Personal Healthcare Monitoring Report 1.2

November 11

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# Personal Healthcare Monitoring Report

The Personal Healthcare Monitoring Report (PHMR) is a document that carries patient measurement data taken by consumer medical devices. The primary use case around which the PHMR is designed is for the automated reporting of measurements taken by Personal Connected Healthcare Alliance (PCHA; formally Continua) compliant Personal Healthcare Monitoring (PHM) consumer devices outside of the health care provider facilities. PCHA compliant devices are required to generate data with certain qualifications. Examples of such consumer devices would be weight scales, blood pressure cuffs, pulse oximeters, glucometers, thermometers, step counters, fitness equipment following the PCHA standard, independent living sensor devices, etc.. No entry of measurement data into the PHMR document by manual means is anticipated (though it is possible) thus the assignedAuthor element of observations is almost always a device. Manual entry of information into the sensor device (such as one's height into a Body Composition Analyzer) is not considered manual entry of measurement data for this specification; the data is still received from the sensor by protocol and software is handling the generation of the PHMR.

This implementation guide is an essential component in the support of the Integrating Healthcare Enterprise (IHE) Remote Patient Monitoring (RPM) Profile for the remote monitoring of patients. The RPM profile reflects the PCHA end-to-end architecture. In the RPM profile the data will be provided to the PHMR content creator either directly from the PHM device or via an IHE HL7 PCD-01 message. Since the entire set of transactions from the PCHA compliant PHM device to the PHMR content creator is standardized, the data available to the PHMR generator is known. However the demographic data necessary for the PHMR document header is not provided by the PHM devices through any standardized protocol and therefore must be provided by the patient or a patient representative. How that is accomplished is not specified by either PCHA or the IHE RPM and is left as a business decision.

PCHA compliant PHM device measurements can all be expressed as IEEE 11073 20601 attributes of IEEE 11073 20601 metric objects. Data that can be expressed in that form is referred to as PCHA data in the IHE RPM profile and this implementation guide will use the same terminology. Examples of PCHA compliant PHM devices that do not follow the IEEE 11073 specializations are several Bluetooth Low Energy health devices that meet the additional expectations of PCHA. In those cases the device data is mapped to PCHA data.

There are three types of IEEE 11073 20601 metric objects; numeric, real-time sample array, and enumerations. Numeric metrics are used when the measurement is expressed as one or more numbers at a single point of time, for example the body temperature or the systolic, diastolic, and MAP blood pressure values. Real-time sample array metrics (RTSAs) are typically used to report wave forms, and consist of a sequence of evenly spaced measurements taken over a period of time, for example an ECG lead voltage signal. Enumeration metrics are used to report measurements that have a constrained set of values and are typically codes, for example one of N possible meal time options (breakfast, lunch, snack, fasting, etc.) reported when one takes a glucose measurement. Associated with these metrics are, of course, context attributes expressing the type (a code that states that this value is, for example, an oral temperature) units, time, etc. Codes reported by these devices or their transcoded measurements use the IEEE 11073 10101 nomenclature. For brevity, this implementation guide will refer to this coding system as 'MDC' codes given that the @codeSystemName of this coding system is 'MDC'.

MDC codes are 32-bit integer numbers where the 16 most significant bits are the partition and the 16 least significant bits are the code. However, the MDC codes are also designated by reference identifiers which are human readable. Thus a reference identifier such as MDC\_DEV\_SPEC\_PROFILE\_PULS\_OXIM is synonomous with the number 528388 (partition 8 and code 4100); 528388 = 8 X 2\*\*16 + 4100. However only the number is used in the code@code, translation@code, value@code, or any other place the code attribute occurs when the MDC coding system is used. The reference identifier, given that it is standardized and human readable, could be part of the @displayName attribute.

PHM devices are identified using the IEEE system id. A UID (universal Identifier) for such devices has been proposed, and its current suggested definition for IEEE PHM devices contains the system id along with other pieces of information such as the serial number. In the current IEEE PHM specification, several but not all of the components of the proposed UID are already present but spread across different attributes. At this time the IEEE Personal Health Device (PHD) working group has not defined a new UID attribute. That may change in future revisions of the IEEE 11073 20601 standard when the methodology of the UID itself has been finalized.

This implementation guide is left open such that additional supplementary templates may be included as needed. For example, notes may be supplied by a disease management service provider and/or medication information may be entered. These entries would typically need to be done manually.

This implementation guide is also designed for international use and thus the clinical coding system (LOINC, SNOMED CT, etc.) for the observations is left up to the realm. Since PCHA compliant devices will always be represented using MDC codes, these codes are required to be present in the code/translation element of the medical observation templates (designated by PHM Metric \* Observation).

Patient Generated Universal Realm Document Header - Draft

[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.29:2015-08-17 (open)]

The PHMR document contains medical measurements of a patient taken by Personal Healthcare Monitoring (PHM) devices. The measurements themselves are typically taken by the patient or a medical assistant in the patient home or at some other facility outside of the health care provider's institution.  The clinical content for the sections in the PHMR, the device and measurement data, is provided by the PHM device directly or indirectly by standardized protocols over various transport mechanisms such as USB or Bluetooth. The demographic information for the PHMR header must be provided by the patient or a patient representative. Given the later requirement and the fact that the PHMR is meant for international use, the Patient Generated Document Header from the Patient Generated Document Header Template implementation guide is used for the basic header constraints. Though not clear from the title, the header is written for the universal realm with the idea that specific realms would appropriately constrain the fields as required for that realm. The Patient Generated Document Header is also used in the Questionnaire Response implementation guide. For convenience, the header constraints as defined in the Patient Generated Document Header Template implementation guide are repeated here.

Table 1: Patient Generated Universal Realm Document Header Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.29:2015-08-17) | | | | | |
| realmCode | 1..1 | SHALL |  | [1141-574](#C_1141-574) |  |
| @code | 1..1 | SHALL |  | [1141-579](#C_1141-579) | urn:oid:2.16.840.1.113883.5.1124 (HL7Realm) |
| typeId | 1..1 | SHALL |  | [1141-413](#C_1141-413) |  |
| @root | 1..1 | SHALL |  | [1141-521](#C_1141-521) | 2.16.840.1.113883.1.3 |
| @extension | 1..1 | SHALL |  | [1141-522](#C_1141-522) | POCD\_HD000040 |
| templateId | 1..1 | SHALL |  | [1141-387](#C_1141-387) |  |
| @root | 1..1 | SHALL |  | [1141-487](#C_1141-487) | 2.16.840.1.113883.10.20.29 |
| id | 1..1 | SHALL |  | [1141-414](#C_1141-414) |  |
| code | 1..1 | SHALL |  | [1141-388](#C_1141-388) |  |
| title | 1..1 | SHALL |  | [1141-389](#C_1141-389) |  |
| effectiveTime | 1..1 | SHALL |  | [1141-390](#C_1141-390) |  |
| confidentialityCode | 1..1 | SHALL |  | [1141-491](#C_1141-491) | urn:oid:2.16.840.1.113883.1.11.16926 (HL7 BasicConfidentialityKind) |
| languageCode | 1..1 | SHALL |  | [1141-524](#C_1141-524) | urn:oid:2.16.840.1.113883.1.11.11526 (Language) |
| setId | 0..1 | MAY |  | [1141-391](#C_1141-391) |  |
| versionNumber | 0..1 | MAY |  | [1141-392](#C_1141-392) |  |
| recordTarget | 1..\* | SHALL |  | [1141-393](#C_1141-393) |  |
| patientRole | 1..1 | SHALL |  | [1141-394](#C_1141-394) |  |
| id | 1..\* | SHALL |  | [1141-494](#C_1141-494) |  |
| addr | 1..\* | SHALL |  | [1141-395](#C_1141-395) |  |
| telecom | 1..\* | SHALL |  | [1141-396](#C_1141-396) |  |
| patient | 1..1 | SHALL |  | [1141-397](#C_1141-397) |  |
| name | 1..1 | SHALL |  | [1141-398](#C_1141-398) |  |
| administrativeGenderCode | 1..1 | SHALL |  | [1141-515](#C_1141-515) |  |
| birthTime | 1..1 | SHALL |  | [1141-399](#C_1141-399) |  |
| guardian | 0..\* | MAY |  | [1141-400](#C_1141-400) |  |
| id | 0..\* | SHOULD |  | [1141-2422](#C_1141-2422) |  |
| code | 0..1 | SHOULD |  | [1141-504](#C_1141-504) | urn:oid:2.16.840.1.113883.1.11.19830 (ResponsibleParty) |
| addr | 0..\* | SHOULD |  | [1141-401](#C_1141-401) |  |
| telecom | 0..\* | MAY |  | [1141-402](#C_1141-402) |  |
| guardianPerson | 1..1 | SHALL |  | [1141-403](#C_1141-403) |  |
| name | 1..\* | SHALL |  | [1141-404](#C_1141-404) |  |
| birthplace | 0..1 | MAY |  | [1141-405](#C_1141-405) |  |
| place | 1..1 | SHALL |  | [1141-406](#C_1141-406) |  |
| languageCommunication | 0..\* | SHOULD |  | [1141-408](#C_1141-408) |  |
| languageCode | 1..1 | SHALL |  | [1141-511](#C_1141-511) | urn:oid:2.16.840.1.113883.1.11.11526 (Language) |
| modeCode | 0..1 | MAY |  | [1141-512](#C_1141-512) | urn:oid:2.16.840.1.113883.1.11.12249 (LanguageAbilityMode) |
| proficiencyLevelCode | 0..1 | MAY |  | [1141-514](#C_1141-514) | urn:oid:2.16.840.1.113883.1.11.12199 (LanguageAbilityProficiency) |
| preferenceInd | 0..1 | MAY |  | [1141-513](#C_1141-513) |  |
| providerOrganization | 0..1 | MAY |  | [1141-409](#C_1141-409) |  |
| id | 1..\* | SHALL |  | [1141-410](#C_1141-410) |  |
| name | 1..\* | SHALL |  | [1141-518](#C_1141-518) |  |
| telecom | 1..\* | SHALL |  | [1141-411](#C_1141-411) |  |
| addr | 1..\* | SHALL |  | [1141-412](#C_1141-412) |  |
| country | 1..1 | MAY |  | [1141-580](#C_1141-580) | urn:oid:2.16.840.1.113883.3.88.12.80.63 (Country) |
| author | 1..\* | SHALL |  | [1141-422](#C_1141-422) |  |
| time | 1..1 | SHALL |  | [1141-423](#C_1141-423) |  |
| assignedAuthor | 1..1 | SHALL |  | [1141-424](#C_1141-424) |  |
| id | 1..\* | SHALL |  | [1141-428](#C_1141-428) |  |
| addr | 1..\* | SHALL |  | [1141-429](#C_1141-429) |  |
| telecom | 1..\* | SHALL |  | [1141-425](#C_1141-425) |  |
| assignedPerson | 0..1 | SHOULD |  | [1141-426](#C_1141-426) |  |
| name | 1..\* | SHALL |  | [1141-427](#C_1141-427) |  |
| assignedAuthoringDevice | 0..1 | MAY |  | [1141-430](#C_1141-430) |  |
| manufacturerModelName | 1..1 | SHALL |  | [1141-535](#C_1141-535) |  |
| softwareName | 1..1 | SHALL |  | [1141-536](#C_1141-536) |  |
| dataEnterer | 0..1 | MAY |  | [1141-415](#C_1141-415) |  |
| assignedEntity | 1..1 | SHALL |  | [1141-416](#C_1141-416) |  |
| id | 1..\* | SHALL |  | [1141-417](#C_1141-417) |  |
| @root | 0..1 | SHOULD |  | [1141-525](#C_1141-525) |  |
| addr | 1..\* | SHALL |  | [1141-418](#C_1141-418) |  |
| telecom | 1..\* | SHALL |  | [1141-419](#C_1141-419) |  |
| assignedPerson | 1..1 | SHALL |  | [1141-420](#C_1141-420) |  |
| name | 1..\* | SHALL |  | [1141-421](#C_1141-421) |  |
| informant | 0..\* | MAY |  | [1141-462](#C_1141-462) |  |
| assignedEntity | 1..1 | MAY |  | [1141-463](#C_1141-463) |  |
| id | 0..\* | SHOULD |  | [1141-467](#C_1141-467) |  |
| code | 0..1 | MAY |  | [1141-582](#C_1141-582) |  |
| addr | 1..\* | SHALL |  | [1141-464](#C_1141-464) |  |
| assignedPerson | 1..1 | SHALL |  | [1141-2426](#C_1141-2426) |  |
| name | 1..\* | SHALL |  | [1141-2427](#C_1141-2427) |  |
| relatedEntity | 1..1 | MAY |  | [1141-2424](#C_1141-2424) |  |
| relatedPerson | 1..1 | SHALL |  | [1141-2428](#C_1141-2428) |  |
| name | 1..\* | SHALL |  | [1141-2429](#C_1141-2429) |  |
| custodian | 1..1 | SHALL |  | [1141-432](#C_1141-432) |  |
| assignedCustodian | 1..1 | SHALL |  | [1141-433](#C_1141-433) |  |
| representedCustodianOrganization | 1..1 | SHALL |  | [1141-434](#C_1141-434) |  |
| id | 1..\* | SHALL |  | [1141-435](#C_1141-435) |  |
| name | 1..1 | SHALL |  | [1141-540](#C_1141-540) |  |
| telecom | 1..1 | SHALL |  | [1141-436](#C_1141-436) |  |
| @use | 0..1 | SHOULD |  | [1141-541](#C_1141-541) |  |
| addr | 1..\* | SHALL |  | [1141-437](#C_1141-437) |  |
| informationRecipient | 0..\* | MAY |  | [1141-438](#C_1141-438) |  |
| intendedRecipient | 1..1 | SHALL |  | [1141-439](#C_1141-439) |  |
| id | 0..\* | SHOULD |  | [1141-585](#C_1141-585) |  |
| informationRecipient | 0..1 | MAY |  | [1141-440](#C_1141-440) |  |
| receivedOrganization | 0..1 | MAY |  | [1141-442](#C_1141-442) |  |
| name | 1..1 | SHALL |  | [1141-544](#C_1141-544) |  |
| legalAuthenticator | 0..1 | SHOULD |  | [1141-443](#C_1141-443) |  |
| time | 1..1 | SHALL |  | [1141-444](#C_1141-444) |  |
| signatureCode | 1..1 | SHALL |  | [1141-445](#C_1141-445) |  |
| @code | 1..1 | SHALL |  | [1141-546](#C_1141-546) | urn:oid:2.16.840.1.113883.5.89 (Participationsignature) = S |
| assignedEntity | 1..1 | SHALL |  | [1141-446](#C_1141-446) |  |
| id | 1..\* | SHALL |  | [1141-447](#C_1141-447) |  |
| code | 0..1 | MAY |  | [1141-649](#C_1141-649) |  |
| addr | 1..\* | SHALL |  | [1141-448](#C_1141-448) |  |
| telecom | 1..\* | SHALL |  | [1141-449](#C_1141-449) |  |
| assignedPerson | 1..1 | SHALL |  | [1141-450](#C_1141-450) |  |
| name | 1..\* | SHALL |  | [1141-451](#C_1141-451) |  |
| authenticator | 0..\* | MAY |  | [1141-452](#C_1141-452) |  |
| time | 1..1 | SHALL |  | [1141-453](#C_1141-453) |  |
| signatureCode | 1..1 | SHALL |  | [1141-454](#C_1141-454) |  |
| @code | 1..1 | SHALL |  | [1141-553](#C_1141-553) | urn:oid:2.16.840.1.113883.5.89 (Participationsignature) = S |
| assignedEntity | 1..1 | SHALL |  | [1141-455](#C_1141-455) |  |
| id | 1..\* | SHALL |  | [1141-456](#C_1141-456) |  |
| code | 0..1 | MAY |  | [1141-461](#C_1141-461) |  |
| addr | 1..\* | SHALL |  | [1141-457](#C_1141-457) |  |
| telecom | 1..\* | SHALL |  | [1141-458](#C_1141-458) |  |
| @use | 0..1 | SHOULD |  | [1141-648](#C_1141-648) |  |
| assignedPerson | 1..1 | SHALL |  | [1141-459](#C_1141-459) |  |
| name | 1..\* | SHALL |  | [1141-460](#C_1141-460) |  |
| participant | 0..\* | MAY |  | [1141-472](#C_1141-472) |  |
| time | 0..1 | MAY |  | [1141-566](#C_1141-566) |  |
| associatedEntity | 1..1 | SHALL |  | [1141-1609](#C_1141-1609) |  |
| associatedPerson | 1..1 | MAY |  | [1141-1612](#C_1141-1612) |  |
| name | 1..\* | SHALL |  | [1141-2312](#C_1141-2312) |  |
| scopingOrganization | 0..1 | MAY |  | [1141-2430](#C_1141-2430) |  |
| name | 1..1 | SHALL |  | [1141-2431](#C_1141-2431) |  |
| inFulfillmentOf | 0..\* | MAY |  | [1141-468](#C_1141-468) |  |
| order | 1..1 | SHALL |  | [1141-469](#C_1141-469) |  |
| id | 1..\* | SHALL |  | [1141-563](#C_1141-563) |  |
| documentationOf | 0..\* | MAY |  | [1141-473](#C_1141-473) |  |
| serviceEvent | 1..1 | SHALL |  | [1141-474](#C_1141-474) |  |
| code | 0..1 | MAY |  | [1141-593](#C_1141-593) |  |
| @code | 1..1 | SHALL |  | [1141-594](#C_1141-594) |  |
| effectiveTime | 1..1 | SHALL |  | [1141-475](#C_1141-475) |  |
| low | 1..1 | SHALL |  | [1141-569](#C_1141-569) |  |
| performer | 0..\* | SHOULD |  | [1141-476](#C_1141-476) |  |
| assignedEntity | 1..1 | SHALL |  | [1141-478](#C_1141-478) |  |
| id | 1..\* | SHALL |  | [1141-480](#C_1141-480) |  |
| code | 0..1 | SHOULD |  | [1141-479](#C_1141-479) |  |
| authorization | 0..\* | MAY |  | [1141-482](#C_1141-482) |  |
| consent | 1..1 | SHALL |  | [1141-483](#C_1141-483) |  |
| id | 0..\* | MAY |  | [1141-575](#C_1141-575) |  |
| code | 0..1 | MAY |  | [1141-484](#C_1141-484) |  |
| statusCode | 1..1 | SHALL |  | [1141-485](#C_1141-485) |  |
| @code | 1..1 | SHALL |  | [1141-577](#C_1141-577) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = completed |
| componentOf | 0..1 | MAY |  | [1141-470](#C_1141-470) |  |
| encompassingEncounter | 1..1 | SHALL |  | [1141-471](#C_1141-471) |  |
| id | 1..\* | SHALL |  | [1141-565](#C_1141-565) |  |
| effectiveTime | 1..1 | SHALL |  | [1141-564](#C_1141-564) |  |

1. SHALL contain exactly one [1..1] realmCode (CONF:1141-574).
   1. This realmCode SHALL contain exactly one [1..1] @code, which SHOULD be selected from CodeSystem HL7Realm (urn:oid:2.16.840.1.113883.5.1124) (CONF:1141-579).
2. SHALL contain exactly one [1..1] typeId (CONF:1141-413).
   1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:1141-521).
   2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF:1141-522).

**templateId**

Additional templateId elements will be required if the header is subject to further realm specific constraints; for example PHMR documents in the US realm will require the templateId 2.16.840.1.113883.10.20.22.1.1 for the C-CDA US realm header.

