**Integrating the Healthcare Enterprise**



**IHE <PCC>**

**Technical Framework Supplement**

**<Remote Patient Monitoring   
(RPM)>**

**Draft in preparation for Public Comment**

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

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

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

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

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

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

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

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

**Foreword**

This is a supplement to the IHE <Domain Name> Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

*<For Public Comment:>* This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/Technical_Framework/public_comment.cfm). In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

*<For Trial Implementation:>* This supplement is published on <Month XX, 201X> for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the <Domain Name> Technical Framework. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/%3cdomain%3e/%3cdomain%3ecomments.cfm).

This supplement describes changes to the existing technical framework documents.

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

Amend section X.X by the following:

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

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

Information about the IHE <Domain Name> domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE <Domain name>Technical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

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

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# Introduction to this Supplement

<Provide a brief overview of the volumes/sections of the Technical Framework that get changed/ added by this supplement. Provide 200 words or less describing this supplement.>

## Open Issues and Questions

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 aPCD or PCC transaction**?**
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. Comments from Paul Schluter
5. A few suggestions:

1.  Indicate that several deployment options are shown, in each of the three horizontal 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 labels 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.

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 were put in landscape mode instead of vertical to make the flow easier to visualize.

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

.

<List the closed issues/questions with their resolutions. These are particularly useful for recording the rationale for closed issues to forestall unnecessary rehashing in the future and/or to make it easier to identify when a closed issue should be re-opened due to new information.>

<Note: The sections following this Introduction will eventually be added as Final Text to Volumes 1 – 4 of the Technical Framework. The material above this note (the Introduction, and Open and Closed Issues section) will be deleted when this Supplement is moved to Final Text.>

# General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

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



Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

**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 and calibration of the device, and the sensor data itself over at least one of several 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).

|  |  |
| --- | --- |
| Transaction | Definition |
| **Communicate PCHA Data-\*** | These transactions use either the IEEE 11073-20601 protocol over one of four transports or the Bluetooth Low Energy attribute protocol to transfer sensor data to a Device Observation Consumer. |

The ‘\*’ in the transaction name represents one of several transports (HDP Bluetooth, PHDC USB, ZigBee, NFC or Bluetooth Low Energy).

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. |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

Volume 1 – Profiles

## <*Copyright Licenses>*

<General copyright licenses and permissions are listed in the IHE Technical Frameworks General Introduction. Add information on any standards referenced in the profile that are not already addressed in the permission section.>

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

## <*Domain-specific additions>*

<Some domains have specific sections, added as subsections to Sections 1 or 2, in their Technical Frameworks. These types of additions are allowed as long as they do not adjust the overall numbering scheme which needs to remain consistent across domains. If there are such additions, they should be included here.>

Add to Section …

<Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter “X” with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>

# X Remote Patient Monitoring (RPM) Profile

The Remote Patient Monitoring Profile describes a standardized means to transmit measurements taken by personal health 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, SpO2 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 personal health devices data is time stamped with a consistent enterprise time. This time stamping is typically not done by the PHD sensor device but by the Device Observation Reporter actor obtaining the PCHA data from Sensor Data Consumer.

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://www.ihe.net/Technical_Framework/index.cfm>.

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.

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 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 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
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 several transports
2. PCD-01 Communicate PCD Data-\* transaction communicates PCD-01 data to the appropriate consumer over two possible transports
3. PCC Document Sharing transaction distributes the PHMR content module by an agreed upon technique (such as XDSb or XDM) to an appropriate consumer

and Content Module:

1. Personal Healthcare Monitoring Report (PHMR).

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.

*<Workflow/Transport Instructions>*

<If this profile does not define workflow or transport transactions, delete the following text and diagram until the “Content Module Instructions” below.>

<Continue here for workflow and/or transport profiles:>

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.

