**Integrating the Healthcare Enterprise**



**IHE Patient Care Coordination (PCC)**

**Technical Framework Supplement**

**Point-of-Care Medical Device Tracking   
(PMDT)**

**Draft in preparation for Public Comment**

<The IHE Documentation Specialist will change the title to just “Draft for Public Comment” upon publication for public comment; leave “as is” until then.>

Date: March 23, 2017

Author: PCC Technical Committee

Email: <domain\_name@ihe.net>

<Instructions to authors are encapsulated in angled brackets as “< … >” and denoted with italicized text. These instructions are to be deleted in their entirety prior to publication.>

<Use of capitalization: Please follow standard English grammar rules-only proper nouns and names are upper case. For example, “Modality Actor” is upper case, but “an actor which fulfills the role of a modality” is lower case. Do not use upper case to emphasize a word/topic.>

<Note: There are editing conventions, such as diagram numbering and how to use Microsoft Word tools, etc., at <http://wiki.ihe.net/index.php?title=Writing_Technical_Frameworks_and_Supplements>. Please review this prior to beginning a new Supplement. This is especially useful for first time authors.>

<This Supplement Template is intended for the development of new Profiles or for making significant changes to Profiles, such as adding formal Options. Simple changes to existing Supplements or Profiles should be made using the Change Proposal (CP) process. See the Technical Framework Development section at <http://wiki.ihe.net/index.php?title=Process#Technical_Framework_Development> for more guidance on Supplements vs. CPs.>

<All of the sections in this document are required. Sections may not be deleted. The outline numbering is intended to be consistent across Profiles and across Domains, so do not adjust the outline numbering. If there is no relevant content for a section, simply state “Section not applicable”, but leave the numbering intact. Sub-sections may be added for clarity.>

*<This Supplement Template includes templates for Volumes 1 (Profiles), 2 (Transactions), 3 (Content Modules), and 4 (National Extensions).>*

*<Volumes 1, 2, and/or 3 are developed together for Public Comment and Trial Implementation submission. Volume 4, National Extensions, is typically developed at a later point in time, usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see* [*http://wiki.ihe.net/index.php?title=National\_Extensions\_Process*](http://wiki.ihe.net/index.php?title=National_Extensions_Process)*.>*

**Foreword**

This is a supplement to the IHE Patient Care Coordination (PCC) Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

*<For Public Comment:>* This supplement is published on <Month XX, 2017> for Public Comment. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/Technical_Framework/public_comment.cfm). In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 2017>.

*<For Trial Implementation:>* This supplement is published on <Month XX, 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 Patient Care Coordination (PCC) Technical Framework. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/%3cdomain%3e/%3cdomain%3ecomments.cfm).

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.

Amend section X.X by the following:

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.

General information about IHE can be found at: [www.ihe.net](http://www.ihe.net).

Information about the IHE Patient Care Coordination (PCC) domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

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/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE Patient Care Coordination (PCC) Technical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

*<Comments may be submitted on IHE Technical Framework templates any time at* [*http://ihe.net/ihetemplates.cfm*](http://ihe.net/ihetemplates.cfm)*. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.*

Contents

[Introduction to this Supplement 1](#_Toc477997444)

[Open Issues and Questions 3](#_Toc477997445)

[Closed Issues 3](#_Toc477997446)

[Relationship to IHE Patient Care Devices (PCD) Technical Framework 4](#_Toc477997447)

[Secure Transport 4](#_Toc477997448)

[Condition associated with a Procedure 4](#_Toc477997449)

[General Introduction 4](#_Toc477997450)

[Scope 6](#_Toc477997451)

[Standards 7](#_Toc477997452)

[Technical Approach 8](#_Toc477997453)

[Appendix A - Actor Summary Definitions 8](#_Toc477997454)

[Appendix B - Transaction Summary Definitions 8](#_Toc477997455)

[Glossary 8](#_Toc477997456)

[Implantable Device 8](#_Toc477997457)

[UDI 9](#_Toc477997458)

[Volume I - Profiles 9](#_Toc477997459)

[1. PMDT profile 9](#_Toc477997460)

[1.1 PMDT Actors, Transaction, and Content Modules 10](#_Toc477997461)

[1.2 Actor Options 16](#_Toc477997462)

[1.3 Required Actor Groupings 16](#_Toc477997463)

[1.4 PDMT Overview 16](#_Toc477997464)

[1.5 Security Consideration 25](#_Toc477997465)

[1.6 Cross Profile Considerations 27](#_Toc477997466)

[Volume 2 - Transactions 28](#_Toc477997467)

[2.1 Register Device 28](#_Toc477997468)

[2.1.1 Scope 28](#_Toc477997469)

[2.1.2 Actor Roles 28](#_Toc477997470)

[2.1.3 Referenced Standards 29](#_Toc477997471)

[2.1.4 Interaction Diagram 29](#_Toc477997472)

[2.1.5 Security Considerations 44](#_Toc477997473)

[2.2 Search Devices 44](#_Toc477997474)

[2.2.1 Scope 44](#_Toc477997475)

[2.1.2 Actor Roles 45](#_Toc477997476)

[2.2.3 Referenced Standards 46](#_Toc477997477)

[2.2.4 Interaction Diagram 46](#_Toc477997478)

[2.2.5 Security Considerations 50](#_Toc477997479)

[2.3 Start Point-of-care Device Procedure 50](#_Toc477997480)

[2.4.1 Scope 50](#_Toc477997481)

[2.4.2 Actor Roles 50](#_Toc477997482)

[2.4.3 Referenced Standards 51](#_Toc477997483)

[2.4.4 Interaction Diagram 52](#_Toc477997484)

[2.4.5 Security Considerations 58](#_Toc477997485)

[2.4 Complete Point-of-care Device Procedure 58](#_Toc477997486)

[2.4.1 Scope 58](#_Toc477997487)

[2.4.2 Actor Roles 58](#_Toc477997488)

[2.4.3 Referenced Standards 59](#_Toc477997489)

[2.4.4 Interaction Diagram 60](#_Toc477997490)

[2.4.5 Security Considerations 68](#_Toc477997491)

[2.5 Search Point-of-Care Device Procedures 69](#_Toc477997492)

[2.5.1 Scope 69](#_Toc477997493)

[2.5.2 Actor Roles 69](#_Toc477997494)

[2.5.3 Referenced Standards 70](#_Toc477997495)

[2.5.4 Interaction Diagram 71](#_Toc477997496)

[2.5.5 Security Considerations 72](#_Toc477997497)

[Volume 3 - Content Modules 73](#_Toc477997498)

[Volume 4 - National Extensions 73](#_Toc477997499)

## Introduction to this Supplement

The Point-of-Care Medical Device Tracking (PMDT) profile will close the loop on data acquisition at the point-of-care in support of reporting data about implantable medical devices (e.g., pacemaker, titanium plates) and from medical devices (e.g. vital sign monitors, pulse oximeters, blood glucose monitors) during a procedure (e.g., Continuous Pulse Oximetry - 4A19XCZ, Insertion Pacemaker - 0JH607Z, Open Reduction Internal Fixation Elbow - 0PSJ04Z).

* Medical device measurements, settings, status, and alarms are transmitted to patient care system (e.g. ICU flowsheet) using existing standard transaction (e.g. IHE PCD-01 transactions based on HL7 Version 2. 7 ORU\_R01). Sometimes, these transactions include only the device identification without patient identification context and thus device information cannot be assigned correctly by the receiving system to a patient record. This means that the receiving system (implementing Device Observation Consumer – DOC actor) is unable to match the device data with the correct patient. This leads to missing or erroneous data and could further lead to patient safety issues.
* Implantable life-sustaining or life-supporting devices must be tracked to the patient and recorded along with procedure in the EHR to meet Meaningful Use 2015 certifications criteria. This information is necessary to address adverse events and recall notices specify to a device instance (based on device unique device identified using the FDA-specified UDI in the US). Currently we do not have a standard-based mechanism to capture the information consistently across care setting (e.g. hospital Operating Room, cardiology clinic, orthopedic surgery clinic).
* Medical device data may be persisted to the patient’s chart (if “validated/accepted” by clinicians), used for decision support, and exchange with other providers across the continuum of care (e.g. as referrals, transfer, discharge summary documents based on HL7 Consolidated CDA).

Implantable medical devices are essential for the treatment and management of a wide variety of medical conditions. These devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products being used for patient care has become a global issue. Post-market surveillance of implantable medical devices can be challenging due to the longevity of the patient and the medical device unless there is a reliable implant tracking method. In 2013, the United States Food and Drug Administration (FDA) issued a unique device identifier (UDI) system designed to identify and track implantable medical devices throughout their distribution and use in the United States. The EU will be developing and adopting similar legislation. The desire is to combine data from premarket approval with post-market settings to help address issues of cost and concerns about illegitimate products and to gain understanding of performance and clinical outcomes of implantable medical devices.

The manufacturer supplies a unique computer-readable identifier on the label of implantable medical devices to enable traceability of where the implantable medical device has been distributed. Unfortunately, it does not enable standardized data exchange from healthcare organizations inventory management systems (IMS) to an EHR and then to a national registry, where activities occur such as infection prevention or guideline development to protect patients from hospital acquired infections (HAIs). The inability to track a medical device from premarket through post-market surveillance systems for adverse event reporting, recalls, corrections, removals/revisions, continued evaluation on safety, effectiveness and reliability of device for intended use, due to the lack of standards available to electronically share the UDI data, makes post-market surveillance of implantable medical devices challenging.

Currently, healthcare organizations collect data on healthcare-associated infections (HAI) caused by certain medical devices (i.e., central venous catheters). Implantable medical device data is collected in a variety of ways, manually entered or partial look up in the electronic health record (EHR), manually entered in an EHR tab that doesn’t become part of the patients EHR, or manually on a study or registry log that is aggregated by a healthcare organization’s Quality Department or special study coordinator that is sent to the national registry. Inoperability of electronic data, manual data entry, and data manipulation lends itself to human error and inaccurate data capture leading to healthcare inefficiencies and patient safety errors.

Implantable medical devices enter healthcare organizations through a variety of methods. No matter the method used to requisition the implantable medical device, once it arrives at the healthcare organization supply chain, inventory control personnel scan the implantable medical device which adds it into the healthcare organization’s inventory and master item file. The UDI, which is embedded in one of the barcodes on the package, is not accepted by the IMS system. The IMS typically only accepts the global trade identification number (GTIN) from the scanned barcode. At the point of use the clinician scans the barcode on the implantable medical device package, if the healthcare organization has an automated identification and data capture (AIDC) technology. Or the clinician manually enters the UDI data into the EHR.

