Integrating the Healthcare Enterprise

IHE

IHE Patient Care Coordination
Technical Framework Supplement

Remote Patient Monitoring
(RPM)

Draft for Public Comment

Date: June 1, 2015
Author: PCC Technical Committee
Email: pcc@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

This is a supplement to the IHE Patient Care Coordination Technical Framework V10.0. Each
30   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 June 1, 2015 for public comment. Comments are invited and
may be submitted at http://www.ihe.net/PCC_Public_Comments. In order to be considered in
development of the trial implementation version of the supplement, comments must be received
35   by July 1, 2015.

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:*

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: 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
50   http://ihe.net/Profiles.

The current version of the IHE IT Infrastructure Technical Framework can be found at:
http://ihe.net/Technical_Frameworks.

_____

55 **CONTENTS**

100

105

110

115

120

125

130

135

140

Introduction to this Supplement

165 This supplement describes a standardized means of reporting measurements taken by Personal Healthcare devices in a remote location whereby remote it means outside of the healthcare provider facilities and is typically the patient's home, and reporting those measurements to the health care provider.

Open Issues and Questions

170 1. How should we partition this profile? At present, it is one profile containing content from PCC and PCD. Should it be restructured as was done for Radiology Clinical Decision Support/PCC Guideline Appropriate Ordering? Is this a PCC or PCD profile in the end?

  2. Related to #1: Should Communicate PCHA Data be a PCD or PCC transaction?

175 3. Shall the Content Creator Actor be a Document Source Actor instead? In this profile there is no responsibility for the Content Creator to be a repository; in other words it does not need to support an unsolicited request for a document. It is not clear to me if the Content Creator is also responsible for supporting unsolicited requests for a document.

  4. Is the CommunicatePDCData SOAP action (defined by PDC) used in any IHE profiles?

180 5. How shall the different Communicate PCHA Data-* transactions be described in Vol 2. The issue is that the IEEE-based transactions are identical except for transport and for all IEEE capable transports are referenced in the same documents.

  6. Comments from Paul Schluter - A few suggestions:

    1. Indicate that several deployment options are shown, in each of the three horizontal
185   bands. A short description of each as a subcaption in small italic text would help the reader understand what is going on.

    2. PCD DOR and PCD DOC are defined by the IHE PCD domain. You need a unique label for your device data observation source and consumer; it should not be the same as those that have been used by IHE PCD for years.

190   3. **Use shaded vertical lines to highlight that the PCHA data transaction(s), IHE PCD DEC (of** which we have many, in addition to the basic PCD-01), and PCC document sharing.

Closed Issues

The suggestions from Paul Schluter have been taken into consideration. Some of the diagrams
195 were put in landscape mode instead of vertical to make the flow easier to visualize. These were later considered too close to workflow diagrams and an additional actor-transaction diagram has been added.

The Content Creator is not required to support unsolicited requests for the content it created. F2F 4/27/2015.

200 General Introduction

Appendix A - Actor Summary Definitions

Actor	Definition
Sensor Data Consumer	This actor receives sensor data from Personal Healthcare Devices (PHDs)

Appendix B - Transaction Summary Definitions

Communicate PCHA Data-* <PCD-xx> – These transactions contain the discrete data from the remote Personal Health Device, such as device identification data, data related to the settings
205 and calibration of the device, and the sensor data itself over at least one of several transport options. The '*' in the name indicates one of the five transport options. To qualify as PCHA data certain time stamping requirements must be met; e.g., all stored data must be time stamped and any device containing timestamps in the measurements must expose its sense of current time and its time synchronization (if any).

210 **Communicate PCD Data-*** <PCD-xx> – These transactions contain the PCD-01 message generated from sensor data. The '*' in the name indicates one of two transport options.

Transaction	Definition
Communicate PCHA Data-BT	This transaction uses the IEEE 11073-20601 protocol over HDP (Health Device Profile) Bluetooth to transfer sensor data to a Sensor Data Consumer.
Communicate PCHA Data-USB	This transaction uses the IEEE 11073-20601 protocol over PHDC (Personal Healthcare Device Class) USB to transfer sensor data to a Sensor Data Consumer.
Communicate PCHA Data-ZB	This transaction uses the IEEE 11073-20601 protocol over ZigBee to transfer sensor data to a Sensor Data Consumer.
Communicate PCHA Data-NFC	This transaction uses the IEEE 11073-20601 protocol over Near Field Communication to transfer sensor data to a Sensor Data Consumer.
Communicate PCHA Data-BTLE	This transaction uses the Generic Attribute protocol over Bluetooth Low Energy to transfer sensor data to a Sensor Data Consumer.
Communicate PCD Data-hData	This transaction uses the RESTful hData protocol to transfer a PCD-01 message to a Device Observation Consumer authenticated by oAuth and encrypted using TLS.
Communicate PCD Data-SOAP	This transaction uses Web services to encapsulate a CommunicatePCDData SOAP action to transfer a PCD-01 message to a Device Observation Consumer authenticated by SAML2.0 and encrypted using TLS. This transaction is defined by IHE PCD for PCHA but is only fully expressed in PCHA guidelines.

215

Glossary

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

Glossary Term	Definition
RPM	Remote Patient Monitoring
PCHA	Personal Connected Health Alliance (Formally Continua)
PCHA Data	Data arriving over the Continua-specified PCHA Transaction from PHD devices. This data is typically provided by sensors and contains sufficient information to generate the non-demographic components of and enterprise time requirements for the IHE PCD-01 or PHMR modules.
PHMR	Personal Healthcare Monitoring Report. A C-CDA document designed primarily to record medical measurements taken on a patient by a sensor device.
PHD	Personal Health Device such as a pedometer, glucometer, blood pressure cuff, thermometer, etc.
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 PCD Data	PCHA sensor data expressed in the form of a PCHA-compliant IHE PCD-01 message.

220

Volume 1 – Profiles

Copyright Licenses

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

NA

Domain-specific additions

225   NA

Add Section X

X Remote Patient Monitoring (RPM) Profile

The Remote Patient Monitoring Profile describes a standardized means to transmit measurements taken by personal healthcare devices in a remote setting to a health care provider, including remote home monitoring, sub-acute therapy devices and wearable technologies. Remote in this case means outside of a care provider facility and is typically in the patient's home. In this manner, a patient's status can be monitored without repetitively travelling to a provider facility until deemed necessary, reducing interference in their day to day lives. In addition patients can be in an environment that they are more familiar and comfortable with. The reduction of personal stress and overall expense is especially beneficial in the case of independent living support, chronic disease management and post-operative recovery.

This profile is, for all practical purposes, an expression of the already existing set of standards and interfaces defined by PCHA for the delivery of remote patient data taken by Personal Healthcare Devices to the care provider in terms of IHE actors and transactions. No new standards or transactions are proposed.

The typical technology used to support remote monitoring includes:

- A Personal Health Device (PHD) which produces various health-related measurements through different kinds of sensors, and

- A collector that gathers data from one or more PHDs and forwards the information to the health information exchange, and

- The health information exchange that stores and makes the data accessible to healthcare providers such as the physician or care coordinator, and

- An electronic health record or care management system that provides healthcare providers or coordinators with access to the patient's health record and monitoring data.

Personal health devices include sensors such as a weight scale, SpO_2 sensors, blood pressure cuffs, and medication dispensers. These devices connect to a data collector using a variety of personal networking protocols, such as Bluetooth®, ZigBee®, and USB connections. Personal health devices tend to use embedded systems to handle data communication, and have limited capabilities. They may not even have a clock to keep track of the date and time a measurement is taken.

Collectors are typically 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 via a health information exchange.

The Remote Patient Monitoring Profile uses transactions that include the transport of data content based on IEEE 11073 terminologies for remote patient monitoring devices. Please see the list of terminologies in Appendix A.

X.1 RPM Actors, Transactions, and Content Modules

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

270 The intent of the RPM Profile is to standardize the representation of device observations and the transactions necessary to get the device observations to the health care provider. This standardization ensures plug and play operation for each component participating in the RPM Profile from the sensor device (Device Observation Source) used by the remotely located patient to the EHR document reader used by the health care provider.

275 The profile consists of the following actors:

1. Device Observation Source Actor which is typically the Personal Health Device (PHD) sensor

2. Sensor Data Consumer Actor that receives the data from the sensor device. In this profile, the Sensor Data Consumer must be grouped with either a Device Observation Reporter or
280 Content Creator.

3. Device Observation Reporter Actor that generates a PCD-01 message from the PCHA data

4. Device Observation Consumer Actor that receives the PCD-01 message from the Device Observation Reporter Actor. In this profile the Device Observation Consumer Actor is
285 typically grouped with a Content Creator Actor that creates PHMR content modules from IHE PCD-01 data. In some use cases the delivery of the data as a PCD-01 message may suffice, however that option is outside the scope of this profile.

5. Content Creator Actor that generates a PHMR content module and makes that Content available to a Content Consumer

290 6. Content Consumer Actor that receives a PHMR content module

and transactions where the '*' in the name indicates one of several possible transports:

1. Communicate PCHA Data-* transaction communicates sensor data to the appropriate consumer over five possible transports

2. PCD-01 Communicate PCD Data-* transaction communicates a PCD-01 message to the
295 appropriate consumer over two possible transports

3. PCC Document Sharing transaction distributes the PHMR content module by an agreed upon technique (such as XDS.b or XDM) to an appropriate consumer

and Content Module:

1. Personal Healthcare Monitoring Report (PHMR).

300 The '*' in the transaction names that support several transports will be used throughout this document for readability except where the specific transport notation is important.

Figure X.1-1 shows the actors and actor groupings directly involved in the RPM Profile and the relevant transactions between them. The dotted boxes indicate actors that are required to be grouped with the actor in the solid box.
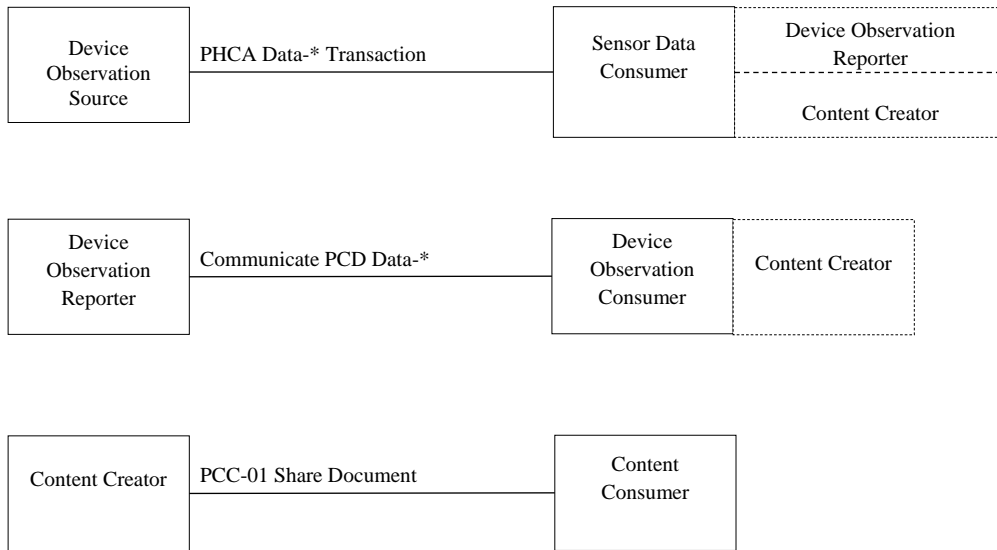
305

Figure X.1-1: RPM Actor Diagram

Figure X.1-2 shows the end to end implementation options of this profile. In some sense the figure indicates a 'workflow' though all the stages (once initiated) are automated. It is envisioned
310 that the primary end to end implementation consists of the four-module version where the Device Observation Source Actor is one component, the Sensor Data Consumer and Device Observation Reporter Actor group is a second component, the Device Observation Consumer and Content Creator Actor group is a third component and the Content Consumer is the fourth component. The separate 'sensor' box in the figure indicates the presence of some hardware that is capable of
315 taking medical measurements. Alternative deployments of this profile that combine the above components such that the total number of transactions is reduced are also shown using boxes with thinner lines. For the most part, costs and maintenance issues make the alternative deployments less attractive. However with the increased ubiquity of mobile devices, combining the sensors with Device Observation Reporter actors onto these mobile platforms is a likely
320 development.
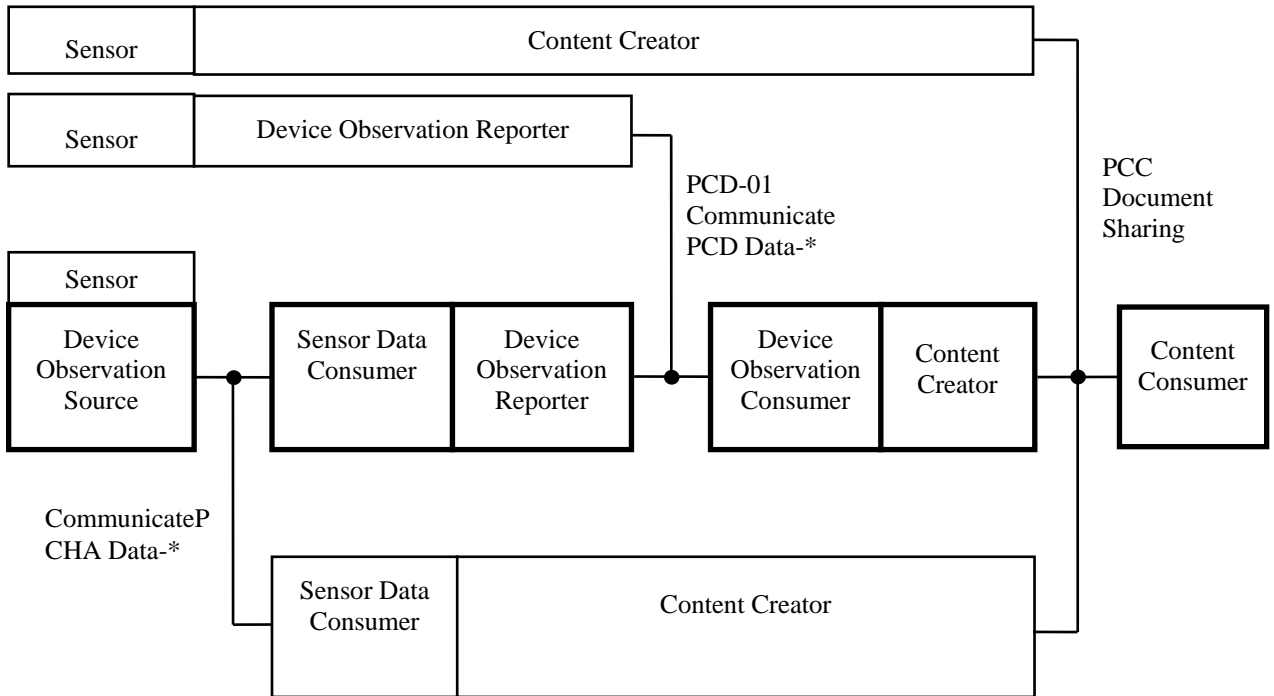
Figure X.1-2: RPM End-to-End 'Flow' Diagram

The equivalent PCHA end-to-end data flow that is analogous to the four component deployment
in Figure X.1-2 is shown in the Figure X.1-3. It should be noted that PCHA also defines the
same alternative deployments as shown in Figure X.1-2 except for a sensor device acting as a
Content Creator.

