Integrating the Healthcare Enterprise

IHE Patient Care Coordination (PCC) Technical Framework Supplement

Point-of-Care Medical Device Tracking (PMDT)

FHIR® STU 3

Using Resources at FMM Level 2-3

Rev. 1.1 – Trial Implementation

Foreword

This is a supplement to the IHE Patient Care Coordination Technical Framework V11.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on September 8, 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 Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/PCC_Public_Comments.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

Where the amendment adds text, make the added text **<u>bold underline</u>**. 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 http://ihe.net.

Information about the IHE Patient Care Coordination domain can be found at http://ihe.net/IHE_Domains.

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

The current version of the IHE Patient Care Coordination Technical Framework can be found at http://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

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

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

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

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

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

FHIR Resource Name	FMM Level
Device	2
Procedure	3

195

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).

200

- 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

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

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

205   transactions based on HL7 Version 2.7 ORU_R01) include only the device identification without patient identification information. 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
210   recorded along with the procedure in the EHR to meet requirements https://www.healthit.gov/sites/default/files/170_315a14_implantable_device_list_v10.pdf . This information is necessary to address adverse events and recall notices specific to a device instance (based on the device's unique device identification using the U.S. FDA UDI Rule. Currently we do not have a standard-based mechanism to capture the
215   information consistently across care settings (e.g., hospital Operating Room, cardiology catheterization laboratories, orthopedic surgery centers).

- Medical device data may be persisted to the patient's chart (if "validated/accepted" by clinicians), used for decision support, and exchanged with other providers across the continuum of care (e.g., as referrals, transfer, discharge summary documents based on
220   HL7 Consolidated-CDA®[3]).

PMDT will provide an HL7 Fast Healthcare Interoperability Resource (FHIR) Standard for Trial Use Release 3 (STU 3), RESTful services, approach to record information acquired at the point-of-care and add it to the set of data maintained by enterprise information systems (e.g., EHR systems, inventory management systems [IMS], flow sheets). Unlike previous approaches that
225   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.

Open Issues and Questions

1. We need to add the new terms to the IHE glossary.

230   2. Should there be a requirement to servers that they must have the ability (above-and-beyond) core-FHIR server expected behavior? Contain a Resource or be able to query multiple Resources and revise all the Resources? Device Resource may be "contained" in the Procedure Resource or referenced (i.e., external references)

Closed Issues

235   1. (2/6/2017)How does this affect/change PCD-01?

- Doesn't change PCD-01 it leverages the medical device status information for the enterprise

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[3] CDA is the registered trademark of Health Level Seven International.

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2. (2/6/2017) When associating the device with the pt using HL7v2 there are several ways to do it, PAM (Patient Administration Management) or PCIM (Point-of-Care Identity Management), is this an option for users?

   Yes, this is an option for FHIR adoption and capturing information easily at the point-of-care.

3. (2/6/2017) How are we handling security within FHIR because you need a server?

   Solution: This profile references Appendix Z developed by IHE ITI for FHIR security.

4. (2/8/2017) 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:

   a. The Procedure resource does not specify a "related condition" but is specifies a "Procedure.context" as a reference to either Encounter.

   b. The Encounter.indication is a reference to the Condition that is "the reason why the encounter takes place". In order to find the Condition associated with a Device, we need to query Procedure.context for the related Encounter, then retrieve the Encounter.indication to identity the condition.

   Solution: The FHIR Procedure resource provides two data elements to support the "associated diagnosis":

   - "reasonReference" - one or more references to the Condition resource

   - "reasonCode" (one or more SNOMED CT disorder codes)

   This item is addressed in Volume 3 as a constraint to the Procedure resource.

5. (2/8/2017) Do we need options specific to a device type or will this profile be sufficient to address point-of-care tracking for: implantable devices, monitoring devices, cardiology devices?

   No, because the information required to track medical devices at the point-of-care is the same regardless of type. Therefore, the generic use cases related to managing devices and associated procedures will apply equally well to any type of device.

6. (2/8/2017) Device Resource - the FHIR Device resource is missing data elements to support: date/time the device was implanted in the patient but that information is provided in the FHIR Procedure resource (using the "performedDateTime" or "performedPeriod"). The associated Procedure provides timing information for both implantable and multiple-use devices (e.g., pulse oximeters).

7. (4/26/2017) **Device Security** - Device Authorization as an authorization of sender of data – cybersecurity?

Solution: This profile references Appendix Z developed by IHE ITI for FHIR security. As far as patient safety, this profile will not have any effects on the operation of the devices tracked at the point-of-care but will provide accurate context and identity information.

8. (4/26/2017) How to display "S" (must support) in the cardinality column for FHIR profiles?

Solution: Because there is no IHE guidance on representing conformance-related constraints to for IHE-produced FHIR profiles. The issue was referred to the IHE/FHIR Workgroup and will also be tracked by IHE Documentation Workgroup. We will add a separate column in the profile table to specify the "must support" constraint for each data element.

General Introduction

285   This supplement is providing a standard-based HL7 Fast Healthcare Interoperability Resources (FHIR) Standard for Trial Use Release 3 (STU3) approach to acquiring medical device information at the point-of-care such that it can be retrieved and reused at a later time. The reuse of the medical device data is out-of-scope for this profile.

290   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

295   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.

300   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

305   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.

310   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 entered on a study or a registry log that is aggregated by a healthcare organization's

315   Quality Department or special study coordinator that is sent to a 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 risks.

   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 in the

320   healthcare organization's 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 label, is not accepted by the organization's inventory management system (IMS). 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 automated identification and data capture (AIDC) technology (i.e., barcode scanner). 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 are as follows: it 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.

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 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 collects surveillance data for implantable medical devices.

When data has to be manipulated by an individual, data quality becomes a factor. Manually transcribing data, because the target system uses one standard and its source uses another, is prone to human error. Incorrect data formatting or missing data can cause rejection of data by a registry submission or rework may need to occur. Patient safety can be jeopardized if incorrect data is transcribed and decisions are made from incorrect data.

This profile is intended to augment Device Manager systems that implement IHE PCD Technical Framework, but it is focused on HL7 FHIR Standard for Trial Use Release 3 (STU3) adoption. 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 HL7 FHIR Standard for Trial Use Release 3 (STU3) based approach to create individual devices and procedure records, as well querying those data sets. The profile will do the following:

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- Create a FHIR Procedure specifying the patient, the device or devices involved, and the operator (i.e., perioperative nurse, respiratory therapist, etc.) or provider who configured the device, validated its configuration and initiated the procedure.

- If the device is implanted, a FHIR Device Resource will associate the patient with the implanted device. The Patient Device List will be created by querying the EHR using a Device.search by patient operation.

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- If a device is used to monitor the patient or administer medication, the procedure indicates duration and the associated medication order.

Appendix A – Actor Summary Definitions

Actor	Definition
Medical Device Reporter	Reports on uses of medical devices.
Medical Device Server	Maintains information about medical devices and medical device related procedures.
Medical Device Requester	Requests for uses of medical devices.

375 ## Appendix B – Transaction Summary Definitions

Transaction	Definition
Register Medical Device	The Register Device transaction records the identity of a device at the point-of-care. If the device is single-use (e.g., implantable) this registration will also identify the patient who received the device.
Start Point-of-Care Device Procedure	The Start Procedure transaction identifies the commencement of a procedure that involves the use or implantation of a device (Procedure). If the device is reusable this Procedure record is used to associate the patient and the device for the duration of the procedure.
Complete Point-of-Care Device Procedure	The End Procedure transaction identifies the conclusion of a procedure that involves the use or implantation of a device. This is effectively an update of a Procedure record.
Search Medical Device	The Search for Device is a query for medical devices that match a set of criteria.
Search for Procedure	The Search for Procedure is query for matching procedures based on a set of criteria.

Glossary

Glossary Term	Definition
Implantable Medical 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)

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Volume 1 – Profiles

Copyright Licenses

NA

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

385

Domain-specific additions

NA

Add new Section X

390

X Point-of-Care Medical Device Tracking (PMDT) Profile

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

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- "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)

400 Both sets of requirements relied on correctly recording the identifier of medical devices, most likely automatically (e.g., barcode scanning), at the point of care, using its Unique Device Identifier (UDI) specified by manufacturers use of standard-based supported formats.

UDIs on implantable medical device labels and packages and in certain cases, directly on the device, 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.
405 These are not only US based concerns, but also international concerns as identified in the International Consortium for Orthopedic Registry (ICOR).

The standards used for this profile are:

- Harmonization Pattern for UDI (referenced by the ONC Standards Advisory for 2017 [draft])
410 https://www.healthit.gov/sites/default/files/2017_draft_interoperability_standards_advisory_8.16.16.pdf or http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf;

- UDI Format by FDA-Accredited Issuing Agency Version 1.2: Global Standards One (GS1), Health Industry Business Communications Council (HIBCC), International
415 Council for Commonality in Blood Banking Automation (ICCBBA) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm or https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf ;
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- Clinical terminology consistent with ONC Health IT certified EHR systems (LOINC, SNOMED-CT, RxNorm) based on the type of data to be represented. For patient care devices (PCD) transactions, we will use the mappings provided by Regenstrief Institute to represent IEEE 11073-10101 concepts in LOINC.

425 The approach outlined here relies on the use of HL7 FHIR Standard for Trial Use Release 3 (STU3) Resources (i.e., RESTful services) to record medical device 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, 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.

X.1 PMDT Profile Actors, Transactions, and Content Modules

The Point-of-Care Medical Device Tracking (PMDT) Integration Profile actors and transactions are intended to support several business use cases detailed in this supplement:

- Implantable Medical Device Registration to an enterprise Device Registry;

- Tracking Implantable Devices at the point of care, during a procedure;

- Vital Signs Monitoring and Documentation using device and patient identity acquired at the point-of-care;

- Cardiology procedures using implantable medical devices (i.e., stent, pacemaker).

These business use cases require the implementation of the HL7 FHIR Standard for Trial Use Release 3 (STU3) Device and Procedure Resources and references to instances of the Patient 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 a Medical Device;

- Register an Implantable Medical Device;

- Start Procedure part of the Manage Point-of-Care Procedure;

- Complete Procedure part of the Manage Point-of-Care Procedure;

- Complete Post-Procedure part of the Manage Point-of-Care Procedure;

- Search a Medical Device and Search an Implantable Medical Device by Patient and Search Implantable Medical Device by UDI;

- Search Point-of-Care Procedure using a variety of criteria.

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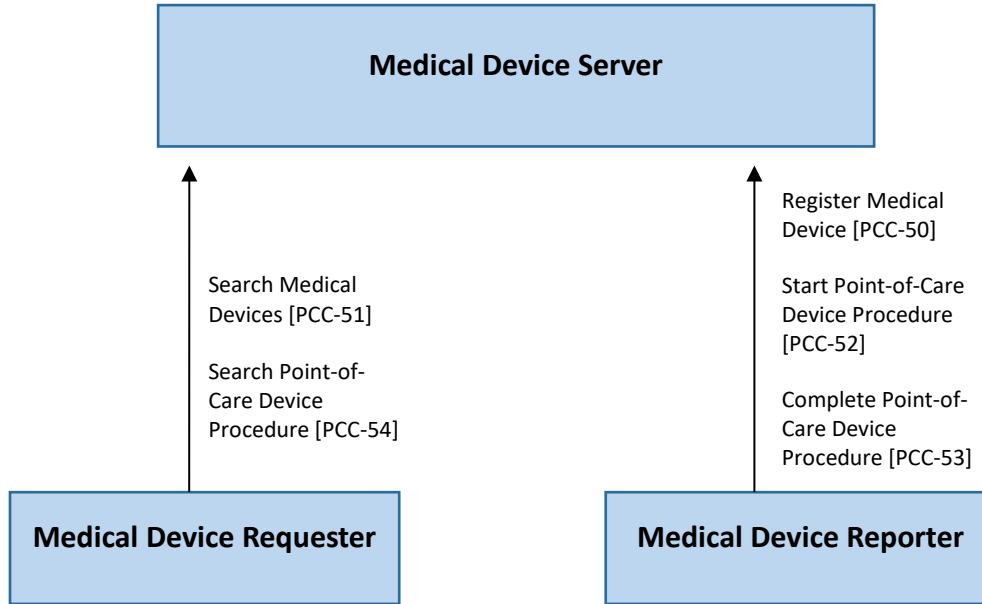
Figure X.1-1: PMDT Profile Actor Diagram

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

Table X.1-1: PMDT Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Medical Device Reporter	Register Medical Device [PCC-50]	R	PCC TF-2: 3.50
	Start Point-of-Care Device Procedure [PCC-52]	O	PCC TF-2: 3.52
	Complete Point-of-Care Device Procedure [PCC-53]	O	PCC TF-2: 3.53
Medical Device Server	Register Medical Device [PCC-50]	R	PCC TF-2: 3.50
	Search Medical Devices [PCC-51]	R	PCC TF-2: 3.51
	Start Point-of-Care Device Procedure [PCC-52]	R	PCC TF-2: 3.52

Actors	Transactions	Optionality	Reference
	Complete Point-of-Care Device Procedure [PCC-53]	R	PCC TF-2: 3.53
	Search Point-of-Care Device Procedure [PCC-54]	R	PCC TF-2: 3.54
Medical Device Requester	Search Medical Devices [PCC-51]	R	PCC TF-2: 3.51
	Search Point-of-Care Device Procedure [PCC-54]	O	PCC TF-2: 3.54

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Figure X.1-1 shows the actors directly involved in the PMDT Profile and the direction that the content is exchanged.

