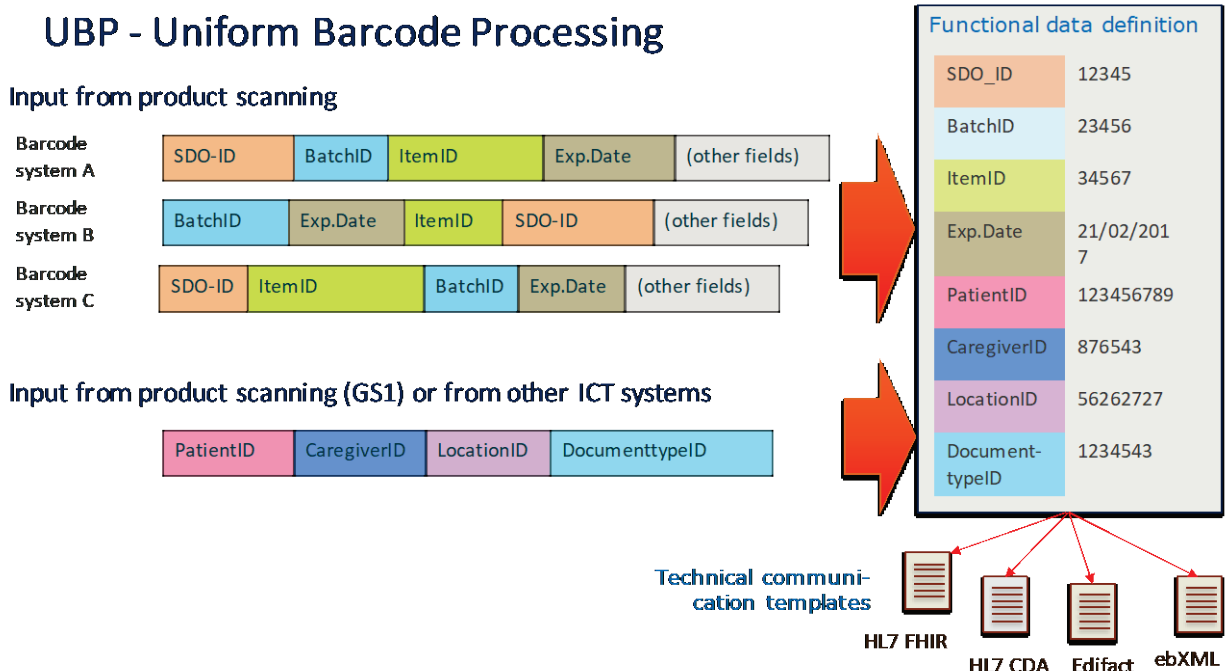


Figure X-1: Structured information in different barcode systems

225 The barcode profile can be used for scanning one of the following items: Pharmaceuticals, Medical Devices, Blood, Patients, Healthcare Professionals, Locations (e.g., rooms, inventory shelves, departments) Documents, Organic Tissue.

Organic Tissue, Blood and other products of human origin are not in scope in the use cases mentioned. As ICCBA is the standardization organization for these products the specific ICCBA message semantics will be excluded for now from this supplement.

230 The barcode reader / consumer can use the information received from the barcode processor for any action, e.g., do a lookup of additional information of the scanned item, like knowing the dose of a pharmaceutical, the quantity of items that are packed together in a box, the brand of the product, the producer of this product, etc.

X.1 UBP Actors, Transactions, and Content Modules

235 This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks.

240 Figure X.1-1 shows the actors directly involved in the UBP Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

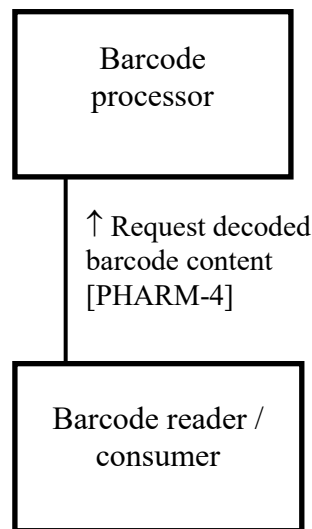


Figure X.1-1: UBP Actor Diagram

245 The barcode actors (reader / consumer and processor) are associated with existing actors (defined in other IHE profiles). For example, this can be an actor from the HMW or MMA Profiles.

Table X.1-1 lists the transactions for each actor directly involved in the UBP Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”).

250

Table X.1-1: Option 1 UBP Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Barcode reader / consumer	Request decoded barcode content [PHARM-4]	R	UBP TF-2: 3.Y
Barcode Processor	Receive request for decoded barcode content [PHARM-4]	R	UBP TF-2: 3.Y

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2). This section documents any additional requirements on profile’s actors.

255 The barcode reader and barcode consumer are used within the same actor – this is the case when an application requires an external party to decode the barcode and gets the response back.

The barcode reader and consumer can be split up as different actors in a way that the barcode reader simply pushes the information that a barcode has been scanned, leaving it to downstream systems to decide what to do with that information. This is typically the case where the reader does not have any functionality and simply informs that a barcode is read. The functionality – administration, inventory, etc. are in this case in the Barcode consumer. For the remaining part of this supplement the barcode reader / consumer is seen as one actor.

260

X.1.1.1 Barcode reader / consumer

265 The Barcode reader is most likely to be grouped with existing actors that play the Barcode consumer role (e.g., Medication Dispenser (HMW Profile), EHR, ERP, Inventory Management System (IMS), etc.)

