

Integrating the Healthcare Enterprise



**IHE Patient Care Device
Technical Framework Supplement**

**Personal Health Device Observation Upload
(POU)**

HL7[®] FHIR[®] R4

Using Resources at FMM Level 2 and Normative

Revision 1.0 – Draft for Public Comment

Date: December 6, 2019
Author: PCD Technical Committee
Email: pcd@ihe.net

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

Foreword

30 This is a supplement to the IHE Patient Care Devices Technical Framework V9.0. 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 December 6, 2019 for public comment. Comments are invited and may be submitted at http://www.ihe.net/PCD_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be
35 received by January 5, 2020.

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.

<i>Amend Section X.X by the following:</i>
--

40 Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold-strikethrough~~**. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

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

Information about the IHE Patient Care Device domain can be found at 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>.

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

CONTENTS

55	Introduction to this Supplement.....	5
	Open Issues and Questions	6
	Closed Issues	7
	IHE Technical Frameworks General Introduction.....	8
9	Copyright Licenses.....	8
60	9.1 Copyright of Base Standards	8
	9.1.1 DICOM (Digital Imaging and Communications in Medicine).....	8
	9.1.2 HL7 (Health Level Seven).....	8
	9.1.3 LOINC (Logical Observation Identifiers Names and Codes)	8
	9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms).....	9
65	10 Trademark	9
	IHE Technical Frameworks General Introduction Appendices.....	10
	Appendix A – Actor Summary Definitions	10
	Appendix B – Transaction Summary Definitions.....	10
	Appendix D – Glossary.....	11
70	Volume 1 – Profiles	13
	Copyright Licenses.....	13
	Domain-specific additions	13
	X Personal Health Device Observation Upload (POU) Profile.....	14
	X.1 POU Actors, IHE Transactions, and Content Modules.....	14
75	X.1.1 Actor Descriptions and Actor Profile Requirements.....	17
	X.1.1.1 Device Observation Reporter	18
	X.1.1.2 Device Observation Consumer	19
	X.2 POU Actor Transaction Options	19
	X.3 POU Required Actor Groupings	19
80	X.4 POU Overview	20
	X.4.1 Concepts	21
	X.4.2 Use Cases	22
	X.4.2.1 Use Case #1: Chronic Disease Management.....	22
	X.4.2.2 Use Case #2: Post-Operative Recovery.....	24
85	X.5 POU Security Considerations	25
	X.6 POU Cross Profile Considerations.....	26
	Appendices to Volume 1.....	27
	Volume 2 – Transactions	28
	3.xx PHD-xx Communicate FHIR Data Transaction	28
90	3.xx.1 Scope	28
	3.xx.2 Actor Roles.....	28
	3.xx.3 Referenced Standards	29
	3.xx.4 Messages	29
	3.xx.4.1 Communicate FHIR Data.....	30
95	3.xx.4.2 Acknowledgement.....	32

	3.xx.5 Security Considerations.....	32
	3.xx.5.1 Security Audit Considerations.....	32
	3.xx.5.2 Device Observation Reporter Specific Security Considerations.....	32
	3.xx.5.3 Device Observation Consumer Specific Security Considerations	33
100	3.yy PHD-xx Communicate FHIR Data RESTful FHIR API Transaction.....	33
	3.yy.1 Scope	33
	3.yy.2 Actor Roles.....	33
	3.yy.3 Referenced Standards	34
	3.yy.4 Messages	34
105	3.yy.4.1 Communicate FHIR Data RESTful FHIR API	35
	3.yy.4.2 Acknowledgement.....	37
	3.yy.5 Security Considerations.....	38
	3.yy.5.1 Security Audit Considerations.....	38
	3.yy.5.2 Device Observation Reporter Specific Security Considerations.....	38
110	3.yy.5.3 Device Observation Consumer Specific Security Considerations	38
	Appendices to Volume 2.....	39
	Appendix A – POU Usage of FHIR Resource and RESTful FHIR API.....	40
	A.1 PhdPatient Resource.....	40
	A.2 PHD Device Resource.....	41
115	A.3 PHG Device Resource.....	41
	A.4 PHD Base Observation Profile.....	41
	A.5 PHD Numeric Observation Resource	42
	A.6 PHD Compound Numeric Observation Resource.....	42
	A.7 PHD Coded Enumeration Observation Resource	42
120	A.8 PHD Bits Enumeration Observation Resource	42
	A.9 PHD String Enumeration Observation Resource	43
	A.10 Phd Rtsa Observation Resource	43
	A.11 PHD Coincident Time Stamp Observation Resource	43
	A.12 Profiled FHIR Resources Personal Health Device Implementation Guide Links	43
125	A.13 Referenced Standards.....	45
	Volume 2 Namespace Additions	45
	Volume 3 – Content Modules.....	46
	Appendices to Volume 3.....	47
	Volume 3 Namespace Additions	47
130		

Introduction to this Supplement

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE domain determines that an emerging standard has high likelihood of industry adoption, and the standard offers significant benefits for the use cases it is attempting to address, the domain may develop IHE profiles based on such a standard. During Trial Implementation, the IHE domain will update and republish the IHE profile as the underlying standard evolves.

Product implementations and site deployments may need to be updated in order for them to remain interoperable and conformant with an updated IHE profile.

This POU Profile is based on Release 4 of the emerging HL7^{®1} FHIR^{®2} specification. HL7 describes FHIR Change Management and Versioning at <https://www.hl7.org/fhir/versions.html>.

HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through N (Normative). See <http://hl7.org/fhir/versions.html#maturity>.

The FMM levels for FHIR content used in this profile are:

FHIR Content (Resources, ValueSets, etc.)	FMM Level
Patient	N
Device	2
Observation	N
Bundle	N
PHD-IG-defined Value Sets	
CodeableConcept11073MDC	
Quantity11073MDC	
Range11073MDC	
String11073MDC	
MDCNotObject	
ASN1Attribute	
ASN1Measurement	
PHD-IG-defined Code System	
ContinuaDeviceIdentifiers	
ASN1ToHL7	
ContinuaHFS	
ContinuaPHD	
PoCD-IG-defined Code System	
measurement-status	

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

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

This supplement describes a standardized means of reporting measurements taken by Personal Healthcare devices as FHIR resources. This supplement does not specify how these measurements are obtained.

- 150 The FHIR representation of the measurement data follows the FHIR Personal Health Device Implementation Guide (PHD IG). The PHD IG uses one code system defined by the FHIR Point of Care Device Implementation Guide (PoCD IG).

Open Issues and Questions

Agreed upon change in Wed meeting 10/30/2019

Content Creator and Content Sharing to become a PCD transaction (name unknown)

- 155 Existing FHIR transaction to become a PCD transaction (name unknown)

Administrative/organizational leaders to communicate with PCC about transaction/actor ‘releases’

- 160 Additional actions: Due to the overloading of the words profile and transaction, I have used POU and avoided the use of the word profile when representing the POU; ‘FHIR’ profile is used to designate the FHIR usage. For transaction, the word is prefixed by IHE or FHIR unless obvious from the context. This additional text can sometimes be cumbersome but it is at least unambiguous.

- 165 The POU Profile is new. It is based upon the PCC Remote Patient Monitoring Profile.. The RPM Profile included upload transactions using SAML-authenticated web services and an OAuth-authenticated POST of [PCD-01] data as well as a Content creator generating a PHMR CDA document. In this profile, these RPM transactions and the PHMR Content Creator have been removed in favor of supporting FHIR transactions only. The rationale is to reduce complexity and the lack of adoption of the existing transactions and the PHMR. FHIR standards (data representation, exchanges, etc.) , supporting tools, including functional servers, are available and free and it is felt that those features will encourage adoption of this profile. It is assumed that this
- 170 profile will be part of care plans and other profiles that require PHD data as FHIR resources.

- 175 If there is demand for upload in [PCD-01] form, it is a simple step to replace the FHIR Bundle in one of the two FHIR upload transactions with a [PCD-01] message. If there is demand for the PHMR, restoring the PHMR Content module in this document is a small task; however, creating the PHMR and supporting the XDS.b transactions over web services remain a complex implementation task.

In addition, the transactions between the PHD and the Personal Health Gateway (PHG) have been removed. This profile only specifies an output; it does not specify how the PHD data is obtained.

- 180 IHE transaction numbering (as of yet unspecified):

- Communicate FHIR Data [PCD-xx]
- Communicate FHIR Data RESTful FHIR API [PCD-yy]

Closed Issues

None

185 IHE Technical Frameworks General Introduction

The [IHE Technical Framework General Introduction](#) is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

190 IHE International hereby grants to each Member Organization, and to any other user of these documents, an irrevocable, worldwide, perpetual, royalty-free, nontransferable, nonexclusive, non-sublicensable license under its copyrights in any IHE profiles and Technical Framework documents, as well as any additional copyrighted materials that will be owned by IHE International and will be made available for use by Member Organizations, to reproduce and
195 distribute (in any and all print, electronic or other means of reproduction, storage or transmission) such IHE Technical Documents.

The licenses covered by this Copyright License are only to those copyrights owned or controlled by IHE International itself. If parts of the Technical Framework are included in products that also include materials owned or controlled by other parties, licenses to use those products are beyond
200 the scope of this IHE document and would have to be obtained from that other party.

9.1 Copyright of Base Standards

IHE technical documents refer to and make use of a number of standards developed and published by several standards development organizations. All rights for their respective base standards are reserved by these organizations. This agreement does not supersede any copyright
205 provisions applicable to such base standards. Copyright license information for frequently referenced base standards is provided below.

9.1.1 DICOM (Digital Imaging and Communications in Medicine)

DICOM[®] is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

210 9.1.2 HL7 (Health Level Seven)

HL7[®], Health Level Seven[®], CDA[®], FHIR[®], and the FHIR [FLAME DESIGN][®] are registered trademarks of Health Level Seven International.

Health Level Seven, Inc. has granted permission to IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights
215 reserved. Material drawn from these documents is credited where used.

9.1.3 LOINC (Logical Observation Identifiers Names and Codes)

LOINC[®] is registered United States trademarks of Regenstrief Institute, Inc.

9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms)

220 Some IHE Profiles incorporate SNOMED® CT, which is used by permission of the International
Health Terminology Standards Development Organisation. SNOMED CT® was originally
created by the College of American Pathologists. SNOMED CT is a registered trademark of the
International Health Terminology Standards Development Organisation, all rights reserved.

