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Introduction to the ITU-T H.810 Continua Design Guidelines

ITU-T

Summary

The Personal Connected Health Alliance (PCHAlliance), previously known as the Continua Health Alliance, is a non-profit organization under HIMSS that aims to make health and wellness an effortless part of daily life. PCHAlliance is dedicated to establishing a system of interoperable personal connected health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals, and provides the opportunity for truly personalized health and wellness management.

Devices such as wireless blood pressure cuffs, weight scales and a wide range of activity trackers can play a critical role in the prevention and improved management of chronic conditions such as diabetes, hypertension and heart disease. Establishing global interoperability standards will stimulate innovation and nourish the personal connected health ecosystem. For manufacturers, standards will decrease time-to-market, reduce development costs and increase efficiencies. In particular, they will enable quicker, less expensive integration to electronic health records (EHR) or health information exchange platforms.

The PCHAlliance publishes and promotes the global adoption of the Continua Design Guidelines (CDG), an open framework for secure and interoperable health data exchange in personal connected health. The CDG is the only successfully designed interoperability guidelines for personal connected health devices, and it has been adopted by the ITU as an international standard starting in December 2013 as Recommendation ITU-T H.810. It currently is in its 4th edition, which aligns with the CDG2017 "Keratin" and is the subject of this document.

To enable this interoperability, the CDG is complemented by a series of conformance testing specifications found in the Recommendations of the ITU-T H.820-850 series to ensure consistent implementation through product certification. A test and certification regime ensures interoperable personal connected health solutions are compliant with the CDG.

The CDG employs near field communications (NFC) for its touch area network, Bluetooth Classic and Bluetooth Low Energy for its personal area network, and ZigBee for its local area network. The IEEE Exchange Protocol was chosen because it provides transport agnostic essential data structures necessary to ensure accurate and comprehensive understanding of the measured data upstream. Furthermore, it simplifies FDA approval of devices maintaining the IEEE protocols.

A wide area network interface employs Integrating the Healthcare Enterprise (IHE) profiles to facilitate sharing of personal health data across departmental and institutional boundaries. The WAN interface standardizes around the data payload, message exchange framework, and security. The resulting interoperability simplifies the integration and consolidation of multiple data streams into a single database.

A health records network interface employs HL7 standards, which are the world's most widely used standards for the exchange, management, and integration of electronic healthcare information for clinical and administrative purposes. Continua implements a continuity of care document-based personal health monitoring record because of its ability to meet current and anticipated future requirements and its growing adoption in the health record community.

As the CDG moves into the mobility space, it is important for mobile device manufacturers and cellular network operators to understand the selected health specifications and implementation to assess properly their impact to mobile product designs and network performance. Just as important, mobile device manufacturers and network operators are strongly encouraged to work with the mobile healthcare community the help it leverage the efficiencies designed into mobile devices and cellular networks.

Change Log

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CONTENTS

	Page
1 SCOPE	1
2 REFERENCES	2
3 GLOSSARY	3
4 ABBREVIATIONS	4
5 INTRODUCTION	6
6 ARCHITECTURE OVERVIEW	7
7 PERSONAL HEALTH DEVICES INTERFACE	8
7.1 BACKGROUND.....	8
7.1.1 <i>IEEE 11073 Family of Standards</i>	8
7.2 COMMON DATA FORMAT AND EXCHANGE	10
7.3 NFC INTERFACE.....	10
7.4 USB INTERFACE.....	11
7.5 ZIGBEE INTERFACE	11
7.6 BLUETOOTH INTERFACE.....	12
7.7 BLUETOOTH LOW ENERGY INTERFACE	12
7.8 SECURITY AND PRIVACY	12
8 SERVICES INTERFACE	12
8.1 BACKGROUND.....	13
8.2 DATA PAYLOADS	13
8.2.1 <i>Mapping IEEE 11073-20601 attributes</i>	14
8.2.2 <i>Observation upload</i>	15
8.2.3 <i>Questionnaire</i>	17
8.2.4 <i>Consent management</i>	17
8.2.5 <i>Capabilities exchange</i>	18
8.2.6 <i>Authenticated persistent session</i>	18
8.3 MESSAGE EXCHANGE FRAMEWORKS.....	18
8.3.1 <i>SOAP & SAML</i>	19
8.3.2 <i>REST & OAuth FHIR</i>	19
8.3.3 <i>REST & OAuth hData</i>	19
8.3.4 <i>Capabilities Exchange</i>	19
8.4 SECURITY & PRIVACY.....	19
8.4.1 <i>Consent Management</i>	19
8.4.2 <i>Consent enforcement</i>	20
8.4.3 <i>Auditing</i>	20
8.4.4 <i>Confidentiality, integrity, and service authentication</i>	20
8.4.5 <i>Entity authentication</i>	20
9 HEALTHCARE INFORMATION SYSTEM INTERFACE	20
9.1 BACKGROUND.....	20
9.2 DATA PAYLOAD	21
9.3 MESSAGE EXCHANGE FRAMEWORK	22
9.4 ONC DIRECT	22
9.5 SECURITY AND PRIVACY	22
9.5.1 <i>Confidentiality, integrity, and service authentication</i>	22
9.5.2 <i>Entity authentication</i>	22
9.5.3 <i>Identity management</i>	23
9.5.4 <i>Consent management</i>	23
9.5.5 <i>Consent enforcement</i>	23
9.5.6 <i>Non-repudiation of origin</i>	23
9.5.7 <i>Auditing</i>	23
10 CONTINUA CERTIFICATION	23
10.1 CONFORMITY ASSESSMENT	23
10.1.1 <i>Personal Health Devices interface assessment</i>	24

	Page
10.1.2 <i>Services interface assessment</i>	24
10.1.3 <i>Healthcare Information Systems interface assessment</i>	24
10.2 INTEROPERABILITY ASSESSMENT	24
10.2.1 <i>PlugFests</i>	24
10.2.2 <i>Connect-a-thons</i>	24
10.3 INDUSTRY ALIGNMENT	25
10.4 CERTIFICATION	25
10.5 DECLARATION OF COMPLIANCE	25
APPENDIX I COMPLETE LIST OF ITU DOCUMENTS ON THE CONTINUA DESIGN GUIDELINES.....	26

List of Figures

	Page
FIGURE 7-1: PERSONAL HEALTH DEVICES INTERFACES IN THE CONTINUA ARCHITECTURE.....	9
FIGURE 7-2: SAMPLE IEEE 11073 MESSAGE	10
FIGURE 7-3: X73-IF PROTOCOL STACK	11
FIGURE 8-1: WAN SCOPE.....	13
FIGURE 8-2: SAMPLE PCD-01 MESSAGE.....	16
FIGURE 8-3: SAMPLE FHIR MESSAGE	17
FIGURE 9-1: HEALTH INFORMATION SYSTEMS INTERFACES IN THE CONTINUA ARCHITECTURE.....	21
FIGURE 9-2: SAMPLE PHMR MESSAGE	21

ITU-T Technical Paper Introduction to the ITU-T H.810 Continua Design Guidelines

1 Scope

This Technical Paper provides a high level overview of the Continua Design Guidelines (CDG), a description of the data that is being exchanged between sensors, gateways, health & fitness servers, and health information services. It contains an introduction to each of the standards and specifications that were chosen to carry this data, and the value-add the CDG provides beyond the referenced standards to make implementations truly interoperable. The reader is invited to read the CDG themselves for a comprehensive understanding.

The Personal Health Device (PHD) interface is briefly summarized along with their rationale for selection as these are more broadly understood in the electronics industry. Overviews of the Services and Healthcare Information System interfaces and their standards selection and rationale are elaborated, as they are less well understood by newcomers to the healthcare industry and to the Continua Design Guidelines.

This edition of the technical paper is aligned with the 4th edition of H.810-series. Table 1 contains a map of the various CDG releases and respective versions as ITU-T Recommendations.

Table 1 – List of designations associated with the various versions of the CDG

CDG release	Transposed as	Version	Designation
2017	ITU-T H.810 (2017)	7	Keratin
2016 plus errata	ITU-T H.810 (2016)	6.1	–
2016	–	6.0	Iris
2015 plus errata	b-ITU-T H.810 (2015)	5.1	–
2015	–	5.0	Genome
2013 plus errata	b-ITU-T H.810 (2013)	4.1	–
2013	–	4.0	Endorphin
2012 plus errata	–	3.1	–
2012	–	3.0	Catalyst
2011 plus errata	–	2.1	–
2011	–	2.0	Adrenaline
2010 plus errata	–	1.6	–
2010	–	1.5	1.5
1.0	–	1.0	–

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3 Glossary

BT SIG	The Bluetooth Special Interest Group is consortium that defines the Bluetooth specification, a wireless technology for exchanging data over short distances.
CCD	The continuity of care document establishes a rich set of templates representing the typical sections of a summary record, and expresses these templates as constraints on CDA. These same templates for vital signs, family history, plan of care, and so on can then be reused in other CDA document types, establishing interoperability across a wide range of clinical use cases.
CCR	The ASTM continuity of care record was designed and implemented as a standard for a comprehensive data summary that aggregates data from multiple sources, health care records, medical legal documents, and health care encounters to form a comprehensive overall clinical picture of a patient's current and relevant historical health care status.
CDA	The HL7 clinical document architecture is intended as an expression of intact documents and not explicitly designed for filtering and providing views onto data. It defines the specific structure and semantics for any clinical document for purposes of exchange.
FHIR	HL7 Fast Healthcare Interoperability Resources is a new set of specifications defining a mechanism for exchanging data between healthcare applications, as an alternative to HL7 v2, HL7 v3 and HL7 PCD. FHIR messages use XML and JSON.
GATT	The Bluetooth Low Energy (BLE) Generic Attribute specification defines a hierarchical data structure that is exposed to connected BLE devices.
HL7	Health Level 7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services. ¹
IEEE 11073	The IEEE 11073 Health informatics – Medical / health device communication family of standards enables agents to interconnect and interoperate with managers and with computerized healthcare information systems. The communication profile defined in this standard takes into account the specific requirements of personal health agents and managers, which are typically used outside a clinical setting (e.g., mobile or in a person's home) [9].
IHE	Integrating the Healthcare Enterprise is an implementation framework, not a standard. It works to ensure that all required information for medical decisions is accurate and available to healthcare professionals. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals.
JSON	The JavaScript Object Notation is a lightweight data-interchange format based on a subset of the JavaScript programming language, which is human-readable and can be efficiently parsed and generated.
PCD-01	IHE Patient Care Device is a set of specifications addressing use cases in which at least one actor is a regulated patient-centric point-of-care medical device that communicates with at least one other actor such as a medical device or information

¹ <http://www.hl7.org/about/index.cfm?ref=nav>.

system. PCD-01 refers to the IHE profile (transaction) for communication of device data within the PCD domain.