This actor is called the Barcode reader / consumer for simplicity. Apart from scanning barcodes this actor also has the option to input barcodes manually or get information from RFID tags.

270 The Barcode reader/consumer sends the encoded barcode directly to the Barcode processor. The code must contain all the digits of the barcode. The reader should not cut off or trim the sequence, before sending it to the Barcode Processor.

275 After the barcode is decoded, the Barcode reader / consumer receives the decoded information from the Barcode Processor. By then the Barcode reader / consumer knows whether the code is defined within specifications of GS1, HIBCC or ICCBA. Information such as the item ID, batch number and expiration date are transferred to this actor.

The barcode reader / consumer can further use this information, for example request additional information about the dose of an item, the quantity of items that are packed in a box, what the brand of the product is, who the producer of the product is and other information related to the itemID, as well as decreasing stock count, registering an administration, etc.

280 **X.1.1.2 Barcode Processor**

The Barcode Processor receives the encoded data from the Barcode reader / consumer. The primary goal of this actor is to decode the received encoded barcode sequence. The code received must contain all the characters of the barcode.

285 Data that can be decoded from the barcode sequence is defined by the Standard Development Organization and can be the sequence from e.g., GS1, HIBCC and ICCBA.

The decoded information is sent back as a response to the Barcode reader / consumer for further processing.

290 It is possible that the barcode corresponds to several resources, e.g., a medication and a patient encoded in a single barcode. This case is less common but is still supported since the response bundles one or more resources.

X.2 UBP Actor Options

The UBP Profile has one transaction and at this moment no other optionality is required.

Table X.2-1: Uniform Barcode Processing - Actors and Options

Actor	Option Name	Reference
Barcode reader / consumer	No options defined	--
Barcode Processor	No options defined	--

295 **X.3 UBP Required Actor Groupings**

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

Table X.3-1: UBP - Required Actor Groupings

UBP Actor	Actor to be grouped with	Reference	Content Bindings Reference
Barcode Processor	None		
Barcode reader / consumer	None		

300

X.4 UBP Overview

The UBP Profile allows systems to send a barcode sequence that is filled according to one of the standard formats (e.g., GS1 and HIBBC) and obtain the decoded content of the barcode in a standard format that can be read by different IT systems supporting this UBP Profile.

305 **X.4.1 Concepts**

The barcode actors (reader / consumer and processor) are usually associated with other existing actors (defined in other profiles). This can, for example, be an actor from the hospital medication workflow profile (HMW). The barcode reader / consumer sends out the raw barcode sequence requesting for a standard decoded message that the reader / consumer can then use to request other additional information belonging to the item that is scanned.

X.4.2 Use Cases

The use cases where barcodes are used are the following:

- Medication administration at the point of use at a patient: This use case is applicable within a hospital setting where a barcode reader / consumer is used to scan the patient and administered pharmaceuticals.
- Traceability of medical devices: This use case is applicable for actual medical devices that needs tracing back to the original supplier and needs to be linked to a specific patient.
- Inventory management: This use case is needed to keep track of how many items of a certain pharmaceutical or medical device are being used and how many are still available for usage within a hospital

In all use cases barcode scanning is involved from possibly different IT systems that need to be able to communicate their barcode in a standard way with other systems.

X.4.2.1 Use Case #1: Administration (and dispense) of medication

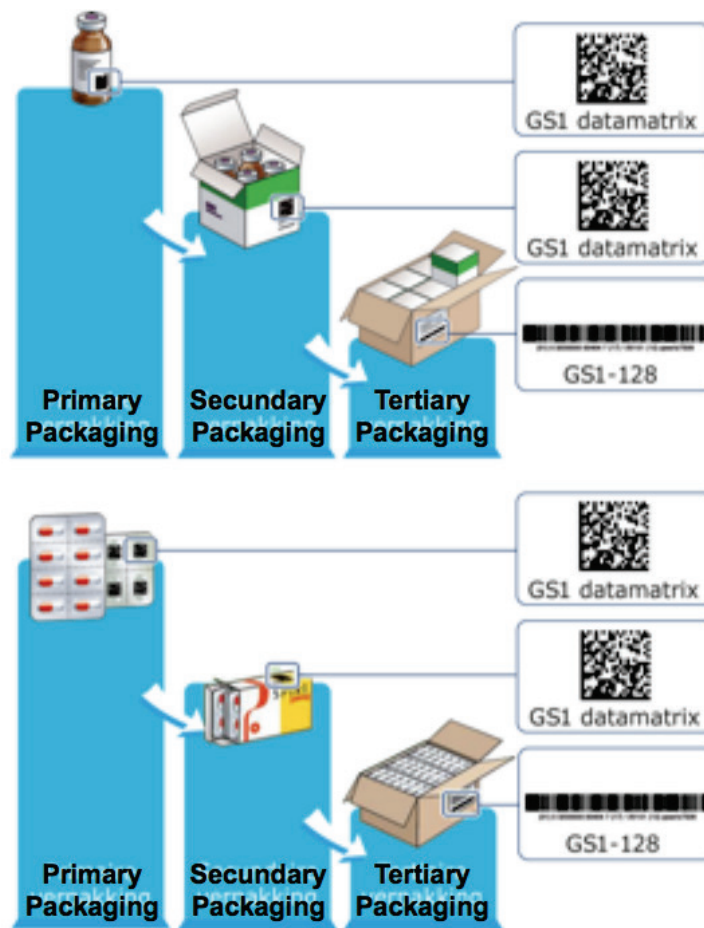
Use case 1 describes how a patient in a hospital bed is administered the pharmaceuticals needed for his or her treatment.