Device Observation Source

Sensor Data Consumer

Device Observation Reporter

Content Creator

Device Observation Reporter

Device Observation Consumer

Content Creator

Content Creator

Content Consumer

PHCA Data-\* Transaction

Communicate PCD Data-\* transaction

PCC-01 Share Document

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 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 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 development.

CommunicatePCHA Data-\*

Transaction 1 [1] ↓

Device Observation Source

PCD-01 Communicate

PCD Data-\*

Device Observation Reporter

PCC

Document Sharing

Sensor Data Consumer

Content

Consumer

Content Creator

Device Observation Consumer

Sensor

Device Observation Reporter

Content Creator

Sensor Data Consumer

Content Creator

Sensor

Sensor

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.

treadmill.pnghouse.pngusbBluetooth[v7_n_zigbee](http://images.google.com/imgres?imgurl=http://images.vnunet.com/v7_images/generic/medium/v7_n_zigbee.gif&imgrefurl=http://www.v3.co.uk/vnunet/analysis/2132125/zigbee-homes-short-range-wireless&usg=__Lt3B48Kw-SBQbLXMVKqFrHoiWSs=&h=110&w=185&sz=3&hl=en&start=7&tbnid=Ww8WGf99xQZ2bM:&tbnh=61&tbnw=102&prev=/images?q=ZigBee+logo&gbv=2&hl=en)[](http://images.google.com/imgres?imgurl=http://alabut.com/nonsense/images/w3c.jpg&imgrefurl=http://alabut.com/nonsense/archive/2007_03_01_index.html&usg=__Z-PsQzjVqNttrVx46ni5uIwxPQg=&h=173&w=140&sz=6&hl=en&start=4&um=1&tbnid=_N2x6-vfVJfzfM:&tbnh=100&tbnw=81&prev=/images?q=W3C&gbv=2&hl=en&um=1)

Health Records

Telehealth Service Center

Aggregation Manager



Devices  
*aka Agents*



***Continua***

***WAN***

***Continua***

***HRN***

***Continua***

***PAN***

***Continua***

***LAN***



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”).

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

| Actors | Transactions | Optionality | Reference |
| --- | --- | --- | --- |
| Device Observation Source | Communicate PCHA Data-BT [PCD-xx] (HDP Bluetooth) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-USB [PCD-xx] (PHDC USB) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-ZB [PCD-xx] (ZigBee) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-NFC [PCD-xx] (Near Field Communication) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-BTLE [PCD-xx] (Bluetooth Low Energy) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Sensor Data Consumer | Communicate PCHA Data-BT [PCD-xx] (HDP Bluetooth) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-USB [PCD-xx] (PHDC USB) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-ZB [PCD-xx] (ZigBee) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-NFC [PCD-xx] (Near Field Communication) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Communicate PCHA Data-BTLE [PCD-xx] (Bluetooth Low Energy) | O1 | PCC TF-2: 3.Y1 or  PCD? |
| Device Observation Reporter | PCD-01 Communicate PCD Data-SOAP (Web services) | O1 | PCD TF-2: 3.1 |
| PCD-01 Communicate PCD Data-hData (RESTful transport) | O1 | PCD TF-2: 3.1 |
| Device Observation Consumer | PCD-01 Communicate PCD Data-SOAP (Web services) | O1 | PCD TF-2: 3.1 |
| PCD-01 Communicate PCD Data-hData (RESTful transport) | O1 | 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  *<this should be a reference to a location in Volume 3)* |
| --- | --- | --- | --- |
| Content Creator | PHMR | R | PCC TF-3: 6.3.1.D |
| Content Consumer | PHMR | R | PCC TF-3: 6.3.1.D |

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

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
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
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.
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:

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 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

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.

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 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
  + HDP Bluetooth
  + PHDC USB
  + ZigBee
  + NFC
* Assorted Health device profiles overs Bluetooth Low Energy Attribute protocol

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) 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 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:

* 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 (XDSb 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 DataConsumer 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 DataConsumer must be grouped with either a Device Observation Reporteror 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.