340

345

350
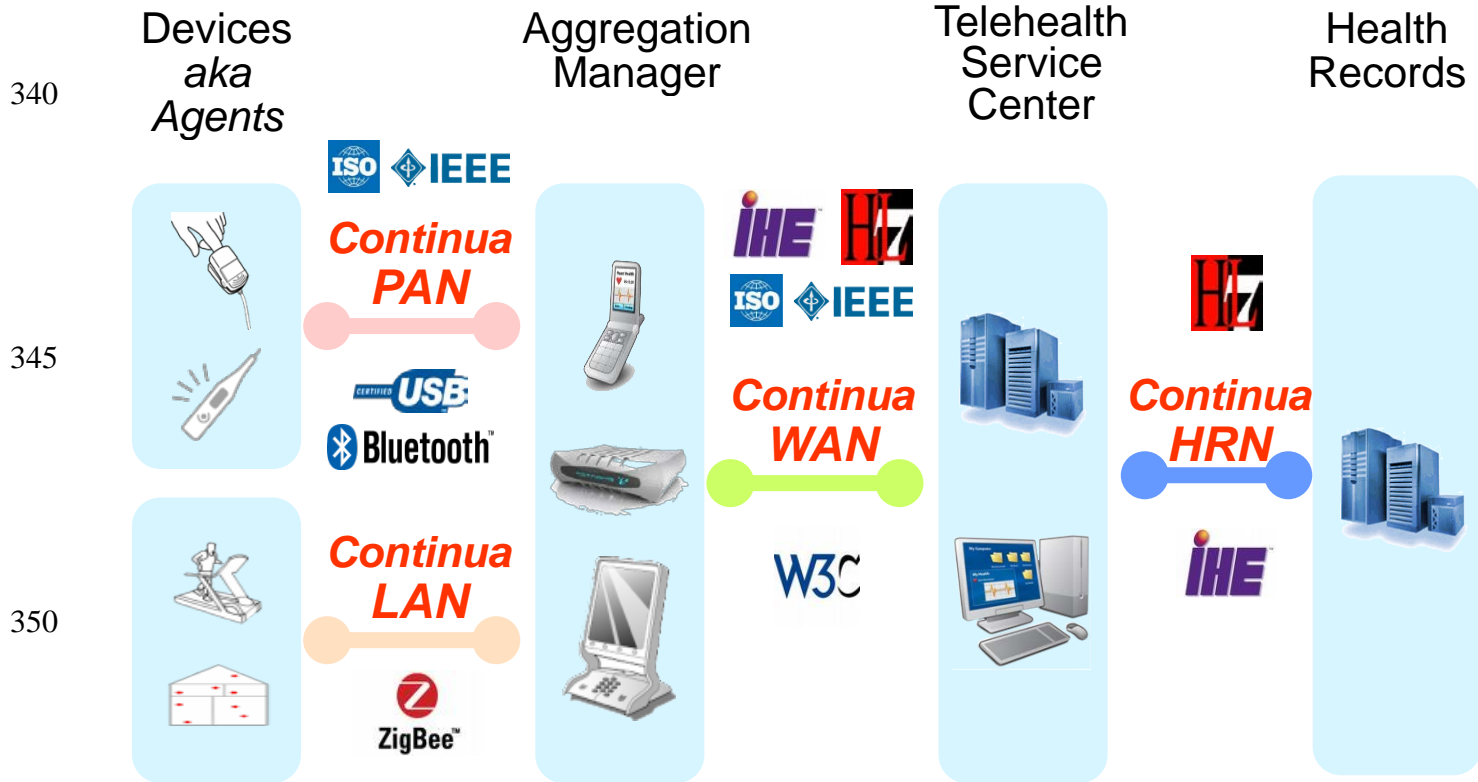
355

Figure X.1-3: PCHA End-to-end Flow Diagram

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

360

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

Actors	Transactions	Optionality	Reference
Device Observation Source	Communicate PCHA Data-BT [PCD-xx] (HDP Bluetooth)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-USB [PCD-xx] (PHDC USB)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-ZB [PCD-xx] (ZigBee)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-NFC [PCD-xx] (Near Field Communication)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-BTLE [PCD-xx] (Bluetooth Low Energy)	O[1]	PCC TF-2: 3.Y1 or PCD?

Actors	Transactions	Optionality	Reference
Sensor Data Consumer	Communicate PCHA Data-BT [PCD-xx] (HDP Bluetooth)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-USB [PCD-xx] (PHDC USB)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-ZB [PCD-xx] (ZigBee)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-NFC [PCD-xx] (Near Field Communication)	O[1]	PCC TF-2: 3.Y1 or PCD?
	Communicate PCHA Data-BTLE [PCD-xx] (Bluetooth Low Energy)	O[1]	PCC TF-2: 3.Y1 or PCD?
Device Observation Reporter	PCD-01 Communicate PCD Data-SOAP (Web services)	O[1]	PCD TF-2: 3.1
	PCD-01 Communicate PCD Data-hData (RESTful transport)	O[1]	PCD TF-2: 3.1
Device Observation Consumer	PCD-01 Communicate PCD Data-SOAP (Web services)	O[1]	PCD TF-2: 3.1
	PCD-01 Communicate PCD Data-hData (RESTful transport)	O[1]	PCD TF-2: 3.1
Content Creator	PCC-1 Document Sharing	R	PCC TF-2: 3.1
Content Consumer	PCC-1 Document Sharing	R	PCC TF-2: 3.1

[1] At least one transport must be supported.

Table X.1-2: RPM Profile - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Content Creator	PHMR	R	PCC TF-3: 6.3.1.D
Content Consumer	PHMR	R	PCC TF-3: 6.3.1.D

365

The Content Creator Actor in this profile depends upon the Consistent Time Profile. Table X.1-3 defines the dependency:

370 **Table X.1-3: Content Module Dependencies**

Integration Profile	Depends on	Dependency Type	Purpose
Remote Patient Monitoring Profile (RPM)	Consistent Time	The Content Creator Actor implementing this profile must implement the Consistent Time Profile	Required for consistent time-stamping of the PHMR content module.

X.1.1 Actor Descriptions and Actor Profile Requirements

The RPM Profile consists of the following actors:

1. Device Observation Source Actor which is typically the Personal Health Device (PHD) sensor
375

2. Sensor Data Consumer Actor that receives the data from the sensor device. In this profile, the Sensor Data Consumer must be grouped with either a Device Observation Reporter or Content Creator Actor.

3. Device Observation Reporter Actor that generates a PCD-01 message from the PCHA data
380

4. Device Observation Consumer Actor that receives PCD-01 messages from the Device Observation Reporter Actor. In this profile the Device Observation Consumer Actor is typically grouped with a Content Creator Actor that creates PHMR content modules from IHE PCD-01 data.

385 5. Content Creator Actor that generates a PHMR content module and makes that Content available to a Content Consumer.

6. Content Consumer Actor that can utilize a PHMR content module.

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

390 1. A sensor device acting as a Device Observation Source supporting one or more transports

2. A sensor device acting as a Device Observation Reporter supporting one or both transports

3. A sensor device acting as a Content Creator

4. A Sensor Data Consumer supporting one or more transports grouped with a Device
395 Observation Reporter supporting one or both transports

5. A Device Observation Consumer supporting one or both transports grouped with a Content Creator

6. A Content Consumer capable of reading a PHMR

7. A Sensor Data Consumer grouped with a Content Creator

400 These seven components do not rule out an implementation where a manufacturer implements, for example, a Sensor Data Consumer grouped with both a Device Observation Reporter and Content Creator. Such a component could provide both a PCD-01 message and/or PHMR content module.

Clearly for interoperability, peer implementations must support the same transports.

405 Due to resource requirements, costs, and maintenance efforts, it is envisioned that the most common set of components satisfying the end-to-end nature of this profile will consist of one or more Device Observation Source components and a Sensor Data Consumer grouped with a Device Observation Reporter component for each patient, and a Device Observation Consumer grouped with a Content Creator component serving several patients sharing PHMR content
410 modules with several Content Consumers.

The transactions involved in this profile utilize multiple transports.

The Communicate PCHA Data-* transaction specified by the PCHA H.811 - TAN-PAN-LAN Interface guidelines currently supports the following transports and protocols

- IEEE 11073-20601 packets over

415 - HDP Bluetooth

- PHDC USB

- ZigBee

- NFC

- Assorted Health device profiles overs Bluetooth Low Energy Attribute protocol

420 The PCHA guidelines place further requirements upon these protocols and transports than defined in the respective IEEE 11073 20601 and corresponding specialization specifications and the Bluetooth Low Energy health device profiles and services. The Device Observation Source Actor implementing this transaction must provide what is referred to as PCHA data in this specification. The PCHA data is required to have certain device information and (conditionally)
425 timing information to allow generation of observation data that can be coordinated and corrected to a UTC synchronized time source by the Sensor Data Consumer / Device Observation Reporter Actor group if the Device Observation Source has not already done so. In particular, any stored measurements MUST provide a time stamp, and any Device Observation Source Actor providing a timestamp in any measurement (stored or live) MUST provide its sense of current time. PCHA
430 has certification requirements on a per-transport basis for this transaction for both the Device Observation Source and Sensor Data Consumer.

The PCD-01 Communicate PCD Data-* transaction communicates observation data in the form of a PCD-01 message to an appropriate consumer. The transaction uses one of the following transport methods:

435 - Continua PCHA hData Observation-Upload

- Continua PCHA SOAP Observation-Upload

as specified in the PCHA H.812.1 - Observation Upload and PCHA H.812 - WAN Interface guidelines. The SOAP Observation-Upload uses the web services based IHE CommunicatePCDData SOAP action over TLS authenticated with SAML. The hData Observation-Upload uses RESTful transports over TLS authenticated by oAuth. How the SAML or oAuth tokens are obtained is not specified by this profile but is a business decision made by the communicating partners.

The PCC Document Sharing transaction uses any IHE specified transport method that is capable of sharing a PHMR document. The PCHA H.813 - HRN Interface guidelines restricts the transaction to IHE XDR (XDS.b Provide and Register Document Set) or IHE XDM. These transports communicate the PHMR C-CDA® content module to the consumer.

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

X.1.1.1 Device Observation Source

Typically the Device Observation Source Actor is a Personal Health Device (sensor) which captures measurements about a patient. These measurements are communicated to the Sensor Data Consumer using one or more of the protocols and transports specified in the Communicate PCHA Data-* transaction as described below.

X.1.1.2 Sensor Data Consumer

The Sensor Data Consumer Actor receives data from the sensor. The data is augmented with personal information and any timing issues are corrected and coordinated. The data is subsequently forwarded to the healthcare provider. In this profile, the Sensor Data Consumer must be grouped with either a Device Observation Reporter or Content Creator Actor to handle the forwarding of the information.

The Device Observation Reporter associates the sensor data with a time stamp, and the patient identity. PHD sensors typically can be used by multiple patients (e.g., a weight scale), and so the Sensor Data Consumer may need to distinguish which patient the device is currently measuring. Additionally, sensors often do not keep track of time and date, and so the Sensor Data Consumer must time stamp the measurements. The Device Observation Reporter should, but is not required to support the IHE Time Client Actor of the Consistent Time protocol. These devices may be wirelessly connected devices which get their time from the cellular network, rather than from an NTP or SNTP server.

X.1.1.3 Device Observation Reporter

The Device Observation Reporter Actor is responsible for transmitting augmented sensor observations one step closer to the healthcare provider.

X.1.1.4 Device Observation Consumer

The Device Observation Consumer accepts augmented device observations. It must be grouped with a Content Creator Actor, and it uses that actor to forward these observations to the healthcare provider.

475 ### X.1.1.5 Content Creator

The Content Creator Actor formats sensor data in the Personal Health Monitoring Report (PHMR) format, a form suitable for consumption by EHR, HIE and other Health IT systems, and which is also human readable.

X.1.1.6 Content Consumer

480 The Content Consumer Actor is used by the healthcare provider to access stored sensor data associated with a patient in the Personal Health Monitoring Report (PHMR) format.

X.2 RPM Actor Options

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

485

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

Actor	Option Name	Reference *<either reference TF-3 or the applicable X.2.x subsection below table>*
Device Observation Source	Communicate PCHA Data-BT	
	Communicate PCHA Data-USB	
	Communicate PCHA Data-ZB	
	Communicate PCHA Data-NFC	
	Communicate PCHA Data-BTLE	
Sensor Data Consumer	Communicate PCHA Data-BT	
	Communicate PCHA Data-USB	
	Communicate PCHA Data-ZB	
	Communicate PCHA Data-NFC	
	Communicate PCHA Data-BTLE	
Device Observation Reporter	PCD-01 Communicate PCD Data-SOAP	
	PCD-01 Communicate PCD Data-hData	
Device Observation Consumer	PCD-01 Communicate PCD Data-SOAP	
	PCD-01 Communicate PCD Data-hData	

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

X.3 RPM Required Actor Groupings

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

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport
495 transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

Section X.5 describes some optional groupings that may be of interest for security considerations
500 and section X.6 describes some optional groupings in other related profiles.

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

RPM Actor	Actor to be grouped with	Reference	Content Bindings Reference
Sensor Data Consumer[1]	Device Observation Reporter	PCC TF-1: X.1.1.2	<Reference to CM bindings section e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1)
Sensor Data Consumer[1]	Content Creator	PCC TF-1: X.1.1.2	
Device Observation Consumer	Content Creator	PCC TF-1: X.1.1.4	
Device Observation Source	None	PCC TF-1: X.1.1.1	
Device Observation Reporter	None	PCC TF-1: X.1.1.3	
Content Creator	None	PCC TF-1: X.1.1.5	
Content Consumer	None	PCC TF-1: X.1.1.6	

[1] The Sensor Data Consumer is required to be grouped with *either* the Device Observation Reporter or Content Creator Actor. It *may* be grouped with both.

505

X.4 RPM Overview

The RPM Profile describes a set of standardized means to deliver patient health measurements and monitoring data in a remote setting to a health care provider. The delivery route can take one of several paths. However, given costs and technological constraints, it is envisioned that most
510 use cases will follow the delivery paths as illustrated in Figure X.4-1.

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 content appropriate for one of several consumers.
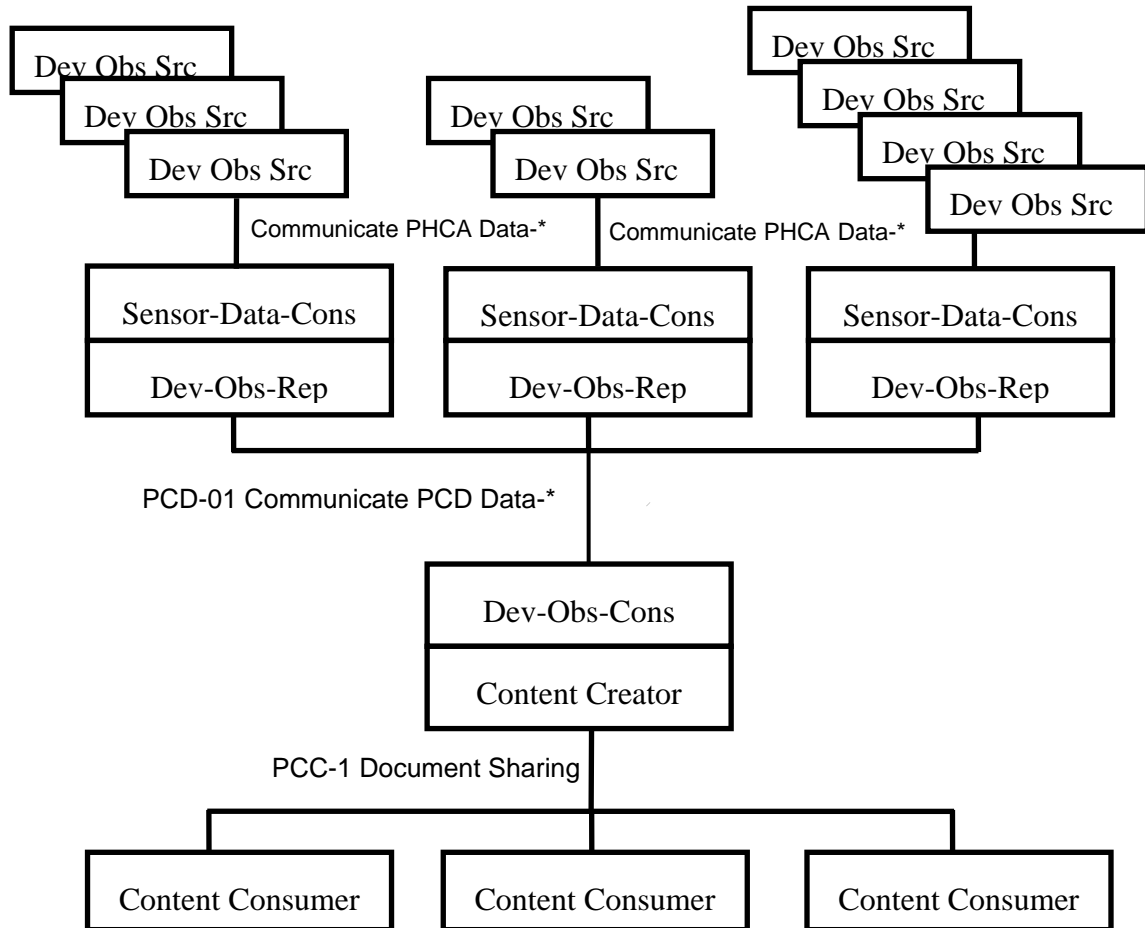
Figure X.4-1: RPM Operational Diagram

515

There are a couple of reasons that the RPM Profile is likely to be implemented as indicated in Figure X.4-1. First, the collector of sensor observations is typically done on low-footprint
520   hardware, such as a mobile phone, tablet, or set-top box. Supporting the Content Creator Actor is resource and power demanding making such collectors more expensive. Second, the amount of supplementary information needed to support the headers of the PHMR content module is quite large compared to the amount of supplementary information needed to support the data coming from the sensor. The task of maintaining and configuring this information then needs to be done
525   for each patient on more expensive hardware if implemented on the local collector. Having a single high end back-end server handling multiple patients and the Content Creator is likely less expensive and easier to maintain. It also allows for a simple approach to filter the data that is

530 reported in the Content Module. The filtering can be configured at a single point for all patients using the backend instead of each individual collector. It should be noted that any filtering is an application option established through business needs and is outside the scope of this profile. Of course, any filtering must still result in a complaint Content Module.