If the clinician has a scanner and finds the correctly formatted barcode, the scanner accepts the UDI. The barcode scanner and EHR system exchange the UDI data and the data becomes part of the patient’s EHR. The EHRs UDI data cannot be exchanged with the IMS for the healthcare organizations business processes because different data standards are being used on the device packaging that can’t be used by the IMS. By transforming the information that is stored in the different barcode formats into a standardized format, healthcare organization’s IMS and EHRs can become interoperable and standardized submission of that data can be exchanged with a national registry or payer organizations.

Implantable medical device failures, infections, or complications cost healthcare organizations and payer associations thousands of dollars. The benefits of this profile will improve patient safety, remove clinicians from manual data entry, foster accurate data capture, and provide an approach for implantable medical device collection to a national registry. This profile will produce the technical specifications for the exchange of implantable medical device data from the various healthcare information systems using the UDI barcode data to exchange with a national registry to track implantable medical device safety, effectiveness, and rates of infection.

## Open Issues and Questions

The following issues are outstanding:

##### *Actor Options*

* Do we need [options](#BKM_C0E96CED_3629_4E07_8E78_05057EA75CE2) specific to a device type or will this profile be sufficient to address point-of-tracking for implantable, monitoring, cardiology ?

**No,** the generic use cases related to managing devices and associated procedures will apply equally well to any type of device.

##### *Device Resource*

The Device resource is missing data elements to support:

* date/time the resource was created at the point-of-care indicating when a device was associated with a patient. In the absence of this data element, the [Procedure.performed](http://build.fhir.org/procedure-definitions.html#Procedure.performed_x_) ([dateTime](http://build.fhir.org/datatypes.html#dateTime)).
* "Device Identifier" portion of the parsed Universal Device Identifier

Our team will discuss these issues with the HL7 Patient Care WG which manages this resource:

http://build.fhir.org/device.html

### Closed Issues

The following issues have been discussed and resolved:

#### Relationship to IHE Patient Care Devices (PCD) Technical Framework

*This profile is intended to augment Device Manager systems that implement IHE PCD Technical Framework but it is focused on FHIR adoption at this time.*

When associating the device with the patient using HL7 V2 transactions implementers have the option to use, PAM (Patient Administration Management) or PCIM (Point-of-Care Identity Management) specification currently under development. This profile provides a FHIR-bases approach to creating individual device and procedure records as well querying those data sets.

#### Secure Transport

FHIR resource security issues are addressed by the IHE IT Intrastructure specification referenced across the IHE PCC Technical Framework (e.g. Transport-level security) - see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E).

#### Condition associated with a Procedure

One of the requirements communicated by the IHE CARD domain was to be able to "search for a device based on the procedure and associated diagnosis". The issue is two-fold:

* The [Procedure](http://build.fhir.org/procedure.html) resource specifies a "related condition" as [Procedure.reasonReference](http://build.fhir.org/procedure-definitions.html#Procedure.reasonReference) (a reference to a Condition) or [Procedure.reasonCodeableConcept](http://build.fhir.org/procedure-definitions.html#Procedure.reasonCodeableConcept) (a reference to SNOMED-CT or ICD-10 concept code).

## General Introduction

This supplement is providing a standard-based approach to acquiring medical device information at the point-of-care such that it can be retrieved and reused at a later time.

Implantable medical devices are essential for the treatment and management of a wide variety of medical conditions. These devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products being used for patient care has become a global issue. Post-market surveillance of implantable medical devices can be challenging due to the longevity of the patient and the medical device unless there is a reliable implant tracking method. In 2013, the United States Food and Drug Administration (FDA) issued a unique device identifier (UDI) system designed to identify and track implantable medical devices throughout their distribution and use in the United States. The EU will be developing and adopting similar legislation. The desire is to combine data from premarket approval with post-market settings to help address issues of cost and concerns about illegitimate products and to gain understanding of performance and clinical outcomes of implantable medical devices.

The manufacturer supplies a unique computer-readable identifier on the label of implantable medical devices to enable traceability of where the implantable medical device has been distributed. Unfortunately, it does not enable standardized data exchange from healthcare organizations inventory management systems (IMS) to an EHR and then to a national registry, where activities occur such as infection prevention or guideline development to protect patients from hospital acquired infections (HAIs). The inability to track a medical device from premarket through post-market surveillance systems for adverse event reporting, recalls, corrections, removals/revisions, continued evaluation on safety, effectiveness and reliability of device for intended use, due to the lack of standards available to electronically share the UDI data, makes post-market surveillance of implantable medical devices challenging.

Currently, healthcare organizations collect data on healthcare-associated infections (HAI) caused by certain medical devices (i.e., central venous catheters). Implantable medical device data is collected in a variety of ways, manually entered or partial look up in the electronic health record (EHR), manually entered in an EHR tab that doesn’t become part of the patients EHR, or manually on a study or registry log that is aggregated by a healthcare organization’s Quality Department or special study coordinator that is sent to the national registry. Inoperability of electronic data, manual data entry, and data manipulation lends itself to human error and inaccurate data capture leading to healthcare inefficiencies and patient safety errors.

Implantable medical devices enter healthcare organizations through a variety of methods. No matter the method used to requisition the implantable medical device, once it arrives at the healthcare organization supply chain, inventory control personnel scan the implantable medical device which adds it into the healthcare organization’s inventory and master item file. The UDI, which is embedded in one of the barcodes on the package, is not accepted by the IMS system. The IMS typically only accepts the global trade identification number (GTIN) from the scanned barcode. At the point of use the clinician scans the barcode on the implantable medical device package if the healthcare organization has an automated identification and data capture (AIDC) technology. Or the clinician manually enters the UDI data into the EHR.

If the clinician has a scanner and finds the correctly formatted barcode, the scanner accepts the UDI. The barcode scanner and EHR system exchange the UDI data and the data becomes part of the patient’s EHR. The EHRs UDI data cannot be exchanged with the inventory management system for the healthcare organizations business processes because different data standards are being used on the device packaging that can’t be used by the IMS. By transforming the information that is stored in the different barcode formats into a standardized format, healthcare organization’s IMS and EHRs can become interoperable and standardized submission of that data can be exchanged with a national registry or payer organizations.

Implantable medical device failures, infections, or complications cost healthcare organizations and payer associations thousands of dollars. The benefits of this profile will improve patient safety, remove clinicians from manual data entry, foster accurate data capture, and provide an approach for implantable medical device collection to a national registry. This profile will produce the technical specifications for the exchange of implantable medical device data from the various healthcare information systems using the UDI barcode data to exchange with a national registry to track implantable medical device safety, effectiveness, and rates of infection.

This supplement supports a combination requirements dealing with managing medical devices at the point-of-care:

* “Implantable Medical Device Registry Workflow Definition (IMDR-WD)” submitted by Denise Downing Informatics Nurse Specialist, Perioperative, AORN Syntegrity®
* “Point-of-care Medical Device Manager to improve patient safety, documentation clarity, and decision support”, submitted by Ioana Singureanu, BSEE, MSCS, FHL7, Standards Architect, Veterans Health Administration (VHA)

Both sets of requirements relied on correctly recording the identifier of medical devices, most likely automatically (e.g. scanning), at the point of care, using its Unique Device Identifier (UDI) specified by manufacturers using of standard-based [supported formats](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm/oUDIformats).

UDIs on implantable medical device labels and packages and in certain cases, directly on the devices, will improve the quality of information for medical device adverse event reporting, to identity product quality issues more quickly, target recalls, and ultimately improve patient safety. These are not only US based concerns, but also international concerns as identified in the International Consortium for Orthopedic Registry (ICOR). ICOR is a US FDA sponsored initiative that represents 14 nations (i.e., England/Wales, Denmark, Portugal, New Zealand) to evaluate implant safety and effectiveness. This international consortium nor U.S. healthcare organizations collect surveillance data for implantable medical devices. When data has to be manipulated by an individual data quality becomes a factor. Manually transcribing data because it uses one standard and its source uses another it prone to human error. Incorrect data formatting or missing data can cause rejection of a registry submission or rework may need to occur. Patient safety can be jeopardized if incorrect data is transcribed and decisions made off of incorrect data.

### Scope

This supplement supports a combination requirements dealing with managing medical devices at the point-of-care:

* “Implantable Medical Device Registry Workflow Definition (IMDR-WD)” submitted by Denise Downing Informatics Nurse Specialist, Perioperative, AORN Syntegrity®
* “Point-of-care Medical Device Manager to improve patient safety, documentation clarity, and decision support”, submitted by Ioana Singureanu, BSEE, MSCS, FHL7, Standards Architect, Veterans Health Administration (VHA)

Both sets of requirements relied on correctly recording the identifier of medical devices, most likely automatically (e.g. scanning), at the point of care, using its Unique Device Identifier (UDI) specified by manufacturers using of standard-based [supported formats](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm/oUDIformats).

UDIs on implantable medical device labels and packages and in certain cases, directly on the devices, will improve the quality of information for medical device adverse event reporting, to identity product quality issues more quickly, target recalls, and ultimately improve patient safety. These are not only US based concerns, but also international concerns as identified in the International Consortium for Orthopedic Registry (ICOR). ICOR is a US FDA sponsored initiative that represents 14 nations (i.e., England/Wales, Denmark, Portugal, New Zealand) to evaluate implant safety and effectiveness. This international consortium nor U.S. healthcare organizations collect surveillance data for implantable medical devices. When data has to be manipulated by an individual data quality becomes a factor. Manually transcribing data because it uses one standard and its source uses another it prone to human error. Incorrect data formatting or missing data can cause rejection of a registry submission or rework may need to occur. Patient safety can be jeopardized if incorrect data is transcribed and decisions made off of incorrect data.

### Standards

* [Harmonization Pattern for UDI](http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf) (referenced by the [ONC Standards Advisory for 2017 (Draft)](https://www.healthit.gov/standards-advisory/draft-2017)
* [UDI Formats by FDA-Accredited issuing agency](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm): GS1, Health Industry Business Communications Council (HIBCC), ICCBBA – the details of the format are explained in the [UDI formats by FDA-Accredited Issuing Agency Version 1.2](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc): March 9, 2016.
* Clinical terminology consistent with Meaningful Use 2015 (LOINC, SNOMED CT, RxNorm) based on the type of data to be represented. For PCD transactions, we will use the LOINC concepts provided by Regenstrief to represent IEEE 11073-10101 concepts.

