Personal Healthcare Monitoring Report 1.2

March 25

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# Personal Healthcare Monitoring Report

The Personal Healthcare Monitoring Report (PHMR) is a document that carries personal healthcare monitoring information.  The information is transmitted as notes and as raw data. Notes may be supplied by a disease management service provider. The information may have multiple characteristics, including:

Representation of measurements captured by devices.

Representation of notes, summaries, and other kinds of narrative information that may be added by caregivers or by the users themselves.

Representation of graphs that may be added by intermediary devices that represent trends of users’ health.

However the primary use case around which the PHMR standard is designed is for the automated reporting of measurements taken by Personal Healthcare Monitoring (PHM) devices outside of the health care provider facilities. Little to no entry of data by manual means is anticipated. This standard is an essential component in the support of the remote monitoring of patients.

Universal Realm Header - Draft

[ClinicalDocument: identifier urn:oid:2.16.840.1.113883.10.20.29 (open)]

This section describes constraints that apply to the header for all documents within the scope of this implementation guide. Header constraints specific to each document type are described in the appropriate document-specific section below. At the current time, only the PHMR is present in this document.

Table 1: Universal Realm Header Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| ClinicalDocument (identifier: urn:oid:2.16.840.1.113883.10.20.29) | | | | | |
| 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..\* | 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..\* | SHALL |  | [1141-398](#C_1141-398) |  |
| administrativeGenderCode | 1..1 | SHALL |  | [1141-515](#C_1141-515) | urn:oid:2.16.840.1.113883.1.11.1 (Administrative Gender (HL7 V3)) |
| birthTime | 1..1 | SHALL |  | [1141-399](#C_1141-399) |  |
| maritalStatusCode | 0..1 | SHOULD |  | [1141-500](#C_1141-500) | urn:oid:2.16.840.1.113883.1.11.12212 (Marital Status) |
| religiousAffiliationCode | 0..1 | MAY |  | [1141-501](#C_1141-501) | urn:oid:2.16.840.1.113883.1.11.19185 (Religious Affiliation) |
| raceCode | 0..1 | MAY |  | [1141-502](#C_1141-502) | urn:oid:2.16.840.1.113883.1.11.14914 (Race) |
| sdtc:raceCode | 0..\* | MAY |  | [1141-516](#C_1141-516) | urn:oid:2.16.840.1.113883.1.11.14914 (Race) |
| ethnicGroupCode | 0..1 | MAY |  | [1141-503](#C_1141-503) | urn:oid:2.16.840.1.114222.4.11.837 (EthnicityGroup) |
| guardian | 0..\* | MAY |  | [1141-400](#C_1141-400) |  |
| 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) |  |
| addr | 1..1 | SHALL |  | [1141-407](#C_1141-407) |  |
| country | 0..1 | SHOULD |  | [1141-510](#C_1141-510) | urn:oid:2.16.840.1.113883.3.88.12.80.63 (Country) |
| 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) |  |
| code | 0..1 | SHOULD |  | [1141-431](#C_1141-431) |  |
| 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 | SHOULD |  | [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) | 2.16.840.1.113883.4.6 |
| code | 0..1 | MAY |  | [1141-1503](#C_1141-1503) |  |
| 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 | SHALL |  | [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 |  | [1141-465](#C_1141-465) |  |
| name | 1..\* | SHALL |  | [1141-466](#C_1141-466) |  |
| informant | 0..\* | MAY |  | [1141-486](#C_1141-486) |  |
| relatedEntity | 1..1 | SHALL |  | [1141-578](#C_1141-578) |  |
| relatedPerson | 1..1 | SHALL |  | [1141-583](#C_1141-583) |  |
| name | 1..\* | SHALL |  | [1141-584](#C_1141-584) |  |
| 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..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..\* | MAY |  | [1141-585](#C_1141-585) |  |
| informationRecipient | 0..1 | MAY |  | [1141-440](#C_1141-440) |  |
| name | 1..\* | SHALL |  | [1141-441](#C_1141-441) |  |
| 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) |  |
| representedOrganization | 0..1 | MAY |  | [1141-587](#C_1141-587) |  |
| name | 1..\* | SHOULD |  | [1141-588](#C_1141-588) |  |
| telecom | 0..\* | SHOULD |  | [1141-589](#C_1141-589) |  |
| addr | 0..\* | SHOULD |  | [1141-590](#C_1141-590) |  |
| 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) |  |
| 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).
3. SHALL contain at least one [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).
4. 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).
5. SHALL contain exactly one [1..1] code (CONF:1141-388).
   1. This code **SHALL** specify the particular kind of document (e.g. Personal Healthcare Monitoring Report, Patient Generated Document, etc.) (CONF:1141-488).
6. 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
7. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-390).
8. 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).
9. 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).
10. MAY contain zero or one [0..1] setId (CONF:1141-391).
    1. If  setId is present versionNumber **SHALL** be present (CONF:1141-492).
11. MAY contain zero or one [0..1] versionNumber (CONF:1141-392).
    1. If versionNumber is present setId **SHALL** be present (CONF:1141-493).
12. 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 at least one [1..\*] name (CONF:1141-398).  
             Note: This version of the UV header is allowing more than one name. The Patient Generated Universal realm (UV) header allows only one
          2. This patient SHALL contain exactly one [1..1] administrativeGenderCode, which SHALL be selected from ValueSet [Administrative Gender (HL7 V3)](#Administrative_Gender_HL7_V3) urn:oid:2.16.840.1.113883.1.11.1 DYNAMIC (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 SHOULD contain zero or one [0..1] maritalStatusCode, which SHALL be selected from ValueSet [Marital Status](#Marital_Status) urn:oid:2.16.840.1.113883.1.11.12212 DYNAMIC (CONF:1141-500).
          5. This patient MAY contain zero or one [0..1] religiousAffiliationCode, which SHALL be selected from ValueSet [Religious Affiliation](#Religious_Affiliation) urn:oid:2.16.840.1.113883.1.11.19185 DYNAMIC (CONF:1141-501).
          6. This patient MAY contain zero or one [0..1] raceCode, which SHALL be selected from ValueSet [Race](#Race) urn:oid:2.16.840.1.113883.1.11.14914 DYNAMIC (CONF:1141-502).  
             Note: To record additional raceCode, use the extension element sdtc:raceCode.
          7. This patient MAY contain zero or more [0..\*] sdtc:raceCode, which SHALL be selected from ValueSet [Race](#Race) urn:oid:2.16.840.1.113883.1.11.14914 DYNAMIC (CONF:1141-516).
          8. This patient MAY contain zero or one [0..1] ethnicGroupCode, which SHALL be selected from ValueSet [EthnicityGroup](#EthnicityGroup) urn:oid:2.16.840.1.114222.4.11.837 DYNAMIC (CONF:1141-503).
          9. This patient MAY contain zero or more [0..\*] guardian (CONF:1141-400).
             1. 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).
             2. The guardian, if present, SHOULD contain zero or more [0..\*] addr (CONF:1141-401).
             3. The guardian, if present, MAY contain zero or more [0..\*] telecom (CONF:1141-402).
             4. 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).