535 Home sensor devices also need to be low footprint, where the bulk of their expense is the sensor itself and the hardware necessary to support transaction protocols and external configuration is minimized. Since many of the sensor devices may be borne on the patient, making the sensor as small and as unobtrusive as possible also limits hardware resources and power demands. These demands make the Communicate PCHA data-* transaction the most likely solution for these devices.

540 In addition personal health device data is time stamped with a consistent enterprise time. For most sensor applications providing a consistent enterprise time is too costly and too power demanding. Consequently this time stamping is typically done by the Device Observation Reporter Actor obtaining the PCHA data from Sensor Data Consumer.

X.4.1 Concepts

545 The RPM Profile as defined in this document is the first stage in providing a standardized means of monitoring patients outside the care provider facilities. This profile currently specifies the transfer of monitoring data from the remote site to the health care facility. PCHA is currently implementing standards for two-way monitoring in the form of consent, questionnaires, IEEE 11073 20601 command and control, and automated persistent sessions. It is anticipated that these standards will either provide enhancements to this profile or be the basis for additional profiles related to the remote monitoring of patients.

550 X.4.2 Use Cases

The generic use case for this profile is any situation in which the health care provider judges that the patient will benefit from being able to be medically and environmentally monitored outside of the health care facility (typically the home). Quality of life and reduction in costs are also important factors in the judgment. Financial stress is a realistic concern for most patients.

555 X.4.2.1 Use Case #1: Chronic Disease Management

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 RPM Profile allows a greater number of such people to live as normal a life as possible.

560 X.4.2.1.1 Chronic Disease Management Use Case Description

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 continuous monitoring could be done on the person without visits to a professional facility. The patient can transfer monitoring measurements to the health care

565 provider at a pre-determined frequency using the RPM. 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

http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_RCK.pdf

A patient suffers from hypertension and is at high risk for stroke. The patient needs to take
570 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 Heath Records (EHRs) as C-CDA®s. The health care professional provides the patient with a blood pressure cuff from BP Manufactures, Inc., a weight scale from WS Solutions, and a medication monitor from AMM GBH containing next month's daily
575 medication doses. All the devices are PCHA compliant. The patient also receives a PCHA compliant set top box from AHD Magic, Inc. The patient was given the choice to use either a set top box or a mobile tablet, the latter of which would display the patient's measurements as received. The patient chose the set top box because the patient is technology challenged and did not want to turn on the device and/or activate the application to see the measurements as they
580 were uploaded from the devices. The chosen set top box is pre-configured to communicate with a PCHA compliant server application developed by Medical Application Services. 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
585 facility requires for its record keeping. A user name and password is 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 then knows to generate a PHMR that is delivered to an XDS.b repository the health care provider can access.

The patient has been instructed on how to use the devices and to plug in the set top box in the
590 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 and converted to an IHE PCD-01 message. The first time this is done, the set top box requests the back end server application for a SAML token using the user name and password configured by
595 the health care provider's facility. If correct, the set top box receives the token from the server application and sends the PCD-01 message in a TLS-secured IHE CommunicatePCDData SOAP action authenticated with the SAML token. The server application validates the token and if valid, converts the data to a PHMR module which it then sends to the XDS repository, using the IHE XDS.b provide and register document set transaction, where the health care provider can
600 now read it.

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

605
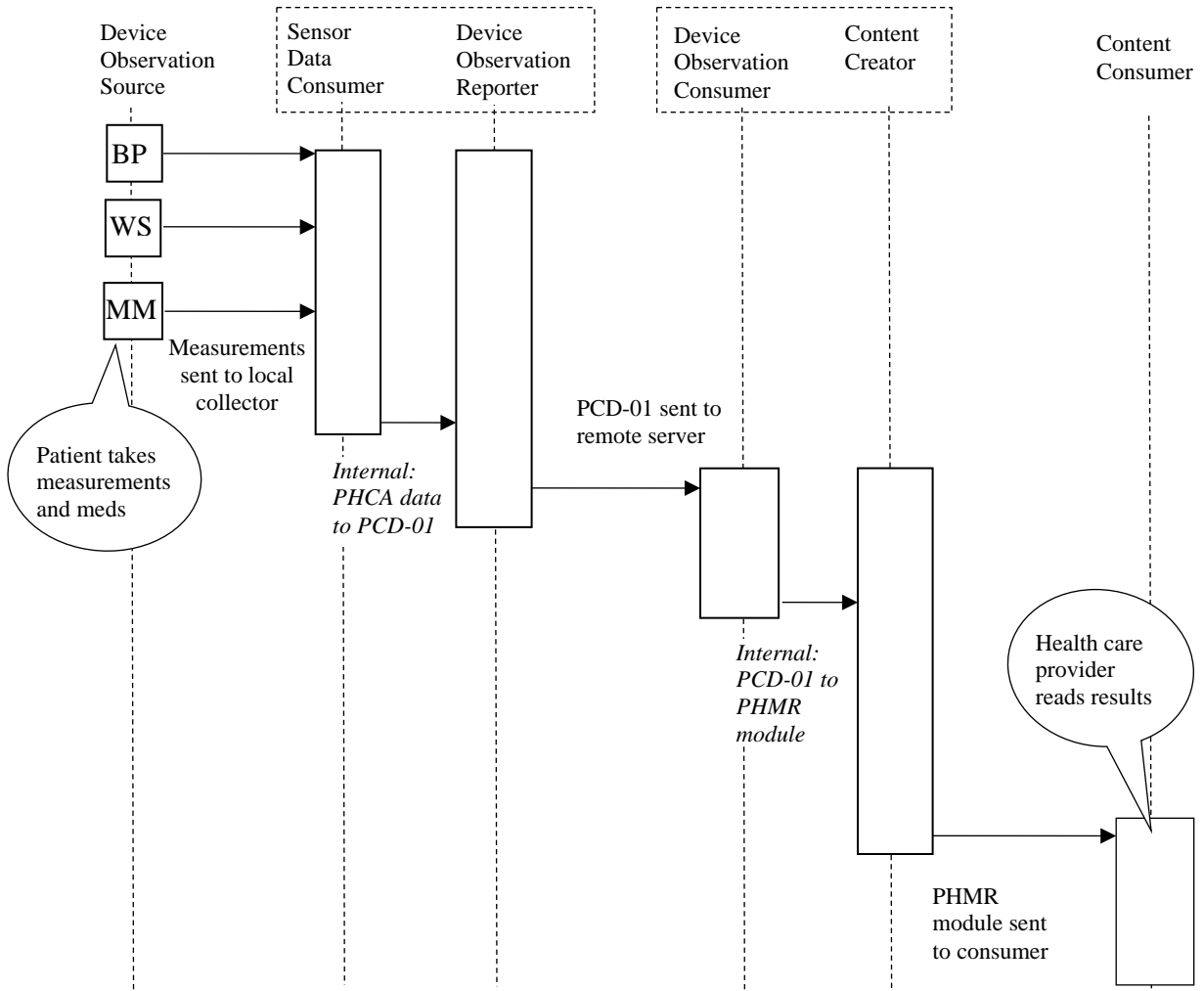
Figure X.4.2.1.2-1: Basic Process Flow in RPM Profile

610 ## 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

615 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.
620   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

625   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 from ViktMasters AB, blood pressure cuff from MedMax Gmbh, pulse oximeter from POSpecialists, Inc, and medication monitor from AMM Masters AB, and installs a PCHA complaint application hosting device application from Medical Mjukvaror AB on the
630   patient's mobile phone. The Medical Mjukvaror AHD application is configured to transfer the data to an application obtained from Medical Servers, Inc. running on the facilities back end 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
635   in the evening. Taking additional weight measurements during other times of the day is encouraged. The patient is instructed to first turn on the mobile device, start the installed Medical Mjukvaror AHD 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
640   goes smoothly though it takes some extra effort to get used to taking blood pressure 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.

645   Once home the patient follows the care giver's instructions; turn on the mobile device, start the PCHA complaint application, and then take the three instructed measurements and the prescribed medications. All devices use the Communicate PCHA Data-BT transaction (Bluetooth) to transfer the measurements and medication indications to the mobile device.

The mobile device then uses the SOAP Observation upload transaction and sends this data as a
650   PCD-01 message to the backend server. The backend server then converts the PCD-01 message to a PHMR module using the supplementary information entered for this patient in the patient's account and uses XDS.b Provide and Register Document Set transaction to send the document to the care provider's repository where it can be examined with the facilities' existing infrastructure.

655   # X.5 RPM Security Considerations

Personal Health Devices are typically simple applications embedded with a sensor that communicate to more complex devices through secure wireless personal networking protocols,

660 or connected to devices through a wired USB connection under the control of the user. While they can store data (e.g., a glucose monitor), many rarely store data for other than a short period of time, and only that data that is measured by the sensor. In addition, Personal Health Devices rarely have personally identifiable information as there is currently no standardized means to transmit such information using the Communicate PCHA Data-* transactions. The devices are subject to typical security concerns, such as theft or loss. The main security concern for these devices is their communication channel with other actors. This profile mandates the use of

665 secured network communications when the device is accessed or transmits data through wireless protocols. This mitigates the risk of data interception, interference, or alteration in transit. It is presumed that the device is under user control when it is attached via a wired connection, and so no encryption is required in this case.

Unlike sensors, data collectors may store both sensor data, as well as personally identifiable

670 information, and will communicate it to upstream systems. Like PHDs, these devices are also subject to theft and loss. These devices are required to synchronize time using either native protocols (e.g., through the cellular network that the device is attached), or through use of the IHE Time Client Actor from the Consistent Time Profile. This profile requires the support pf encryption of any upstream network transmissions using Transport Layer Security and

675 authentication of the user via SAML when web services are used or oAuth when using RESTful hData as specified in the IHE ITI Technical Framework Supplement: Internet User Authentication (IUA). 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 Actor from the IHE ATNA Profile to ensure that communications are audited, users are authenticated and

680 transmissions are secured between known entities.

Back office, departmental and EHR systems used by the healthcare provider to access the sensor data or translate it to a persistent, human readable format will need to be further secured. See the Security Considerations section for IHE transport protocols used by the Content Creator and Content Consumer actors (e.g., XDS and XDM) for further details related to those transports.

685 Those transports typically mandate grouping with the Secure Node or Secure Application actors from ATNA.

X.6 RPM Cross Profile Considerations

NA

690
Volume 2 – Transactions

Add Section 3.Y

3.Y PCC-Y Communicate PCHA Data-* Transaction

3.Y.1 Scope

These transactions are used to transfer measurement data from Personal Health Device (PHD)
695 Device Observation Source Actors to an appropriate consumer in a standardized manner. These
transactions allow a single Sensor Data Consumer Actor to process data from any compliant
sensor device (blood pressure cuffs, glucometers, coagulation meters, sleep apnea breathing
therapy equipment, etc.)

In the RPM Profile, these transactions are typically the only point at which a human is involved.
700 Once the measurement data is received by the Sensor Data Consumer, the process of delivering
the data to its final destination in its final form at a Content Consumer is automated.

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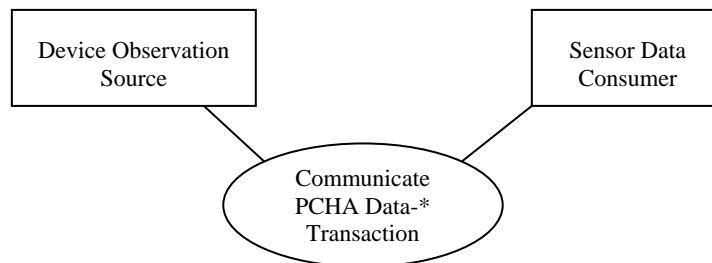
Figure 3.Y.2-1: Use Case Diagram

705

Table 3.Y.2-1: Actor Roles

Actor:	Device Observation Source
Role:	This actor is responsible for taking the measurement on the patient, packaging it into a standardized form and sending it to a consumer in a standardized manner.
Actor:	Sensor Data Consumer
Role:	This actor receives measurement data from one or more Device Observation Source actors (sensor devices)

3.Y.3 Referenced Standards

710

715

720

The Communicate PCHA data-* transactions are specified in the PCHA H.811 - TAN-PAN-LAN Interface. The PCHA standard relies upon the *IEEE 11073 20601 Optimized Exchange Protocol* and supporting IEEE 11073 104xx device specialization standards, the Bluetooth transport uses the Health Device Profile specified in the Bluetooth SIG documents *Health Device Profile* (HDP) and the *Multi-Channel Adaptation Profile* (MCAP), the USB transport requirements are specified in the *Universal Serial Bus Device Class Definition for Personal Healthcare Devices*, ZigBee transports requirements are specified in the *ZigBee Health Profile Specification*, and NFC transport requirements are specified in NFC Forum's *Personal Health Device Communication* specification. For Bluetooth Low Energy transports the specifications are defined in the Bluetooth Low Energy Health Device Profiles and Services documents, and the Bluetooth SIG *Personal Health Devices Transcoding White Paper*. The transcoding white paper maps PCHA compatible Bluetooth Low Energy attribute contents to IEEE 11073 20601 objects, attributes, and most importantly, nomenclature codes. The White Paper specifies a standardized means to translate BTLE data into PCD-01 OBX segments.

3.Y.4 Interaction Diagram

725

730

The Communicate PCHA Data-* transaction has two implementations, an IEEE 11073 20601 based packet exchange over any transport that is both reliable and delivers packets in order (currently four transports are recognized by PCHA), and an exchange using the Bluetooth Low Energy (BTLE) Generic Attribute (GATT) protocol. Both implementations first require the establishment of a connection. Once the connection is established, a series of exchanges take place that provide the Sensor Data Consumer with configuration and capability information about the Device Observation Source. When the endpoints have completed this configuration, measurement data can be is transferred.