### Technical Approach

The approach outlined here relies on the use of FHIR resources (i.e. RESTful services) to record information acquired at the point-of-care and add it to the set of data maintained by enterprise information system (e.g. EHR systems, IMS systems, flow sheets).

Unlike previous approaches that put the emphasis and responsibility on the enterprise to manage the point-of-care and ancillary systems, this integration profile adds new capabilities to the point-of-care systems (e.g. device managers) to enhance patient safety and effectiveness.

## Appendix A - Actor Summary Definitions

*<Add any actor definitions for new actors defined specifically for this profile. These will be added to the IHE TF General Introduction list of Actors namespace.>*

NOTE: this section be added after finalizing Volume 1.

## Appendix B - Transaction Summary Definitions

*<Add any transaction definitions for new transactions defined specifically for this profile. These will be added to the IHE TF General Introduction list of Transactions namespace.>*

NOTE: this section be added after finalizing Volume 1.

## Glossary

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

### Implantable Device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:1) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life- control of conception; disinfections of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body and: 2) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. (Reference: GHT)

### UDI

Unique Device Identifier - An identifier of an entity, such as persistent document, that has been generated by an algorithm guaranteeing its global uniqueness. [http://wiki.ihe.net/index.php/IHE\_Glossary#M](http://wiki.ihe.net/index.php/ihe_glossary#m)

The U.S. Food and Drug Admnistration (FDA) specifies that:

A UDI is a unique numeric or alphanumeric code that consists of two parts: **a device identifier (DI**), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and a **production identifier (PI**), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

* the lot or batch number within which a device was manufactured;
* the serial number of a specific device;
* the expiration date of a specific device;
* the date a specific device was manufactured;
* the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. ([FDA UDI Basics](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm))

## Volume I - Profiles

This supplement is intended to enable the industry to create standard-based Point-of-care Medical Device Managers and Medical Device Registries.

### 1. PMDT profile

The Point-of-Care Medical Device Tracking (PMDT) Integration Profile actors and transactions intended to support several business use cases detailed in [this document:](#BKM_09E050EC_D05B_4A0F_B8C2_7DFA040E3090)

* [Implantable Medical Registration](#BKM_DF3BF2A8_D89E_404D_81D5_C61C2A3CD03A) to a enterprise [Device Registry](#BKM_F04A1DF8_A267_47B3_A0BC_7F4A91AFCF3C);
* [Tracking Implantable Devices](#BKM_2C0AECCF_07C8_4B81_9E85_BBCE043D22CC) at the point of care, during a procedure;
* [Vital Signs Monitoring and Charting](#BKM_CA8A279F_BFE0_469F_ADC3_B0CC9FC33D4A) using device and patient identity acquired at the point-of-care;
* [Cardiology - Implanted Stent](#BKM_C3F4BE69_7F0E_40B0_93FB_EC9DC7040079)
* [Cardiology - Pacemaker](#BKM_AC936C7C_D64F_429C_8C0C_5A9982279914)

These business use cases require the implementation of to main FHIR STU3 resources [Device](http://build.fhir.org/device.html), [Procedure](http://build.fhir.org/procedure.html) and references to instances of [Patient](http://build.fhir.org/patient.html) resources identified by an "identifier" attribute.

Analysis of the business requirements identified several interoperability requirements necessary to exchange information from the pont-of-care to enterprise systems to:

* [Register Medical Device](#BKM_3E99AADD_148D_46E8_98FE_74CC8A2FD69D)
* [Register Implantable Device](#BKM_38ADD49B_F109_4A8E_9B77_8DEA93DD504C)
* [Start Procedure](#BKM_F2CFD98C_F10A_4639_90BA_138A867E3578) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Complete Procedure](#BKM_DA44E8E8_005A_4F53_947D_74E75A4647EB) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Complete Post-Procedure](#BKM_8835C6BF_013E_4710_B40A_EF037C587C28) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Search Medical Device](#BKM_9ECEE198_2D4A_455E_9D2C_60F946776094) and the specialization [Search Implantable Device by Patient](#BKM_3F13ECF9_137C_4730_8000_00ED3BB76A67) and variations for [Search Implantable Device by UDI](#BKM_01751BC1_EE8B_4615_91F7_6245B4F66E7D)
* [Search Point-of-Care Procedure](#BKM_60507CE1_C383_426A_9518_9FB77B63E6C6) using a variety of criteria.

These requirements are organized into two use case analyzed as [Use Case #1: Manage and Search Device information](#BKM_111002FF_8A3D_457C_92AC_F5E29EDDC902) and [Use Case #2: Manage and Serach Point-of-care Procedures](#BKM_BDB8079F_8211_432C_A5AA_307ED839EDE8).

#### 1.1 PMDT Actors, Transaction, and Content Modules

This section identifies the system behavior ("actors") and the FHIR resource operations as transactions initiated at the point-of-care.

##### *1.1.1 Actor Descriptions and Actor Profile Requirements*

This section describes the Actors defined by this Profile and the transaction supported by each:

Table 1.1.1-1 lists the transactions for each actor directly involved in the PMDT P Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

| Actors | Transactions | Optionality | Reference |
| --- | --- | --- | --- |
| **Medical Device Reporter** | **Register Device** (initiate) | R |  |
| **Start Procedure** (initiate) | O |  |
| **Complete Procedure** (initiate) | O |  |
| **Medical Device Server** | **Register Device** | R |  |
| **Search Device** | R |  |
| **Start Procedure** | R |  |
| **Complete Procedure** | R |  |
| **Search Procedure** | R |  |
| **Medical Device Requester** | **Search Device** (initiate) | R |  |
| **Search Procedure** (initiate) | O |  |

Table 1.1.1-1 PDMT Profile - Actors and Transactions

The following diagram shows the device-management related actors and transactions:



Figure 2: PMDT Actors: Device Server, Reporter, Requester

The following diagram identifies the actors and the information FHIR resources implemented to complete each transaction/operation. The two resources are Procedure and Device as seen below and Device Server provides the two resources to the other actors to create, update, and search information related to procedures and device information acquired at the point-of-care :



Figure 3: FHIR Implementation of Actors

Medical Device Reporter

This actor reports on the use of medical devices and any associated procedures involving those devices at the point-of-care

This actor may also be responsible for sending procedure code, status, and related information to consumer(s) . Initiates the creation and update of a procedure for a vital sign monitoring session. It is used to identify the type procedure that implants a life-supporting or life-sustaining medical device or uses the device (e.g. pulse oximetry, vital sign monitoring, IV drug administration). The reporter is implemented by a point-of-care system (e.g. Medical Device Manager).

In FHIR terms, this actor is as a FHIR Device and Procedure resources client that creates Device resource instances. The Device resource will reference the patient who received the implant. If the device is used to monitor a patient, the Device resource does not require a reference to the Patient. The Device resource includes the UDI of the device as human readable text representation of the scanned bar code.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send register Device()** | The actor initiates an new device registration ( [register Device(Device, Patient)](#BKM_27551DF6_A046_42E4_82CE_136974DC802B) ) that associates a device with a patient based on information acquired at the point-of-care.  Since FHIR Devcies resource does not record when the device was assigned to a patient. a second Procedure-related transaction would be used to specify the complete context. | Device ] device  Patient ] referencedPatient |
| **send start Procedure()** | The Start Procedure transaction identifies the commencement of an intervention that uses a device at the point-of-care.  In FHIR, the reporter uses this transaction to creates a **new** Procedure resource with status "***in-progress***" to indicate a new point-of-care procedure was initiated. The Procedure references the Device and the Patient using the identifiers read at the point-of-care (e.g. bar code, RFID). | Procedure ] procedure  Patient ] patient  Device ] device |
| **send complete Procedure()** | The Complete Procedure transaction identifies the completion of an intervention that uses a device at the point-of-care.  In FHIR terms, the reporter **updates** theProcedure resource with status "***completed***" to indicate a new point-of-care procedure was completed. In addition to the status, the "performedPeriod.end" is set to the date/time when the procedure was completed. | Procedure ] procedure  Patient ] patient  Device ] device |

Medical Device Server

This actor maintains information about medical devices and medical device related procedures reported from the point-of-care,

In FHIR terms,this actor is FHIRS server processes the request to create and search Device resources. This actor could be implemented by Medical Device Registries for implantable devices.The type of queries (aka search operations) may be more extensive than the example shown in this proposal (e.g. “search by patient Id”).

This actor may also process the requests and maintains the Procedure resources across the enterprise. It stores a record of the procedure used to implant a device or a procedure that uses a medical device (e.g. vital sign monitoring). The procedure will provide unambiguous documentation of procedures that use a medical device or equipment at the point-of-care.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **register Device()** | The device server processes the request (to "create" a device record) . It creates a new device record based on the data provide by the client/reporter at the point-of-care. | Device ] device  Patient ] referencedPatient |
| **start Procedure()** | The server receives and validate a **new** procedure recorded initiated at the point-of-care procedure. The status of this procedure is "in-progress". | Procedure ] procedure  Patient ] patient  Device ] device |
| **complete Procedure()** | The server processes **update** and revises the status ( "completed") and the "performedPeriod.end" to indicate a new point-of-care procedure was completed. | Procedure ] procedure  Patient ] patient  Device ] device |
| **search Devices()** Device | The device server responds queries for device records that match specific criteria or "search parameters" (e.g. device UDI, patient identifier specified in [Device Search Parameters](#BKM_3D38DBC0_F4A1_4300_9207_23E3726450E5) ). The Device resource does not record **when** the device was assigned to a patient or the diagnosis or problem the device is intended to address if the device is implementable. This information is recorded in the associated procedure (as the date/time when the procedure was completed). | Device Search Parameters ] searchParameter |
| **search Procedure()** Procedure | This server returns the Procedure resources that match the criteria (i.e. search parameters) specified by the requester (i.e. procedure code, patient identifier). In addition to the pre-specified compartment/search parameters, the server may also support other search parameters specified by the FHIR specification (e.g. date when the procedure was performed). The references to diagnosis and focal devices are not available as search parameters but they can be used by the client to filter the matching resources. | Procedure Search Parameters ] searchParameters |

Medical Device Requester

This actor request information about device identity and associated procedures and implements the “search” operation. This actor uses a set of search parameters to specify one or more devices or procedures related to the use of devices at the point-of-care.