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Actor – 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). It initiates the creation and update of a procedure for a monitoring session. It is used to identify the type of procedure that implants a life-supporting or life-sustaining medical device or uses the device (e.g., pulse oximetry, vital sign monitoring, IV medication administration). The reporter is implemented by a point-of-care system (e.g., Medical Device Manager).

This actor is a FHIR Device and Procedure Resources client that creates Device Resource instances. The Device Resource will reference the patient who received the implanted medical device. 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 on the label of the implantable medical device or on the medical device equipment.

X.1.1.2 Actor – Medical Device Server

This actor maintains information about medical devices and implantable medical devices related procedures reported from the point-of-care. This actor is a FHIR Server that 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, or search operations, may be more extensive than the example shown in this profile (e.g., "search by patient Id").

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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 medical device or a procedure
that uses a medical device (e.g., vital sign monitoring). The procedure will provide unambiguous
documentation of procedures that use an implantable medical device or medical device
495   equipment at the point-of-care.

X.1.1.3 Actor – Medical Device Requester

This actor requests 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.

500   This actor could be implemented by systems that compile an Implantable Medical Device list for
a patient consistent with the Meaningful Use 2015 EHR system certification requirements. This
actor is a client that performs "search" operations against the Medical Device Server.

X.2 PMDT Profile Actor Options

There are no options for actors in this profile.

505   ### X.2.1 Option Name

NA

X.3 PMDT Profile Required Actor Groupings

The actors describe in this profile are organized around the FHIR Device and Procedure
Resources. Based on the high-level business Use Cases we have identified the need to capture
510   patient identity, device identity, and point-of-care procedure information right at the point-of-
care which does not require any actor groupings for this profile.

Table X.3-1: Point-of-Care Medical Device Tracking Profile Name - Required Actor Groupings

PMDT Actor	Actor to be grouped with	Reference	Content Bindings Reference
Medical Device Server	None	None	None
Medical Device Requester	None	None	None
Medical Device Reporter	None	None	None

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X.4 PMDT Profile Overview

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The goal of this profile is to enable the registration, exchange, and query of a medical device information recorded at the point-of-care. This profile leverages the wide adoption of medical device's unique device identifiers (e.g., FDA UDI in the US).

520 Volume 3 of this profile uses HL7 FHIR Standard for Trial Use Release 3 (STU3) Device and Procedure Resources and includes guidance rated to referencing instances of the Patient resources.

X.4.1 Concepts

The term medical device encompasses a broad range of items, including complicated, high-risk devices such as artificial heart valves, to simple, low-risk devices such as a bedpan. A medical
525 device can be an instrument, a machine, an invitro reagent, or a metal joint. The device may have many components (e.g., software, batteries, wires) and uses (e.g., diagnose a disease, cure an illness, prevent a health condition). Within healthcare organizations, to document medical devices used at the point-of-care, clinicians use a variety of query tools to manually identify a medical device. The manual process results in a clinician potentially documenting the wrong
530 medical device in the patient's EHR which presents patient safety and financial risks to the healthcare organization. Secondary uses of medical device information (e.g., recalls, adverse event reporting, infection rates, billing) are important for medical device patient safety and post-market surveillance, but are out-of-scope for this profile.

This profile supports the electronic capture and storing of a medical devices UDI once a clinician
535 has scanned the standardized barcode, based on the UDI issuing agency, on the medical device packaging or on the device itself. Storing the UDI will enable exchange of the medical devices UDI within the healthcare organizations systems (e.g., IMS, EHR, financial systems) or with outside agencies. Without accurate UDI data capture at the point-of-care and the ability to exchange the medical devices data internally and externally from the healthcare enterprise
540 system, a medical devices quality and effectiveness cannot be recognized.

The Use Cases described below uses different medical devices, but the workflow processes of each Use Case is very similar. The medical device is either a medical device machine used for monitoring a patient's physiological status or an implantable medical device used to support the patient's anatomical or physiological processes.

545 The following Use Cases are described below:

- Tracking Implantable Medical Devices – Orthopedic Implant

- Tracking Implantable Medical Devices – Medical Device/Tissue Implant

- Tracking Implantable Medical Devices – Cardiovascular Stent Implant

- Tracking Implantable Medical Devices – Pacemaker Implant

550 - Medical Device Monitoring – Vital Sign Monitor

X.4.2 Use Cases

X.4.2.1 Use Case #1: Tracking Implantable Medical Devices - Orthopedic

This Use Case describes the ordering, association, and tracking of an implantable orthopedic medical device for a patient that has a preoperative diagnosis of degenerative arthritis – right knee.

X.4.2.1.1 Tracking Implantable Medical Devices - Orthopedic Use Case Description

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 ensures the correct implantable medical device is available for Mr. Smith's scheduled procedure. 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 displayed on the implantable medical device packing because the scanner will not scan the barcodes on the implantable 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.

575 X.4.2.1.2 Tracking Implantable Medical Devices – Orthopedic Process Flow
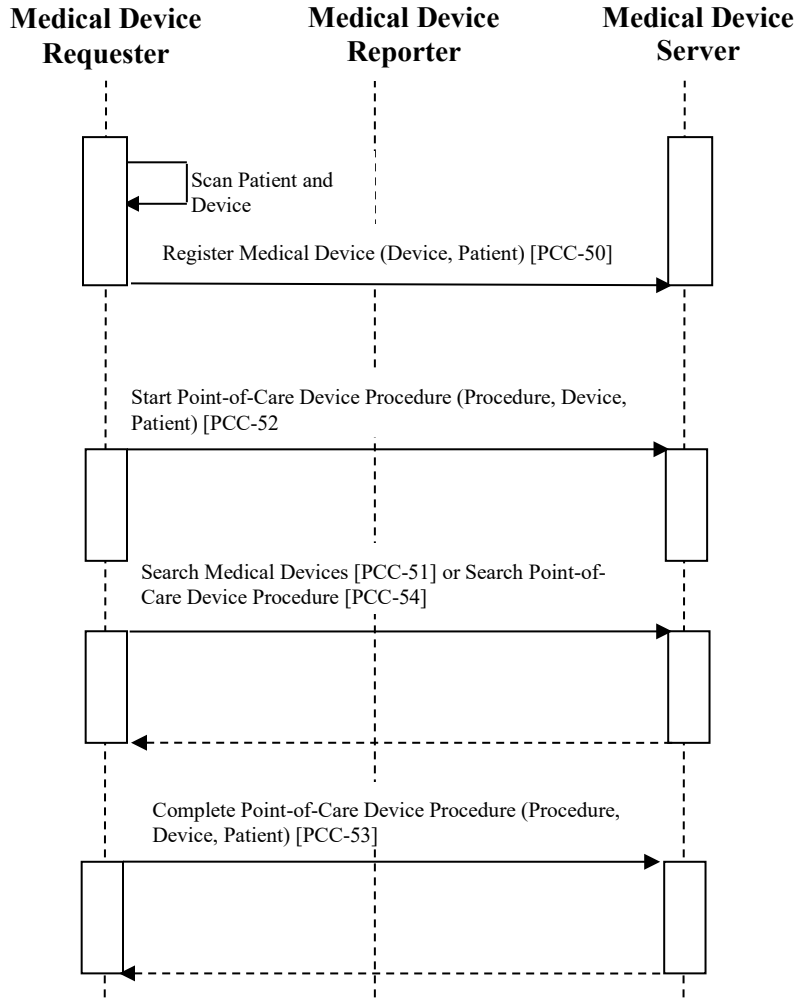
Figure X.4.2.1.2-1: Basic Process Flow in PMDT Profile

Pre-conditions:

580 Patient identity (e.g., Medical Record Number - MRN), device identifier (UDI) is 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.

Main Flow:

The system at the point of care that implements the Medical Device Reporter registers the device. The Medical Device Server returns success indicating that a new Device record was

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585 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 the system that implements the Medical Device 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 main distinction is that the

590 implantable device procedure may be recorded as "completed" while a monitoring session may start and end.

Post-conditions:

The system that implements the Medical Device Manager has persisted the device and procedure information and associated the medical devices, the patients, and procedures in which they were

595 applied to patient care.

X.4.2.2 Use Case #2: Tracking Implantable Medical Devices – Medical Device/Tissue

This Use Case describes the ordering, tracking, and implantation of biological tissue medical device for a specific disease or diagnosis.

600 ### X.4.2.2.1 Tracking Implantable Medical Devices – Medical Device/Tissue Use Case Description

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

605 criteria (e.g., clinical size) and orders the device (based on device identifier [DI] which is a portion of the UDI) for the procedure (HCPCS). The VA physician looks up a suitable device using an organizational list, such as an item master, based on the FDA's 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 SNOMED-CT device taxonomy codes.

610 This local list allows the enterprise application to look up devices based on: by type, model, version, vendor, and clinical size. Ms. Martin, a VA clerk reviews the order before forwarding the information from the VA-approved distributor to obtain the device required for SSgt. Sam. A procedure is scheduled for SSgt. Sam, the device is implanted by Dr. Wilson and the UDI is scanned by the designated nurse into the healthcare organization's electronic medical record. The

615 UDI is associated with the patient and available to community providers in the "Patient Device List" as a CCD[®4]. 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.

---

[4] CCD is the registered trademark of Health Level Seven International.

X.4.2.2.2 Tracking Implantable Medical Devices – Medical Device/Tissue Process Flow
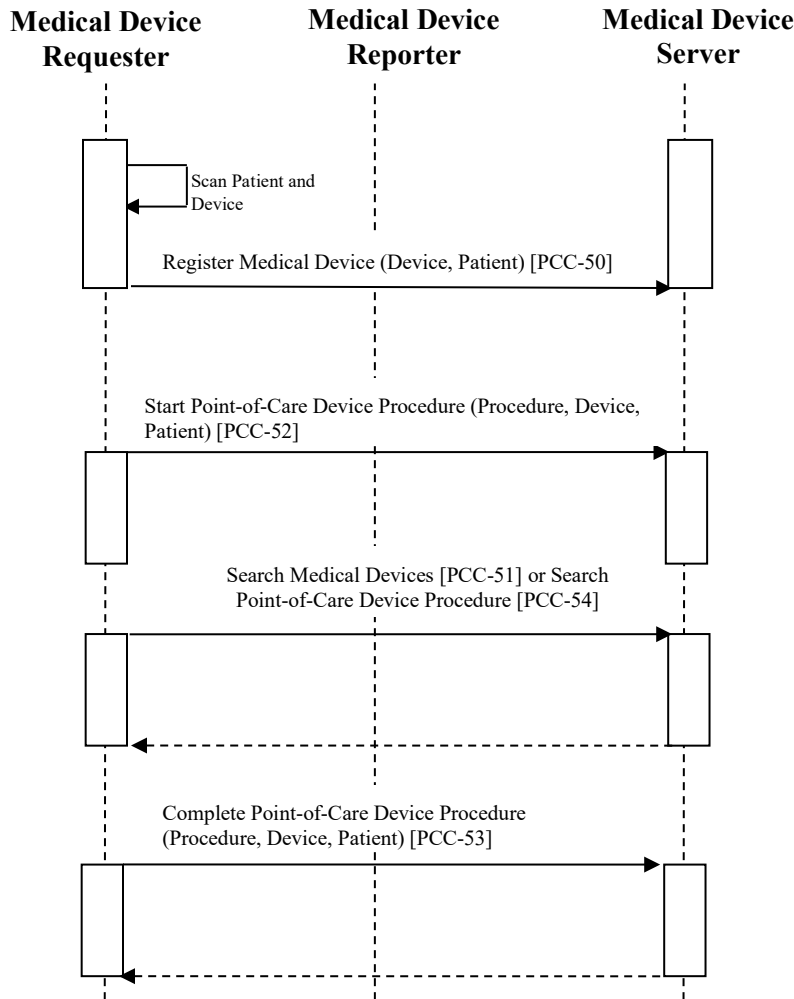
620

Figure X.4.2.2.2-1: Basic Process Flow in PMDT Profile

Pre-conditions:

The system that implements the Medical Device Server Manager has persisted the device and procedure information and associated the medical devices, the patients, and procedures in which 625 they were applied to patient care. The Patient Resource may be required to lookup the patient identifier.