10 Trademark

225 IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems
Society in the United States and trademarks of IHE Europe in the European Community. They
may only be used with the written consent of the IHE International Board Operations
Committee, which may be given to a Member Organization in broad terms for any use that is
consistent with the IHE mission and operating principles.

230 IHE Technical Frameworks General Introduction Appendices

The [IHE Technical Framework General Introduction Appendices](#) are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

235 *Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices the IHE Technical Frameworks General Introduction located [here](#).*

240 **NEW: REQUIRED APPROVAL OF ACTORS, TRANSACTIONS and TERMS** - To avoid duplication and ensure consistency across domains, all **new or modified** actors, transactions and glossary terms need approval by IHE's Domain Coordination Committee (DCC) before they are published in a trial implementation supplement. Please see [this Wiki page](#) for additional guidance and links to the forms for approval submission.

245 Appendix A – Actor Summary Definitions

Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:

No new actors.

250

New (or modified) Actor Name	Definition
<Verb-Noun format (e.g., Store Image, Register Document Set)>	If this is a modified actor description, add the original description and use <u>bold underline</u> to indicate where the amendment adds text and bold strikethrough where the amendment removes text

Appendix B – Transaction Summary Definitions

Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:

255

New (or modified) Transaction Name and Number	Definition
Communicate FHIR Data [PCD-xx]	Communicates a complete FHIR Bundle to the appropriate consumer over RESTful POST transports, secured using TLS, and authenticated using OAuth2 bearer tokens.
Communicate FHIR Data RESTful FHIR API [PCD-yy]	Delivers FHIR resources to a FHIR server using the RESTful FHIR API, is secured using TLS, and authenticated using OAuth2 bearer tokens.

Appendix D – Glossary

Add the following **new or updated glossary** terms to the IHE Technical Frameworks General Introduction Appendix D.

260

New (or modified) Glossary Term	Definition	Acronym
Application Hosting Device	Old name for a PCHA PHG, now deprecated.	AHD
Complete FHIR Bundle	In the POU Profile, the complete FHIR Bundle is a transaction Bundle whose resources contain no references to resources external to the Bundle. The transaction Bundle shall also be able to be uploaded to a RESTful FHIR server by this profile's Content Creator.	
FHIR profile	Profiles as used and defined by FHIR. The 'FHIR' is used to distinguish between the term 'profile' as used in FHIR versus that used in IHE.	
FHIR transaction	Transaction defined by FHIR. The 'FHIR' is used to distinguish between the term 'transaction' as used in RESTful FHIR versus that used in IHE.	
IEEE-11073-20601	Optimized Exchange Protocol. A transport-agnostic packet-based protocol for exchanging health data. Currently used only over local transports (PHCD USB, ZigBee, HDP Bluetooth, NFC)	
IHE transaction	Transaction defined by IHE. The 'IHE' is used to distinguish between the term 'transaction' as used in IHE versus that used in FHIR.	
Personal Connected Health Alliance	A membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies.	PCHA
PCHA Data	Data from PHD devices that contains sufficient information to generate the non-demographic components of, and time requirements for, the generated FHIR resources.	
Personal Health Device	Personal health devices include pedometers glucometers, blood pressure cuffs, thermometers, etc.	PHD

New (or modified) Glossary Term	Definition	Acronym
Personal Health Gateway	Collects PHD data and delivers it to, often remotely located, destinations. Formerly known as an AHD.	PHG
RESTful POST	Terminology used by the POU to indicate the use of only the RESTful create (HTTP POST) operation of the data to a server. It is not fully 'RESTful' in the sense that no further RESTful exchanges or RESTful hierarchies need to be supported by the server. An important aspect of the use of this term in the POU is that there is no assumed persistence of the uploaded data.	
RESTful FHIR	Terminology used by the FHIR standard http://build.fhir.org/conformance-rules.html to indicate compliance to the FHIR RESTful API and FHIR resource model. An additional important aspect of the use of this term in the POU is that the FHIR server persists uploaded resources and thus once a resource is uploaded, it generally does not need to be uploaded again	

Volume 1 – Profiles

Copyright Licenses

<i>Add the following to the IHE Technical Frameworks General Introduction Copyright section:</i>
--

270 NA

Domain-specific additions

NA

275

<i>Add Section X</i>

X Personal Health Device Observation Upload (POU) Profile

280 The Personal Health Device Observation Upload Profile describes a standardized means of representing personal healthcare device (PHD) data as FHIR resources. PHDs are typically used by patients at home. The POU is anticipated to supplement any IHE profile or activity requiring a patient to use PHDs.

285 Examples of PHDs are weight scales, pulse oximeters, blood pressure cuffs, and glucose monitors. PHDs tend to be portable, often run on batteries, and have limited computational resources. In that respect, these devices typically use low footprint binary protocols that connect to a local data collector using a variety of personal networking protocols, such as Bluetooth®, ZigBee®, and USB connections. They may not even have a clock to keep track of the date and time a measurement is taken.

290 Collectors are applications built into devices such as a set-top box attached to a cable or local area network, or a mobile device such as a cellular phone, tablet or personal computer. These applications collect data from one or more PHDs and send them on to the healthcare provider either directly or via a health information exchange.

However, certain types of sensors are starting to be incorporated on mobile phones and related wearables allowing the merger of the PHD and collector unit into a single entity. Such devices may both take the measurement and create FHIR resources from it.

295 The POU does not specify how the PHD data is obtained, but only how it is represented in FHIR and transmitted to some endpoint where it is accessible for use. The transmission to this endpoint may involve ‘health information exchanges’ or it may be direct.

300 Health information exchanges in this context are servers used to coordinate and manage large numbers of remotely located collectors and transform and transmit the collected data into the desired content for the consumer. Since the health information exchange is not required to persist data in the management and translation process it reduces the possibility of exposing personal health information.

X.1 POU Actors, IHE Transactions, and Content Modules

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

310 The intent of the POU is to standardize the representation of PHD observations and the IHE transactions necessary to get the PHD observations to a health care service provider. This standardization ensures plug and play operation for each component participating in the POU from the generator of the FHIR resources to the EHR document reader used by the health care provider.

The POU Profile uses the following actors:

1. Device Observation Reporter that generates a *complete FHIR Bundle* from the PHD data. A complete FHIR Bundle contains all the resources pertinent to the measurements and all resources in the Bundle only have references to resources within the Bundle.

2. Device Observation Consumer that receives the complete FHIR Bundle from the Device Observation Reporter. In the POU, the Device Observation Consumer is typically grouped with a Device Observation Reporter that uploads the FHIR data from the complete FHIR Bundle to a RESTful FHIR server.

The POU also defines the following IHE transactions:

1. Communicate FHIR Data [PCD-xx] transaction communicates a complete FHIR Bundle to the appropriate consumer over RESTful POST transports, secured using TLS, and authenticated using OAuth2 bearer tokens.
2. Communicate FHIR Data RESTful FHIR API [PCD-yy] transaction delivers FHIR resources to a FHIR server using the RESTful FHIR API, is secured using TLS, and authenticated using OAuth2 bearer tokens.

Figure X.1-1 shows the actors and actor groupings directly involved in this profile and the relevant IHE transactions between them. The dotted boxes indicate actors that are required to be grouped with the actor in the solid box.

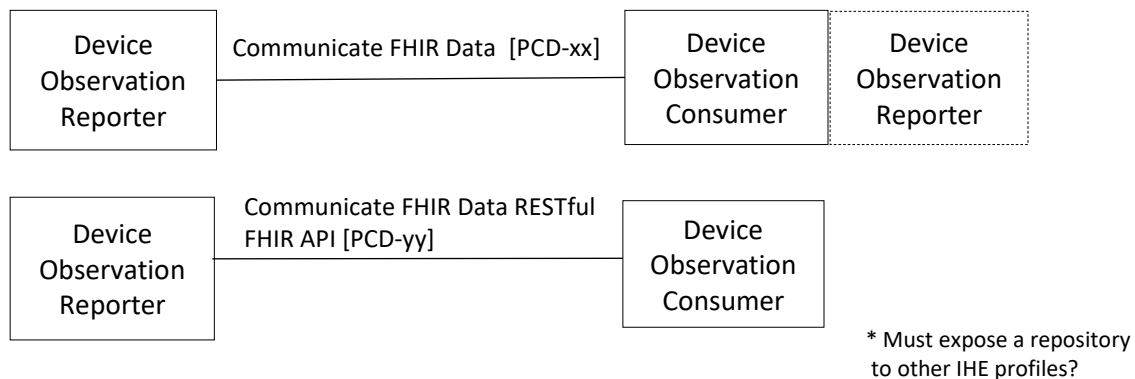
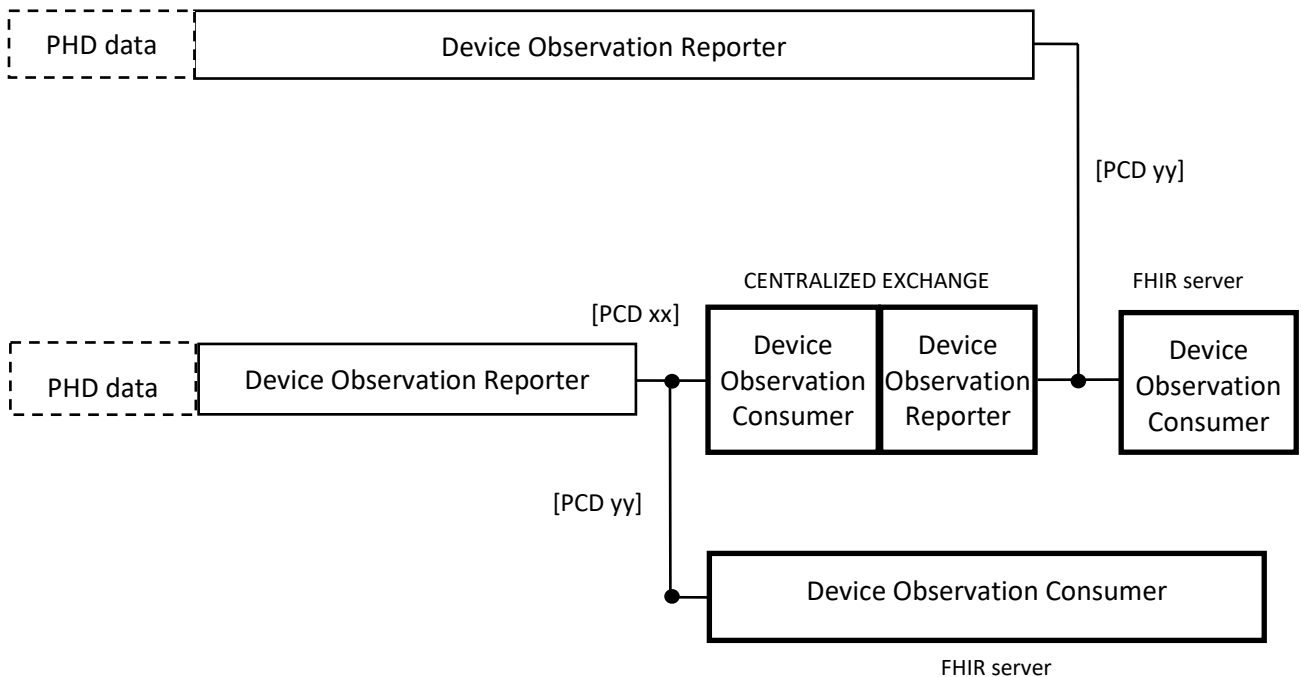