1. SHALL contain exactly one [1..1] templateId (CONF:1141-387) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.29" (CONF:1141-487).
2. SHALL contain exactly one [1..1] id (CONF:1141-414).
   1. This id **SHALL** be a globally unique identifier for the document (CONF:1141-523).
3. SHALL contain exactly one [1..1] code (CONF:1141-388).
   1. This code **SHALL** specify the particular kind of Patient Generated Document (CONF:1141-488).
4. SHALL contain exactly one [1..1] title (CONF:1141-389).  
   Note: The title can either be a locally defined name or the display name corresponding to clinicalDocument/code
5. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-390).
6. SHALL contain exactly one [1..1] confidentialityCode, which SHOULD be selected from ValueSet [HL7 BasicConfidentialityKind](#HL7_BasicConfidentialityKind) urn:oid:2.16.840.1.113883.1.11.16926 STATIC (CONF:1141-491).
7. SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet [Language](#Language) urn:oid:2.16.840.1.113883.1.11.11526 DYNAMIC (CONF:1141-524).
8. MAY contain zero or one [0..1] setId (CONF:1141-391).
   1. If  setId is present versionNumber **SHALL** be present (CONF:1141-492).
9. MAY contain zero or one [0..1] versionNumber (CONF:1141-392).
   1. If versionNumber is present setId **SHALL** be present (CONF:1141-493).

**RecordTarget**

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element. If the document receiver is interested in setting up a translator for the encounter with the patient, the receiver of the document will have to infer the need for a translator, based upon the language skills identified for the patient, the patients language of preference and the predominant language used by the organization receiving the CDA.

The patient MAY include 0..\* guardian(s). When that role is present, it SHOULD include a code element. The guardian/code element encodes the relationship between the person in the role of guardian and the patient.

HL7 Vocabulary simply describes guardian as a relationship to a ward. This need not be a formal legal relationship. When a guardian relationship exists for the patient, it may be represented, regardless of who is present at the time the document is generated. Examples for the use of the patient/guardian role:

• A child’s parent MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “mother” for the child’s mom or “father” for the child’s dad.

An elderly person’s child MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “daughter” or “son”, or if a legal relationship existed, the relationship of “legal guardian” could be encoded.

1. SHALL contain at least one [1..\*] recordTarget (CONF:1141-393).
   1. Such recordTargets SHALL contain exactly one [1..1] patientRole (CONF:1141-394).
      1. This patientRole SHALL contain at least one [1..\*] id (CONF:1141-494).
      2. This patientRole SHALL contain at least one [1..\*] addr (CONF:1141-395).
      3. This patientRole SHALL contain at least one [1..\*] telecom (CONF:1141-396).
      4. This patientRole SHALL contain exactly one [1..1] patient (CONF:1141-397).
         1. This patient SHALL contain exactly one [1..1] name (CONF:1141-398).
         2. This patient SHALL contain exactly one [1..1] administrativeGenderCode (CONF:1141-515).
         3. This patient SHALL contain exactly one [1..1] birthTime (CONF:1141-399).
            1. **SHALL** be precise to year (CONF:1141-498).
            2. **SHOULD** be precise to day (CONF:1141-499).
         4. This patient MAY contain zero or more [0..\*] guardian (CONF:1141-400).
            1. The guardian, if present, SHOULD contain zero or more [0..\*] id (CONF:1141-2422).
            2. The guardian, if present, SHOULD contain zero or one [0..1] code, which SHALL be selected from ValueSet [ResponsibleParty](#ResponsibleParty) urn:oid:2.16.840.1.113883.1.11.19830 DYNAMIC (CONF:1141-504).
            3. The guardian, if present, SHOULD contain zero or more [0..\*] addr (CONF:1141-401).
            4. The guardian, if present, MAY contain zero or more [0..\*] telecom (CONF:1141-402).
            5. The guardian, if present, SHALL contain exactly one [1..1] guardianPerson (CONF:1141-403).

This guardianPerson SHALL contain at least one [1..\*] name (CONF:1141-404).

* + - 1. This patient MAY contain zero or one [0..1] birthplace (CONF:1141-405).
         1. The birthplace, if present, SHALL contain exactly one [1..1] place (CONF:1141-406).
      2. This patient SHOULD contain zero or more [0..\*] languageCommunication (CONF:1141-408).
         1. The languageCommunication, if present, SHALL contain exactly one [1..1] languageCode, which MAY be selected from ValueSet [Language](#Language) urn:oid:2.16.840.1.113883.1.11.11526 DYNAMIC (CONF:1141-511).
         2. The languageCommunication, if present, MAY contain zero or one [0..1] modeCode, which MAY be selected from ValueSet [LanguageAbilityMode](#LanguageAbilityMode) urn:oid:2.16.840.1.113883.1.11.12249 DYNAMIC (CONF:1141-512).
         3. The languageCommunication, if present, MAY contain zero or one [0..1] proficiencyLevelCode, which SHOULD be selected from ValueSet [LanguageAbilityProficiency](#LanguageAbilityProficiency) urn:oid:2.16.840.1.113883.1.11.12199 DYNAMIC (CONF:1141-514).
         4. The languageCommunication, if present, MAY contain zero or one [0..1] preferenceInd (CONF:1141-513).

If more than one languageCommunication is present, only one languageCommunication element **SHALL** have a preferenceInd with a value of 1 (CONF:1141-2423).

**ProviderOrganization**

If present, this organization represents the provider organization where the person is claiming to be a patient.

* + 1. This patientRole MAY contain zero or one [0..1] providerOrganization (CONF:1141-409).
       1. The providerOrganization, if present, SHALL contain at least one [1..\*] id (CONF:1141-410).
       2. The providerOrganization, if present, SHALL contain at least one [1..\*] name (CONF:1141-518).
       3. The providerOrganization, if present, SHALL contain at least one [1..\*] telecom (CONF:1141-411).
       4. The providerOrganization, if present, SHALL contain at least one [1..\*] addr (CONF:1141-412).
          1. Such addrs MAY contain exactly one [1..1] country, which SHALL be selected from CodeSystem Country (urn:oid:2.16.840.1.113883.3.88.12.80.63) DYNAMIC (CONF:1141-580).

**Author**

The author element represents the creator of the clinical document. The author may be a device, or a person. The person is the patient or the patient’s representative.

1. SHALL contain at least one [1..\*] author (CONF:1141-422).
   1. Such authors SHALL contain exactly one [1..1] time (CONF:1141-423).
   2. Such authors SHALL contain exactly one [1..1] assignedAuthor (CONF:1141-424).
      1. This assignedAuthor SHALL contain at least one [1..\*] id (CONF:1141-428).
         1. The id SHOULD utilize the combined @root and @extension attributes to record the person’s or the device’s identity in a trusted, and unique way (CONF:1141-533).
      2. This assignedAuthor SHALL contain at least one [1..\*] addr (CONF:1141-429).
      3. This assignedAuthor SHALL contain at least one [1..\*] telecom (CONF:1141-425).
      4. This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson (CONF:1141-426).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:1141-427).
      5. This assignedAuthor MAY contain zero or one [0..1] assignedAuthoringDevice (CONF:1141-430).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName (CONF:1141-535).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName (CONF:1141-536).
      6. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:1141-538).  
         Note: It is anticipated that in the common use case the PHMR will be machine generated and thus the assignedAuthoringDevice will be the likely entry.
      7. If the assigned author is an assignedPerson, it **SHALL** contain exactly one 1..1] code (CONF:1141-2435).
         1. The code, **SHALL** contain exactly one 1..1] @code, which **SHOULD** be selected from the Personal And Legal Relationship Role Type 2.16.840.1.113883.11.20.12.1 (CONF:1141-2436).

**DataEnterer**

The dataEnterer element represents the person who transferred the content, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation, and the dataEnterer adds that information to the electronic system. In other words, a dataEnterer transfers information from one source to another (e.g., transcription from paper form to electronic system). If the DataEnterer is missing, this role is assumed to be played by the Author.

1. MAY contain zero or one [0..1] dataEnterer (CONF:1141-415).
   1. The dataEnterer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:1141-416).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:1141-417).
         1. Such ids SHOULD contain zero or one [0..1] @root (CONF:1141-525).
      2. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:1141-418).
      3. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:1141-419).
      4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:1141-420).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:1141-421).

**Informant**

The informant element describes the source of the information in a medical document.

Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.

When the informant is a personal relation, that informant is represented in the relatedEntity element, even if the personal relation is medical professional. The code element of the relatedEntity describes the relationship between the informant and the patient. The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document. If the informant element is missing, the Author is presumed to be the informant.

1. MAY contain zero or more [0..\*] informant (CONF:1141-462) such that it  
   Note: An informant can contain either an assignedEntity or a relatedEntity. The constraints here apply to assignedEntity.
   1. MAY contain exactly one [1..1] assignedEntity (CONF:1141-463).
      1. This assignedEntity SHOULD contain zero or more [0..\*] id (CONF:1141-467).
      2. This assignedEntity MAY contain zero or one [0..1] code (CONF:1141-582).
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:1141-464).
      4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:1141-2426).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:1141-2427).
   2. MAY contain exactly one [1..1] relatedEntity (CONF:1141-2424).
      1. This relatedEntity SHALL contain exactly one [1..1] relatedPerson (CONF:1141-2428).
         1. This relatedPerson SHALL contain at least one [1..\*] name (CONF:1141-2429).
   3. **SHALL** contain exactly one 1..1] assignedEntity OR exactly one 1..1] relatedEntity (CONF:1141-2425).

**Custodian**

The custodian element represents the organization or person that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The custodian participation satisfies the CDA definition of Stewardship. Because CDA is an exchange standard and may not represent the original form of the authenticated document (e.g., CDA could include scanned copy of original), the custodian represents the steward of the original source document. The custodian may be the document originator, a health information exchange, or other responsible party. Also, the custodian may be the patient or an organization acting on behalf of the patient, such as a PHR organization.

1. SHALL contain exactly one [1..1] custodian (CONF:1141-432).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:1141-433).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF:1141-434).
         1. This representedCustodianOrganization SHALL contain at least one [1..\*] id (CONF:1141-435).
         2. This representedCustodianOrganization SHALL contain exactly one [1..1] name (CONF:1141-540).
         3. This representedCustodianOrganization SHALL contain exactly one [1..1] telecom (CONF:1141-436).
            1. This telecom SHOULD contain zero or one [0..1] @use (CONF:1141-541).
         4. This representedCustodianOrganization SHALL contain at least one [1..\*] addr (CONF:1141-437).

**InformationRecipient**

The informationRecipient element records the intended recipient of the information at the time the document is created. For example, in cases where the intended recipient of the document is the patient's health chart, set the receivedOrganization to be the scoping organization for that chart.

1. MAY contain zero or more [0..\*] informationRecipient (CONF:1141-438).
   1. The informationRecipient, if present, SHALL contain exactly one [1..1] intendedRecipient (CONF:1141-439).
      1. This intendedRecipient SHOULD contain zero or more [0..\*] id (CONF:1141-585).
         1. Such ids MAY reference the id of a person or organization entity specified elsewhere in the document (CONF:1141-586).
      2. This intendedRecipient MAY contain zero or one [0..1] informationRecipient (CONF:1141-440).
      3. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization (CONF:1141-442).
         1. The receivedOrganization, if present, SHALL contain exactly one [1..1] name (CONF:1141-544).

**LegalAuthenticator**

In a patient authored document, the legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. (Note that per the following section, there may also be one or more document authenticators.)

Based on local practice, patient authored documents may be provided without legal authentication. This implies that a patient authored document that does not contain this element has not been legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All patient documents have the potential for legal authentication, given the appropriate legal authority.

Local policies MAY choose to delegate the function of legal authentication to a device or system that generates the document. In these cases, the legal authenticator is the person accepting responsibility for the document, not the generating device or system.

Note that the legal authenticator, if present, must be a person.

1. SHOULD contain zero or one [0..1] legalAuthenticator (CONF:1141-443).
   1. The legalAuthenticator, if present, SHALL contain exactly one [1..1] time (CONF:1141-444).
   2. The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:1141-445).
      1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature urn:oid:2.16.840.1.113883.5.89 STATIC) (CONF:1141-546).
   3. The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:1141-446).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:1141-447).
      2. This assignedEntity MAY contain zero or one [0..1] code (CONF:1141-649).
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:1141-448).
      4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:1141-449).
      5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:1141-450).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:1141-451).

**Authenticator**

The authenticator identifies a participant or participants who attested to the accuracy of the information in the document.

1. MAY contain zero or more [0..\*] authenticator (CONF:1141-452).
   1. The authenticator, if present, SHALL contain exactly one [1..1] time (CONF:1141-453).
   2. The authenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:1141-454).
      1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature urn:oid:2.16.840.1.113883.5.89 STATIC) (CONF:1141-553).
   3. The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:1141-455).
      1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:1141-456).
      2. This assignedEntity MAY contain zero or one [0..1] code (CONF:1141-461).
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:1141-457).
      4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:1141-458).
         1. Such telecoms SHOULD contain zero or one [0..1] @use (CONF:1141-648).
      5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:1141-459).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:1141-460).

**Participant (Support)**

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

1. MAY contain zero or more [0..\*] participant (CONF:1141-472) such that it  
   Note: In general, many types of participant are possible. When participant/@typeCode is IND (individual), associatedEntity/@classCode must be from the specified value set, unless this requirement is overridden by the document type's header.
   1. MAY contain zero or one [0..1] time (CONF:1141-566).
   2. SHALL contain exactly one [1..1] associatedEntity (CONF:1141-1609).
      1. This associatedEntity MAY contain exactly one [1..1] associatedPerson (CONF:1141-1612).
         1. This associatedPerson SHALL contain at least one [1..\*] name (CONF:1141-2312).
      2. This associatedEntity MAY contain zero or one [0..1] scopingOrganization (CONF:1141-2430).
         1. The scopingOrganization, if present, SHALL contain exactly one [1..1] name (CONF:1141-2431).
      3. Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:1141-2432).
   3. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes STATIC (CONF:1141-1505).

**InFulfillmentOf**

The inFulfillmentOf element represents orders that are fulfilled by this document.

1. MAY contain zero or more [0..\*] inFulfillmentOf (CONF:1141-468).
   1. The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order (CONF:1141-469).
      1. This order SHALL contain at least one [1..\*] id (CONF:1141-563).
         1. Such ids **MAY** represent a scheduled appointment or service event in a practice management system (CONF:1141-592).

**DocumentationOf/serviceEvent**

A serviceEvent represents the main act being documented. Documentation of a serviceEvent includes the performers of the act, which can be clinicians or individuals.

1. MAY contain zero or more [0..\*] documentationOf (CONF:1141-473).
   1. The documentationOf, if present, SHALL contain exactly one [1..1] serviceEvent (CONF:1141-474).
      1. This serviceEvent MAY contain zero or one [0..1] code (CONF:1141-593).
         1. The code, if present, SHALL contain exactly one [1..1] @code (CONF:1141-594).
            1. The @code **SHOULD** be selected from a value set established by the document-level template for a specific type of Patient Generated Document (CONF:1141-2433).
      2. This serviceEvent SHALL contain exactly one [1..1] effectiveTime (CONF:1141-475).
         1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:1141-569).
      3. This serviceEvent SHOULD contain zero or more [0..\*] performer (CONF:1141-476).
         1. The performer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:1141-478).
            1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:1141-480).
            2. This assignedEntity SHOULD contain zero or one [0..1] code (CONF:1141-479).

**Authorization/consent**

The header can record information about the patient’s consent.

The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code. Consents in the header have been finalized (consent/statusCode must equal Completed) and should be on file. This specification does not address how Privacy Consent’ is represented, but does not preclude the inclusion of ‘Privacy Consent’.

1. MAY contain zero or more [0..\*] authorization (CONF:1141-482) such that it
   1. SHALL contain exactly one [1..1] consent (CONF:1141-483).
      1. This consent MAY contain zero or more [0..\*] id (CONF:1141-575).
      2. This consent MAY contain zero or one [0..1] code (CONF:1141-484).  
         Note: The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code.
         1. The type of consent (e.g., a consent to perform the related serviceEvent) **SHALL** be conveyed in consent/code (CONF:1141-2434).
      3. This consent SHALL contain exactly one [1..1] statusCode (CONF:1141-485).
         1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1141-577).

**ComponentOf**

The componentOf element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or ServiceEvent occurred.

In order to represent providers associated with a specific encounter, they are recorded within the encompassingEncounter as participants.

The encompassingEncounter may be used when documenting a specific encounter and its participants. All relevant encounters may be listed in the encounters section.

Unless specifically authored to document an encounter with a provider, the patient generated document should NOT use componentOf/encompassingEncounter.

1. MAY contain zero or one [0..1] componentOf (CONF:1141-470).
   1. The componentOf, if present, SHALL contain exactly one [1..1] encompassingEncounter (CONF:1141-471).
      1. This encompassingEncounter SHALL contain at least one [1..\*] id (CONF:1141-565).
      2. This encompassingEncounter SHALL contain exactly one [1..1] effectiveTime (CONF:1141-564).

Personal Healthcare Monitoring Report 1.2 - Draft

[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.36:2015-08-17 (open)]

Table 2: Personal Healthcare Monitoring Report 1.2 Contexts

| Contained By: | Contains: |
| --- | --- |
|  | [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie)  [PHMR Results Section (entries required)](#S_PHMR_Results_Section_entries_required)  [PHMR Vital Signs Section (entries required)](#S_PHMR_Vital_Signs_Section_entries_requ) |

The PHMR is designed to support international usage and thus the header component is based upon the universal realm version of the Patient Generated Document header. It is anticipated that regional requirements will further refine the form of the header. This section specifies the requirements imposed by this implementation guide on the resulting header and subsequent body elements regardless of realm.

Certain elements of the Patient Generated Document header are unlikely to be present in the scenarios where the PHMR is used. In the IHE Remote Patient Monitoring profile and/or the PCHA end-to-end architecture the only time the process is not automated is at that point time where a measurement is taken on the patient with a PHM device. The device data is propagated by standardized transactions to the software that is responsible for generating and, if necessary, transmitting the PHMR document. The patient or patient representative supplied demographic information is provided as necessary to the PHMR generator. How the demographic data is supplied (database, via PCD-01 messaging, etc.) is implementation dependent. The document author is therefore the software generating the PHMR and the observation entry author is the PHM device supplying the data for that observation. The DataEnterer and Informant elements, generally referring to personnel, are unlikely to be relevant.

For the clinical content a PHMR must contain three sections. At least the Vital Signs or Results section must contain observation entries. However, the template is otherwise open. One is free to include additional sections.