Main Flow:

The system that implements the Medical 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 the manufacturer) or to compile a patient device list to support continuity of care. The Medical Device Server Manager returns the resources matching the search criteria to the Requester.

Post-conditions:

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

X.4.2.3 Use Case #3: Tracking Implantable Medical Devices – Cardiovascular Stent Implant

This Use Case describes the ordering, tracking, and implantation of an implantable medical device for a specific cardiovascular disease or diagnosis.

X.4.2.3.1 Tracking Implantable Medical Devices – Cardiovascular Stent Implant Use Case Description

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's medical record. SSgt. Sam is transferred to the Cardiac Care Unit for post-procedure care.

X.4.2.3.2 Tracking Implantable Medical Devices – Cardiovascular Implant Process Flow
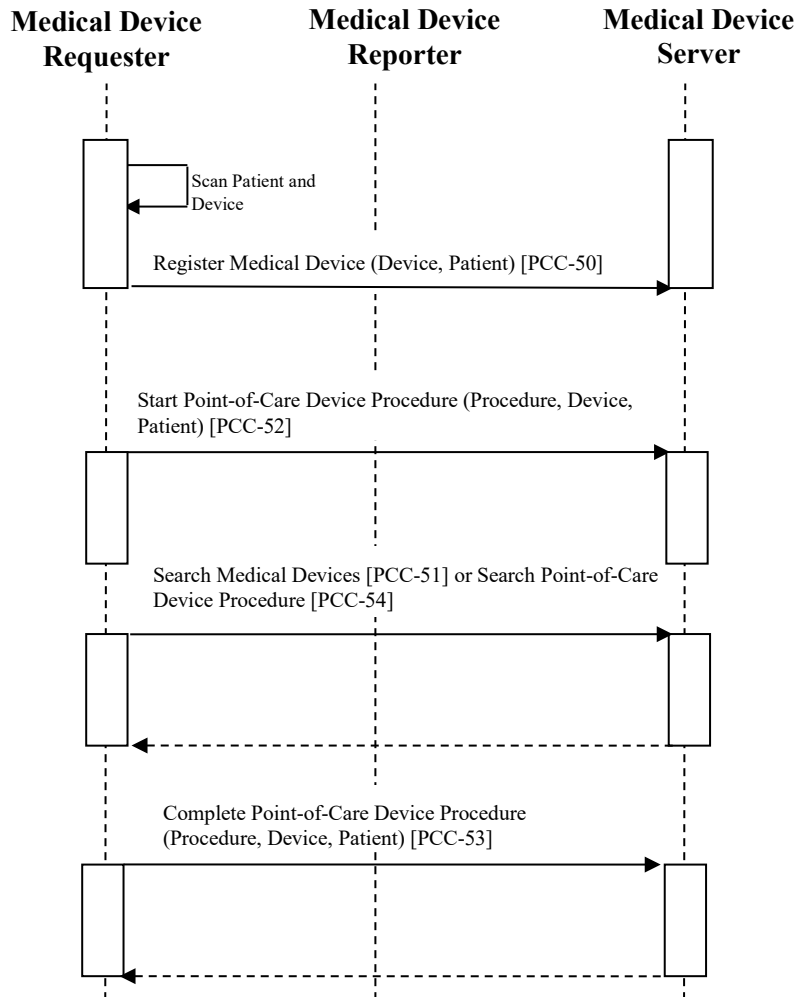
660   **Figure X.4.2.3.2-1: Basic Process Flow in PMDT Profile**

Pre-conditions:

Patient identity (e.g., Medical Record Number - MRN), device identifier (UDI) is 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.

665 **Main Flow:**

The system at the point of care that implements the Medical Device Reporter registers the device. The Medical 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.

670 The user of the system that implements the Medical Device 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 main distinction is that the implantable device procedure may be recorded as "completed" while a monitoring session may start and end.

675 **Post-conditions:**

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

### X.4.2.4. Use Case #4: Tracking Medical Devices – Cardiovascular Pacemaker
680 Implant

This Use Case describes the ordering, tracking, and implantation of an implantable medical device for a specific cardiovascular disease or diagnosis.

X.4.2.4.1 Tracking Medical Devices – Cardiovascular Pacemaker Implant Use Case Description

685 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
690 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
695 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.

700 **X.4.2.4.2 Tracking Medical Devices – Cardiovascular Pacemaker Implant Process Flow**
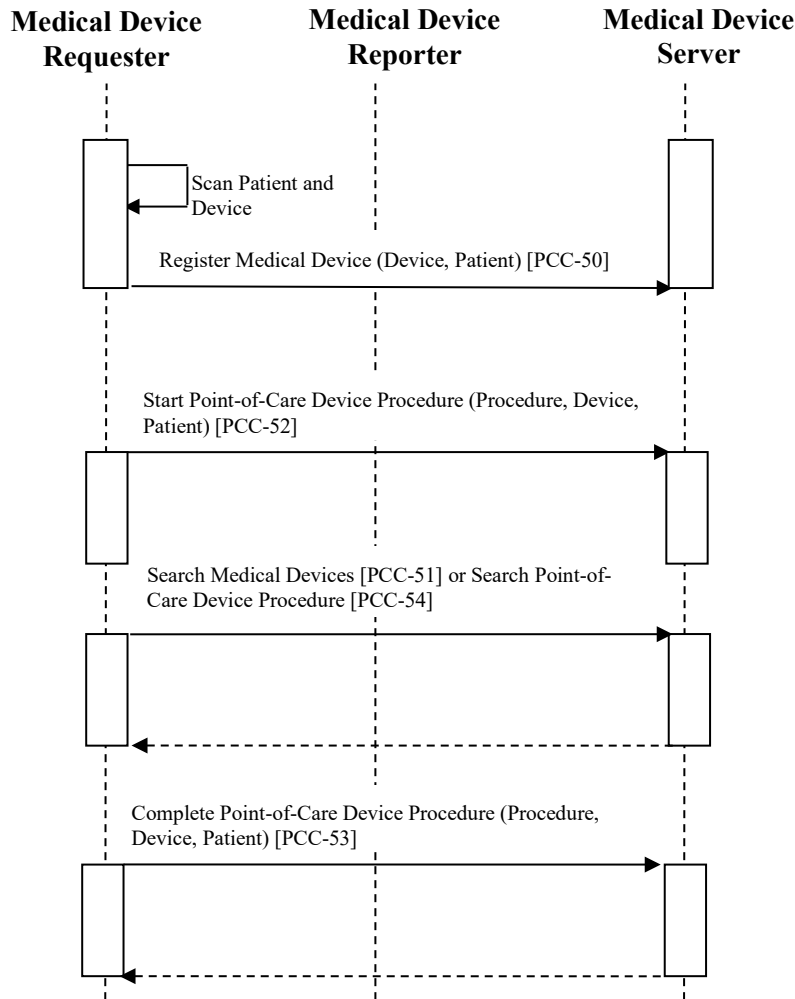
Figure X.4.2.4.2-1: Basic Process Flow in PMDT Profile

Pre-conditions:

705 Patient identity (e.g., Medical Record Number - MRN), device identifier (UDI) is 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.

Main Flow:

710   The system at the point of care that implements the Medical Device Reporter registers the device. The Medical 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 the system that implements the Medical Device Reporter allows the clinicians to record a Procedure at the point-of-care indicating the start and end of a procedure. This

715   procedure may represent the context for the device record. The main distinction is that the implantable device procedure may be recorded as "completed" while a monitoring session may start and end.

Post-conditions:

The system that implements the Medical Device Manager has persisted the device and procedure

720   information and associated the medical devices, the patients, and procedures in which they were applied to patient care.

X.4.2.5. Use Case #5: Medical Device Monitoring – Vital Signs Monitor

This Use Case describes the ordering, tracking, and use of a medical device (i.e., machine, apparatus, instrument, appliance) to assist with the monitoring, diagnosing, treatment, or

725   evaluation of a specific disease or diagnosis.

X.4.2.5.1 Medical Device Monitoring – Vital Signs Monitor Use Case Description

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

730   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. are acquired by the device is exchanged with the flowchart system that persists the measurement in

735   the healthcare organization's electronic medical record database using a common device integration adapter. **LOINC, SNOMED-CT**, and **UCUM** are used to convey the measurements. Throughout the monitoring session, Ms. Nightingale validates the data entered by the integrated device into the healthcare organization's electronic medical record. The validated results become part of Sam's legal health record. The CCD includes relevant/pertinent vital signs along with

740   other treatment information.

X.4.2.5.2 Medical Device Monitoring – Vital Signs Process Flow
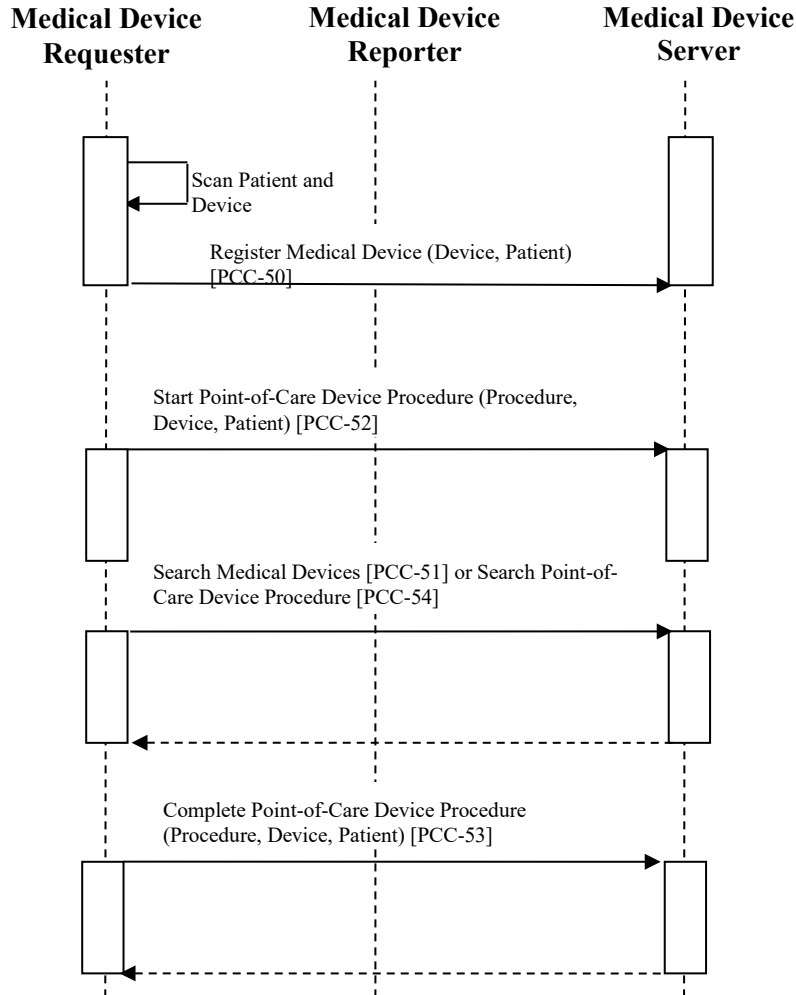
Figure X.4.2.5.2-1: Basic Process Flow in PMDT Profile

745   The following use case would apply to any reusable medical device tracked by clinicians at the point-of-care:

Pre-conditions:

Both the patient and the device have a readable, unique identifier (e.g., a bar code or RFID) that can be captured the point-of-care. The nurse uses the patient's id wristband to lookup the identity
750   of the patient and confirm it before initiating a monitoring session.

Patient monitoring may be precipitated by a change in health status or may be ordered by an authorized clinician.

Main Flow:

The nurse scans/captures the identity of the patient, the unique device identifier (e.g., UDI), and starts a "continuous monitoring" session using a point-of-care system or tablet. Upon submitting this procedure information, the receiving system (i.e., FHIR server) validates the information and records the start of a new procedure using the referenced vitals sign monitor identified by its UDI.

The device sends transactions using IHE PCD – PCD-01 to the server while the patient is being monitored. When the monitoring session is about to end, the nurse updates the procedure indicating that monitoring was completed. The system automatically fills in the date/time information. The receiving system (the server) updates the information (i.e., creates a new version of the Procedure resource) indicating its change in status and its end date/time.