- PHMR The HL7 personal health monitoring report carries personal healthcare monitoring information that is transmitted as notes and raw data, including representation of measurements captured by devices such as weigh scales, blood pressure cuffs, glucometers, pulse oximeters, etc.
- PHR The personal healthcare record is patient-centric software application that allows individual patient/consumer to enter, store, and organize personal health information.
- PIX The patient identifier cross-reference profile supports the cross-referencing of patient identifiers from multiple patient identifier domains. These cross-referenced patient identifiers can then be used by "identity consumer" systems to correlate information about a single patient from sources that "know" the patient by different identifiers. This allows a clinician to have more complete view of the patient information.
- XDM The cross-enterprise document media interchange provides document interchange using a common file and directory structure over several standard media. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents.
- XDR The cross-enterprise document reliable interchange integration profile is focused on providing a standards-based specification for managing the interchange of documents that healthcare enterprises (anywhere from a private physician to a clinic to an acute care in-patient facility) have decided to explicitly exchange using a reliable point-to-point network communication. It complements the XDS integration profile when a sharing infrastructure is not needed.
- XDS Cross-enterprise document sharing enables a number of healthcare delivery organizations belonging to cooperate in the care of a patient by sharing clinical records in the form of documents as they proceed with their patients' care delivery activities. XDS registries store metadata used to retrieve documents from XDS repositories. XDS is the core specification of a group of related IHE specifications and profiles.
- XDS.b The cross-enterprise document sharing-b core profile that facilitates the registration, distribution, and access across health enterprises of patient electronic health records based on use of the web services and ebXML Reg/Rep standards that are consistent with the current developments and best practices in the industry.
- XUA The cross-enterprise user assertion provides a means to communicate claims about the identity of an authenticated principal (user, application, system, etc.) in transactions that cross enterprise boundaries. The XUA profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication.

4 Abbreviations

- ADT Admit discharge transfer
- AHD Application hosting device
- BLE Bluetooth low energy

BSP	Basic security profile
BR/EDR	(Bluetooth) Basic Rate/Enhanced Data Rate
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CD	Compact disc
CDA	Clinical document architecture
CDG	(ITU-T H.810) Continua Design Guidelines
DEC	Device enterprise communication
DEN	Document encryption
DICOM	Digital Imaging and Communications in Medicine
DSG	Document digital signature
ebXML	Electronic business xml
EHR	Electronic health record
HDP	Health device profile
FHIR	Fast healthcare interoperability resources
HIS	Health information systems
HIMSS	Healthcare Information and Management System Society
HL7	Health Level 7
HRN	Health records network
HTTP	Hypertext transport protocol
IHE	Integrating the Healthcare Enterprise
IIHI	Individually identifiable health information
IP	Internet protocol
IT	Information technology
ITI	It infrastructure
LAN	Local area network
MDC	Medical device communication
MIME	Multi-purpose internet mail extensions
MTOM	Message transmission optimization mechanism
NFC	Near-field communications
NIST	National Institute of Standards and Technology
OBX	Observation report
PAN	Personal area network
PCD	Patient care device
PHD	Personal health device
PHDC	Personal healthcare device class

PHM	Personal health monitoring
PHMR	Personal health monitoring record
PIX	Patient identifier cross-reference
POC	Point of care
RIM	Registry information model; reference information model
RSNA	Radiological Society of North America
S-MIME	Secure-MIME
SAML	Security assertion markup language
SIG	Special interest group
SNOMED	Systemized Nomenclature of Medicine Clinical Terms
SOAP	Simple object access protocol
TAN	Touch area network
TCP	Transport control protocol
TF	Technical framework
TLS	Transport layer security
USB	Universal serial bus
W3C	World Wide Web Consortium
WAN	Wide area network
WS	Web services
WS-I	Web services – interoperability
XDM	Cross-enterprise document media interchange
XDR	Cross-enterprise document reliable interchange
XDS	Cross-enterprise document sharing
XDS.b	Cross-enterprise document sharing-b
XML	Extensible markup language
XUA	Cross-enterprise user assertion
ZIP	Compressed file format

5 Introduction

The Continua Design Guidelines (CDG) is an open framework for secure and interoperable health data exchange in personal connected health. The CDG provides a set of clearly defined interfaces that enable the secure flow of medical data among sensors, gateways, and end services, removing ambiguity in underlying standards to ensure a consistent and interoperable ecosystem of personal connected health devices. To enable reliable interoperability it also contains additional implementation guidelines that further clarify these standards and specifications by reducing options in the underlying standard or specification or by adding a feature missing in the underlying standard or specification.

The Personal Health Devices interface standardizes around the IEEE 11073 *Personal Health Device* and Bluetooth Low Energy *Generic Attribute (GATT)* families of specifications for data format and

exchange between the sensor and the gateway. The Services interface standardizes around the IHE *PCD-01 Transaction* and the HL7 *FHIR* specifications to move data between a Personal Health Gateway and Health & Fitness Services (e.g. tele-health service). The Healthcare Information System interface standardizes around the HL7-based *Personal Healthcare Monitoring Report (PHMR)* to move information between a Health & Fitness Service and Healthcare Information Service provider (e.g. Electronic Health Record, or EHR).

The Continua Test and Certification program [14] ensures this interoperability by verifying that products conform to the Continua Design Guidelines and its underlying standards.

6 Architecture overview

The objective of the CDG is to enable medical device manufacturers to design and certify sensors, gateways, Health & Fitness Servers (HFS) and Health Information Systems / Electronic Health Record (HIS/EHR) systems that will interoperate over wired and wireless local area and wide area networks with sensors, gateways, and EHR systems from a broad range of manufacturers. It is expected that this approach will enable scaling of health and fitness services to the levels enjoyed by the mobile industry where device choice is an absolute customer right that is granted by the vigorous implementation of standards across the ecosystem and applications and services are ubiquitously available.

The CDG defines a black-box on-the-wire architecture (i.e. it defines only the data that may or must be transmitted between devices) at the application protocol and transport layers that help ensure interoperability between sensors, hubs, service platforms, and electronic health record systems manufactured by a variety of vendors. To realize this interoperability, the Continua architecture is based on the four components illustrated in Figure 6-1:

- The Personal Health Devices (PHD) – such as a blood pressure meter, pedometer, or personal alarm.
- The Personal Health Gateway (PHG) – which may be a cell phone, PC, or specialist device.
- The Health & Fitness Server (HFS) – typically a tele-health remote monitoring service platform.
- The Health Information System (HIS) – typically a physician's electronic health record.

The CDG set out the requirements for the interfaces between these components. To accommodate a broad range of requirements the guidelines provide for a range of different transport options for interfaces between the Personal Health Device (PHD) and the Personal Health Gateway (PHG). The PHD interface employs the IEEE 11073 PHD family of standards for data format and exchange between the PHD and the PHG over Bluetooth BR/EDR, NFC, USB, and ZigBee. Data transferred via Bluetooth Low Energy (BLE) profile implementations can be transcoded into IEEE 11073 compatible sensor data.

To communicate between the PHG and HFS (e.g. a tele-health service), the Services interface employs an IHE PCD-01 message packaged in SOAP and authenticated using SAML, HL7 FHIR Resources exchanged via REST and OAuth, or IHE PCD-01 message sent over HL7 hData Framework coupled with the hData REST transport binding.

The HIS interface employs HL7 CDA R2-based Personal Health Monitoring Report packaged in SOAP over HTTP to communicate between the HFS and HIS (e.g., hospital EHR system).

The CDG addresses end-to-end security and privacy through a combination of identity management, consent management and enforcement, entity authentication, confidentiality, integrity and authentication, non-repudiation of origin, and auditing.

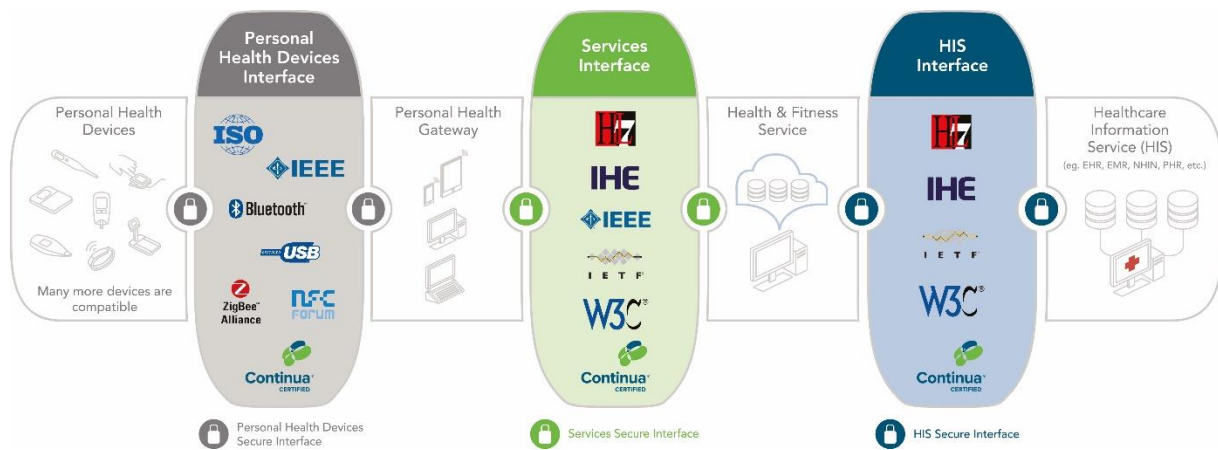


Figure 6-1: Continua end-to-end reference architecture

7 Personal Health Devices interface

The Personal Health Devices interface defines a framework of underlying standards and criteria that ensure the interoperability of devices and data used for personal connected health services. It provides additional design guidelines for interoperability which further clarify or reduce the options in underlying standards or specifications, or that add a feature missing in an underlying standard or specification. The implementations specified include NFC, USB, ZigBee, Bluetooth BR/EDR, and Bluetooth Low Energy (see Figure 7-1). See the ITU-T H.811 [2] for more information.