X.4.2.1.1 Medication administration - Use Case Description

The pharmaceuticals are prescribed by a doctor in a digital description system. When a nurse or physician administers the drugs, the system will check if it is the right patient and care giver for these drugs and also checks the dose and time of administration. This method of registering prescribed pharmaceuticals to a patient in a health care organization guarantees a high level of patient safety ensuring the right patient getting the right drug at the right time in the right dose and by the right care giver.

Pharmaceuticals and medical devices are provided with barcodes containing ProductId, Expiry Date and BatchNumber. Eventually also Serial Number. Patients and Healthcare Professionals are identified with a corresponding key.

For pharmaceuticals, the supplier assigns uniform barcodes to all product levels as depicted below. The lowest level will be scanned before administering to a patient. The other levels are relevant for logistic purposes: warehousing, ordering, invoicing etc.



340

Figure X.4.2.1.1-1: Different levels of packaging

For the treatment of Patient X, who lies in a hospital bed, a nurse consults the Medication Administration System which contains the patients' Medication Administration Records (MARs) with the planned medications. At the scheduled time, the system may notify the nurse, who then identifies the patient by scanning a bar code on a wrist band of the patient.

345

The nurse scans the patient's wristband and sends the barcode content for decoding. The server responds with a patient identification.

From the patient identification, the nurse sees that the medication "hyoscine butylbromide 10 mg" is required.

350

Since the ward contains some products in their commercial package, the system displays to the nurse the name that can be recognized in the package: BUSCOPAN IBS RELIEF. To administer the drug to the patient, the nurse takes one pack of BUSCOPAN IBS RELIEF from the ward shelf, and scans its barcode.

355

The scanned barcode content (5012917021912) is sent to a system that decodes the barcode and provides the decoded content, which in this case is just the Package code (GTIN). The

drug administration system receives this information and from the available information, it confirms that this is the right drug.

360 The nursing system informs the Pharmacy Dispensing System and the Computerized Physician Order Entry System that this medicinal product has been consumed and administered in that quantity.

Pre-conditions:

A nurse gets a signal that a patient needs his medication and administers it after collecting the medication and finding out where the patient is located within the hospital. Barcode scanning and decoding is then started.

365 **Main Flow:**

1. The barcode (wristband) of the patient is scanned
2. The barcode reader / consumer shows additional details of the patient.
3. The nurse or physician checks that it is the right patient that needs the medication.
4. The nurse checks the list of medication to be administered and scans the first item.
- 370 5. The system gives feedback that it is the right administration for this patient
6. The medication is administered and the medication list is updated with administered.
7. This way the right patient gets the right drug at the right time in the right dose and by the right care giver.

