Personal Connected Health Alliance

Continua®

White Paper

Fundamentals of Data Exchange

April 2017

Contents

Figures

1 Introduction

The Personal Connected Health Alliance (PCHAlliance) aims to make health and wellness an effortless part of daily life. A non-profit organization formed by HIMSS, the alliance believes that health is personal and extends beyond healthcare. The PCHAlliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. Its members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

The PCHAlliance publishes and promotes the global adoption of the Continua Design Guidelines (CDG), an open framework implementation guide for user-friendly, secure and interoperable health data exchange in personal connected health. The Continua Design Guidelines are recognized by the United Nations International Telecommunication Union (ITU-T) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices.

National Health Ministers representing countries around the world are releasing tenders to build scalable managed healthcare services that conform to established industry standards. These standards include IEEE 11073 Personal Health Device Standards, the Integrating the Healthcare Enterprise (IHE) Patient Care Device PCD-01 Transaction, and the Health Level Seven International (HL7) FHIR® (Fast Healthcare Interoperability Resources) and Personal Health Monitoring Report (PHMR).

2 Purpose & Scope

The purpose of this white paper is to provide a basic description of the data that is being exchanged between sensors, gateways, and end services and value-add the Continua Design Guidelines provide beyond the referenced standards to make implementations truly interoperable. The ITU-T Technical Paper "HSTP-H810 Introduction to the ITU-T H.810 Continua Design Guidelines" and the ITU-T H.810 Continua Design Guidelines themselves provide a more comprehensive understanding of these interfaces.

3 Architecture in Brief

The Personal Health Devices Interface standardizes around the IEEE 11073 Personal Health Device family of standards 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 standard 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 PHMR to move information between a Health & Fitness Service and Healthcare Information Service provider (e.g. electronic health record, EHR).

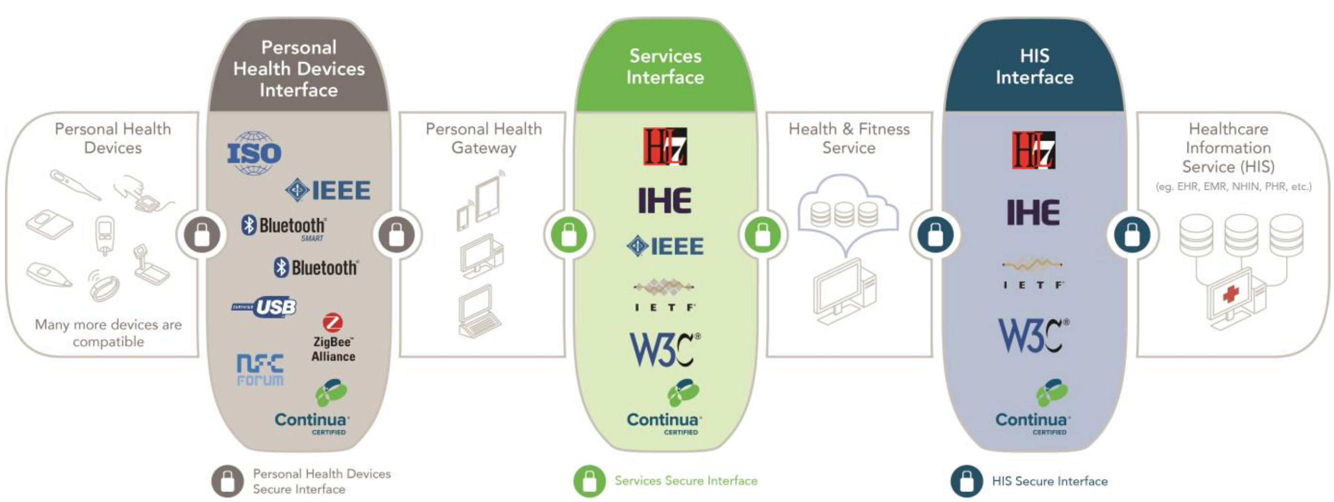

Figure 1: High Level Architecture

The Continua Design Guidelines address 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.