This actor could be implemented by systems that compile an Implantable Device list for a patient consistent with the Meaningful Use 2015 EHR system certification requirements.

In FHIR terms, this actor is a client that performs "search"operations against the Server actor.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send search Procedure()** Procedure | The Search for Procedures searches, queries the server for a procedure with a device against a procedure resource.  This transaction allows the requester to search/queries procedures of a for a certain patient or procedure code. Since the condition/diagnosis identified the"reason for the procedure" is not a pre-defined compartment, this cannot be used as a "search parameter". Therefore the requester is expected to filter the matching results based on the **Procedure.reasonCodeableConcept** or **Procedure.reasonReference**.  Other search parameters supported are:   * date : Date/Period the procedure was performed (path: Procedure.performed[x] ) * performer: Reference to the practitioner (path: Procedure.performer.actor ) * status (e.g. "in-progress", "completed") | Procedure Search Parameters ] searchParamerters |
| **send search Devices()** Device | The Search for Devices queries the server for a medical device that matches specific criteria.  The requester initiates queries for device records that match specific criteria or "search parameters" (e.g. device UDI, patient identifier specified in [Device Search Parameters](#BKM_3D38DBC0_F4A1_4300_9207_23E3726450E5) ). | Device Search Parameters ] searchParameter |

#### 1.2 Actor Options

See [Open Issues and Questions](#BKM_E94030AB_95CA_41DA_87AE_6310E34A2862) - [Actor Options](#BKM_387E1B76_C99A_461E_A871_EEE4C9885684)

#### 1.3 Required Actor Groupings

The actors describe in this profiles organized around the Device and Procedure resources. Based on the high-level  [Business Use Cases](#BKM_5289EADE_7006_470F_AD4E_23174A6D703B) we have identified the need to capture patient identity, device identity, and point-of-care procedure information right at the point-of-care.

#### 1.4 PDMT Overview

The use case analysis in this section provides informative background information and requirements for both Volumes 1 and 2 of this profile.

##### *1.4.1 Concepts*

*Not applicable.*

##### *1.4.2 Use Cases*

The following use case analysis includes both business and technical use cases

###### 1.4.2.1 Business Use Cases

The following scenarios were analyzed to create the use cases identified in this section:

Implantable Medical Registration

Mr. Smith is a 65-year-old male who lives in Colorado and is very active, but his right knee arthritis has finally put a stop to his ability to hike. Mr. Smith goes to his primary care physician who refers him to Dr. Denver, an orthopedic surgeon. Dr. Denver performs an exam, sends Mr. Smith for some diagnostic studies, and determines a right total knee replacement is necessary. Mr. Smith is scheduled for a right total knee replacement, at St Castles Medical Center, using XYZ manufacturer’s knee replacement systems. Dr. Denver’s office schedules Mr. Smith’s total knee replacement with the operating room scheduling system.

St. Castles’ operating room has an Orthopedic/Spine Coordinator who reviews the surgical schedule to make sure the correct implantable medical devices are available for the scheduled procedures. XYZ manufacturer has a contract with St Castles Medical Center, but they do not stock the system that is needed for Mr. Smith. The Orthopedic Coordinator notifies the operating room (OR) materials manager (MM) to purchase the total knee components needed for Mr. Smith. The MM creates a purchase order (PO) using the medical center’s enterprise revenue program (ERP). The ERP system interfaces with the medical centers ORs materials (inventory) management information system (ORMMIS) for development of the ORs item master. The ORMMIS doesn’t exchange data within the medical center’s EHRs to capture specialty medical supplies and implantable medical devices used for patient care. If the UDI data was exchanged, the circulator nurse could then validate she has the correct implant for the patient by scanning and validating the barcode that came for the ORMMIS to the one she scanned on the package(s) - similar to identifying correct meds being administered.

Mr. Smith has his scheduled procedure and has XYZ implantable medical device implanted. The OR circulating nurse, using the medical centers’ EHR, manually documents the XYZ UDI barcode numbers on the packing because the scanner will not scan the barcodes on the medical device packaging used for Mr. Smith’s right total knee replacement procedure. Dr. Denver is part of a national orthopedic registry that is collecting data on total knee procedures. The Quality Department is given a list of all orthopedic procedures that Dr. Denver performed during the week and they begin to review each patient’s medical record for data elements that should be sent to the national registry.

Tracking Implantable Devices

* SSgt. Sam Share, a **veteran**, receives a **consult** from Dr. Lister at a VA facility to treat his combat-related **condition**. It requires an implantable device to improve Sam’s health status.
* Dr. Lister, **VA physician**, prescribes an **implantable device or tissue** based on device type and other criteria (e.g. clinical size) and **orders** the **device** (based on device identifier (DI portion of UDI) the **procedure** (HCPCS)
  + The VA physician Looks up a suitable device using **prosthetic** list based on the FDA Global Unique Device Identifier Database (GUDID) or uses the pre-loaded “gold” Master Device Identifier file which is a local subset of device identifier records including SNOME CT device taxonomy codes. This local list allows enterprise application to look up devices based on: type, model, version, vendor, clinical size
* Ms. Martin, a **VA clerk** reviews the order before forwarding the information from the VA-approved distributor and obtains the device required for SSgt. Sam. Once the implantable medical device arrives at the medical center, its id is scanned and cross-referenced with the GUDID to ensure device legitimacy and recalls.
* A **procedure** is **scheduled** for SSgt. Sam, the device is implanted by Dr. Wilson and the UDI is scanned by the designated nurse into VistA. The UDI is associated with the patient and available to community providers in the “Patient Device List” of a CCD. If a recall is initiated, the manufacturer notifies VA to inform Sam and other patients using the same type of device in the affected production.

Vital Signs Monitoring and Charting

* SSgt. Sam Share (ret.) is admitted at the VA medical center and requires **continuous monitoring** of vital signs including oximetry. Dr. Lister orders monitoring for the next **24 hours**.
* Nurse Nightingale starts the monitoring session by **assigning** a standard-based vital sign monitor to Sam by **scanning the device label** and Sam’s **wrist band** (UDIßàPID) and her badge (PIDßàEID). She uses the vendor-provided medical device manager or a VA-provided device gateway to record the devices associated with this procedure and patient.
* Once the patient-to-device association is completed any measurements, status information, reference ranges, etc. acquired by the device is exchanged with the flowchart system that persists the measurement in the VistA database using a common device integration adapter. **LOINC, SNOMED, UCUM** used to convey the measurements.
* Throughout the monitoring session, Ms. Nightingale validates the data entered by the integrated device into VistA. The validated results become part of Sam’s legal health record
* The CCD includes relevant/pertinent vital signs along with other treatment information

Cardiology - Implanted Stent

SSgt. Sam was having some chest pain so he goes to see his primary care physician who orders some diagnostic tests and refers him to Dr. Heart, a cardiologist. Dr. Heart sees SSgt. Sam and determines he has a blocked cardiac artery and needs a cardiac stent inserted. Dr. Heart orders the cardiac stent procedure with the Cardiac Catheterization Laboratory. On the request Dr. Heart has identified which implantable cardiac stent he would like to implant into SSgt. Sam. Prior to the procedure, the requested cardiac stent’s UDI is verified with the FDA’s GUDID to ensure there has not been a recall or any other adverse events. During the stent placement procedure Dr. Heart determines a different cardiac stent is needed for SSgt. Sam. The cardiac nurse obtains the requested implantable medical devices, scans it for verification against the FDA GUDID, and the stent is inserted without complications. The **scanned** UDI data from the cardiac stent’s label **is transmitted automatically to** SSgt. Sam medical record. SSgt. Sam is transferred to the Cardiac Care Unit for post-procedure care.

Cardiology - Pacemaker

SSgt. Sam was having some chest pain so he goes to see his primary care physician who orders some diagnostic tests and refers him to Dr. Heart, a cardiologist. Dr. Heart sees SSgt. Sam and determines he needs a cardiac pacemaker inserted. Dr. Heart orders an insertion of pacemaker (ICD10 code - 0JH605Z) with the Cardiac Catheterization Laboratory (or this can be in the OR – it depends on the HCO where these are performed). On the request Dr. Heart identifies which pacemaker and leads he would like to implant into SSgt. Sam. Prior to the procedure, the pacemaker and leads UDI are verified with the FDA GUDID to ensure there has not been a recall or any other adverse events for the requested implantable medical devices. During the pacemaker insertion procedure, Dr. Heart drops a lead. The cardiac nurse obtains another lead, scans it to verify it against the GUDID, aseptically gives it to Dr. Heart and the pacemaker and lead are inserted without complications. The cardiac nurse ensures the UDI data on each implantable medical device label inserted into SSgt. Sam **is automatically transmitted** to in his medical **record using a point-of-care system to avoid data entry errors**. Prior to being transferred to the Cardiac Intensive Care Unit for post-procedure care, SSgt Sam has an external pacemaker medical device attached to him per the cardiac surgery protocol.

###### 1.4.2.3 PDMT Use Cases

The following sequence diagrams illustrate the system interactions including the related PCD transactions that are needed to support:

* **Tracking passive devices** - those devices that are tracked (e.g. but they are not able of sending information. This also includes procedure information.

See [Use Case #1: Track devices and procedures at the point of care](#BKM_B55D6394_E6F2_4FA6_A792_B910EC0E3C52)

* **Tracking active device** - those devices that have a UDI and are capable of sending information (e.g. vital signs monitors, pulse oximeters, etc.) . This also includes procedure information.

See [Use Case #1: Track devices and procedures at the point of care](#BKM_B55D6394_E6F2_4FA6_A792_B910EC0E3C52)

* **Searching/querying device information -** a system that requires information about a device, a list of devices associated with a patient, the patient who received a specific device, a procedure involving device identified by its UDI, etc.

See [Use Case #2 Query Device and Procedure Data](#BKM_5049E933_25F7_411F_AA64_4017F5C83EF7)

These generic use cases apply to any type of device and provide a consistent way to exchange information from the point-of-care (e.g. OR, ICU, Cardiology office, Medical Surgical, Respiratory Therapy).