This place SHALL contain exactly one [1..1] addr (CONF:1141-407).

This addr SHOULD contain zero or one [0..1] country, which SHALL be selected from ValueSet [Country](#Country) urn:oid:2.16.840.1.113883.3.88.12.80.63 DYNAMIC (CONF:1141-510).

* + - 1. 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 SHALL 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 SHALL 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 SHALL 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).
    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) (CONF:1141-580).

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 SHOULD contain zero or one [0..1] code (CONF:1141-431).
         1. If the assigned author is an assignedPerson, 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:1141-581).
      3. This assignedAuthor SHALL contain at least one [1..\*] addr (CONF:1141-429).
      4. This assignedAuthor SHALL contain at least one [1..\*] telecom (CONF:1141-425).
      5. 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).
      6. This assignedAuthor SHOULD 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).
      7. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:1141-538).
2. 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="2.16.840.1.113883.4.6" National Provider Identifier (CONF:1141-525).
      2. This assignedEntity MAY contain zero or one [0..1] code (CONF:1141-1503).  
         Note: This assignedEntity may contain zero or one [0..1] code to encode the relationship of the person to the recordTarget
      3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:1141-418).
      4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:1141-419).
      5. 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).
3. 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. SHALL contain exactly one [1..1] assignedEntity (CONF:1141-463).
      1. This assignedEntity SHOULD contain zero or more [0..\*] id (CONF:1141-467).
         1. If assignedEntity/id is a provider then this id, SHOULD include zero or one 0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:1141-561).
      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:1141-465).
         1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:1141-466).
4. MAY contain zero or more [0..\*] informant (CONF:1141-486) such that it  
   Note: An informant can contain either an assignedEntity or a relatedEntity. This template does not place any constraints on a relatedEntity.
   1. SHALL contain exactly one [1..1] relatedEntity (CONF:1141-578).
      1. This relatedEntity SHALL contain exactly one [1..1] relatedPerson (CONF:1141-583).
         1. This relatedPerson SHALL contain at least one [1..\*] name (CONF:1141-584).
5. 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 exactly one [1..1] addr (CONF:1141-437).
6. 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 MAY 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).
         1. The informationRecipient, if present, SHALL contain at least one [1..\*] name (CONF:1141-441).
      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).
7. 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).
      6. This assignedEntity MAY contain zero or one [0..1] representedOrganization (CONF:1141-587).
         1. The representedOrganization, if present, SHOULD contain at least one [1..\*] name (CONF:1141-588).
         2. The representedOrganization, if present, SHOULD contain zero or more [0..\*] telecom (CONF:1141-589).
         3. The representedOrganization, if present, SHOULD contain zero or more [0..\*] addr (CONF:1141-590).
8. 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).
9. 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. Such participants, if present, **SHALL** contain associatedEntity/associatedPerson or associatedEntity/scopingOrganization (CONF:1141-1504).
   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).
10. 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).
11. 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 (CONF:1141-595).
       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).
12. 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.
       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).
13. 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).