Figure X.1-1: POU Actor Diagram

Figure X.1-2 shows the upload implementation options of the POU. In some sense the figure indicates a ‘workflow’ though all the stages except for the patient taking the measurement are automated. How the PHD data is obtained is not specified.



335

Figure X.1-2: POU 'Flow' Diagram

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

340

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

Actors	Transactions	Optionality	Reference
Device Observation Reporter	Communicate FHIR Data [PCD-xx]	R	PCD TF-2: 3.xx
Device Observation Consumer	Communicate FHIR Data [PCD-xx]	R	PCD TF-2: 3.xx
Device Observation Reporter	Communicate FHIR Data RESTful FHIR API [PCD-yy]	R	PCD TF-2: 3.yy
Device Observation Consumer	Communicate FHIR Data RESTful FHIR API [PCD-yy]	R	PCD TF-2: 3.yy

X.1.1 Actor Descriptions and Actor Profile Requirements

345 The POU actors have the following requirements:

1. Device Observation Reporter that generates a complete FHIR Bundle from the PHD data. This actor is required to be synchronized to a time source and to ‘convert’ the PHD data to PCHA data before generating the FHIR resources. The primary aspect of this ‘conversion’ to PCHA data is to validate the time stamps in the PHD data and correct them if needed.
2. Device Observation Consumer that receives a complete FHIR Bundle from the Device Observation Reporter. In the POU, this actor is required to either make the resources available for usage or by passing the FHIR Bundle to a Device Observation Reporter that supports the Communicate FHIR Data RESTful FHIR API transaction.

355 A product that claims conformance to the POU could implement one of the following actors or actor groups:

1. A Device Observation Reporter supporting a RESTFUL POST (a PCHA PHG could support this feature)
2. A Device Observation Reporter supporting the RESTful FHIR API (a PCHA PHG could support this feature)
3. A Device Observation Consumer grouped with a Device Observation Reporter supporting the RESTful FHIR API or other IHE transactions.
4. A Device Observation Consumer supporting a FHIR server.

365 These components do not rule out implementations where the features are combined, for example, a PCHA PHG may support a Device Observation Reporter that supports both IHE transactions specified in the POU.

370 An important element in the POU is that PHD data must be obtained electronically (not manually entered by a patient) and the PHD data must possess sufficient information to be converted to a form that can be uploaded. PHD data sourced from devices certified to the IEEE 11073 20601 protocol are guaranteed to have this information. For the Device Observation Reporter (DOR) to generate the FHIR resources the PHD data must be on a contiguous timeline and if the measurements contain time stamps, the DOR must be able to coordinate the PHD’s sense of current time with the DOR’s sense of current time. Since the DOR is required to be synchronized to UTC, this coordination allows the DOR to validate the PHD time stamps and to correct them if they are not, convert any relative times to wall clock times, and provide time stamps for those measurements that do not contain time stamps. The latter requires that the DOR knows the time of reception of the measurement from the PHD on the DOR’s time line. The PHD must also report its state of time synchronization. If the PHD is better synchronized than the DOR, no modifications of time stamps occur.

380 The Communicate FHIR Data transaction communicates observation data in the form of a complete FHIR Bundle to a Device Observation Consumer (DOC). The transaction uses an HTTP POST operation. The DOR and DOC are required to support oAuth2 bearer token

authentication using client or resource owner credentials and Transport Level Security (TLS).

385 The requirements do not mean that certain business implementations must use these features; for example, the DOR and DOC are within the same institution on a secured network and the risks for security breaches are considered to be too low to warrant the overhead of authentication and TLS.

390 The Communicate FHIR Data RESTful FHIR API transaction uses the RESTful FHIR API to deliver FHIR resources to a FHIR server. The IHE transaction requires support of oAuth2 and TLS analogous to the Communicate FHIR Data transaction. As in the case of the Communicate FHIR Data transaction, the requirement does not mean certain business implementations must use these features. Since the Communicate FHIR Data RESTful FHIR API transaction is delivering the data to a Device Observation Consumer that is assumed to persist the data, the POU requires the prevention of data duplication by the DOR. One way the DOR can prevent
395 data duplication is to use the RESTful FHIR conditional create FHIR transactions on all resources that could potentially create duplicates. Observation resources created from stored data as well as Device and Patient resources could potentially already exist on the server. For efficiency, the POU encourages the Device Observation Reporter (DOR) supporting the Communicate FHIR Data RESTful FHIR API transaction to use some type of filtering
400 mechanism to prevent duplicates in lieu of conditional creates. For example, if the DOR is using transaction Bundles, since the uploaded Device resource describing a PHD is static, after a first-time upload using a conditional create, the DOR can use the returned logical id for the Device in the Observation.device resource elements in subsequent transaction Bundles and skip the inclusion of the Device resource. As an alternative, the DOR could query the server for the
405 existence of the resource before uploading.

Details of these requirements are documented in Transactions (Volume 2). This section documents any additional requirements on the POU Profile's actors.

X.1.1.1 Device Observation Reporter

410 The Device Observation Reporter (DOR) generates FHIR resources from PHD data and uploads them either as

- a complete Bundle to a Device Observation Consumer using the Communicate FHIR Data transaction or
- individually or as Bundles to a Device Observation Consumer using the Communicate FHIR Data RESTful FHIR API transaction.

415 In order to do these tasks, the DOR first associates the PHD data with a time stamp and patient identity. A single PHD can be used by multiple patients (e.g., a weight scale), thus the DOR may need to distinguish which patient the device is currently measuring. How this association is done is up to the implementation. The DOR should, but is not required to, support the IHE Time Client of the IHE Consistent Time protocol. The DOR may be implemented on a platform that is
420 wirelessly connected and may get their time from the cellular network or Wi-Fi rather than directly from an NTP or SNTP server mitigating the need to support a Time Client.

PHDs

- may not keep track of time and date when sending data in real time,
- their time clocks may be in error when a real time clock is supported,
- they may use relative time stamps,
- or they may be synchronized to an NTP or SNTP time server.

The DOR is responsible for handling the time stamps in each case. This handling may require the correction of the PHD time stamps, using the time of reception as the time stamp, conversion of relative times to wall clock time, or accepting the PHD time stamps as they are. The Personal Health Device Implementation Guide describes in detail the role of the DOR in time handling in the following sections:

<http://build.fhir.org/ig/HL7/PHD/CoincidentTimeStampObservationProfile.html>
<http://build.fhir.org/ig/HL7/PHD/CoincidentTimeStamp.html>.

X.1.1.2 Device Observation Consumer

The Device Observation Consumer accepts the uploaded FHIR resources in a complete Bundle or as a FHIR server. In the first case it must be grouped with a Device Observation Reporter that dispatches the information to other IHE profiles.

X.2 POU Actor Transaction Options

Transaction options that may be selected for each actor in this profile are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: POU - Actors and Options

Actor	Transaction Option	Reference
Device Observation Reporter	Communicate FHIR Data	PCD TF-2: 3.xx
	Communicate FHIR Data RESTful FHIR API	PCD TF-2: 3.yy
Device Observation Consumer	Communicate FHIR Data	PCD TF-2: 3.xx
	Communicate FHIR Data RESTful FHIR API	PCD TF-2: 3.yy

Note: Each actor must support at least one of the transaction transports.

X.3 POU Required Actor Groupings

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

Section X.5 describes some optional groupings that may be of interest for security.

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

POU Actor	Actor to be grouped with	Reference	Content Bindings Reference
Device Observation Consumer	Device Observation Reporter	PCD TF-1: X.3.?	
Device Observation Reporter	None	PCC TF-1: X.3.?	

X.4 POU Overview

The POU Profile describes a set of standardized means to deliver patient health measurements from PHDs to a health care provider. The delivery route can take one of several paths. Two scenarios are shown.