7.1 Background

The PCHAlliance works closely with the IEEE to develop the *IEEE 11073 Personal Health Device* family of standards to address specifically the interoperability of personal health devices (e.g. thermometer, blood pressure monitor) with an emphasis on personal use and a more simple communication model than defined in the *IEEE 11073 Point of Care* standards. This family of standards ensures that the user of the data knows exactly what was measured where and how, and that this critical information is not lost as it is transported from the sensor, to the gateway, and ultimately to the electronic health record system (see Figure 7-2). Furthermore, one of the main reasons to use the 11073 PHD family of standards in the Continua architecture is that it runs on top of USB, Bluetooth, NFC and ZigBee transport protocols supported by the CDG.

7.1.1 IEEE 11073 Family of Standards

IEEE 11073 family of standards includes the *IEEE 11073-10101 Nomenclature*, *11073-10201 Domain Information Model*, *11073-20601 Optimized Exchange Protocol*, and the device specializations in the *IEEE 11073-104xx-series*.

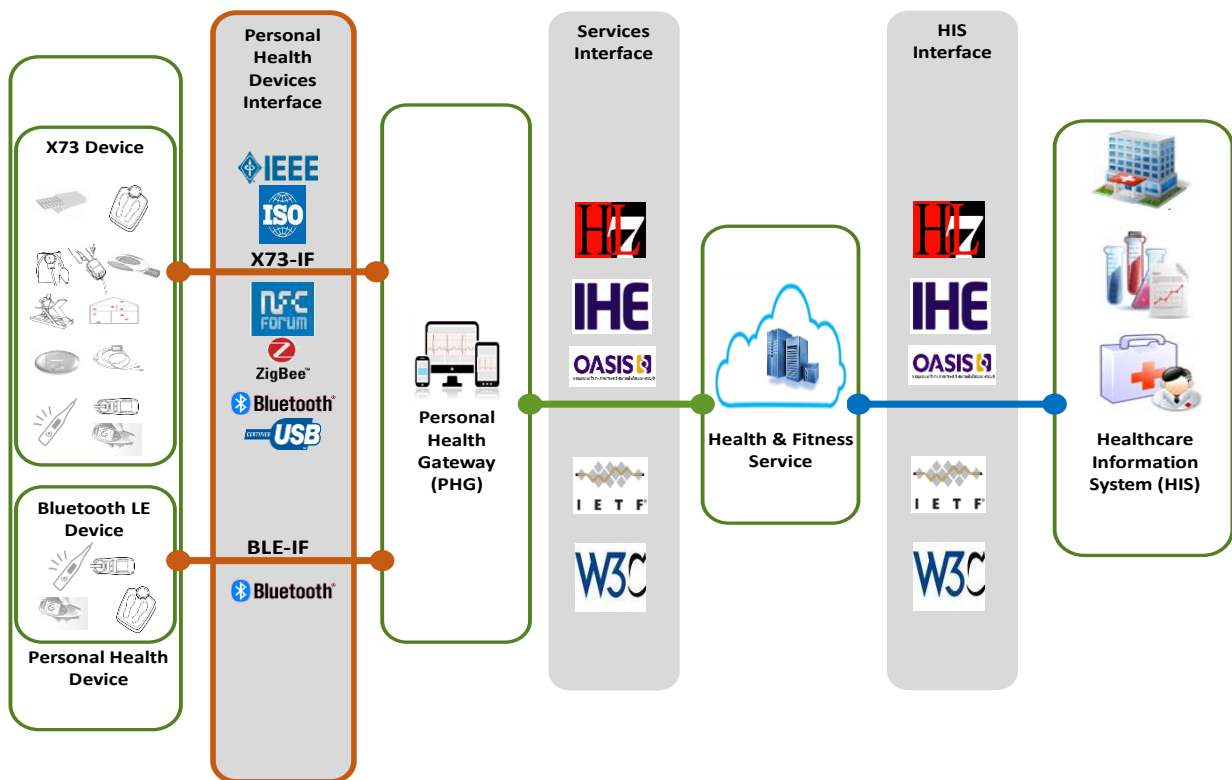


Figure 7-1: Personal Health Devices interfaces in the Continua Architecture

The *IEEE 11073-10101 Nomenclature* standard defines the overall architecture of the organization and relationships among nomenclature components along with specific semantics and syntaxes. The NIST Rosetta Terminology Mapping Management Service (RTMMS) [16] is the ultimate on-line reference for the nomenclature codes.

The *11073-10201 Domain Information Model* standard addresses the definition and structuring of information that is communicated or referred to in communication between devices.

The *11073-20601 Optimized Exchange Protocol* standard defines a common framework for making an abstract model of personal health data available in transport independent syntax. It also contains a much simpler model than the one described in IEEE 11073-10201, allowing greater efficiencies for remote patient monitoring applications.

The *IEEE 11073-104xx-series Device Specializations* standards define how the Domain Information Model is used to model data for specific device types and provide details on the communication of this data.

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x3E	CHOICE.length = 62
0x00 0x3C	OCTET STRING.length = 60
0x00 0x54	invoke-id
0x01 0x01	CHOICE (Remote Operation Invoke Confirmed Event Report)
0x00 0x36	CHOICE.length = 5
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x49 0x00 0x50	event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1D	event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x2C	event-info.length = 44
0xF0 0x00	ScanReportInfoFixed.data-req-id = 0xF000
0x00 0x00	ScanReportInfoFixed.scan-report-no = 0
0x00 0x02	ScanReportInfoFixed.obs-scan-fixed.count = 2
0x00 0x24	ScanReportInfoFixed.obs-scan-fixed.length = 36
0x00 0x01	ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 1
0x00 0x12	ScanReportInfoFixed.obs-scan-fixed.value[0].obs-val-data.length = 18
0x00 0x03	Compound Object count (3 entries)
0x00 0x06	Compound Object length (6 bytes)
0x00 0x78	Systolic = 120
0x00 0x50	Diastolic = 80
0x00 0x64	MAP = 100
0x20 0x07 0x12 0x06	Absolute-Time-Stamp = 2007-12-06T12:10:0000
0x12 0x10 0x00 0x00	
0x00 0x02	ScanReportInfoFixed.obs-scan-fixed.value[1].obj-handle = 2
0x00 0x0A	ScanReportInfoFixed.obs-scan-fixed.value[1].obs-val-data.length = 10
0xF2 0x58	Basic-Nu-Observed-Value = 60.0 (BPM)
0x20 0x07 0x12 0x06	Absolute-Time-Stamp = 2007-12-06T12:10:0000
0x12 0x10 0x00 0x00	

Figure 7-2: Sample IEEE 11073 Message

7.2 Common Data Format and Exchange

The CDG employs an application layer that is common across the X73 PHD, with the notable exception of the Bluetooth LE interface. (X73 is a term coined to capture the common elements of the PHD-IF architecture with design guidelines that apply to all PHDs and PHGs implementing the PHD-IF using an IEEE 11073 PHD device specialization.) The X73-IF is composed of different layers. Appropriate standards are selected for the individual layers to establish interoperability in the personal health ecosystem. Figure 7-3 gives an overview of the protocol stack for the X73-IF.

Widely supported transport technologies and profiles have been selected for wireless and wired versions of the X73-IF. However, for the application level data/messaging there is considerable commonality. A common solution has been selected to serve as the data/messaging layer on top of the supported transport protocols

The IEEE 11073-20601 Optimized Exchange Protocol has been selected as the basis of the application protocol for the X73-IF. This internationally harmonized standard provides an interoperable messaging protocol and has definitions and structures in place to convert from an abstract data format into a transmission format. Thus, a consistent data exchange layer is enabled for the X73-IF. The IEEE 11073-20601 protocol defines a common information model that is further filled-in by device specializations (ISO/IEEE 11073-104XX family of standards) and an optimized exchange protocol to exchange data from this model. This protocol is bound to the various lower-layer transport layers. The selected device specialization standards specify the data model and nomenclature terms to be used for individual devices. The CDG provides implementation guidance for 23 device specializations at the time of this publication. The device specializations and selected transport protocols are also illustrated in Figure 7-3.

7.3 NFC interface

NFC enables a Continua PHD to communicate with a Continua PHG by touch. NFC PHDC has been selected to serve as the transports for the NFC interface (NFC-IF). The selected protocol for the transport layer ensures interoperable set-up and teardown of the communication channel for the transfer of control and data messages across all domains. For the data and messaging layer of the

NFC-IF, the IEEE 11073 PHD family of standards has been selected. NFC is intended for a batch communication style. For a NFC solution, it is assumed that the physical action of the user touching two devices provides a level of security to prevent inadvertent leakage of data to a different PHG.