Post-conditions:

The server recorded the procedure start date/time and end date/time, the device, the patient, and related procedure information (e.g., SNOMED-CT code). This information is later used to ensure that the PCD-01 results transmitted by the vital sign monitor are matched correctly with the patient record.

If the PCD-01 includes relevant patient id information, the procedure resource server constitutes added validation. Otherwise, if the PCD-01 transactions do not identify the patient, the procedure and device records may be the only source of accurate patient-to-device association. Secondly, the server tracks every time a device was used for quality and calibration reasons.

X.5 PMDT Profile Security Considerations

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

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. See HL7 FHIR Standard for Trial Use Release 3 (STU 3) Security http://hl7.org/fhir/STU3/security.html.

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).

790 User authentication on mobile devices and browsers is typically handled by more lightweight authentication schemes such as HTTP Authentication, OAuth, 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 PCC
795 Dynamic Care Planning (DCP) Profile. The use of strong trust keys is encouraged.

Actors in the PMDT Profile should make use of the audit logging (ATNA) Profile. However, support for ATNA-based audit logging on mobile devices and lightweight browser applications may be beyond their ability. The operational environment must choose how to mitigate the risk of relying only on the service-side audit logging on the Care Plan Service. It is recommended
800 that DCP Actors implement the Internet User Authentication (IUA) Profile, incorporating the subject of the IUA token in audit messages.

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
805 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.

Additional security considerations can be found by referencing ITI Appendix Z - ITI TF-2.x IHE Appendix on HL7 FHIR – Appendix Z.8 "Mobile Security Considerations".

X.6 PMDT Cross Profile Considerations

810 This profile is related to existing technical frameworks (IHE ITI, IHE PCD). The IHE PCD Device Observation Reporter and Device Observation are similar, but not exactly fulfilling the same actor role or involvement with the transactions in the PMDT Profile.

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
815 US enterprises that employ Office of National Coordinator (ONC) Health IT certified EHR systems.

Appendices

Appendix A – PMDT Business Workflow Process Diagrams

820 ## A.1 Point-of-Care Swimlane Process Flow Diagram – Implantable Medical Devices
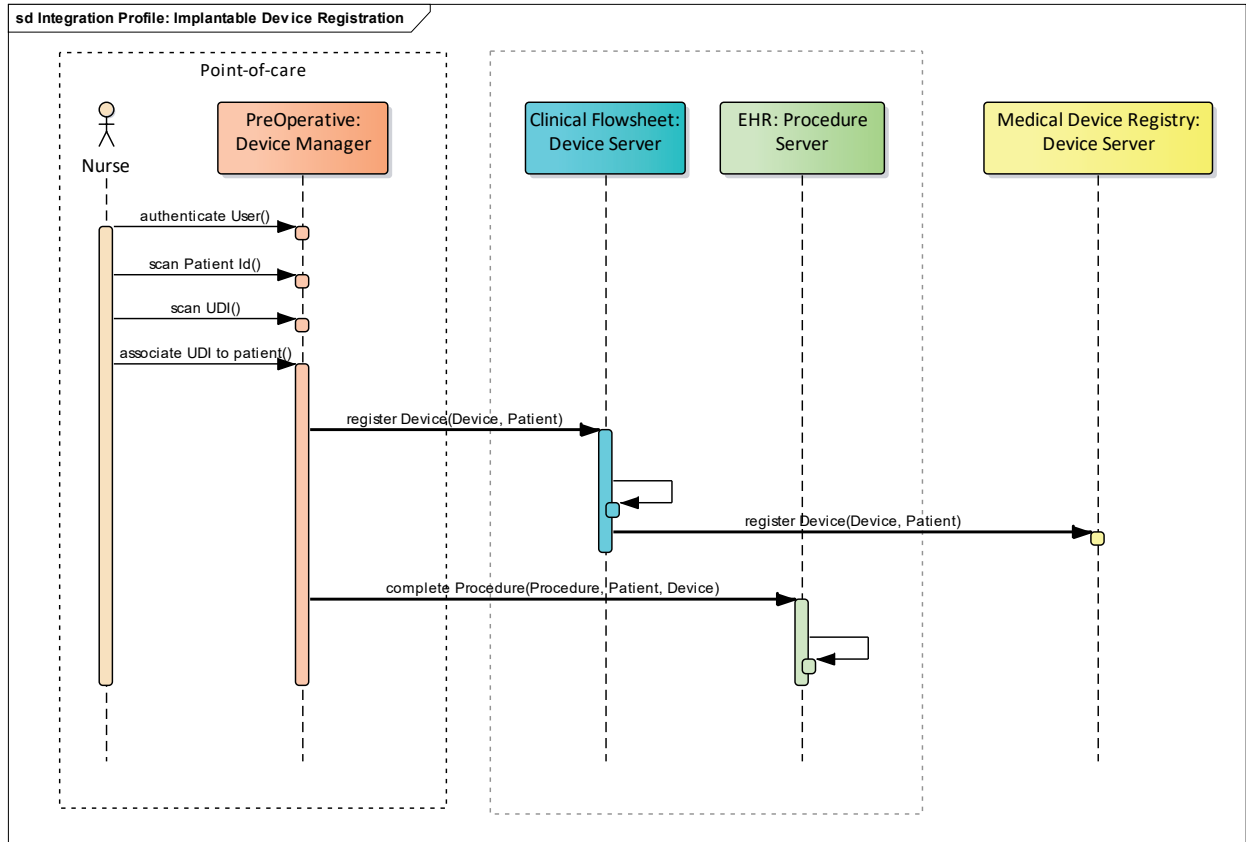
Figure A.1-1: Point-of-Care Swimlane Process Flow Diagram – Implantable Medical Devices

825 Figure A.1-1 displays the clinical workflow at the point-of-care when an implantable medical device is associated with a patient and a surgical procedure. An HL7 FHIR Standard for Trial Use Release 3 (STU3) Device Resource will associate the patient with the implanted device and nurse who scanned the implantable medical device. The device will be identified using the UDI scanned at the point-of-care along with the patient's wristband for patient identification and the
830 nurse's AIDC employee badge. The Patient Device List will be created by querying the EHR using a Device.search (by patient) operation. An HL7 FHIR Standard for Trial Use Release 3 (STU3) Procedure Resource is created to document the start and end of the procedure.

A.2 Medical Device Monitoring Swimlane Process Flow Diagram
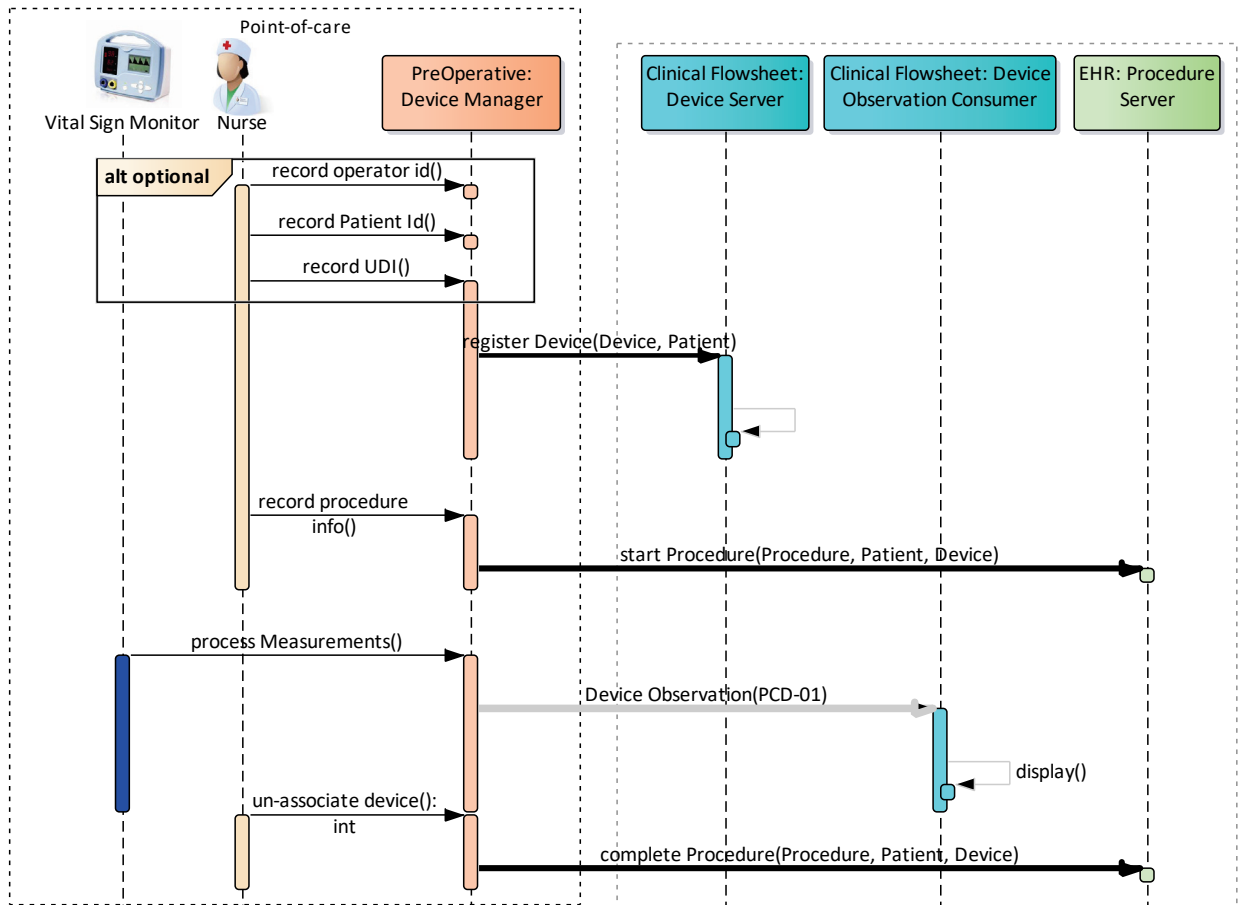
835

Figure A.2-1: Medical Device Monitoring Swimlane Process Flow Diagram

Figure A.2-1 displays the clinical workflow at the point-of-care when a medical device used for monitoring a medical condition is associated with a patient and a surgical procedure. An HL7 FHIR Standard for Trial Use Release 3 (STU3) Device Manager will associate a patient to their monitoring device. The Device Manager implements several HL7 FHIR Standard for Trial Use Release 3 (STU3) Resources (as a client) in order to start and end a monitoring session as a Procedure (start procedure) and updates the procedure at the end of the monitoring session (and sets the status to "end" or "complete"). An HL7 FHIR Standard for Trial Use Release 3 (STU3) Device Resource will be created for each device used during a procedure (a monitoring session) and the procedure indicates duration.

A.3 Tracking Implantable Medical Devices Workflow Diagram – Cardiovascular Devices
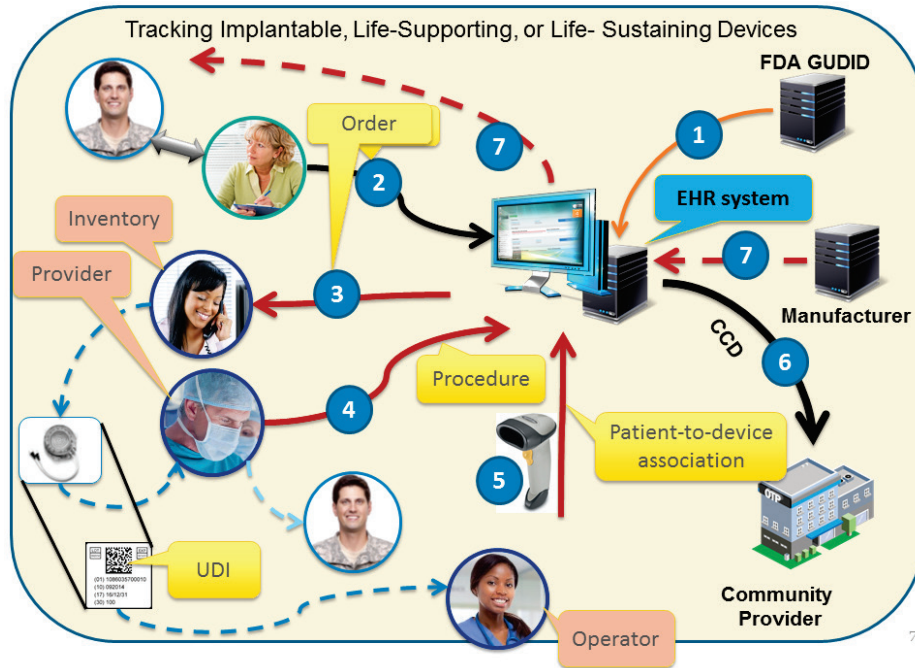
Figure A.3-1: Tracking Implantable Medical Devices Workflow Diagram – Cardiovascular Devices

Figure A.3-1 provides a visual of the providers and the clinical workflow for Use Case #3 and #4 when a cardiovascular medical device is implanted into a patient. The capture and exchange of UDI data is numbered in the process.