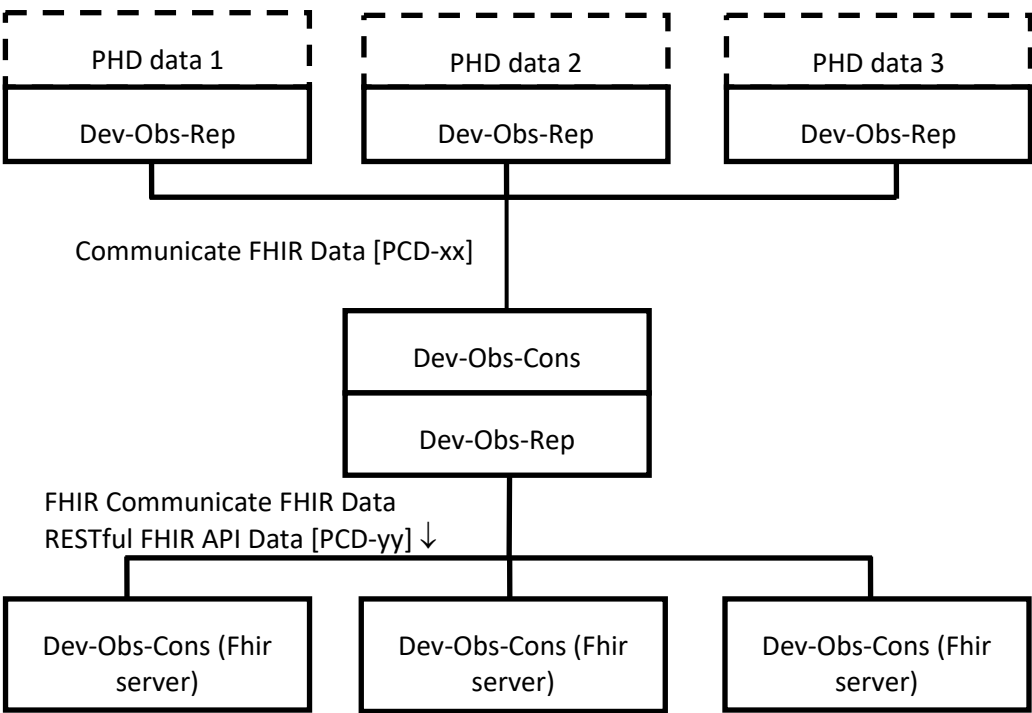


Figure X.4-1: POU Operational Diagram

In this case, there are several monitored patients, each with their own set of sensor devices and a local collector of those sensor observations. Each collector then sends its clinical data to a single back end server that generates the FHIR resources for one of several consumers.

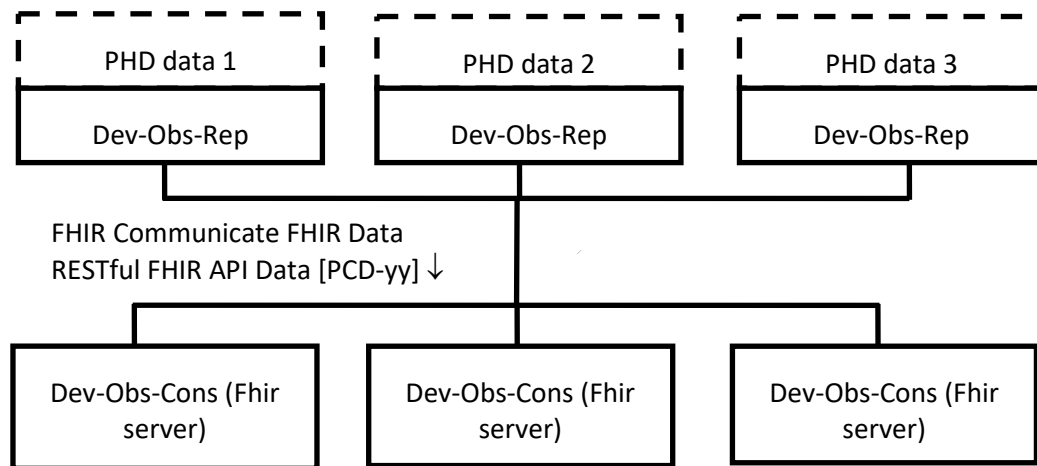


Figure X.4-2: POU Operational Diagram

In this case, there are once again several monitored patients, each with their own set of sensor devices and a local collector of those sensor observations. However, each collector sends the data directly to a FHIR server for consumption.

X.4.1 Concepts

The POU as defined in this document provides a standardized and *generic* means of representing PHD data in FHIR format. The generic representation is based upon the *type of value* (scalar, vector, code) versus the measurement *type* (temperature, weight, miles run, etc.). PHDs only report six value types

- A single scalar or number such as a temperature, weight, miles run, pulse rate, etc. How this value type is mapped to FHIR is given here:
<http://build.fhir.org/ig/HL7/PHD/NumericObservationProfile.html>
- A vector consisting of multiple numbers such as the x, y, z components of an acceleration or the systolic, diastolic, or mean components of a blood pressure.* How this value type is mapped to FHIR is given here:
<http://build.fhir.org/ig/HL7/PHD/CompoundNumericObservationProfile.html>
- A code such as the meal context. How this value type is mapped to FHIR is given here:
<http://build.fhir.org/ig/HL7/PHD/CodedEnumerationObservationProfile.html>
- A binary state or event. How this value type is mapped to FHIR is given here:
<http://build.fhir.org/ig/HL7/PHD/BITSEnumerationObservationProfile.html>
- A periodic sequence of scalars. How this value type is mapped to FHIR is given here:
<http://build.fhir.org/ig/HL7/PHD/RtsaObservationProfile.html>

- A human readable string (very rare). How this value type is mapped to FHIR is given here: <http://build.fhir.org/ig/HL7/PHD/StringEnumerationObservationProfile.html>

485 **One could always argue that each vector measurement component be reported as a scalar and that is a viable alternative. However, that decision has been made by the designers of the IEEE 11073 104xx specializations and the POU follows those decisions.*

An alternative approach would be to create FHIR resources based upon what the measurement is; thus, a temperature measurement would be mapped differently than a glucose concentration measurement. Given that the number of different scalar measurements reported by PHDs is large, the alternative approach puts a great burden on implementers that wish to handle many measurements. With the generic approach, an implementation need only handle six cases, and which case it handles can be determined by the FHIR meta.profile element.

490 The concept of generic mapping is central to the POU and is often difficult and confusing to readers who are not familiar with it. More information about the generic modelling approach can be found in the Personal Health Device Implementation Guide here <http://build.fhir.org/ig/HL7/PHD/GenericModel.html> and here <http://build.fhir.org/ig/HL7/PHD/ProfileConsumers.html>.

500 It should be pointed out that the IEEE 11073 standards have always used generic measurement modelling, and the Point of Care Device Implementation Guide takes this same generic approach.

X.4.2 Use Cases

505 The POU is designed to fulfill any situation where measurements taken by a patient using PHDs is needed. An example would be a care plan where part of that care requires a patient to be monitored for certain conditions, but that monitoring can be done by having the patient take measurements using one of more PHDs while at home.

X.4.2.1 Use Case #1: Chronic Disease Management

510 Chronic Disease Management allows compromised individuals managing disorders such as diabetes, hypertension, heart disease, sleep apnea, etc. to go through their daily lives with as minimal intrusion as possible. The POU Profile allows a greater number of such people to live as normal a life as possible.

X.4.2.1.1 Chronic Disease Management Use Case Description

515 People can become physically and medically compromised for several reasons. However, in many cases, these people would be able to live a fairly normal and functional life with minimal intrusion if, as much of the monitoring as possible, could be performed on the person without visits to a professional facility. The POU profile covers the transfer of measurements from the patient's home to the healthcare provider at a pre-determined frequency. The health care provider can then decide whether additional monitoring and thus a visit to the provider are warranted.

X.4.2.1.2 Chronic Disease Management Process Flow

520 A patient suffers from hypertension and is at high risk for stroke. The patient needs to take certain medications each day and ideally needs to lose some weight. The health care professional's institution already has the infrastructure to create, read, and distribute IHE compatible Electronic Health Records (EHRs) in the form of FHIR resources. The health care professional provides the patient with a blood pressure cuff, a weight scale, and a medication monitor containing next month's daily medication doses. All the devices are PCHA compliant thus the PHD data is known to contain the necessary information to be mapped to FHIR following the POU. A set top box is provided that collects the measurements from these devices and implements a Device Observation Reporter. The set top box is pre-configured to communicate with a server application supporting a Device Observation Consumer and subsequent Device Observation Reporter that supports the Communicate FHIR Data RESTful FHIR API transaction and dispatches the data to a FHIR server. This application has been installed on a system at the health care provider's facility. The server application has a web interface that allows the health care provider to generate an account for a given patient. The account will contain information about the given patient that the health care facility requires for its record keeping. A user-name and password are required to access this account and that information has been configured into the patient's set top box. When the server application receives data from this patient it knows to activate the Device Observation Reporter that generates FHIR resources that can be delivered to a FHIR server the health care provider can access.

540 The patient has been instructed on how to use the devices and to plug in the set top box in the area where the devices are to be used. Each morning the patient is to take a blood pressure reading, a weight measurement, and the daily medications. When the patient performs these tasks, a PCHA compliant message is sent to the set top box which gives a beep of approval when the measurement is received and converted to complete FHIR bundle. The first time this is done, 545 the set top box requests the back end server application for an OAuth token using the user name and password configured by the health care provider's facility. If correct, the set top box receives the token from the server application and sends FHIR bundle authenticated with the OAuth token. The server application validates the token and if valid, extracts the FHIR resources which it then sends to the FHIR Server following the RESTful FHIR guidelines, where the health care 550 provider can now use them. Since the backend server and the FHIR server are co-located within the same institution, no OAuth procedures are considered necessary.

In this manner the health care provider can monitor the patient and make medical decisions based on the uploaded observations, allowing the patient to go about his/her daily tasks with minimal intrusion. This monitoring does not preclude the patient from directly contacting the 555 health care provider.