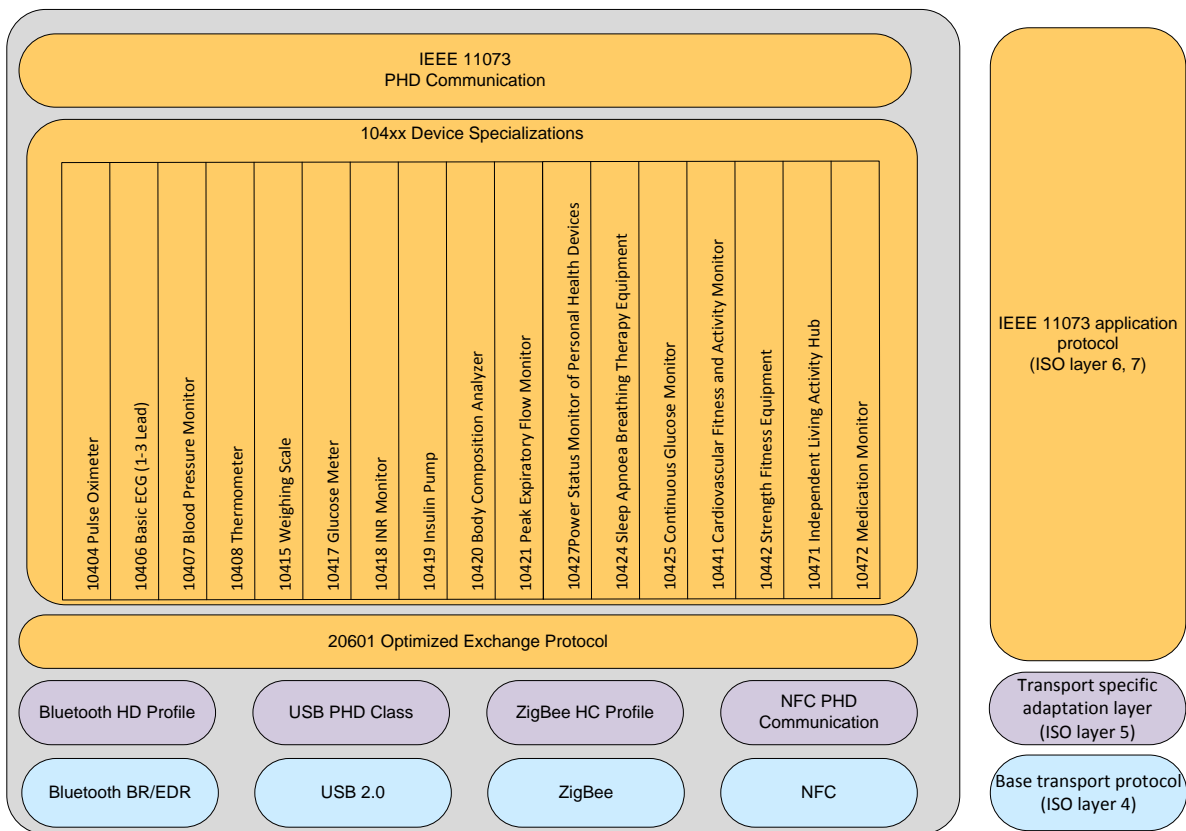


Figure 7-3: X73-IF Protocol Stack

7.4 USB interface

USB enables a Continua PHD to communicate with a Continua PHG to allow bidirectional sensor control and information exchange. The interface is further structured into three distinct layers, with appropriate standards selected to represent the individual layers and established interoperability in the personal health system. For the data and messaging layer of the standard USB-IF, the standards from the IEEE 11073 Personal Health Device family of standards have been selected. The protocols selected in the USB-IF permits the device to transfer data using transaction, streaming, and batch communication styles. For security, it is assumed that the physical action of the user connecting a USB PHD to the PHG provides the necessary security to prevent inadvertent leakage of data to a different PHG.

7.5 ZigBee interface

The ZigBee interface enables sensors (or actuators) to send their measured data to (or to be controlled by) one or many Continua PHGs that are placed around the same house, building, facility or campus. The interface is structured into distinct layers with appropriate standards selected to represent the individual layers and established interoperability in the personal health system. The ZigBee Health Care profile version 1.0 has been selected as the wireless lower layer protocol to serve as the transport for the ZigBee interface. The selected protocol for the transport layer ensures interoperable set-up and teardown of the communication network for transfer of control information and transfer of data messages across all domains. For the data and messaging

layer of the ZigBee interface, the standards from the IEEE 11073 personal health device family of standards have been selected. Procedures for the commissioning of ZigBee PHDs, which include network-joining and application-pairing of devices, and device discovery, as well as security mechanisms are as defined in the ZigBee Health Care Profile version 1.0.

7.6 Bluetooth interface

The connectivity in the Bluetooth BR/EDR interface (BR/EDR-IF) is tailored to satisfy three basic requirements that are uniform across the application domains serviced by CDG-certified products: bidirectional sensor control, bidirectional sensor information exchange, and appropriate linkage between a PHD and PHG. The interface is further structured into three distinct layers, with appropriate standards selected to represent the individual layers and established interoperability in the personal health system. The CDG defines a profile for discovery and pairing, user notification, quality of service, and simple secure pairing.

7.7 Bluetooth Low Energy interface

The Bluetooth Low Energy protocol is a Continua supported transport technology for the PHD-IF as a widely supported low-energy, low-bandwidth, limited range wireless protocol. The Bluetooth Special Interest Group (BT-SIG) has defined device specific profiles and services on top of the Bluetooth Low Energy Attribute Profile that are supported by the PHD-IF. The Bluetooth LE interface does not utilize the IEEE 11073-20601 protocol for data exchange. The Bluetooth LE interface utilizes the Bluetooth LE protocol with data types compatible to the IEEE 11073-10101 nomenclature and the IEEE 11073-20601 domain information model (DIM). For the characteristics defined in the Bluetooth LE profiles, the *Personal Health Devices Transcoding White Paper* describes how to transcode into an equivalent IEEE DIM and/or nomenclature representation. At a minimum, this covers the mandatory attributes from the supported ISO/IEEE 11073-104XX device specializations. The CDG defines further guidelines for device discovery, connection establishment, pairing, service discovery and bonding, user notification, authentication, device information requirements, date and time requirements, certification and regulatory aspects, and transcoding to ensure interoperability and appropriate security.

7.8 Security and Privacy

Data confidentiality and integrity across the PHD interface is achieved via the underlying network communication technology associated with each device. For example, a PHD interface employing the Bluetooth LE transport would utilize LE security mechanisms such as Passkey Entry Pairing, association models, key generation, and encryption.

Data authentication, authorization, integrity, confidentiality, privacy, availability, accessibility and traceability on the application level may be incorporated into the IEEE 11073 base standard and device specializations in the future and would then be supported in the Continua Design Guidelines.

8 Services interface

The Services interface provides for uploading device observations, exchange of questionnaires and responses, consent management, capabilities exchange, and authenticated persistent sessions over a wide area network. The CDG ensure interoperability by constraining IHE specifications and HL7 standards and providing implementation guidance and interface certification. The interface is defined in terms of data payload, message exchange framework, and security. See the Continua Design Guidelines H.812 "Services interface Design Guidelines" for more information.

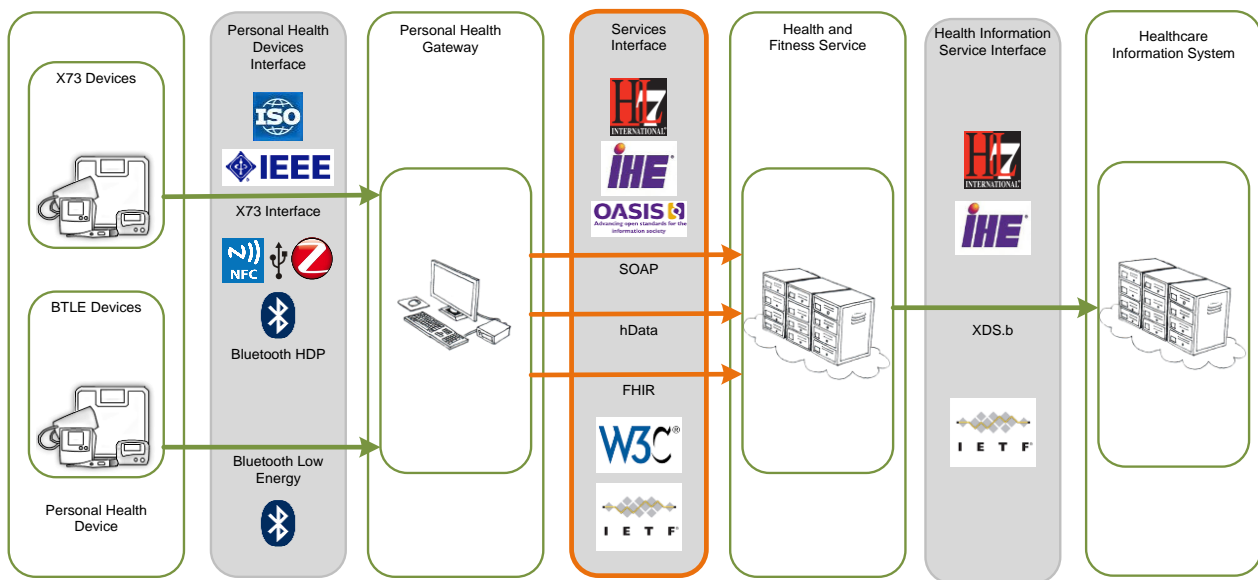


Figure 8-1: WAN scope

8.1 Background

IHE's PCD-01 transaction was chosen for a number of considerations. It allows the use of common nomenclature, defined by the ISO/IEEE 11073 committee, for all devices across all interfaces. This common nomenclature has the added benefit of simplifying FDA approvals of devices carrying this data. It is capable of supporting personal health devices for all three market segments in remote health monitoring targeted by Continua: health and fitness, aging independently, and disease management. Use of PCD-01 leveraged IEEE's observation reporting interface, savings years of work to translate ISO/IEEE 11073-based messaging and data representation to HL7. The PCD-01 unsolicited observation result provides a well-defined, self-contained message uniform for transmitting one or more observations enabling less state-full message exchange between the PHG observation sender and HFS observation receiver, which improves scalability.

HL7 version 2.6 was chosen over HL7 version 3.0 in part for its compact messaging structure that minimizes bandwidth. HL7 V2.6 currently addresses the interfaces among various healthcare IT systems that send or receive patient admissions/registration, discharge or transfer (ADT) data, queries, resource and patient scheduling, orders, results, clinical observations, billing, master file update information, medical records, scheduling, patient referral, patient care, clinical laboratory automation, application management and personnel management messages. It works to standardize the exchange of this information to eliminate or substantially reduce the custom interface programming and program maintenance that may otherwise be required.

8.2 Data payloads

The information contained in the data payload is formatted in accordance with the IHE PCD-01 transaction: Communicate PCD data specification. This PCD technical framework constrains the use of HL7 V2.6 messages, requiring that observations be exchanged using an unsolicited observation result message. The payload portion of the Services interface is based on the PCD-01 transaction of the device enterprise communication (DEC) profile sponsored by IHE PCD. It uses HL7 V2.6 messaging and the IEEE 11073 nomenclatures, including the nomenclature extensions that support PHDs.

The IHE patient care device technical framework volume 2 defines specific implementations of established standards to achieve integration goals for the patient care domain (PCD). The PCD-01

communicate PCD data transaction defines how to transmit patient care device data between systems.

The unsolicited observation result message is a segment of the PCD-01 message used to transmit a single observation or observation fragment in a very specific structured format. It represents the smallest indivisible unit of a report. This observation report (OBX) segment can also contain encapsulated data such as a CDA document or a DICOM image. Nomenclature codes called out in the first OBX segment illustrates how IEEE nomenclatures are maintained in the PCD-01 message structure to ensure accurate and comprehensive understanding of the measured data to upstream interfaces. IHE PCD technical framework volume 2 defines each segment of the PCD-01 message.

The DEC profile provides an optional "Publish/Subscribe" mechanism for applications to negotiate which IHE PCD pre-defined messages are communicated to a given application based on negotiated predicates.

8.2.1 Mapping IEEE 11073-20601 attributes

The CDG provides general guidelines for mapping IEEE 11073-20601 attributes to IHE PCD-01 and HL7 FHIR payloads.

8.2.1.1 IEEE 11073-20601 attributes to PCD-01

The CDG provides general guidelines for creating the PCD-01 payload. Not all 20601 objects are required and therefore are not mapped into the PCD-01 message. Additional nomenclature codes not defined in 20601 but required for Continua services are defined for PHG and MDS-OBX segments.