375

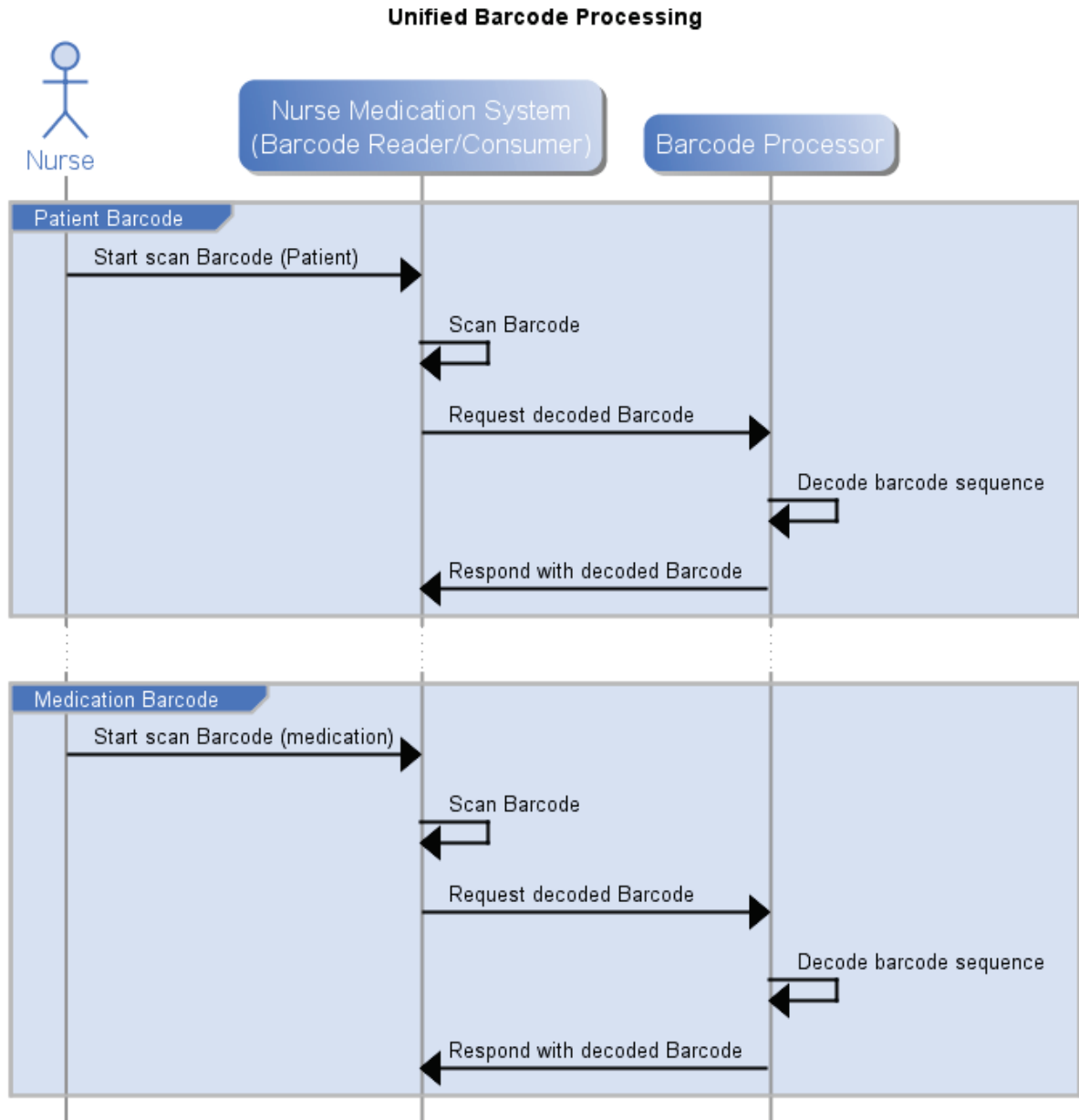


Figure X.4.2.1.1-2: Process Flow - Administration (and dispense) of medication

Post-conditions:

380 The patient has been identified by the barcode and the medication has been administered. If more medication needs to be administered the nurse or physician can start the previous flow again or administer medication to another patient on the ward.

385 **X.4.2.2 Use Case #2: Traceability of Medical devices in the Health care organization**

This use case concerns the traceability of medical devices in the health care organization in case of recall. Traceability could also be used to go to the source of the product manufacturer.

X.4.2.2.1 Traceability of Medical devices - Use Case Description

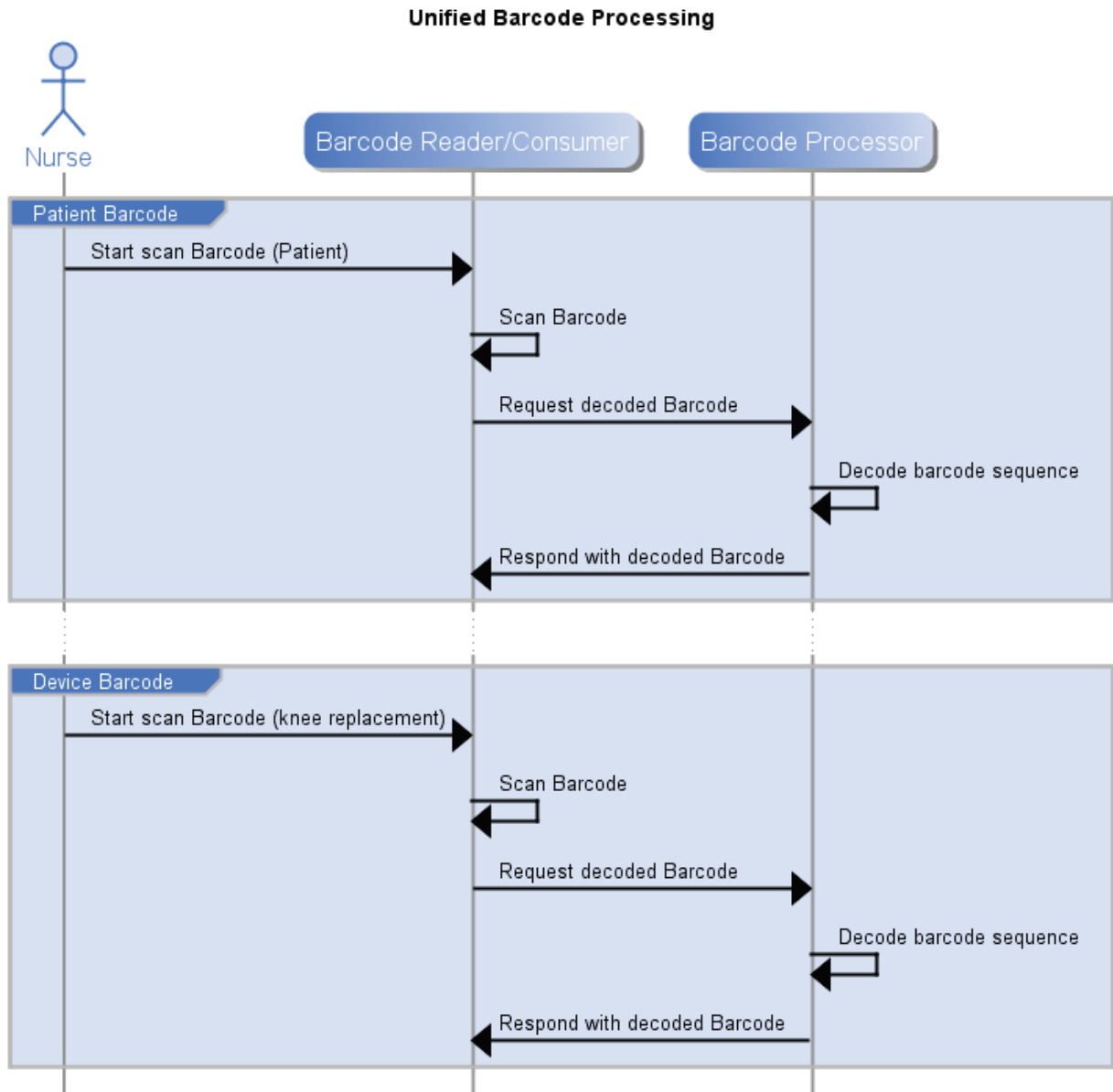
390 A patient needs an operation, in this case a knee replacement. Before and during the operation the barcodes on the used products, knee, stitches, power tools etc., are scanned and the information from the barcodes is registered in a central system to link them to the patient. A manufacturer discovers a defect and notifies all parties of the need for a direct recall. The hospital takes the required steps to recall all products implanted as well as in inventory. This
395 requires that the barcode is decoded.