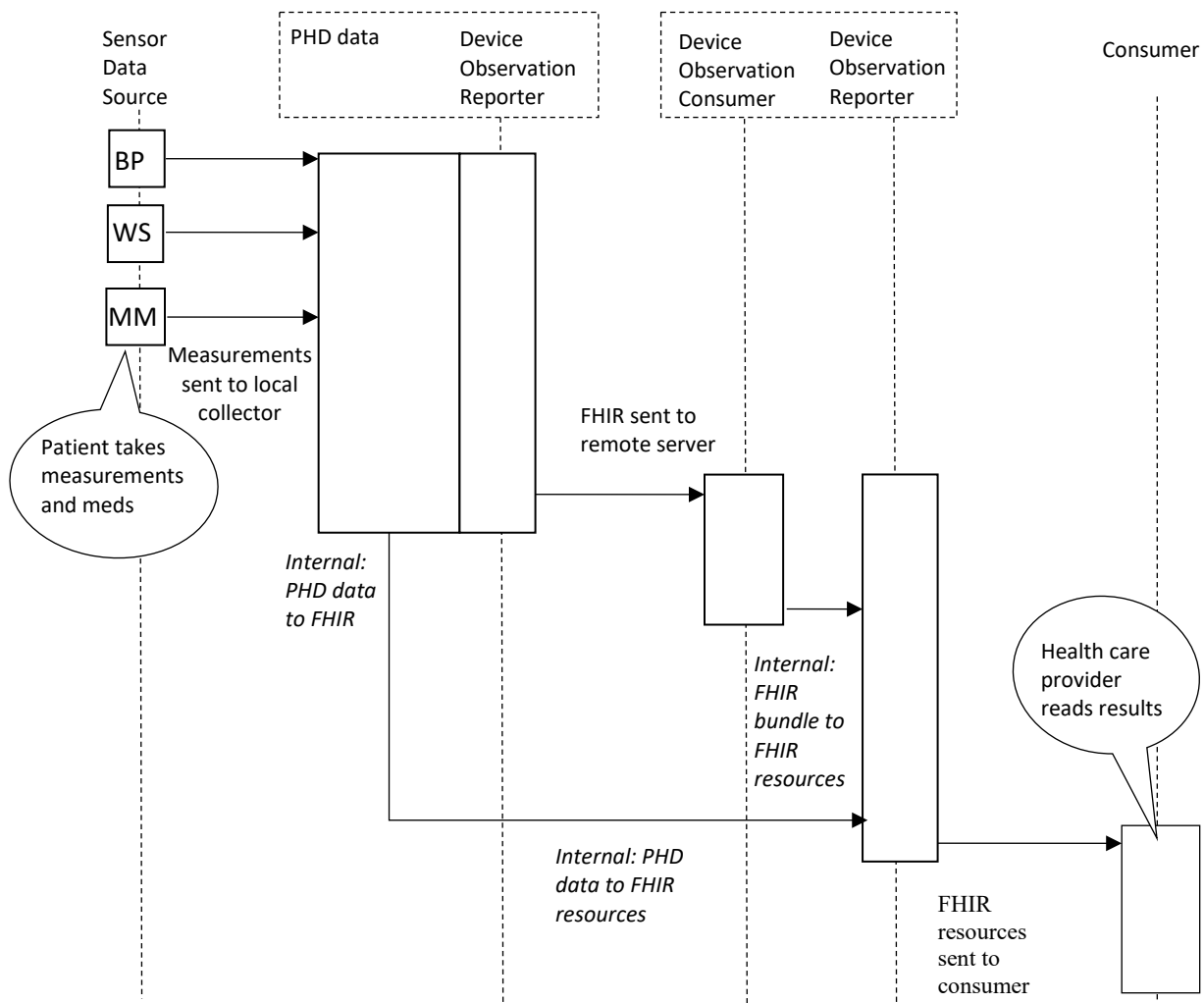


Figure X.4.2.1.2-1: Basic Process Flow in POU Profile

560 X.4.2.2 Use Case #2: Post-Operative Recovery

Remote Post-Operative recovery allows a patient to recover from the effects of surgery or other traumatic procedures (such as chemotherapy) amongst family and friends in a familiar environment.

X.4.2.2.1 Post-Operative Recovery Use Case Description

565 A patient that has had surgery, or chemotherapy, or radiation treatment, or has undergone some other medically traumatic event will often need to be monitored for potential complications. In some cases (such as a broken bone) the potential for complications is so low that it is standard procedure that recovery is at home. In many other cases monitoring is needed but it is fairly

simple, and any complications that might be detected from the monitoring will not be acute.

570 Nevertheless, the patient is either required to stay at the facility to receive this monitoring or is required to frequently visit the facility to be monitored, both of which are inconvenient and expensive. If the patient can be provided with the monitoring equipment, recovery can take place in the home and visits to the facility take place only when warranted.

X.4.2.2.2 Post-Operative Recovery Process Flow

575 A patient has just undergone heart surgery. The surgery appears to have gone well and the patient shows no signs of complications. The care giver provides the patient with a PCHA-compliant weight scale, blood pressure cuff, pulse oximeter, and medication monitor, and installs a PCHA complaint personal health gateway (PHG) on the patient's mobile phone. The PHG supports a Device Observation Reporter supporting a Communicate FHIR Data RESTful FHIR
580 API transaction and is configured to transfer the data to an application running on the facilities back end FHIR server. The health care staff has configured an account for the patient on this server. The care giver instructs the patient to take a weight measurement, blood pressure measurement, and pulse oximeter reading twice a day along with medication instructions; once in the morning, and once in the evening. Taking additional weight measurements during other
585 times of the day is encouraged. The patient is instructed to first turn on the mobile device, start the installed PHG application, and then use the three provided devices to take the measurements. Medications are dispensed from a special pill box. The patient is given a few practice sessions with the devices, the use of the medication dispenser, and mobile phone application. Everything goes smoothly though it takes some extra effort to get used to taking blood pressure
590 measurements. The patient sees the measurements displayed and medications taken on the mobile device and an indication that the data is dispatched to the care provider. The care provider then accesses the data from the examination room terminal and shows the patient the sent measurements.

595 Once home the patient follows the care giver's instructions; turns on the mobile device, starts the PHG application, and then takes the three instructed measurements and the prescribed medications. All devices transfer the measurements and medication indications to the mobile device.

The mobile device then converts the PHD data to FHIR resources and uploads the resources to a FHIR server using OAuth authenticated RESTful FHIR specifications.

600 X.5 POU Security Considerations

PHD data collectors may store both sensor data, as well as personally identifiable information, and will communicate it to upstream systems. These devices are subject to theft and loss. The POU requires the support of encryption of any upstream network transmissions using Transport Layer Security and authentication of the user via OAuth2 bearer tokens using either client or
605 resource owner credentials. While audit logging is not required to enable certain kinds of devices the ability to function, they may consider using the Secure Node or Secure Application from the IHE ATNA Profile to ensure that communications are audited, users are authenticated, and transmissions are secured between known entities.

- 610 Further protection of Personal Health Information can be obtained by only populating the Patient resource with opaque identifiers which can only be mapped to a personally identifiable information by appropriate personnel at the health care provider’s institution. The POU also supports a Device Observation Reporter Option where no patient information needs to reside on the hosting device. In this case, the Device Observation Reporter is provided the logical id of the Patient resource by some out-of-band means and a Patient resource is never created.
- 615 Back office, departmental and EHR systems used by the healthcare provider to access the sensor data or to translate it to a persistent, human readable format will need to be further secured. RESTful FHIR by itself does not support any security operations, thus the POU requires that the Device Observation Consumer of the Device Observation Reporter’s FHIR uploads supports OAuth2 client or resource owner credential authentication over TLS. The FHIR server will need
- 620 to be secured in the same manner as any other EHR system containing personal health data.

X.6 POU Cross Profile Considerations

NA

Appendices to Volume 1

None

625

Volume 2 – Transactions

3.xx PHD-xx Communicate FHIR Data Transaction

3.xx.1 Scope

630 This IHE transaction is used to transfer collected patient measurement data from a PHD to a Device Observation Consumer in the form of a complete FHIR Bundle.

3.xx.2 Actor Roles

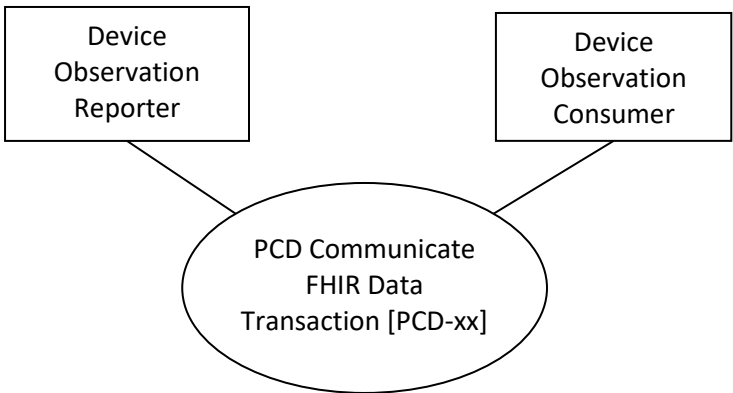


Figure 3.xx.2-1: Use Case Diagram

635

Table 3.xx.2-1: Actor Roles

Actor:	Device Observation Reporter
Role:	This actor is responsible for packaging patient measurement data into a complete FHIR Bundle and sending it to a Device Observation Consumer
Actor:	Device Observation Consumer
Role:	This actor receives the FHIR Bundle from one or more Device Observation Reporters

640

645

Since the Device Observation Reporter (DOR) does not receive any patient demographic information from the PHD, at least a patient identifier and authorization code for each patient are required to create a compliant Patient resource. How this information is obtained is not defined by the POU. Only the owner of the dictionary that maps these identifiers to a person needs to be concerned about personal health information. However, the DOR may include personal information in the Patient resource; that option is a business decision. How the DOR implementation maps the patient information to the PHD data is implementation dependent. The person number provided by some PHDs may be used or there may be some biosensor involved. A DOR implementation may also provide a filter such that only certain measurements are

forwarded in the FHIR Bundle. An example might be the exclusion of streaming pulse oximeter measurements and retention of spot measurements. Using such a filter is implementation dependent and outside the scope of the POU, but clearly use of the filter must allow the generation of a compliant FHIR Bundle.

3.xx.3 Referenced Standards

The Communicate FHIR data transaction is specified in the PCHA H.812.5 – FHIR Upload, PCHA H.812 WAN IF Common Certified Device Class Guidelines, and PCHA H.812.3 Capability Exchange documents. The hData record format is specified in HL7 Version 3 Standard: hData Record Format Release, 1 though the only aspect of the RESTful function required is the create (POST) action. The PCHA guidelines are sufficient for implementation of the Communicate FHIR Data transaction.

3.xx.4 Messages

The diagram below illustrates the Communicate FHIR Data transaction. How one obtains the authentication token is not specified by the POU.

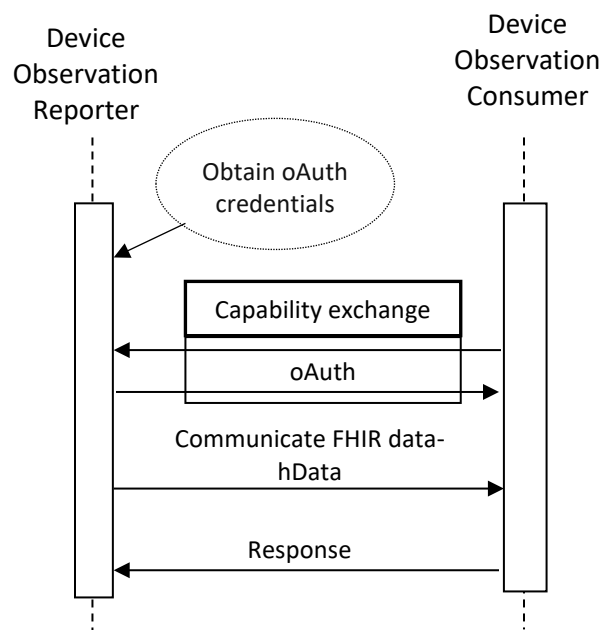


Figure 3.xx.4-1: Communicate FHIR Data Transaction

The Capability Exchange and OAuth exchanges as used in this IHE transaction are described in H.812-5.

