**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: <Month xx, 20xx>

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 2

Open Issues and Questions 3

Actor Options 3

Device Resource 3

Closed Issues 4

Relationship to IHE Patient Care Devices (PCD) Technical Framework 4

Secure Transport 4

Condition associated with a Procedure 4

General Introduction 5

Scope 6

Standards 7

Technical Approach 7

Appendix A - Actor Summary Definitions 8

Appendix B - Transaction Summary Definitions 9

Glossary 10

Implantable Device 10

UDI 10

Volume I - Profiles 11

1. PMDT profile 11

1.1 PMDT Actors, Transaction, and Content Modules 12

1.1.1 Actor Descriptions and Actor Profile Requirements 12

Device Data Reporter 14

Device Server 15

Device Data Requester 16

1.2 Actor Options 17

1.3 Required Actor Groupings 17

1.4 PDMT Overview 17

1.4.1 Concepts 17

1.4.2 Use Cases 18

1.4.2.1 Business Use Cases 18

Implantable Medical Registration 18

Tracking Implantable Devices 19

Vital Signs Monitoring and Charting 19

Cardiology - Implanted Stent 20

Cardiology - Pacemaker 20

1.4.2.3 PDMT Use Cases 20

Use Case #1: Track devices and procedures at the point of care 24

Use Case #2 Query Device and Procedure Data 24

1.5 Security Consideration 25

1.6 Cross Profile Considerations 25

IHE PCD DEC 25

IHE PCD DEC Device Observation Reporter and Device Observation 26

# 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 Infrastructure 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 FHIR-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 point-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 Search 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 X.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 |
| --- | --- | --- | --- |
| **Device Data Reporter** | **Register Device** (initiate) | R |  |
| **Start Procedure** (initiate) | O |  |
| **Complete Procedure** (initiate) | O |  |
| **Device Server** | **Register Device** | R |  |
| **Search Device** | R |  |
| **Start Procedure** | R |  |
| **Complete Procedure** | R |  |
| **Search Procedure** | R |  |
| **Device Data 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, Consumer

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: Actors

###### Device Data Reporter

This actor is implemented as a FHIR Device resource 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.

This actor may also be responsible for sending procedure code, status, and related information to consumer(s) in the enterprise and is implemented as FHIR Procedure resource client. 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).

| **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 a patient based on information acquired at the point-of-care. This transaction creates a new instance of a Device. The Device resource does not record when the device was assigned to a patient. This information is recorded in the associated procedure (as the date/time when the procedure was completed). | Device ] device  Patient ] referencedPatient |
| **send start Procedure()** | The reporter 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 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 |

###### Device Server

This actor 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 (i.e. “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 instance) . 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 receives and validate a **new** Procedure resource 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 (e.g. device UDI, patient identifier). The Device resource does not record when the device was assigned to a patient. This information is recorded in the associated procedure (as the date/time when the procedure was completed). | Device.patient (reference) ] patient  Device.udi.carrierAIDC ] udi-carrier-aidc  Device.udi.carrierHRF ] udi-carrier-hrf |
| **search Procedure()** Procedure | This server returns the Procedure resources that match the criteria 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.code ] code  A code to identify a procedure  Procedure.subject ] patient  Search by subject - a patient |

###### Device Data Requester

Implemented as a FHIR Device resource client that implements the “search” operation and uses the parameters supported by the FHIR specification. 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.

This actor also queries the Procedure Server for the information related to point-of-care procedures.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send search Procedure()** Procedure | 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.code ] code  Procedure.subject ] patient |
| **send search Device()** Device | The requester initiates queries for device records that match specific criteria (e.g. device UDI, patient identifier). | Device.patient ] patient  Device.udi.carrierAIDC ] udi-carrier |

### 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** (UDI->PID) and her badge (PID->EID). 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 1.4.2.3: PDMT Use Cases

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

###### 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.

### 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.

### 1.6 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 DEC 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.