735

740

The following interaction diagrams illustrate the sequence of processes for the IEEE and BTLE exchanges. When there are two flow illustrations in the figures, the IEEE exchange is to the left and the BTLE exchange is to the right. Figure 3.Y.4-1 illustrates the sequence from connection establishment to data exchange exposing some of the details of the setup exchanges. Figures 3.Y.4-2 and 3.Y.4-3 illustrate the sequences for the data exchanges. Figure 3.Y.4-2 illustrates the behavior when there is persistently stored data and Figure 3.Y.4-3 illustrates the behavior for non-persistently stored data. It should be noted that a Device Observation Source may have both types of data and the sequences illustrated in Figures 3.Y.4-2 and 3.Y.4-3 can happen simultaneously and/or in the same connection. Figure 3.Y.4-4 summarizes the sequences into two groups, setup and data exchange. The triggering events, semantics, and expected actions of for the summary sequence are then discussed in detail with references to the individual cases when needed.
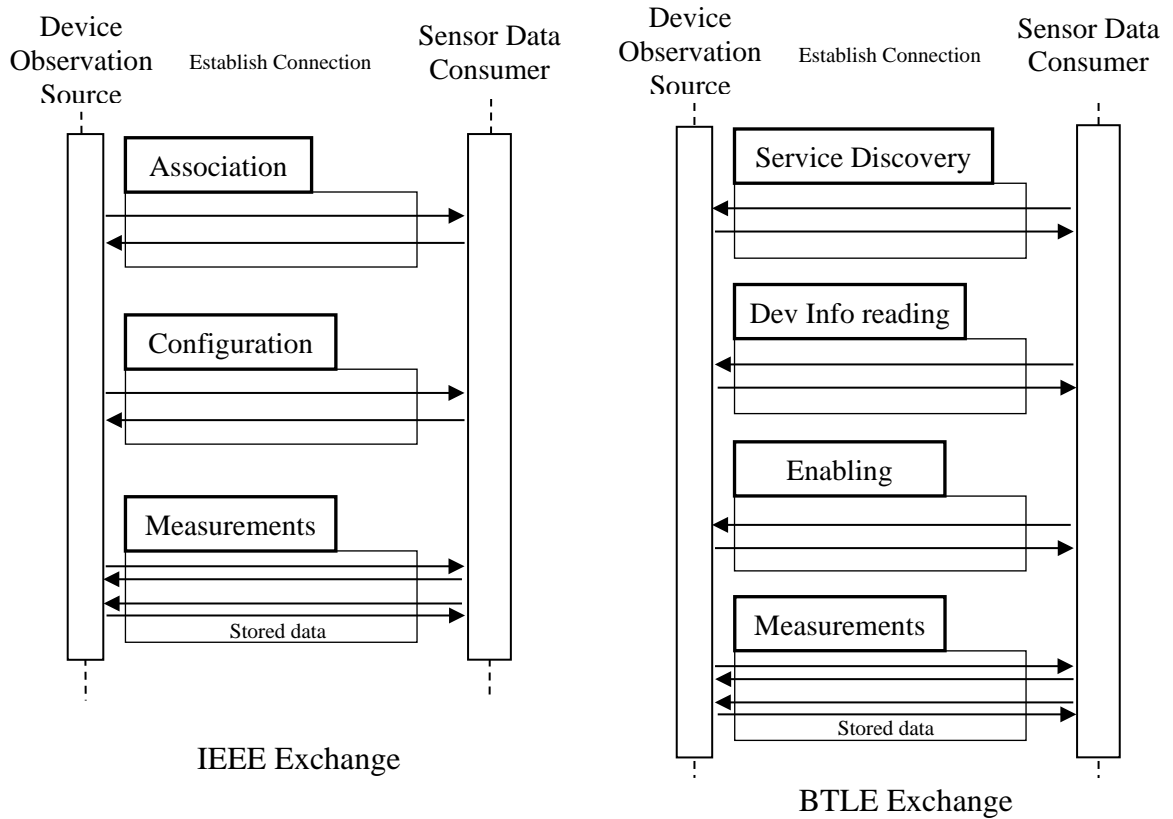
745 **Figure 3.Y.4-1: Complete PCHA Data Transaction**

The above Figure illustrates the sequence of events that take place in the two different implementations of the PCHA transaction. In both cases there is series of exchanges that allow the Sensor Data Consumer to either receive or request measurement data from the Device
750 Observation Source. It should be noted that the Sensor Data Consumer only requests data from the Device Observation Source if the Device Observation Source indicates that it has permanently stored data.
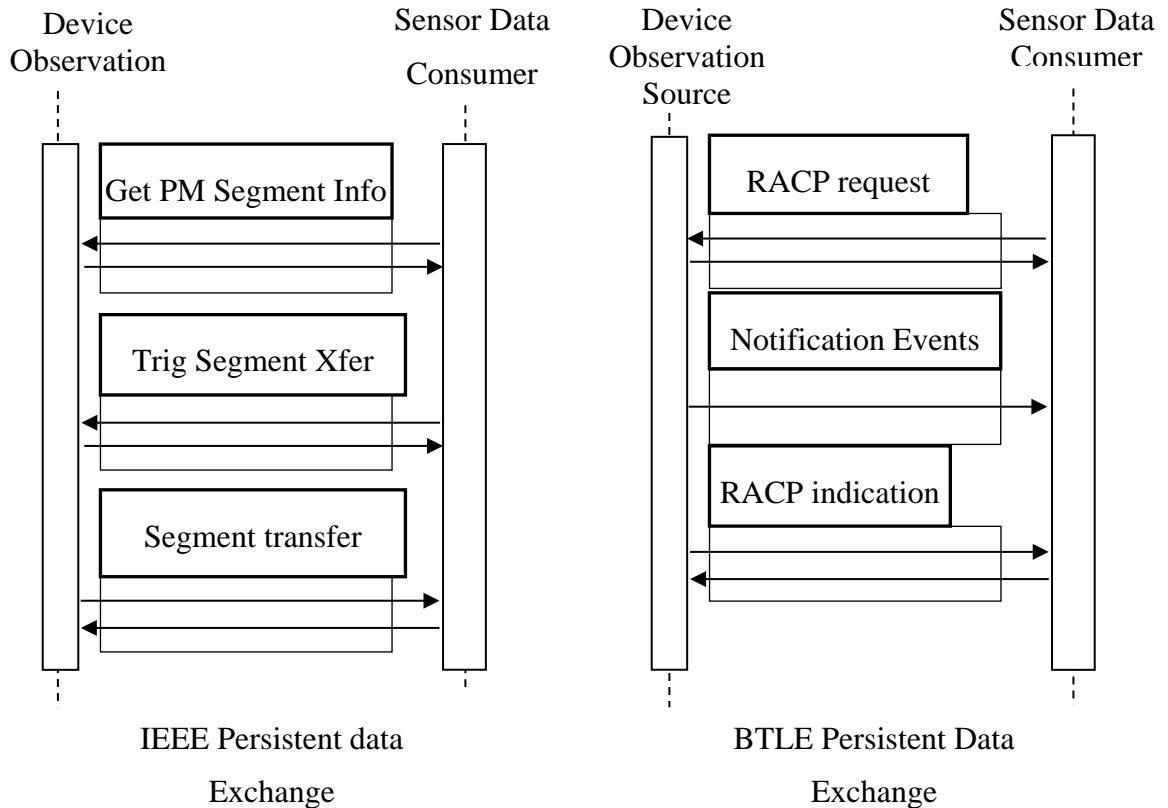

Figure 3.Y.4-2: Persistent Data Exchanges

Figure 3.Y.4-2 illustrates the exchanges for persistently stored data. In the IEEE case, the stored data is exposed as a set of PM Stores (analogous to directories) containing PM Segments
760 (analogous to files). Thus the Sensor Data Consumer must query for the PM segments in the various PM Stores and then decide which PM Segment to transfer. It then requests the transfer of the given PM segment and the Device Observation Source makes the transfer. In the BTLE case, there is but one 'file' but the Record Access Control Point (RACP) processes allow querying for its size as well as for transferring only parts of the entire data set. Once the RACP transfer is
765 initiated the records are sent in notification events (they are NOT acknowledged). However when the transfer is completed, an RACP indication (which IS acknowledged) indicates that the transfer is complete. Sequence numbers indicate to the Device Observation Consumer that all requested records have been received.
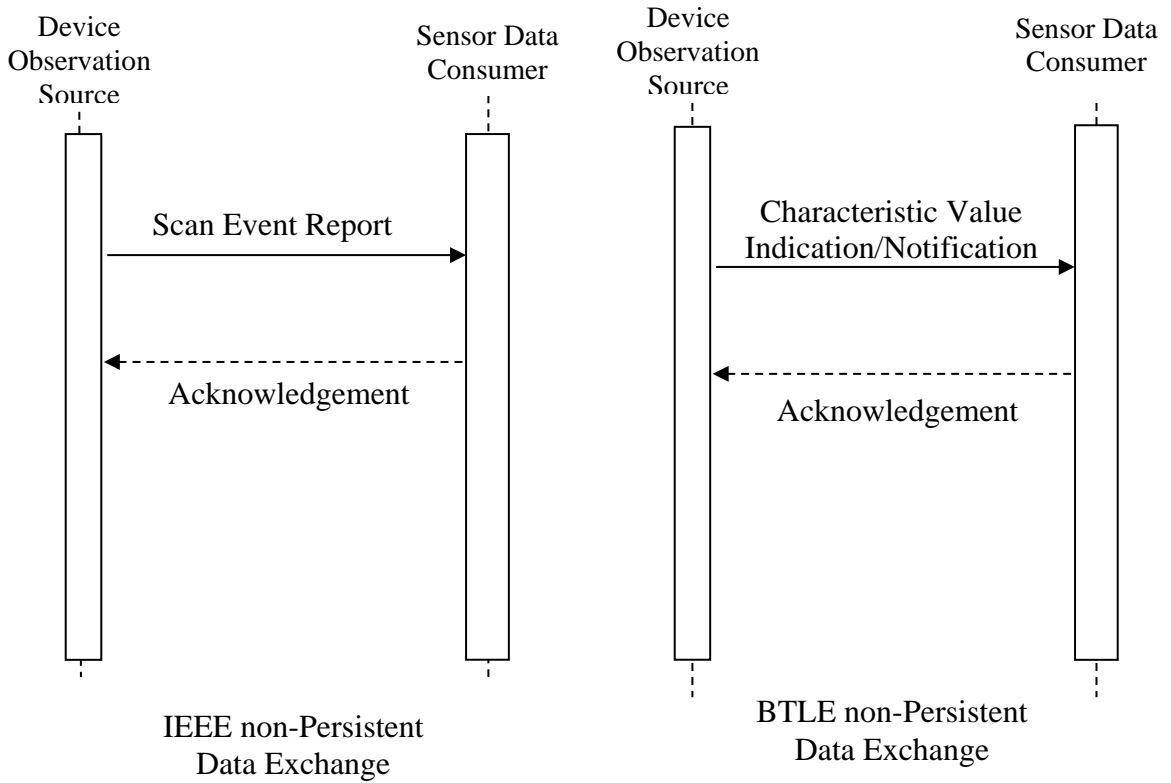
770

Figure 3.Y.4-3 'Live' Measurement Exchanges

Figure 3.Y.4-3 illustrates the PCHA sequences for IEEE and BTLE when the Device
775 Observation Source and Sensor Data Consumer have been configured and there is non-persistent
data to transfer. In this case the Device Observation Source sends the data unsolicited. Some
transmissions are not acknowledged by the Sensor Data Consumer. Unacknowledged
transmissions tend to be for streaming or waveform data.
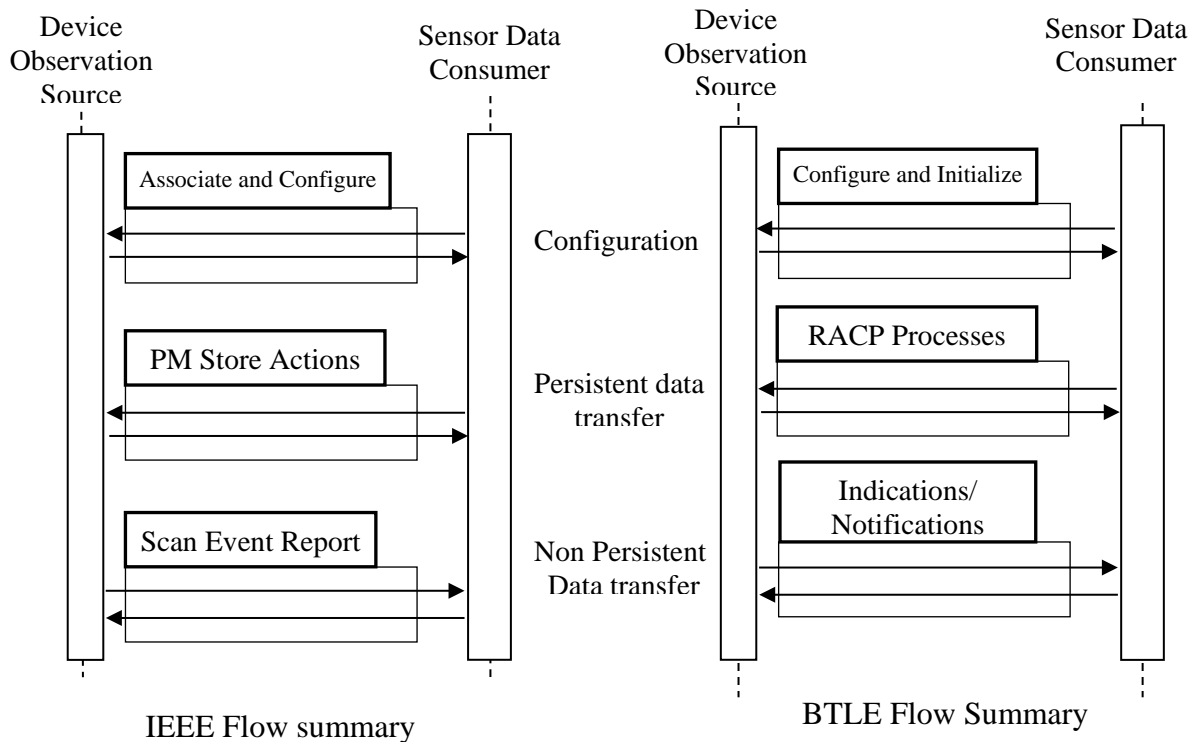
Figure 3.Y.4-4: All Measurement Data Exchanges

Figure 3.Y.4-4 summarizes the Communicate PCHA Data-* transactions for the IEEE and BTLE implementations. In both cases there is a configuration stage preparing the actors for data transfer. And then in both cases there a data transfer mechanism for persistent and non-persistent data. In both cases the Device Observation Source sends non-persistent data unsolicited and in both cases the Sensor Data Consumer initiates the request for persistent data.

3.Y.4.1 Configuration

For all transports supported by the Communicate PCHA data-* transactions there is a configuration stage where the Sensor Data Consumer obtains information about the Device Observation Source. This information is necessary in order for the Sensor Data Consumer to receive and interpret the measurement data from the Device Observation Source.

3.Y.4.1.1 Trigger Events

The typical trigger events fall into two groups. The first is that the Device Observation Source has measurement data to upload and the patient initiates the process for data upload. The second is that the patient is in the process of taking a measurement and a Sensor Data Consumer is either in range (wireless) or connected (wired) and active.

3.Y.4.1.2 Message Semantics

In the IEEE implementation the configuration messages consist of ASN.1 structures describing the IEEE 11073 20601 attributes present in the metric objects (measurements) the Device Observation Source supports. There are also ASN.1 structures describing the Device Observation Source properties (time capabilities, serial number, identifiers, etc.). ASN.1 structures are self-describing through the use of codes (or ids) and their TLV (Type, Length, Value) organization allow parse and ignore. These structures and their use in the objects, attributes, and APDUs are defined in Annex A of IEEE 11073 20601 Optimized Exchange Protocol. The major advantage of this protocol is that it is extensible. Since new specializations seldom define new ASN.1 structures, existing implementations are able to exchange data with, and decode data from, the new specializations without additional coding. Graphical displays will, however, need to provide human readable text for new nomenclature codes such as that code describing the new specialization; for example this is a continuous glucose monitoring device.

In the BTLE configuration the messages consist of GATT attributes to describe the services, characteristics, and descriptors on the Device Observation Source. The services indicate what the Device Observation Source supports, such as a thermometer service, heart rate service, blood pressure service, battery service, device information service, current time service, etc. If the right security has been established, the Sensor Data Consumer can read the characteristics in some of these services if it knows them and enable other characteristics to receive data. Every GATT service specifies its own set of characteristic and descriptors. They are unique and can only be decoded by knowing the specifications for the contained characteristic and descriptor attributes. Profile documents specify the services used by a given entity, for example the Glucose Profile specification. Separate service documents specify the characteristics and descriptors for the contained service(s) within a profile such as the Glucose Service and Device Information Service. The Bluetooth Special Interest Group maintains these documents. They also maintain a development portal at https://developer.bluetooth.org/Pages/default.aspx where implementers can easily access the contents of these GATT attributes for all the currently defined services and profiles. Unlike the IEEE 11073 20601 specification which is extensible and new specializations require only the recognition of new nomenclature codes, new BTLE device profiles will require the addition of new GATT attributes and thus new profile and service specifications. Existing implementations will be unable to handle these new specifications.