Figure 4: 1.4.2.3 PDMT Use Cases

*User*

*Use Case #1: Track devices and procedures at the point of care*

**Pre-conditions:** Patient identity (e.g. Medical Record Number - MRN) , device identifier (UDI) as scanned at the point-of-care in preparation for a procedure. The Patient registry may be queried based on the patient identifier scanned at the point-of-care.

**Flow of events:**

The system at the point of care that implement the Device Data Reporter actor registers the device. The Device Server returns success indicating that a new Device record was created. If the device is implantable, the Device record will reference the Patient resource identified by the MRN scanned at the point of care.

The user of system that implements the Device Data Reporter allows the clinicians to record a Procedure at the point-of-care indicating the start and end of a procedure. This procedure may represent the context for the device record.

The following diagram details this workflow for monitoring or implantable devices. The main distinction is that the implantable device procedure may be recorded as "completed" while a monitoring session may start and end:

* [1.4.2.3 PDMT Use Cases : Implantable Device Registration - Actors Only](#BKM_B93BFDE8_E140_4503_9176_BE0B9BC78776)
* [1.4.2.3 PDMT Use Cases : Point-of-Care Monitoring - Actors Only](#BKM_2CB1F36B_9FEC_4BB7_B7A9_0AD41D4E1B4F)

**Post-conditions:**

The system that implement the Device Manager actor has persisted the device and procedure information and associated the medical devices the patients and procedures in which they were applied to patient care.

*Use Case #2 Query Device and Procedure Data*

**Post-conditions:**

The system that implement the Device Manager actor has persisted the device and procedure information and associated the medical devices the patients and procedures in which they were applied to patient care.

The Patient resource may be required to lookup the patient identifier.

**Flow of events:**

The system that implements the Device Data Requester will invoke a "search" operation on either the Device or Procedure to support a recall notice (based on UDI information provided by manufacturer) or to compile a patient device list to support continuity of care.

The Device Manager returns the resources matching the search criteria to the Requester.

**Post-condition:**

The Requester may further filter the data based on additional criteria (e.g. procedure "reason" condition) before displaying the information to the end user.

Workflow Diagrams

The following diagram describes the interactions required to support patient-to-device association for vital signs monitoring using information acquired at the point-of-care focusing strictly on the actor defined in this profile (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 5: Point-of-Care Monitoring - Actors Only

The following diagram describes the interactions required to support device tracking and registration based on information recorded at the point-of-care. This diagram ignores the business triggers and focuses exclusively on the actors defined in this profile (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 6: Implantable Device Registration - Actors Only

The following diagram describes the interactions required to support the use Device and Procedure resources recorded at the point-of-care. This diagram focuses on the actors involved (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 7: Search Devices and Procedures from Device Registry - Actors Only

optional

#### 1.5 Security Consideration

In many other uses of the HTTP/REST pattern, applications are accessing far less sensitive information than patient identifiers and protected health information. When the mobile environment comes into use, the challenges of security and privacy controls are unique, simply because the devices are harder to physically control. The PMDT Profile provides access to the patient identifiers and other protected health information managed in healthcare. These factors present a unique and difficult challenge for the security model. It is recommended that application developers utilize a Risk Assessment in the design of the applications, and that the operational environment utilize a Risk Assessment in the design and deployment of the operational environment.

There are many reasonable methods of security for interoperability transactions, which can be implemented without modifying the characteristics of the PMDT Profile transactions. The use of TLS is encouraged, as is the use of the ATNA Profile (see ITI TF-1:9).

User authentication on mobile devices and browsers is typically handled by more lightweight authentication schemes such as HTTP Authentication, OAuth2, or OpenID Connect. IHE has a set of profiles for user authentication including: Enterprise User Authentication (EUA) on devices using HTTP and Internet User Authorization (IUA) for REST-based authentication. In all of these cases, the network communication security, and user authentication are layered in the HTTP transport layer and do not modify the interoperability characteristics defined in the DCP Profile. The use of strong trust keys is encouraged.

The Resource URL pattern defined in this profile means many requests may include Patient ID, names, or other demographic data as parameters for query. The advantage of this pattern is ease of implementation and clear distinction of a patient’s identity. The URL pattern does present a risk when using typical web server audit logging of URL requests and browser history. In both of these cases the URL with the Patient ID or Name query parameters is clearly visible.

##### *1.5.1 Medical Device Security*

The attack model outlined in the "Security and Interoperable Medical Device Systems" paper (authored by Krishna K. Venkatasubramanian, Eugene Y. Vasserman, Oleg Sokolsky, and Insup Lee) is very sobering but not insurmountable in any way. Reprogramming and Denial of Service are disturbing if we are talking about an implantable or therapeutic device (FDA Class III - high risk for adverse events ) but such attacks could be a addressed by a robust authorization framework that extends to device users and software components that control devices in any way:

**Disturb**

These attacks modify the data available to some or all of the entities in the environment to prevent them from operating correctly. Examples include replay and man- in-the-middle attacks.

**Reprogram**

A special subset of disturb attacks, these attacks modify data or code in a medical device, the coordinator, or the alarm system such that I doesn’t perform its designated operation. For example, an attacker could modify an infusion pump’s software to deliver extra medication [or increase the rate of an IV medication to dangerous levels to patient respiration]. Reprogramming can be done locally or remotely if a device provides over- the-network programmability.

**Denial of Service**

These attacks target the network but also affect the devices, coordinator, or alarm system to prevent effective interoperation. For example, an attacker could burn out an infusion pump’s motors through overuse, pre- venting the device from performing the required therapeutic functions.[this could also disable one or more device components]

**Eavesdrop**

These attacks involve listening in on the IMD environment’s network to learn sensitive health information. Because these attacks (unlike the previous ones) don’t disrupt system operation, detecting them is difficult.

There’s nothing fundamentally new about the attack vectors we presented. However, their use in the context of the coordinating devices and middleware can cause a variety of failures, many of which can’t be easily detected because they’re silent. In part 2, we’ll build on this attack model and demonstrate how adversaries can cause various types of failures in IMD environments, and these failures’ security consequences. We’ll also introduce the concept of device criticality as a way to assess attacks’ potential damage. Finally, we’ll conclude with the lessons learned from performing this attack analysis.

For additional details refer to:

Security and Interoperable Medical Device Systems by Krishna K. Venkatasubramanian, Eugene Y. Vasserman, Oleg Sokolsky, and Insup Lee

Part 1: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797602/

Part 2:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797599/

#### 1.6 Cross Profile Considerations

This profile is related to existing technical frameworks (IHE ITI, IHE PCD) and the items discussed and documented as [Relationship to IHE Patient Care Devices (PCD) Technical Framework](#BKM_BCF0DAE0_ED18_427E_ABC7_C810C1B70F4B).

##### *IHE PCD DEC*

IHE PCD De Device Observation Reporter and Device Observation

This specification is localized for use in the US, therefore the device unique identifier used in the PCD-01 transactions and any terminology requirements will be adapted to apply in the context of US enterprises that employ Meaningful Use certified EHR system.

## Volume 2 - Transactions

### 2.1 Register Device

#### 2.1.1 Scope

This transaction is intended to record information about a device identity (e.g. UDI) and associated it with a patient from data acquired directly at the point-of-care and report it enterprise systems. This transaction relies on patient and device identity information scanned/entered at the point-of-care by the front-line clinicians.

#### 2.1.2 Actor Roles

The following diagram identifies the transaction/use case and actors participating in this transaction.



Figure 8: 2.1.2 Use Case Diagram

###### Actor Roles

|  | **Notes** |
| --- | --- |
| **Initiating Actor:** Medical Device Reporter  Public | Initiates the device registration |
| **Responding Actor:** Medical Device Server  Public | This actor receive, validates the information, and stores the information if it's valid; otherwise the registration is rejected. |

#### 2.1.3 Referenced Standards

HL7 FHIR STU3 Device and Patient resources.

#### 2.1.4 Interaction Diagram

The following is detailed description of the actors and transactions initiated:

This transaction creates a new data set (e.g. FHIR resource) using a synchronous call (e.g. RESTful service).



Figure 9: 2.1.4 Interaction Diagram

##### *2.1.4.1 Register Device*

The following sections describe the details of this transaction:

###### 2.1.4.1.1 Trigger Events

This transaction is triggered by clinician at the point-of-care based on device identify and patient identity acquired using a barcode or refid scanner. The information is entered in the medical device manager at the point-of-care.

The business trigger could be a perioperative, postoperative, the start of a patient monitoring procedure when a patient is associated with a device.

###### 2.1.4.1.2 Message Semantics

The messages semantics for this transaction rely on STU3 Device and may include a Patient resource to specify the identity of the patient recorded at the point-of-care.

Device

The following data elements are specified for this transaction to register a device by creating a new FHIR Device resource. The following section describes the structure and built-in value sets used to describe a device record using FHIR STU3.

Device

This resource identifies an instance or a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device. Medical devices includes durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cellphone, computer, application, etc.

|  | **Notes** |
| --- | --- |
| **identifier** Identifier  Public    [0..1] | Unique instance identifiers assigned to a device by manufacturers other organizations or owners. This element may be used to specify the serial number of a device if it supported by the PI component of the UDI. |
| **udi** Device.Udi  Public | [Unique device identifier (UDI)](device.html#5.11.3.2.2) assigned to device label or package.  For the purposes of this profile, the components of the UDI below would be specified.   * the lot or batch number within which a device was manufactured; * the serial number of a specific device; * the expiration date of a specific device; * the date a specific device was manufactured;   the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. ([FDA UDI Basics](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm)) |
| **status** FHIRDeviceStatus  Public | Status of the Device availability. The default value is "active". |
| **type** CodeableConcept  Public    [0] | Code or identifier to identify a kind of device. For this profile, implementers will use Device.udi.deviceIdentifier. |
| **lotNumber** string  Public    [0..1] | Lot number assigned by the manufacturer. This data element should be parsed from the UDI, if supported. |
| **manufacturer** string  Public    [0] | A name of the manufacturer. |
| **manufactureDate** dateTime  Public    [0..1] | The date and time when the device was manufactured. This data element should be parsed from the UDI, if supported. |
| **expirationDate** dateTime  Public    [0..1] | The date and time beyond which this device is no longer valid or should not be used (if applicable). This data element should be parsed from the UDI, if supported. |
| **model** string  Public    [0] | The "model" is an identifier assigned by the manufacturer to identify the product by its type. This number is shared by the all devices sold as the same type. |
| **version** string  Public    [0] | The version of the device, if the device has multiple releases under the same model, or if the device is software or carries firmware. |
| **patient** Reference  Public    [0..1] | Patient information, If the device is affixed to a person. |
| **owner** Reference  Public    [0..1] | An organization that is responsible for the provision and ongoing maintenance of the device. |
| **contact** ContactPoint  Public    [0..\*] | Contact details for an organization or a particular human that is responsible for the device. |
| **location** Reference  Public    [0..1] | The place where the device can be found. |
| **url** uri  Public    [0] | A network address on which the device may be contacted directly. |
| **note** Annotation  Public    [0..\*] | Descriptive information, usage information or implantation information that is not captured in an existing element. |
| **safety** CodeableConcept  Public    [0] | Provides additional safety characteristics about a medical device. For example devices containing latex. This is not relevant for this profile, Implementers are advised to refer to the GUDID (Global UDI Database) and use the Device Identifier to lookup other metadata about the device. |