Table 3: Personal Healthcare Monitoring Report 1.2 Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36:2015-08-17) | | | | | |
| realmCode | 1..1 | SHALL |  | [1141-72](#C_1141-72) |  |
| @code | 1..1 | SHALL |  | [1141-280](#C_1141-280) | urn:oid:2.16.840.1.113883.5.1124 (HL7Realm) |
| templateId | 1..1 | SHALL |  | [1141-15](#C_1141-15) |  |
| @root | 1..1 | SHALL |  | [1141-2](#C_1141-2) | 2.16.840.1.113883.10.20.36 |
| @extension | 1..1 | SHALL |  | [1141-2356](#C_1141-2356) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-66](#C_1141-66) |  |
| @code | 1..1 | SHALL |  | [1141-67](#C_1141-67) | 53576-5 |
| @codeSystem | 1..1 | SHALL |  | [1141-68](#C_1141-68) | urn:oid:2.16.840.1.113883.6.1 (LOINC) |
| @displayName | 0..1 | SHOULD |  | [1141-1605](#C_1141-1605) | Personal Healthcare Monitoring Report |
| documentationOf | 1..1 | SHALL |  | [1141-17](#C_1141-17) |  |
| serviceEvent | 1..1 | SHALL |  | [1141-20](#C_1141-20) |  |
| @classCode | 1..1 | SHALL |  | [1141-382](#C_1141-382) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = MPROT |
| effectiveTime | 1..1 | SHALL |  | [1141-21](#C_1141-21) |  |
| low | 1..1 | SHALL |  | [1141-383](#C_1141-383) |  |
| high | 0..1 | MAY |  | [1141-384](#C_1141-384) |  |
| component | 1..1 | SHALL |  | [1141-3](#C_1141-3) |  |
| structuredBody | 1..1 | SHALL |  | [1141-1442](#C_1141-1442) |  |
| component | 1..1 | SHALL |  | [1141-1443](#C_1141-1443) |  |
| section | 1..1 | SHALL |  | [1141-1446](#C_1141-1446) | [PHMR Medical Equipment Section (Entries Optional) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17](#S_PHMR_Medical_Equipment_Section_Entrie) |
| component | 1..1 | MAY |  | [1141-1444](#C_1141-1444) |  |
| section | 1..1 | SHALL |  | [1141-1447](#C_1141-1447) | [PHMR Results Section (entries required) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17](#S_PHMR_Results_Section_entries_required) |
| component | 1..1 | MAY |  | [1141-1445](#C_1141-1445) |  |
| section | 1..1 | SHALL |  | [1141-1462](#C_1141-1462) | [PHMR Vital Signs Section (entries required) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17](#S_PHMR_Vital_Signs_Section_entries_requ) |

Properties

1. Conforms to [Patient Generated Universal Realm Document Header](#D_Patient_Generated_Universal_Realm_Doc) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.29:2015-08-17).
2. SHALL contain exactly one [1..1] realmCode (CONF:1141-72) such that it
   1. SHALL contain exactly one [1..1] @code, which SHOULD be selected from CodeSystem HL7Realm (urn:oid:2.16.840.1.113883.5.1124) DYNAMIC (CONF:1141-280).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-15) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36" This template indicates that this document complies with the constraints of the PHMR (CONF:1141-2).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2356).
4. SHALL contain exactly one [1..1] code (CONF:1141-66).
   1. This code SHALL contain exactly one [1..1] @code="53576-5" Personal Healthcare Monitoring Report (CONF:1141-67).
   2. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1141-68).
   3. This code SHOULD contain zero or one [0..1] @displayName="Personal Healthcare Monitoring Report" (CONF:1141-1605).

Note on the PHMR **recordTarget/patientRole/id** entry

The @root OID is specific to an institution's record identifier system. The id@extension would correspond to the PCD-01 PID segment PID-3 patient identifier component provided by the said institution and the id@assigningAuthorityName would correspond to the PCD-01 PID segment PID-3 assigningAuthority component. provided by the said institution. These valuse are used, for example, in the IHE XDSb registry.

1. SHALL contain exactly one [1..1] documentationOf (CONF:1141-17).
   1. This documentationOf SHALL contain exactly one [1..1] serviceEvent (CONF:1141-20).
      1. This serviceEvent SHALL contain exactly one [1..1] @classCode="MPROT" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:1141-382).
      2. This serviceEvent SHALL contain exactly one [1..1] effectiveTime (CONF:1141-21).
         1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:1141-383).
         2. This effectiveTime MAY contain zero or one [0..1] high (CONF:1141-384).

component

1. SHALL contain exactly one [1..1] component (CONF:1141-3).
   1. This component SHALL contain exactly one [1..1] structuredBody (CONF:1141-1442) such that it  
      Note: Additional sections may be added if the business use requires it via the inclusion of additional component element
      1. SHALL contain exactly one [1..1] component (CONF:1141-1443) such that it
         1. SHALL contain exactly one [1..1] [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17) (CONF:1141-1446).
      2. MAY contain exactly one [1..1] component (CONF:1141-1444) such that it
         1. SHALL contain exactly one [1..1] [PHMR Results Section (entries required)](#S_PHMR_Results_Section_entries_required) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17) (CONF:1141-1447).
      3. MAY contain exactly one [1..1] component (CONF:1141-1445) such that it
         1. SHALL contain exactly one [1..1] [PHMR Vital Signs Section (entries required)](#S_PHMR_Vital_Signs_Section_entries_requ) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17) (CONF:1141-1462).
      4. The PHMR **SHALL** contain either a PHMR Vital Signs Section OR the PHMR Results Section or both (CONF:1141-2162).  
         Note: The purpose of a PHMR document is to report patient measurement data. Measurement data is placed in the Vital Signs section or the Results section depending upon the type of measurement. Thus a valid PHMR document shall contain measurement data, it may be in the vital signs section or the results section or both. A document containing a Vital Signs section and Results section where neither encapsulate a measurement observation entry is invalid and violates the above guideline as well as the purpose of this document.

Coding and resolution of the time elements

1. If present, times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day and **SHOULD** be precise to the second (CONF:1141-2373).
2. If present, times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time, and encounterParticipant/time elements **SHALL** be precise at least to the year and **SHOULD** be precise to the day (CONF:1141-1604).
3. All times or time intervals in a PHMR document **SHALL** include a time zone if more precise than to the day (CONF:1141-2374).

# section

PHMR Medical Equipment Section (Entries Optional) - Draft

[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17 (open)]

Table 4: PHMR Medical Equipment Section (Entries Optional) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) (required) | [Device Information Organizer](#E_Device_Information_Organizer) |

This section defines and gives the properties of a patient's medical devices.

Table 5: PHMR Medical Equipment Section (Entries Optional) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17) | | | | | |
| templateId | 1..1 | SHALL |  | [1141-1463](#C_1141-1463) |  |
| @root | 1..1 | SHALL |  | [1141-1464](#C_1141-1464) | 2.16.840.1.113883.10.20.36.1 |
| @extension | 1..1 | SHALL |  | [1141-2359](#C_1141-2359) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1364](#C_1141-1364) |  |
| @code | 1..1 | SHALL |  | [1141-1370](#C_1141-1370) | 46264-8 |
| @codeSystem | 1..1 | SHALL |  | [1141-1371](#C_1141-1371) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| @displayName | 0..1 | SHOULD |  | [1141-2407](#C_1141-2407) |  |
| title | 1..1 | SHALL |  | [1141-1372](#C_1141-1372) |  |
| text | 1..1 | SHALL |  | [1141-1373](#C_1141-1373) |  |
| entry | 0..\* | SHOULD |  | [1141-1375](#C_1141-1375) |  |
| @typeCode | 0..1 | SHOULD |  | [1141-2408](#C_1141-2408) |  |
| organizer | 1..1 | SHALL |  | [1141-1377](#C_1141-1377) | [Device Information Organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17](#E_Device_Information_Organizer) |

1. SHALL contain exactly one [1..1] templateId (CONF:1141-1463) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.1" (CONF:1141-1464).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2359).
2. SHALL contain exactly one [1..1] code (CONF:1141-1364).
   1. This code SHALL contain exactly one [1..1] @code="46264-8" Medical Equipment (CONF:1141-1370).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1141-1371).
   3. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-2407).
3. SHALL contain exactly one [1..1] title (CONF:1141-1372).
4. SHALL contain exactly one [1..1] text (CONF:1141-1373).
5. SHOULD contain zero or more [0..\*] entry (CONF:1141-1375).  
   Note: A separate entry will be present for each medical device.
   1. The entry, if present, SHOULD contain zero or one [0..1] @typeCode (CONF:1141-2408).  
      Note: For medical equipment in the context of a PHMR a entry@typeCode="COMP" is reasonable.
   2. The entry, if present, SHALL contain exactly one [1..1] [Device Information Organizer](#E_Device_Information_Organizer) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17) (CONF:1141-1377).  
      Note: This organizer describes the properties of a single medical device.
6. If no medical devices are defined, this section's text element **SHALL** note this fact (CONF:1141-1378).

PHMR Results Section (entries required) - Draft

[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17 (open)]

Table 6: PHMR Results Section (entries required) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) (optional) | [PHMR Result Organizer](#E_PHMR_Result_Organizer) |

This section contains the results of observations that are not categorized as vital signs. For PHM devices examples would be glucose concentrations, insulin amounts, miles run, steps taken, number of apnoea events, etc.. A PHMR shall always have at least one observation entry. It may be a PHMR vital signs organizer entry or a PHMR results organizer entry. If this section is present it shall have at least one observation entry.

Table 7: PHMR Results Section (entries required) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17) | | | | | |
| templateId | 1..1 | SHALL |  | [1141-1389](#C_1141-1389) |  |
| @root | 1..1 | SHALL |  | [1141-1392](#C_1141-1392) | 2.16.840.1.113883.10.20.36.14 |
| @extension | 1..1 | SHALL |  | [1141-2361](#C_1141-2361) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1390](#C_1141-1390) |  |
| @code | 1..1 | SHALL |  | [1141-1394](#C_1141-1394) | 30954-2 |
| @codeSystem | 1..1 | SHALL |  | [1141-1395](#C_1141-1395) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| @displayName | 0..1 | SHOULD |  | [1141-2415](#C_1141-2415) |  |
| title | 1..1 | SHALL |  | [1141-1396](#C_1141-1396) |  |
| text | 1..1 | SHALL |  | [1141-1397](#C_1141-1397) |  |
| entry | 0..\* | SHALL |  | [1141-1388](#C_1141-1388) |  |
| @typeCode | 0..1 | SHOULD |  | [1141-2416](#C_1141-2416) |  |
| organizer | 1..1 | SHALL |  | [1141-1391](#C_1141-1391) | [PHMR Result Organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17](#E_PHMR_Result_Organizer) |

1. SHALL contain exactly one [1..1] templateId (CONF:1141-1389) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.14" (CONF:1141-1392).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2361).
2. SHALL contain exactly one [1..1] code (CONF:1141-1390).
   1. This code SHALL contain exactly one [1..1] @code="30954-2" Relevant diagnostic tests and/or laboratory data (CONF:1141-1394).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1141-1395).
   3. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-2415).
3. SHALL contain exactly one [1..1] title (CONF:1141-1396).
4. SHALL contain exactly one [1..1] text (CONF:1141-1397).
5. SHALL contain zero or more [0..\*] entry (CONF:1141-1388) such that it
   1. SHOULD contain zero or one [0..1] @typeCode (CONF:1141-2416).  
      Note: A reasonable value for the entry@typeCode is "DRIV" (derived) for a PHMR implementation
   2. SHALL contain exactly one [1..1] [PHMR Result Organizer](#E_PHMR_Result_Organizer) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17) (CONF:1141-1391).

PHMR Vital Signs Section (entries required) - Draft

[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17 (open)]

Table 8: PHMR Vital Signs Section (entries required) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) (optional) | [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) |

The PHMR Vital Signs Section contains that subset of health measurements that have been defined by the medical establishment and by practice as vital signs. These measurements consist of the blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pulse oximetry, temperature, and body surface area. Other PHM device medical measurements such as glucose concentration or number of apnoea events are reported in the PHMR Results Section.

A PHMR shall always have at least one observation entry. It may be a PHMR vital signs organizer entry or a PHMR results organizer entry. If this section is present, it shall have at least one observation entry.

Table 9: PHMR Vital Signs Section (entries required) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17) | | | | | |
| templateId | 1..1 | SHALL |  | [1141-1450](#C_1141-1450) |  |
| @root | 1..1 | SHALL |  | [1141-1453](#C_1141-1453) | 2.16.840.1.113883.10.20.36.15 |
| @extension | 1..1 | SHALL |  | [1141-2363](#C_1141-2363) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1451](#C_1141-1451) |  |
| @code | 1..1 | SHALL |  | [1141-1455](#C_1141-1455) | 8716-3 |
| @codeSystem | 1..1 | SHALL |  | [1141-1456](#C_1141-1456) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| @displayName | 0..1 | SHOULD |  | [1141-2411](#C_1141-2411) |  |
| title | 1..1 | SHALL |  | [1141-1457](#C_1141-1457) |  |
| text | 1..1 | SHALL |  | [1141-1458](#C_1141-1458) |  |
| entry | 0..\* | SHALL |  | [1141-1449](#C_1141-1449) |  |
| @typeCode | 0..1 | SHOULD |  | [1141-2412](#C_1141-2412) |  |
| organizer | 1..1 | SHALL |  | [1141-1452](#C_1141-1452) | [PHMR Vital Signs Organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17](#E_PHMR_Vital_Signs_Organizer) |

1. SHALL contain exactly one [1..1] templateId (CONF:1141-1450) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.15" (CONF:1141-1453).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2363).
2. SHALL contain exactly one [1..1] code (CONF:1141-1451).
   1. This code SHALL contain exactly one [1..1] @code="8716-3" Vital Signs (CONF:1141-1455).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1141-1456).
   3. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-2411).
3. SHALL contain exactly one [1..1] title (CONF:1141-1457).
4. SHALL contain exactly one [1..1] text (CONF:1141-1458).
5. SHALL contain zero or more [0..\*] entry (CONF:1141-1449) such that it
   1. SHOULD contain zero or one [0..1] @typeCode (CONF:1141-2412).  
      Note: An appropriate typeCode for vital signs entries would be entry@typeCode="DRIV" (derived)
   2. SHALL contain exactly one [1..1] [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17) (CONF:1141-1452).

# entry

Device Accuracy Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17 (open)]

Table 10: Device Accuracy Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Accuracy observation MAY be present as one or more entries in the Device information organizer. The accuracy gives a measure of how much the observation may deviate from the reported value, for example, the values reported by a device may be within +/- 3% of the actual value. When reported by the device it is reported in the numeric metric object in the Accuracy attribute. The accuracy is reported in the units of the measurement being referenced, and since more than one measurement type may be reported (for example SpO2 in % and pulse rate in beats per minute on a pulse oximeter) there may be more than one accuracy to report. If the accuracies are not reported by the device they may, for example, be manually entered or derived through other means.

Table 11: Device Accuracy Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1328](#C_1141-1328) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1329](#C_1141-1329) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1319](#C_1141-1319) |  |
| @root | 1..1 | SHALL |  | [1141-1322](#C_1141-1322) | 2.16.840.1.113883.10.20.36.3 |
| @extension | 1..1 | SHALL |  | [1141-2350](#C_1141-2350) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1320](#C_1141-1320) |  |
| @code | 1..1 | SHALL |  | [1141-1323](#C_1141-1323) | MDC\_ATTR\_NU\_ACCUR\_MSMT |
| @codeSystem | 1..1 | SHALL |  | [1141-1324](#C_1141-1324) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1325](#C_1141-1325) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1590](#C_1141-1590) |  |
| text | 0..1 | MAY |  | [1141-2266](#C_1141-2266) |  |
| reference | 0..1 | SHOULD |  | [1141-2380](#C_1141-2380) |  |
| @value | 0..1 | SHOULD |  | [1141-2381](#C_1141-2381) |  |
| value | 1..1 | SHALL | PQ | [1141-1321](#C_1141-1321) |  |
| @value | 1..1 | SHALL |  | [1141-1326](#C_1141-1326) |  |
| @unit | 1..1 | SHALL |  | [1141-1327](#C_1141-1327) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1328).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1329).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1319) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.3" (CONF:1141-1322).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2350).
4. SHALL contain exactly one [1..1] code (CONF:1141-1320).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ATTR\_NU\_ACCUR\_MSMT" numerical value: 67194 (CONF:1141-1323).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1324).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1325).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1590).  
      Note: One could put the reference Id of the measurement accuracy attribute, MDC\_ATTR\_NU\_ACCUR\_MSMT, in the displayName attribute as it is standardized.
5. MAY contain zero or one [0..1] text (CONF:1141-2266).  
   Note: The text element may be used to provide a simple description of the accuracy
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2380).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2381).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2382).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1141-1321).
   1. This value SHALL contain exactly one [1..1] @value (CONF:1141-1326).
   2. This value SHALL contain exactly one [1..1] @unit (ValueSet: [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839) (CONF:1141-1327).

Device Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17 (open)]

The Device Information observation forms the 'base' template for device information related observations or perhaps better stated, properties, whose values are represented by strings. For example the manufacturer name, model number, serial number, system id, software, firmware, and hardware revision numbers, etc.. The templates which then infer (inherit in object-oriented language) this template differ primarily in the @code attribute of the code element.

Table 12: Device Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1823](#C_1141-1823) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1824](#C_1141-1824) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1813](#C_1141-1813) |  |
| @root | 1..1 | SHALL |  | [1141-1816](#C_1141-1816) | 2.16.840.1.113883.10.20.36.17 |
| @extension | 1..1 | SHALL |  | [1141-2346](#C_1141-2346) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1814](#C_1141-1814) |  |
| @code | 1..1 | SHALL |  | [1141-1817](#C_1141-1817) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-1818](#C_1141-1818) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1819](#C_1141-1819) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1820](#C_1141-1820) |  |
| text | 0..1 | SHOULD |  | [1141-2376](#C_1141-2376) |  |
| reference | 1..1 | SHOULD |  | [1141-2377](#C_1141-2377) |  |
| @value | 1..1 | SHOULD |  | [1141-2378](#C_1141-2378) |  |
| value | 1..1 | SHALL | ST | [1141-1825](#C_1141-1825) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1823).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1824).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1813) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.17" (CONF:1141-1816).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2346).
4. SHALL contain exactly one [1..1] code (CONF:1141-1814).
   1. This code SHALL contain exactly one [1..1] @code (CONF:1141-1817).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1818).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1819).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1820).
5. SHOULD contain zero or one [0..1] text (CONF:1141-2376).
   1. The text, if present, SHOULD contain exactly one [1..1] reference (CONF:1141-2377).
      1. This reference SHOULD contain exactly one [1..1] @value (CONF:1141-2378).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2379).
6. SHALL contain exactly one [1..1] value with @xsi:type="ST" (CONF:1141-1825).

Device Firmware Revision Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17 (open)]

Table 13: Device Firmware Revision Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Firmware Revision Information Observation reports the firmware version of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute or the Device Information Service on Bluetooth Low Energy health devices.

The LOINC code 74716-2, Vendor firmware version, appears to be an acceptable translation code for firmware revision.

Table 14: Device Firmware Revision Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1847](#C_1141-1847) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1848](#C_1141-1848) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1851](#C_1141-1851) |  |
| @root | 1..1 | SHALL |  | [1141-1852](#C_1141-1852) | 2.16.840.1.113883.10.20.36.18 |
| @extension | 1..1 | SHALL |  | [1141-2137](#C_1141-2137) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1841](#C_1141-1841) |  |
| @code | 1..1 | SHALL |  | [1141-1843](#C_1141-1843) | MDC\_ID\_PROD\_SPEC\_FW |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1847).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1848).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1851) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.18" (CONF:1141-1852).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2137).
5. SHALL contain exactly one [1..1] code (CONF:1141-1841).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_FW" numerical value: 531976 (CONF:1141-1843).

Device GMDN Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17 (open)]

Table 15: Device GMDN Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device GMDN Information Observation reports the GMDN (Global Medical Device Nomenclature) of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute. It is not transmitted by Bluetooth Low Energy health devices.