3.Y.4.1.3 Expected Actions

When the Device Observation Source implements one or more of the PCHA BTLE Health Device Profiles then the initiation and configuration messages shall be performed using BTLE.

When the Device Observation Source implements the PCHA IEEE 11073 20601 based option then the initiation and configuration messages shall be performed using IEEE 11073 20601 packets over one or more of USB, ZigBee, Bluetooth, or Near Field Communication (NFC) transport.

When the Sensor Data Consumer sends the confirmation to the Configuration sequence, the Sensor Data Consumer is expected to be ready to handle the reception of measurement data and the Device Observation Source is expected to be ready to deliver measurement data.

3.Y.4.2 Persistent Data Transfer

840 For the IEEE implementation the Sensor Data Consumer uses the IEEE 11073 PM Store *actions* which are ASN.1 packets sent to the Device Observation Source to query about and initiate the transfer of persistent data. For the BTLE implementation the Sensor Data Consumer uses the Record Access Control Point (RACP) processes which consist of writing to certain characteristics on the Device Observation Source for the same purposes. This process is

845 described in the Glucose Profile. For both implementations the Device Observation Source responds with the requested data transfer.

3.Y.4.2.1 Trigger Events

This message is triggered by the existence of persistent data storage capabilities on the Device Observation Source. The Sensor Data Consumer learns of these capabilities during

850 configuration. Though most consumer implementations initiate the processes automatically, manual initiation is allowed.

3.Y.4.2.2 Message Semantics

In the IEEE implementation the actions initiated from the Sensor Data Consumer are ASN.1 structures indicating to the Device Observation Source what to do. These instructions range from

855 requesting information about the PM Segments (files) for a given PM Store (directory), beginning the transfer of a given PM Segment contained in a PM Store, to clearing one or more PM Segments contained in a PM Store. In the BTLE implementation the Sensor Data Consumer writes to RACP characteristics on the Device Observation Source whose values indicate what to do. Similar to the IEEE implementation, the instructions request how much data is available,

860 what data to transfer, and what data to clear.

In the IEEE implementation the data is transferred in Segment Data Event packets and in the BTLE implementation the data is transferred in notification events. Sequence numbers keep track of the transfers and assure data consistency.

3.Y.4.2.3 Expected Actions

865 Upon seeing that the Device Observation Source has persistent storage capabilities, the Sensor Data Consumer is expected to query for the existence of any data and request the transfer of data it wants. The Device Observation Source is expected to provide the information and/or transfer the measurement data as instructed by the Sensor Data Consumer.

Deletion requests of the data by the Sensor Data Consumer are allowed. However the Device

870 Observation Source is not required to support deletion and may refuse deletion.

When the Sensor Data Consumer acknowledges the receipt of this transfer it has taken responsibility for the data and passes it on to the Device Observation Reporter. The Device Observation Source is now free to release any resources associated with the stored measurements.

___

875 ### 3.Y.4.3 Non Persistent Data Transfer

In the IEEE implementation non persistent data is sent unsolicited in scan event report packets. Scan event reports contain ASN.1 Observation Scan structures that contain the updated components of the measurements. In the BTLE implementation non-persistent data is sent unsolicited in characteristic value change indication or notification events. The characteristic
880 value may contain one or more different measurements.

3.Y.4.3.1 Trigger Events

This message is triggered when the endpoints complete configuration and have data to send.

3.Y.4.3.2 Message Semantics

In the IEEE implementation the scan event report packets are ASN.1 structures containing the
885 *changed* attributes of one or more metric objects (measurements) in ASN.1 Observation Scans. These changed attributes are combined with the unchanged attributes which have been mirrored on the Sensor Data Consumer to create the final completed measurements. In the BTLE implementation the indications or notifications typically contain one or more full measurements. Decoding is only possible if one knows the specification for the given characteristic.

890 ### 3.Y.4.3.3 Expected Actions

When the Sensor Data Consumer acknowledges the receipt of this message it has taken responsibility for the data and passes it on to the Device Observation Reporter. The Device Observation Source is now free to release any resources associated with the measurement.

3.Y.5 Security Considerations

895 The Communicate PCHA Data-* transactions are local; that is the Device Observation Source is expected to be in the proximity of the Sensor Data Consumer. In the case of wired transports (USB), the security risks in the exchange are considered to be so low the data is transferred without any encryption. However, unencrypted wireless transports could be intercepted and modified by a malicious third party and the PCHA transaction requires the use of the available
900 encryption options in the wireless protocols.

3.Y.5.1 Security Audit Considerations

There are no auditing requirements in these transactions.

3.Y.5.1.1 Device Observation Source Specific Security Considerations

The primary security risk facing the Device Observation Source is the compromising of personal
905 health data via theft of the device. This risk is, in practice, quite low since the Device Observation Source rarely contains any personal information since the transport protocols of the Communicate PCHA Data-* transactions do not support the transmission of personal data to the Sensor Data Consumer. The Communicate PCHA Data-* transactions also do not currently support control and or configuration of the Device Observation Source from the Sensor Data
910 Consumer thus the threat of malicious configuration of the device is low. However there are

___

_____

current developments in the Communicate PCHA Data-* transactions for the configuration/control of the Device Observation Source from the Sensor Data Consumer. That option will demand additional security considerations that have not yet been worked out.

3.Y.5.1.2 Sensor Data Consumer Specific Security Considerations

915 The greatest security risk facing the Sensor Data Consumer is the compromising of personal data via theft of the device. Unlike the Device Observation Source, the Sensor Data Consumer is often a personal mobile device such as an Android phone or tablet and these devices may have all kinds of personal information; including financial. The Sensor Data Consumer implementation may also store the medical data for review. What the Sensor Data Consumer

920 does with the received data beyond passing the data to the Device Observation Reporter or Content Creator is not specified by the Communicate PCHA Data-* transactions. Local storage of the data and whether or not it is encrypted is application dependent.

3.Z PCC-Y PCD Communicate PCD Data-hData Transaction

3.Z.1 Scope

925 These transactions are used to transfer collected patient measurement data to a Device Observation Consumer in the form of a PCD-01 message

3.Z.2 Actor Roles
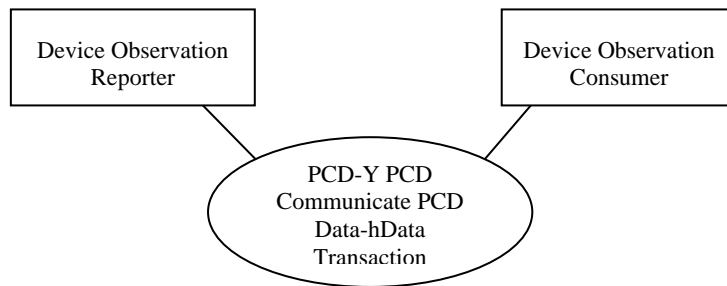
Figure 3.Z.2-1: Use Case Diagram

930

Table 3.Z.2-1: Actor Roles

Actor:	Device Observation Reporter
Role:	This actor is responsible for packaging patient measurement data into a PCD-01 message and sending it to a Device Observation Consumer
Actor:	Device Observation Consumer
Role:	This actor receives the PCD-01 message from one or more Device Observation Reporters

_____

Since the Device Observation Reporter does not receive any patient demographic information from the PHD device; at least the patient name, a patient identifier and authorization code are required to create a compliant PID segment for the PCD-01 message. The Device Observation Reporter implementation will be required to provide this supplemental information, and when appropriate, map it to the optional person-id that is sometimes provided by PHD devices. A Device Observation Reporter implementation may also provide a filter such that only certain measurements are forwarded in the PCD-01 message. Such a filter is implementation dependent and outside the scope of this profile, but clearly the filter must still generate a compliant PCD-01 message.

3.Z.3 Referenced Standards

The PCD Communicate PCD data-hData transaction is specified in the PCHA H.812.1 – Observation 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. Authentication is further specified in IHE Technical Framework Supplement: Internet User Authentication.

3.Z.4 Interaction Diagram

The diagram below illustrates the Communicate PCD Data-hData transaction. How one obtains the authentication token is not specified by this profile.
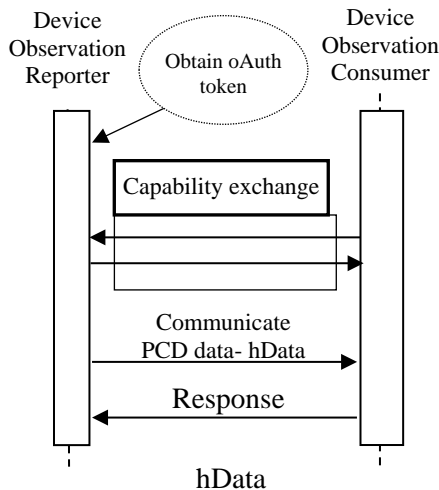

Figure 3.Z.4-1: Communication PCD Data-hData Transaction

3.Z.4.1 Capability Exchange

955 The Capability exchange encapsulates the first stage of all hData transactions which consist of obtaining the root.xml. This file provides the Device Observation Reporter with the features and resource directory of the Device Observation Consumer in a standardized manner.

3.Z.4.1.1 Trigger Events

The typical trigger event is initialization of communications between the Device Observation
960 Reporter and Device Observation Consumer. This initialization may not happen until the Device Observation Reporter is passed measurement data.

3.Z.4.1.2 Message Semantics

In RESTful hData transactions the root.xml file is obtained using an HTTP GET on the base URL. The base URL is obtained by an out-of-band means. The root.xml is to hData what the
965 WSDL is to Web Services. The request for the root.xml is the first action all hData clients take in order to interoperate with an hData server. The PCHA H 812.3 Capability Exchange utilizes the profile, section, representation, and resourceType elements of the hData record format to specify what PCHA certified device classes are supported by the Device Observation Consumer as well as the information needed by the client to interoperate with these certified device classes. The
970 hData Observation-upload is one of the certified device classes that shall be described in the root.xml if the endpoint supports the transaction. Figures 7-2 to 7-5 in the PCHA H 812.1 Observation Upload specification show examples of the capability elements as they might appear for a Device Observation Consumer that supports (1) observation upload by hData, (2) observation upload by SOAP web services, (3) an STS SAML Token server, and (4) an oAuth
975 2.0 authentication service. Only the observation upload by hData capability is required for hData servers that support that capability, since the web services capabilities are not RESTful and web service clients will not be expected to access and understand hData root.xmls. However specifying the web services capabilities in the exchange can make for a more user friendly experience on dual capability clients.

980 For the Communicate PCD Data hData transaction, the Capability Exchange Profile/path element provides the Device Observation Reporter with the URL for the HTTP POST of the PCD-01 message. The Capability Exchange in general also provides the location of any schemas, the form of the document (xml, text, etc.), and the document specifying the standard for the transaction. Extension elements can be used to provide additional information.

985 ### 3.Z.4.1.3 Expected Actions

The handling of this message is primarily internal and no expected actions result. However, the obtained information is essential in order for the Device Observation Reporter to invoke the RESTful Communicate PCD Data-hData transaction.

3.Z.4.2 Communicate PCD Data-hData

990 The Communicate PCD Data-hData transaction used in this profile uses RESTful HL7 hData Record Format specified in HL7® Version 3 Standards: Record Data Format Release 1 to

transfer the PCD-01 message to the Device Observation Consumer. The PCHA H.812.1 Observation upload specification requires that the Device Observation Consumer and Device Observation Reporter Actor support TLS security and oAuth authentication on the hData
995   transport. ATNA auditing is an option.

It is this component of the message that transfers the measurement data as a PCD-01 message to the Device Observation Consumer. The security and authentication requirements are present since this transaction is not locally bound like the Communicate PCHA Data-* transactions and in this profile it is the transaction responsible for transferring the medical data from the remote
1000   location of the patient to an enterprise or third party server which can be located anywhere there is connectivity. Typically this would be the internet and it could occur from an unsecured public network.

Full on-the-wire examples of the hData transaction including the request for the oAuth token is given in PCHA H 812.1 Observation Upload section 8.11. The example is repeated with the
1005   capability exchange in Appendix J. The PCHA H 812.1 Observation Upload specification also provides a detailed description of how to map IEEE 11073 20601 metric object attributes to PCD-01 MDS and Metric OBX segments in Annex D.0 – D.1.4. Given the Bluetooth Low Energy Transcoding White Paper the same mapping descriptions can be used for PCHA-compliant Bluetooth Low Energy devices. In addition to the generic mapping description, the
1010   PCHA H 812.1 Observation Upload has a set of tables that map the IEEE 11073 20601 device specialization attributes to metric OBX segments in Annex E.

3.Z.4.2.1 Trigger Events

The typical trigger event is the passing of a collection of measurement data to the Device Observation Reporter Actor.

1015   ### 3.Z.4.2.2 Message Semantics

The RESTful transport implementation of this message contains both an oAuth identity token and the PCD-01 message which represents the measurement sequence taken upon the patient. The message consists of a simple HTTP POST containing the oAuth token to the URL specified by the Device Observation Consumer in its root.mxl obtained during Capability Exchange. The
1020   body of the message is the PCD-01 message. 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 third party service trusted by the Device Observation Consumer, or the token may be obtained by
1025   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.

3.Z.4.2.3 Expected Actions

The expected behavior by the Device Observation Consumer upon reception of this message is to
1030   first authenticate the identity of the sender and if authenticated to transfer the PCD-01 message

to the Content Creator Actor. The Device Observation Consumer is then expected to indicate to the Device Observation Reporter whether or not the transfer is successful by responding with an appropriate acknowledgement.

3.Z.4.3 Acknowledgement

1035 The Acknowledgement is a response to the Communicate PCD Data-hData message and indicates the status of the transaction. The consequence of this message indicates whether or not responsibility for the data is transferred from the Device Observation Reporter to the Device Observation Consumer.

3.Z.4.3.1 Trigger Events

1040 The Acknowledgement is triggered by the reception of the Communicate PCD Data-hData at the Device Observation Consumer.

3.Z.4.3.2 Message Semantics

This message consists of an HTTP response indicating the status of the transaction plus a PCD-01 response message as defined in IHE PCD-TF Vol 2 Transactions. The PCD-01 response
1045 consists of up to three segments where the ERR segment is optional. In spite of its name, the ERR segment may also be present when the received PCD-01 message is handled successfully. The ERR segment provides a field ERR-6 that may contain any additional information the server wishes to add. ERR-1 and/or ERR-2 provide error codes, and one of the codes indicates success. The server could indicate to the client that the PCD-01 message was successfully archived or
1050 successfully converted to a PHMR and transferred to its final repository.

3.Z.4.3.3 Expected Actions

Upon a successful transaction the Device Observation Reporter is free to release any resources associated with the measurement data. The Device Observation Consumer is expected to transfer the data to the Content Creator.

1055 ### 3.Z.5 Security Considerations

The Communicate PCD Data-hData transaction is subject to perhaps the greatest security threat of all the transactions in the RPM Profile as it is likely to utilize the public internet and unsecure public networks. To assure some level of consistent security, this profile requires, at minimum, support for TLS encryption and the support of oAuth BearerToken authentication in this
1060 transaction.

3.Z.5.1 Security Audit Considerations

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

3.Z.5.2 Device Observation Reporter Specific Security Considerations

1065 Being part of the Sensor Data Consumer or Device Observation Source, the Device Observation Reporter faces the same security risks as those actors; the primary risk being compromising of personal data via theft of the device. The Device Observation Reporter is often a personal mobile device such as an Android phone or tablet and these devices may have all kinds of personal information; including financial. The Device Observation Reporter implementation will store
1070 medical data on failed transfers and it may also store the medical data for review. Given that the unit is often in the home, it falls outside of HIPPA jurisdiction. Given that the range of data sensitivity in a remote patient monitoring situation is so great, this profile does not specify any non-transaction based security requirements. Encryption of local data, and password, fingerprint, facial recognition, etc. access to the unit hosting the Device Observation Reporter software is left
1075 up to the implementation.

3.Z.5.3 Device Observation Consumer Specific Security Considerations

The Device Observation Consumer Actor 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. But given its professional
1080 environment, it is also subject to HIPPA requirements.