3.xx.4.1 Communicate FHIR Data

665 The Communicate FHIR Data transaction used in the POU uses a RESTful POST to transfer the FHIR Bundle to the Device Observation Consumer. A RESTful POST is an HTTP POST operation with the complete FHIR Bundle as the body. The Device Observation Consumer and Device Observation Reporter Actors shall support TLS security and OAuth authentication for this IHE transaction transport as specified in H.812-5. ATNA auditing is an option.

670 It is this component of the message that transfers the measurement data as a FHIR Bundle to the Device Observation Consumer. The security and authentication requirements are present since this transaction is not locally bound like the communication between a PHD and PHG. In the POU, it is the IHE transaction that is responsible for transferring the medical data from the remote location of the patient to an enterprise or third-party server which can be located
675 anywhere there is connectivity. Typically, this connectivity would be the internet and it could occur from an unsecured public network.

3.xx.4.1.1 Trigger Events

The typical trigger event is the passing of a collection of measurement data from a PHD to the Device Observation Reporter. How this PHD measurement data is obtained is not specified by
680 the POU.

3.xx.4.1.2 Message Semantics

The RESTful POST transport implementation of this message contains both an OAuth identity token and the complete FHIR Bundle which represents the measurement sequence taken upon the patient. The message consists of a simple HTTP POST containing the OAuth token to the
685 URL specified by the Device Observation Consumer obtained through Capability Exchange. The body of the message is the FHIR Bundle. The OAuth identity token must be recognized by the Device Observation Consumer for acceptance of the message but how that identity token is obtained is a business trust relationship decision. The Device Observation Consumer may be an OAuth Authentication Server, or the Device Observation Reporter may obtain the token from a
690 third-party service trusted by the Device Observation Consumer, or the token may be obtained by an out of band means.

This message also represents an attempt to pass responsibility of the data from the Device Observation Reporter to the Device Observation Consumer. Once delivered, there is no further responsibility of the Device Observation Reporter to persist the information. In addition, the
695 Device Observation Reporter shall assume that the Device Observation Consumer does not persist any of the uploaded information, thus the requirement that the FHIR bundle contain the Patient and Device resources every time, even if they have been uploaded in previous bundles and have not changed.

However, the POU places further restrictions on the complete FHIR Bundle

- 700
- The Bundle shall be a FHIR transaction Bundle

- Only the create, conditional create, and conditional update FHIR transactions shall be specified in the Bundle
- The Patient, PHD Device, PHG Device, are sent every time
- 705 • The Patient, PHD Device, and PHG Device resource entries shall specify the conditional create FHIR transaction or conditional update* on the identifier value and system elements. The population of these elements is specified in the Personal Health Device Implementation Guide in the Phd Patient, PhdDevice, and PhgDevice profiles listed here <http://build.fhir.org/ig/HL7/PHD/profiles.html>.
- 710 • Observation resource entries created from stored data shall specify the conditional create FHIR transaction on the identifier value element. The creation of the identifier element is specified in the Personal Health Device Implementation Guide in the various observation profiles listed here <http://build.fhir.org/ig/HL7/PHD/profiles.html>.

**A conditional update FHIR transaction on the identifier value and system elements is discouraged. The reason is that if this Bundle is uploaded to a RESTful FHIR server, the existing*
715 *Patient or Device resources will go into the history archives, and not all servers support searches and GETs of resources by history even if the references themselves contain the history. Consequently, when one searches for the Patient or Device resources referenced in Observations referencing the original Patient or Device resource, the search will retrieve the latest version and not the original, even though the Observations point to the correct historical version.*

720 The reason for the FHIR transaction requirements is that this Bundle can then be uploaded unmodified to a FHIR server supporting the RESTful FHIR API. This Bundle allows an H&FS supporting a Device Observation Consumer to also support a Device Observation Reporter (DOR) supporting the Communicate FHIR Data RESTful FHIR API IHE transaction. This
725 Bundle provides the DOR implementation with sufficient information to pre-filter duplicates in the same manner a DOR that works directly with PHD data can.

If the destination of the Bundle is to an endpoint that is only interested in the resources, the FHIR transactions specified in the entry elements of the Bundle can be ignored.

3.xx.4.1.3 Expected Actions

730 The expected behavior by the Device Observation Consumer (DOC) upon reception of this message is to first authenticate the identity of the sender and if authenticated, indicate to the Device Observation Reporter whether or not the transfer is successful by responding with an appropriate acknowledgement.

735 The DOC may transfer the FHIR Bundle to a grouped Device Observation Reporter that dispatches the information using another IHE transaction, for example a PCD transaction containing a V2 message or any other IHE actor that can make use of this data and dispatch it to consumer actors.

3.xx.4.2 Acknowledgement

740 The Acknowledgement is a response to the Communicate FHIR Data message and indicates the status of the IHE transaction. Sending this message indicates whether or not responsibility for the data is transferred from the Device Observation Reporter to the Device Observation Consumer. A successful transfer indicates that the Device Observation Consumer has taken responsibility for the data.

3.xx.4.2.1 Trigger Events

745 The Acknowledgement is triggered by the reception of the Communicate FHIR Data at the Device Observation Consumer.

3.xx.4.2.2 Message Semantics

This message consists of an HTTP response indicating the status of the IHE transaction.

3.xx.4.2.3 Expected Actions

750 Upon a successful transaction, the Device Observation Reporter is free to release any resources associated with the measurement data.

3.xx.5 Security Considerations

755 The Communicate FHIR Data transaction is subject to any of the security threats of IHE transactions that utilize the public internet and unsecure public networks. To assure some level of consistent security, this IHE transaction requires, at minimum, support for TLS encryption and the support of OAuth Bearer Token authentication in this transaction. It is possible that this IHE transaction occurs within the context of a secured network. The business use case may choose not to take these extra precautions.

3.xx.5.1 Security Audit Considerations

760 There are no auditing requirements in this IHE transaction though the use of ATNA auditing is optional.

3.xx.5.2 Device Observation Reporter Specific Security Considerations

765 The primary risk of the Device Observation Reporter is the compromising of personal data via theft of the uploading device. The Device Observation Reporter is often a personal mobile device such as an Android phone or tablet and these devices may have extensive personal information; including financial. The Device Observation Reporter implementation will store medical data on failed transfers, and it may also store the medical data for review. Since the unit is often in the home, it may fall outside of any regional safeguards that might be in place for health care providers and associated supporting partners that will handle personal medical data. On the other hand, given that the range of data sensitivity in a remote patient monitoring situation is so great, security requirements are only required on the IHE transactions. Encryption of local data, and password, fingerprint, facial recognition, etc. access to the unit hosting the Device Observation Reporter software is left up to the implementation.

770

If personal health data is of concern in this part of the use case role, a dedicated upload implementation in a set-top box containing only the opaque institutional identity codes and institutional patient identifiers is an alternative. Such a box would not allow the storage of any information that can identify the person.

3.xx.5.3 Device Observation Consumer Specific Security Considerations

The Device Observation Consumer is typically resident on a third-party remote server or a server located at the institution of the health care provider. This actor has all the security risks that any medical data stored in a professional environment faces. It is likely subject to regional safeguards for the handling of personal medical data.

3.yy PHD-xx Communicate FHIR Data RESTful FHIR API Transaction

3.yy.1 Scope

This IHE transaction is used to transfer collected patient measurement data to a Device Observation Consumer in the form of FHIR resources using certain exchanges in the RESTful FHIR API <http://build.fhir.org/http.html>.

3.yy.2 Actor Roles

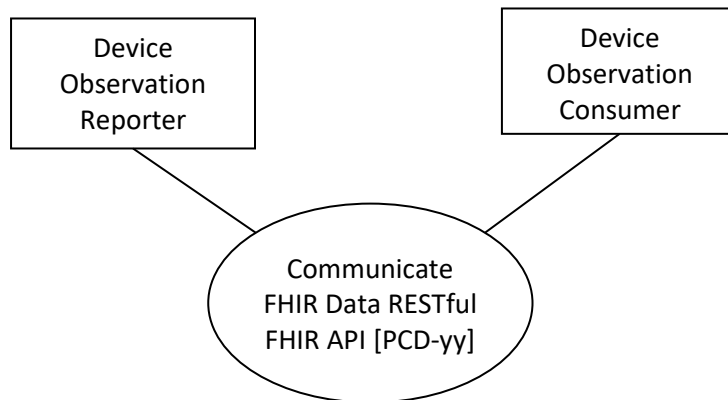


Figure 3.yy.2-1: Use Case Diagram

Table 3.yy.2-1: Actor Roles

Actor:	Device Observation Reporter
Role:	This actor is responsible for converting patient measurement data into FHIR resources and uploading it to a Device Observation Consumer using the RESTful FHIR API
Actor:	Device Observation Consumer
Role:	This actor receives the FHIR Resources from one or more Device Observation Reporters and persists them on a “FHIR” Server.