A.4 Medical Device Monitoring Workflow Diagram – Vital Signs

855
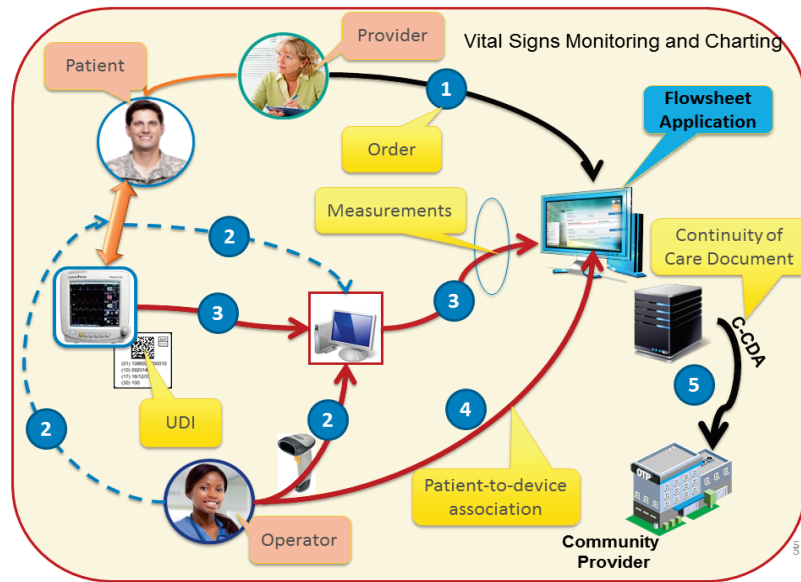
Figure A.4-1: Medical Device Monitoring Workflow Diagram – Vital Signs

Figure A.4-1 provides a visual of the providers and the clinical workflow for Use Case #5 when a medical device is used for monitoring a patient's illness. The capture and exchange of UDI

860   data is numbered.

A.5 Tracking Medical Devices Sequence Diagram
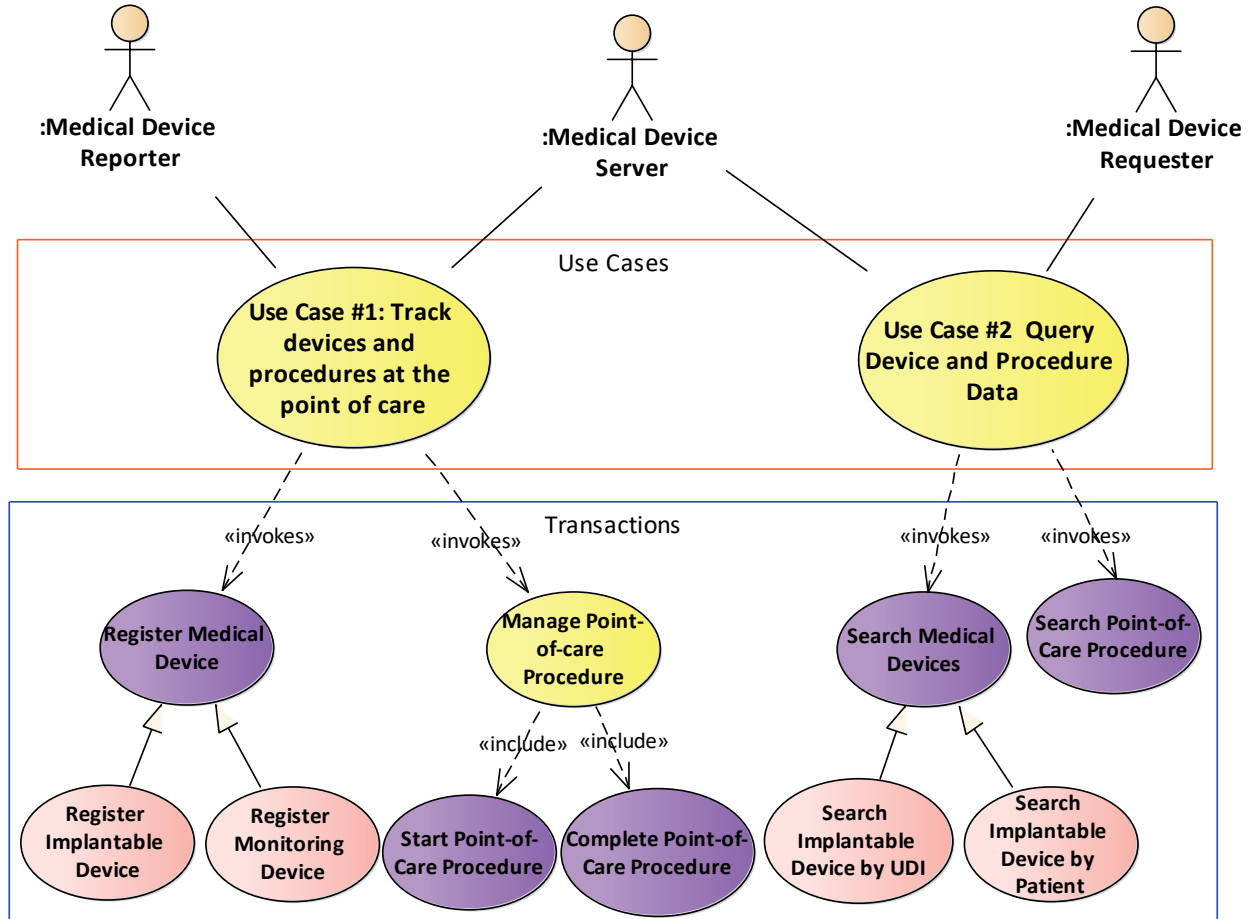
Figure A.5-1: Medical Device Monitoring Workflow Process

Figure A.5-1 provides a sequence diagram of the three actors in the profile and how those actors are associated to the Use Cases and the transactions that occur during each Use Case.

Volume 2 – Transactions

Add new Sections 3.50 through 3.54

3.50 Register Medical Device [PCC-50]

870   ### 3.50.1 Scope

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

875   ### 3.50.2 Actor Roles

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

```
┌──────────────────┐              ┌──────────────────┐
│ Medical Device   │              │    Medical       │
│   Reporter       │              │ Device Server    │
└──────────────────┘              └──────────────────┘
            \                         /
             \                       /
              ╭───────────────────╮
              │  Register Medical │
              │  Device [PCC-50]  │
              ╰───────────────────╯
```
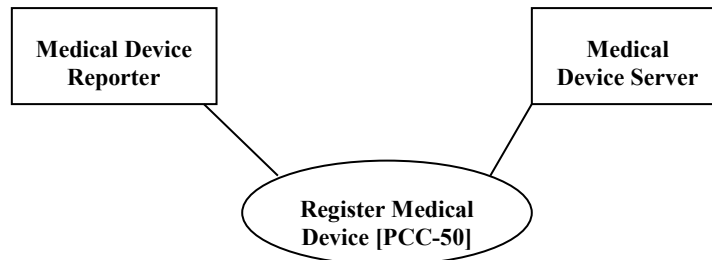
Figure 3.50.2-1: Use Case Diagram

880   **Table 3.50.2-1: Actor Roles**

Actor:	Medical Device Reporter
Role:	Initiates the device registration by sending a new device record.
Actor:	Medical Device Server
Role:	Receives, validates, and stores the information if it's valid. Otherwise the registration is rejected.

3.50.3 Referenced Standards

This transaction uses the HL7 FHIR Standard for Trial Use Release 3 (STU3) Device and Patient Resources.

3.50.4 Interaction Diagram

885 The following is a 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).
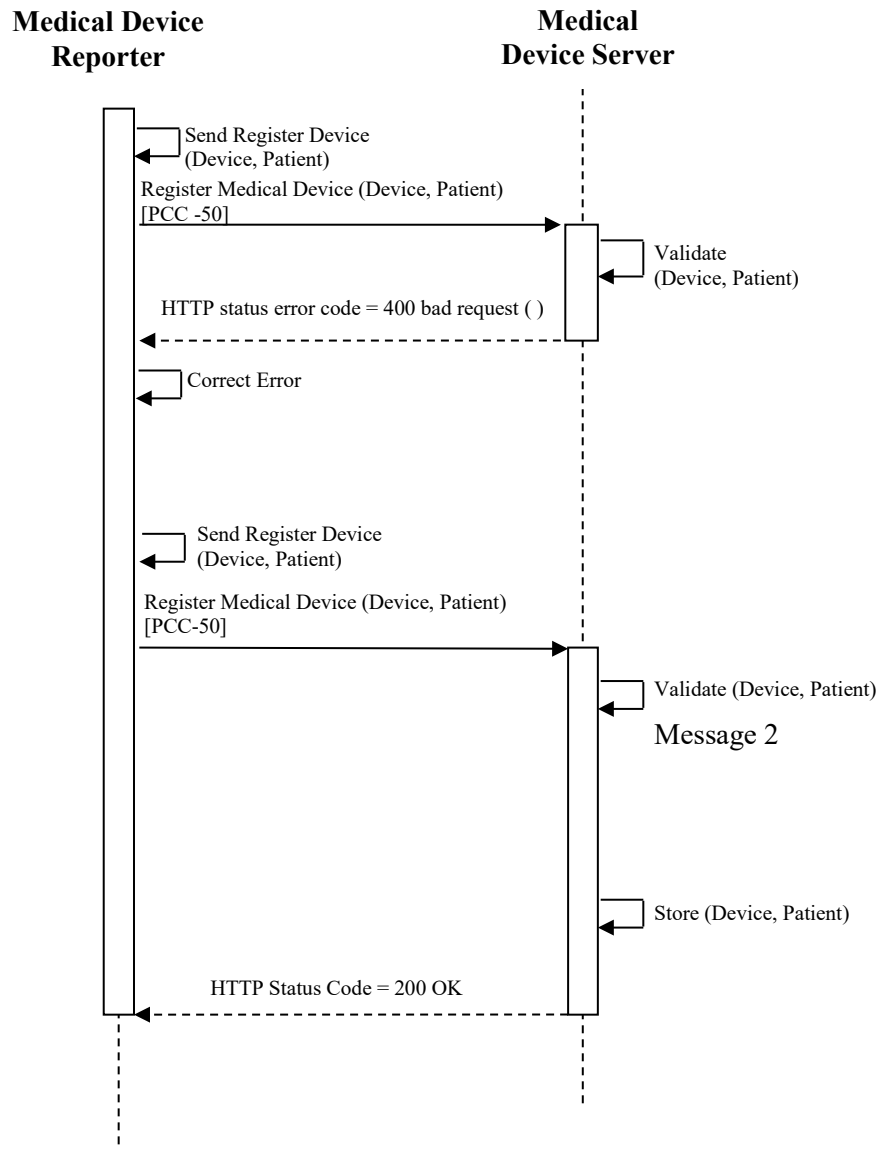
3.50.4.1 Register Medical Device

The Register Medical Device transaction sends the medical device data to the Medical Device
890 Server to support queries.

The following sections describe the details of this transaction.

3.50.4.1.1 Trigger Events

This transaction is triggered by clinicians at the point-of-care based on device identity and patient identity acquired using a barcode or rfid scanner. The information is entered in the medical device manager at the point-of-care. The business trigger could be the patient enters the perioperative department for a scheduled or emergent surgical procedure or at the start of a patient monitoring procedure when a patient is associated with a device.

3.50.4.1.2 Message Semantics

The message semantics for this transaction relies on Standard for Trial Use Release 3 (STU3) an HTTP or HTTPS PUT of a FHIR STU3 "Device" resource, as constrained by the Device content profile. HTTP PUT is preferred to HTTP POST because HTTP PUT will create or update a resource. It will place a resource on the server if there isn't one or it will modify the file on the server if there is one, whereas HTTP POST will only create a resource and expects the server to handle the request. Refer to HL7 FHIR https://www.hl7.org/fhir/http.html.The messages semantics for this transaction rely on STU3 Device Resource and may include a Patient Resource to specify the identity of the patient recorded at the point-of-care. See https://www.hl7.org/fhir/device.html.

3.50.4.1.3 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.

3.50.5 Security Considerations

For security considerations refer to Section X.5 Security Considerations in Volume 1.

3.51 Search Medical Device [PCC-51]

3.51.1 Scope

This transaction is intended to provide a synchronous query mechanism.