Table 16: Device GMDN Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1861](#C_1141-1861) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1862](#C_1141-1862) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1864](#C_1141-1864) |  |
| @root | 1..1 | SHALL |  | [1141-1865](#C_1141-1865) | 2.16.840.1.113883.10.20.36.19 |
| @extension | 1..1 | SHALL |  | [1141-2135](#C_1141-2135) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1855](#C_1141-1855) |  |
| @code | 1..1 | SHALL |  | [1141-1857](#C_1141-1857) | MDC\_ID\_PROD\_SPEC\_GMDN |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1861).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1862).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1864) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.19" (CONF:1141-1865).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2135).
5. SHALL contain exactly one [1..1] code (CONF:1141-1855).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_GMDN" numerical value: 531978 (CONF:1141-1857).

Device Hardware Version Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17 (open)]

Table 17: Device Hardware Version Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Hardware Revision Information Observation reports the hardware version of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute or the Device Information Service on Bluetooth Low Energy health devices.

Table 18: Device Hardware Version Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1874](#C_1141-1874) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1875](#C_1141-1875) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1876](#C_1141-1876) |  |
| @root | 1..1 | SHALL |  | [1141-1877](#C_1141-1877) | 2.16.840.1.113883.10.20.36.20 |
| @extension | 1..1 | SHALL |  | [1141-2153](#C_1141-2153) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1868](#C_1141-1868) |  |
| @code | 1..1 | SHALL |  | [1141-1870](#C_1141-1870) | MDC\_ID\_PROD\_SPEC\_HW |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1874).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1875).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1876) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.20" (CONF:1141-1877).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2153).
5. SHALL contain exactly one [1..1] code (CONF:1141-1868).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_HW" numerical value: 531974 (CONF:1141-1870).

Device Manufacturer Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17 (open)]

Table 19: Device Manufacturer Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Manufacturer Information Observation reports the Manufacturer name of the device. In PCHA compliant devices, this information is provided by the System Model attribute or the Device Information Service on Bluetooth Low Energy health devices.

LOINC code  74719-6   Manufacturer name

Table 20: Device Manufacturer Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2130](#C_1141-2130) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-2131](#C_1141-2131) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1889](#C_1141-1889) |  |
| @root | 1..1 | SHALL |  | [1141-1890](#C_1141-1890) | 2.16.840.1.113883.10.20.36.21 |
| @extension | 1..1 | SHALL |  | [1141-2133](#C_1141-2133) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1880](#C_1141-1880) |  |
| @code | 1..1 | SHALL |  | [1141-1882](#C_1141-1882) | MDC\_ID\_MODEL\_MANUFACTURER |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-2130).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-2131).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1889) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.21" (CONF:1141-1890).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2133).
5. SHALL contain exactly one [1..1] code (CONF:1141-1880).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_MODEL\_MANUFACTURER" numerical value: 531970 (CONF:1141-1882).

Device Model Number Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17 (open)]

Table 21: Device Model Number Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Model Number Information Observation reports the Model number of the device. In PCHA compliant devices, this information is provided by the System Model attribute or the Device Information Service on Bluetooth Low Energy health devices.

LOINC code  74717-0   Vendor model number

Table 22: Device Model Number Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1899](#C_1141-1899) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1900](#C_1141-1900) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1902](#C_1141-1902) |  |
| @root | 1..1 | SHALL |  | [1141-1903](#C_1141-1903) | 2.16.840.1.113883.10.20.36.22 |
| @extension | 1..1 | SHALL |  | [1141-2151](#C_1141-2151) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1893](#C_1141-1893) |  |
| @code | 1..1 | SHALL |  | [1141-1895](#C_1141-1895) | MDC\_ID\_MODEL\_NUMBER |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1899).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1900).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1902) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.22" (CONF:1141-1903).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2151).
5. SHALL contain exactly one [1..1] code (CONF:1141-1893).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_MODEL\_NUMBER" numerical value: 531969 (CONF:1141-1895).

Device Part Number Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17 (open)]

Table 23: Device Part Number Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Part Number Information Observation reports the Part number of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute. It is not transmitted by Bluetooth Low Energy health devices.

Table 24: Device Part Number Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1912](#C_1141-1912) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1913](#C_1141-1913) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1914](#C_1141-1914) |  |
| @root | 1..1 | SHALL |  | [1141-1915](#C_1141-1915) | 2.16.840.1.113883.10.20.36.23 |
| @extension | 1..1 | SHALL |  | [1141-2149](#C_1141-2149) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1906](#C_1141-1906) |  |
| @code | 1..1 | SHALL |  | [1141-1908](#C_1141-1908) | MDC\_ID\_PROD\_SPEC\_PART |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1912).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1913).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1914) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.23" (CONF:1141-1915).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2149).
5. SHALL contain exactly one [1..1] code (CONF:1141-1906).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_PART" numerical value: 531973 (CONF:1141-1908).

Device PCHA Version Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17 (open)]

Table 25: Device PCHA Version Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device PCHA Version Information Observation reports the PCHA (Continua) version of the device. In a PCHA compliant device, this information is provided by the RegCertDataList attribute or the RegCertData characteristic of the Device Information Service on a Bluetooth Low Energy Health device.

Table 26: Device PCHA Version Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1961](#C_1141-1961) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1962](#C_1141-1962) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1963](#C_1141-1963) |  |
| @root | 1..1 | SHALL |  | [1141-1964](#C_1141-1964) | 2.16.840.1.113883.10.20.36.27 |
| @extension | 1..1 | SHALL |  | [1141-2147](#C_1141-2147) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1955](#C_1141-1955) |  |
| @code | 1..1 | SHALL |  | [1141-1957](#C_1141-1957) | MDC\_REG\_CERT\_DATA\_CONTINUA\_VERSION |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1961).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1962).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1963) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.27" (CONF:1141-1964).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2147).
5. SHALL contain exactly one [1..1] code (CONF:1141-1955).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_REG\_CERT\_DATA\_CONTINUA\_VERSION" numerical value: 532352 (CONF:1141-1957).

Device Protocol Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17 (open)]

Table 27: Device Protocol Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Protocol Information Observation reports the internal protocol of the device. On PCHA compliant devices it is reported in the Production specification attribute.

Table 28: Device Protocol Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1834](#C_1141-1834) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1835](#C_1141-1835) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1838](#C_1141-1838) |  |
| @root | 1..1 | SHALL |  | [1141-1839](#C_1141-1839) | 2.16.840.1.113883.10.20.36.30 |
| @extension | 1..1 | SHALL |  | [1141-2145](#C_1141-2145) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1828](#C_1141-1828) |  |
| @code | 1..1 | SHALL |  | [1141-1830](#C_1141-1830) | MDC\_ID\_PROD\_SPEC\_PROTOCOL |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1834).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1835).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1838) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.30" (CONF:1141-1839).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2145).
5. SHALL contain exactly one [1..1] code (CONF:1141-1828).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_PROTOCOL" numerical value: 531977 (CONF:1141-1830).

Device Serial Number Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17 (open)]

Table 29: Device Serial Number Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Serial Number Information Observation reports the serial number of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute or the Device Information Service on Bluetooth Low Energy health devices.

The LOINC code for device serial number is

74715-4   Vendor serial number

Table 30: Device Serial Number Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1949](#C_1141-1949) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1950](#C_1141-1950) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1951](#C_1141-1951) |  |
| @root | 1..1 | SHALL |  | [1141-1952](#C_1141-1952) | 2.16.840.1.113883.10.20.36.26 |
| @extension | 1..1 | SHALL |  | [1141-2143](#C_1141-2143) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1943](#C_1141-1943) |  |
| @code | 1..1 | SHALL |  | [1141-1945](#C_1141-1945) | MDC\_ID\_PROD\_SPEC\_SERIAL |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1949).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1950).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1951) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.26" (CONF:1141-1952).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2143).
5. SHALL contain exactly one [1..1] code (CONF:1141-1943).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_SERIAL" numerical value: 531972 (CONF:1141-1945).

Device Software Revison Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17 (open)]

Table 31: Device Software Revison Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Software Revision Information Observation reports the software version of the device. In PCHA compliant devices, this information is provided by the Production Specification attribute and in the Device Information Service by Bluetooth Low Energy health devices.

LOINC code 55081-4   Product version code Software

Table 32: Device Software Revison Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1924](#C_1141-1924) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1925](#C_1141-1925) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1926](#C_1141-1926) |  |
| @root | 1..1 | SHALL |  | [1141-1927](#C_1141-1927) | 2.16.840.1.113883.10.20.36.24 |
| @extension | 1..1 | SHALL |  | [1141-2141](#C_1141-2141) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1918](#C_1141-1918) |  |
| @code | 1..1 | SHALL |  | [1141-1920](#C_1141-1920) | MDC\_ID\_PROD\_SPEC\_SW |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1924).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1925).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1926) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.24" (CONF:1141-1927).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2141).
5. SHALL contain exactly one [1..1] code (CONF:1141-1918).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_SW" numerical value: 531975 (CONF:1141-1920).

Device Specification Unspecified Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17 (open)]

Table 33: Device Specification Unspecified Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Specification Unspecified Information Observation reports information about a device that does not fit the specified categories. In PCHA compliant devices, this information is provided by the Production Specification attribute. It is not transmitted by Bluetooth Low Energy health devices.

Table 34: Device Specification Unspecified Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1937](#C_1141-1937) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1938](#C_1141-1938) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1939](#C_1141-1939) |  |
| @root | 1..1 | SHALL |  | [1141-1940](#C_1141-1940) | 2.16.840.1.113883.10.20.36.25 |
| @extension | 1..1 | SHALL |  | [1141-2139](#C_1141-2139) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1931](#C_1141-1931) |  |
| @code | 1..1 | SHALL |  | [1141-1933](#C_1141-1933) | MDC\_ID\_PROD\_SPEC\_UNSPECIFIED |

1. Conforms to [Device Information Observation](#E_Device_Information_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1937).
3. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1938).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1939) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.25" (CONF:1141-1940).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2139).
5. SHALL contain exactly one [1..1] code (CONF:1141-1931).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ID\_PROD\_SPEC\_UNSPECIFIED" numerical value: 531971 (CONF:1141-1933).

Device Information Organizer - Draft

[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17 (open)]

Table 35: Device Information Organizer Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) (optional) | [Device Accuracy Observation](#E_Device_Accuracy_Observation)  [Device Firmware Revision Information Observation](#E_Device_Firmware_Revision_Information_)  [Device GMDN Information Observation](#E_Device_GMDN_Information_Observation)  [Device Hardware Version Information Observation](#E_Device_Hardware_Version_Information_O)  [Device Manufacturer Information Observation](#E_Device_Manufacturer_Information_Obser)  [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation)  [Device Model Number Information Observation](#E_Device_Model_Number_Information_Obser)  [Device Part Number Information Observation](#E_Device_Part_Number_Information_Observ)  [Device PCHA Version Information Observation](#E_Device_PCHA_Version_Information_Obser)  [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template)  [Device Protocol Information Observation](#E_Device_Protocol_Information_Observati)  [Device Regulation Status Information Observation](#E_Device_Regulation_Status_Information_)  [Device Resolution Observation](#E_Device_Resolution_Observation)  [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation)  [Device Serial Number Information Observation](#E_Device_Serial_Number_Information_Obse)  [Device Software Revison Information Observation](#E_Device_Software_Revison_Information_O)  [Device Specification Unspecified Information Observation](#E_Device_Specification_Unspecified_Info)  [Device Time Synchronization Information Observation](#E_Device_Time_Synchronization_Informati) |

This template encodes information about the identity and properties of the medical device reporting the measurements. There shall be one such entry element containing this organizer for each device that provides results or vital signs observations that are present in this document. This organizer encapsulates all the properties of a given medical device versus organizing the set of medical devices that have contributed to measurements in this document. The properties include unique device identifiers such as the IEEE EUI-64 system id, the specialization type or types, the manufacturing product information such as a serial number and regulatory status, as well as the capabilities of the sensors such as the accuracy, resolution, and time synchronization. IEEE 11073 20601 devices and Personal Care Health Alliance (PCHA) compliant Bluetooth Low Energy devices are required to report a certain subset of this information.

Table 36: Device Information Organizer Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1338](#C_1141-1338) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
| @moodCode | 1..1 | SHALL |  | [1141-1339](#C_1141-1339) | urn:oid:2.16.840.1.113883.5.1001 (ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [1141-2419](#C_1141-2419) |  |
| @root | 1..1 | SHALL |  | [1141-2420](#C_1141-2420) | 2.16.840.1.113883.10.20.36.4 |
| @extension | 1..1 | SHALL |  | [1141-2421](#C_1141-2421) | 2015-08-17 |
| code | 0..\* | MAY |  | [1141-1342](#C_1141-1342) |  |
| statusCode | 1..1 | SHALL |  | [1141-1334](#C_1141-1334) |  |
| @code | 1..1 | SHALL |  | [1141-1343](#C_1141-1343) | urn:oid:2.16.840.1.113883.11.20.9.39 (Result Status) |
| effectiveTime | 1..1 | SHALL |  | [1141-1336](#C_1141-1336) |  |
| participant | 1..1 | SHALL |  | [1141-1639](#C_1141-1639) |  |
| participantRole | 1..1 | SHALL |  | [1141-1640](#C_1141-1640) | [Device PHMR Product Instance Template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17](#E_Device_PHMR_Product_Instance_Template) |
| component | 0..\* | MAY |  | [1141-1350](#C_1141-1350) |  |
| observation | 1..1 | SHALL |  | [1141-1354](#C_1141-1354) | [Device Accuracy Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17](#E_Device_Accuracy_Observation) |
| component | 0..1 | MAY |  | [1141-1787](#C_1141-1787) |  |
| observation | 1..1 | SHALL |  | [1141-1853](#C_1141-1853) | [Device Firmware Revision Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17](#E_Device_Firmware_Revision_Information_) |
| component | 0..1 | MAY |  | [1141-1789](#C_1141-1789) |  |
| observation | 1..1 | SHALL |  | [1141-1866](#C_1141-1866) | [Device GMDN Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17](#E_Device_GMDN_Information_Observation) |
| component | 0..1 | MAY |  | [1141-1791](#C_1141-1791) |  |
| observation | 1..1 | SHALL |  | [1141-1878](#C_1141-1878) | [Device Hardware Version Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17](#E_Device_Hardware_Version_Information_O) |
| component | 0..1 | MAY |  | [1141-1793](#C_1141-1793) |  |
| observation | 1..1 | SHALL |  | [1141-1891](#C_1141-1891) | [Device Manufacturer Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17](#E_Device_Manufacturer_Information_Obser) |
| component | 0..1 | MAY |  | [1141-1795](#C_1141-1795) |  |
| observation | 1..1 | SHALL |  | [1141-1904](#C_1141-1904) | [Device Model Number Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17](#E_Device_Model_Number_Information_Obser) |
| component | 0..1 | MAY |  | [1141-1797](#C_1141-1797) |  |
| observation | 1..1 | SHALL |  | [1141-1916](#C_1141-1916) | [Device Part Number Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17](#E_Device_Part_Number_Information_Observ) |
| component | 0..1 | MAY |  | [1141-1799](#C_1141-1799) |  |
| observation | 1..1 | SHALL |  | [1141-1928](#C_1141-1928) | [Device Software Revison Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17](#E_Device_Software_Revison_Information_O) |
| component | 0..1 | MAY |  | [1141-1801](#C_1141-1801) |  |
| observation | 1..1 | SHALL |  | [1141-1929](#C_1141-1929) | [Device Specification Unspecified Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17](#E_Device_Specification_Unspecified_Info) |
| component | 0..1 | MAY |  | [1141-1803](#C_1141-1803) |  |
| observation | 1..1 | SHALL |  | [1141-1941](#C_1141-1941) | [Device Serial Number Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17](#E_Device_Serial_Number_Information_Obse) |
| component | 0..1 | MAY |  | [1141-1805](#C_1141-1805) |  |
| observation | 1..1 | SHALL |  | [1141-1806](#C_1141-1806) | [Device Regulation Status Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17](#E_Device_Regulation_Status_Information_) |
| component | 0..1 | MAY |  | [1141-1807](#C_1141-1807) |  |
| observation | 1..1 | SHALL |  | [1141-1953](#C_1141-1953) | [Device PCHA Version Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17](#E_Device_PCHA_Version_Information_Obser) |
| component | 0..1 | MAY |  | [1141-1809](#C_1141-1809) |  |
| observation | 1..1 | SHALL |  | [1141-1810](#C_1141-1810) | [Device Time Synchronization Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17](#E_Device_Time_Synchronization_Informati) |
| component | 0..1 | MAY |  | [1141-1811](#C_1141-1811) |  |
| observation | 1..1 | SHALL |  | [1141-1812](#C_1141-1812) | [Device Protocol Information Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17](#E_Device_Protocol_Information_Observati) |
| component | 0..\* | MAY |  | [1141-1351](#C_1141-1351) |  |
| observation | 1..1 | SHALL |  | [1141-1355](#C_1141-1355) | [Device Sampling Frequency Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17](#E_Device_Sampling_Frequency_Observation) |
| component | 0..\* | MAY |  | [1141-1352](#C_1141-1352) |  |
| observation | 1..1 | SHALL |  | [1141-1356](#C_1141-1356) | [Device Resolution Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17](#E_Device_Resolution_Observation) |
| component | 0..\* | MAY |  | [1141-1353](#C_1141-1353) |  |
| observation | 1..1 | SHALL |  | [1141-1357](#C_1141-1357) | [Device Measurement Range Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17](#E_Device_Measurement_Range_Observation) |