4 Personal Health Devices Interface

The PCHAlliance works closely with the IEEE to develop the *IEEE 11073 Personal Health Device* family of standards to specifically address the interoperability of personal health devices (e.g. thermometer, blood pressure monitor) with an emphasis on personal use and a more simple communication model. 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. Furthermore, one of the main reasons to use the 11073 family of standards in the Continua architecture is that it runs on top of USB, Bluetooth®, NFC and ZigBee transport protocols.

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 11073-10400-series*. The Nomenclature standard defines the overall architecture of the organization and relationships among nomenclature components along with specific semantics and syntaxes. The Domain Information Model standard addresses the definition and structuring of information that is communicated or referred to in communication between devices. The Optimized Exchange Protocol standard defines a common framework for making an abstract model of personal health data available in transport independent syntax. Device Specializations standards define communications between compute engines (e.g. personal health gateway) and specific personal health tele-health devices.

A typical 11073 observation message captures a variety of measurement techniques, common device attributes, device specific attributes, and device events. By way of example, a message from a blood pressure monitor could communicate use of the oscillometric technique, up to 18 common device attributes (e.g. model, manufacturer), 25 or more device specific attributes (e.g. measurement units, status, time), and 7 events (e.g. configuration, update). The protocol to communicate these makes sure that only changed data needs to be sent. In the example below in Figure 2 the units of blood pressure are not sent as they are already known by the receiver. See IEEE 11073-10407 Device Specialization – Blood Pressure Monitor for more detail.

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 0x12 0x10 0x00 0x00	Absolute-Time-Stamp = 2007-12-06T12:10:0000
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-V alue = 60.0 (BPM)
0x20 0x07 0x12 0x06 0x12 0x10 0x00 0x00	Absolute-Time-Stamp = 2007-12-06T12:10:0000

Figure 2: Sample IEEE 11073 Message

Communicating such an exhaustive set of attributes may not be necessary or practical in all healthcare monitoring applications. Therefore, the PCHAlliance works within the healthcare community to agree on a subset of attributes that are sufficient for consumer-friendly healthcare monitoring solutions. In the blood pressure monitor, for example, Continua has identified four device specific attributes that must be communicated. The PCHAlliance also works closely with the Bluetooth SIG to ensure that Bluetooth low energy technology healthcare profiles include these attributes (characteristics) and that they are compatible with the IEEE 11073 data format. Recently completed IEEE 11073-104XX specializations include monitoring for sleep apnea breathing therapy, continuous glucose, and insulin pump, bringing the total number of supported profiles to 32. See H.811 Personal Health Devices Interface Design Guidelines for a detailed list.

Data confidentiality, integrity and authentication across the Personal Health Devices Interface is achieved via the underlying communication technology associated with each device (e.g. Bluetooth Security).

5 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 design guidelines ensure interoperability by constraining IHE specifications and HL7 standards and providing implementation guidance and interface certification. For the Services Interface, security is achieved through consent management (HL7 CDA R2 Consent Directive), consent enforcement (XML Encryption Specification), auditing (IHE ATNA), confidentiality, integrity and service authentication (WS-I BSP, TLS v1.2), and entity authentication (WS-I BSP, WS-Security + SAML 2.0, or OAuth).

5.1 Device Observation

Device observations are one-way, point-to-point transmission of single and batch measurements between a Personal Health Gateway and a Health & Fitness Service. The Continua Design Guidelines specify three implementations for uploading HL7 V2.6 Observations payloads:

- IHE PCD-01 message packaged in SOAP and authenticated using SAML,
- HL7 FHIR Resources via REST and OAuth, and
- IHE PCD-01 message sent over HL7 hData Framework and hData REST transport binding.

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. Personal Health Gateway) to a device observation consumer (e.g. Health & Fitness Service). *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 design guidelines map the ISO-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 packaged in SOAP then transported over the internet using industry standard web services and secured using TLS and SAML. A sample PCD-01 message is shown in Figure 3.