Figure 1: Universal Realm Header Example

<ClinicalDocument>

<realmCode code="XXX" />

<typeId root="2.16.840.1.113883.1.3" extension="POCD\_HD000040" />

<templateId root="2.16.840.1.113883.10.20.29" />

<id root="6418be0c-4567-4888-b627-ad9a78218a6e">

<!--PRIMITIVE: This id \*SHALL\* be a globally unique identifier for the document-->

</id>

<code>

<!--PRIMITIVE: This code \*SHALL\* specify the particular kind of document (e.g. Personal Healthcare Monitoring Report, Patient Generated Document, etc.)-->

</code>

<title />

<effectiveTime value="20150317153312" />

<confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N" />

<languageCode />

<setId root="db8689c6-5faf-4389-bc42-c6c3c46d41b7">

<!--PRIMITIVE: If setId is present versionNumber \*SHALL\* be present-->

</setId>

<versionNumber value="1">

<!--PRIMITIVE: If versionNumber is present setId \*SHALL\* be present-->

</versionNumber>

<recordTarget>

<patientRole>

<id root="7e39c12d-7716-4e9f-a405-d64d89b72ef9" />

<addr>

<delimiter />

</addr>

<telecom />

<patient>

<name>

<delimiter />

</name>

<administrativeGenderCode code="F" displayName="Female" codeSystem="2.16.840.1.113883.5.1" codeSystemName="AdministrativeGender" />

<birthTime value="19650317153312">

<!--PRIMITIVE: \*SHALL\* be precise to year-->

<!--PRIMITIVE: \*SHOULD\* be precise to day-->

</birthTime>

<maritalStatusCode />

<religiousAffiliationCode />

<raceCode />

<raceCode />

<ethnicGroupCode />

<guardian>

<code />

<addr>

<delimiter />

</addr>

<telecom />

<guardianPerson>

<name>

<delimiter />

</name>

</guardianPerson>

</guardian>

<birthplace>

<place>

<addr>

<delimiter />

<country />

</addr>

</place>

</birthplace>

<languageCommunication>

<languageCode />

<modeCode />

<proficiencyLevelCode />

<preferenceInd />

</languageCommunication>

</patient>

<providerOrganization>

<id root="89bc4380-bbd9-4512-b1b0-6deb74b685e1" />

<name>

<delimiter />

</name>

<telecom />

<addr>

<delimiter />

<country />

</addr>

</providerOrganization>

</patientRole>

</recordTarget>

<author>

<time value="20150317153312" />

<assignedAuthor>

<id root="ab175c72-4949-4046-a687-29d14ace21a4">

<!--PRIMITIVE: 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.-->

</id>

<code>

<!--PRIMITIVE: If the assigned author is an assignedPerson, 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-->

</code>

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

<assignedAuthoringDevice>

<manufacturerModelName />

<softwareName />

</assignedAuthoringDevice>

<!--PRIMITIVE: There \*SHALL\* be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice-->

</assignedAuthor>

</author>

<dataEnterer>

<assignedEntity>

<id root="2.16.840.1.113883.4.6" />

<code />

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</dataEnterer>

<informant>

<assignedEntity>

<id root="6ba4b0fe-4f77-4c57-9cb1-3a01e2b8ba6d">

<!--PRIMITIVE: If assignedEntity/id is a provider then this id, SHOULD include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier-->

</id>

<code />

<addr>

<delimiter />

</addr>

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</informant>

<informant>

<assignedEntity>

<id root="79bcf07f-d2ad-4401-96fa-4a22028281a5" />

</assignedEntity>

<relatedEntity classCode="YYY">

<relatedPerson>

<name>

<delimiter />

</name>

</relatedPerson>

</relatedEntity>

</informant>

<custodian>

<assignedCustodian>

<representedCustodianOrganization>

<id root="8352c515-95ca-40e8-bb4f-5f97daa6f310" />

<name>

<delimiter />

</name>

<telecom use="XXX" />

<addr>

<delimiter />

</addr>

</representedCustodianOrganization>

</assignedCustodian>

</custodian>

<informationRecipient>

<intendedRecipient>

<id root="8397cf97-a020-472c-82c0-ce4b9074ca86">

<!--PRIMITIVE: Such ids MAY reference the id of a person or organization entity specified elsewhere in the document-->

</id>

<informationRecipient>

<name>

<delimiter />

</name>

</informationRecipient>

<receivedOrganization>

<name>

<delimiter />

</name>

</receivedOrganization>

</intendedRecipient>

</informationRecipient>

<legalAuthenticator>

<time value="20150317153312" />

<signatureCode code="S" />

<assignedEntity>

<id root="74cfcc17-85c4-4439-983e-d3ca2682deb3" />

<code />

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

<representedOrganization>

<name>

<delimiter />

</name>

<telecom />

<addr>

<delimiter />

</addr>

</representedOrganization>

</assignedEntity>

</legalAuthenticator>

<authenticator>

<time value="20150317153312" />

<signatureCode code="S" />

<assignedEntity>

<id root="10fd18af-bfce-4c0b-992a-4bbf621c5224" />

<code />

<addr>

<delimiter />

</addr>

<telecom use="XXX" />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</authenticator>