Handling of Bluetooth Low Energy attributes is done by semantically mapping its attributes to ISO/IEEE 11073-20601 attributes and using the guidelines provided in the CDG to generate the PCD-01 message payload. The Transcoding White Paper provides the mapping from Bluetooth LE to 20601.

The CDG provides detailed guidelines for the mapping of ISO/IEEE 11073-20601 objects and attributes to OBX segments. Only a subset of the ISO/IEEE 11073-20601 objects and attributes are used in this mapping. The guidelines in this annex apply to any sensor whose information and/or observations are mapped to ISO/IEEE 11073-20601 objects and attributes whether or not they are ISO/IEEE 11073-20601 sensors. An example would be Bluetooth Low Energy sensors whose transactions have been mapped to the necessary ISO/IEEE 11073-20601 objects and attributes in the Transcoding White Paper.

The mapping of ISO/IEEE 11073-20601 to PCD-01 is primarily through nomenclature codes. They include ASN.1 BITS, FLOAT and SFLOAT, and Sequence number and containment. The CDG address encoding the PHG-OBX segments:

- Guidelines for Encoding the PHG-OBX Segments
- Guidelines for Encoding the MDS-OBX Segments
- Guidelines for Encoding the Metric-OBX Segments
- Special Situations
- Timestamping and Time Synchronization
- Metric Object Attribute Mappings Overview

The CDG contains specific guidance for the correct mapping of all devices including the hierarchy for MDS objects and detailed models of the Metric-OBXes for each of the device specializations. It includes a quick reference of the HL7 Unsolicited Observation Result detail from the Services

interface usage point of view, HL7 Data Types – Observations, HL7 Data Types – Other, and HL7 Control Characters.

8.2.1.2 IEEE 11073-20601 attributes to FHIR

The mapping of ISO/IEEE 11073-20601 objects and attributes to FHIR resources models HL7 V2.6 Observations so that they provide the same semantic content as the PCD-01 payload. This mapping applies to any sensor whose information and/or observations are mapped to IEEE 11073-20601 objects and attributes even if they are not IEEE 11073-20601 sensors. An example would be Bluetooth LE sensors whose transactions have been mapped to the necessary IEEE 11073-20601 objects and attributes in the Transcoding White Paper [15].

As with the PCD-01 to Continua services, mapping is primarily through nomenclature codes. They include ASN.1 BITS, and FLOAT and SFLOAT. Additional nomenclature codes not defined in ISO/IEEE 11073-20601 are defined in the CDG to describe sub-structures of attributes that have no nomenclature codes. Logical IDs are assigned to differentiate resources. Guidelines are provided to encode FHIR resources, PHG resources, PHD resources, coincident time stamp, and metric measurements.

8.2.2 Observation upload

Device observations are one-way, point-to-point transmission of single and batch measurements between a PHG and a HFS. Continua specifies three implementations for uploading HL7 V2.6 Observations payloads: IHE PCD-01 message packaged in SOAP and authenticated using SAML, HL7 FHIR Resources exchanged via REST and OAuth, and IHE PCD-01 message sent over HL7 hData Framework coupled with the hData REST transport binding.

8.2.2.1 PCD-01 SOAP

The HL7 Messaging Standard Version 2.6 (HL7 V2.6 Observations) is used in the IHE PCD-01 Transaction to communicate Patient Care Device data from a device observation reporter (e.g. PHG) to a device observation consumer (e.g. HFS). *HL7 V2 Unsolicited Observation Result* (ORU^R01) message structure is used to capture and transmit sensor data. There are four key segments in this message structure: message header, patient identification, observation request, and observation result. The CDG map the IEEE 11073-20601 attributes to the PCD-01 message and preserves the IEEE 11073 nomenclatures to ensure the measurement information is clearly understood by the consumer of the observation. This PCD-01 message is uploaded using a web services transport layer defined in Appendix V of IHE ITI-TF-2, which specifies the usage of SOAP 1.2 over HTTP version 1.1 and otherwise conforms to the Web Services Interoperability Organization's Basic Profile (BP) Version 1.1 and Basic Security Profile (BSP) 1.0. A sample PCD-01 message is shown in Figure 8-2.

8.2.2.2 FHIR REST

HL7 V2.6 Observations content may also be uploaded using the HL7 FHIR standard. The Continua Design Guidelines specify how to map ISO-IEEE 11073-20601 attributes received from a sensor to FHIR resources. These resources are used to model HL7 V2.6 Observations employing three FHIR resource types: a Patient resource, a DeviceComponent resource, and an Observation resource. These resources (individual or as a transaction bundle) form a FHIR data payload that is transported over the Internet using RESTful style web services and secured using TLS and OAuth. A sample transaction bundle containing an Observation resource is shown in Figure 8-3.

MSH|^~\&|LNI_AHD^ecde3d4e58532d31^EUI-64|||20170307160528-0500|ORU^R01^ORU_R01|1|P|2.6|||NE|AL|||IHE PCD ORU-
R012006^HL7^2.16.840.1.113883.9.n.m^HL7

PID|||sisansarahId^^^Android-Gateway&1.2.3.4.5.6.7.8.10&ISO^P||Piggy^Sisansarah^Lorianthah^^^L

OBR|1|LNI_AHD^LNI MOXP_AHD^ecde3d4e58532d31^EUI-64|LNI_AHD^LNI MOXP_AHD^ecde3d4e58532d31^EUI-64|182777000^monitoring of
patient^SNOMED-CT|||20170307160511.000-0500|20170307160527-0500

OBX|1||531981^MDC_MOC_VMS_MDS_AHD^MDC|0|||||X|||||ecde3d4e58532d31^ecde3d4e58532d31^EUI-64
OBX|2|CWE|68218^MDC_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.1|2^auth-body-continua||||R
OBX|3|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|0.0.0.1.1|5.0||||R
OBX|4|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|0.0.0.1.2|4||||R
OBX|5|CWE|68218^MDC_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.2|2^auth-body-continua||||R
OBX|6|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|0.0.0.2.1|1^unregulated(0)|||R
OBX|7|CWE|68218^MDC_REG_CERT_DATA_AUTH_BODY^MDC|0.0.0.3|2^auth-body-continua||||R
OBX|8|CWE|532355^MDC_REG_CERT_DATA_CONTINUA_AHD_CERT_LIST^MDC|0.0.0.3.1|0^observation-upload-soap~3^observation-upload-
hdata~7^observation-upload-fhir~2^capability-exchange~6^aps||||R
OBX|9|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|0.0.0.4|532226^MDC_TIME_SYNC_NTPV4^MDC||||R
OBX|10||528388^MDC_DEV_SPEC_PROFILE_PULS_OXIM^MDC|1|||||X|||||001c050100651437^001c050100651437^EUI-64-00:1C:05:65:14:37^Bluetooth
SIG^00:1C:05:65:14:37^BT-MAC
OBX|11|ST|531970^MDC_ID_MODEL_MANUFACTURER^MDC|1.0.0.1|ACME Medical, Inc.||||R
OBX|12|ST|531969^MDC_ID_MODEL_NUMBER^MDC|1.0.0.2|Model 1234||||R
OBX|13|ST|531972^MDC_ID_PROD_SPEC_SERIAL^MDC|1.0.0.3|0100651437||||R|||||0^PrivateOID^001c050100651437^EUI-64
OBX|14|ST|531976^MDC_ID_PROD_SPEC_FW^MDC|1.0.0.4|0.99||||R|||||1^PrivateOID^001c050100651437^EUI-64
OBX|15|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.5|2^auth-body-continua||||R
OBX|16|ST|532352^MDC_REG_CERT_DATA_CONTINUA_VERSION^MDC|1.0.0.5.1|1.0||||R
OBX|17|NM|532353^MDC_REG_CERT_DATA_CONTINUA_CERT_DEV_LIST^MDC|1.0.0.5.2|4||||R
OBX|18|CWE|68218^MDC_ATTR_REG_CERT_DATA_AUTH_BODY^MDC|1.0.0.6|2^auth-body-continua||||R
OBX|19|CWE|532354^MDC_REG_CERT_DATA_CONTINUA_REG_STATUS^MDC|1.0.0.6.1|0^unregulated(0)^This device is regulated||||R
OBX|20|CWE|68219^MDC_TIME_CAP_STATE^MDC|1.0.0.7|1^mds-time-capab-real-time-clock(0)~1^mds-time-capab-set-clock(1)~1^mds-time-capab-relative-
time(2)|||R
OBX|21|CWE|68220^MDC_TIME_SYNC_PROTOCOL^MDC|1.0.0.8|532224^MDC_TIME_SYNC_NONE^MDC||||R
OBX|22|NM|68222^MDC_TIME_RES_ABS^MDC|1.0.0.9|1000000|264339^MDC_DIM_MICRO_SEC^MDC||||R
OBX|23|NM|68223^MDC_TIME_RES_REL^MDC|1.0.0.10|80|264339^MDC_DIM_MICRO_SEC^MDC||||R
OBX|24|DTM|67975^MDC_ATTR_TIME_ABS^MDC|1.0.0.11|20071001000003.000||||R|||20170307160456.828-0500
OBX|25|NM|67983^MDC_ATTR_TIME_REL^MDC|1.0.0.12|3580000|264339^MDC_DIM_MICRO_SEC^MDC||||R|||20170307160456.828-0500
OBX|26|NM|150456^MDC_PULS_OXIM_SAT_O2^MDC|1.0.0.13|98|262688^MDC_DIM_PERCENT^MDC||||R|||20170307160511.000-0500
OBX|27|CWE|68193^MDC_ATTR_SUPPLEMENTAL_TYPES^MDC|1.0.0.14|150588^MDC_MODALITY_SPOT^MDC||||R
OBX|28|NM|149530^MDC_PULS_OXIM_PULS_RATE^MDC|1.0.0.14|53|264864^MDC_DIM_BEAT_PER_MIN^MDC||||R|||20170307160511.000-0500
OBX|29|CWE|68193^MDC_ATTR_SUPPLEMENTAL_TYPES^MDC|1.0.0.14.1|150588^MDC_MODALITY_SPOT^MDC||||R