3.ZA PCC-Y PCD Communicate PCD Data-SOAP Transaction

3.ZA.1 Scope

This transaction is used to transfer collected patient measurement data to a Device Observation Consumer in the form of a PCD-01 message using secured Web Services CommunicatePCDData
1085 SOAP action authenticated by SAML.

3.ZA.2 Actor Roles
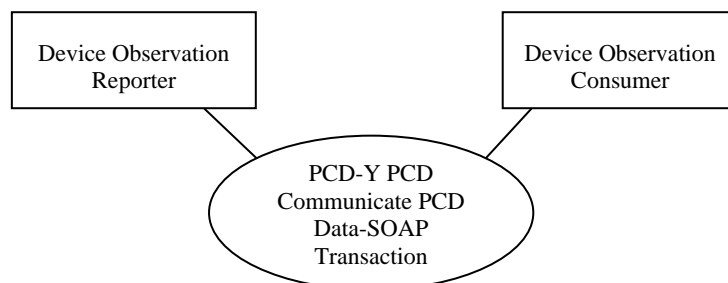
Figure 3.ZA.2-1: Use Case Diagram

1090

_____

Table 3.ZA.2-1: Actor Roles

Actor:	Device Observation Reporter
Role:	This actor is responsible for packaging patient measurement data into a PCD-01 message and sending it to a Device Observation Consumer
Actor:	Device Observation Consumer
Role:	This actor receives the PCD-01 message from one or more Device Observation Reporters

Since the Device Observation Reporter does not receive any patient demographic information
1095   from the PHD device; at least the patient name, a patient identifier and authorization code are
required to create a compliant PID segment for the PCD-01 message. The Device Observation
Reporter implementation will be required to provide this supplemental information, and when
appropriate, map it to the optional person-id that is sometimes provided by PHD devices. A
Device Observation Reporter implementation may also provide a filter such that only certain
1100   measurements are forwarded in the PCD-01 message. Such a filter is implementation dependent
and outside the scope of this profile, but clearly the filter must still generate a compliant PCD-01
message.

3.ZA.3 Referenced Standards

The PCD Communicate PCD data-SOAP transaction is specified in the PCHA H.812.1
1105   Observation Upload specification which references the CommunicatePCDData SOAP action in
PCD TF-1to3.

3.ZA.4 Interaction Diagram

The figure below illustrates the Communicate PCD Data-SOAP transaction. The transaction
requires an out-of-band action to obtain a SAML2.0 authentication token.

_____
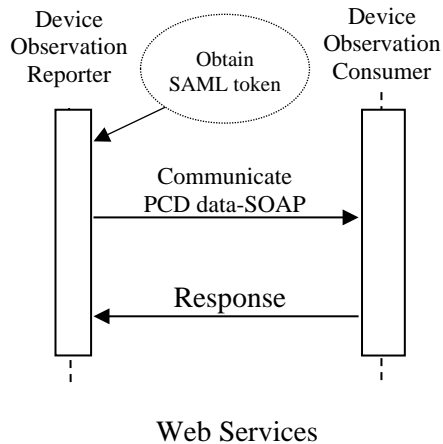
Web Services

1110

Figure 3.ZA.4-1: Communication PCD-Data – SOAP Transaction

3.ZA.4.1 Communicate PCD Data-SOAP

The Communicate PCD Data-SOAP transaction transfers a PCD-01 message in a
1115 CommunicatePDCData SOAP action over web services. This transport is specified in the PCD
TF-1to3. The PCHA H.812.1 Observation upload specification requires that the Device
Observation Consumer Actor support TLS security, SAML 2.0 authentication, and WS reliable
messaging on this web services transport. The same requirements are placed upon the Device
Observation Reporter except that Reliable messaging is optional. ATNA auditing is an option.

1120 It is this component of the message that transfers the measurement data as a PCD-01 message to
the Device Observation Consumer. The security and authentication requirements are present
since this transaction is not locally bound like the Communicate PCHA Data-* transactions and
in this profile it is the transaction responsible for transferring the medical data from the remote
location of the patient to an enterprise or third party server which can be located anywhere there
1125 is connectivity. Typically this would be the internet and the transaction could take place from
exposed public networks.

Full on-the-wire examples of the SOAP transaction including requests for the SAML token is
given in PCHA H 812.1 Observation Upload sections 8.10. The example is repeated in Appendix
K. The PCHA H 812.1 Observation Upload specification also provides a detailed description of
1130 how to map IEEE 11073 20601 metric object attributes to PCD-01 MDS and Metric OBX
segments in Annex D.0 – D.1.4. Given the Bluetooth Low Energy Transcoding White Paper the
same mapping descriptions can be used for PCHA-compliant Bluetooth Low Energy devices. In
addition to the generic mapping description, the PCHA H 812.1 Observation Upload has a set of
tables that map the IEEE 11073 20601 device specialization attributes to metric OBX segments
1135 in Annex E.

3.ZA.4.1.2 Trigger Events

The typical trigger event is the passing of a collection of measurement data to the Device Observation Reporter Actor.

3.ZA.4.1.3 Message Semantics

1140 The transport implementation of this message contains both a SAML2.0 identity token and the PCD-01 message which represents the measurement sequence taken upon the patient. The PCD-01 message is encapsulated in a CommunicatePCDData SOAP action. WS-Addressing and WS-Security elements housing the SAML2.0 token are present in the SOAP header. The SAML identity token must be recognized and validated by the Device Observation Consumer for
1145 acceptance of the message but how that identity token is obtained is a business trust relationship decision. The Device Observation Consumer may be a SAML token Server, or the Device Observation Consumer may rely upon a third party service to provide the token to the Device Observation Reporter, or the Device Observation Reporter may obtain the token by another out of band means.

1150 This transaction also represents an attempt to pass responsibility of the data from the Device Observation Reporter to the Device Observation Consumer.

3.ZA.4.1.4 Expected Actions

The expected behavior by the Device Observation Consumer upon reception of this message is to first authenticate the identity of the sender and if authenticated to transfer the PCD-01 message
1155 to the Content Creator Actor. The Device Observation Consumer is then expected to indicate to the Device Observation Reporter whether or not the transfer is successful by responding with an appropriate acknowledgement.

3.ZA.4.2 Acknowledgement

The Acknowledgement is a response to the Communicate PCD Data-SOAP message and
1160 indicates the status of the transaction. The consequence of this message indicates whether or not responsibility for the data is transferred from the Device Observation Reporter to the Device Observation Consumer.

3.ZA.4.2.1 Trigger Events

The Acknowledgement is triggered by the reception of the Communicate PCD Data-SOAP
1165 transaction at the Device Observation Consumer.

3.ZA.4.2.2 Message Semantics

This message consists of Web services WS-Addressing and WS_Security header with a CommunicatePCDDataResponse SOAP action containing a PCD-01 response message as defined in IHE PCD-TF Vol 2 Transactions. The PCD-01 response consists of up to three
1170 segments where the ERR segment is optional. In spite of its name, the ERR segment may also be present when the received PCD-01 message is handled successfully. The ERR segment provides

---

a field ERR-6 that may contain any additional information the server wishes to add. ERR-1 and/or ERR-2 provide error codes, and one of the codes indicates success. The server could indicate to the client that the PCD-01 message was successfully archived or successfully converted to a PHMR and transferred to its final repository.

3.ZA.4.2.3 Expected Actions

Upon a successful transaction the Device Observation Reporter is free to release any resources associated with the measurement data. The Device Observation Consumer is expected to transfer the data to the Content Creator.

3.ZA.5 Security Considerations

The Communicate PCD Data-SOAP transaction is subject to perhaps the greatest security threat of all the transactions in the RPM Profile as it is likely to utilize the public internet and unsecure public networks. To assure some level of consistent security, this profile requires, at minimum, support for TLS encryption and the support of SAML authentication in this transaction. Additional security restrictions such as message level security are optional and are determined by business needs.

3.ZA.5.1 Security Audit Considerations

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

3.ZA.5.2 Device Observation Reporter Specific Security Considerations

Being part of the Sensor Data Consumer or Device Observation Source, the Device Observation Reporter faces the same security risks as those actors; the primary risk being compromising of personal data via theft of the device. The Device Observation Reporter is often a personal mobile device such as an Android phone or tablet and these devices may have all kinds of 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. Given that the unit is often in the home, it falls outside of HIPPA jurisdiction. Given that the range of data sensitivity in a remote patient monitoring situation is so great, this profile does not specify any non-transaction based security requirements. 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.

3.ZA.5.3 Device Observation Consumer Specific Security Considerations

The Device Observation Consumer Actor 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. But given its professional environment, it is also subject to HIPPA requirements.

Appendices

None

1210 ## Volume 2 Namespace Additions

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

None

Volume 3 – Content Modules

1215

5 Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

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.

1220   *Add to section 5.1.1 IHE Format Codes*

Profile	Format Code	Media Type	Template ID
Personal Health Monitoring Report (PHMR)	urn:ihe:pcc:phmr:2015	Text/xml	TBD

6.3.1 CDA® Document Content Modules

Add to section 6.3.1 CDA Document Content Modules

1225

6.3.1.D Personal Healthcare Monitoring Report (PHMR) Document Content Module

6.3.1.D.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:pcc:phmr:2015**

6.3.1.D.2 Parent Template

1230   This document is a specialization of the IHE PCC Medical Document template (OID = 1.3.6.1.4.1.19376.1.5.3.1.1.1).

6.3.1.D.3 Referenced Standards

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

1235

Table 6.3.1.D.3-1: PHMR - Referenced Standards

Abbreviation	Title	URL
PHMR	Personal Health Monitoring Report	TBD
CDA	HL7 Clinical Document Architecture	TBD

Appendices

1240

Appendix J – Communicate PCD Data -hData Transaction Example

The following sequence shows the Communicate PCD Data-hData transaction as it would appear on the wire. For completeness it is assumed the Device Observation Consumer implementation supports an oAuth authentication server and the patient has been registered with the authentication server by the healthcare provider. The healthcare provider has entered the

1245 username and password as well as the URL to the Device Observation Consumer server on the Sensor Data Consumer / Device Observation Reporter implementation running on an Android based mobile phone and given it to the patient. Once home, the patient turns on the mobile phone and starts the collector implementation. The patient takes a measurement with a PCHA

1250 compliant PHD blood pressure cuff and the data is sent to the phone. The PHD device disassociates and disconnects.

The Device Observation Reporter begins the capabilities exchange. This request is sent using TLS but that is not required.

1255
```
GET /root.xml HTTP/1.1
Content-Type: application/xml
User-Agent: HealthLink-mOXP
Host: 192.168.1.3:8443
```

The Device Observation Consumer responds with the root.xml document containing the server
1260 capabilities.

```
HTTP/1.1 200 OK
Server: Jetty/1.9
Content-Type: application/xml
1265 Cache-Control: no-store
Pragma: no-cache
<?xml version="1.0" encoding="UTF-8"?>
<Root xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="http://hl7.org/schemas/hdata/2013/08/hrf">
1270     <id>urn:uuid:ab443e5e-b6a7-e951-956c-caef491bbc08</id>
    <version>2.0</version>
    <created>2013-07-14T15:07:38.6875000-05:00</created>
    <lastModified>2013-07-16T08:12:02.2832000-05:00</lastModified>

1275     <!-- This is the capability exchange -->
    <profile>
        <id>CapabilityExchange</id>
        <reference>http://continuaalliance.org/ccdc/2015/CapabilityExchange</reference>
    </profile>
1280
    <!-- This is the capability for hData Observation upload -->
    <profile>
    <!-- Specified value -->
        <id>observation-upload-hData</id>
1285        <reference>http://www.continuaalliance.org/upload2013/01/H.812.1.pdf</reference>
    </profile>

    <!-- This is the Unsolicited capability for APS-CDC -->
    <profile>
```

```
1290        <id>APS-CDC-WAN</id>
            <reference>http://www.continuaalliance.org/hData/APS/2013/01/H.810.2.4.pdf</reference>
        </profile>

        <!-- This is the Unsolicited capability for lampreynetworks.com.private -->
1295    <profile>
            <id>lampreynetworks.com.private</id>
            <reference>http://lampreynetworks.com./hData/APS/2013/01/LNI Private APS.pdf</reference>
        </profile>

1300    <!-- This is the capability for oAuth authentication service -->
        <profile>
            <!-- Specified value -->
            <id>oAUTH</id>
            <reference>http://www.continuaalliance.org/upload2013/01/H.810.2.1.pdf</reference>
1305    </profile>


        <section>
            <!-- chosen by the WAN service; empty on AHD -->
            <path>oAUTH_Service</path>
1310    <port>8441</port>
            <profileID>oAUTH</profileID>
            <resourceTypeID>oAUTH-Bearer</resourceTypeID>
        </section>

1315    <section>
            <path>pcd01</path>
            <port>8441</port>
            <profileID>observation-upload-hData</profileID>
            <resourceTypeID>observation</resourceTypeID>
1320    </section>

        <section>
            <!-- This is where an AHD may post ITs root.xml file [baseURL/roots] -->
            <path>roots</path>
1325    <port>8441</port>
            <profileID>CapabilityExchange</profileID>
            <resourceTypeID>root</resourceTypeID>
        </section>

1330    <!-- The path the AHD would POST to establish an APS is then: baseurl/APS -->
        <section>
            <!-- chosen by the WAN server; where the AHD does a POST of its APB xml -->
            <path>APS</path>
            <port>8442</port>
1335    <profileID>APS-CDC-WAN</profileID>
            <!-- optional but recommended -->
            <resourcePrefix>true</resourcePrefix>
            <resourceTypeID>APB</resourceTypeID>
        </section>
1340
        <!-- The path the AHD would POST to establish an APS is then: baseurl/APS -->
        <section>
            <!-- chosen by the WAN server; where the AHD does a POST of its APB xml -->
            <path>APS</path>
1345    <port>8442</port>
            <profileID>lampreynetworks.com.private</profileID>
            <!-- optional but recommended -->
            <resourcePrefix>true</resourcePrefix>
            <resourceTypeID>APB</resourceTypeID>
1350    </section>

        <resourceType>
            <id>observation</id>
            <!-- location of reference that describes the Observation upload standard -->
1355    <reference>http://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol2.pdf</reference>
            <representation>
```

```
                    <mediaType>application/txt</mediaType>
                    <!-- Schema for the resource -->
                </representation>
1360        </resourceType>

        <resourceType>
            <id>root</id>
            <reference>
1365                http://www.hl7.org/implement/standards/product_brief.cfm?product_id=261
            </reference>
            <representation>
                <mediaType>application/xml</mediaType>
                <validator>
1370                http://www.projecthdata.org/hdata/schemas/2013/root.xsd
                </validator>
            </representation>
        </resourceType>

1375    <resourceType>
            <id>APB</id>
            <!-- location of reference that describes the APS standard -->
            <reference>
http://www.continuaalliance.org/hData/APS/2013/01/ITU_APS_Implementation_Guidelines.docx
1380        </reference>
            <representation>
                <mediaType>application/xml</mediaType>
                <!-- Schema for the APS xml -->
                <validator>
1385                http://www.continuaalliance.org/hData/APS/2013/01/APBConfigResource.xsd
                </validator>
            </representation>
        </resourceType>

1390    <resourceType>
            <id>oAUTH-Bearer</id>
            <!-- location of reference that describes the oAuth standard -->
            <reference>http://tools.ietf.org/html/rfc6750</reference>
            <representation>
1395            <mediaType>application/json</mediaType>
            </representation>
        </resourceType>
    </Root>
```

Note that the Device Observation Consumer server indicates support for an oAuth Bearer token
1400 authentication service (highlighted in green) and observation upload using hData (highlighted in
yellow). There are ids which link the sets of profile, section, and resourceType elements together
to describe the capability. Note that the root.xml indicates support for other features that are, for
the moment, outside of the scope of interest for the Remote Patient Monitoring Profile. The
Device Observation Reporter ignores these items.