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 Device 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 4.

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.


```
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^PI||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-continual||||||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-continual||||||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-continual||||||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-continual||||||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-continual||||||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|1.0.0.13.1|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 3: Sample PCD-01 Message

5.2 Questionnaires

Patient reported outcome measures, or questionnaires, are used in a clinical setting to collect information directly from the patient. The design guidelines 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 RLUS Specification 1.0.1.

5.3 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 Health & Fitness Service and the Personal Health Gateway 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 XML encryption standard targeting a specific recipient.


```
{
"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"
}
}
]
},
"request": {
"method": "POST",
"url": "Observation",
"ifNoneExist": "identifier=sisansarahId-
urn:oid:1.2.3.4.5.6.7.8.10~1234567800000033~160368
~20170306163009.000~95"
}
},
{
"fullUrl": "urn:oid:3.14159.20170306163008.245",
"resource": {
"resourceType": "Observation",
"text": {
"status": "additional",
"div": "<div
xmlns=\"http://www.w3.org/1999/xhtml\">CoincidentTim
eStamp-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"
}
}]
}
```


Figure 4: Sample FHIR Message

5.4 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 design guidelines enable this exchange of capability information between a Personal Health Gateway and a Health & Fitness Service (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.

5.5 Authenticated Persistent Session

Continua'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.

6 Healthcare Information System Interface

The Healthcare Information System (HIS) Interface provides for the electronic exchange of health records employing an HL7-based PHMR. The PHMR is defined by HL7 to carry personal healthcare monitoring information to electronic medical record systems and includes representation of measurements captured by devices. The PHMR is used by Continua to communicate patient information based on a collection of one or more PCD-01 messages.

The CDG specifies the transport of these reports using IHE XDS or ONC DIRECT. IHE XDS is a distributed collaborated approach that enables healthcare documents to be shared over a wide area network between hospitals and care providers. IHE XDS registries store metadata used to retrieve documents, while any number of XDS repositories store documents. IHE *Patient Identifier Cross-Reference* (PIX) and *Cross-Enterprise Document Sharing* (XDS) are used by the HIS interface for cross-referencing patient identifiers and cross-enterprise document sharing. ONC DIRECT provides a simple and secure standard-based method for sending health information to the known and trusted participants via email over the Internet.

For the Healthcare Information System Interface, security is achieved through confidentiality, integrity and authentication (TLS v1.1 and IHE XDM S/MIME), entity authentication (IHE XUA, IHE XUA++), identity management (IHE Patient Identity Feed HL7 V3, IHE PIXV3 Query transaction, and IHE Patient Demographics Query HL7 V3 transaction), consent management (HL7 CDA R2 Consent Directive), consent enforcement (IHE Document Encryption Profile), non-repudiation of origin (IHE Document Digital Signature), and auditing (IHE ATNA).