Pre-conditions:

A patient needs an operation to receive a knee replacement. All items used during the operation have a barcode according to the GS1 or HIBCCC standard and also the patient has a wristband with barcode.

400 **Main Flow:**

1. The barcode (wristband) of the patient is scanned.
2. Whenever a tool is used it is being scanned by the surgeon assistant.
3. Whenever a device (e.g., knee replacement) is used it is scanned
4. The scanned barcode sequence is send to the barcode processor
- 405 5. The response of the barcode processor is a standard formatted message that the reader / consumer can use to request additional information
6. The tool used by the surgeon or the device being implanted is registered in a central system linked to the specific procedure and patient.



410

Figure X.4.2.2.1-1: Process Flow – Traceability of Medical Devices

Post-conditions:

All tools and devices used during the knee replacement are registered in a central system that can be queried for further analysis, but also if a recall is needed for certain devices.

415 **X.4.2.3 Use Case #3: Inventory Management**

The visibility and management of medical devices in the OR Inventory Room ensures availability as well as usability.

X.4.2.3.1 Inventory Management - Use Case Description

420 Thanks to a procurement directive that mandates lot-traceability, the product packages contain structured barcodes which contain not only the item, but also lot number and expiry date:



7(01)07612345678900

(17)141231(10)LX02374834

425 At the end of the year, the pharmacist goes through the inventory locations, and counts the items in stock. The pharmacist starts by identifying the location that is expected to be scanned. This can be done by scanning the barcode that is on a shelf:

The products scanned are:

- 4 boxes of item 07612345678900. This box has lot LL1233223 and an expiry date 12-2016.
- 430 • 8 boxes of item 07612345678900. This box has lot LX02374834 and an expiry date 03-2017.
- 1 box of item 07612345678900. This box has lot LA00012224 and an expiry date 02-2015.
- 435 • The barcode reader / consumer sends the product information to the barcode processor which forwards it to the inventory system.
- From the parsed barcode content, the inventory system automatically interprets this scanning as a location identification. The remote application requests from the central Pharmacy information about the expected inventory for that location. This will allow to display any discrepancies in real time.

440 The last item is an item that is about to expire and was not used earlier.

After scanning all the items, the remote application displays a summary of the scan results, including the discrepancies - 4 boxes of lot LL1233223, instead of 5, and 1 unexpected box of lot LA00012224.

445 The pharmacist inspects the package and confirms that the item is indeed of that lot, about to expire. The remote system submits the report to the Pharmacy system, informing of the new inventory status. The Pharmacy system updates this information in its database.

Pre-conditions:

The pharmacist is triggered that a yearly stock count of inventory at different locations is needed

Main Flow:

- 450
1. The pharmacist travels to a location where several product packages of a certain lot are in stock
 2. The pharmacist scans an item
 3. The barcode sequence is read and decoded by the barcode processor
 4. Additional information of the item is requested including lot number and expiry date
- 455
5. The pharmacist sees that the item is past its expiry date and can no longer be used.
 6. The item is taken off the inventory and will no longer be used and is destroyed