3.51.2 Actor Roles

The following diagram identifies the transaction and actors participating in this transaction.
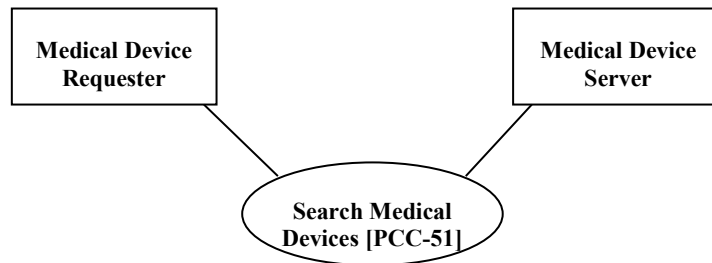
920

Figure 3.51.2-1: Use Case Diagram

Table 3.51.2-1: Actor Roles

Actor:	Medical Device Requester
Role:	Requests device records matching a specific set of criteria (i.e., search parameters).
Actor:	Medical Device Server
Role:	Receives the request, processes the search parameters and returns matching device records to the initiating actor.

3.51.3 Referenced Standards

925   This transaction used the HL7 FHIR Standard for Trial Use Release 3 (STU3) Device and Patient Resources.

3.51.4 Interaction Diagram

The following is a detailed description of the actors and transactions initiated.

Medical Device
Requester

Medical
Device Server

Create Device List ( )

Device Process

Search Medical Devices (Device Search
Parameter): Device [PCC-51]

Validate ( )

HTTP status error code = 400 bad request ( )

Correct Error

Device/Patient Process

Search Medical Devices (Device Search
Parameters): Device [PCC-51]

Validate ( )

Message 2

Query Repository

Device Bundle, HTTP Status Code =
200 OK

930

3.51.4.1 Search Medical Device

The Search Medical Device transaction sends a query to the Medical Device Server to support query the server for medical devices based on the devices UDI.

The following sections describe the details of this transaction.

935 **3.51.4.1.1 Trigger Events**

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

3.51.4.1.2 Message Semantics

The message semantics for this transaction relies on an HTTP or HTTPS GET of a Device
940 Resource, as constrained by this profile.

The semantics of a search/query focuses on the use of search criteria (i.e., search parameters). The search parameters could be sent by the initiating actor to the Medical Device Server. The Medical Device Server will return zero or more matching Device resources (in a bundle). See https://www.hl7.org/fhir/device.html.

945 **3.51.4.1.3 Expected Actions**

The Medical Device 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 Medical Device Server will return an empty set. Since the underlying standard uses HTTP, the sender needs to be able to handle HTTP error
950 codes. See https://www.hl7.org/fhir/http.html#operations.

3.51.5 Security Considerations

For security considerations refer to Section X.5 Security Considerations in Volume 1.

3.51.5.1 Security Audit Considerations

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

3.52 Start Point-of-Care Device Procedure [PCC-52]

3.52.1 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
960 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.

3.52.2 Actor Roles

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

965

Figure 3.52.2-1: Use Case Diagram

Table 3.52.2-1: Actor Roles

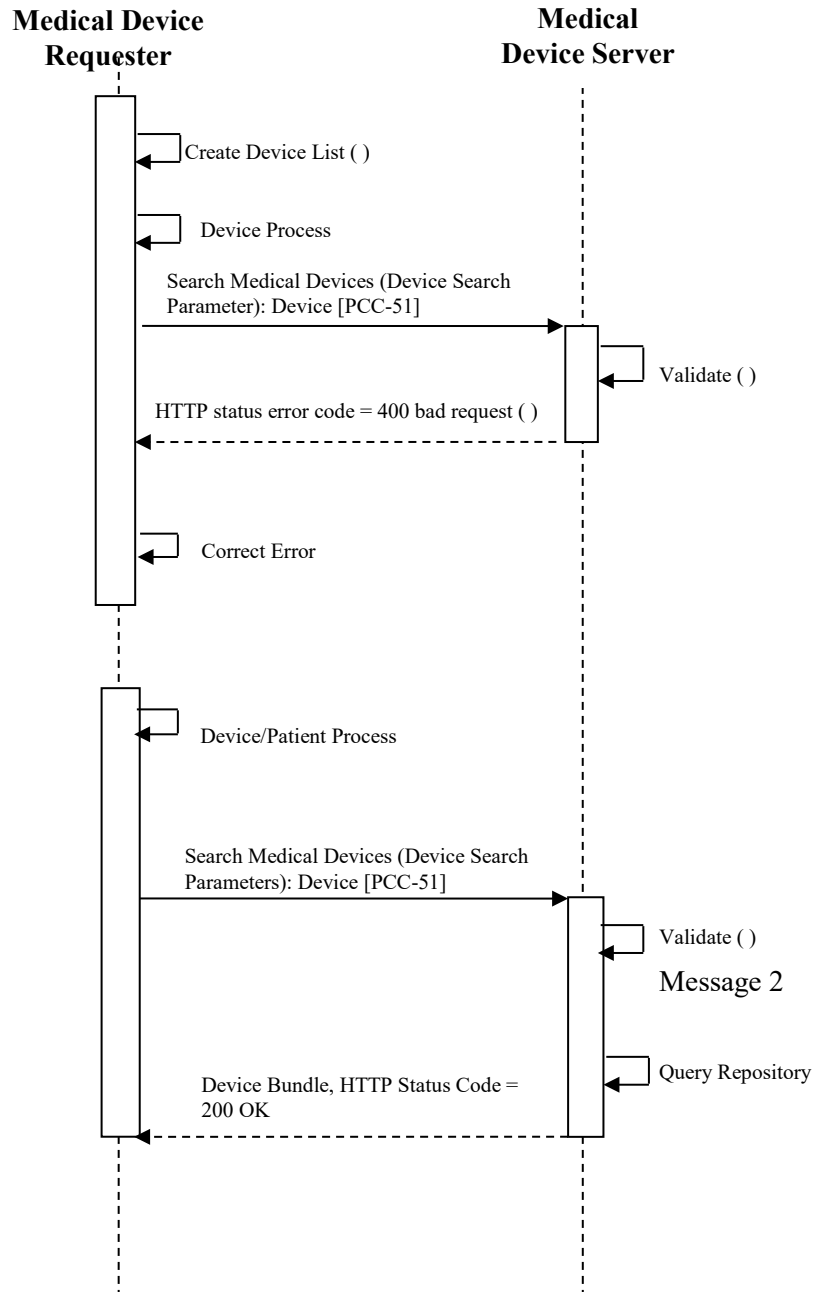| Actor:	Medical Device Reporter
Role:	Initiates the device registration by starting a new procedure at the point-of-care.
Actor:	Medical Device Server
Role:	Receives, validates, and stores the information if it's valid. If the information is not valid the registration is rejected. If the procedure record does not exist, a new record is added. If a procedure record exists, the record is updated.

3.52.3 Referenced Standards

970   This transaction uses HL7 FHIR Standard for Trial Use Release 3 (STU3) Procedure Resource,
SNOMED-CT, ICD-10-PCS, and CPT-4 procedure codes.

3.52.4 Interaction Diagram

The following is a 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).
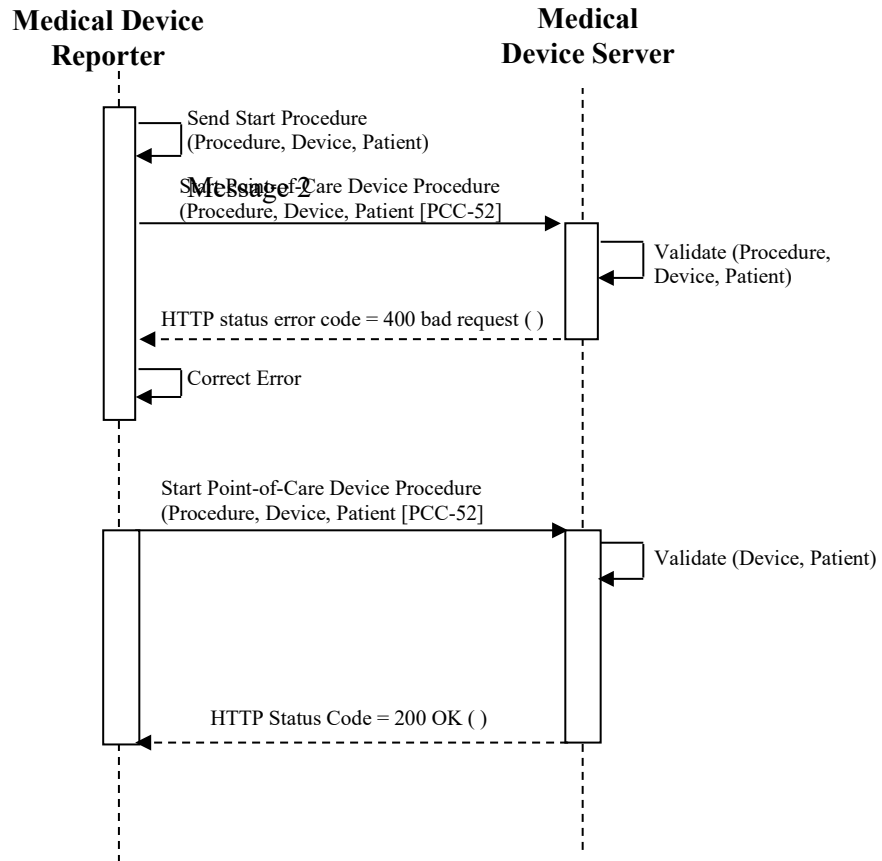
975

3.52.4.1 Start Point-of-Care Device Procedure

The Start Point-of-Care Device Procedure transaction sends UDI, procedure, and patient data to the Medical Device Server to support queries for medical devices based on the device's UDI used during the procedure performed.

980

3.52.4.1.1 Trigger Events

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

3.52.4.1.2 Message Semantics

985 The transaction cvonsist consists of a Procedure "create" operation using an HTTP/HTTPS PUT of a Procedure Resource, as constrained by this profile to specify a point-of-care procedure.

The semantics of a Start Point-of-Care Device Procedure focuses on the use of the FHIR Procedure Resource parameters. The Start Point-of-Care Device Procedure will register the Procedure specific parameter in the Medical Device Server for querying. See https://www.hl7.org/fhir/procedure.html.

3.52.4.1.3 Expected Actions

The Medical Device Reporter is intended to send a Procedure.status of "in-progress" to the Medical Device Server for storage. The Medical Device Server validates the information about the medical device's UDI, the referenced patient identity, and the Procedure prior to setting the Procedure.status.

3.52.5 Security Considerations

For security considerations refer to Section X.5 Security Considerations in Volume 1.

3.52.5.1 Security Audit Considerations

None, this transaction does not need to be audited as it is explicitly persisted by the server.
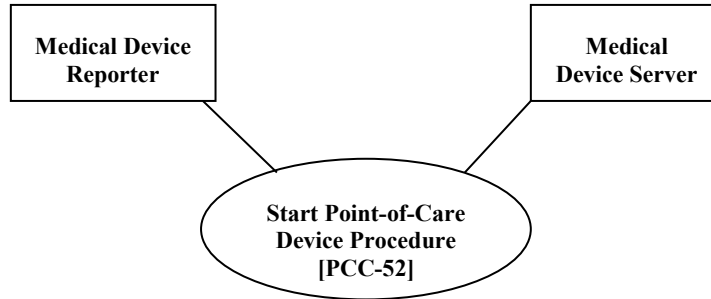
3.53 Complete Point-of-Care Device Procedure [PCC-53]

3.53.1 Scope

This transaction is intended to record information about the completion 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 used or implanted.

3.53.2 Actor Roles

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

Figure 3.53.2-1: Use Case Diagram

Table 3.53.2-1: Actor Roles

Actor:	Medical Device Reporter
Role:	Initiates the transaction to create/update a procedure record as end/completed.
Actor:	Medical Device Server
Role:	Receives, validates, and stores the information, if it's valid. If the information is not valid the request is rejected. If the procedure record does not exist, a new record is added. If a procedure record exists, the record is updated.

3.53.3 Referenced Standards

1015

This transaction uses HL7 FHIR Standard for Trial Use Release 3 (STU3) Procedure Resource, SNOMED-CT, ICD-10, and CPT-4 procedure codes.