#### 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

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

<Modify the following Table listing the actors in this profile, the options available for each, and references to sections that state requirements for compliance to each Option. For actors with no options, state “No options defined” in the Options column.>

<Note: Options are directly carried over to the Integration Statements which are published by vendors for review by buyers. Too many options can be confusing for readers.>

< Try to **minimize** options for Actors and only use if necessary.>

<Several options for Content Consumers are defined in PCC TF-2 section 3.1.1-3.1.4. It is recommended that these options are reused for content module definitions, but read the option definitions thoroughly to be certain that they apply. If they do apply in their entirety, you will need to define a corresponding option in this profile. The recommended naming convention for a similar, but different, option is, for example, “View Option - <profile acronym>, etc., “View Option – CIRC”.>

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.

Table X.2-1: <Profile Name> - 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.2.1 <Option Name>

<Consider including a high level description of the option.>

<e.g., The Content Consumer actor is required to support at least one of the View or Discrete Data Import options. The Document Import and Section Import options also require the View option.>

<Repeat this section (and increment numbering) as needed for additional options.>

## X.3 RPM Required Actor Groupings

*<Describe any requirements for actors in this profile to be grouped with other actors.>*

*<Note that this section effectively combines the previous “Profile Dependencies” Section (formerly Vol. 1, Section 2.1) and the previous “Groupings” section.>*

*<This section is for REQUIRED Actor Groupings (although “required” sometimes allows for a selection of one of several). To suggest other profile groupings or helpful references for other profiles to consider, use Section X.6 Cross Profile Considerations. Use X.5 for security profile recommendations.>*

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 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 and section X.6 describes some optional groupings in other related profiles.

<All Actors from this profile should be listed in Column 1. If no mandatory required grouping exists, “none” should be listed in Column 2. If the content module actor is bound to a transport or workflow actor it will be listed **with at least one** binding reference. Do not use “XD\*” as an actor name.>

<In some cases, required groupings are defined as at least one of an enumerated set of possible actors; to designate this create a row for each potential actor grouping and merge column one to form a single cell containing the profile actor which should be grouped with at least one of the actors in the spanned rows. In addition, a note should be included to explain the enumerated set. See example below showing Document Consumer needing to be grouped with at least one of XDS.b Document Consumer, XDR Document Recipient or XDM Portable Media Importer>

<The author should pay special consideration to IT and security profiles in this grouping section. Consideration should be given to Consistent Time (CT) Client, ATNA, as well as other profiles. For the sake of clarity and completeness, even if this table begins to become long, a line should be added for each actor for each of the required grouping for IT and security. Also see the ITI document titled ‘Cookbook: Preparing the IHE Profile Security Section’ at http://www.ihe.net/Technical\_Framework/index.cfm for a list of suggested IT and security groupings.>

<The Bindings column is used when a Content Module profile actor is grouped with a workflow or transport actor. Otherwise, mark it as “--”.>

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

| <this Profile Acronym> Actor | Actor to be grouped with | Reference | Content Bindings Reference |
| --- | --- | --- | --- |
| Sensor DataConsumer1 | Device Observation Reporter | <reference the section where the actors are defined in that profile, e.g., <Domain Acronym TF-1: x.x.x> | <Reference to CM bindings section  e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1) |
| Sensor DataConsumer1 | Content Creator | <reference the section where the actors are defined in that profile, e.g., <Domain Acronym TF-1: x.x.x> | <Reference to CM bindings section  e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1) |
| Device Observation Consumer | Content Creator | <reference the section where the actors are defined in that profile, e.g., <Domain Acronym TF-1: x.x.x> | <Reference to CM bindings section  e.g., <Domain Acronym TF-3:Z.xxx > (e.g., PCC TF-2 :4.1) |
| Device Observation Source | None |  |  |
| Device Observation Reporter | None |  |  |
| Content Creator | None |  |  |
| Content Consumer | None |  |  |

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.