<participant typeCode="YYY">

<time value="20150317153312">

<low />

<center />

</time>

<associatedEntity classCode="XXXX" />

<!--PRIMITIVE: Such participants, if present, \*SHALL\* contain associatedEntity/associatedPerson or associatedEntity/scopingOrganization -->

<!--PRIMITIVE: 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-->

</participant>

<inFulfillmentOf>

<order>

<id root="3f107229-6b0a-41ff-a19a-13e1e261b3a7">

<!--PRIMITIVE: Such ids \*MAY\* represent a scheduled appointment or service event in a practice management system-->

</id>

</order>

</inFulfillmentOf>

<documentationOf>

<serviceEvent>

<code code="XXX">

<!--PRIMITIVE: The code SHOULD be selected from a value set established by the document-level template-->

</code>

<effectiveTime value="20150317153312">

<low />

<center />

</effectiveTime>

<performer typeCode="YYY">

<assignedEntity>

<id root="1f8f50e3-5267-4576-ab3d-23d6bf36821a" />

<code />

</assignedEntity>

</performer>

</serviceEvent>

</documentationOf>

<authorization>

<consent>

<id root="4c729e3f-4f31-4268-b3d9-677537d3c519" />

<code />

<statusCode code="completed" />

</consent>

</authorization>

<componentOf>

<encompassingEncounter>

<id root="52252160-451b-4db1-915e-ed51c7e85418" />

<effectiveTime value="20150317153312">

<low />

<center />

</effectiveTime>

</encompassingEncounter>

</componentOf>

<component>

<nonXMLBody>

<text />

</nonXMLBody>

</component>

</ClinicalDocument>

Personal Healthcare Monitoring Report 1.2 - Draft

[ClinicalDocument: identifier urn:oid:2.16.840.1.113883.10.20.36 (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 optional) (V2)](#S_PHMR_Results_Section_entries_optional)  [PHMR Vital Signs Section (entries optional) (V2)](#S_PHMR_Vital_Signs_Section_entries_opti) |

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

Table 3: Personal Healthcare Monitoring Report 1.2 Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| ClinicalDocument (identifier: urn:oid:2.16.840.1.113883.10.20.36) | | | | | |
| 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 |
| templateId | 1..1 | SHALL |  | [1141-1501](#C_1141-1501) |  |
| @root | 1..1 | SHALL |  | [1141-1502](#C_1141-1502) | 2.16.840.1.113883.10.20.29 |
| templateId | 0..\* | MAY |  | [1141-270](#C_1141-270) |  |
| 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) |
| 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:oid:2.16.840.1.113883.10.20.36.1](#S_PHMR_Medical_Equipment_Section_Entrie) |
| component | 1..1 | SHALL |  | [1141-1444](#C_1141-1444) |  |
| section | 1..1 | SHALL |  | [1141-1447](#C_1141-1447) | [PHMR Results Section (entries optional) (V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.14](#S_PHMR_Results_Section_entries_optional) |
| component | 1..1 | SHALL |  | [1141-1445](#C_1141-1445) |  |
| section | 1..1 | SHALL |  | [1141-1462](#C_1141-1462) | [PHMR Vital Signs Section (entries optional) (V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.15](#S_PHMR_Vital_Signs_Section_entries_opti) |

Properties

1. Conforms to [Universal Realm Header](#D_Universal_Realm_Header) template (identifier: urn:oid:2.16.840.1.113883.10.20.29).
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 standard (CONF:1141-2).
4. SHALL contain exactly one [1..1] templateId (CONF:1141-1501) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.29" This template indicates that this document conforms to the constraints of the universal realm header (CONF:1141-1502).
5. MAY contain zero or more [0..\*] templateId (CONF:1141-270).
   1. The document may support headers designed to additional realms that are a subset of the universal realm. If the document has been designed such that the header supports additional realms, the template Id for those headers **SHALL** be added (CONF:1141-647).
6. 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).

documentationOf

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).
      1. This structuredBody SHALL contain exactly one [1..1] component (CONF:1141-1443).
         1. This component SHALL contain exactly one [1..1] [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) (identifier: urn:oid:2.16.840.1.113883.10.20.36.1) (CONF:1141-1446).
      2. This structuredBody SHALL contain exactly one [1..1] component (CONF:1141-1444).
         1. This component SHALL contain exactly one [1..1] [PHMR Results Section (entries optional) (V2)](#S_PHMR_Results_Section_entries_optional) (identifier: urn:oid:2.16.840.1.113883.10.20.36.14) (CONF:1141-1447).
      3. This structuredBody SHALL contain exactly one [1..1] component (CONF:1141-1445).
         1. This component SHALL contain exactly one [1..1] [PHMR Vital Signs Section (entries optional) (V2)](#S_PHMR_Vital_Signs_Section_entries_opti) (identifier: urn:oid:2.16.840.1.113883.10.20.36.15) (CONF:1141-1462).