3.53.4 Interaction Diagram

The following is a 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).
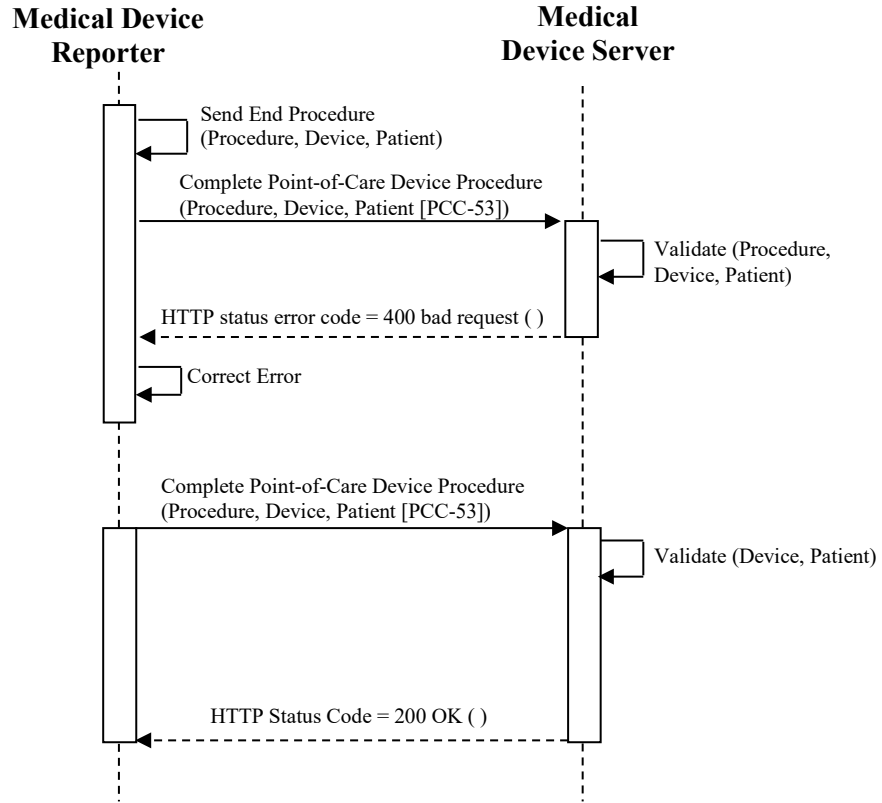
1020

3.53.4.1 Complete Point-of-Care Device Procedure

The Complete Point-of-Care Device Procedure transaction sends the updated procedure status
along with the medical devices UDI and patient data to the Medical Device Server to support
queries for medical devices based on the device's UDI or the procedure performed.

1025 #### 3.53.4.1.1 Trigger Events

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

3.53.4.1.2 Message Semantics

The transaction consists of updating a FHIR STU3 "Procedure" using HTTP/HTTPS PUT. The
1030 Procedure resource is constrained by the FHIR Procedure content profiles. The associated profile
specify data elements required to specify the completion of point-of-care procedure using a
FHIR Procedure. This transaction provides two content profile variations to specify the

completion of a patient monitoring session or implanting a new device: a "contained" reference to the Device resource or an external reference (see http://hl7.org/fhir/references.html).

1035 The FHIR Procedure Resource is used to specify the point-of-care procedure, whether it be a surgical, a monitoring, or a treatment procedure that was completed by a clinician at the point-of-care. The Procedure Resource may also be used to specify the associated patient diagnosis as the "reason" for the procedure (see http://hl7.org/fhir/procedure.html).

3.53.4.1.3 Expected Actions

1040 The Medical Device Reporter is intended to send a procedure status update of "completed" to the Medical Device Server for storage. The Medical Device Server validates the information about the medical device's UDI, the referenced patient identity, and the procedure prior to setting the procedure status.

3.53.5 Security Considerations

1045 For security considerations refer to Section X.5 Security Considerations in Volume 1.

3.53.5.1 Security Audit Considerations

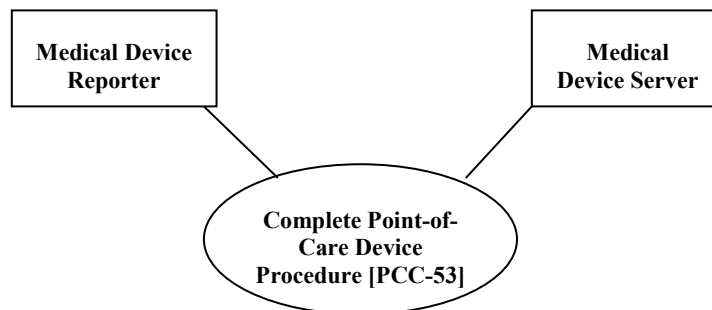None, these transactions do not need to be audited as they are explicitly persisted by the server.

3.54 Search Point-of-Care Device Procedures [PCC-54]

3.54.1 Scope

1050 This section describes the transaction used to query information about procedures performed at the point-of-care and reported from the point-of-care.

3.54.2 Actor Roles

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

1055
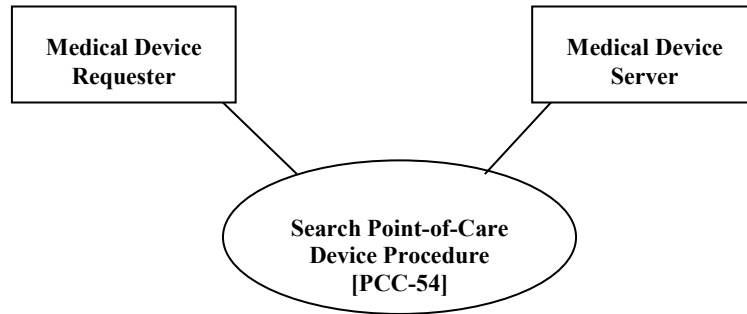
Figure 3.54.2-1: Use Case Diagram

Table 3.54.2-1: Actor Roles

Actor:	Medical Device Requester
Role:	Requests procedure records matching a specific set of criteria (i.e., search parameters).
Actor:	Medical Device Server
Role:	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.

1060

3.54.3 Referenced Standards

This transaction uses HL7 FHIR Standard for Trial Use Release 3 (STU3) Procedure Resource, SNOMED-CT, ICD-10, and CPT-4 codes.

3.54.4 Interaction Diagram

1065 The following is a 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).
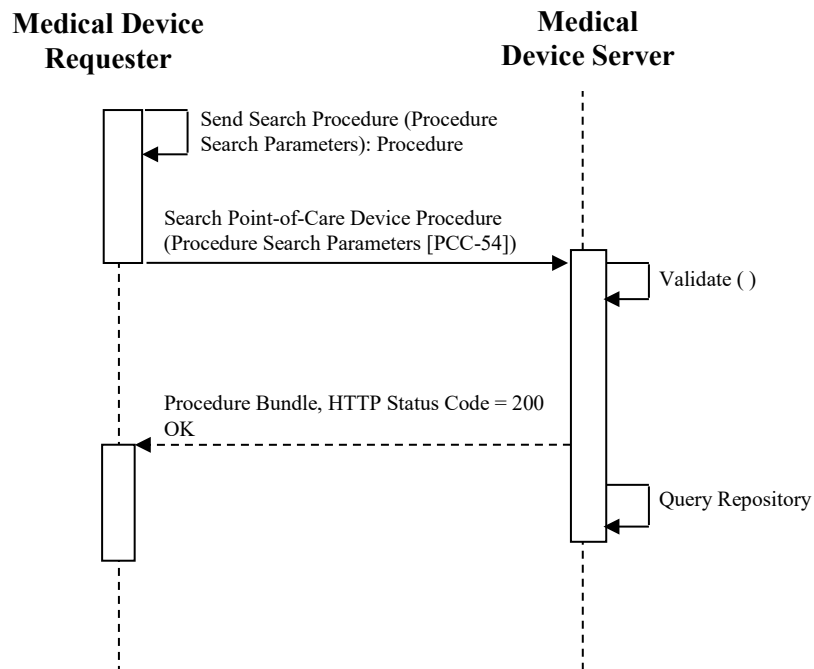
3.54.4.1 Search Point-of-Care Device Procedure

1070 The Search Point-of-Care Medical Device Procedure transaction sends a query from the Medical Device Requester to the Medical Device Server querying the server for medical devices, based on the medical devices UDI, associated to a procedure.

The following sections describe the details of this transaction.

3.54.4.1.1 Trigger Events

1075 This transaction can be invoked on-demand based on a user action, recall notice, or another type business trigger that requires specific medical device records.

3.54.4.1.2 Message Semantics

The transaction consists in FHIR Proecedure"search" using HTTP/HTTPS GET.

The semantics of this transaction refers to the search parameters supported by FHIR to search for Procedure Resources such as the associated diagnosis (i.e., Procedure.reasonCode or
1080 Procedure.reason) but the "search" operation may use the default search parameters specified by the FHIR STU3 specification: http://hl7.org/fhir/procedure.html.

3.54.4.1.3 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").

3.54.5 Security Considerations

For security considerations refer to Section X.5 Security Considerations in Volume 1.

3.54.5.1 Security Audit Considerations

None, this transaction does not need to be audited as they are explicitly persisted by the server.

Appendices

1090

None

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

None

1095

Volume 3 – Content Modules

5 Namespaces and Vocabularies

Add to Section 5 Namespaces and Vocabularies

Not applicable for this profile.

1100

Add to Section 5.1.1 IHE Format Codes

Not applicable for this profile.

Add to Section 5.1.2 IHE ActCode Vocabulary

1105   Not applicable for this profile.

Add to Section 5.1.3 IHE RoleCode Vocabulary

Not applicable for this profile.

6 Content Modules

6.3.1 CDA Document Content Modules

CDA Content Modules are not applicable to this HL7 FHIR Standard for Trial Use Release 3 (STU3) profile.

6.6 HL7 FHIR Content Modules

6.6.1 FHIR Resources

The following section describes the content profiles structure and built-in value sets used required to manage procedures records and medical device records (including implantables) using HL7 FHIR Standard for Trial Use Release 3 (STU).

This PMDT Profile requires creation/update of two resources:

- Procedure
- Device

This profile also references other resources:

- Patient: mandatory contextual for Procedure and Device
- Practitioner: optional
- Organization: optional reference

Mandatory data elements are identified by the "must support" ("S") conformance flag (see http://hl7.org/fhir/profiling.html).

6.6.1.1 FHIR Patient Resource

The patient information captured at the point-of-care may be very brief and include only one Patient.identifier instance. However, this information is sufficient to lookup the patient record using a "search" operation and retrieve an external reference or, alternatively, create "contained" Patient reference to convey the business identifier captured at the point of care using a barcode scanner

The following section describes the identifiers that may have been captured at the point-of-care (e.g., by scanning a barcoded wristband) and can be used to search and reference the Patient record using either a "contained" or externally-referenced patient logical identity metadata – the "id" element (see http://hl7.org/fhir/resource.html#metadata).

6.6.1.2 Referencing a FHIR Patient Resource

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

1140

Table 6.6.1.2-1: FHIR Patient Resource – Referencing Data Elements

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
identifier Identifier	S	[0..*]	The business identifier of the patient referenced by the Procedure or Device resource created or updated.	For this content 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. This information is validated at the point-of-care or perioperative by the clinician. If this information cannot be matched to a Patient resource, the "search" operation using this search parameter will not return any matches. Similarly if there are not Patient instances with tis

6.6.2 FHIR Device Resource Content Profile

The following section describes the structure and built-in value sets used to describe a device
record using HL7 FHIR Standard for Trial Use Release 3 (STU3).

1145 ### 6.6.2.1 FHIR Device Profile Definition

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
1150 for healthcare and public health. Non-medical devices may include items such as a machine,
cellphone, computer, application, etc.

Table 6.6.2.1-1: FHIR Device Profile Definition

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
identifier	S	[1..**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. The Device.identifer will be used for serial number which is a component of the production identifier (PI), a conditional, variable portion of a UDI. The identifier.type code should be set to "SNO" (Serial Number) and the system left empty. The SNO can be representing the Distinct Identification Code (DIC), based on the UDI labeler, for a medical devices containing HCT/Ps.	The device identifier is mandatory for this profile
udi Device.Udi	S	[**1**..1]	[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)	This profile is constraining the identifier from zero to one, to one to one to indicate there is one unique device identifier per each medical device.
status FHIRDeviceStatus		[0..1]	Status of the Device availability. The default value is "active".	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
type CodeableConcept		[0..0]	Code or identifier to identify a kind of device. This may be the GMDN or SNOMED-CT concept.	
lotNumber string	S	[0..1]	Lot number assigned by the manufacturer. This data element should be parsed from the UDI, if supported.	
manufacturer string	S	[0..0]	A name of the manufacturer.	
Manufacture0ate dateTime	S	[0..1]	The date and time when the device was manufactured. This data element should be parsed from the UDI, if supported.	
expirationDate dateTime	S	[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		[0..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		[0..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		[0..1]	Patient information, If the device is affixed to a person.	
owner Reference		[0..1]	An organization that is responsible for the provision and ongoing maintenance of the device.	
contact ContactPoint		[0..*]	Contact details for an organization or a particular human that is responsible for the device.	
location Reference		[0..1]	The place where the device can be found.	
url uri		[0..0]	A network address on which the device may be contacted directly.	
note Annotation		[0..*]	Descriptive information, usage information or implantation information that is not captured in an existing element.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
Safety CodeableConcept		[0..1]	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.	