1405 This step does not have to be repeated until the next time the application powers up.

Next the Device Observation Reporter obtains the oAuth Bearer token. The capability exchange
indicates where to POST the request. Since entering that capability is optional in the capability
exchange (even if the server supports an oAuth authentication server) the URL to such a service
may need to be provided to the application via a user interface or some other means. The oAuth
1410 request is encrypted using TLS.

```
POST /oAUTH_Service HTTP/1.1
Content-Type: application/x-www-form-urlencoded
User-Agent: HealthLink-mOXP
1415 Host: 192.168.1.3:8443
```

```
Connection: Keep-Alive
Accept: application/x-www-form-urlencoded
Content-Length: 87
grant_type=password&username=Sisansarah&password=publicpassword&scope=ObservationUpload
```

1420 The authentication server checks its data base and sees that user *Sisansarah* with password *publicpassword* has been authorized for the *ObservationUpload* capability transaction. The authentication server responds with the token and a refresh token:

```
HTTP/1.1 200 OK
Server: Jetty/1.9
Content-Type: application/json;charset=UTF-8
Cache-Control: no-store
Pragma: no-cache
{
"access_token":"2YotnFZFEjr1zCsicMWpAA",
"token_type":"Bearer",
"expires_in":3600,
"refresh_token":"tGzv3JOkF0XG5Qx2TlKWIA",
"scope":"ObservationUpload"
}
```

The token is good for an hour after which time the refresh token will be needed or a new request made. Thus until the token expires, the Device Observation Reporter can upload as many messages as it wants without repeating the oAuth request.

1440

With the token in hand the upload of the PCD-01 message can start. The capability exchange has indicated to the Device Observation Source where to POST the PCD-01 message resource. This transaction is encrypted using TLS.

```
POST /pcd01 HTTP/1.1
Content-Type: application/txt
User-Agent: HealthLink-mOXP
Content-Encoding: UTF-8
Host: 192.168.1.3:8443
Connection: Keep-Alive
Accept: application/txt
Authorization: Bearer 2YotnFZFEjr1zCsicMWpAA
Content-Length: 2818
MSH|^~\&amp;|LNI Example AHD^ECDE3D4E58532D31^EUI-64||||20130301115450.720-0500||ORU^R01^ORU_R01|
    002013030111545720|P|2.6|||NE|AL|||||IHE PCD ORU-
R012006^HL7^2.16.840.1.113883.9.n.m^HL7&#xD;
PID|||28da0026bc42484^^^&1.19.6.24.109.42.1.3&ISO^PI||Piggy^Sisansarah^L.^^^^L&#xD;
OBR|1|JOXP-PCD^LNI Example AHD^ECDE3D4E58532D31^EUI-64|
    JOXP-PCD^LNI Example AHD^ECDE3D4E58532D31^EUI-64|182777000^monitoring of patient^SNOMED-
CT|||
    20130301115452.000-0500|20130301115455.001-0500&#xD;
OBX|1||531981^MDC_MOC_VMS_MDS_AHD^MDC|0|||||||X|||||||ECDE3D4E58532D31^^ECDE3D4E58532D31^EUI-
64&#xD;
OBX|2|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.1|2^auth-body-continua||||||R&#xD;
OBX|3|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|0.0.0.1.1|5.0||||||R&#xD;
OBX|4|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|0.0.0.1.2|4||||||R&#xD;
OBX|5|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.2|2^auth-body-continua||||||R&#xD;
OBX|6|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|0.0.0.2.1|1^unregulated(0)||||||R&#xD;
OBX|7|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.3|2^auth-body-continua||||||R&#xD;
OBX|8|CWE|532355^MDC_REG_CERT_DATA_CONTINUA_AHD_CERT_LIST^MDC|0.0.0.3.1|0^observation-upload-
soap||||||R&#xD;
OBX|9|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|0.0.0.4|532234^MDC_TIME_SYNC_NONE^MDC||||||R&#xD;
OBX|10|NM|8221^MDC_TIME_SYNC_ACCURACY^MDC
|0.0.0.5|120000000|264339^MDC_DIM_MICRO_SEC^MDC||||||R&#xD;
OBX|11||528391^MDC_DEV_SPEC_PROFILE_BP^MDC|1|||||||X|||||||1234567800112233^^1234567800112233^EUI
-64&#xD;
```

```
      OBX|12|ST|531970^MDC_ID_MODEL_MANUFACTURER^MDC|1.0.0.1|Lamprey Networks||||||R&#xD;
      OBX|13|ST|531969^MDC_ID_MODEL_NUMBER^MDC|1.0.0.2|Blood Pressure 1.0.0||||||R&#xD;
      OBX|14|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.3|2^auth-body-continua||||||R&#xD;
1480  OBX|15|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|1.0.0.3.1|2.0||||||R&#xD;
      OBX|16|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|1.0.0.3.2|24583~8199~16391~7||||||R
      &#xD;
      OBX|17|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.4|2^auth-body-continua||||||R&#xD;
      OBX|18|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|1.0.0.4.1|1^unregulated(0)||||||R&#xD
1485  ;
      OBX|19|CWE|68219^MDC_TIME_CAP_STATE^MDC|1.0.0.5|1^mds-time-capab-real-time-clock(0)||||||R&#xD;
      OBX|20|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|1.0.0.6|532224^MDC_TIME_SYNC_NONE^MDC||||||R&#xD;
      OBX|21|DTM|67975^MDC_ATTR_TIME_ABS^MDC|1.0.0.7|20130301115423.00||||||R|||20130301115450.733-
      0500&#xD;
1490  OBX|22||150020^MDC_PRESS_BLD_NONINV^MDC|1.0.1|||||||X|||20130301115452.733-0500&#xD;
      OBX|23|NM|150021^MDC_PRESS_BLD_NONINV_SYS^MDC|1.0.1.1|105|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
      OBX|24|NM|150022^MDC_PRESS_BLD_NONINV_DIA^MDC|1.0.1.2|70|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
      OBX|25|NM|150023^MDC_PRESS_BLD_NONINV_MEAN^MDC|1.0.1.3|81.7|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
      OBX|26|NM|149546^MDC_PULS_RATE_NON_INV^MDC|1.0.0.8|80|264864^MDC_DIM_BEAT_PER_MIN^MDC|||||R|||201
1495  30301115453.733-0500&#xD;
```

To which the Device Observation Consumer responds

```
      HTTP/1.1 200 OK
      Server: Jetty/1.9
1500  Content-Type: application/txt


      Cache-Control: no-store
      Pragma: no-cache
      MSH|^~\&amp;|LNI^d0bed0bed0beabee^EUI-64||||20130301115441.444-0500||ACK^R01^ACK|
1505      00120130301115453695|P|2.6|||NE|AL|||||IHE PCD ORU-
      R012006^HL7^2.16.840.1.113883.9.n.m^HL7&#xd;
      MSA|AA|00120130301115453695&#xd;
      ERR|||0^Message_accepted^HL7|I|||PcdToPHMR: XDS Send was successful. Response: null&#xd;
```

The response message indicates that the PCD-01 message was received with no problems. It also
1510 indicates that the message was successfully converted to a PHMR document and sent to the
configured destination.

Template Rev. 10.3

Appendix K – Communicate PCD Data -SOAP Transaction Example

1515 The following sequence shows the Communicate PCD Data-SOAP transaction as it would appear on the wire. For completeness it is assumed the Device Observation Consumer implementation supports an SAML token authentication server using WS-Trust Username Password token and the patient has been registered with the authentication server by the healthcare provider. The healthcare provider has entered the username and password as well as the URL to the Device Observation Consumer server on the Sensor Data Consumer / Device

1520 Observation Reporter implementation running on an Android based mobile phone and given it to the patient. Both the URL to the STS Token service AND the observation upload service are provided. Once home, the patient turns on the mobile phone and starts the collector implementation. The patient takes a measurement with a PCHA compliant PHD blood pressure cuff and the data is sent to the phone. The PHD device disassociates and disconnects.

1525 In this case it is assumed that the Device Observation Reporter does not support hData and is, therefore, not going to request a root.xml. The Device Observation Consumer may support both hData as well as SOAP and could have capability elements which give the path to the STS token service as well as the observation upload SOAP service saving the user the effort of entering them.

1530 The WS-Trust STS token request is encrypted using TLS.

```
POST /axis2/services/STS_Username HTTP/1.1
Content-Type: application/soap+xml; charset=UTF-8;
action="http://schemas.xmlsoap.org/ws/2005/02/trust/RST/Issue"
User-Agent: Dalvik/1.6.0 (Linux; U; Android 4.0.4; Nexus S Build/IMM26)
Host: 192.168.1.3:8443
Connection: Keep-Alive
Accept-Encoding: gzip
Content-Length: 2414

<?xml version='1.0' encoding='UTF-8'?>
<soapenv:Envelope xmlns:soapenv="http://www.w3.org/2003/05/soap-envelope">
  <soapenv:Header xmlns:wsa="http://www.w3.org/2005/08/addressing">
    <wsse:Security soapenv:mustUnderstand="true"
  xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd"
  xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
      <wsu:Timestamp wsu:Id="Timestamp-3">
        <wsu:Created>2013-03-01T16:54:53.797</wsu:Created>
        <wsu:Expires>2013-03-01T16:59:53.797</wsu:Expires>
      </wsu:Timestamp>

      <wsse:UsernameToken wsu:Id="UsernameToken-ID">
        <wsse:Username>Sisansarah</wsse:Username>
        <wsse:Password Type="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-username-
  token-profile-1.0#PasswordText">
            publicpassword
        </wsse:Password>
      </wsse:UsernameToken>

    </wsse:Security>
    <wsa:To soapenv:mustUnderstand="true">
      https://192.168.1.3:8443/axis2/services/STS_Username
    </wsa:To>
    <wsa:ReplyTo soapenv:mustUnderstand="true">
      <wsa:Address>http://schemas.xmlsoap.org/ws/2004/08/addressing/role/anonymous</wsa:Address>
    </wsa:ReplyTo>
    <wsa:MessageID soapenv:mustUnderstand="true">urn:uuid:0_1362156893800</wsa:MessageID>
```

```
      <wsa:Action
soapenv:mustUnderstand="true">http://schemas.xmlsoap.org/ws/2005/02/trust/RST/Issue
      </wsa:Action>
    </soapenv:Header>
    <soapenv:Body>
      <wst:RequestSecurityToken xmlns:wst="http://docs.oasis-open.org/ws-sx/ws-trust/200512">
        <wst:RequestType>http://docs.oasis-open.org/ws-sx/ws-trust/200512/Issue</wst:RequestType>
        <wst:Lifetime>
          <wsu:Created xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-
wssecurity-utility-1.0.xsd">2013-03-01T16:59:53.797</wsu:Created>
          <wsu:Expires xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-
wssecurity-utility-1.0.xsd">2013-03-01T17:04:53.797</wsu:Expires>
        </wst:Lifetime>
        <wst:TokenType>
          http://docs.oasis-open.org/wss/oasis-wss-saml-token-profile-1.1#SAMLV2.0
        </wst:TokenType>
        <wst:KeyType>http://docs.oasis-open.org/ws-sx/ws-trust/200512/SymmetricKey</wst:KeyType>
        <wst:KeySize>256</wst:KeySize>
        <wst:Entropy>
          <wst:BinarySecret Type="http://docs.oasis-open.org/ws-sx/ws-trust/200512/Nonce">
            i369jzmWbYlMB8uEAQwXghli9iORbIRM4IQCQFICrwI=
          </wst:BinarySecret>
        </wst:Entropy>
        <wst:ComputedKeyAlgorithm>
          http://docs.oasis-open.org/ws-sx/ws-trust/200512/CK/PSHA1
        </wst:ComputedKeyAlgorithm>
        <wst:Claims Dialect="SomeURI">Continua</wst:Claims>
      </wst:RequestSecurityToken>
    </soapenv:Body>
</soapenv:Envelope>
```