Generic Requirements

1. Instances **SHOULD NOT** include the xsi:schemaLocation element due to security risks. Receivers that choose to perform validation will need to use a locally cached schema (CONF:1141-1593).
2. All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements **SHALL** have a name (CONF:1141-1594).
3. All patientRole, assignedAuthor, associatedEntity, guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject, and participantRole  elements **SHOULD** have addr and telecom elements (CONF:1141-1595).
4. All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization, and serviceProviderOrganization elements **SHALL** have name, addr, and telecom elements (CONF:1141-1596).  
   Note: When name, address, or telecom information is unknown and where these elements are required to be present, if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

Figure 2: Personal Healthcare Monitoring Report 1.2 Example

<ClinicalDocument>

<realmCode code="XXX" />

<typeId root="2.16.840.1.113883.1.3" extension="POCD\_HD000040" />

<templateId root="2.16.840.1.113883.10.20.36" />

<templateId root="2.16.840.1.113883.10.20.29" />

<templateId>

<!--PRIMITIVE: The document may support headers designed to additional realms that are a subset of the universal realm. If the document has been designed such that the header supports additional realms, the template Id for those headers \*SHALL\* be added.-->

</templateId>

<id root="a36d8f57-f306-41b4-b2ef-53deb9bb31e4">

<!--PRIMITIVE: This id \*SHALL\* be a globally unique identifier for the document-->

</id>

<code code="53576-5" codeSystem="XXX" />

<title />

<documentationOf>

<serviceEvent classCode="MPROT">

<effectiveTime value="20150317135332">

<low />

<high />

<center />

</effectiveTime>

</serviceEvent>

</documentationOf>

<effectiveTime value="20150317135332" />

<component>

<nonXMLBody>

<text />

</nonXMLBody>

<structuredBody>

<component>

<section />

</component>

<component>

<section />

</component>

<component>

<section />

</component>

</structuredBody>

</component>

<confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N" />

<languageCode />

<setId root="015d4780-44c3-451c-b31d-49ef837d5b54">

<!--PRIMITIVE: If setId is present versionNumber \*SHALL\* be present-->

</setId>

<versionNumber value="1">

<!--PRIMITIVE: If versionNumber is present setId \*SHALL\* be present-->

</versionNumber>

<recordTarget>

<patientRole>

<id root="0466b3fc-48d4-435a-af49-f2f9fd272387" />

<addr>

<delimiter />

</addr>

<telecom />

<patient>

<name>

<delimiter />

</name>

<administrativeGenderCode code="F" displayName="Female" codeSystem="2.16.840.1.113883.5.1" codeSystemName="AdministrativeGender" />

<birthTime value="19650317135332">

<!--PRIMITIVE: \*SHALL\* be precise to year-->

<!--PRIMITIVE: \*SHOULD\* be precise to day-->

</birthTime>

<maritalStatusCode />

<religiousAffiliationCode />

<raceCode />

<raceCode />

<ethnicGroupCode />

<guardian>

<code />

<addr>

<delimiter />

</addr>

<telecom />

<guardianPerson>

<name>

<delimiter />

</name>

</guardianPerson>

</guardian>

<birthplace>

<place>

<addr>

<delimiter />

<country />

</addr>

</place>

</birthplace>

<languageCommunication>

<languageCode />

<modeCode />

<proficiencyLevelCode />

<preferenceInd />

</languageCommunication>

</patient>

<providerOrganization>

<id root="25374762-067f-4470-87b9-7c8d84fb6f81" />

<name>

<delimiter />

</name>

<telecom />

<addr>

<delimiter />

<country />

</addr>

</providerOrganization>

</patientRole>

</recordTarget>

<author>

<time value="20150317135332" />

<assignedAuthor>

<id root="d667ef4a-9a4a-4288-982f-2720107825c5">

<!--PRIMITIVE: 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.-->

</id>

<code>

<!--PRIMITIVE: If the assigned author is an assignedPerson, 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-->

</code>

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

<assignedAuthoringDevice>

<manufacturerModelName />

<softwareName />

</assignedAuthoringDevice>

<!--PRIMITIVE: There \*SHALL\* be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice-->

</assignedAuthor>

</author>

<dataEnterer>

<assignedEntity>

<id root="2.16.840.1.113883.4.6" />

<code />

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</dataEnterer>

<informant>

<assignedEntity>

<id root="9ce1af7f-fd5c-4b7a-a267-1411ea2ccd78">

<!--PRIMITIVE: If assignedEntity/id is a provider then this id, SHOULD include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier-->

</id>

<code />

<addr>

<delimiter />

</addr>

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</informant>

<custodian>

<assignedCustodian>

<representedCustodianOrganization>

<id root="4adaa3d6-0b0e-4b88-a01a-37b16938cef6" />

<name>

<delimiter />

</name>

<telecom use="XXX" />

<addr>

<delimiter />

</addr>

</representedCustodianOrganization>

</assignedCustodian>

</custodian>

<informationRecipient>

<intendedRecipient>

<id root="bd69b887-926b-423d-b146-6d0d15ebe06a">

<!--PRIMITIVE: Such ids MAY reference the id of a person or organization entity specified elsewhere in the document-->