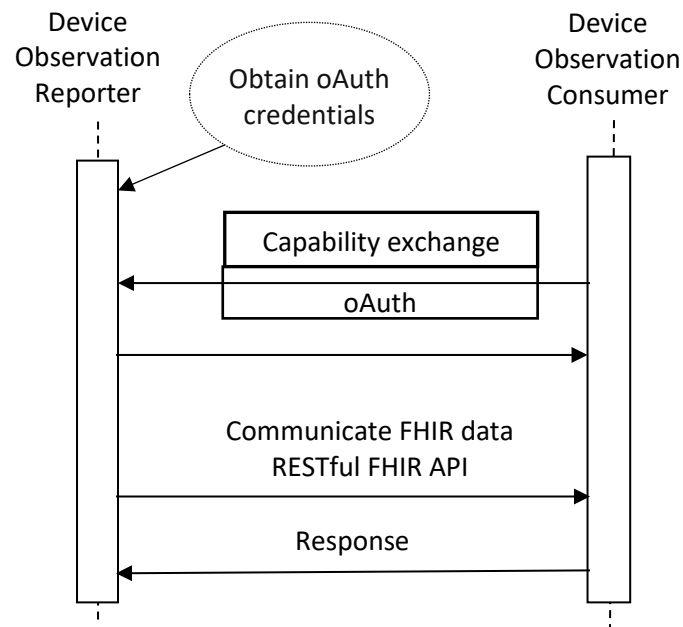
Since the Device Observation Reporter (DOR) does not receive any patient demographic information from the PHD, at least a patient identifier and authorization code for each patient are required to create a compliant Patient resource. How this information is obtained is not defined by the POU. Only the owner of the dictionary that maps these identifiers to a person needs to be concerned about personal health information. However, the DOR may include personal information in the Patient resource; that option is a business decision. How the DOR implementation maps the patient information to the PHD data is implementation dependent. The person number provided by some PHDs may be used or there may be some biosensor involved. A DOR implementation may also provide a filter such that only certain measurements are forwarded. An example might be the exclusion of streaming pulse oximeter measurements and retention of spot measurements. Using such a filter is implementation dependent and outside the scope of the POU, but clearly use of the filter must allow the generation of FHIR resources with all their proper resource references.

3.yy.3 Referenced Standards

The Communicate FHIR Data RESTful FHIR API transaction is specified by the FHIR guidelines <http://build.fhir.org/http.html> with additional requirements specified in the PCHA H.812.5 – FHIR Upload, PCHA H.812 WAN IF Common Certified Device Class Guidelines, and PCHA H.812.3 Capability Exchange documents. The hData record format is specified in HL7 Version 3 Standard: hData Record Format Release, 1 though the only aspect of the RESTful function required is the create (POST) action.

3.yy.4 Messages

The diagram below illustrates the Communicate FHIR Data RESTful FHIR API transaction. How one obtains the authentication token is not specified by the POU.



815 **Figure 3.yy.4-1: Communicate FHIR Data RESTful FHIR API Transaction**

The Capability Exchange and oAuth exchanges and used in this IHE transaction are described in H.812-5.

3.yy.4.1 Communicate FHIR Data RESTful FHIR API

820 The Communicate FHIR Data RESTful FHIR API transaction specified in the POU uses a restricted set of the RESTful FHIR API to upload Patient, Device, and Observation resources individually or in the context of a transaction Bundle. The allowed RESTful FHIR API exchanges and the creation of the resources is given in Appendix C. The Device Observation Consumer and Device Observation Reporter Actors shall support TLS security and oAuth authentication for this IHE transaction. ATNA auditing is an option.

825 It is this component of the message that transfers the measurement data as one of more FHIR resources to the Device Observation Consumer. The security and authentication requirements are present since this IHE transaction is not locally bound like the communication between a PHD and PHG. In the POU, it is the IHE transaction that is responsible for transferring the PHD medical data from the remote location of the patient to an enterprise or third-party server which
830 can be located anywhere there is connectivity. Typically, this connectivity would be the internet and it could occur from an unsecured public network.

3.yy.4.1.1 Trigger Events

The typical trigger event is the passing of a collection of PHD measurement data to the Device Observation Reporter. How this PHD is obtained it not specified by the POU.

835 3.yy.4.1.2 Message Semantics

The RESTful FHIR transport implementation of this message contains both an oAuth identity token and the FHIR resource which represents a measurement (single upload*) or measurement sequence (Bundled upload) taken upon the patient. The message consists of an HTTP POST or PUT containing the oAuth token to the URL supporting the RESTful FHIR API. The URL is
840 likely obtained through Capability Exchange. The body of the message is either a Patient, Device, Observation, or Bundle resource. The oAuth identity token must be recognized by the Device Observation Consumer for acceptance of the message but how that identity token is obtained is a business trust relationship decision. The Device Observation Consumer may be an oAuth Authentication Server, or the Device Observation Reporter may obtain the token from a
845 third-party service trusted by the Device Observation Consumer, or the token may be obtained by an out of band means.

This message also represents an attempt to pass responsibility of the data from the Device Observation Reporter to the Device Observation Consumer. Once delivered, there is no further responsibility of the Device Observation Reporter to persist the information used to create the
850 resource(s). In this transaction the Device Observation Consumer is assumed to persist the data.

**It should be noted that uploads of single resources can be a challenging task if the resources reference other Observation resources. All Observations generated from measurements containing a time stamp from the PHD will reference a Coincident Time Stamp Observation. The uploader must either upload this resource first and obtain the logical id in the response before
855 uploading subsequent Observations or use a FHIR transaction Bundle and temporary ids as specified in the FHIR standard. The second approach is often easier to implement.*

The POU places the following restrictions on the RESTful FHIR API and resources

- The Bundle, when used, shall be a FHIR transaction Bundle
- The Device Observation Reporter (DOR) shall either assure that the Patient, PHD
860 Device, and PHG Device resource does not exist on the server (perhaps by doing a GET) or the DOR shall use the conditional create or conditional** update transaction on the identifier value. The population of these elements is specified in the Personal Health Device Implementation Guide in the Phd Patient, PhdDevice, and PhgDevice FHIR profiles listed here <http://build.fhir.org/ig/HL7/PHD/profiles.html>.
- Observation resource entries created from stored data shall specify the conditional create
865 FHIR transaction on the identifier value element. The creation of the identifier element is specified in the Personal Health Device Implementation Guide in the various observation FHIR profiles listed here <http://build.fhir.org/ig/HL7/PHD/profiles.html>.

- The upload should attempt to filter duplicate resources instead of relying on the conditional create and conditional update FHIR transactions. Filtering will minimize bandwidth and reduce overhead on the server.

***A conditional update FHIR transaction on the identifier value and system elements is discouraged. The reason is that the existing Patient or Device resources will go into the history archives, and not all servers support searches and GETs of resources by history even if the references themselves contain the history. Consequently, when one searches for the Patient or Device resources referenced in Observations referencing the original Patient or Device resource, the search will retrieve the latest version and not the original, even though the Observations point to the correct historical version.*

3.yy.4.1.3 Expected Actions

The expected behavior by the Device Observation Consumer (DOC) upon reception of the upload message is to first authenticate the identity of the sender and if authenticated, indicate to the Device Observation Reporter whether or not the transfer is successful by responding with an appropriate acknowledgement.

3.yy.4.2 Acknowledgement

The Acknowledgement is a response to the Communicate FHIR Data RESTful FHIR API message and indicates the status of the IHE transaction. The body of the response will contain information about the actions taken by server according to the FHIR specification. One important piece of information the Device Observation Report can obtain from the response is the logical id of the uploaded resource. The logical id can be used in the Observation resources of subsequent uploads. Sending this message indicates whether or not responsibility for the data is transferred from the Device Observation Reporter to the Device Observation Consumer. A successful transfer indicates that the Device Observation Consumer has taken responsibility for the data.

3.yy.4.2.1 Trigger Events

The Acknowledgement is triggered by the reception of the Communicate FHIR Data RESTful FHIR API at the Device Observation Consumer.

3.yy.4.2.2 Message Semantics

This message consists of an HTTP response indicating the status of the IHE transaction and a body containing information about the transaction according to the FHIR specification.

3.yy.4.2.3 Expected Actions

Upon a successful transaction, the Device Observation Reporter is free to release any resources associated with the measurement data used to create the uploaded resource(s).

3.yy.5 Security Considerations

905 The Communicate FHIR Data RESTful FHIR API IHE transaction is subject to any of the security threats of IHE transactions that utilize the public internet and unsecure public networks. To assure some level of consistent security, this IHE transaction requires, at minimum, support for TLS encryption and the support of OAuth Bearer Token authentication. It is possible that this IHE transaction occurs within the context of a secured network. The business use case may choose not to take these extra precautions.

3.yy.5.1 Security Audit Considerations

910 There are no auditing requirements in this IHE transaction though the use of ATNA auditing is optional.

3.yy.5.2 Device Observation Reporter Specific Security Considerations

915 The primary risk of the Device Observation Reporter is the compromising of personal data via theft of the uploading device. The Device Observation Reporter is often a personal mobile device such as an Android phone or tablet and these devices may have extensive personal information; including financial. The Device Observation Reporter implementation will store medical data on failed transfers, and it may also store the medical data for review. Since the unit is often in the home, it may fall outside of any regional safeguards that might be in place for health care
920 providers and associated supporting partners that will handle personal medical data. On the other hand, given that the range of data sensitivity in a remote patient monitoring situation is so great, requirements are only required on the IHE transaction. Encryption of local data, and password, fingerprint, facial recognition, etc. access to the unit hosting the Device Observation Reporter software is left up to the implementation.

925 If personal health data is of concern in this part of the use case role, a dedicated upload implementation in a set-top box containing only the opaque institutional identity codes and institutional patient identifiers is an alternative. Such a box would not allow the storage of any information that can identify the person.

3.yy.5.3 Device Observation Consumer Specific Security Considerations

930 The Device Observation Consumer is typically resident on a third-party remote server or a server located at the institution of the health care provider. This actor has all the security risks that any medical data stored in a professional environment faces. It is likely subject to regional safeguards for the handling of personal medical data.

935

Appendices to Volume 2

Appendix A – POU Usage of FHIR Resource and RESTful FHIR API

The Device Observation Reporter supporting the Communicate FHIR Data RESTful FHIR API [PCD-yy] transaction requires the use of the Patient, Device, Observation, and optionally Bundle resources. Use of any other resource is out of scope for the POU. The elements used in these resources shall be compatible with FHIR version 4.0.0. The information that is required to be entered into the FHIR profiled resources, except the Patient resource, comes from the PHD via the 11073-20601 exchange protocol or mapped equivalent; no additional entry by the user of the PHD shall be required. The creation of these resources from the PHD and PHG data is detailed in the Personal Health Device Implementation Guide (PHD IG) <http://build.fhir.org/ig/HL7/PHD>. The mapping in this guide is also appropriate for the creation of the complete bundle resource in the Communicate FHIR Data [PCD-xx] transaction.