Device.Udi

This resource identifies an instance or a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device. Medical devices includes durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cellphone, computer, application, etc.

|  | **Notes** |
| --- | --- |
| **deviceIdentifier** string  Public    [0..1] | The device identifier (DI) is a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device. |
| **name** string  Public    [0..1] | Name of device as used in labeling or catalog. |
| **jurisdiction** uri  Public    [0..1] | The identity of the authoritative source for UDI generation within a jurisdiction. All UDIs are globally unique within a single namespace. with the appropriate repository uri as the system. For example, UDIs of devices managed in the U.S. by the FDA, the value is http://hl7.org/fhir/NamingSystem/fda-udi. |
| **carrierHRF** string  Public    [0..1] | The full UDI carrier as the human readable form (HRF) representation of the barcode string as printed on the packaging of the device. This version of UDI is not expected for this profile |
| **carrierAIDC** base64Binary  Public | The full UDI carrier of the Automatic Identification and Data Capture (AIDC) technology representation of the barcode string as printed on the packaging of the device - E.g a barcode or RFID. Because of limitations on character sets in XML and the need to round-trip JSON data through XML, AIDC Formats \*SHALL\* be base64 encoded. |
| **issuer** uri  Public | Organization that is charged with issuing UDIs for devices. For example, the US FDA issuers include :  1) GS1:  http://hl7.org/fhir/NamingSystem/gs1-di,  2) HIBCC:  http://hl7.org/fhir/NamingSystem/hibcc-dI,  3) ICCBBA for blood containers:  http://hl7.org/fhir/NamingSystem/iccbba-blood-di,  4) ICCBA for other devices:  http://hl7.org/fhir/NamingSystem/iccbba-other-di. |
| **entryType** UDIEntryType  Public | A coded entry to indicate how the data was entered. |

FHIRDeviceStatus

The availability status of the device.

|  | **Notes** |
| --- | --- |
| **value** FHIRDeviceStatus-list  Public |  |

UDIEntryType

Codes to identify how UDI data was entered

|  | **Notes** |
| --- | --- |
| **value** UDIEntryType-list  Public |  |

FHIRDeviceStatus-list

Values allowed for Device.status:

|  | **Notes** |
| --- | --- |
| **active** code-primitive  Public | Active is the default state. |
| **inactive** code-primitive  Public | Inactive |
| **entered-in-error** code-primitive  Public | Entered in Error |
| **unknown** code-primitive  Public | Unknown |

UDIEntryType-list

Device.udi.entryType values:

|  | **Notes** |
| --- | --- |
| **barcode** code-primitive  Public | BarCode |
| **rfid** code-primitive  Public | RFID |
| **manual** code-primitive  Public | Manual |
| **card** code-primitive  Public | Card |
| **self-reported** code-primitive  Public | Self Reported |
| **unknown** code-primitive  Public | Unknown |

Patient

The following are data structures required to add the patient identity as a contained resource to a Device resource:

Patient

The Patient resource is used to record the patient identity acquired at the point-of-care.

|  | **Notes** |
| --- | --- |
| **identifier** Identifier  Public    [0..\*] | An identifier for this patient. For this profile the identifier may be medical record number recorded on the patient's wristband. The server is expected to match the identifier against known Patient records and validate that the information supplied from the point-of-care against the enterprise patient registry information before accepting the Device record. If the patient identifying traits do not match, the transaction is supposed to fail |
| **active** boolean  Public    [0..1] | Whether this patient record is in active use. |
| **name** HumanName  Public    [0..\*] | A name associated with the individual. |
| **telecom** ContactPoint  Public    [0] | A contact detail (e.g. a telephone number or an email address) by which the individual may be contacted. |
| **gender** AdministrativeGender  Public | Administrative Gender - the gender that the patient is considered to have for administration and record keeping purposes. |
| **birthDate** date  Public | The date of birth for the individual. This information is verified at the point-of-care and it is also recorded on patient's identity wristbands. |
| **deceased[x]** deceasedChoice  Public    [0..1] | Indicates if the individual is deceased or not. If missing, the default is "false". |
| **address** Address  Public    [0] | Addresses for the individual. |
| **maritalStatus** CodeableConcept  Public    [0] | This field contains a patient's most recent marital (civil) status. |
| **multipleBirth[x]** mulitpleBirthChoice  Public    [0..1] | Whether patient is part of a multiple birth. If missing, the default is "false". |
| **photo** Attachment  Public    [0..\*] | Image of the patient. A photograph may be recorded at the point-of-care. |
| **contact** Patient.Contact  Public    [0] | A contact party (e.g. guardian, partner, friend) for the patient. |
| **animal** Patient.Animal  Public    [0..1] | This patient is known to be an animal. |
| **communication** Patient.Communication  Public    [0..\*] | Languages which may be used to communicate with the patient about his or her health. |
| **generalPractitioner** Reference  Public    [0] | Patient's nominated care provider. |
| **managingOrganization** Reference  Public | Organization that is the custodian of the patient record. |
| **link** Patient.Link  Public    [0..\*] | Link to another patient resource that concerns the same actual patient. |

Patient.Animal

Demographics and other administrative information about an individual or animal receiving care or other health-related services. This information is applicable only if the Patient.animal data element is used.

|  | **Notes** |
| --- | --- |
| **species** CodeableConcept  Public | Identifies the high level taxonomic categorization of the kind of animal. |
| **breed** CodeableConcept  Public    [0..1] | Identifies the detailed categorization of the kind of animal. |
| **genderStatus** CodeableConcept  Public    [0..1] | Indicates the current state of the animal's reproductive organs. |

Patient.Communication

Demographics and other administrative information about an individual or animal receiving care or other health-related services. This element is not used by this profile.

|  | **Notes** |
| --- | --- |
| **language** CodeableConcept  Public | The ISO-639-1 alpha 2 code in lower case for the language, optionally followed by a hyphen and the ISO-3166-1 alpha 2 code for the region in upper case; e.g. "en" for English, or "en-US" for American English versus "en-EN" for England English. |
| **preferred** boolean  Public    [0..1] | Indicates whether or not the patient prefers this language (over other languages he masters up a certain level). |

Patient.Contact

Demographics and other administrative information about an individual or animal receiving care or other health-related services. This element is not used by this profile.

|  | **Notes** |
| --- | --- |
| **relationship** CodeableConcept  Public    [0..\*] | The nature of the relationship between the patient and the contact person. |
| **name** HumanName  Public    [0..1] | A name associated with the contact person. |
| **telecom** ContactPoint  Public    [0..\*] | A contact detail for the person, e.g. a telephone number or an email address. |
| **address** Address  Public    [0..1] | Address for the contact person. |
| **gender** AdministrativeGender  Public    [0..1] | Administrative Gender - the gender that the contact person is considered to have for administration and record keeping purposes. |
| **organization** Reference  Public    [0..1] | Organization on behalf of which the contact is acting or for which the contact is working. |
| **period** Period  Public    [0..1] | The period during which this contact person or organization is valid to be contacted relating to this patient. |

Patient.Link

Demographics and other administrative information about an individual or animal receiving care or other health-related services. This element is not required by this profile.

|  | **Notes** |
| --- | --- |
| **other** Reference  Public | The other patient resource that the link refers to. |
| **type** LinkType  Public | The type of link between this patient resource and another patient resource. |

LinkType

The type of link between this patient resource and another patient resource. This element is not constrained by this profile.

|  | **Notes** |
| --- | --- |
| **value** LinkType-list  Public |  |

deceasedChoice

Indicates if the individual is deceased or not. This choice element is not constrained by this profile.

|  | **Notes** |
| --- | --- |
| **deceasedBoolean** boolean  Public |  |
| **deceasedDateTime** dateTime  Public |  |

mulitpleBirthChoice

Indicates whether the patient is part of a multiple (bool) or indicates the actual birth order (integer). This choice element is not constrained by this profile.

|  | **Notes** |
| --- | --- |
| **multipleBirthBoolean** boolean  Public |  |
| **multipleBirthInteger** integer  Public |  |

LinkType-list

This enumeration represents the patient link types supported by the FHIR Patient resource.

|  | **Notes** |
| --- | --- |
| **replaced-by** code-primitive  Public | Replaced-by |
| **replaces** code-primitive  Public | Replaces |
| **refer** code-primitive  Public | Refer |
| **seealso** code-primitive  Public | See also |

###### 2.1.4.1.3 Expected Actions

The responding actor is intended to validate the information about the device and the referenced patient identity before storing the new device record and associating it to a known patient.

#### 2.1.5 Security Considerations

This transaction could be subject to "Eavesdrop" attacks as outlined in Volume 1 (see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E) ).

##### *2.1.5.1 Security Audit Considerations*

None, these transactions do not need to be audited as they are explicitly persisted by the server.

### 2.2 Search Devices

#### 2.2.1 Scope

Transaction is intended to provide a synchronous query mechanism

#### 2.1.2 Actor Roles

The following diagram identifies the transaction/use case and actors participating in this transaction.



Figure 10: 2.1.2 Actor Roles

###### Actor Roles

|  | **Notes** |
| --- | --- |
| **Initiating Actor:** Medical Device Requester  Public | This actor requests device records matching a specific set of criteria (i.e. search parameters). |
| **Responding Actor:** Medical Device Server  Public | This actor receives the request, processes the search parameters and returns matching device records to the initiating actor. |

#### 2.2.3 Referenced Standards

HL7 FHIR STU3 Device and Patient resources.