Figure 8-2: Sample PCD-01 Message

8.2.2.3 hData REST

Alternatively, HL7 V2.6 Observations may be uploaded using the HL7 *hData framework standard* coupled with the *hData REST transport binding (OMG)*. hData, is a RESTful application programming interface (API) specification used for lightweight, scalable information exchange that defines remote operations for accessing components of a health record and sending messages to an EHR system. hData organizes this information for web access, defines web services for consuming and producing data, standardizes metadata annotation of data, and enables popular authentication and authorization models, such as OpenID and OAuth 2.0. hData has been standardized by both HL7 and OMG.

```

{
  "resourceType": "Bundle",
  "id": "2017-03-06T16:30:12.436-05:00",
  "type": "transaction",
  "entry": [
    {
      "fullUrl": "urn:oid:1.0.0.1",
      "resource": {
        "resourceType": "Observation",
        "identifier": [
          {
            "value": "sisansarahId-urn:oid:1.2.3.4.5.6.7.8.10~1234567800000033~160368~20170306163009.000~95"
          }
        ],
        "status": "final",
        "code": {
          "coding": [
            {
              "system": "urn:iso:std:iso:11073:10101",
              "code": "160368",
              "display": "MDC_CONC_GLU_UNDETERMINED_PLASMA"
            }
          ]
        },
        "subject": {
          "reference": "Patient/PatientId-sisansarahId"
        },
        "effectiveDateTime": "2017-03-06T16:30:10.245-05:00",
        "performer": [
          {
            "reference": "Patient/PatientId-sisansarahId"
          }
        ],
        "valueQuantity": {
          "value": 95,
          "unit": "mg/dl",
          "system": "urn:iso:std:iso:11073:10101",
          "code": "264274"
        },
        "device": {
          "reference": "Device/SysId-1234567800000033"
        },
        "related": [
          {
            "type": "qualified-by",
            "target": {
              "reference": "urn:oid:3.14159.20170306163008.245"
            }
          }
        ]
      }
    },
    {
      "fullUrl": "urn:oid:3.14159.20170306163008.245",
      "resource": {
        "resourceType": "Observation",
        "text": {
          "status": "additional",
          "div": "<div xmlns='http://www.w3.org/1999/xhtml'>CoincidentTimeStamp-20170306163008.245-0500</div>"
        },
        "status": "final",
        "code": {
          "coding": [
            {
              "system": "urn:iso:std:iso:11073:10101",
              "code": "67975",
              "display": "MDC_ATTR_TIME_ABS"
            }
          ]
        },
        "subject": {
          "reference": "Patient/PatientId-sisansarahId"
        },
        "effectiveDateTime": "2017-03-06T16:30:08.245-05:00",
        "valueDateTime": "2017-03-06T16:30:07.000-05:00",
        "device": {
          "reference": "Device/SysId-1234567800000033"
        }
      }
    }
  ],
  "request": [
    {
      "method": "POST",
      "url": "Observation",
      "ifNotExist": "identifier=sisansarahId-urn:oid:1.2.3.4.5.6.7.8.10~1234567800000033~160368~20170306163009.000~95"
    },
    {
      "method": "POST",
      "url": "Observation"
    }
  ]
}

```

Figure 8-3: Sample FHIR message

8.2.3 Questionnaire

Patient reported outcome measures, or questionnaires, are used in a clinical setting to collect information directly from the patient. The CDG enable the interoperable exchange of questionnaires across the Services interface. Questionnaires are presented according to the *HL7 Implementation Guide for Questionnaire Form Definition* document HL7 CDA QFD. Responses to a questionnaire are then presented according to the *HL7 Implementation Guide Questionnaire Response* document HL7 CDA QRD. Questionnaires are transported per HL7 Version 3 Standard: hData Record Format, Release 1 and Object Management Group (OMG) hData REST Binding for RLU Specification 1.0.1.

8.2.4 Consent management

Consent management is a system, process, or set of policies that enable patients to choose what health information they are willing to permit their healthcare providers to access and share. The design guidelines provide for the capturing and transferring of consent policy in electronic form between the HFS and the PHG via the Services interface. Consent representation is per *HL7 Implementation Guide for CDA Release 2.0: Consent Directive*. hData over HTTP is used as the transport protocol for the exchange of consent documents. Consent enforcement is enabled through the use of the IHE DEN profile. Alternatively, *IHE IT Infrastructure Technical Framework Supplement Cross-Enterprise Document Reliable Interchange (XDR)* can be used as transport protocol for uploading consent documents to the server. When the XDR protocol is used, consent enforcement uses the XML encryption standard targeting a specific recipient.

8.2.5 Capabilities exchange

Capability exchange reduces the amount of information that must be pre-configured on a device in order to obtain plug-n-play interoperability. The CDG enable this exchange of capability information between a PHG and a HFS (e.g. tele-health service). Properties of a device or service and how to start the exchange of this information are defined. This information is exchanged in XML or JSON per *HL7 Version 3 Specification: hData Record Format, Release 1* over TLS v1.1 using OAuth.

8.2.6 Authenticated persistent session

CDG's authenticated persistent session (APS) enables a cloud service to have a persistent secure channel to a gateway in the cellular environment where bandwidth, power, and IP resources may be limited and/or intermittent. The channel is persistent in that it stays in place even when IP connectivity is lost, continuing data delivery once IP connectivity is re-established. Industry standard SMS messaging can be used to wake up a cellular gateway that has gone into a low power state, or lost its IP connectivity. The APS allows the cloud service to issue commands to the gateway and get timely responses without requiring continuous polling. This reduces bandwidth needs and conserves gateway power. The APS uses RESTful exchanges to establish the communications channel and MQTT, a lightweight publish-subscribe based protocol standard, to exchange messages.

8.3 Message exchange frameworks

Due to security and privacy concerns, as well as the technical feasibility of the overall system, the Services-IF requires that all connections be initiated from the PHG. The message exchange framework employed by the Services interface is dependent upon the data payload:

- For exchanging IHE PCD-01 messages, a web services transport layer defined by IHE IT infrastructure technical framework volume II, appendix V, which specifies the usage of SOAP over HTTP and otherwise conforms to the WS-I BP and WS-I BSP. Authentication is a SAML 2.0 token.
- For uploading HL7 V2.6 Observations as FHIR resources, the message exchange framework uses REST over HTTP and otherwise conforms to the WS-I BP and WS-I BSP. Authentication is via OAuth 2.0.
- For uploading HL7 V2.6 Observations using hData, the HL7 hData framework standard coupled with the hData REST transport binding is used. Authentication is via OAuth 2.0 Authorization Framework.
- For exchanging Questionnaires, messages are transported per HL7 Version 3 Standard: hData Record Format, Release 1 and OMG hData REST Binding for RLUS Specification 1.0.1.
- For Consent Management, hData over HTTP is used as the transport protocol for the exchange of consent documents.
- For Capabilities Exchange, information is exchanged in XML or JSON per *HL7 Version 3 Specification: hData Record Format, Release 1* over TLS v1.1 using OAuth.
- For APS, RESTful exchanges are used to establish the communications channel and MQTT, a lightweight publish-subscribe based protocol standard, to exchange messages.

The CDG does not specify how the PHG obtains authentication tokens, as that process is dependent upon the trust relationship established between the parties.

8.3.1 SOAP & SAML

The Continua Services interface uses a web services transport layer defined in Appendix V of IHE ITI-TF-2, which specifies the usage of SOAP 1.2 over HTTP version 1.1 and otherwise conforms to the WS-I BP Version 1.1 and WS-I BSP 1.0. The Services message exchange framework further specifies conformance to the draft Reliable Secure Profile (WS-I RSP) to constrain the optional use of additional web service standards.

The Services Observation Upload sender is also required to provide an indication that it has been authenticated and that it is authorized to perform this transaction using a SAML 2.0 token.

8.3.2 REST & OAuth FHIR

An HFS FHIR Observation Server and PHG FHIR Observation Client support OAuth 2.0. A PHG FHIR Observation Client supports one or more grant types: Resource Owner Credential, Client Credential, Authorization Code, and Jason Web Token (JWT) Bearer. An HFS FHIR Observation Server supports Resource Owner Credential and Client Credential grant types, and optionally a JWT Bearer grant type.

8.3.3 REST & OAuth hData

Observation Upload using hData uses the HL7 hData framework standard (2013)² coupled with the hData REST transport binding standard (OMG, 2013). These two documents in turn rely on HTTPS and the Internet Standard HTTP and TCP/IP protocol stacks. Observation Upload using REST requires implementation of the hData Content Profile Document for Observation Upload which contains narrative text and an XML Schema, that defines the specific encoding of the mandatory and optional elements of the hData Framework that are to be used for Observation Upload

8.3.4 Capabilities Exchange

Observation-upload receivers and senders using FHIR and hData are required to support capabilities exchange. The primary purpose of the exchange is to allow PHG applications to discover what capability classes the receiver supports. The capability elements also often provide a URL 'starting point', for example where to POST the PCD-01 message for observation-upload device classes or where to POST the PHG components of the ABP resource in APS establishment for APS device classes.

8.4 Security & Privacy

The Services interface security guidelines are based on ISO 27000 concepts of confidentiality, integrity, availability, accountability, authentication, authorization, and access control. The scope is limited to a single session-oriented, synchronous, and point-to-point communication. Security is achieved through consent management, consent enforcement, auditing, confidentiality, integrity and service authentication, and entity authentication as constrained by the CDG. The tools used to provide the secure communication are selected from the WS-I BSP.

8.4.1 Consent Management

Consent management is achieved via the HL7 CDA Release 2 Consent Directive. This directive documents a bilateral agreement between the patient and an individual or organization, which grants or withholds authorization to access individually identifiable health information about the patient. HL7 has produced a draft standard for trial use for implementing consent directives using CDA Release 2.

² <http://wiki.hl7.org/index.php?title=HData>.

8.4.2 Consent enforcement

Consent Enforcement is realized by implementing the W3C XML Encryption Standard to enable enforcement of patient consent by encrypting the measurement or questionnaire payload in addition to using point-to-point link security. This enables both the sender and the receiver of the payload to control access to the payload based on the consent policy. In the case of the transport protocol using hData over HTTP, consent enforcement is enabled using the IHE DEN profile.

8.4.3 Auditing

Auditing is accomplished via IHE's Audit Trail and Node Authentication (ATNA) Integration Profile, creating a secured domain by ensuring that communicating entities are authenticated by local systems (e.g., ITU-T X.509 [17]) before allowing network access.

8.4.4 Confidentiality, integrity, and service authentication

Confidentiality, Integrity and Service Authentication employs web services layer security between the gateway and EHR via the Web Services Interoperability Basic Security Profile. This profile provides interoperability guidance for core web service specifications such as SOAP (WS-I BSP, TLS v1.2).