</id>

<informationRecipient>

<name>

<delimiter />

</name>

</informationRecipient>

<receivedOrganization>

<name>

<delimiter />

</name>

</receivedOrganization>

</intendedRecipient>

</informationRecipient>

<legalAuthenticator>

<time value="20150317135332" />

<signatureCode code="S" />

<assignedEntity>

<id root="f73c2d09-fe4b-4f35-9867-4a140817815b" />

<code />

<addr>

<delimiter />

</addr>

<telecom />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

<representedOrganization>

<name>

<delimiter />

</name>

<telecom />

<addr>

<delimiter />

</addr>

</representedOrganization>

</assignedEntity>

</legalAuthenticator>

<authenticator>

<time value="20150317135332" />

<signatureCode code="S" />

<assignedEntity>

<id root="a3920974-8e1c-4085-bc7d-7ca1a577a58b" />

<code />

<addr>

<delimiter />

</addr>

<telecom use="XXX" />

<assignedPerson>

<name>

<delimiter />

</name>

</assignedPerson>

</assignedEntity>

</authenticator>

<participant typeCode="YYY">

<time value="20150317135332">

<low />

<center />

</time>

<associatedEntity classCode="XXXX" />

<!--PRIMITIVE: Such participants, if present, \*SHALL\* contain associatedEntity/associatedPerson or associatedEntity/scopingOrganization -->

<!--PRIMITIVE: 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-->

</participant>

<inFulfillmentOf>

<order>

<id root="32c4911c-bd06-40fb-8eee-3a26bb8e56ab">

<!--PRIMITIVE: Such ids \*MAY\* represent a scheduled appointment or service event in a practice management system-->

</id>

</order>

</inFulfillmentOf>

<authorization>

<consent>

<id root="e51f9d3a-af40-4bac-b960-7d6a5bdbf2f7" />

<code />

<statusCode code="completed" />

</consent>

</authorization>

<componentOf>

<encompassingEncounter>

<id root="45d24fc7-e318-4f2a-b1b1-cdab375ed846" />

<effectiveTime value="20150317135332">

<low />

<center />

</effectiveTime>

</encompassingEncounter>

</componentOf>

</ClinicalDocument>

# section

PHMR Medical Equipment Section (Entries Optional) - Draft

[section: identifier urn:oid:2.16.840.1.113883.10.20.36.1 (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 Definition Organizer](#E_Device_Definition_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:oid:2.16.840.1.113883.10.20.36.1) | | | | | |
| 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 |
| 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 |
| title | 1..1 | SHALL |  | [1141-1372](#C_1141-1372) |  |
| text | 1..1 | SHALL |  | [1141-1373](#C_1141-1373) |  |
| entry | 1..\* | SHOULD |  | [1141-1375](#C_1141-1375) |  |
| organizer | 1..1 | SHALL |  | [1141-1377](#C_1141-1377) | [Device Definition Organizer (identifier: urn:oid:2.16.840.1.113883.10.20.36.4](#E_Device_Definition_Organizer) |

1. SHALL contain exactly one [1..1] templateId (CONF:1141-1463).
   1. This templateId 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] 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. SHALL contain exactly one [1..1] title (CONF:1141-1372).
4. SHALL contain exactly one [1..1] text (CONF:1141-1373).
5. SHOULD contain at least one [1..\*] entry (CONF:1141-1375).
   1. Such entries SHALL contain exactly one [1..1] [Device Definition Organizer](#E_Device_Definition_Organizer) (identifier: urn:oid:2.16.840.1.113883.10.20.36.4) (CONF:1141-1377).
6. If no medical devices are defined, this section's text element **SHALL** note this fact (CONF:1141-1378).

Figure 3: PHMR Medical Equipment Section Example

<section>

<templateId root="2.16.840.1.113883.10.20.36.1" />

<code code="46264-8" codeSystem="2.16.840.1.113883.6.1" />

<title />

<text>

<!-- If no medical devices are defined, this text element SHALL note this fact. -->

<content>

<content>

<linkHtml>

<footnote>

<sub />

</footnote>

</linkHtml>

</content>

</content>

</text>

<entry>

<!—The Device Definition Organizer element goes here. -->

</entry>

</section>

PHMR Results Section (entries optional) (V2) - Draft

[section: identifier urn:oid:2.16.840.1.113883.10.20.36.14 (open)]

Table 6: PHMR Results Section (entries optional) (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) (required) | [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) |

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..

Table 7: PHMR Results Section (entries optional) (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:oid:2.16.840.1.113883.10.20.36.14) | | | | | |
| 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 |
| 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 |
| title | 1..1 | SHALL |  | [1141-1396](#C_1141-1396) |  |
| text | 1..1 | SHALL |  | [1141-1397](#C_1141-1397) |  |
| entry | 0..\* | SHOULD |  | [1141-1388](#C_1141-1388) |  |
| organizer | 1..1 | SHALL |  | [1141-1391](#C_1141-1391) | [PHMR Result Organizer (V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.16](#E_PHMR_Result_Organizer_V2) |

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] 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. SHALL contain exactly one [1..1] title (CONF:1141-1396).
4. SHALL contain exactly one [1..1] text (CONF:1141-1397).
5. SHOULD contain zero or more [0..\*] entry (CONF:1141-1388) such that it
   1. SHALL contain exactly one [1..1] [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.16) (CONF:1141-1391).
6. If no results are reported this section shall have a text element stating so (CONF:1141-1424).