#### 2.2.4 Interaction Diagram

The following is detailed description of the actors and transactions initiated:



Figure 11: 2.2.4 Interaction Diagram

##### *2.2.4.1 Search Devices*

The following sections describe the details of this transaction:

###### 2.2.4.1.1 Trigger Events

This transaction can be invoke on-demand based on a user action, recall notice, or another type business trigger that requires specific medical device records.

###### 2.2.4.1.2 Message Semantics

The semantics of a search/query focuses on the use of search criteria (i.e. search parameters) described below:

*Device Search Parameters*

The following search parameters could be send by the initiating actor to the sever. The server will return zero or more matching Device resources (in a bundle).

|  | **Notes** |
| --- | --- |
| **device-name** string  Public | It matches Device.udi.name or Device.type.coding.display or Device.type.text.  (Device.udi.name | Device.type.text | Device.type.coding.display) |
| **identifier** token  Public | Instance id from manufacturer, owner, and others - it may be used to represent the serial number of a device (Device.identifier). |
| **location** reference  Public | A location, where the device is found (Device.location) . |
| **manufacturer** string  Public | The manufacturer of the device (Device.manufacturer). |
| **model** string  Public | The model of the device (Device.model). |
| **organizatoin** reference  Public | The organization responsible for the device.(Device.owner - Organization). |
| **patient** reference  Public | Patient information, if the resource is affixed to a person (Device.patient - Patient). |
| **status** token  Public | It matches the Device.status from (active | inactive | entered-in-error | unknown). |
| **type** token  Public | The type of the device - it matches Device.type. |
| **udi-carrier** string  Public | It matches either Device.udi.carrierHRF or Device.udi.carrierAIDC  - UDI Barcode (RFID or other technology) string either in HRF format or AIDC format converted to base64 string. |
| **udi-di** string  Public | The udi Device Identifier (DI) matches the Device.udi.deviceIdentifier data element. |
| **url** int  Public | Network address to contact device; it matches Device.url. |

###### 2.2.4.1.3 Expected Actions

The server attempts to match the search criteria with the (similar to the SQL WHERE clause) to return a bundle of matching resources. If the criteria don't match any resources or they match all the resources, the server will return an empty set. If the parameters are invalid (e.g. an. incorrectly formatted URL) the query may fail.

#### 2.2.5 Security Considerations

This transaction could be subject to "Eavesdrop" attacks as outlined in Volume 1 (see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E) ).

##### *2.1.5.1 Security Audit Considerations*

In some cases, if the Consumer actor is not in the same domain or covered entity, the Server should persist an audit event for the search request.

### 2.3 Start Point-of-care Device Procedure

#### 2.4.1 Scope

This transaction is intended to record information about the start of a new device-related procedure. This transaction relies on patient and device identity information scanned/entered at the point-of-care by the front-line clinicians. It also allows clinicians to record information about the type of procedure in which the device was use or implanted.

#### 2.4.2 Actor Roles

The following diagram identifies the transaction/use case and actors participating in this transaction.



Figure 12: 2.4.2 Actor Roles

###### Actor Roles

|  | **Notes** |
| --- | --- |
| **Initiating Actor:** Medical Device Reporter  Public | This actor initiates the transaction to create a new procedure record. |
| **Responding Actor:** Medical Device Server  Public | This actor responds to the request, validates its contents, and persists the procedure information, if valid. |

#### 2.4.3 Referenced Standards

HL7 STU3 Procedure, SNOMED CT, ICD-10, CPT-4

#### 2.4.4 Interaction Diagram

The following is detailed description of the actors and transactions initiated:



Figure 13: 2.4.4 Interaction Diagram

##### *2.4.4.1 Start Point-of-care Device Procedure*

###### 2.4.4.1.1 Trigger Events

This transaction is initiated when a device is associated with a patient at the point-of-care part of a surgical, monitoring, or diagnostic procedure.

###### 2.4.4.1.2 Message Semantics

The following section specifies the data required to specify a new pont-of-care procedure using a FHIR Procedure:

Procedure

The following describe how the FHIR Procedure resource is used to specify that a new "in-progress" point-of-care procedure.

Start Device Monitoring Procedure

This profile shows how a FHIR Procedure resource can be used to record a monitoring procedure that was initiated by a clinician at the point-of-care.

|  | **Notes** |
| --- | --- |
| **identifier** Identifier  Public    [0..\*] | This records identifiers associated with this procedure that are defined by business processes and/or used to refer to it when a direct URL reference to the resource itself is not appropriate (e.g. in CDA documents, or in written / printed documentation). |
| **definition** Reference  Public    [0] | A protocol, guideline, orderset or other definition that was adhered to in whole or in part by this procedure. |
| **basedOn** Reference  Public    [0] | A reference to a resource that contains details of the request for this procedure. |
| **partOf** Reference  Public    [0] | A larger event of which this particular procedure is a component or step. |
| **status** EventStatus  Public | A code specifying the state of the procedure. The status is set to "in-progress" by this transaction. |
| **notDone** boolean  Public    [0..1] | Set this to true if the record is saying that the procedure was NOT performed. |
| **notDoneReason** CodeableConcept  Public    [0] | A code indicating why the procedure was not performed. |
| **category** CodeableConcept  Public    [0..1] | A code that classifies the procedure for searching, sorting and display purposes (e.g. "Surgical Procedure"). |
| **code** CodeableConcept  Public | The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy"). |
| **subject** Reference  Public | The person, animal or group on which the procedure was performed. |
| **context** Reference  Public    [0..1] | The encounter during which the procedure was performed. |
| **performedPeriod** Period  Public | The period the procedure was performed. In this transaction the "start" is set to the date/time the monitoring procedure was initiated. |
| **performer** Procedure.Performer  Public    [0..\*] | Limited to 'real' people rather than equipment. |
| **location** Reference  Public    [0..1] | The location where the procedure actually happened. E.g. a newborn at home, a tracheostomy at a restaurant. |
| **reasonCode** CodeableConcept  Public    [0..\*] | The coded reason/diagnosis why the procedure was performed. This may be coded entity of some type, or may simply be present as text. Th |
| **reasonReference** Reference  Public    [0..\*] | The condition that is the reason why the procedure was performed. |
| **bodySite** CodeableConcept  Public    [0..\*] | Detailed and structured anatomical location information. Multiple locations are allowed - e.g. multiple punch biopsies of a lesion. |
| **outcome** CodeableConcept  Public    [0] | The outcome of the procedure - did it resolve reasons for the procedure being performed? |
| **report** Reference  Public    [0] | This could be a histology result, pathology report, surgical report, etc.. |
| **complication** CodeableConcept  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. These are generally tracked separately from the notes, which will typically describe the procedure itself rather than any 'post procedure' issues. |
| **complicationDetail** Reference  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. |
| **followUp** CodeableConcept  Public    [0] | If the procedure required specific follow up - e.g. removal of sutures. The followup may be represented as a simple note, or could potentially be more complex in which case the CarePlan resource can be used. |
| **note** Annotation  Public    [0] | Any other notes about the procedure. E.g. the operative notes. |
| **focalDevice** Procedure.FocalDevice  Public    [1..\*] | A device that is implanted, removed or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure. |
| **usedReference** Reference  Public    [0..\*] | Identifies medications, devices and any other substance used as part of the procedure. |
| **usedCode** CodeableConcept  Public    [0..\*] | Identifies coded items that were used as part of the procedure. |

Procedure.FocalDevice

An action that is or was performed on a patient. This can be a physical intervention like an operation, or less invasive like counseling or hypnotherapy.

|  | **Notes** |
| --- | --- |
| **action** CodeableConcept  Public    [0..1] | The kind of change that happened to the device during the procedure. |
| **manipulated** Reference  Public | The device that was manipulated (changed) during the procedure. This is a reference to a registered device (i.e. a Device resource) that was created using [2.1 Register Device](#BKM_C3BE5CEB_F63C_4277_9D6E_D0FC021F8584) transaction. |

Procedure.Performer

An action that is or was performed on a patient. This can be a physical intervention like an operation, or less invasive like counseling or hypnotherapy.

|  | **Notes** |
| --- | --- |
| **role** CodeableConcept  Public    [0..1] | For example: surgeon, anaethetist, endoscopist. |
| **actor** Reference  Public | The practitioner who was involved in the procedure. |
| **onBehalfOf** Reference  Public    [0..1] | The organization the device or practitioner was acting on behalf of. |

###### 2.4.4.1.3 Expected Actions

#### 2.4.5 Security Considerations

This transaction could be subject to "Eavesdrop" attacks as outlined in Volume 1 (see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E) ). This transaction creates a new data set (e.g. FHIR resource) using a synchronous call (e.g. RESTful service).

##### *2.4.5.1 Security Audit Considerations*

None, these transactions do not need to be audited as they are explicitly persisted by the server.

### 2.4 Complete Point-of-care Device Procedure

#### 2.4.1 Scope

#### 2.4.2 Actor Roles



Figure 14: 2.4.2 Actor Roles

###### Actor Roles

|  | **Notes** |
| --- | --- |
| **Initiating Actor:** Medical Device Reporter  Public | This actor initiates the transaction to create a create/update a procedure end/completion record. |
| **Responding Actor:** Medical Device Server  Public | This actor responds to the request, validates its contents, and persists the procedure information, if valid. If the procedure does not exist, a new record is added. Otherwise the procedure record is updated. |

#### 2.4.3 Referenced Standards

HL7 STU3 Procedure, SNOMED CT, ICD-10, CPT-4

#### 2.4.4 Interaction Diagram

The following is detailed description of the actors and transactions initiated:

##### *2.4.4.1 Complete Point-of-care Device Procedure*

###### 2.4.4.1.1 Trigger Events

This transaction is triggered by the end of surgical, monitoring, or diagnostic procedure involving one or more medical devices.

###### 2.4.4.1.2 Message Semantics

The following section specifies the data required to specify the completion of pont-of-care procedure using a FHIR Procedure:

Procedure

The following describe how the FHIR Procedure resource is used to specify that a point-of-care procedure was completed.