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1141-1338).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:1141-1339).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-2419) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.4" (CONF:1141-2420).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2421).
4. MAY contain zero or more [0..\*] code (CONF:1141-1342).  
   Note: This code can represent a category of devices. The code is strictly optional, and is not currently limited to any value set or code system. Implementers may use it if they wish to provide optional coded information about the group of medical equipment to which this device belongs.
5. SHALL contain exactly one [1..1] statusCode (CONF:1141-1334).  
   Note: For most PHM device measurements the status will be "completed"
   1. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet [Result Status](#Result_Status) urn:oid:2.16.840.1.113883.11.20.9.39 STATIC (CONF:1141-1343).
6. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-1336).  
   Note: The effectiveTime can be used to show the time period over which the patient will be using or has used the set of equipment for the measurements contained in this document. For most PHM device use cases this will be the time of the measurement or the time range of the measurements such as reported in OBR-7 and OBR-8 of a PCD-01 document.
   1. If the measurement data reported is at a single time and the reported measurements are not designated as spanning a period of time, the time stamp **SHALL** appear in the value attribute. If the measurements reported span a duration of time, the start time **SHALL** appear in the 'low' element and the finish time in the 'high' element and the effectiveTime/@value attribute **SHALL** be absent (CONF:1141-2375).
7. SHALL contain exactly one [1..1] participant (CONF:1141-1639).
   1. This participant SHALL contain exactly one [1..1] [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17) (CONF:1141-1640).
8. MAY contain zero or more [0..\*] component (CONF:1141-1350).  
   Note: There may be multiple of these component elements since the device may have more than one accuracy to report, for example a pulse oximeter might report an accuracy for the oxygen saturation and pulse rate measurements.
   1. The component, if present, SHALL contain exactly one [1..1] [Device Accuracy Observation](#E_Device_Accuracy_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17) (CONF:1141-1354).
9. MAY contain zero or one [0..1] component (CONF:1141-1787).
   1. The component, if present, SHALL contain exactly one [1..1] [Device Firmware Revision Information Observation](#E_Device_Firmware_Revision_Information_) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17) (CONF:1141-1853).
10. MAY contain zero or one [0..1] component (CONF:1141-1789).
    1. The component, if present, SHALL contain exactly one [1..1] [Device GMDN Information Observation](#E_Device_GMDN_Information_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17) (CONF:1141-1866).
11. MAY contain zero or one [0..1] component (CONF:1141-1791).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Hardware Version Information Observation](#E_Device_Hardware_Version_Information_O) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17) (CONF:1141-1878).
12. MAY contain zero or one [0..1] component (CONF:1141-1793).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Manufacturer Information Observation](#E_Device_Manufacturer_Information_Obser) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17) (CONF:1141-1891).
13. MAY contain zero or one [0..1] component (CONF:1141-1795).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Model Number Information Observation](#E_Device_Model_Number_Information_Obser) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17) (CONF:1141-1904).
14. MAY contain zero or one [0..1] component (CONF:1141-1797).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Part Number Information Observation](#E_Device_Part_Number_Information_Observ) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17) (CONF:1141-1916).
15. MAY contain zero or one [0..1] component (CONF:1141-1799).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Software Revison Information Observation](#E_Device_Software_Revison_Information_O) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17) (CONF:1141-1928).
16. MAY contain zero or one [0..1] component (CONF:1141-1801).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Specification Unspecified Information Observation](#E_Device_Specification_Unspecified_Info) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17) (CONF:1141-1929).
17. MAY contain zero or one [0..1] component (CONF:1141-1803).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Serial Number Information Observation](#E_Device_Serial_Number_Information_Obse) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17) (CONF:1141-1941).
18. MAY contain zero or one [0..1] component (CONF:1141-1805).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Regulation Status Information Observation](#E_Device_Regulation_Status_Information_) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17) (CONF:1141-1806).
19. MAY contain zero or one [0..1] component (CONF:1141-1807).
    1. The component, if present, SHALL contain exactly one [1..1] [Device PCHA Version Information Observation](#E_Device_PCHA_Version_Information_Obser) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17) (CONF:1141-1953).
20. MAY contain zero or one [0..1] component (CONF:1141-1809).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Time Synchronization Information Observation](#E_Device_Time_Synchronization_Informati) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17) (CONF:1141-1810).
21. MAY contain zero or one [0..1] component (CONF:1141-1811).
    1. The component, if present, SHALL contain exactly one [1..1] [Device Protocol Information Observation](#E_Device_Protocol_Information_Observati) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17) (CONF:1141-1812).
22. MAY contain zero or more [0..\*] component (CONF:1141-1351).  
    Note: There may be multiple of these component elements since the device may have more than one frequency of data delivery. For example a sleep apnoea breathing therapy device might report respiration and leakage rates at different intervals. Waveform frequencies are NOT reported here; they are reported in the PHM Measurement Waveform Sample Period Observation. Instead, what would be reported here is the frequency at which waveform series are sent over the wire. For example a pulse oximeter may deliver a Pleth waveform with a sample period of one millisecond once per second (each delivery containing 1000 measurements). The sample period is the 1 millisecond interval. What would be reported here is the 1 second interval of measurement delivery. PCHA PHM devices do not report this value by protocol. It would have to be inferred by the recipient of the device data.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17) (CONF:1141-1355).
23. MAY contain zero or more [0..\*] component (CONF:1141-1352).  
    Note: There may be multiple of these component elements since the device may have more than one measurement resolution to report, for example a pulse oximeter might have a resolution of 0.5% for the oxygen saturation and a 1 beat per minute resolution for the pulse rate. PCHA PHM devices do not report this value by protocol. It would have to be derived from another source and entered by some other means.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Resolution Observation](#E_Device_Resolution_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17) (CONF:1141-1356).
24. MAY contain zero or more [0..\*] component (CONF:1141-1353).  
    Note: There may be multiple of these component elements since the device may have more than one measurement range, for example a pulse oximeter might have a range of 0 to 100 % for the oxygen saturation and a range of 10 bpm to 300 bpm for the pulse rate. PCHA PHM devices do not report this value by protocol. It would have to be derived from another source and entered by some other means.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17) (CONF:1141-1357).

Device Measurement Range Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17 (open)]

Table 37: Device Measurement Range Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Measurement Range observation MAY be present as an entry in the Device definition organizer. The measurement range of the device gives the range of possible values that may be reported by the device, for example, a thermometer may report values between 0 and 100 degrees Celsius. However, the range value may not be directly available from device data. Instead it may, for example, be manually entered or derived through other means. Currently IEEE 11073 20601 PHM devices do not support the reporting of a measurement range and these values would need to be determined by other means.

Table 38: Device Measurement Range Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1278](#C_1141-1278) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1279](#C_1141-1279) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1257](#C_1141-1257) |  |
| @root | 1..1 | SHALL |  | [1141-1271](#C_1141-1271) | 2.16.840.1.113883.10.20.36.5 |
| @extension | 1..1 | SHALL |  | [1141-2351](#C_1141-2351) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1258](#C_1141-1258) |  |
| @code | 1..1 | SHALL |  | [1141-1280](#C_1141-1280) | MDC\_ATTR\_NU\_RANGE\_MSMT |
| @codeSystem | 1..1 | SHALL |  | [1141-1281](#C_1141-1281) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1282](#C_1141-1282) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1591](#C_1141-1591) |  |
| text | 0..1 | SHOULD |  | [1141-2383](#C_1141-2383) |  |
| reference | 0..1 | SHOULD |  | [1141-2384](#C_1141-2384) |  |
| @value | 0..1 | SHOULD |  | [1141-2385](#C_1141-2385) |  |
| value | 1..1 | SHALL | IVL\_PQ | [1141-1277](#C_1141-1277) |  |
| low | 1..1 | SHALL |  | [1141-1283](#C_1141-1283) |  |
| @unit | 1..1 | SHALL |  | [1141-1606](#C_1141-1606) |  |
| high | 1..1 | SHALL |  | [1141-1284](#C_1141-1284) |  |
| @unit | 1..1 | SHALL |  | [1141-1607](#C_1141-1607) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1278).
2. SHALL contain exactly one [1..1] @moodCode="DEF" Event (CONF:1141-1279).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1257) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.5" (CONF:1141-1271).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2351).
4. SHALL contain exactly one [1..1] code (CONF:1141-1258).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ATTR\_NU\_RANGE\_MSMT" numerical value: 67198 (CONF:1141-1280).  
      Note: This attribute is currently unused in IEEE 11073 20601 Personal Healthcare Devices.
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1281).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1282).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1591).  
      Note: Here one could also show the refId for this attribute (MDC\_ATTR\_NU\_RANGE\_MSMT)
5. SHOULD contain zero or one [0..1] text (CONF:1141-2383).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2384).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2385).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2386).
6. SHALL contain exactly one [1..1] value with @xsi:type="IVL\_PQ" (CONF:1141-1277).
   1. This value SHALL contain exactly one [1..1] low (CONF:1141-1283).
      1. This low SHALL contain exactly one [1..1] @unit (CONF:1141-1606).
   2. This value SHALL contain exactly one [1..1] high (CONF:1141-1284).
      1. This high SHALL contain exactly one [1..1] @unit (CONF:1141-1607).

Device PHMR Product Instance Template - Draft

[participantRole: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17 (open)]

Table 39: Device PHMR Product Instance Template Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (required) |  |

The Device PHMR Product Instance Template describes the properties of the medical device. Typically the device will be an IEEE 11073-based medical device conforming to an IEEE 11073-based medical device standard. This template defines the participantRole element of the Device Information Organizer. Medical observations taken by the device described by this template that are present in this document reference this participant element in the author element of the observation entry. The reference points to the Device Information Organizer that contains all the information relevant to the medical device that generated the measurement.

Table 40: Device PHMR Product Instance Template Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| participantRole (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1568](#C_1141-1568) | urn:oid:2.16.840.1.113883.5.110 (RoleClass) = MANU |
| templateId | 1..1 | SHALL |  | [1141-1565](#C_1141-1565) |  |
| @root | 1..1 | SHALL |  | [1141-1569](#C_1141-1569) | 2.16.840.1.113883.10.20.22.4.37 |
| templateId | 1..1 | SHALL |  | [1141-1573](#C_1141-1573) |  |
| @root | 1..1 | SHALL |  | [1141-1574](#C_1141-1574) | 2.16.840.1.113883.10.20.36.9 |
| @extension | 1..1 | SHALL |  | [1141-2353](#C_1141-2353) | 2015-08-17 |
| id | 1..\* | SHALL |  | [1141-1570](#C_1141-1570) |  |
| @root | 1..1 | SHALL |  | [1141-1575](#C_1141-1575) |  |
| @extension | 1..1 | SHALL |  | [1141-1576](#C_1141-1576) |  |
| @assigningAuthorityName | 1..1 | SHALL |  | [1141-1577](#C_1141-1577) |  |
| playingDevice | 1..1 | SHALL |  | [1141-1566](#C_1141-1566) |  |
| code | 1..1 | SHALL |  | [1141-1571](#C_1141-1571) |  |
| @code | 1..1 | SHALL |  | [1141-1580](#C_1141-1580) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-1581](#C_1141-1581) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1582](#C_1141-1582) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1579](#C_1141-1579) |  |
| translation | 0..\* | MAY |  | [1141-1584](#C_1141-1584) |  |
| manufacturerModelName | 1..1 | SHALL |  | [1141-1585](#C_1141-1585) |  |
| scopingEntity | 0..1 | SHOULD |  | [1141-2344](#C_1141-2344) |  |
| desc | 1..1 | SHALL |  | [1141-2345](#C_1141-2345) |  |

1. SHALL contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass urn:oid:2.16.840.1.113883.5.110 STATIC) (CONF:1141-1568).
2. SHALL contain exactly one [1..1] templateId (CONF:1141-1565) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.37" Indicates conformance to the C-CDA Product Instance (CONF:1141-1569).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1573) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.9" Indicates conformance to the Device PHMR Product Instance (CONF:1141-1574).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2353).
4. SHALL contain at least one [1..\*] id (CONF:1141-1570).
   1. Such ids SHALL contain exactly one [1..1] @root (CONF:1141-1575).
   2. Such ids SHALL contain exactly one [1..1] @extension (CONF:1141-1576).
   3. Such ids SHALL contain exactly one [1..1] @assigningAuthorityName (CONF:1141-1577).
   4. The @root **SHALL** be the OID of device numbering space and the @extension is a valid device ID within that space. For PCHA compliant devices @root is 1.2.840.10004.1.1.1.0.0.1.0.0.1.2680 and @extension is a valid EUI-64 device ID such as obtained from the system ID attribute of IEEE 11073 20601 devices or the System Id characteristic of the Device Information Service of BTLE devices and the @assigningAuthorityName is EUI-64 (CONF:1141-1578).
5. SHALL contain exactly one [1..1] playingDevice (CONF:1141-1566).
   1. This playingDevice SHALL contain exactly one [1..1] code (CONF:1141-1571).
      1. This code SHALL contain exactly one [1..1] @code (CONF:1141-1580).  
         Note: This code would, for example, be the code representing the device specialization, for example the code corresponding to MDC\_DEV\_SPEC\_PROFILE\_BP
      2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1581).
      3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1582).
      4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1579).  
         Note: For PCHA compliant devices one could place the ref id, for example MDC\_DEV\_SPEC\_PROFILE\_BP for a Blood Pressure Monitor, in the description as well as a more human readable string.
      5. This code MAY contain zero or more [0..\*] translation (CONF:1141-1584).  
         Note: Translation elements may be present giving an equivalent SNOMED CT, LOINC, or other code representations for the device type.
   2. This playingDevice SHALL contain exactly one [1..1] manufacturerModelName (CONF:1141-1585).  
      Note: For PHM devices the entry here may be a duplicate of that found in the Device Manufacturer Information Observation or Device Model Number Information Observation.
6. SHOULD contain zero or one [0..1] scopingEntity (CONF:1141-2344).
   1. The scopingEntity, if present, SHALL contain exactly one [1..1] desc (CONF:1141-2345).  
      Note: The manufacturer name is entered here.

Device Regulation Status Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17 (open)]

Table 41: Device Regulation Status Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Regulation Status Information Observation reports the regulation status of the device. In a PCHA compliant device, this information is provided by the RegCertDataList attribute or the RegCertData characteristic of the Device Information Service on a Bluetooth Low Energy Health device. The device is either regulated or unregulated. Though there are additional fields in the RegCertDataList attribute, none of them except for the regulated or unregulated status have yet to be defined.

Table 42: Device Regulation Status Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1770](#C_1141-1770) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1771](#C_1141-1771) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1763](#C_1141-1763) |  |
| @root | 1..1 | SHALL |  | [1141-1765](#C_1141-1765) | 2.16.840.1.113883.10.20.36.28 |
| @extension | 1..1 | SHALL |  | [1141-2365](#C_1141-2365) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1764](#C_1141-1764) |  |
| @code | 1..1 | SHALL |  | [1141-1766](#C_1141-1766) | MDC\_REG\_CERT\_DATA\_CONTINUA\_REG\_STATUS |
| @codeSystem | 1..1 | SHALL |  | [1141-1767](#C_1141-1767) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1768](#C_1141-1768) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1769](#C_1141-1769) |  |
| text | 0..1 | SHOULD |  | [1141-2387](#C_1141-2387) |  |
| reference | 0..1 | SHOULD |  | [1141-2388](#C_1141-2388) |  |
| @value | 0..1 | SHOULD |  | [1141-2389](#C_1141-2389) |  |
| value | 1..1 | SHALL | BN | [1141-1772](#C_1141-1772) |  |
| @value | 1..1 | SHALL |  | [1141-1773](#C_1141-1773) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1770).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1771).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1763) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.28" (CONF:1141-1765).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2365).
4. SHALL contain exactly one [1..1] code (CONF:1141-1764).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_REG\_CERT\_DATA\_CONTINUA\_REG\_STATUS" numerical value: 532354 (CONF:1141-1766).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1767).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1768).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1769).  
      Note: It is highly recommended that at least the ref id be displayed.
5. SHOULD contain zero or one [0..1] text (CONF:1141-2387).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2388).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2389).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2390).
6. SHALL contain exactly one [1..1] value with @xsi:type="BN" (CONF:1141-1772).
   1. This value SHALL contain exactly one [1..1] @value (CONF:1141-1773).  
      Note: A value of "true" indicates that the device is regulated. In the regulation status bit field of the attribute the device is UNregulated when the bit is set which is a little confusing and backwards.

Device Resolution Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17 (open)]

Table 43: Device Resolution Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Resolution Observation MAY be present as an entry in the Device definition organizer. The resolution gives the smallest difference between two measurements that can be reported by the device, for example, a thermometer may report a resolution of 0.1 degrees Celsius. However, the resolution value may not be directly available from device data. Instead it may, for example, be manually entered or derived through other means. Currently, the IEEE 11073-20601 standard does not provide a means for the device to transmit such information.

Table 44: Device Resolution Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1310](#C_1141-1310) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1311](#C_1141-1311) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1301](#C_1141-1301) |  |
| @root | 1..1 | SHALL |  | [1141-1304](#C_1141-1304) | 2.16.840.1.113883.10.20.36.6 |
| @extension | 1..1 | SHALL |  | [1141-2354](#C_1141-2354) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1302](#C_1141-1302) |  |
| @code | 1..1 | SHALL |  | [1141-1305](#C_1141-1305) | 17441009 |
| @codeSystem | 1..1 | SHALL |  | [1141-1306](#C_1141-1306) | 2.16.840.1.113883.6.96 |
| @displayName | 0..1 | SHOULD |  | [1141-2348](#C_1141-2348) |  |
| text | 0..1 | SHOULD |  | [1141-2391](#C_1141-2391) |  |
| reference | 0..1 | SHOULD |  | [1141-2392](#C_1141-2392) |  |
| @value | 0..1 | SHOULD |  | [1141-2393](#C_1141-2393) |  |
| value | 1..1 | SHALL | PQ | [1141-1303](#C_1141-1303) |  |
| @value | 1..1 | SHALL |  | [1141-1317](#C_1141-1317) |  |
| @unit | 1..1 | SHALL |  | [1141-1318](#C_1141-1318) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1310).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1311).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1301) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.6" (CONF:1141-1304).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2354).
4. SHALL contain exactly one [1..1] code (CONF:1141-1302).
   1. This code SHALL contain exactly one [1..1] @code="17441009" (CONF:1141-1305).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" SNOMED CT (CONF:1141-1306).
   3. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-2348).
5. SHOULD contain zero or one [0..1] text (CONF:1141-2391).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2392).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2393).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2394).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1141-1303).
   1. This value SHALL contain exactly one [1..1] @value (CONF:1141-1317).
   2. This value SHALL contain exactly one [1..1] @unit (ValueSet: [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839) (CONF:1141-1318).  
      Note: Dimensionless units are indicated by 1

Device Sampling Frequency Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17 (open)]

Table 45: Device Sampling Frequency Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Sampling Frequency observation MAY be present as an entry in the Device definition organizer. The Device Sampling Frequency is the frequency the device generates measurements. However, the frequency value may not be directly available from device data. For example some Pulse Oximeters generate oxygen saturation and pulse rate values at a regular interval, say once every N seconds but that frequency is not sent as part of the measurement or in any device information attribute. The value must, instead, be manually entered or derived by other means from the received data.

Table 46: Device Sampling Frequency Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1296](#C_1141-1296) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1297](#C_1141-1297) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1287](#C_1141-1287) |  |
| @root | 1..1 | SHALL |  | [1141-1290](#C_1141-1290) | 2.16.840.1.113883.10.20.36.10 |
| @extension | 1..1 | SHALL |  | [1141-2355](#C_1141-2355) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1288](#C_1141-1288) |  |
| @code | 1..1 | SHALL |  | [1141-1291](#C_1141-1291) | MDC\_ATTR\_TIME\_PD\_SAMP |
| @codeSystem | 1..1 | SHALL |  | [1141-1292](#C_1141-1292) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1293](#C_1141-1293) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1592](#C_1141-1592) |  |
| text | 0..1 | SHOULD |  | [1141-2395](#C_1141-2395) |  |
| reference | 0..1 | SHOULD |  | [1141-2396](#C_1141-2396) |  |
| @value | 0..1 | SHOULD |  | [1141-2397](#C_1141-2397) |  |
| value | 1..1 | SHALL | PQ | [1141-1289](#C_1141-1289) |  |
| @value | 1..1 | SHALL |  | [1141-1298](#C_1141-1298) |  |
| @unit | 1..1 | SHALL |  | [1141-1299](#C_1141-1299) | ms |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1296).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1297).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1287) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.10" (CONF:1141-1290).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2355).
4. SHALL contain exactly one [1..1] code (CONF:1141-1288).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_ATTR\_TIME\_PD\_SAMP" numerical value: 67981 (CONF:1141-1291).  
      Note: Even though the MDC\_ATTR\_TIME\_PD\_SAMP IEEE 11073 10101 reference id is used to specify the code, the value for this entry does not come from the MDC\_ATTR\_TIME\_PD\_SAMP attribute of the RTSA metric object in IEEE 11073 20601 devices. That value is placed in the Phm Measurement Waveform Observation entry.
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1292).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1293).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1592).  
      Note: The description here could show the refId for this attribute MDC\_ATTR\_TIME\_PD\_SAMP
5. SHOULD contain zero or one [0..1] text (CONF:1141-2395).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2396).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2397).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2398).
6. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1141-1289).
   1. This value SHALL contain exactly one [1..1] @value (CONF:1141-1298).
   2. This value SHALL contain exactly one [1..1] @unit="ms" milliseconds (CONF:1141-1299).