Figure 4: PHMR Results Section Example

<section>

<templateId root="2.16.840.1.113883.10.20.36.14" />

<code code="30954-2" codeSystem="2.16.840.1.113883.6.1" />

<title />

<text>

<!-- If no results are reported this text element shall state so.-->

<content>

<content>

<linkHtml>

<footnote>

<sub />

</footnote>

</linkHtml>

</content>

</content>

</text>

<entry>

<!—The Phmr Results Organizer element goes here.->

</entry>

</section>

PHMR Vital Signs Section (entries optional) (V2) - Draft

[section: identifier urn:oid:2.16.840.1.113883.10.20.36.15 (open)]

Table 8: PHMR Vital Signs Section (entries optional) (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) (required) | [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) |

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.

Table 9: PHMR Vital Signs Section (entries optional) (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:oid:2.16.840.1.113883.10.20.36.15) | | | | | |
| 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 |
| 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 |
| title | 1..1 | SHALL |  | [1141-1457](#C_1141-1457) |  |
| text | 1..1 | SHALL |  | [1141-1458](#C_1141-1458) |  |
| entry | 0..\* | SHOULD |  | [1141-1449](#C_1141-1449) |  |
| organizer | 1..1 | SHALL |  | [1141-1452](#C_1141-1452) | [PHMR Vital Signs Organizer (V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.2](#E_PHMR_Vital_Signs_Organizer_V2) |

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] 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. SHALL contain exactly one [1..1] title (CONF:1141-1457).
4. SHALL contain exactly one [1..1] text (CONF:1141-1458).
5. SHOULD contain zero or more [0..\*] entry (CONF:1141-1449) such that it
   1. SHALL contain exactly one [1..1] [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) (identifier: urn:oid:2.16.840.1.113883.10.20.36.2) (CONF:1141-1452).
6. If no vital signs are reported this section **SHALL** have a text element that states so (CONF:1141-1465).

Figure 5: PHMR Vital Signs Section Example

<section>

<templateId root="2.16.840.1.113883.10.20.36.15" />

<code code="8716-3" codeSystem="2.16.840.1.113883.6.1" />

<title />

<text>

<!-- If no vital signs are reported this text element SHALL state so.-->

<content>

<content>

<linkHtml>

<footnote>

<sub />

</footnote>

</linkHtml>

</content>

</content>

</text>

<entry>

<!-- Phmr vital signs organizer goes here.-->

</entry>

</section>

# entry

Device Accuracy Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.3 (open)]

Table 10: Device Accuracy Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Definition Organizer](#E_Device_Definition_Organizer) (optional) |  |

The Device Accuracy observation MAY be present as one or more entries in the Device definition 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:oid:2.16.840.1.113883.10.20.36.3) | | | | | |
| @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 |
| code | 1..1 | SHALL |  | [1141-1320](#C_1141-1320) |  |
| @code | 1..1 | SHALL |  | [1141-1323](#C_1141-1323) | 67194 |
| @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) |  |
| value | 0..1 | MAY | 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) |
| value | 0..1 | MAY | ST | [1141-1330](#C_1141-1330) |  |

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).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.3" (CONF:1141-1322).
4. SHALL contain exactly one [1..1] code (CONF:1141-1320).
   1. This code SHALL contain exactly one [1..1] @code="67194" This is the MDC\_ATTR\_NU\_ACCUR\_MSMT attribute (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 refId 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] value with @xsi:type="PQ" (CONF:1141-1321).
   1. The value, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1326).
   2. The value, if present, SHALL contain exactly one [1..1] @unit (ValueSet: [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839) (CONF:1141-1327).
6. MAY contain zero or one [0..1] value with @xsi:type="ST" (CONF:1141-1330).
7. A value element **SHALL** be present whose data type is either PQ  (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the accuracy measurement. The units, when expressed, **SHALL** be a valid UCUM expression) (CONF:1141-1331).

Figure 6: Device Accuracy Observation Example

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.3"/>

<code code="67194" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="MDC\_ATTR\_NU\_ACCUR\_MSMT (Measurement accuracy)"/>

<value xsi:type="PQ" value="0.05" unit="hPa"/>

</observation>

Device Definition Organizer - Draft

[organizer: identifier urn:oid:2.16.840.1.113883.10.20.36.4 (open)]

Table 12: Device Definition 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 Measurement Range Observation](#E_Device_Measurement_Range_Observation)  [Device Resolution Observation](#E_Device_Resolution_Observation)  [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) |

This template represents the properties of the medical device reporting the measurements.