DORs following the POU shall **only** use the following RESTful FHIR operations for *uploading*:

- Create
- Conditional Create
- Conditional Update

Health and Fitness Servers supporting the Communicate FHIR Data RESTful FHIR API transaction shall support create, conditional create, and conditional update of the RESTful FHIR API. It shall support the Patient, Device, and Observation resources as well as the FHIR transaction Bundle.

A.1 PhdPatient Resource

Patient information is a highly sensitive issue. To support protection of Personal Health Information (PHI) the POU Profile supports an option where the Device Observation Reporter (DOR) is given the *logical* id (not the identifier) of a Patient resource by the service provider. How this logical id is obtained is not specified by the POU Profile. In that case, the DOR shall not upload a Patient resource. It shall use the logical id in all resources that require a reference to a Patient resource. The Device Observation Consumer (DOC) shall not reject such a resource due to the Patient resource reference, but it does not mean that the referenced Patient resource is accessible from the DOC.

If the logical id is not provided by the service provider, the DOR is responsible for generating the resource and uploading the resource in such a manner that duplicate resources are not created. The DOR must either assure the resource does not exist on the server before using a create operation or use a conditional create or conditional update operation on the identifier system and value elements. The only element required by the PHD patient FHIR profile is the identifier such as the XDSb patient and enterprise identifiers. These values are obtained from the service provider. How these values are obtained is not specified by the POU. Since no additional information is required in the case where a Patient resource is generated by the DOR, this option also allows protection of PHI as long as the enterprise's dictionary mapping patient identifiers to patients is secured. The construction of the Patient resource is given here <http://build.fhir.org/ig/HL7/PHD/PhdPatientProfile.html>.

A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdPatient.html>.

A.2 PHD Device Resource

980 PHDs expose their specializations, an IEEE EUI-64 system identifier, manufacturer name, model number, production specification (such as serial number and firmware version) information, as well as properties about its real-time clock if the PHD has a real-time clock. PCHA compliant PHDs also expose regulation and certification data.

985 PHDs are static devices. The Device Observation Reporter (DOR) shall assure that duplicate resources are not created. The DOR must either assure the resource does not exist on the server before using a create operation or use a conditional create or conditional update operation on the identifier system and value elements.

All Observation resources generated from the PHD measurements reference this Device resource in the Observation.device element. The construction of the PHD Device resource is given here <http://build.fhir.org/ig/HL7/PHD/PhdDeviceProfile.html>.

A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdDevice.html>.

990 A.3 PHG Device Resource

This resource is used to map the PHG properties. PHGs also have an IEEE EUI-64 system identifier, manufacturer name, model number, production specification, real-time clock properties, regulation, and certification information.

995 PHGs are static. The Device Observation Reporter (DOR) shall assure that duplicate resources are not created. The DOR must either assure the resource does not exist on the server before using a create operation or use a conditional create or conditional update operation on the identifier system and value elements.

1000 All Observation resources generated by the PHG Content Creator are referenced through the HL7 gateway extension element in the Observation. The construction of the PHG Device resource is given here <http://build.fhir.org/ig/HL7/PHD/PhgDeviceProfile.html>.

A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhgDevice.html>.

A.4 PHD Base Observation Profile

1005 The Base Observation Profile is not an instantiable resource but defines all the features that are common to the FHIR profiled Observation resources. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/BaseObservationProfile.html>. The mapping of the common elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/BaseObservationProfile.html>.

1010 PHDs can have stored data and some PHDs have no means of deleting the stored data and will resend the old measurements every connection. The Device Observation Reporter (DOR) shall prevent resource duplication by either assuring the resource does not already exist before performing a create operation or it shall use the conditional create operation on the identifier

value. The generation of the identifier value for data duplication prevention is specified in the various Phd Observation profiles in the Personal Health Device Implementation Guide. Links to the individual profiles are given in the following sections. In some situations, the measurements are known to be new; for example, live measurements or streamed measurements with no time stamps. In these cases, the DOR can use the create operation without concern for creating duplicates. The DOR may also invoke algorithms to filter out duplicate data instead of relying on the conditional create transaction. Such filtering reduces bandwidth and saves the server the overhead of processing the conditional create transaction.

A.5 PHD Numeric Observation Resource

This FHIR profile is used when the PHD sends a metric measurement that is a scalar such as a body temperature or glucose concentration. Scalar measurements are the most common type of PHD measurement. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdNumericObservation.html>. The mapping to the Observation value-related elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/NumericObservationProfile.html>.

A.6 PHD Compound Numeric Observation Resource

This FHIR profile is used when the PHD sends a metric measurement that is a vector and requires one or more scalar values to represent. Examples would be the x, y, z components of an acceleration or the systolic, diastolic, and mean components of a blood pressure. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdCompoundNumericObservation.html>. The mapping to the Observation elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/CompoundNumericObservationProfile.html>.

A.7 PHD Coded Enumeration Observation Resource

This FHIR profile is used when the PHD sends a metric measurement that is an IEEE 11073 10101 code such as a glucose meal context. In IEEE language these types of measurements are referred to as ‘enumerations’ since they are finite and fixed. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdCodedEnumerationObservation.html>. The mapping to the Observation value-related elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/CodedEnumerationObservationProfile.html>.

A.8 PHD Bits Enumeration Observation Resource

This FHIR profile is used when the PHD sends a metric measurement that is an IEEE 11073 BITs field such as a device and sensor status. IEEE 11073 BITs measurements represent one or more states and/or events that can occur simultaneously. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdBitsEnumerationObservation.html>. This kind of measurement poses certain challenges in HL7 and requires special treatment. More information is given at <http://build.fhir.org/ig/HL7/PHD/ASN1BITsCodeSystem.html> and <http://build.fhir.org/ig/HL7/PHD/ProfileConsumers.html#measurement-values-that-are-events->

1050 [or-states](#). The mapping to the Observation elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/BITSEnumerationObservationProfile.html>.

A.9 PHD String Enumeration Observation Resource

1055 This FHIR profile is used when the PHD sends an enumeration metric measurement that is a human readable string such as the cardio specialization exercise program name. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdStringEnumerationObservation.html>. The mapping to the Observation elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/StringEnumerationObservationProfile.html>.

A.10 Phd Rtsa Observation Resource

1060 This FHIR profile is used when the PHD sends a real-time-sample array (waveform) metric measurement such as an ECG trace. A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdRtsaObservation.html>. The mapping to the Observation elements from the PHD measurement metrics is given here <http://build.fhir.org/ig/HL7/PHD/RtsaObservationProfile.html>.

1065 A.11 PHD Coincident Time Stamp Observation Resource

This FHIR profile is used for the coincident time stamp. The coincident time stamp is essentially a ‘measure’ of the PHD’s current time at the current time of the PHG. This information, along with the static time information of the PHD and PHG is used to potentially correct and map the PHD measurement time stamps to local time plus UTC offset. More information about the Coincident Time Stamp is given here <http://build.fhir.org/ig/HL7/PHD/CoincidentTimeStamp.html>. The generation of the Coincident Time Stamp Observation from the PHD and PHG time clocks is given here <http://build.fhir.org/ig/HL7/PHD/CoincidentTimeStampObservationProfile.html>.

1075 A link to the structure definition is given by <http://build.fhir.org/ig/HL7/PHD/PhdCoincidentTimeStampObservation.html>.

A.12 Profiled FHIR Resources Personal Health Device Implementation Guide Links

1080 The link to the Personal Health Device Implementation Guide home page is given by <http://build.fhir.org/ig/HL7/PHD/>. The following table gives the links to the structure definitions and PHD data to FHIR mapping instructions for each of the profiled resources:

Table A.12-1: Links to Profiled FHIR Resources

Profiled Resource	Information	Links
PHD Patient	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdPatient.html

Profiled Resource	Information	Links
	Mapping details	http://build.fhir.org/ig/HL7/PHD/PhdPatientProfile.html
PHD Device	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdDevice.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/PhdDeviceProfile.html
PHG Device	structure definition	http://build.fhir.org/ig/HL7/PHD/PhgDevice.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/PhgDeviceProfile.html
PHD Base Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdBaseObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/BaseObservationProfile.html
PHD Numeric Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdNumericObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/NumericObservationProfile.html
PHD Compound Numeric Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdCompoundNumericObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/CompoundNumericObservationProfile.html
PHD Coded Enumeration Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdCodedEnumerationObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/CodedEnumerationObservationProfile.html
PHD Bits Enumeration Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdBitsEnumerationObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/BITSEnumerationObservationProfile.html
PHD String Enumeration Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdStringEnumerationObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/StringEnumerationObservationProfile.html
PHD Coincident Time Stamp Observation	structure definition	http://build.fhir.org/ig/HL7/PHD/PhdCoincidentTimeStampObservation.html
	Mapping details	http://build.fhir.org/ig/HL7/PHD/CoincidentTimeStampObservationProfile.html

The following links in the PHD Implementation Guide may also be of interest to those implementing some element of this PHD Observation Upload IHE Profile:

- 1085
- Technical background giving an overview of IEEE 11073 20601 constructs and its relation to FHIR resources for implementers of Remote Patient Monitoring Personal Health Gateways (PHGs): <http://build.fhir.org/ig/HL7/PHD/TechnicalImplementationGuidance.html>
- 1090
- Description of the *contents* of the PHG-generated FHIR resources for consumers of the FHIR resources: <http://build.fhir.org/ig/HL7/PHD/ProfileConsumers.html>. This page does not require knowledge of the IEEE protocols.

A.13 Referenced Standards

All standards which are referenced in this document are listed below with their common abbreviation, full title, and link to the standard.

1095

Table A.13-1: FHIR - Referenced Standards

Abbreviation	Title	URL
FHIR	Fast Healthcare Interoperability Resources	http://build.fhir.org/
FHIR PHD IG	Personal Health Device Implementation Guide	http://build.fhir.org/ig/HL7/PHD/

Volume 2 Namespace Additions

<i>Add the following terms to the IHE General Introduction Appendix G:</i>
--

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.24	ISO/IEEE 11073-10101 Medical Device Communication Nomenclature	See http://www.hl7.org/oid/index.cfm?Comp_OID=2.16.840.1.113883.6.24 for more details.

1100

Volume 3 – Content Modules

1105 Not applicable.

Appendices to Volume 3

None.

1110

Volume 3 Namespace Additions

<i>Add the following terms to the IHE Namespace:</i>
--

None.