```
<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"/>
                        </code>
                        <statusCode code="completed"/>
                        <effectiveTime value="20080501104033-
0600"/>
                        <value xsi:type="PQ" value="99.9"
unit="[degF]"/>
                        <participant typeCode="DEV">
                              <participantRole>
                        <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>
                        </participant>
                  </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="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"/>
                        </code>
                        <statusCode code="completed"/>
                        <effectiveTime value="20080501104033-
0600"/>
                        <value xsi:type="PQ" value="88.8"
unit="[degF]"/>
                        <participant typeCode="DEV">
                              <participantRole>
                        <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>
                        </participant>
                  </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"/>
                              </code>
                        <statusCode code="completed"/>
                        <effectiveTime value="20080501104033-
0600"/>
                        <value xsi:type="PQ" value="37.5"
unit="Cel"/>
                        <participant typeCode="DEV">
                              <participantRole>
                        <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>
                        </participant>
                  </observation>
            </component>
      </organizer>
  </entry>
</section>
```


Figure 5: Sample PHMR Message

7 Certification

The PCHAlliance's Continua Test and Certification program ensures interoperability by verifying that products conform to the Continua Design Guidelines and its underlying standards. Certification of sensor devices ensures that IEEE 11073 conformant data is securely received at the gateway. Certification of the Services interface ensures that each field of every segment in the PCD-01 message contains a valid value. Certification of the HIS interface ensures the syntax and semantics of the XML message.

8 Foundational Specifications & Standards

IEEE drives the functionality, capabilities and interoperability of a wide range of products and services that transform the way people live, work and communicate. The *IEEE 11073 Personal Health Devices* family of standards enables communication between medical, health care and wellness devices and with external computer systems.

Integrating the Healthcare Enterprise is an initiative by care providers and vendors to improve the way information systems communicate to support patient care. Integration profiles describe clinical requirements for systems integration and well-defined and highly constrained solutions to address them. Transactions are used to specify in careful detail the roles for each component in the system and are based on standards such as IEEE 11073 and HL7.

HL7 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.

9 References

HSTP-H810 Introduction to the ITU-T H. 810 Continua Design Guidelines
ITU-T H.810 Interoperability Design Guidelines for Personal Health Systems
ITU-T H.811 Personal Health Devices Interface Design Guidelines
IEEE 11073-10101 Nomenclature and subsequent amendments
IEEE 11073-10201 Domain Information Model
IEEE 11073-20601 Optimized Exchange Protocol and subsequent corrigenda
IEEE 11073-10407 Device Specialization – Blood Pressure Monitor
Continua Certification Process

10 Glossary

API	Application Programming Interface
APS	Authenticated Persistent Session
ATNA	Audit Trail and Node Authentication
BSP	Basic Security Profile
CDA	Clinical Document Architecture
DEC	Device Enterprise Communication
DEN	Document Encryption
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HIMSS	Healthcare Information Management Systems Society
HIS	Healthcare Information System
HL7	Health Level 7 International
HTTP	Hypertext Transfer Protocol
IHE	Integrating the Healthcare Enterprise
IP	Internet Protocol
IT	Information Technology
ITU	International Telecommunications Union
JSON	JavaScript Object Notation
MQTT	Message Queuing Telemetry Transport
NFC	Near-Field Communications
OMG	Object Management Group
ONC	Office of the National Coordinator for Health Information Technology
ORU	Unsolicited Result Observation

PCD	Personal Connected Device
PCHA	Personal Connected Health Alliance
PHMR	Personal Health Monitoring Report
PIX	Patient Identifier Cross-Reference
QFD	Questionnaire Form Definition
QRD	Questionnaire Response Document
REST	Representational State Transfer
RLUS	Retrieval, Location and Update Service
S/MIME	Secure/Multipurpose Internet Mail Extensions
SAML	Security Assertion Markup Language
SOAP	Simple Object Access Protocol
TLS	Transport Layer Security
USB	Universal Serial Bus
WS-I	Web Services – Interoperability
XDM	Cross-Enterprise Document Media Interchange
XDR	Cross-Enterprise Document Reliable Interchange
XDS	Cross-Enterprise Document Sharing
XML	Extensible Markup Language
XUA	Cross-Enterprise User Assertion

11 About Personal Connected Health Alliance

The Personal Connected Health Alliance (PCHAlliance) aims to make health and wellness an effortless part of daily life. The PCHAlliance, a non-profit organization formed by HIMSS, believes that health is personal and extends beyond healthcare. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world. To support its vision, PCHAlliance convenes the global personal connected health community at the annual Connected Health Conference, the premier international event for the exchange of research, evidence, ideas, innovations and opportunities in personal connected health. The Alliance publishes and promotes adoption of the Continua Design Guidelines. Continua is recognized by the International Telecommunication Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices. PCHAlliance accelerates technical, business, policy and social strategies necessary to advance personal connected health through its flagship Academy for Healthy Longevity to promote lifelong health and wellness.

12 For More Information

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13 Legal