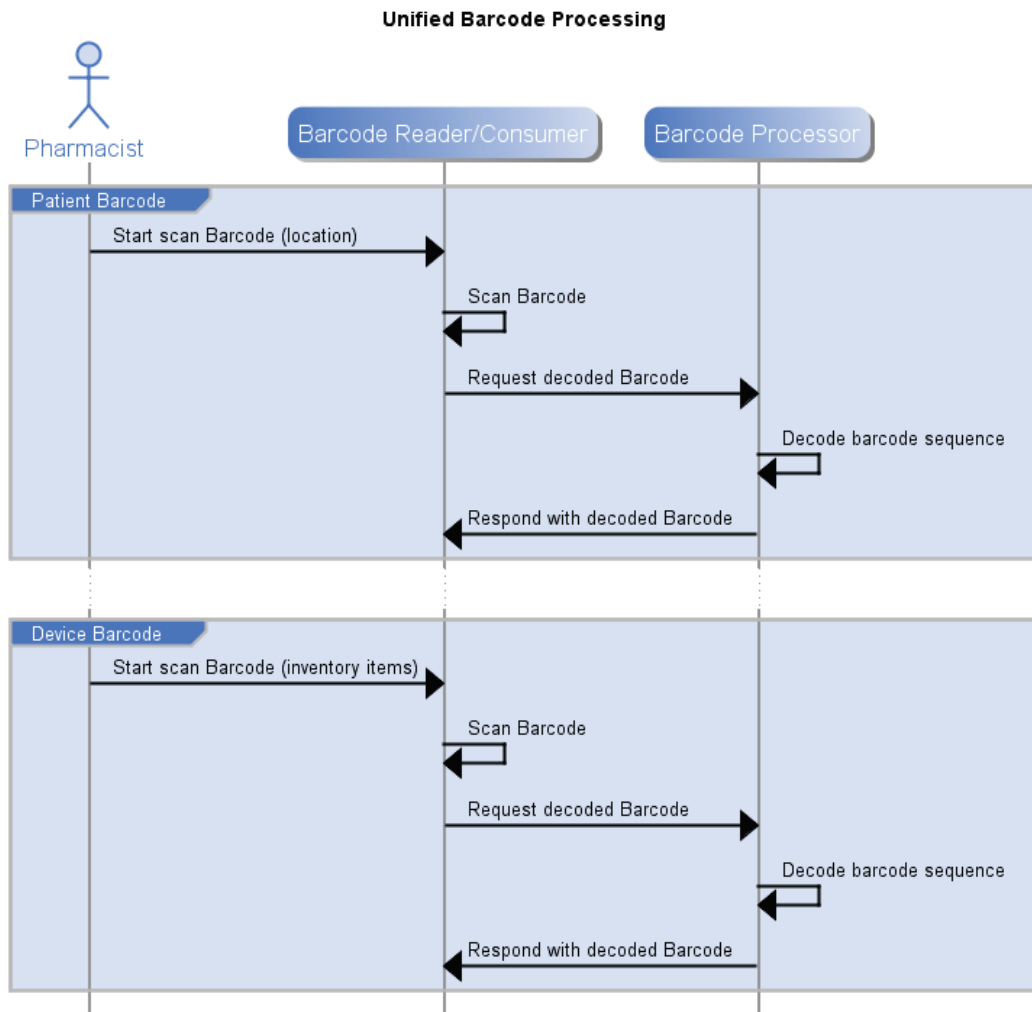


Figure X.4.2.3.1-1: Process Flow – Inventory counting

Post-conditions:

460 By scanning all items, the system has information about what is really in stock and which items are close or past their expiry date, allowing users to take necessary actions.

X.5 UBP Security Considerations

See ITI TF-2x: Z.8 “Mobile Security Considerations” for general background on “Mobile” security considerations, and recommendations regarding security. UBP Profile provides an API for accessing Data Element level details that are identifiable to a specific Patient. Thus all the data communicated, including the query parameters, should be considered Patient Identifiable data. The grouping with IUA, or some similar User Authentication and Authorization solution, is critical to enforcing Privacy and Security. All accesses to this data should be recorded as audit log for security surveillance and Privacy 510 reporting. These topics are discussed in Appendix Z.8 with recommendations.

X.6 UPB Cross Profile Considerations

The UBP Profile provides the mechanisms to decode a barcode content. The actual functionality – registering an administration, counting inventory, etc. - is managed by other actors. The following actors are notable examples:

- 475 • Medication Administration Performer (MMA Profile)
- Medication Administration Informer (HMW Profile)
- Patient Demographics Consumer (PDQm Profile)

Other actors are expected to be added to this list when the IHE Supply and Catalog transactions are added to the IHE Technical Framework.

480

Volume 2 – Transactions

Add Section 3.Y

3.Y Request Decoded Barcode content

3.Y.1 Scope

485 This transaction is used to request structured decoded information extracted from the barcode.

3.Y.2 Actor Roles

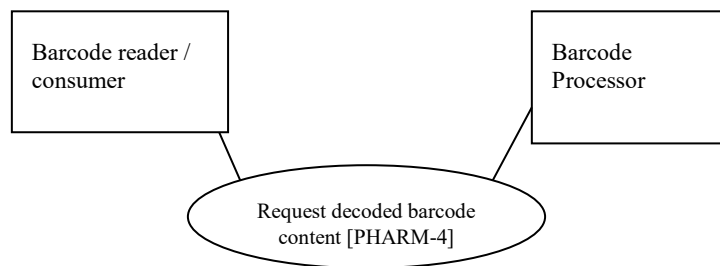


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

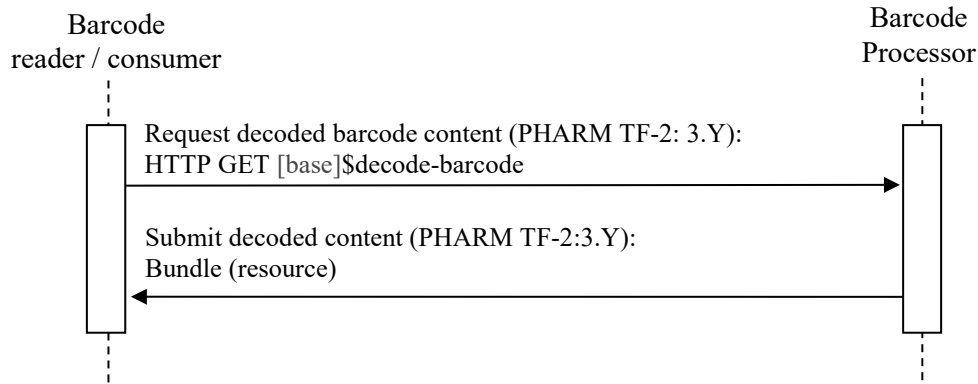
Actor:	Barcode reader / consumer
Role:	Request the decoded barcode sequence from the Barcode processor
Actor:	Barcode processor
Role:	Receive encoded barcode sequence for decoding and respond with decoded Barcode content