Device Time Synchronization Information Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17 (open)]

Table 47: Device Time Synchronization Information Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Information Organizer](#E_Device_Information_Organizer) (optional) |  |

The Device Time Synchronization Information Observation indicates the time synchronization method of the device. In PCHA compliant devices it comes from the MdsTimeInfo attribute.

Table 48: Device Time Synchronization Information Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1781](#C_1141-1781) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1782](#C_1141-1782) | DEF |
| templateId | 1..1 | SHALL |  | [1141-1774](#C_1141-1774) |  |
| @root | 1..1 | SHALL |  | [1141-1776](#C_1141-1776) | 2.16.840.1.113883.10.20.36.29 |
| @extension | 1..1 | SHALL |  | [1141-2366](#C_1141-2366) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1775](#C_1141-1775) |  |
| @code | 1..1 | SHALL |  | [1141-1777](#C_1141-1777) | MDC\_TIME\_SYNC\_PROTOCOL |
| @codeSystem | 1..1 | SHALL |  | [1141-1778](#C_1141-1778) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1779](#C_1141-1779) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-1780](#C_1141-1780) |  |
| text | 0..1 | SHOULD |  | [1141-2399](#C_1141-2399) |  |
| reference | 0..1 | SHOULD |  | [1141-2400](#C_1141-2400) |  |
| @value | 0..1 | SHOULD |  | [1141-2401](#C_1141-2401) |  |
| value | 1..1 | SHALL | CD | [1141-1783](#C_1141-1783) |  |
| @code | 1..1 | SHALL |  | [1141-1784](#C_1141-1784) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-1785](#C_1141-1785) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1786](#C_1141-1786) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-2349](#C_1141-2349) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1781).
2. SHALL contain exactly one [1..1] @moodCode="DEF" (CONF:1141-1782).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1774) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.29" (CONF:1141-1776).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2366).
4. SHALL contain exactly one [1..1] code (CONF:1141-1775).
   1. This code SHALL contain exactly one [1..1] @code="MDC\_TIME\_SYNC\_PROTOCOL" numerical value: 68220 (CONF:1141-1777).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1778).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1779).
   4. This code SHOULD contain zero or one [0..1] @displayName (CONF:1141-1780).  
      Note: It is highly recommended that at least the ref id be displayed.
5. SHOULD contain zero or one [0..1] text (CONF:1141-2399).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2400).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2401).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2402).
6. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:1141-1783).
   1. This value SHALL contain exactly one [1..1] @code (CONF:1141-1784).  
      Note: The codes currently defined have reference ids (ref ids) MDC\_TIME\_SYNC\_NONE, MDC\_TIME\_SYNC\_NTPV3, MDC\_TIME\_SYNC\_NTPV4, MDC\_TIME\_SYNC\_SNTPV4, MDC\_TIME\_SYNC\_SNTPV4330, MDC\_TIME\_SYNC\_BTV1, MDC\_TIME\_SYNC\_RADIO, MDC\_TIME\_SYNC\_HL7\_NCK, MDC\_TIME\_SYNC\_CDMA, MDC\_TIME\_SYNC\_GSM, MDC\_TIME\_SYNC\_EBWW, MDC\_TIME\_SYNC\_USB\_SOF. More may be added.
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1785).
   3. This value SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1786).
   4. This value SHOULD contain zero or one [0..1] @displayName (CONF:1141-2349).

PHM Measurement Waveform Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17 (open)]

Table 49: PHM Measurement Waveform Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) (required) |  |

The PHM Measurement Waveform observation represents a series of periodic observations for a given length of time using the SLIST\_PQ data type. The use of this template is in association with the PHM Metric Waveform Series Observation. The PHM Metric Waveform Series Observation has an entryRelationship/observation element that acts as a container for the PHM Measurement Waveform Sample Period observation that specifies the information about the data periodicity of the wave form and this PHM Measurement Waveform Observation that contains the data. In PHM devices these types of measurements are typically from IEEE 11073 Real Time Sample Array (RTSA) metric objects. Measurement data from RTSAs are sent on the wire as a sequence of data points that match the SLIST\_PQ data type almost perfectly. However, PHM devices can also send data from IEEE 11073 Numeric Metric objects periodically. On the wire there is but a single measurement in the packet but several such measurement packets are sent. The collector of that data could itself determine the frequency of the data noting, for example, that measurements come once per second, and combine a sequence of N of them to populate the SLIST\_PQ data type value element of this observation entry and determine the associated information about the period to populate the PHM Measurement Waveform Sample Period Observation to generate the final PHM Measurement Waveform Series Observation.

Table 50: PHM Measurement Waveform Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2194](#C_1141-2194) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-2195](#C_1141-2195) | EVN |
| templateId | 1..1 | SHALL |  | [1141-2198](#C_1141-2198) |  |
| @root | 1..1 | SHALL |  | [1141-2201](#C_1141-2201) | 2.16.840.1.113883.10.20.36.36 |
| @extension | 1..1 | SHALL |  | [1141-2367](#C_1141-2367) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-2340](#C_1141-2340) |  |
| text | 0..1 | SHOULD |  | [1141-2403](#C_1141-2403) |  |
| reference | 0..1 | SHOULD |  | [1141-2404](#C_1141-2404) |  |
| @value | 0..1 | SHOULD |  | [1141-2405](#C_1141-2405) |  |
| statusCode | 1..1 | SHALL |  | [1141-2342](#C_1141-2342) |  |
| @code | 1..1 | SHALL |  | [1141-2343](#C_1141-2343) | completed |
| value | 0..1 | MAY | SLIST\_PQ | [1141-2197](#C_1141-2197) |  |
| origin | 1..1 | SHALL |  | [1141-2199](#C_1141-2199) |  |
| @value | 1..1 | SHALL |  | [1141-2202](#C_1141-2202) |  |
| @unit | 0..1 | MAY |  | [1141-2203](#C_1141-2203) |  |
| scale | 1..1 | SHALL |  | [1141-2200](#C_1141-2200) |  |
| @value | 1..1 | SHALL |  | [1141-2204](#C_1141-2204) |  |
| @unit | 0..1 | MAY |  | [1141-2205](#C_1141-2205) |  |
| digits | 1..1 | SHALL |  | [1141-2206](#C_1141-2206) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-2194).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-2195).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-2198) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.36" (CONF:1141-2201).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2367).
4. SHALL contain exactly one [1..1] code (CONF:1141-2340).
   1. The fields of the code element **SHALL** be identical to those of the PHM Metric WaveForm Series Observation (CONF:1141-2341).
5. SHOULD contain zero or one [0..1] text (CONF:1141-2403).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-2404).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-2405).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-2406).
6. SHALL contain exactly one [1..1] statusCode (CONF:1141-2342).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" (CONF:1141-2343).
7. MAY contain zero or one [0..1] value with @xsi:type="SLIST\_PQ" (CONF:1141-2197).

The origin entry describes the physical quantity a 0-value in the actual sequence of digits would represent. In most cases, the value will be 0 and the units will be the units of the measurement. However, it could be that the '0' value of the digits represents some 'base' measure of the actual physical quantity, for example it might represent 37 C in a temperature sequence. The units attribute would then be degC.

* 1. The value, if present, SHALL contain exactly one [1..1] origin (CONF:1141-2199).
     1. This origin SHALL contain exactly one [1..1] @value (CONF:1141-2202).
     2. This origin MAY contain zero or one [0..1] @unit (CONF:1141-2203).  
        Note: If the units are dimensionless, '1' is used.

The scale entry describes what factor the digits need to be multiplied by to obtain the actual values. The final values are given by x(i)=xo + s × d(i) where xo is the origin value and s is the scale value and d(i) is the ith digit in the list.

* 1. The value, if present, SHALL contain exactly one [1..1] scale (CONF:1141-2200).
     1. This scale SHALL contain exactly one [1..1] @value (CONF:1141-2204).
     2. This scale MAY contain zero or one [0..1] @unit (CONF:1141-2205).  
        Note: If the units are dimensionless, '1' is used.

The sequence of data as integers. For PHM devices supporting RTSAs this would be the sequence of integers in the Simple-Sa-Observed-Value attribute. The origin and scale values would be derived from the Scale-and-Range-Specification attribute where s = (upper-absolute-value – lower-absolute-value) / (upper-scaled-value – lower-scaled-value)

and

xo = upper-absolute-value – (s × upper-scaled-value)

* 1. The value, if present, SHALL contain exactly one [1..1] digits (CONF:1141-2206).

PHM Measurement Waveform Sample Period Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17 (open)]

Table 51: PHM Measurement Waveform Sample Period Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) (required) |  |

The PHM Waveform Sample observation is the entry that describes the time characteristics (start time and period between each data point) of the actual device waveform data. This entry is part of the PHM Metric Waveform Series observation as one of the entry relationships describing the waveform data. If the waveform is being sent by an IEEE 11073 20601 PHM device, time between each data point is contained in the Sample-period attribute.

Table 52: PHM Measurement Waveform Sample Period Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1042](#C_1141-1042) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1043](#C_1141-1043) | EVN |
| templateId | 1..1 | SHALL |  | [1141-1026](#C_1141-1026) |  |
| @root | 1..1 | SHALL |  | [1141-1033](#C_1141-1033) | 2.16.840.1.113883.10.20.36.13 |
| @extension | 1..1 | SHALL |  | [1141-2358](#C_1141-2358) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1027](#C_1141-1027) | urn:oid:2.16.840.1.113883.5.4 (ActCode) |
| @code | 1..1 | SHALL |  | [1141-1559](#C_1141-1559) | TIME\_ABSOLUTE |
| @codeSystem | 1..1 | SHALL |  | [1141-1560](#C_1141-1560) | 2.16.840.1.113883.5.4 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1561](#C_1141-1561) | ActCode |
| @displayName | 0..1 | MAY |  | [1141-1562](#C_1141-1562) | Absolute Time |
| text | 0..1 | SHOULD |  | [1141-1028](#C_1141-1028) |  |
| reference | 0..1 | SHOULD |  | [1141-1029](#C_1141-1029) |  |
| @value | 0..1 | SHOULD |  | [1141-1030](#C_1141-1030) |  |
| value | 1..1 | SHALL | GLIST\_TS | [1141-1045](#C_1141-1045) | urn:oid:2.16.840.1.113883.5.4 (ActCode) |
| head | 1..1 | SHALL |  | [1141-1046](#C_1141-1046) |  |
| @value | 1..1 | SHALL |  | [1141-1047](#C_1141-1047) |  |
| increment | 1..1 | SHALL |  | [1141-1048](#C_1141-1048) |  |
| @value | 1..1 | SHALL |  | [1141-1049](#C_1141-1049) |  |
| @unit | 1..1 | SHALL |  | [1141-1050](#C_1141-1050) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1042).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-1043).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1026) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.13" Device Waveform observation (CONF:1141-1033).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2358).
4. SHALL contain exactly one [1..1] code (CodeSystem: ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:1141-1027).
   1. This code SHALL contain exactly one [1..1] @code="TIME\_ABSOLUTE" (CONF:1141-1559).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CONF:1141-1560).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="ActCode" (CONF:1141-1561).
   4. This code MAY contain zero or one [0..1] @displayName="Absolute Time" (CONF:1141-1562).
5. SHOULD contain zero or one [0..1] text (CONF:1141-1028).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-1029).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-1030).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-935) (CONF:1141-1036).
6. SHALL contain exactly one [1..1] value with @xsi:type="GLIST\_TS" (CodeSystem: ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:1141-1045).
   1. This value SHALL contain exactly one [1..1] head (CONF:1141-1046).  
      Note: The head element contains the start time of the waveform data.
      1. This head SHALL contain exactly one [1..1] @value (CONF:1141-1047).
   2. This value SHALL contain exactly one [1..1] increment (CONF:1141-1048).  
      Note: This value comes from the sample period attribute in the IEEE 11073 20601 RTSA object
      1. This increment SHALL contain exactly one [1..1] @value (CONF:1141-1049).  
         Note: This value shall be the time between each waveform sample.
      2. This increment SHALL contain exactly one [1..1] @unit (ValueSet: [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839) (CONF:1141-1050).  
         Note: The unit indicates the time units of the interval; milliseconds, seconds, etc.

PHM Metric Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17 (open)]

The PHM Metric observation provides a base template for expressing observations from PHM devices. Use of this template and its derivatives indicates that the measurements were most likely obtained from the device via machine readable transfers and that the device data content conforms to the PCHA requirements. The expected use case where the data meets these expectations is in the primary sequence of the IHE Remote Patient Monitoring (RPM) Profile and/or a PCHA end-to-end architecture implementation. The primary sequence in the IHE RPM profile consists of a PCHA compliant PHM device sending data to a local PCHA compliant collector which then sends the data in the form of an IHE PCD-01 message to a PCHA compliant receiver which then generates the PHMR from the PCD-01 message and patient-supplied demographic information. There is no manual entry of measurement data in the transfer once the device sent its measurements to the collector (an operator may be required to enter data on the medical device but that is not considered a manual entry in this context). The fact that the data came directly from the sensor device means that the MDC 'TYPE' code defines exactly what the measurement is.

The derivative templates of this template differ in the data type of the value.

Since the PHMR is a document meant for international use, it does not mandate what clinical coding system is used to describe the type of the measurement OR if the measurement itself is a code, what clinical coding system is used to describe the measurement. That choice will depend upon the regional requirements and laws. The data being transcoded to this template will always have MDC codes. If a realm-desired mapping to the MDC code does not exist or is not known, a nullFlavor of 'UNK' is used. However, since the MDC code is always available, this implementation guide requires the entry of the MDC code in a translation element. The presence of this MDC code in the translation element also addresses the issue of degeneracy (more than one MDC code maps to the same clinical code) for those situations where knowing the distinctions might be important. This implementation guide encourages additional translation elements to other clinical coding systems.

A downside of this approach is that any realm that accepts the MDC coding system as its preferred coding system and uses the MDC codes for the code@code value will still have to have the MDC translation element making a duplicate.

For convenience the attribute values for some coding systems are provided here:

@codeSystemName         @codeSystem

SNOMED CT                     2.16.840.1.113883.6.96

LOINC                               2.16.840.1.113883.6.1

MDC                                  2.16.840.1.113883.6.24

Table 53: PHM Metric Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1983](#C_1141-1983) |  |
| @moodCode | 1..1 | SHALL |  | [1141-1984](#C_1141-1984) | EVN |
| templateId | 1..1 | SHALL |  | [1141-1965](#C_1141-1965) |  |
| @root | 1..1 | SHALL |  | [1141-1985](#C_1141-1985) | 2.16.840.1.113883.10.20.36.32 |
| @extension | 1..1 | SHALL |  | [1141-2370](#C_1141-2370) | 2015-08-17 |
| code | 1..1 | SHALL |  | [1141-1966](#C_1141-1966) |  |
| @nullFlavor | 0..1 | MAY |  | [1141-2317](#C_1141-2317) | UNK |
| translation | 1..1 | SHALL |  | [1141-1988](#C_1141-1988) |  |
| @code | 0..1 | SHALL |  | [1141-2019](#C_1141-2019) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-2020](#C_1141-2020) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-2021](#C_1141-2021) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-2022](#C_1141-2022) |  |
| text | 0..1 | SHOULD |  | [1141-1968](#C_1141-1968) |  |
| reference | 0..1 | SHOULD |  | [1141-1969](#C_1141-1969) |  |
| @value | 0..1 | SHOULD |  | [1141-1970](#C_1141-1970) |  |
| statusCode | 1..1 | SHALL |  | [1141-1971](#C_1141-1971) |  |
| @code | 1..1 | SHALL |  | [1141-1992](#C_1141-1992) | completed |
| effectiveTime | 1..1 | SHALL |  | [1141-1967](#C_1141-1967) |  |
| value | 1..1 | SHALL |  | [1141-2017](#C_1141-2017) |  |
| author | 1..1 | SHALL |  | [1141-1973](#C_1141-1973) |  |
| assignedAuthor | 1..1 | SHALL |  | [1141-1974](#C_1141-1974) |  |
| id | 1..1 | SHALL |  | [1141-1976](#C_1141-1976) |  |
| @root | 1..1 | SHALL |  | [1141-2023](#C_1141-2023) |  |
| @extension | 1..1 | SHALL |  | [1141-2024](#C_1141-2024) |  |
| @assigningAuthorityName | 1..1 | SHALL |  | [1141-2025](#C_1141-2025) |  |
| assignedAuthoringDevice | 1..1 | SHALL |  | [1141-1975](#C_1141-1975) |  |
| @classCode | 1..1 | SHALL |  | [1141-1996](#C_1141-1996) | DEV |
| @determinerCode | 1..1 | SHALL |  | [1141-1997](#C_1141-1997) | INSTANCE |
| entryRelationship | 0..\* | MAY |  | [1141-2012](#C_1141-2012) |  |

1. SHALL contain exactly one [1..1] @classCode (CONF:1141-1983).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-1984).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1965) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.32" PHM Metric observation (CONF:1141-1985).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2370).
4. SHALL contain exactly one [1..1] code (CONF:1141-1966).
   1. This code MAY contain zero or one [0..1] @nullFlavor="UNK" (CONF:1141-2317).

At least one translation element will always be present containing the IEEE 11073 10101 MDC code.

* 1. This code SHALL contain exactly one [1..1] translation (CONF:1141-1988) such that it  
     Note: Translations to additional coding systems is encouraged.
     1. SHALL contain zero or one [0..1] @code (CONF:1141-2019).  
        Note: This code is typically the value of the TYPE attribute from IEEE 11073 devices or the OBX-3 entry of PCD-01 messages containing the measurement to be represented in this observation element.
     2. SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-2020).
     3. SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-2021).
     4. SHOULD contain zero or one [0..1] @displayName (CONF:1141-2022).

1. SHOULD contain zero or one [0..1] text (CONF:1141-1968).  
   Note: The purpose of this text element is to locate the narrative describing the measurement contents of this entry. The narrative is located in the section containing this entry in the section/text element. The reference points to the location within that section/text element that has the measurement data of this entry.
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-1969).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-1970).
         1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:1141-1991).
2. SHALL contain exactly one [1..1] statusCode (CONF:1141-1971).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CONF:1141-1992).
3. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-1967).  
   Note: Represents the clinically effective time of the measurement, which may be when the measurement was performed if the medical device reports such information when it takes the measurement or it may be when the data was obtained from the device if the device does not report time. 11073 devices are required to report the time of measurement if the data is stored. Recall that all timestamps in a PHMR document that are more precise than to the day must include the time zone.
   1. If a device reports a single time stamp for a measurement and the measurement is not designated as spanning a period of time, the time stamp **SHALL** appear in the value attribute. If a duration value from a measurement duration attribute or waveform series is being represented, the start time **SHALL** appear in the 'low' element and the finish time in the 'high' element and the effectiveTime/@value attribute **SHALL** be absent (CONF:1141-1990).  
      Note: Examples of measurements that would have durations and thus have 'low' (start) and 'high' (end) times would be wave forms, since they extend over a period of time, and exercise sessions.
4. SHALL contain exactly one [1..1] value (CONF:1141-2017).
5. SHALL contain exactly one [1..1] author (CONF:1141-1973).
   1. This author SHALL contain exactly one [1..1] assignedAuthor (CONF:1141-1974).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF:1141-1976).
         1. This id SHALL contain exactly one [1..1] @root (CONF:1141-2023).
         2. This id SHALL contain exactly one [1..1] @extension (CONF:1141-2024).
         3. This id SHALL contain exactly one [1..1] @assigningAuthorityName (CONF:1141-2025).
         4. The @root, @extension, and @assigningAuthorityName **SHALL** be taken from the equivalent attributes of the Device PHMR Product Instance participantRole/id element that generated the measurements referenced in this observation (CONF:1141-1998).
      2. This assignedAuthor SHALL contain exactly one [1..1] assignedAuthoringDevice (CONF:1141-1975).
         1. This assignedAuthoringDevice SHALL contain exactly one [1..1] @classCode="DEV" (CONF:1141-1996).
         2. This assignedAuthoringDevice SHALL contain exactly one [1..1] @determinerCode="INSTANCE" (CONF:1141-1997).