Complete Device Monitoring Procedure

This profile shows how a FHIR Procedure resource can be used to record a monitoring procedure that was completed by a clinician at the point-of-care.

|  | **Notes** |
| --- | --- |
| **identifier** Identifier  Public    [0..\*] | This records identifiers associated with this procedure that are defined by business processes and/or used to refer to it when a direct URL reference to the resource itself is not appropriate (e.g. in CDA documents, or in written / printed documentation). |
| **definition** Reference  Public    [0] | A protocol, guideline, orderset or other definition that was adhered to in whole or in part by this procedure. |
| **basedOn** Reference  Public    [0] | A reference to a resource that contains details of the request for this procedure. |
| **partOf** Reference  Public    [0] | A larger event of which this particular procedure is a component or step. |
| **status** EventStatus  Public | A code specifying the state of the procedure. The status is updated to "completed" by this transaction. |
| **notDone** boolean  Public    [0..1] | Set this to true if the record is saying that the procedure was NOT performed. |
| **notDoneReason** CodeableConcept  Public    [0] | A code indicating why the procedure was not performed. |
| **category** CodeableConcept  Public    [0..1] | A code that classifies the procedure for searching, sorting and display purposes (e.g. "Surgical Procedure"). |
| **code** CodeableConcept  Public | The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy"). |
| **subject** Reference  Public | The person, animal or group on which the procedure was performed. |
| **context** Reference  Public    [0..1] | The encounter during which the procedure was performed. |
| **performedPeriod** Period  Public | The period the procedure was performed. In this transaction the "end" date/time is set to the date/time the monitoring procedure was initiated.  Allows a period to support complex procedures that span more than one date, and also allows for the length of the procedure to be captured. For this profile, this data element specifies when a device-related procedure started and ended. |
| **performer** Procedure.Performer  Public    [0..\*] | Limited to 'real' people rather than equipment. |
| **location** Reference  Public    [0..1] | The location where the procedure actually happened. E.g. a newborn at home, a tracheostomy at a restaurant. |
| **reasonCode** CodeableConcept  Public    [0..\*] | The coded reason/diagnosis why the procedure was performed. This may be coded entity of some type, or may simply be present as text. Th |
| **reasonReference** Reference  Public    [0..\*] | The condition that is the reason why the procedure was performed. |
| **bodySite** CodeableConcept  Public    [0..\*] | Detailed and structured anatomical location information. Multiple locations are allowed - e.g. multiple punch biopsies of a lesion. |
| **outcome** CodeableConcept  Public    [0] | The outcome of the procedure - did it resolve reasons for the procedure being performed? |
| **report** Reference  Public    [0] | This could be a histology result, pathology report, surgical report, etc.. |
| **complication** CodeableConcept  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. These are generally tracked separately from the notes, which will typically describe the procedure itself rather than any 'post procedure' issues. |
| **complicationDetail** Reference  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. |
| **followUp** CodeableConcept  Public    [0] | If the procedure required specific follow up - e.g. removal of sutures. The followup may be represented as a simple note, or could potentially be more complex in which case the CarePlan resource can be used. |
| **note** Annotation  Public    [0] | Any other notes about the procedure. E.g. the operative notes. |
| **focalDevice** Procedure.FocalDevice  Public    [1..\*] | A device that is implanted, removed or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure. |
| **usedReference** Reference  Public    [0..\*] | Identifies medications, devices and any other substance used as part of the procedure. |
| **usedCode** CodeableConcept  Public    [0..\*] | Identifies coded items that were used as part of the procedure. |

Complete Implantable Device Procedure

This profile shows how a FHIR Procedure resource can be used to specify when a devices was implanted and the type of surgical procedure used to accomplish it. This resource may also be used to specify the associated diagnosis (as the "reason" for the procedure).

|  | **Notes** |
| --- | --- |
| **identifier** Identifier  Public    [0..\*] | This records identifiers associated with this procedure that are defined by business processes and/or used to refer to it when a direct URL reference to the resource itself is not appropriate (e.g. in CDA documents, or in written / printed documentation). |
| **definition** Reference  Public    [0] | A protocol, guideline, orderset or other definition that was adhered to in whole or in part by this procedure. |
| **basedOn** Reference  Public    [0] | A reference to a resource that contains details of the request for this procedure. |
| **partOf** Reference  Public    [0] | A larger event of which this particular procedure is a component or step. |
| **status** EventStatus  Public | A code specifying the state of the procedure. The status is updated to "completed" by this transaction. |
| **notDone** boolean  Public    [0..1] | Set this to true if the record is saying that the procedure was NOT performed. |
| **notDoneReason** CodeableConcept  Public    [0] | A code indicating why the procedure was not performed. |
| **category** CodeableConcept  Public    [0..1] | A code that classifies the procedure for searching, sorting and display purposes (e.g. "Surgical Procedure"). |
| **code** CodeableConcept  Public | The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy"). |
| **subject** Reference  Public | The person, animal or group on which the procedure was performed. |
| **context** Reference  Public    [0] | The encounter during which the procedure was performed. |
| **performedDateTime** dateTime  Public | The date(time)he procedure was performed. The date/time is used if the start of procedure is not necessary as in the case when medical device is implanted. |
| **performer** Procedure.Performer  Public    [0..\*] | Limited to 'real' people rather than equipment. |
| **location** Reference  Public    [0..1] | The location where the procedure actually happened. E.g. a newborn at home, a tracheostomy at a restaurant. |
| **reasonCode** CodeableConcept  Public    [0..\*] | The coded reason why the procedure was performed. This may be coded entity of some type, or may simply be present as text. |
| **reasonReference** Reference  Public    [0] | The condition that is the reason why the procedure was performed. |
| **bodySite** CodeableConcept  Public    [0..\*] | Detailed and structured anatomical location information. Multiple locations are allowed - e.g. multiple punch biopsies of a lesion. |
| **outcome** CodeableConcept  Public    [0..1] | The outcome of the procedure - did it resolve reasons for the procedure being performed? |
| **report** Reference  Public    [0] | This could be a histology result, pathology report, surgical report, etc.. |
| **complication** CodeableConcept  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. These are generally tracked separately from the notes, which will typically describe the procedure itself rather than any 'post procedure' issues. |
| **complicationDetail** Reference  Public    [0] | Any complications that occurred during the procedure, or in the immediate post-performance period. |
| **followUp** CodeableConcept  Public    [0] | If the procedure required specific follow up - e.g. removal of sutures. The followup may be represented as a simple note, or could potentially be more complex in which case the CarePlan resource can be used. |
| **note** Annotation  Public    [0] | Any other notes about the procedure. E.g. the operative notes. |
| **focalDevice** Procedure.FocalDevice  Public    [1..\*] | A device that is implanted, removed or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure. |
| **usedReference** Reference  Public    [0..\*] | Identifies medications, devices and any other substance used as part of the procedure. |
| **usedCode** CodeableConcept  Public    [0..\*] | Identifies coded items that were used as part of the procedure. |

Procedure.FocalDevice

An action that is or was performed on a patient. This can be a physical intervention like an operation, or less invasive like counseling or hypnotherapy.

|  | **Notes** |
| --- | --- |
| **action** CodeableConcept  Public    [0..1] | The kind of change that happened to the device during the procedure. |
| **manipulated** Reference  Public | The device that was manipulated (changed) during the procedure. This is a reference to a registered device (i.e. a Device resource) that was created using [2.1 Register Device](#BKM_C3BE5CEB_F63C_4277_9D6E_D0FC021F8584) transaction. |

Procedure.Performer

An action that is or was performed on a patient. This can be a physical intervention like an operation, or less invasive like counseling or hypnotherapy.

|  | **Notes** |
| --- | --- |
| **role** CodeableConcept  Public    [0..1] | For example: surgeon, anaethetist, endoscopist. |
| **actor** Reference  Public | The practitioner who was involved in the procedure. |
| **onBehalfOf** Reference  Public    [0..1] | The organization the device or practitioner was acting on behalf of. |

###### 2.4.4.1.3 Expected Actions

#### 2.4.5 Security Considerations

This transaction could be subject to "Eavesdrop" attacks as outlined in Volume 1 (see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E) ). This transaction creates a new data set (e.g. FHIR resource) using a synchronous call (e.g. RESTful service).

##### *2.4.5.1 Security Audit Considerations*

None, these transactions do not need to be audited as they are explicitly persisted by the server.

### 2.5 Search Point-of-Care Device Procedures

#### 2.5.1 Scope

This section describes the transaction used to query information about procedures performed at the point-of-care and reported from the point-of-care.

#### 2.5.2 Actor Roles



Figure 15: 2.5.2 Actor Roles

###### Actor Roles

|  | **Notes** |
| --- | --- |
| **Initiating Actor:** Medical Device Requester  Public | This actor requests procedure records matching a specific set of criteria (i.e. search parameters). |
| **Responding Actor:** Medical Device Server  Public | This actor receives the request, processes the search parameters and returns matching procedure records to the initiating actor. If the criteria are invalid an error status and error detail structure will be returned. |

#### 2.5.3 Referenced Standards

HL7 STU3 Procedure, SNOMED CT, ICD-10, CPT-4

#### 2.5.4 Interaction Diagram

The following is detailed description of the actors and transactions initiated:



Figure 16: 2.5.4 Interaction Diagram

##### *2.5.4.1 Search Point-of-Care Device Procedures*

###### 2.5.4.1.1 Trigger Events

This transaction can be invoke on-demand based on a user action, recall notice, or another type business trigger that requires specific medical device records.

###### 2.5.4.1.2 Message Semantics

The semantics of this transaction refers to the search parameters supported by FHIR to search for Procedure resources:

Procedure Search Parameters

The following is subset of search parameters applicable to a point-of-care procedure query. At this time the associated diagnosis (i.e. Procedure.reasonCode or Procedure.reason) are not available as search criteria:

|  | **Notes** |
| --- | --- |
| **date** int  Public | Date/Period the procedure was performed (Procedure.performed) |
| **identifier** token  Public | A unique identifier for a procedure Procedure.identifier |
| **patient** reference  Public | Search by subject patient (Procedure.subject). |
| **status** token  Public | Procedure.status (**preparation | in-progress | suspended | aborted | completed | entered-in-error | unknown )** |

###### 2.5.4.1.3 Expected Actions

If the server identifies matching procedures, it returns them in a bundle. Otherwise, the server may return a HTTP status code (e.g. 400 for "bad request") and an error structure (e.g. "parameter x not supported").

#### 2.5.5 Security Considerations

This transaction could be subject to "Eavesdrop" attacks as outlined in Volume 1 (see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E) ).

##### *2.5.5.1 Security Audit Considerations*

In some cases, if the Consumer actor is not in the same domain or covered entity, the Server should persist an audit event for the search request.

## Volume 3 - Content Modules

### 

## Volume 4 - National Extensions