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3.Y.3 Referenced Standards

HL7 FHIR	Fast Healthcare Interoperability Resources DSTU3 http://hl7.org/fhir/DSTU3/index.html
IETF RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

3.Y.4 Interaction Diagram



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3.Y.5 Request decoded barcode content

This message represents an HTTP GET to trigger the operation defined for decoding the barcode.

500 3.Y.5.1 Submit Encoded Content - Query

3.Y.5.1.1 Trigger Events

When the barcode reader / consumer reads a barcode and requests that barcode to be decoded.

3.Y.5.1.2 Message Semantics

505 The Submit encoded content is triggered by the Barcode reader / consumer by executing an HTTP GET against the server, using the barcode string as a parameter.

The search target follows the FHIR http specification (see <http://hl7.org/fhir/STU3>)

```
GET [base]$decode-barcode?[aidc_string][parameters]{&_format=[mime-type]}
```

510 This URL is configured by the Barcode reader / consumer. The [aidc_string] represents the barcode string as it is read from the barcode reader. Additional [parameters] can be added to modify the behavior of the Barcode processor such as response format, or pagination.

3.Y.5.1.2.1 Parameter

The Barcode reader / consumer SHALL provide the aidc_string as a string. This string may be the actual content, or in any encoding such as a base-64 encoded string.

Note that the aidc_parameter is mandatory.

515 Table 3.Y.5.1.2.1-1 shows the parameters used:

Table 3.Y.5.1.2.1-1: Request Decoded Barcode content – Query parameter

Attribute	Type	repeat	Meaning
aidc_string	string	N	The barcode string to be parsed and decoded

aidc_string

520 This required parameter of type `string` represents the barcode string as it is provided by the barcode reader. The use of encoding rules, for example check digits, base 64 encoding, etc. are local implementation decisions.

3.Y.5.1.3 Expected Actions

525 In response to the request, the Barcode Processor shall return a response with the response codes described below. The Barcode Processor may include an actual resource that matches the barcode string as part of the response.

530 If the Barcode reader / consumer supplied an invalid parameter, or used a query parameter modifier which the Barcode processor is not capable of utilizing, then the Barcode Processor shall respond with an **HTTP 400** (Bad request) status code and an `OperationOutcome` resource indicating the parameters in error.

The Barcode Processor shall respond to the request as described in the cases below:

Case 1: The Barcode Processor is able to decode the barcode string and sends one resource matching the barcode string as defined in the section Submit Decoded Content.

HTTP 200 (OK) is returned as the HTTP status code.

535 A resource SHALL be returned– a medication, device, etc. resource, with the decoded attributes as per the barcode’s content. A resource `bundle` may be returned containing the decoded resource or resources.

Case 2: The Barcode Processor fails to decode the barcode string.

HTTP 400 (Bad Request) is returned as the HTTP status code.

540 An `OperationOutcome` Resource is returned indicating that the barcode could not be decoded in an `issue` having:

Attribute	Value
severity	error
code	{http://hl7.org/fhir/issue-type.html, ,not-supported}

The Barcode Processor shall, at minimum, be capable of producing XML and JSON encodings.

545 The Barcode Processor may return other HTTP status codes to represent specific error conditions. When HTTP error status codes are returned by the Barcode processor, they shall conform to the HTTP standard RFC2616. Their use is not further constrained or specified by this transaction.

3.Y.5.2 Submit Decoded Content - Response

550 **3.Y.5.2.1 Trigger Events**

The response is triggered when the Barcode Processor successfully decodes the barcode content as a result of the request from the Barcode reader / consumer.

3.Y.5.2.2 Message Semantics

The content of the resource depends on the resource type.

555 The following logical attributes are normalized, independently of their position in the FHIR resources:

Logic Attribute	Description
Product code	The code of the product or medication
Expiration Date	The expiry or “use-by” date
Lot or Batch number	The lot or batch number
Serial Number	The serial number
Patient ID	For patients, a unique PatientID

Appendix A shows how these attributes are defined indifferent encoding standards.

560 The mapping of each of these fields to the actual FHIR resources is described below.

The constraints specified in Section 3.Y.5.2.2 – namely in the tables in Sections 3.Y.5.2.2.1, 3.Y.5.2.2.2 and 3.Y.5.2.2.3 - represent the minimum set of information that must be implemented by a system implementing the Barcode reader / consumer actor. This does not prevent the Barcode Processor from sending additional FHIR attributes in a response, such as extensions, text, etc. The Barcode reader / consumer shall ignore additional attributes and extensions if not understood.

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3.Y.5.2.2.1 Medication Resource

Logic Attribute	Attribute
Product code	Medication.code
Expiration Date	Medication.package.batch.expirationDate
Lot or Batch number	Medication.package.batch.lotNumber

Logic Attribute	Attribute
Serial Number	Medication.serialNumber (extension)

570 The serialNumber extension is not part of the FHIR core specification. It is defined in the Pharmacy Technical Framework for the MMA Profile.