The server responds with

```
HTTP/1.1 200 OK
Server: Apache-Coyote/1.1
Content-Type: application/soap+xml;action="urn:RequestSecurityTokenResponse";charset=UTF-8
Transfer-Encoding: chunked
Date: Fri, 01 Mar 2013 16:54:27 GMT

<?xml version='1.0' encoding='UTF-8'?><soapenv:Envelope
xmlns:soapenv="http://www.w3.org/2003/05/soap-envelope">
  <soapenv:Header xmlns:wsa="http://www.w3.org/2005/08/addressing">
    <wsse:Security
     xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-
1.0.xsd"
       xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-
1.0.xsd"
           soapenv:mustUnderstand="true">
      <wsu:Timestamp wsu:Id="TS-13">
        <wsu:Created>2013-03-01T16:54:27.880Z</wsu:Created>
        <wsu:Expires>2013-03-01T16:59:27.880Z</wsu:Expires>
      </wsu:Timestamp>
    </wsse:Security>
    <wsa:Action soapenv:mustUnderstand="true">urn:RequestSecurityTokenResponse</wsa:Action>
    <wsa:RelatesTo soapenv:mustUnderstand="true">urn:uuid:0_1362156893800</wsa:RelatesTo>
  </soapenv:Header>
  <soapenv:Body>
    <wst:RequestSecurityTokenResponseCollection
         xmlns:wst="http://docs.oasis-open.org/ws-sx/ws-trust/200512">
      <wst:RequestSecurityTokenResponse>
        <wst:TokenType>
            http://docs.oasis-open.org/wss/oasis-wss-saml-token-profile-1.1#SAMLV2.0
        </wst:TokenType>
        <wst:KeySize>256</wst:KeySize>
        <wst:RequestedAttachedReference>
          <wsse:SecurityTokenReference
```

```
        xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-
     1.0.xsd">
                <wsse:Reference URI="#urn:uuid:CCD9102DB9CE2669531362156867799"
1635             ValueType="http://docs.oasis-open.org/wss/oasis-wss-saml-token-profile-
     1.1#SAMLV2.0"/>
               </wsse:SecurityTokenReference>
             </wst:RequestedAttachedReference>
             <wst:RequestedUnattachedReference>
1640           <wsse:SecurityTokenReference
        xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-
     1.0.xsd">
                <wsse:Reference URI="urn:uuid:CCD9102DB9CE2669531362156867799"
                 ValueType="http://docs.oasis-open.org/wss/oasis-wss-saml-token-profile-1.1#SAMLV2.0"
1645 />
               </wsse:SecurityTokenReference>
             </wst:RequestedUnattachedReference>
             <wst:Lifetime>
               <wsu:Created
1650     xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-
     1.0.xsd">
                   2013-03-01T16:54:27.792Z
               </wsu:Created>
               <wsu:Expires
1655     xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-
     1.0.xsd">
                   2013-03-01T17:37:39.792Z
               </wsu:Expires>
             </wst:Lifetime>
1660         <wst:RequestedSecurityToken>

     <!-- ============================= Requested SAML Token -->
             <saml2:Assertion
                 xmlns:saml2="urn:oasis:names:tc:SAML:2.0:assertion"
1665             xmlns:xs="http://www.w3.org/2001/XMLSchema"
                 ID="urn:uuid:CCD9102DB9CE2669531362156867799"
                 IssueInstant="2013-03-01T16:54:27.792Z"
                 Version="2.0">
               <saml2:Issuer>LNI SAML Token Service</saml2:Issuer>
1670           <ds:Signature xmlns:ds="http://www.w3.org/2000/09/xmldsig#">
                 <ds:SignedInfo>
                   <ds:CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-
     c14n#"/>
                   <ds:SignatureMethod Algorithm="http://www.w3.org/2000/09/xmldsig#rsa-sha1"/>
1675               <ds:Reference URI="#urn:uuid:CCD9102DB9CE2669531362156867799">
                     <ds:Transforms>
                       <ds:Transform
                           Algorithm="http://www.w3.org/2000/09/xmldsig#enveloped-signature"/>
                       <ds:Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#">
1680                     <ec:InclusiveNamespaces
                           xmlns:ec="http://www.w3.org/2001/10/xml-exc-c14n#" PrefixList="xs"/>
                       </ds:Transform>
                     </ds:Transforms>
                     <ds:DigestMethod Algorithm="http://www.w3.org/2000/09/xmldsig#sha1"/>
1685                 <ds:DigestValue>hL3WFtfHoQamGfaXGbMfGS7Nn0o=</ds:DigestValue>
                   </ds:Reference>
                 </ds:SignedInfo>
                 <ds:SignatureValue>
     dldKDhBH2YIAT7hQVdAFn1dbgZtQguJKHNOTz0QtfwAAAKb8iwYZMQuv/DwlgC0cIYprGWqp+4qnpX0Jp3OY8PpQESbrTl9/M
1690 umZcmQYEla8Ojey1l6mBGPiYmpnp1lNQvwwaZBqvOTChXRj0uns13wRteQy7vx99eQeubneIgo=
                 </ds:SignatureValue>
                 <ds:KeyInfo>
                   <ds:X509Data>
                     <ds:X509Certificate>MIICvjCCAiegAwIBAgIES1f+AjANBgkqhkiG9w0BAQUFADCBiTEhMB8GCSqGSIb3DQEJARYSbmFuZ
1695 GFuYUBhcGFjaGUub3JnMQswCQYDVQQGEwJMSzEQMA4GA1UECAwHV2VzdGVybjEQMA4GA1UEBwwHQ29sb21ibzEPMA0GA1UECg
     wGQXBhY2hlMRAwDgYDVQQLDAdSYW1wYXJ0MRAwDgYDVQQDDAdzZXJ2aWNlMB4XDTEwMDEyMTA3MTA1OFoXDTM1MDExNTA3MTA
     1OFowgYkxITAfBgkqhkiG9w0BCQEWEm5hbmRhbmFAYXBhY2hlLm9yZzELMAkGA1UEBhMCTEsxEDAOBgNVBAgMB1dlc3Rlcm4x
     EDAOBgNVBAcMB0NvbG9tYm8xDzANBgNVBAoMBkFwYWNoZTEQMA4GA1UECwwHUmFtcGFydDEQMA4GA1UEAwwHc2VydmljZTCBn
```

```
zANBgkqhkiG9w0BAQEFAAOBjQAwgYkCgYEAlAwDwx/FRgDReNc8Xuzo7/gHejimFkseCm+7WaFZp0dGwTnEJWNwWZk4yMw/1F
qWCgGHAbJBT25TAljleKDMUlZJPaU6PkJD8Hn94AlEstBDYA70pH3wt1moDxYbcG2QLxClWrFM6aqR3NB92zG8T3Q9X4jxGGW
Pkd39IndfdDMCAwEAAaMxMC8wHQYDVR0lBBYwFAYIKwYBBQUHAwEGCCsGAQUFBwMCMA4GA1UdDwEB/wQEAwIEsDANBgkqhkiG
9w0BAQUFAAOBgQBeAOERzydvAUNipBKOVg3FcjGTyMg3lzo7SlDFg7qTM4FZwUf2zw9XMagVLJRsaw+Asj8mqnugTpB4jBJCr
CGZ7YEviXz4PnqQjuuov5rXtFIc1Bp/PQmQt+LiZ2zln+fFxnSoHEzUsqs5zhdy/uIP0srAtBosdHxL9BJHxd7wQw==</ds:X
509Certificate>
                        </ds:X509Data>
                    </ds:KeyInfo>
                </ds:Signature>
                <saml2:Subject>
                    <saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key">
                        <saml2:SubjectConfirmationData
                            xmlns:xsi=" http://www.w3.org/2001/XMLSchema-instance"
                            NotBefore="2013-03-01T16:54:27.792Z"
                            NotOnOrAfter="2013-03-01T17:37:39.792Z"
                            xsi:type="saml2:KeyInfoConfirmationDataType">
                        <ds:KeyInfo xmlns:ds="http://www.w3.org/2000/09/xmldsig#">
                            <xenc:EncryptedKey
                                xmlns:xenc="http://www.w3.org/2001/04/xmlenc#"
                                Id="EK-C82A2592DB5193D51C13621568677947">
                            <xenc:EncryptionMethod
                                Algorithm="http://www.w3.org/2001/04/xmlenc#rsa-1_5"/>
                            <ds:KeyInfo>
                                <wsse:SecurityTokenReference
    xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-
1.0.xsd">
                                <wsse:KeyIdentifier
    EncodingType="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-soap-message-security-
1.0#Base64Binary"
    ValueType="http://docs.oasis-open.org/wss/oasis-wss-soap-message-security-
1.1#ThumbprintSHA1">
                                    EPlMdE3oRiNlo8bGg3BLR3uGWT8=
                                </wsse:KeyIdentifier>
                            </wsse:SecurityTokenReference>
                        </ds:KeyInfo>
                        <xenc:CipherData>
                            <xenc:CipherValue>
JkAWwNH+FdRevF6o9zjB+FTmwxe58jYFeHQO684YNeM5zSLvKna47h/v1OowtnDf5htaBo3uEqp8xPf+IDOYjNQLHfsDHZ60E
vVUjrHKXALE5pRcFtqX93iiUE/Ke4zpVvGQjyMxer454Qo/SL98xd6v4jpDc/zKMK4iGPO+YaI=
                            </xenc:CipherValue>
                        </xenc:CipherData>
                    </xenc:EncryptedKey>
                </ds:KeyInfo>
            </saml2:SubjectConfirmationData>
        </saml2:SubjectConfirmation>
    </saml2:Subject>
    <saml2:Conditions NotBefore="2013-03-01T16:54:27.792Z" NotOnOrAfter="2013-03-
01T17:37:39.792Z" />
                <saml2:AttributeStatement>
                    <saml2:Attribute
                      Name="program"
                      NameFormat="urn:oasis:names:tc:SAML:2.0:attrname-format:unspecified">
                    <saml2:AttributeValue
                        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                        xsi:type="xs:string">
                        Continua
                    </saml2:AttributeValue>
                </saml2:Attribute>
                <saml2:Attribute
                      Name="user"
                      NameFormat="urn:oasis:names:tc:SAML:2.0:attrname-format:unspecified">
                    <saml2:AttributeValue
                        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                        xsi:type="xs:string">Sisansarah</saml2:AttributeValue>
                </saml2:Attribute>
            </saml2:AttributeStatement>
        </saml2:Assertion>
```

```
<!-- ============================ End of SAML Token -->

              </wst:RequestedSecurityToken>
              <wst:RequestedProofToken>
                <wst:ComputedKey>
                  http://docs.oasis-open.org/ws-sx/ws-trust/200512/CK/PSHA1
                </wst:ComputedKey>
              </wst:RequestedProofToken>
              <wst:Entropy>
                <wst:BinarySecret
                  Type="http://docs.oasis-open.org/ws-sx/ws-trust/200512/Nonce">
                  2dDQACinnpN2oNV2kFINXEqAN8SMvTQOGpZKB3IAC9c=
                </wst:BinarySecret>
              </wst:Entropy>
          </wst:RequestSecurityTokenResponse>
        </wst:RequestSecurityTokenResponseCollection>
      </soapenv:Body>
</soapenv:Envelope>
```

Note that the username and password in the request is sent in clear text (though encrypted on the wire using TLS). The reason is that the server stores only irreversible hashes of the password which means the server does not know what the password is. If the client sends the password as a hash (which is a WS-Trust Option) the server MUST know the clear-text password in order to validate the request. If a hacker breaks into the server, thousands of passwords could be compromised. On the other hand, if a hacker breaks the client's TLS, only one password is compromised. Examining the "NotBefore" and "NotOnOrAfter" fields in the SAML token indicates that the token is only valid for a little more than 43 minutes. After that time the application will need to request another token before sending more data.

With the SAML token in hand the Device Observation Reporter can upload the PCD-01 document. The message is encrypted using TLS.

```
POST /axis2/services/Exchange HTTP/1.1
Content-Type: application/soap+xml; charset=UTF-8; action="urn:ihe:pcd:2010:CommunicatePCDData"
User-Agent: Dalvik/1.6.0 (Linux; U; Android 4.0.4; Nexus S Build/IMM26)
Host: 192.168.1.3:8443
Connection: Keep-Alive
Accept-Encoding: gzip
Content-Length: 8348

<?xml version='1.0' encoding='UTF-8'?><soapenv:Envelope
xmlns:soapenv="http://www.w3.org/2003/05/soap-envelope">
  <soapenv:Header xmlns:wsa="http://www.w3.org/2005/08/addressing">
    <wsse:Security soapenv:mustUnderstand="true"
   xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd"
    xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-
1.0.xsd">
      <wsu:Timestamp wsu:Id="Timestamp-3">
        <wsu:Created>2013-03-01T16:54:54.336</wsu:Created>
        <wsu:Expires>2013-03-01T16:59:54.336</wsu:Expires>
      </wsu:Timestamp>
<!-- ================== SAML Token goes here -->
    </wsse:Security>
    <wsa:To
soapenv:mustUnderstand="true">https://192.168.1.3:8443/axis2/services/Exchange</wsa:To>
    <wsa:ReplyTo soapenv:mustUnderstand="true">
      <wsa:Address>http://schemas.xmlsoap.org/ws/2004/08/addressing/role/anonymous</wsa:Address>
    </wsa:ReplyTo>
    <wsa:MessageID soapenv:mustUnderstand="true">urn:uuid:1_1362156894340</wsa:MessageID>
    <wsa:Action soapenv:mustUnderstand="true">urn:ihe:pcd:2010:CommunicatePCDData</wsa:Action>
  </soapenv:Header>
  <soapenv:Body>
```

```
1825        <pcd:CommunicatePCDData xmlns:pcd="urn:ihe:pcd:dec:2010">
     MSH|^~\&amp;|LNI Example AHD^ECDE3D4E58532D31^EUI-64||||20130301115450.720-0500||ORU^R01^ORU_R01|
            002013030111545720|P|2.6|||NE|AL|||||IHE PCD ORU-
     R012006^HL7^2.16.840.1.113883.9.n.m^HL7&#xD;
     PID|||28da0026bc42484^^^&amp;1.19.6.24.109.42.1.3&amp;ISO^PI||Piggy^Sisansarah^L.^^^^L&#xD;
1830 OBR|1|JOXP-PCD^LNI Example AHD^ECDE3D4E58532D31^EUI-64|
            JOXP-PCD^LNI Example AHD^ECDE3D4E58532D31^EUI-64|182777000^monitoring of patient^SNOMED-
     CT|||
            20130301115452.000-0500|20130301115455.001-0500&#xD;
     OBX|1||531981^MDC_MOC_VMS_MDS_AHD^MDC|0|||||||X|||||||ECDE3D4E58532D31^^ECDE3D4E58532D31^EUI-
1835 64&#xD;
     OBX|2|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.1|2^auth-body-continua||||||R&#xD;
     OBX|3|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|0.0.0.1.1|5.0||||||R&#xD;
     OBX|4|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|0.0.0.1.2|4||||||R&#xD;
     OBX|5|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.2|2^auth-body-continua||||||R&#xD;
1840 OBX|6|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|0.0.0.2.1|1^unregulated(0)||||||R&#xD;
     OBX|7|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.3|2^auth-body-continua||||||R&#xD;
     OBX|8|CWE|532355^MDC_REG_CERT_DATA_CONTINUA_AHD_CERT_LIST^MDC|0.0.0.3.1|0^observation-upload-
     soap||||||R&#xD;
     OBX|9|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|0.0.0.4|532234^MDC_TIME_SYNC_NONE^MDC||||||R&#xD;
1845 OBX|10|NM|8221^MDC_TIME_SYNC_ACCURACY^MDC
     |0.0.0.5|120000000|264339^MDC_DIM_MICRO_SEC^MDC||||||R&#xD;
     OBX|11||528391^MDC_DEV_SPEC_PROFILE_BP^MDC|1|||||||X|||||||1234567800112233^^1234567800112233^EUI
     -64&#xD;
     OBX|12|ST|531970^MDC_ID_MODEL_MANUFACTURER^MDC|1.0.0.1|Lamprey Networks||||||R&#xD;
1850 OBX|13|ST|531969^MDC_ID_MODEL_NUMBER^MDC|1.0.0.2|Blood Pressure 1.0.0||||||R&#xD;
     OBX|14|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.3|2^auth-body-continua||||||R&#xD;
     OBX|15|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|1.0.0.3.1|2.0||||||R&#xD;
     OBX|16|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|1.0.0.3.2|24583~8199~16391~7||||||R
     &#xD;
1855 OBX|17|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.4|2^auth-body-continua||||||R&#xD;
     OBX|18|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|1.0.0.4.1|1^unregulated(0)||||||R&#xD
     ;
     OBX|19|CWE|68219^MDC_TIME_CAP_STATE^MDC|1.0.0.5|1^mds-time-capab-real-time-clock(0)||||||R&#xD;
     OBX|20|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|1.0.0.6|532224^MDC_TIME_SYNC_NONE^MDC||||||R&#xD;
1860 OBX|21|DTM|67975^MDC_ATTR_TIME_ABS^MDC|1.0.0.7|20130301115423.00||||||R|||20130301115450.733-
     0500&#xD;
     OBX|22||150020^MDC_PRESS_BLD_NONINV^MDC|1.0.1|||||||X|||20130301115452.733-0500&#xD;
     OBX|23|NM|150021^MDC_PRESS_BLD_NONINV_SYS^MDC|1.0.1.1|105|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
     OBX|24|NM|150022^MDC_PRESS_BLD_NONINV_DIA^MDC|1.0.1.2|70|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
1865 OBX|25|NM|150023^MDC_PRESS_BLD_NONINV_MEAN^MDC|1.0.1.3|81.7|266016^MDC_DIM_MMHG^MDC|||||R&#xD;
     OBX|26|NM|149546^MDC_PULS_RATE_NON_INV^MDC|1.0.0.8|80|264864^MDC_DIM_BEAT_PER_MIN^MDC|||||R|||201
     30301115453.733-0500&#xD;
            </pcd:CommunicatePCDData>
         </soapenv:Body>
1870 </soapenv:Envelope>
```

For brevity, the SAML token is not re-printed but its location in the <wsse:Security> header is indicated. The SOAP action "CommunicatePCDData" is present in the WS-addressing action element. Note that both the WS-Trust request and the PCD-01 upload have a time-security element. This element requires that the requests arrive at the server within a five minute window (based on UTC time). A clock skew between the client and server would be enough to cause the request to be rejected even if it were sent in a timely manner.

The Device Observation Consumer then sends the response.

```
1880 HTTP/1.1 200 OK
     Server: Apache-Coyote/1.1
     Content-Type:
     application/soap+xml;action="urn:ihe:pcd:2010:CommunicatePCDDataResponse";charset=UTF-8
     Transfer-Encoding: chunked
     Date: Fri, 01 Mar 2013 16:54:41 GMT
1885
     <?xml version='1.0' encoding='UTF-8'?>
```

```
       <soapenv:Envelope xmlns:soapenv="http://www.w3.org/2003/05/soap-envelope">
         <soapenv:Header xmlns:wsa="http://www.w3.org/2005/08/addressing">
           <wsse:Security
1890         xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-
       1.0.xsd"
             xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-
       1.0.xsd"
           soapenv:mustUnderstand="true">
1895         <wsu:Timestamp wsu:Id="TS-14">
               <wsu:Created>2013-03-01T16:54:41.458Z</wsu:Created>
               <wsu:Expires>2013-03-01T16:59:41.458Z</wsu:Expires>
             </wsu:Timestamp>
           </wsse:Security>
1900         <wsa:Action
       soapenv:mustUnderstand="true">urn:ihe:pcd:2010:CommunicatePCDDataResponse</wsa:Action>
             <wsa:RelatesTo soapenv:mustUnderstand="true">urn:uuid:1_1362156894340</wsa:RelatesTo>
           </soapenv:Header>
           <soapenv:Body>
1905         <pcd:CommunicatePCDDataResponse xmlns:pcd="urn:ihe:pcd:dec:2010">
       MSH|^~\&amp;|LNI^d0bed0bed0beabee^EUI-64||||20130301115441.444-0500||ACK^R01^ACK|
           00120130301115453695|P|2.6|||NE|AL|||||IHE PCD ORU-
       R012006^HL7^2.16.840.1.113883.9.n.m^HL7&#xd;
       MSA|AA|00120130301115453695&#xd;
1910   ERR|||0^Message_accepted^HL7|I|||||PcdToPHMR: XDS Send was successful. Response: null&#xd;
           </pcd:CommunicatePCDDataResponse>
         </soapenv:Body>
       </soapenv:Envelope>
```

The PCD-01 response message indicates success and the ERR segment indicates that the
1915   message was successfully converted to a PHMR and sent to its configured destination.

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

NA