The **entryRelationship** element may be used in any case where an observation further describes or is somehow related to the parent observation. An example might be the context  observations of the IEEE 11073 20601 Glucometer specialization where the context measurments describes the situation around the taking of a concentration reading, such as in a state of fasting, time of day, exercise, general state of health, etc.. The set of context observations could be placed in the **entryRelationship/observation** element in lieu of placing it in its own PHM Metric observation element.. Facet OBX entries in PCD-01 messages could also be expressed in this **entryRelationship/observation** element, for example the modality of a pulse oximeter measurement.

1. MAY contain zero or more [0..\*] entryRelationship (CONF:1141-2012).

PHM Metric Coded Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17 (open)]

Table 54: PHM Metric Coded Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) (optional) |  |

The PHM Metric Coded observation is used when the PHM device delivers a measurement whose value is a code such as a Glucose meal context. A PHM device always delivers the measurement code using the MDC coding system. The value@code, value@codeSystem, and value@codeSystemName attributes is populated using the realm desired clinical coding system for measurement values which may be different than the desired clinical coding system for measurement types. If the provided MDC code cannot be translated to the desired clinical coding system, the code@nullFlavor attribute is set to OTH. In all cases, a translation element will be populated with the MDC code, and additional translation elements to other clinical coding systems is encouraged.

Table 55: PHM Metric Coded Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17) | | | | | |
| templateId | 1..1 | SHALL |  | [1141-2112](#C_1141-2112) |  |
| @root | 1..1 | SHALL |  | [1141-2113](#C_1141-2113) | 16.840.1.113883.10.20.36.34 |
| @extension | 1..1 | SHALL |  | [1141-2114](#C_1141-2114) | 2015-08-17 |
| value | 1..1 | SHALL | CD | [1141-2106](#C_1141-2106) |  |
| @nullFlavor | 0..1 | MAY |  | [1141-2321](#C_1141-2321) | UNK |
| translation | 1..1 | SHALL |  | [1141-2111](#C_1141-2111) |  |
| @code | 1..1 | SHALL |  | [1141-2322](#C_1141-2322) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-2323](#C_1141-2323) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-2324](#C_1141-2324) | MDC |
| @displayName | 0..1 | SHOULD |  | [1141-2325](#C_1141-2325) |  |

1. Conforms to [PHM Metric Observation](#E_PHM_Metric_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17).
2. SHALL contain exactly one [1..1] templateId (CONF:1141-2112) such that it
   1. SHALL contain exactly one [1..1] @root="16.840.1.113883.10.20.36.34" (CONF:1141-2113).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2114).

**Value**

Since the PHMR is a document meant for international use, it does not mandate what clinical coding system is used to describe the type of the measurement OR if the measurement itself is a code, what clinical coding system is used to describe the measurement. That choice will depend upon the regional requirements and laws. The data being transcoded to this template will always have MDC codes. If a realm-desired mapping to the MDC code does not exist or is not known, a nullFlavor of 'OTH' is used. However, since the MDC code is always available, this implementation guide requires the entry of the MDC code in a translation element. The presence of this MDC code in the translation element also addresses the issue of degeneracy (more than one MDC code maps to the same clinical code) for those situations where knowing the distinctions might be important. This implementation guide encourages additional translation elements to other clinical coding systems.

1. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:1141-2106).
   1. This value MAY contain zero or one [0..1] @nullFlavor="UNK" (CONF:1141-2321).

When a PHM device reports a measurement as a code it uses the MDC coding system and thus that code will always be available. This implementation guide, being developed for international use, allows the realm to decide which clinical coding system to use for the code@code value which may be nullFlavor if no mapping from the MDC code is known. However, given that the MDC code is always available, this implementation guide reserves at least one translation element for that code.

* 1. This value SHALL contain exactly one [1..1] translation (CONF:1141-2111) such that it  
     Note: Translations to additional coding systems is encouraged.
     1. SHALL contain exactly one [1..1] @code (CONF:1141-2322).
     2. SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-2323).
     3. SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-2324).
     4. SHOULD contain zero or one [0..1] @displayName (CONF:1141-2325).

PHM Metric Enum Integer Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17 (open)]

Table 56: PHM Metric Enum Integer Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) (optional) |  |

The PHM Metric Enum Integer observation is a template for the reporting of PHM data that is in the form of an ASN.1 BITs field. This method of reporting uses each bit of a 16-bit or 32-bit number to indicate something. There is no data type in HL7 that represents such an encoding. Proper reporting of this ASN.1 BITs data requires the creation of a Value Set that gives codes and their meanings for each of the BITs entries. In the absence of such a value set, this observation reports just the 16 bit or 32 bit number as an integer. The only means of decoding this information is to use the MDC code provided in the code element. The meaning for each of the BITs in the number is given in the IEEE specialization document that defines the MDC code.

There is extensive use of this type of measurement in the independent living specialization where one has detectors that indicate whether or not a person has fallen, smoke is present, person has left a room, etc. Otherwise, the most common use of this type of reporting in most specializations is for device and sensor status information such as 'battery low'. Regardless, each of these ASN.1 BITs settings also has a standardized set of strings that are defined by the specialization for each bit setting. Thus a human can obtain the meaning of a bit setting by reading the associated string. For example, a fall sensor device sets bit 0 to 1 when a fall is detected and its string code is "fall-detected". This template encourages implementers to use an optional second value element of data type 'text' to list the standardized ASN.1 strings associated with the given BITs field if known. Note that IEEE MDER encoding defines bit settings backwards; bit 0 is the high order bit!

Table 57: PHM Metric Enum Integer Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2298](#C_1141-2298) |  |
| @moodCode | 1..1 | SHALL |  | [1141-2299](#C_1141-2299) | EVN |
| templateId | 1..1 | SHALL |  | [1141-2302](#C_1141-2302) |  |
| @root | 1..1 | SHALL |  | [1141-2318](#C_1141-2318) | 16.840.1.113883.10.20.36.38 |
| @extension | 1..1 | SHALL |  | [1141-2369](#C_1141-2369) | 2015-08-17 |
| value | 1..1 | SHALL | INT | [1141-2301](#C_1141-2301) |  |
| value | 0..1 | SHOULD | Text | [1141-2303](#C_1141-2303) |  |
| list | 1..1 | SHALL |  | [1141-2304](#C_1141-2304) |  |

1. Conforms to [PHM Metric Observation](#E_PHM_Metric_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode (CONF:1141-2298).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-2299).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-2302) such that it
   1. SHALL contain exactly one [1..1] @root="16.840.1.113883.10.20.36.38" (CONF:1141-2318).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2369).
5. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:1141-2301).

If known, a second value element containing the ASN.1 text string designators for each of the active BITs settings as a list would provide a human readable meaning for the BITs value. For example, in the Glucometer specialization the device and sensor status annunciation measurement (MDC reference id MDC\_GLU\_METER\_DEV\_STATUS) BITs field text string designators is:

bit 0: device-battery-low

bit 1: sensor-malfunction

bit 2: sensor-sample-size-insufficient

bit 3: sensor-strip-insertion

bit 4: sensor-strip-type-incorrect

bit 5: sensor-result-too-high

bit 6: sensor-result-too-low

bit 7: sensor-temp-too-high

bit 8: sensor-temp-too-low

bit 9: sensor-read-interrupt

bit 10: device-gen-fault

bit 11: sensor-temp-out-of-range

The reader will need to know that 'bit 0' is actually the high-order bit and bit 15 (in this case) is the low order bit and that the above event occurs when the bit is set.

1. SHOULD contain zero or one [0..1] value with @xsi:type="Text" (CONF:1141-2303).
   1. The value, if present, SHALL contain exactly one [1..1] list (CONF:1141-2304).

PHM Metric Numeric Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17 (open)]

Table 58: PHM Metric Numeric Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) (optional)  [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) (optional) |  |

The PHM Metric numeric observation are for those measurements which are physical quantities.

Table 59: PHM Metric Numeric Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2128](#C_1141-2128) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-2129](#C_1141-2129) | EVN |
| templateId | 1..1 | SHALL |  | [1141-2064](#C_1141-2064) |  |
| @root | 1..1 | SHALL |  | [1141-2065](#C_1141-2065) | 2.16.840.1.113883.10.20.36.33 |
| @extension | 1..1 | SHALL |  | [1141-2066](#C_1141-2066) | 2015-08-17 |
| value | 1..1 | SHALL | PQ | [1141-2061](#C_1141-2061) |  |
| @value | 1..1 | SHALL |  | [1141-2062](#C_1141-2062) |  |
| @unit | 1..1 | SHALL |  | [1141-2063](#C_1141-2063) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |

1. Conforms to [PHM Metric Observation](#E_PHM_Metric_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-2128).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:1141-2129).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-2064) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.33" (CONF:1141-2065).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2066).
5. SHALL contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1141-2061).  
   Note: Though there are specific data types provided for maximum, minimum, or standard deviation values, the PQ data type is used for these cases as well. Whether or not the value is a maximum, minimum, or standard deviation is given by the code element.
   1. This value SHALL contain exactly one [1..1] @value (CONF:1141-2062).
   2. This value SHALL contain exactly one [1..1] @unit, which SHALL be selected from ValueSet [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:1141-2063).

PHM Metric String Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17 (open)]

Table 60: PHM Metric String Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) (optional) |  |

The PHM Metric String observation is used when the PHM device delivers a measurement whose value is a human readable string. Such a measurement type is used rarely as it cannot be interpreted by a machine.

Table 61: PHM Metric String Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2157](#C_1141-2157) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-2158](#C_1141-2158) | EVN |
| templateId | 1..1 | SHALL |  | [1141-2117](#C_1141-2117) |  |
| @root | 1..1 | SHALL |  | [1141-2124](#C_1141-2124) | 16.840.1.113883.10.20.36.35 |
| @extension | 1..1 | SHALL |  | [1141-2125](#C_1141-2125) | 2015-08-17 |
| value | 1..1 | SHALL | ST | [1141-2116](#C_1141-2116) |  |

1. Conforms to [PHM Metric Observation](#E_PHM_Metric_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-2157).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:1141-2158).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-2117) such that it
   1. SHALL contain exactly one [1..1] @root="16.840.1.113883.10.20.36.35" (CONF:1141-2124).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2125).
5. SHALL contain exactly one [1..1] value with @xsi:type="ST" (CONF:1141-2116).  
   Note: String measurements reported from PHM devices are very rare.

PHM Metric Waveform Series Observation - Draft

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17 (open)]

Table 62: PHM Metric Waveform Series Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) (optional)  [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) (optional) | [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation)  [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) |

The PHM Waveform Series Observation describes a waveform measurement from a medical device. The waveform may contain several data points and thus span an interval of time. The waveform data is represented in the PHM Metric Waveform Observation using an SLIST\_PQ data type. However, the SLIST\_PQ data type is a generic sequence of scaled physical quantities with no implied semantic context; it could be a list of statistics. It is necessary to indicate that the sequence of numbers represents a set of periodic measurements.

To describe the device waveform series data two additional waveform observation entry types are present in the entry relationship elements of this observation, the PHM Measurement Waveform Sample Period Observation entry describing the start time and period, and one or more PHM Metric Waveform Observation entries containing the data. An entry relationship containing a reference to unstructured content is also a possibility, such as the waveform itself as a jpg image,

Table 63: PHM Metric Waveform Series Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-2238](#C_1141-2238) | OBSSER |
| @moodCode | 1..1 | SHALL |  | [1141-2239](#C_1141-2239) | EVN |
| templateId | 1..1 | SHALL |  | [1141-2207](#C_1141-2207) |  |
| @root | 1..1 | SHALL |  | [1141-2233](#C_1141-2233) | 2.16.840.1.113883.10.20.36.37 |
| @extension | 1..1 | SHALL |  | [1141-2371](#C_1141-2371) | 2015-08-17 |
| value | 1..1 | SHALL |  | [1141-2305](#C_1141-2305) |  |
| @nullFlavor | 1..1 | SHALL |  | [1141-2306](#C_1141-2306) | NA |
| entryRelationship | 1..1 | SHALL |  | [1141-2326](#C_1141-2326) |  |
| @typeCode | 1..1 | SHALL |  | [1141-2327](#C_1141-2327) | COMP |
| observation | 1..1 | SHALL |  | [1141-2328](#C_1141-2328) |  |
| @classCode | 1..1 | SHALL |  | [1141-2329](#C_1141-2329) | OBSCOR |
| @moodCode | 1..1 | SHALL |  | [1141-2330](#C_1141-2330) | EVN |
| code | 1..1 | SHALL |  | [1141-2331](#C_1141-2331) |  |
| @nullFlavor | 1..1 | SHALL |  | [1141-2334](#C_1141-2334) | NA |
| entryRelationship | 1..1 | SHALL |  | [1141-2332](#C_1141-2332) |  |
| @typeCode | 1..1 | SHALL |  | [1141-2335](#C_1141-2335) | COMP |
| observation | 1..1 | SHALL |  | [1141-2336](#C_1141-2336) | [PHM Measurement Waveform Sample Period Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17](#E_PHM_Measurement_Waveform_Sample_Perio) |
| entryRelationship | 1..1 | SHALL |  | [1141-2337](#C_1141-2337) |  |
| @typeCode | 1..1 | SHALL |  | [1141-2338](#C_1141-2338) | COMP |
| observation | 1..1 | SHALL |  | [1141-2339](#C_1141-2339) | [PHM Measurement Waveform Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17](#E_PHM_Measurement_Waveform_Observation) |
| entryRelationship | 0..\* | SHOULD |  | [1141-2227](#C_1141-2227) |  |
| @typeCode | 1..1 | SHALL |  | [1141-2258](#C_1141-2258) | COMP |
| observationMedia | 1..1 | SHALL |  | [1141-2228](#C_1141-2228) |  |
| @classCode | 1..1 | SHALL |  | [1141-2262](#C_1141-2262) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-2263](#C_1141-2263) | EVN |
| id | 0..\* | SHOULD |  | [1141-2229](#C_1141-2229) |  |
| @root | 0..1 | SHOULD |  | [1141-2259](#C_1141-2259) |  |
| value | 1..1 | SHALL |  | [1141-2230](#C_1141-2230) |  |
| @mediaType | 1..1 | SHOULD |  | [1141-2261](#C_1141-2261) |  |
| reference | 1..1 | SHALL |  | [1141-2231](#C_1141-2231) |  |
| @value | 1..1 | SHALL |  | [1141-2260](#C_1141-2260) |  |

1. Conforms to [PHM Metric Observation](#E_PHM_Metric_Observation) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17).
2. SHALL contain exactly one [1..1] @classCode="OBSSER" (CONF:1141-2238).
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-2239).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-2207) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.37" (CONF:1141-2233).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2371).
5. SHALL contain exactly one [1..1] value (CONF:1141-2305).
   1. This value SHALL contain exactly one [1..1] @nullFlavor="NA" (CONF:1141-2306).
6. SHALL contain exactly one [1..1] entryRelationship (CONF:1141-2326).
   1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-2327).
   2. This entryRelationship SHALL contain exactly one [1..1] observation (CONF:1141-2328).  
      Note: The purpose of this observation element is to correlate or bind the waveform period information in the PHM measurement period observation and the actual waveform data in the PHM Metric Waveform observation together to describe the wave series.
      1. This observation SHALL contain exactly one [1..1] @classCode="OBSCOR" (CONF:1141-2329).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:1141-2330).
      3. This observation SHALL contain exactly one [1..1] code (CONF:1141-2331).
         1. This code SHALL contain exactly one [1..1] @nullFlavor="NA" (CONF:1141-2334).
      4. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:1141-2332).
         1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-2335).
         2. This entryRelationship SHALL contain exactly one [1..1] [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17) (CONF:1141-2336).
      5. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:1141-2337).
         1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-2338).
         2. This entryRelationship SHALL contain exactly one [1..1] [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17) (CONF:1141-2339).
7. SHOULD contain zero or more [0..\*] entryRelationship (CONF:1141-2227).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-2258).
   2. The entryRelationship, if present, SHALL contain exactly one [1..1] observationMedia (CONF:1141-2228).
      1. This observationMedia SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-2262).
      2. This observationMedia SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:1141-2263).
      3. This observationMedia SHOULD contain zero or more [0..\*] id (CONF:1141-2229).
         1. The id, if present, SHOULD contain zero or one [0..1] @root (CONF:1141-2259).
      4. This observationMedia SHALL contain exactly one [1..1] value (CONF:1141-2230).
         1. This value SHOULD contain exactly one [1..1] @mediaType (CONF:1141-2261).
         2. This value SHALL contain exactly one [1..1] reference (CONF:1141-2231).
            1. This reference SHALL contain exactly one [1..1] @value (CONF:1141-2260).

PHMR Result Organizer - Draft

[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17 (open)]

Table 64: PHMR Result Organizer Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Results Section (entries required)](#S_PHMR_Results_Section_entries_required) (required) | [PHM Metric Coded Observation](#E_PHM_Metric_Coded_Observation)  [PHM Metric Enum Integer Observation](#E_PHM_Metric_Enum_Integer_Observation)  [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation)  [PHM Metric String Observation](#E_PHM_Metric_String_Observation)  [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) |

This template provides a mechanism for grouping result observations. This grouping also includes grouping a set of measurements in time. For PHM devices, result observations are those that are not classified as vital signs.

Table 65: PHMR Result Organizer Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1404](#C_1141-1404) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
| @moodCode | 1..1 | SHALL |  | [1141-1405](#C_1141-1405) | urn:oid:2.16.840.1.113883.5.1001 (ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [1141-1399](#C_1141-1399) |  |
| @root | 1..1 | SHALL |  | [1141-1406](#C_1141-1406) | 2.16.840.1.113883.10.20.36.16 |
| @extension | 1..1 | SHALL |  | [1141-2360](#C_1141-2360) | 2015-08-17 |
| id | 1..\* | SHALL |  | [1141-1408](#C_1141-1408) |  |
| code | 0..1 | MAY |  | [1141-2417](#C_1141-2417) |  |
| statusCode | 1..1 | SHALL |  | [1141-1401](#C_1141-1401) |  |
| @code | 1..1 | SHALL |  | [1141-1411](#C_1141-1411) | urn:oid:2.16.840.1.113883.11.20.9.39 (Result Status) |
| effectiveTime | 0..1 | MAY |  | [1141-1402](#C_1141-1402) |  |
| low | 1..1 | SHALL |  | [1141-1413](#C_1141-1413) |  |
| high | 1..1 | SHALL |  | [1141-1414](#C_1141-1414) |  |
| component | 0..\* | MAY |  | [1141-1398](#C_1141-1398) |  |
| observation | 1..1 | SHALL |  | [1141-1403](#C_1141-1403) | [PHM Metric Numeric Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17](#E_PHM_Metric_Numeric_Observation) |
| component | 0..\* | MAY |  | [1141-1417](#C_1141-1417) |  |
| observation | 1..1 | SHALL |  | [1141-1419](#C_1141-1419) | [PHM Metric Waveform Series Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17](#E_PHM_Metric_Waveform_Series_Observation) |
| component | 0..\* | MAY |  | [1141-1418](#C_1141-1418) |  |
| observation | 1..1 | SHALL |  | [1141-1420](#C_1141-1420) | [PHM Metric Coded Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17](#E_PHM_Metric_Coded_Observation) |
| component | 0..\* | MAY |  | [1141-2159](#C_1141-2159) |  |
| observation | 1..1 | SHALL |  | [1141-2160](#C_1141-2160) | [PHM Metric String Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17](#E_PHM_Metric_String_Observation) |
| component | 0..\* | MAY |  | [1141-2319](#C_1141-2319) |  |
| observation | 1..1 | SHALL |  | [1141-2320](#C_1141-2320) | [PHM Metric Enum Integer Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17](#E_PHM_Metric_Enum_Integer_Observation) |

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1141-1404).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:1141-1405).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1399) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.16" (CONF:1141-1406).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2360).
4. SHALL contain at least one [1..\*] id (CONF:1141-1408).
5. MAY contain zero or one [0..1] code (CONF:1141-2417).
6. SHALL contain exactly one [1..1] statusCode (CONF:1141-1401).  
   Note: For IEEE 11073 20601 devices this would most likely be 'completed'
   1. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet [Result Status](#Result_Status) urn:oid:2.16.840.1.113883.11.20.9.39 STATIC (CONF:1141-1411).
7. MAY contain zero or one [0..1] effectiveTime (CONF:1141-1402).  
   Note: The effectiveTime is an interval that spans the effectiveTimes of the contained result observations. Because all contained result observations have a required time stamp, it is not required that this effectiveTime be populated.
   1. The effectiveTime, if present, SHALL contain exactly one [1..1] low (CONF:1141-1413).
   2. The effectiveTime, if present, SHALL contain exactly one [1..1] high (CONF:1141-1414).