8.4.5 Entity authentication

Entity Authentication constrain the Web Services (WS) Security profile from the WS-Interoperability Basic Security Profile by using only the WS- Security Header with the SAML 2.0 assertion as security token and allowing the use of any other token for providing the identity information, including OAuth. Assertion is utilized via SAML 2.0 within HTTP/SOAP uploads and OAuth access tokens are used in REST/hData uploads.

9 Healthcare information system interface

The purpose of the HIS interface is to transfer patient information from a Continua HFS (HIS Sender) to either another HFS or an electronic health record device (HIS Receiver). The HIS Sender can be, for example, the Remote Patient Monitoring (RPM) server of a Disease Management service provider or the Application Server of an Ageing Independently or Health & Fitness Service. The patient information for transfer may include a report summarizing the patient's current status, a detailed listing of specific patient results, readings from one or more personal health devices, or a combination of these. The electronic health record device may contain a hospital's EHR, a physician's Electronic Medical Record (EMR) or a Personal Health Record service (PHR) used by the patient. See H.813 [8] for more information on the HIS interface.

The CDG establishes the basic standards, rules and restrictions in the data, message, and transport protocols necessary to enable the transfer of pertinent information from a HIS Sender to a HIS Receiver.

9.1 Background

HL7 PHMR was developed as a standard for conveying information to health record systems. As the PHMR is meant to be a report detailing a wide assortment of patient-centred information, the information conveyed could be from a myriad of data sources. These data sources may be in-home devices but they can also be information gathered at other points in the complete health care spectrum.

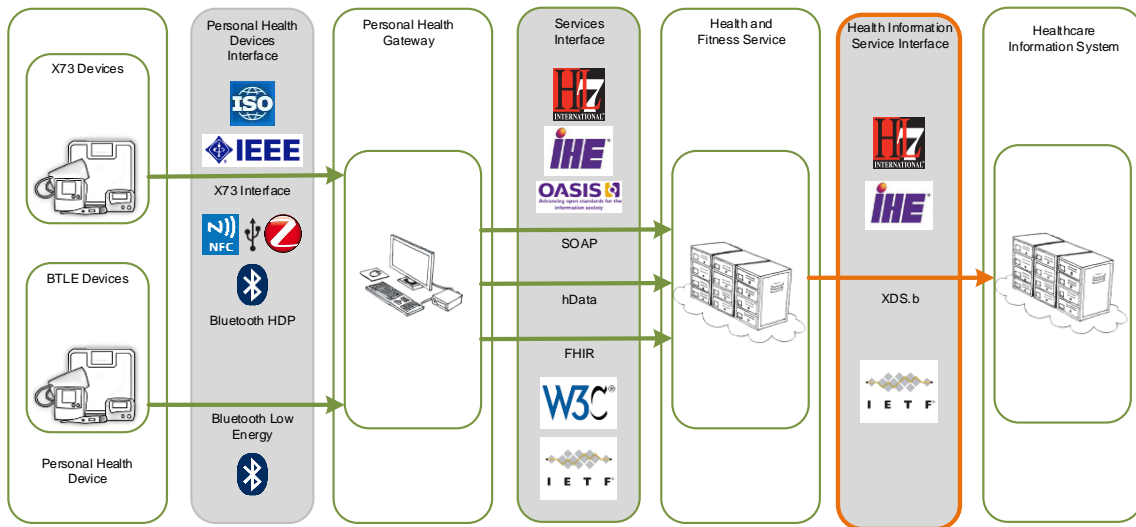


Figure 9-1: Health Information Systems interfaces in the Continua Architecture

9.2 Data payload

The HL7 PHMR was chosen to facilitate the accurate transfer of both coded patient results from personal health devices and textual summary results from patient caregivers. The PHMR implementation is based on the HL7 V3 architecture and is a derivative of the CDA R2. As such, it is a structured, XML-based file that has specified clauses for various types of health information. Placing the data derived from Services interface messages (PCD-01 or FHIR) entails placing the data in specific document clauses in their proper format. Along with any desired data from other sources, this total set of information comprises a single PHMR document. See Figure 9-2 for a sample PHMR message.

```

<section>
  <templateId root="2.16.840.1.113883.10.20.1.16"/>
  <templateId root="2.16.840.1.113883.10.20.9.2"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Vital Signs</title>
  <text>
    <paragraph>Thermometer Results</paragraph>
    <table border="1" width="100%">
      <tbody>
        <tr>
          <th>Date/Time</th>
          <th>Body Temp</th>
          <th>Finger Temp</th>
          <th>Oral Temp</th>
        </tr>
        <tr>
          <td>20080501104033</td>
          <td>99.9 deg F</td>
          <td>88.8 deg F</td>
          <td>37.5 deg C</td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
      <!-- Vital sign data/ Test Groups -->
      <!-- A VITAL SIGNS ORGANIZER IS USED TO GROUP
    RELATED -->
    <templateId root="2.16.840.1.113883.10.20.1.35"/>
    <id root="b606a959-baab-4836-84a8-97c4e9857533"/>
    <code code="46680005" codeSystem="2.16.840.1.113883.6.96" displayName="Vital signs"/>
    <statusCode code="completed"/>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.31"/>
        <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
        <code code="386725007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Body Temperature"/>
        <translation code="MDC TEMP BODY" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Body Temperature"/>
        <statusCode code="completed"/>
        <effectiveTime value="20080501104033-0600"/>
        <value xsi:type="PQ" value="99.9" unit="[degF]"/>
        <participant typeCode="DEV">
          <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
        </participantRole>
      </observation>
    </component>
  </entry>
  </organizer>
</section>
  <templateId root="2.16.840.1.113883.10.20.1.31"/>
  <templateId root="2.16.840.1.113883.10.20.9.8"/>
  <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
  <code code="433588001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Temperature of digit of hand"/>
  <translation code="MDC TEMP FINGER" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Finger Temperature"/>
  <statusCode code="completed"/>
  <effectiveTime value="20080501104033-0600"/>
  <value xsi:type="PQ" value="88.8" unit="[degF]"/>
  <participant typeCode="DEV">
    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
  </participantRole>
  </observation>
</component>
  <component>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.31"/>
      <templateId root="2.16.840.1.113883.10.20.9.8"/>
      <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
      <code code="415945006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Oral Temperature"/>
      <translation code="MDC TEMP ORAL" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Oral Temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="20080501104033-0600"/>
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      <participant typeCode="DEV">
        <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
      </participantRole>
    </observation>
  </component>
</organizer>
</section>
  <component>
    <component>
      <observation classCode="OBS" moodCode="EVN">

```

Figure 9-2: Sample PHMR Message

9.3 Message exchange framework

The IHE Patient Identifier Cross-Referencing (PIX) profile³ was selected to provide a standards-based interface for managing identifiers across organizational and political domains ensuring that HIS Senders and Receivers can correctly associate personal health data with the right patient.

The IHE Cross-Enterprise Document Sharing (XDS) profile⁴ was selected for exchanging patient information between providers via secure connection over the Internet, secure email, or delivery on portable media (e.g. memory stick).

The IHE Cross-Enterprise Document Reliable Interchange (XDR)⁵ was selected for explicit exchange of patient information between providers using a reliable point-to-point network communication.

The IHE Cross-Enterprise Document Media Interchange (XDM)⁶ employing ZIP and S-MIME was selected for secure indirect communication of pertinent patient information between caregivers.

9.4 ONC DIRECT

The ONC DIRECT project of the United States Department of Health and Human Services Health Information Technology defines a mechanism to securely exchange health data between trusted parties using electronic mail. The CDG indicates how to implement DIRECT as an extension of the HIS Sender. The ZIP package is generated by the HIS Sender and is sent via Simple Mail Transport Protocol per the DIRECT specification.

9.5 Security and privacy

For the Healthcare Information System interface, security is achieved through confidentiality, integrity and authentication, entity authentication, identity management, consent management, consent enforcement, non-repudiation of origin, and auditing as constrained by the CDG.

9.5.1 Confidentiality, integrity, and service authentication

Confidentiality, Integrity and Authentication employs transport layer security as specified in IHE's XDR profile for direct communications. For indirect communications via the IHE XDM profile, the exported file is delivered via email using S/MIME to ensure security (TLS v1.1 and IHE XDM S/MIME).

9.5.2 Entity authentication

Entity Authentication is achieved via the IHE Cross-Enterprise User Assertion Profile (XUA), to provide a means to communicate claims about the identity of an authenticated principal (e.g., user, application, and system) in transactions that cross enterprise boundaries. The IHE Cross- Enterprise User Assertion Profile – Attribute Extension (XUA++), extends the XUA profile with options that enable access controls on the service side (consumer of the data).

³ http://wiki.ihe.net/index.php/Patient_Identifier_Cross-Referencing.

⁴ https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing.

⁵ https://wiki.ihe.net/index.php/Cross-enterprise_Document_Reliable_Interchange.

⁶ https://wiki.ihe.net/index.php/Cross-enterprise_Document_Media_Interchange.

9.5.3 Identity management

Identity Management is realized via the following specifications:

- *IHE Patient Identity Feed Transaction to communicate patient identification and demographic data and IHE Patient Identifier Cross-Reference HL7 Version 3 (PIXV3)* to provide cross-referencing of patient identifiers from multiple Patient Identifier Domains (systems that share a common identification scheme and issuing authority for patient identifiers); and
- *Patient Demographics Query HL7 Version 3 (PDQV3)* to allow multiple distributed applications to query a patient information server for a list of patients (based on user-defined search criteria) and to retrieve a patient's demographic information directly into the application (*IHE Patient Identity Feed HL7 V3, IHE PIXV3 Query transaction, and IHE Patient Demographics Query HL7 V3 transaction*).

9.5.4 Consent management

Consent management is accomplished via the *HL7 CDA Release 2 Consent Directive* that, as explained earlier, grants or withholds authorization to access individually identifiable health information about the patient.

9.5.5 Consent enforcement

Consent enforcement is achieved via the IHE Document Encryption Profile, which provides a means to encrypt health documents independent of particular transport, healthcare application, or document type, thereby supporting end-to-end confidentiality in heterogeneous or unanticipated workflows.

9.5.6 Non-repudiation of origin

Non-repudiation of origin, which is the assurance that someone cannot deny something, such as the receipt of a message or the authenticity of a statement or contract, is realized via the IHE Document Digital Signature profile that specifies the use of digital signatures for documents that are shared between organizations.

9.5.7 Auditing

Auditing is accomplished via IHE's ATNA Integration Profile, creating a secured domain by ensuring that communicating entities are authenticated by local systems (e.g., ITU-T X.509 [17]) before allowing network access.