1155 A FHIR StructureDefinition can be found in implementation materials – see ITI TF-2x: Appendix W for instructions on how to get to the implementation materials.

The FHIR Device Profile Definition uses the UDI structure described below:

Table 6.6.2.1-2: FHIR Device.UDI Structure

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
deviceIdentifier string		[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		[0..1]	Status of the Device availability. The default value is "active".	
jurisdiction uri		[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	S	[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.	If the UDI was entered manual this data element must be supported.

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
carrierAIDC base64Binary	S	[0..1]	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.	If the UDI was acquired automatically this data element must be supported.
issuer uri	S	[1..1]	Organization that is charged with issuing UDIs for devices. For example, the US FDA issuers include : 1) GS1: http://hl7.org/fhir/NamingSystem/gs1-di2) 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	This profile is constraining the issuer uri from zero to one, to one to one to indicate there is one unique device identifier in the labeler's format for each medical device.
entryType DIEntryType	S	[0..1]	A coded entry to indicate how the data was entered.	This profile is constraining the entryType from zero to one, to one to one to indicate there is one unique device identifier for each medical device.

A FHIR StructureDefinition can be found in implementation materials – see ITI TF-2x:
1160   Appendix W for instructions on how to get to the implementation materials.

6.6.2.1.1 FHIR Device.Status Value Set

Values allowed for Device.Status are listed in the table below:

Table 6.6.2.1.1-1: FHIR Device.Status Value Set

Code	Display	Definition
active	Active	The Device is available for use. Note: This means for *implanted devices* the device is implanted in the patient.
inactive	Inactive	The Device is no longer available for use (e.g., lost, expired, damaged). Note: This means for *implanted devices* the device has been removed from the patient.
entered-in-error	Entered in Error	The Device was entered in error and voided.
unknown	Unknown	The status of the device has not been determined.

6.6.2.1.2 FHIR UDI.Entry.Type Value Set

Values allowed for UDI Device.Entry.Type are listed in the table below:

Table 6.6.2.1.2-1: FHIR UDI.Entry.Type Value Set

Code	Display	Definition
barcode	BarCode	A Barcode scanner captured the data from the device label.
rfid	RFID	An RFID chip reader captured the data from the device label.
manual	Manual	The data was read from the label by a person and manually entered. (e.g., via a keyboard).
card	Card	The data originated from a patient's implant card and read by an operator.
self-reported	Self Reported	The data originated from a patient source and not directly scanned or read from a label or card.
unknown	Unknown	The method of data capture has not been determined.

6.6.2.2 FHIR Device Search Parameters

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

The lot number and serial number could be listed as Device.identifiers, therefore the "identifier" criterion could be used to search all the devices that match a serial or lot number.

Table 6.6.2.2-1: FHIR Device Search Parameters

Search Parameter	Notes
device-name string	It matches Device.udi.name or Device.type.coding.display or Device.type.text. (Device.udi.name | Device.type.text | Device.type.coding.display)

Search Parameter	Notes
identifier token	Instance id from manufacturer, owner, and others - it may be used to represent the serial number of a device (Device.identifier). The Device.identifer will be used for serial number which is a component of the production identifier (PI), a conditional, variable portion of a UDI. The identifier.type code should be set to "SNO" (Serial Number) and the system left empty.
location reference	A location, where the device is found (Device.location).
manufacturer string	The manufacturer of the device (Device.manufacturer).
model string	The model of the device (Device.model).
organization reference	The organization responsible for the device (Device.owner - Organization).
patient reference	Patient information, if the resource is affixed to a person (Device.patient - Patient).
status token	It matches the Device.status from (active | inactive | entered-in-error | unknown).
type token	The type of the device - it matches Device.type.
udi-carrier string	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	The udi Device Identifier (DI) matches the Device.udi.deviceIdentifier data element.
url uri	Network address to contact device; it matches Device.url.

1175

6.6.3 FHIR Procedure Profiles

The following data elements are specified for the transactions start and complete a medical device procedure and search parameters by describing how the HL7 FHIR Procedure resource is used to specify a new "in-progress" point-of-care procedure. The following section describes the 1180 structure and built-in value sets used to describe a procedure record using HL7 FHIR Standard for Trial Use Release 3 (STU3).

6.6.3.1 FHIR "Start Medical Device Monitoring Procedure" Profile

The following are data structures required to record a medical device monitoring procedure that was initiated by a clinician at the point-of-care. The medical device is a contained element in the 1185 Procedure resource. The subject element is used to record the patient identity acquired at the point-of-care.

Note that the implantable device procedure does not require a start and end transaction and they can be easily document in one transactions.

The profile below specifies the content of transaction used to initiate a monitoring session using 1190 a device capable of sending status or measurements:

Table 6.6.3.1-1: FHIR "Start Medical Device Monitoring Procedure" Profile

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
identifier Identifier		[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		[0...**0**]	A protocol, guideline, orderset or other definition that was adhered to in whole or in part by this procedure.	
basedOn Reference		[0...**0**]	A reference to a resource that contains details of the request for this procedure.	
partOf Reference		[0...**0**]	A larger event of which this particular procedure is a component or step.	
status EventStatus		[1...**1**]	A code specifying the state of the procedure.	The status is set to "in-progress" by this transaction.
notDone boolean		[0...1]	Set this to true if the record is saying that the procedure was NOT performed.	
notDoneReason CodeableConcept		[0...**0**]	A code indicating why the procedure was not performed.	
category CodeableConcept		[0...1]	A code that classifies the procedure for searching, sorting and display purposes (e.g., "Surgical Procedure").	
code CodeableConcept	S	[**1**...1]	The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g., "Laparoscopic Appendectomy").	
subject Reference	S	[1...1]	The person, animal or group on which the procedure was performed.	
context Reference		[0...1]	The encounter during which the procedure was performed.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
performedPeriod Period	S	[**1**...1]	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		[0...*]	Limited to 'real' people rather than equipment.	
location Reference		[0...1]	The location where the procedure actually happened, e.g., a newborn at home, a tracheostomy at a restaurant.	
reasonCode CodeableConcept	S	[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.	
reasonReference Reference	S	[0...*]	The condition that is the reason why the procedure was performed.	
bodySite CodeableConcept		[0...*]	Detailed and structured anatomical location information. Multiple locations are allowed, e.g., multiple punch biopsies of a lesion.	
outcome CodeableConcept		[0...**0**]	The outcome (results) of the procedure – was the procedure successful, unsuccessful, etc.	
report Reference		[0...**0**]	This could be a histology result, pathology report, surgical report, etc.	
complication CodeableConcept		[0...**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		[0...**0**]	Any complications that occurred during the procedure, or in the immediate post-performance period.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
followUp CodeableConcept		[0...**0**]	If the procedure required specific follow up - e.g., removal of sutures. The follow-up may be represented as a simple note, or could potentially be more complex in which case the CarePlan resource can be used.	
note Annotation		[0...**0**]	Any other notes about the procedure, e.g., the operative notes, nurses note.	
focalDevice Procedure.FocalDevice	S	[**1**...*]	A device that is implanted, removed or otherwise manipulated (e.g., calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure.	
usedReference Reference		[0...*]	Identifies medications, devices and any other substance used as part of the procedure.	
usedCode CodeableConcept		[0...*]	Identifies coded items that were used as part of the procedure.	

A FHIR StructureDefinition can be found in implementation materials – see ITI TF-2x: Appendix W for instructions on how to get to the implementation materials.

6.6.3.2 FHIR Complete Medical Device Monitoring Procedure Profile

1195 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.

Table 6.6.3.2-1: FHIR Complete Medical Device Monitoring Procedure Profile

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
identifier Identifier		[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		[0...**0**]	A protocol, guideline, orderset or other definition that was adhered to in whole or in part by this procedure.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
basedOn Reference		[0...**0**]	A reference to a resource that contains details of the request for this procedure.	
partOf Reference		[0...**0**]	A larger event of which this particular procedure is a component or step.	
status EventStatus		[1...**1**]	A code specifying the state of the procedure.	The status is set to "**completed**" by this transaction.
notDone boolean		[0...1]	Set this to true if the record is saying that the procedure was NOT performed.	
notDoneReason CodeableConcept		[0...0]	A code indicating why the procedure was not performed.	
category CodeableConcept		[0...1]	A code that classifies the procedure for searching, sorting and display purposes (e.g., "Surgical Procedure").	
code CodeableConcept	S	[**1**...1]	The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g., "Laparoscopic Appendectomy").	
subject Reference	S	[1...1]	The person, animal or group on which the procedure was performed.	
context Reference		[0...1]	The encounter during which the procedure was performed.	
performedPeriod Period	S	[1...1]	The period the procedure was performed.	In this transaction the "end" is set to the date/time the monitoring procedure was completed.
performer Procedure.Performer		[0...*]	Limited to 'real' people rather than equipment.	
location Reference		[0...1]	The location where the procedure actually happened, e.g., a newborn at home, a tracheostomy at a restaurant.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
reasonCode CodeableConcept	S	[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.	
reasonReference Reference	S	[0...*]	The condition that is the reason why the procedure was performed.	
bodySite CodeableConcept		[0...*]	Detailed and structured anatomical location information. Multiple locations are allowed, e.g., multiple punch biopsies of a lesion.	
outcome CodeableConcept		[0...0]	The outcome (results) of the procedure – was the procedure successful, unsuccessful, etc.	
report Reference		[0...0]	This could be a histology result, pathology report, surgical report, etc.	
complication CodeableConcept		[0...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		[0...0]	Any complications that occurred during the procedure, or in the immediate post-performance period.	
followUp CodeableConcept		[0...0]	If the procedure required specific follow up - e.g., removal of sutures. The follow-up may be represented as a simple note, or could potentially be more complex in which case the CarePlan resource can be used.	
note Annotation		[0...0]	Any other notes about the procedure, e.g., the operative notes, nurses note.	
focalDevice Procedure.FocalDevice	S	[1...*]	A device that is implanted, removed or otherwise manipulated (e.g., calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure.	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
usedReference Reference		[0...*]	Identifies medications, devices and any other substance used as part of the procedure.	
usedCode CodeableConcept		[0...*]	Identifies coded items that were used as part of the procedure.	

1200 A FHIR StructureDefinition can be found in implementation materials – see ITI TF-2x: Appendix W for instructions on how to get to the implementation materials.

6.6.3.3 FHIR Complete Implantable Medical Device Procedure Profile

This profile shows how a FHIR Procedure resource can be used to specify when a device 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).

1205 The following profile constrains "FHIR Complete Medical Device Monitoring Procedure Reference Concepts" by specifying a simple date of the procedure for future reference rather than capturing the duration. The performedDateTime date is used specify when an implantable device was associated with a patient.

Table 6.6.3.3-1: FHIR Complete Implantable Medical Device Procedure Profile

Name	Flag	Cardinality	Description & Constraints	Comments
performedDateTime dateTime	S	**[1...1]**	The date (time) the 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.	

1210 ### 6.6.3.3.1 FHIR 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.

Table 6.6.3.3.1-1: FHIR Procedure.FocalDevice

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
action CodeableConcept		[0..1]	The kind of change that happened to the device during the procedure.	
manipulated Reference		[1..1]	The device that was manipulated (changed) during the procedure. This is a reference to a registered device (i.e., a Device resource) that was	

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
			created using Register Medical Device [PCC 50].)	

1215 6.6.3.3.2 FHIR Procedure.Preformer

This is the individuals who participated the procedure and the role they performed during it.

Table 6.6.3.3.2-1: FHIR Procedure.Performer

Name	Conformance Flag	Cardinality	Descriptions & Constraints	Comments
role CodeableConcept		[0..1]	For example: surgeon, anesthesiologist, anesthetist, neurosurgeon, etc.	
actor Reference		[1..1]	The practitioner who was involved in the procedure.	
onBehalfOf Reference		[0..1]	Organization the device or practitioner was acting on behalf of.	

6.6.3.4 FHIR Point-of-Care "Procedure Search" Parameters

1220 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) is not available as search criteria.

Table 6.6.3.4-1: FHIR Point-of-Care "Procedure Search" Parameters

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

1225

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

None

1230