At least one of these components must have an observation element.

1. MAY contain zero or more [0..\*] component (CONF:1141-1398) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17) (CONF:1141-1403).
2. MAY contain zero or more [0..\*] component (CONF:1141-1417) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17) (CONF:1141-1419).
3. MAY contain zero or more [0..\*] component (CONF:1141-1418) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Coded Observation](#E_PHM_Metric_Coded_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17) (CONF:1141-1420).
4. MAY contain zero or more [0..\*] component (CONF:1141-2159) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric String Observation](#E_PHM_Metric_String_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17) (CONF:1141-2160).
5. MAY contain zero or more [0..\*] component (CONF:1141-2319) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Enum Integer Observation](#E_PHM_Metric_Enum_Integer_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17) (CONF:1141-2320).

PHMR Vital Signs Organizer - Draft

[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17 (open)]

Table 66: PHMR Vital Signs Organizer Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Vital Signs Section (entries required)](#S_PHMR_Vital_Signs_Section_entries_requ) (required) | [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation)  [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) |

This template provides a mechanism for grouping vital signs (e.g., grouping systolic blood pressure and diastolic blood pressure). It also provides a means of more efficiently reporting multiple measurements of a single set of vital signs over a period of time, such as a sequence of heart rates and/or oxygen saturation values from a pulse oximeter.

Table 67: PHMR Vital Signs Organizer Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1430](#C_1141-1430) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER |
| @moodCode | 1..1 | SHALL |  | [1141-1431](#C_1141-1431) | urn:oid:2.16.840.1.113883.5.1001 (ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [1141-1426](#C_1141-1426) |  |
| @root | 1..1 | SHALL |  | [1141-1432](#C_1141-1432) | 2.16.840.1.113883.10.20.36.2 |
| @extension | 1..1 | SHALL |  | [1141-2362](#C_1141-2362) | 2015-08-17 |
| id | 1..\* | SHALL |  | [1141-1434](#C_1141-1434) |  |
| code | 1..1 | SHALL |  | [1141-1428](#C_1141-1428) |  |
| @code | 1..1 | SHALL |  | [1141-1438](#C_1141-1438) | 8716-3 |
| @codeSystem | 1..1 | SHALL |  | [1141-1439](#C_1141-1439) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| statusCode | 1..1 | SHALL |  | [1141-1427](#C_1141-1427) |  |
| @code | 1..1 | SHALL |  | [1141-1435](#C_1141-1435) | urn:oid:2.16.840.1.113883.5.14 (ActStatus) = completed |
| effectiveTime | 0..1 | MAY |  | [1141-1436](#C_1141-1436) |  |
| component | 0..\* | MAY |  | [1141-1425](#C_1141-1425) |  |
| observation | 1..1 | SHALL |  | [1141-1429](#C_1141-1429) | [PHM Metric Numeric Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17](#E_PHM_Metric_Numeric_Observation) |
| component | 0..\* | MAY |  | [1141-1440](#C_1141-1440) |  |
| observation | 1..1 | SHALL |  | [1141-1441](#C_1141-1441) | [PHM Metric Waveform Series Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17](#E_PHM_Metric_Waveform_Series_Observation) |

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" CLUSTER (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1141-1430).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:1141-1431).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1426) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.2" (CONF:1141-1432).
   2. SHALL contain exactly one [1..1] @extension="2015-08-17" (CONF:1141-2362).
4. SHALL contain at least one [1..\*] id (CONF:1141-1434).
5. SHALL contain exactly one [1..1] code (CONF:1141-1428).
   1. This code SHALL contain exactly one [1..1] @code="8716-3" Vital signs (CONF:1141-1438).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1 " (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1141-1439).
6. SHALL contain exactly one [1..1] statusCode (CONF:1141-1427).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus urn:oid:2.16.840.1.113883.5.14 STATIC) (CONF:1141-1435).
7. MAY contain zero or one [0..1] effectiveTime (CONF:1141-1436).  
   Note: The effectiveTime is an interval that spans the effectiveTimes of the contained vital signs observations. Because all contained vital signs observations have a required time stamp, it is not required that this effectiveTime be populated.

At least one of the components must have an observation entry.

1. MAY contain zero or more [0..\*] component (CONF:1141-1425) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17) (CONF:1141-1429).
2. MAY contain zero or more [0..\*] component (CONF:1141-1440) such that it
   1. SHALL contain exactly one [1..1] [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17) (CONF:1141-1441).

# Template Ids in This Guide

Table 68: Template List

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Patient Generated Universal Realm Document Header](#D_Patient_Generated_Universal_Realm_Doc) | document | urn:hl7ii:2.16.840.1.113883.10.20.29:2015-08-17 |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) | document | urn:hl7ii:2.16.840.1.113883.10.20.36:2015-08-17 |
| [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17 |
| [PHMR Results Section (entries required)](#S_PHMR_Results_Section_entries_required) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17 |
| [PHMR Vital Signs Section (entries required)](#S_PHMR_Vital_Signs_Section_entries_requ) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17 |
| [Device Accuracy Observation](#E_Device_Accuracy_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17 |
| [Device Firmware Revision Information Observation](#E_Device_Firmware_Revision_Information_) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17 |
| [Device GMDN Information Observation](#E_Device_GMDN_Information_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17 |
| [Device Hardware Version Information Observation](#E_Device_Hardware_Version_Information_O) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17 |
| [Device Information Observation](#E_Device_Information_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17 |
| [Device Information Organizer](#E_Device_Information_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17 |
| [Device Manufacturer Information Observation](#E_Device_Manufacturer_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17 |
| [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17 |
| [Device Model Number Information Observation](#E_Device_Model_Number_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17 |
| [Device Part Number Information Observation](#E_Device_Part_Number_Information_Observ) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17 |
| [Device PCHA Version Information Observation](#E_Device_PCHA_Version_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17 |
| [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17 |
| [Device Protocol Information Observation](#E_Device_Protocol_Information_Observati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17 |
| [Device Regulation Status Information Observation](#E_Device_Regulation_Status_Information_) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17 |
| [Device Resolution Observation](#E_Device_Resolution_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17 |
| [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17 |
| [Device Serial Number Information Observation](#E_Device_Serial_Number_Information_Obse) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17 |
| [Device Software Revison Information Observation](#E_Device_Software_Revison_Information_O) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17 |
| [Device Specification Unspecified Information Observation](#E_Device_Specification_Unspecified_Info) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17 |
| [Device Time Synchronization Information Observation](#E_Device_Time_Synchronization_Informati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17 |
| [PHM Metric Coded Observation](#E_PHM_Metric_Coded_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17 |
| [PHM Metric Enum Integer Observation](#E_PHM_Metric_Enum_Integer_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17 |
| [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17 |
| [PHM Metric Observation](#E_PHM_Metric_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17 |
| [PHM Metric String Observation](#E_PHM_Metric_String_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17 |
| [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17 |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17 |
| [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17 |

Table 69: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Patient Generated Universal Realm Document Header](#D_Patient_Generated_Universal_Realm_Doc) | document | urn:hl7ii:2.16.840.1.113883.10.20.29:2015-08-17 |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) | document | urn:hl7ii:2.16.840.1.113883.10.20.36:2015-08-17 |
| [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.1:2015-08-17 |
| [Device Information Organizer](#E_Device_Information_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.4:2015-08-17 |
| [Device Accuracy Observation](#E_Device_Accuracy_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.3:2015-08-17 |
| [Device Firmware Revision Information Observation](#E_Device_Firmware_Revision_Information_) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.18:2015-08-17 |
| [Device GMDN Information Observation](#E_Device_GMDN_Information_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.19:2015-08-17 |
| [Device Hardware Version Information Observation](#E_Device_Hardware_Version_Information_O) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.20:2015-08-17 |
| [Device Manufacturer Information Observation](#E_Device_Manufacturer_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.21:2015-08-17 |
| [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.5:2015-08-17 |
| [Device Model Number Information Observation](#E_Device_Model_Number_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.22:2015-08-17 |
| [Device Part Number Information Observation](#E_Device_Part_Number_Information_Observ) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.23:2015-08-17 |
| [Device PCHA Version Information Observation](#E_Device_PCHA_Version_Information_Obser) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.27:2015-08-17 |
| [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.9:2015-08-17 |
| [Device Protocol Information Observation](#E_Device_Protocol_Information_Observati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.30:2015-08-17 |
| [Device Regulation Status Information Observation](#E_Device_Regulation_Status_Information_) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.28:2015-08-17 |
| [Device Resolution Observation](#E_Device_Resolution_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.6:2015-08-17 |
| [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.10:2015-08-17 |
| [Device Serial Number Information Observation](#E_Device_Serial_Number_Information_Obse) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.26:2015-08-17 |
| [Device Software Revison Information Observation](#E_Device_Software_Revison_Information_O) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.24:2015-08-17 |
| [Device Specification Unspecified Information Observation](#E_Device_Specification_Unspecified_Info) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.25:2015-08-17 |
| [Device Time Synchronization Information Observation](#E_Device_Time_Synchronization_Informati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.29:2015-08-17 |
| [PHMR Results Section (entries required)](#S_PHMR_Results_Section_entries_required) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.14:2015-08-17 |
| [PHMR Result Organizer](#E_PHMR_Result_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.16:2015-08-17 |
| [PHM Metric Coded Observation](#E_PHM_Metric_Coded_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.34:2015-08-17 |
| [PHM Metric Enum Integer Observation](#E_PHM_Metric_Enum_Integer_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.38:2015-08-17 |
| [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17 |
| [PHM Metric String Observation](#E_PHM_Metric_String_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.35:2015-08-17 |
| [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17 |
| [PHMR Vital Signs Section (entries required)](#S_PHMR_Vital_Signs_Section_entries_requ) | section | urn:hl7ii:2.16.840.1.113883.10.20.36.15:2015-08-17 |
| [PHMR Vital Signs Organizer](#E_PHMR_Vital_Signs_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.2:2015-08-17 |
| [PHM Metric Numeric Observation](#E_PHM_Metric_Numeric_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.33:2015-08-17 |
| [PHM Metric Waveform Series Observation](#E_PHM_Metric_Waveform_Series_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.37:2015-08-17 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.36:2015-08-17 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.13:2015-08-17 |
| [Device Information Observation](#E_Device_Information_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.17:2015-08-17 |
| [PHM Metric Observation](#E_PHM_Metric_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.36.32:2015-08-17 |

# Value Sets In This Guide

Table 70: HL7 BasicConfidentialityKind

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: HL7 BasicConfidentialityKind urn:oid:2.16.840.1.113883.1.11.16926  A value set of HL7 Code indication the level of confidentiality an act.  Value Set Source: [http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary\_tables/infrastructure/vocabulary/vocabulary.html](http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vocabulary.html%20) | | | |
| Code | Code System | Code System OID | Print Name |
| N | ConfidentialityCode | urn:oid:2.16.840.1.113883.5.25 | normal |
| R | ConfidentialityCode | urn:oid:2.16.840.1.113883.5.25 | restricted |
| V | ConfidentialityCode | urn:oid:2.16.840.1.113883.5.25 | very restricted |

Table 71: ResponsibleParty

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: ResponsibleParty urn:oid:2.16.840.1.113883.1.11.19830  A value set of applicable RoleCodes indicating the role played by a party who has legal responsibility for another party.  Value Set Source: <http://www.hl7.org> | | | |
| Code | Code System | Code System OID | Print Name |
| RESPRSN | RoleCode | urn:oid:2.16.840.1.113883.5.111 | responsible party |
| EXCEST | RoleCode | urn:oid:2.16.840.1.113883.5.111 | executor of estate |
| GUADLTM | RoleCode | urn:oid:2.16.840.1.113883.5.111 | guardian ad lidem |
| GUARD | RoleCode | urn:oid:2.16.840.1.113883.5.111 | guardian |
| POWATT | RoleCode | urn:oid:2.16.840.1.113883.5.111 | power of attorney |
| DPOWATT | RoleCode | urn:oid:2.16.840.1.113883.5.111 | durable power of attorney |
| HPOWATT | RoleCode | urn:oid:2.16.840.1.113883.5.111 | healthcare power of attorney |
| SPOWATT | RoleCode | urn:oid:2.16.840.1.113883.5.111 | special power of attorney |

Table 72: Language

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Language urn:oid:2.16.840.1.113883.1.11.11526  A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes.  Value Set Source: <http://www.loc.gov/standards/iso639-2/php/code_list.php> | | | |
| Code | Code System | Code System OID | Print Name |
| aa | Language | urn:oid:2.16.840.1.113883.6.121 | Afar |
| ab | Language | urn:oid:2.16.840.1.113883.6.121 | Abkhazian |
| ace | Language | urn:oid:2.16.840.1.113883.6.121 | Achinese |
| ach | Language | urn:oid:2.16.840.1.113883.6.121 | Acoli |
| ada | Language | urn:oid:2.16.840.1.113883.6.121 | Adangme |
| ady | Language | urn:oid:2.16.840.1.113883.6.121 | Adyghe; Adygei |
| ae | Language | urn:oid:2.16.840.1.113883.6.121 | Avestan |
| af | Language | urn:oid:2.16.840.1.113883.6.121 | Afrikaans |
| afa | Language | urn:oid:2.16.840.1.113883.6.121 | Afro-Asiatic (Other) |
| afh | Language | urn:oid:2.16.840.1.113883.6.121 | Afrihili |
| ... | | | |

Table 73: LanguageAbilityMode

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: LanguageAbilityMode urn:oid:2.16.840.1.113883.1.11.12249  This identifies the language ability of the individual. A value representing the method of expression of the language.  Value Set Source: <http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vocabulary.html> | | | |
| Code | Code System | Code System OID | Print Name |
| ESGN | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Expressed signed |
| ESP | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Expressed spoken |
| EWR | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Expressed written |
| RSGN | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Received signed |
| RSP | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Received spoken |
| RWR | LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 | Received written |

Table 74: LanguageAbilityProficiency

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: LanguageAbilityProficiency urn:oid:2.16.840.1.113883.1.11.12199  Value Set Source: <http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vocabulary.html> | | | |
| Code | Code System | Code System OID | Print Name |
| E | LanguageAbilityProficiency | urn:oid:2.16.840.1.113883.5.61 | Excellent |
| F | LanguageAbilityProficiency | urn:oid:2.16.840.1.113883.5.61 | Fair |
| G | LanguageAbilityProficiency | urn:oid:2.16.840.1.113883.5.61 | Good |
| P | LanguageAbilityProficiency | urn:oid:2.16.840.1.113883.5.61 | Poor |

Table 75: UnitsOfMeasureCaseSensitive

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: UnitsOfMeasureCaseSensitive urn:oid:2.16.840.1.113883.1.11.12839  The UCUM code system provides a set of structural units from which working codes are built. There is an unlimited number of possible valid UCUM codes.  Value Set Source: <http://unitsofmeasure.org/ucum.html> | | | |
| Code | Code System | Code System OID | Print Name |
| min | UCUM | urn:oid:2.16.840.1.113883.6.8 | minute |
| hour | UCUM | urn:oid:2.16.840.1.113883.6.8 | hr |
| % | UCUM | urn:oid:2.16.840.1.113883.6.8 | percent |
| cm | UCUM | urn:oid:2.16.840.1.113883.6.8 | centimeter |
| g | UCUM | urn:oid:2.16.840.1.113883.6.8 | gram |
| g/(12.h) | UCUM | urn:oid:2.16.840.1.113883.6.8 | gram per 12 hour |
| g/L | UCUM | urn:oid:2.16.840.1.113883.6.8 | gram per liter |
| mol | UCUM | urn:oid:2.16.840.1.113883.6.8 | mole |
| [IU] | UCUM | urn:oid:2.16.840.1.113883.6.8 | international unit |
| Hz | UCUM | urn:oid:2.16.840.1.113883.6.8 | Hertz |
| ... | | | |

Table 76: Result Status

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Result Status urn:oid:2.16.840.1.113883.11.20.9.39  Value Set Source: <http://www.hl7.org/documentcenter/public/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vocabulary.html> | | | |
| Code | Code System | Code System OID | Print Name |
| aborted | ActStatus | urn:oid:2.16.840.1.113883.5.14 | aborted |
| active | ActStatus | urn:oid:2.16.840.1.113883.5.14 | active |
| cancelled | ActStatus | urn:oid:2.16.840.1.113883.5.14 | cancelled |
| completed | ActStatus | urn:oid:2.16.840.1.113883.5.14 | completed |
| held | ActStatus | urn:oid:2.16.840.1.113883.5.14 | held |
| suspended | ActStatus | urn:oid:2.16.840.1.113883.5.14 | suspended |

# Code Systems in This Guide

Table 77: Code Systems

| Name | OID |
| --- | --- |
| ActCode | urn:oid:2.16.840.1.113883.5.4 |
| ActMood | urn:oid:2.16.840.1.113883.5.1001 |
| ActStatus | urn:oid:2.16.840.1.113883.5.14 |
| ConfidentialityCode | urn:oid:2.16.840.1.113883.5.25 |
| Country | urn:oid:2.16.840.1.113883.3.88.12.80.63 |
| HL7ActClass | urn:oid:2.16.840.1.113883.5.6 |
| HL7Realm | urn:oid:2.16.840.1.113883.5.1124 |
| Language | urn:oid:2.16.840.1.113883.6.121 |
| LanguageAbilityMode | urn:oid:2.16.840.1.113883.5.60 |
| LanguageAbilityProficiency | urn:oid:2.16.840.1.113883.5.61 |
| LOINC | urn:oid:2.16.840.1.113883.6.1 |
| Participationsignature | urn:oid:2.16.840.1.113883.5.89 |
| RoleClass | urn:oid:2.16.840.1.113883.5.110 |
| RoleCode | urn:oid:2.16.840.1.113883.5.111 |
| UCUM | urn:oid:2.16.840.1.113883.6.8 |