10 Continua certification

The Continua Product Certification program run by the PCHAlliance includes conformance and interoperability testing. It ensures that Continua-certified products conform to the specifications in the CDG. Devices featuring the Continua logo indicate that they meet Continua conformance requirements as well as basic interoperability requirements with other Continua devices.

10.1 Conformity assessment

Conformance testing using the ITU-T H.820-H.850 series ensures that products conform to the CDG when connected in a personal health system. The Continua Product Certification program further ensures that Continua-certified products implement all CDG interoperability guidelines required for their certified capability class. Conformance testing verifies certification from other SIGs/SDOs and conformance to Continua interoperability guidelines and foundational standards that have no other certification programs.

Continua devices are certified across the interface(s) that they support. A device must pass all tests in the test specification in order to become certified. If a device includes optional features, it must pass the set of compliance tests that apply to these features.

10.1.1 Personal Health Devices interface assessment

Certification of sensor devices ensures that IEEE 11073 conformant data is securely received at the gateway. Data/protocol testing ensures conformance to data and messaging defined in ISO/IEEE 11073-20601 as well as one or more device specializations of the ISO/IEEE 11073-104XX series. Transport testing ensures conformance to the applicable Bluetooth, ZigBee, or USB specifications.

10.1.2 Services interface assessment

For devices featuring PCD-01 message uploads, certification of the Services interface ensures that each field of every segment in the PCD-01 message contains a valid value. Testing includes conformance to rules for each transaction in the IHE PCD Technical Framework PCD-01, and conformance to WS-I Basic Profile and WS-I Reliable Secure Profile.

For devices featuring FHIR-based HL7 V2.6 uploads, certification of the Services interface ensure proper mapping of IEEE 11073-20601 attributes into FHIR resources creating an HL7 V2.6 Observation, and that a FHIR data payload is transported over the internet from a FHIR Observation Client to a FHIR Observation Server using RESTful web services and secured using TLS and OAuth.

10.1.3 Healthcare Information Systems interface assessment

Certification of the HIS interface ensures the syntax and semantics of the XML message. HIS Sender certifications are granted following self-test and self-declaration using tools provided by PCHAlliance that ensure conformance with the CDG.

10.2 Interoperability assessment

Interoperability testing ensures that Continua devices are able to communicate and share data with each other or with Continua reference devices when connected. Interoperability testing for the purposes of certification is limited to procedures that run the device through the normal behaviours expected for the device type. The device being certified is paired against up to three reference devices that have already achieved Continua Certification. These devices are selected by the testing lab from a list of pre-approved certified devices.

10.2.1 PlugFests

Plugfests are activities where CDG PHD and PHG vendors bring pre-release versions of their products. Each PHD has a chance to be paired with each PHG and run through basic interoperability tests. Time is left to debug products and retest. In addition, any issues found in the Continua referenced standards or in the Continua Interoperability Guidelines are noted.

10.2.2 Connect-a-thons

IHE Connect-a-thons are a cross-vendor, live, supervised and structured testing event where industry leaders test implementations of IHE Profiles to advance health IT interoperability. All tests are evaluated on interoperability and conformance to IHE Profiles found in IHE's Technical Frameworks. IHE Connect-a-thons take place annually in various countries across the world to advance health IT and patient safety.

10.3 Industry alignment

The Continua Product Certification program is aligned with the E-health Interoperability Conformity Assessment Scheme for Europe (EURO-CAS) that is developing a sustainable Conformity Assessment Scheme (CAS) for Europe, which promotes the adoption and take-up of interoperability testing of eHealth solutions against identified eHealth standards and profiles defined in the *Refined eHealth European Interoperability Framework*⁷. The project is led by IHE-Europe and coordinated by EIBIR, and is joined by fourteen national and regional government bodies, competence centres, and associations.

10.4 Certification

Continua Certification provides governments, health ministers, healthcare providers, or any other requesting entity an impartial 3rd party confirmation that the device under procurement, or under consideration for procurement, has successfully satisfied all pre-defined conformity assessment criteria. The certification process consists of the product vendor, test laboratory and Continua certification administrator working together to document and verify that a product has met the requirements for certification described in the Conformity Assessment Scheme for Continua⁸. Continua grants four types of certifications: new product, multiple-type, derivative, and white label.

10.5 Declaration of compliance

Continua's Declaration of Compliance provides a freely available uniform pre-approval process enabling any vendor the ability to self-declare directly to a customer via 1st party attestation of compliance that its products are compliant to the CDG. This program is targeted to markets that may be unable to require 3rd party certification.

⁷ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf.

⁸ <https://members.pchalliance.org/document/dl/1221>.

Appendix I

Complete list of ITU documents on the Continua Design Guidelines

Technical papers

[ITU-T HSTP-H810-XCHF](#) (2017-10), *Fundamentals of data exchange within ITU-T H.810 Continua Design Guideline architecture.*

[ITU-T HSTP-H810](#) (2017-10), *Introduction to the ITU-T H.810 Continua Design Guidelines.*

The CDG specifications

[ITU-T H.810](#), *Interoperability design guidelines for personal connected health systems: Introduction.*

[ITU-T H.811](#), *Interoperability design guidelines for personal connected health systems: Personal Health Devices interface.*

[ITU-T H.812](#), *Interoperability design guidelines for personal connected health systems: Services interface.*

[ITU-T H.812.1](#), *Interoperability design guidelines for personal connected health systems: Services interface: Observation upload capability.*

[ITU-T H.812.2](#), *Interoperability design guidelines for personal connected health systems: Services interface: Questionnaire capability.*

[ITU-T H.812.3](#), *Interoperability design guidelines for personal connected health systems: Services interface: Capability Exchange capability.*

[ITU-T H.812.4](#), *Interoperability design guidelines for personal connected health systems: Services interface: Authenticated persistent session capability.*

[ITU-T H.813](#), *Interoperability design guidelines for personal connected health systems: Healthcare Information System interface.*

CDG specification for trial implementation

[ITU-T HSTP-H812-FHIR](#) (2017-10), *Interoperability design guidelines for personal health systems: Services interface: FHIR Observation Upload for trial implementation.*

Conformance testing specifications

[ITU-T H.821](#), *Conformance of ITU-T H.810 personal health system: Healthcare information system interface.*

[ITU-T H.830.1](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 1: Web services interoperability: Health & Fitness Service sender.*

[ITU-T H.830.2](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 2: Web services interoperability: Health & Fitness Service receiver.*

[ITU-T H.830.3](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 3: SOAP/ATNA: Health & Fitness Service sender.*

[ITU-T H.830.4](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 4: SOAP/ATNA: Health & Fitness Service receiver.*

[ITU-T H.830.5](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 5: PCD-01 HL7 Messages: Health & Fitness Service sender.*

[ITU-T H.830.6](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 6: PCD-01 HL7 Messages: Health & Fitness Service receiver.*

[ITU-T H.830.7](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 7: Consent Management: Health & Fitness Service sender.*

[ITU-T H.830.8](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 8: Consent Management: Health & Fitness Service receiver.*

[ITU-T H.830.9](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 9: hData Observation Upload: Health & Fitness Service sender.*

[ITU-T H.830.10](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 10: hData Observation Upload: Health & Fitness Service receiver.*

[ITU-T H.830.11](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 11: Questionnaires: Health & Fitness Service sender.*

[ITU-T H.830.12](#), *Conformance of ITU-T H.810 personal health system: Services interface Part 12: Questionnaires: Health & Fitness Service receiver.*

[ITU-T H.831](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 1: Web services interoperability: Sender.*

[ITU-T H.832](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 2: Web services interoperability: Receiver.*

[ITU-T H.833](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 3: SOAP/ATNA: Sender.*

[ITU-T H.834](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 4: SOAP/ATNA: Receiver.*

[ITU-T H.835](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 5: PCD-01 HL7 messages: Sender.*

[ITU-T H.836](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 6: PCD-01 HL7 messages: Receiver.*

[ITU-T H.837](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 7: Consent management: Sender.*

[ITU-T H.838](#), *Conformance of ITU-T H.810 personal health devices: WAN interface Part 8: Consent management: Receiver.*

[ITU-T H.840](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface: USB host.*

[ITU-T H.841](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 1: Optimized Exchange Protocol: Personal Health Device.*

[ITU-T H.842](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 2: Optimized Exchange Protocol: Personal Health Gateway.*

[ITU-T H.843](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 3: Continua Design Guidelines: Personal Health Device.*

[ITU-T H.844](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 4: Continua Design Guidelines: Personal Health Gateway.*

[ITU-T H.845.1](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5A: Weighing scales.*

[ITU-T H.845.2](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5B: Glucose meter.*

[ITU-T H.845.3](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5C: Pulse oximeter.*

[ITU-T H.845.4](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5D: Blood pressure monitor.*

[ITU-T H.845.5](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5E: Thermometer.*

[ITU-T H.845.6](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5F: Cardiovascular fitness and activity monitor.*

[ITU-T H.845.7](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5G: Strength fitness equipment.*

[ITU-T H.845.8](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5H: Independent living activity hub.*

[ITU-T H.845.9](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5I: Adherence monitor.*

[ITU-T H.845.10](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5I: Insulin pump.*

[ITU-T H.845.11](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5K: Peak expiratory flow monitor.*

[ITU-T H.845.12](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5L: Body composition analyser.*

[ITU-T H.845.13](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5M: Basic electrocardiograph.*

[ITU-T H.845.14](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5N: International normalized ratio.*

[ITU-T H.845.15](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5O: Sleep apnoea breathing therapy equipment.*

[ITU-T H.845.16](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5P: Continuous glucose monitor.*

[ITU-T H.846](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 6: Personal Health Gateway.*

[ITU-T H.847](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 7: Continua Design Guidelines for Bluetooth Low Energy: Personal Health Devices.*

[ITU-T H.848](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 8: Continua Design Guidelines for Bluetooth Low Energy: Personal Health Gateway.*

[ITU-T H.849](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 9: Transcoding for Bluetooth Low Energy: Personal Health Devices.*

[ITU-T H.850](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10: Transcoding for Bluetooth Low Energy: Personal Health Gateway - General requirements.*

[ITU-T H.850.1](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10A: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Thermometer.*

[ITU-T H.850.2](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10B: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Blood pressure.*

[ITU-T H.850.3](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10C: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Heart-rate.*

[ITU-T H.850.4](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10D: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Glucose meter.*

[ITU-T H.850.5](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10E: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Weighing scales.*

[ITU-T H.850.6](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10F: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Pulse oximeter.*

[ITU-T H.850.7](#), *Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 10G: Transcoding for Bluetooth Low Energy: Personal Health Gateway - Continuous glucose monitoring.*