## 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 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.

Communicate PHCA Data-\*

Transaction 1 [1] ↓

Dev Obs Src

Actor A

Content Consumer

Actor F

Sensor-Data-Cons

Actor F

Dev-Obs-Cons

Actor F

PCD-01 Communicate PCD Data-\*

PCC-1 Document Sharing

Transaction 1 [1] ↓

Sensor-Data-Cons

Actor F

Sensor-Data-Cons

Actor F

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Dev Obs Src

Actor A

Communicate PHCA Data-\*

Transaction 1 [1] ↓

Dev-Obs-Rep

Actor F

Dev-Obs-Rep

Actor F

Dev-Obs-Rep

Actor F

Content Creator

Actor F

Content Consumer

Actor F

Content Consumer

Actor F

Dev Obs Src

Actor A

Figure X.4-1: RPM Operational Diagram

There are a couple of reasons that the RPM profile is likely to be implemented as indicated in Figure X.4-1. First is that the collector of sensor observations is typically done on low-footprint 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 is that 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 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 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.

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.

*<Volume 2 documents each transaction/content module in isolation. This section shows how the transactions/content modules of the profile are combined to address the use cases.>*

*<Use Cases are informative, not normative, and “SHALL” language is not allowed in use cases.>*

### X.4.1 Concepts

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.

### 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.

#### 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 apnoea, 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.

##### 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 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 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-CDAs. 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 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 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 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 XDSb respository 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 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 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 and sends it to the XDS respository using the IHE XDSb provide and register document set transaction where the health care provider can 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.

Measurements sent to local collector

Sensor

Data

Consumer

*Internal: PHCA data*

*to PCD-01*

Device Observation

Source

BP

WS

MM

Device Observation Reporter

Device Observation

Consumer

Content

Creator

PCD-01 sent to remote server

*Internal: PCD-01 to PHMR*

*module*

Content

Consumer

PHMR module sent to consumer

Health care provider reads results

Patient takes measurements and meds

Figure X.4.2.2-1: Basic Process Flow in RPM Profile

Pre-conditions:

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

Main Flow:

<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>

Post-conditions:

<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>

#### 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

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. 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

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 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 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 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.

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 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 XDSb 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.

## 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, 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 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 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, and to encrypt any upstream network transmissions using Transport Layer Security and authenticate 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 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. Those transports typically mandate grouping with the Secure Node or Secure Application actors from ATNA.

## X.6 RPM Cross Profile Considerations

<other profile acronym> - <other profile name>  
A <other profile actor name> in <other profile name> might be grouped with a <this profile actor name> to <describe benefit/what is accomplished by grouping>.

Volume 2 – Transactions

Add section 3.Y

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

*<The “Y” in the heading should be the same as the # in the [Domain Acronym -#] title>*

### 3.Y.1 Scope

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

In the RPM profile, these transactions are typically the only point at which a human is involved. 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. *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

### 3.Y.2 Actor Roles

<Optional: if desired, in addition to the table, add a diagram as shown below to illustrate the actors included in this transaction, or delete the diagram altogether.>

Device Observation Source

Actor ABC

Sensor Data Consumer

Actor DEF

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

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) |

*<The assignment and use of Role Names in transaction specifications has proved to be very effective/efficient in Radiology, especially when existing transactions are re-used by additional actors. Following is an alternative example of the Role section. Delete which ever form of the role section you choose not to use.>*

### 3.Y.3 Referenced Standards

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 specialization standards, the Bluetooth Low Energy Health Device Profiles and Services, 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.

<e.g., HL7 2.3.1 Chapters 2, 3>

<e.g., DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD>

### 3.Y.4 Interaction Diagram

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.