3.Y.5.2.2.2 Device Resource

Logic Attribute	Attribute
Product code	Device.udi.DeviceIdentifier
Expiration Date	Device.expirationDate
Lot or Batch number	Device.lotNumber
Serial Number	Device.identifier

3.Y.5.2.2.3 Patient Resource

575 The patient identifier only has one identifier

Logic Attribute	Attribute
Patient ID	Patient.identifier

3.Y.5.2.3 Expected Actions

580 The reader / consumer shall process the response in some manner specific to its application function (for example: displaying on a user interface, or forwarding to another actor). This application behavior is not specified by IHE.

3.Y.5.2.4 Capability Statement

Barcode Processors implementing [PHARM-4] should provide a CapabilityStatement, describing the UBP Profile and constraints specified in this profile.

3.Y.6 Security Considerations

585 The barcode reader / consumer and processor shall be grouped with a Secure Node.

Systems implementing the barcode reader / consumer and the processor shall implement the Secure Application in ATNA.

3.Y.6.1 Security Audit Considerations

590 The auditing considerations defined in ITI TF-2x: Appendix Z apply.

Appendices

Appendix A – Relation to standard barcodes

595 The table below shows the traceability between the IHE UBP Logical Model Items, Attributes and Data Types, FHIR Resources, GS1 barcodes³.

A.1 GS1

Logic Attribute / Data Type	GS1 Name	GS1 AI4	GS1 Format	FHIR resource attribute	Description	GS1 Example
Medical Device				FHIR Resource = device		
	AIDC Carrier string			udi.carrierAIDC	The content encoded in the barcode. Transmitted electronically as a base-64 encoded string.	
Product Code	GTIN Product Identification	01	N2+N14	udi.deviceIdentifier	Unique code for the identification of a product. Also known as 'article or product number'	08712345670206
Expiration Date	Expiration Date	17	YYMMDD, N2+N6	expirationDate	The expiration date is the date that determines the limit of consumption or use of a product / coupon. Its meaning is determined based on the trade item context (e.g., for food, the date will indicate the possibility of a direct health risk resulting from use of the product after the date, for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is often referred to as "use by date" or "maximum durability date."	270620
Lot / Batch number	Lot / Batch number	10	N2+X..20	lotNumber	The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the element string is applied. The data may refer to the trade item itself or to items contained. The number may be, for example, a production lot number, a shift number, a machine number, a time, or an internal production code.	G1709176
Serial number	Serial number	21	N2+X..20	lotNumber	A serial number is assigned to an entity for its lifetime. When combined with a GTIN, a serial number uniquely identifies an individual item.	ab2376891011

³ Information obtained from: "HL7 Domain Analysis Model: Unique Device Identifier (UDI) Implementation Guidance, Release 1 - sep 2017 - Appendix A"

⁴ AI = Application Identifier

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Medicinal Product				FHIR Resource = medication		
	AIDC Carrier string			udi.carrierAIDC	The content encoded in the barcode. Transmitted electronically as a base-64 encoded string.	
Product Code	GTIN Product Identification	01	N2+N14	udi.deviceIdentifier	Unique code for the identification of a product. Also known as 'article or product number'	08712345670206
Expiration Date	Expiration Date	17	YYMMDD, N2+N6	package.batch.expirationDate	The expiration date is the date that determines the limit of consumption or use of a product / coupon. Its meaning is determined based on the trade item context (e.g., for food, the date will indicate the possibility of a direct health risk resulting from use of the product after the date, for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is often referred to as "use by date" or "maximum durability date."	270620
Lot / Batch number	Lot / Batch number	10	N2+X..20	package.batch.lotNumber	The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the element string is applied. The data may refer to the trade item itself or to items contained. The number may be, for example, a production lot number, a shift number, a machine number, a time, or an internal production code.	G1709176
Serial number	Serial number	21	N2+X..20	serialNumber (extension)	A serial number is assigned to an entity for its lifetime. When combined with a GTIN, a serial number uniquely identifies an individual item.	ab2376891011
Patient				FHIR Resource = patient		
Patient Identifier	GSRN - Recipient	8018	N4+N18	identifier	A serial number is assigned to an entity for its lifetime. When combined with a GTIN, a serial number uniquely identifies an individual item.	
Healthcare Professional				FHIR Resource = practitioner		
Healthcare Professional Identifier	GSRN - Provider	8017	N4+N18	identifier	a unique identifier for a Healthcare professional	
Location				FHIR Resource = location		
Location Identifier	GLN	414	N3+N13	identifier	A unique identifier for a location	

A.2 HIBCC

Logic Attribute / DataType	HIBCC Name	HIBCC AI ⁵	FHIR resource attribute	Description	GS1 Example
Device			FHIR Resource = Device		
ProductIdentification	Health Industry Bar Code (HIBC)	25P	udi.deviceIdentifier		
Expiration Date	Expiration Date	14D	expirationDate	The Expiration Date	+ A 9 9 9 1 2 3 4 5 / \$ \$ 5 2 0 0 0 1 5 1 0 X 3 3
Lot / Batch number	Lot	1T	lotNumber	Traceability Number assigned by the Supplier	
Serial number	Serial Number	S	serialNumber (extension)	Serial number or code assigned by the Supplier	

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⁵ AI = Application Identifier