The following interaction diagrams illustrate the sequence of processes for the IEEE and BTLE exchanges. When there are two flow illustrations in the diagrams, the IEEE exchange is to the left and the BTLE exchange is to the right. Diagram 3.Y.4-1 illustrates the sequence from connection establishment to data exchange exposing some of the details of the setup exchanges. Diagrams 3.Y.4-2 and 3.Y.4-3 illustrate the sequences for the data exchanges. Diagram 3.Y.4-2 illustrates the behavior when there is persistently stored data and diagram 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 Diagrams 3.Y.4-2 and 3.Y.4-3 can happen simultaneously and/or in the same connection. Diagram 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.

<The interaction diagram shows the detailed standards-based message exchange that makes up the IHE transaction.>

Stored data

Stored data

Device Observation Source

Actor A

Association

Message 1

Sensor Data Consumer

Configuration

Message 1

Measurements

Message 1

Device Observation Source

Actor A

Service Discovery

Message 1

Sensor Data Consumer

Dev Info reading

Message 1

Enabling

Message 1

Measurements

Message 1

Establish Connection

Establish Connection

IEEE Exchange

BTLE Exchange

**Diagram 3.Y.4-1**

The above diagram 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 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.

Device Observation Source

Actor A

Get PM Segment Info

Message 1

Sensor Data Consumer

Trig Segment Xfer

Message 1

Segment transfer

Message 1

Device Observation Source

Actor A

RACP request

Message 1

Sensor Data Consumer

Notification Events

Message 1

RACP indication

Message 1

IEEE Persistent data

Exchange

BTLE Persistent Data

Exchange

**Diagram 3.Y.4-2**

Diagram 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 (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 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.

Scan Event Report

Device Observation Source

Actor A

Sensor Data Consumer

Device Observation Source

Actor A

Sensor Data Consumer

IEEE non-Persistent

Data Exchange

BTLE non-Persistent

Data Exchange

Acknowledgement

Characteristic Value

Indication/Notification

Acknowledgement

**Diagram 3.Y.4-3**

Diagram 3.Y.4-3 illustrates the PCHA sequences for IEEE and BTLE when the Device 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 tends to be for streaming or waveform data.

Non Persistent

Data transfer

Persistent data

transfer

Configuration

Device Observation Source

Actor A

Associate and Configure

Message 1

Sensor Data Consumer

PM Store actions

Message 1

Scan Event Report

Message 1

Device Observation Source

Actor A

Configure and initialize

Message 1

Sensor Data Consumer

Indications/

notifications

Message 1

IEEE Flow summary

BTLE Flow Summary

RACP processes

Message 1

**Diagram 3.Y.4-4**

Diagram 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.

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

##### 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

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

<One or two sentence summary of what Message 2 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

<Repeat this section as necessary based on the number of messages in the interaction diagram.>

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

<Description of the real world events that cause the sender (Actor A) to send Message 1(e.g., an operator or an automated function determines that a new workitem is needed).>

##### 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 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, 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.

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.2.3 Expected Actions

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 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.

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

#### 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 value may contain one or more different measurements.

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

##### 3.Y.4.3.1 Trigger Events

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

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Y.4.3.2 Message Semantics

In the IEEE implementation the scan event report packets are ASN.1 structures containing the *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.

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Y.4.3.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

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

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 encryption options in the wireless protocols.

<Description of the transaction specific security consideration; such as use of security profiles.>

#### 3.Y.5.1 Security Audit Considerations

There are no auditing requirements in these transactions.

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

##### 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 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 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

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 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-\* Transaction

*<The “Y” in the heading should be the same as the # in the [Domain Acronym -#] title>*

### 3.Z.1 Scope

These transactions are used to transfer collected patient measurement data to a Device Observation Consumer in the form of a PCD-01 message. *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

### 3.Z.2 Actor Roles

<Optional: if desired, in addition to the table, add a diagram as shown below to illustrate the actors included in this transaction, or delete the diagram altogether.>

Device Observation Reporter

Actor ABC

Device Observation Consumer

Actor DEF

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

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 |

The actors and the web services based transport of this transaction are found in the PCHA H.812.1 Observation Upload specification which references the IHE PCD Technical Framework Volumes 1 to 3. The PCHA H.812.1 Observation upload specifies an additional transport mechanism using the RESTful HL7 hData record format not specified in the IHE PCD TF volumes. The RESTful transport is further specified in the PCHA documents H.812.3 Capability Exchange and H.812 WAN IF Common Certified Device Class Guidelines.

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.

*<The assignment and use of Role Names in transaction specifications has proved to be very effective/efficient in Radiology, especially when existing transactions are re-used by additional actors. Following is an alternative example of the Role section. Delete which ever form of the role section you choose not to use.>*

### 3.Z.3 Referenced Standards

The PCD Communicate PCD data-\* transactions are 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. The hData record format is specified in HL7 Version 3 Standard: hData Record Format Release, 1. Authentication is specified in IHE Technical Framework Supplement: Internet User Authentication.

IHE PCD Technical Frameworks Vol1-Vol3 referencing PCD-01 and the Communicate PCD Data transaction

<e.g., HL7 2.3.1 Chapters 2, 3>

<e.g., DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD>

### 3.Z.4 Interaction Diagram

The diagram below illustrates the Communicate PCD Data-\* transaction for both the Web services and hData transport options. Both transports require and out-of-band action to obtain an authentication token.

<The interaction diagram shows the detailed standards-based message exchange that makes up the IHE transaction.>

Device Observation Consumer

Device Observation Reporter

Actor A

Communicate PCD data-SOAP

Response

Message 2

Device Observation Consumer

Device Observation Reporter

Actor A

Communicate PCD data- hData

Response

Message 2

Capability exchange

Message 1

Web Services

Message 2

hData

Message 2

#### 3.Z.4.1 Capability Exchange

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.

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

##### 3.Z.4.1.1 Trigger Events

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

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new work item is needed).>

##### 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 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 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 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.

For the Communicate PCD Data 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.

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 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.

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

#### 3.Z.4.2 Communicate PCD Data-\*

The Communicate PCD Data-\* transactions used in this profile support two transport mechanisms. The web service transport implementation is specified in the IHE PCD Transactions Volumes 1 to 3. 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 the web services transport. Reliable messaging is optional for the Device Observation Reporter. The second transport 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 actor support TLS security and oAuth authentication on the hData 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 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.

Full on-the-wire examples of the SOAP and hData transactions including requests for the SAML and oAuth tokens are given in PCHA H 812.1 Observation Upload sections 8.10 and 8.11. 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 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.

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

##### 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.

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new work item is needed).>

##### 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 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 it may rely upon a third party service, or it may be obtained by another out of band transaction.

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

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Z.4.2.3 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 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.

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

#### 3.Z.5.3 Acknowledgement

The Acknowledgement is a response to the Communicate PCD Data-\* 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.

<One or two sentence summary of what Message 2 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

<Repeat this section as necessary based on the number of messages in the interaction diagram.>

##### 3.Z.5.3.1 Trigger Events

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

<Description of the real world events that cause the sender (Actor A) to send Message 1(e.g., an operator or an automated function determines that a new workitem is needed).>

##### 3.Z.5.3.2 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 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 successfully converted to a PHMR and transferred to its final respository.

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

##### 3.Z.5.3.3 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.

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

### 3.Z.6 Security Considerations

The Communicate PCD Data-\* transactions are 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, PCHA requires at minimum TLS encryption and the support of SAML or oAuth authentication. Additional security restrictions such as message level security are optional and are determined by business needs.

<Description of the transaction specific security consideration; such as use of security profiles.>

#### 3.Z.6.1 Security Audit Considerations

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

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

##### 3.Z.6.1.1 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.Z.6.1.2 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

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2x. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.>

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 2 Namespace Additions

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

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 3 – Content Modules

# 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. |

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

#### 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

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.

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

Appendix J – hData Transport

This appendix should describe briefly the hData transport details by referencing the PCHA specifications.

J.1 <Add Title>

Appendix J.1 text goes here

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above by the author, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>