Table 13: Device Definition Organizer Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:oid:2.16.840.1.113883.10.20.36.4) | | | | | |
| @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 |  | [1141-1333](#C_1141-1333) |  |
| @root | 1..1 | SHALL |  | [1141-1340](#C_1141-1340) | 2.16.840.1.113883.10.20.36.4 |
| id | 1..\* | SHALL |  | [1141-1341](#C_1141-1341) |  |
| code | 0..1 | 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) |  |
| low | 1..1 | SHALL |  | [1141-1345](#C_1141-1345) |  |
| high | 1..1 | SHALL |  | [1141-1346](#C_1141-1346) |  |
| participant | 1..1 | SHALL |  | [1141-1347](#C_1141-1347) |  |
| @typeCode | 1..1 | SHALL |  | [1141-1348](#C_1141-1348) | DEV |
| participantRole | 1..1 | SHALL |  | [1141-1385](#C_1141-1385) |  |
| component | 0..\* | MAY |  | [1141-1350](#C_1141-1350) |  |
| observation | 1..1 | SHALL |  | [1141-1354](#C_1141-1354) | [Device Accuracy Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.3](#E_Device_Accuracy_Observation) |
| component | 0..\* | MAY |  | [1141-1351](#C_1141-1351) |  |
| observation | 1..1 | SHALL |  | [1141-1355](#C_1141-1355) | [Device Sampling Frequency Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.10](#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:oid:2.16.840.1.113883.10.20.36.6](#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:oid:2.16.840.1.113883.10.20.36.5](#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:1141-1333) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.4" (CONF:1141-1340).
4. SHALL contain at least one [1..\*] id (CONF:1141-1341).
5. MAY contain zero or one [0..1] 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.
6. 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).
7. 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. This effectiveTime SHALL contain exactly one [1..1] low (CONF:1141-1345).
   2. This effectiveTime SHALL contain exactly one [1..1] high (CONF:1141-1346).
8. SHALL contain exactly one [1..1] participant (CONF:1141-1347).
   1. This participant SHALL contain exactly one [1..1] @typeCode="DEV" (CONF:1141-1348).
   2. This participant SHALL contain exactly one [1..1] participantRole (CONF:1141-1385).
   3. The participantRole element **SHALL** contain a single Device PHMR Product Instance template (templateId 2.16.840.1.113883.10.20.36.9) as the partiticpantRole (CONF:1141-1349).
9. 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:oid:2.16.840.1.113883.10.20.36.3) (CONF:1141-1354).
10. 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.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.10) (CONF:1141-1355).
11. 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.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Resolution Observation](#E_Device_Resolution_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.6) (CONF:1141-1356).
12. 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.
    1. The component, if present, SHALL contain exactly one [1..1] [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.5) (CONF:1141-1357).

Figure 7: Device Definition Organizer Example

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.4"/>

<id root="9f3daba8-025f-490d-aae1-b1d80a7a3de0"/>

<statusCode code="completed"/>

<effectiveTime>

<!-- The low and high time could be equal if there is no effective time range -->

<low value="20150322170922.86-0500"/>

<high value="20150322170923.86-0500"/>

</effectiveTime>

<participant typeCode="DEV">

<!-- Here is where the Phmr Product Instance participantRole element is inserted -->

</participant>

<component>

<!-- Here one can insert the Device Sampling Frequency Observation element if there is one -->

</component>

<component>

<!-- Here one can insert the Device Resolution Observation element if there is one -->

</component>

<component>

<!-- Here one can insert the Device Measurement Range Observation element if there is one -->

---------------------------------------------

</component>

<component>

<!-- Here one can insert Device Accuracy Observation element if there is one -->

</component>

</organizer>

<!-- Fully populated example -->

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.4"/>

<id root="9f3daba8-025f-490d-aae1-b1d80a7a3de0"/>

<statusCode code="completed"/>

<effectiveTime>

<!-- The low and high time could be equal if there is no effective time range -->

<low value="20150322170922.86-0500"/>

<high value="20150322170923.86-0500"/>

</effectiveTime>

<participant typeCode="DEV">

<!-- Here is where the Phmr Product Instance is inserted -->

<participantRole classCode="MANU">

<templateId root="2.16.840.1.113883.10.20.36.9" />

<templateId root="2.16.840.1.113883.10.20.22.4.37" />

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI64"/>

<playingDevice>

<code code="528409" displayName="MDC\_DEV\_SPEC\_PROFILE\_SABTE (Sleep Apnoae Breathing Therapy Equipment)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This element uses the PCD-01 OBX-3 CWE data type to make the device information machine parcable -->

<manufacturerModelName>

|531970^MDC\_ID\_MODEL\_MANUFACTURER^MDC^^PHMR Device Maker|

|531969^MDC\_ID\_MODEL\_NUMBER^MDC^^USB-AutoCPAP-2015-S|

|531971^MDC\_ID\_PROD\_SPEC\_UNSPECIFIED^MDC^^Certified by Continua (2.16.840.1.113883.3.1817)|

|531972^MDC\_ID\_PROD\_SPEC\_SERIAL^MDC^^20150322||531973^MDC\_ID\_PROD\_SPEC\_PART^MDC^^655437-t|

|531974^MDC\_ID\_PROD\_SPEC\_HW^MDC^^Unit-939455|

|531975^MDC\_ID\_PROD\_SPEC\_SW^MDC^^2.2.11|

|531976^MDC\_ID\_PROD\_SPEC\_FW^MDC^^1.1|

|531977^MDC\_ID\_PROD\_SPEC\_PROTOCOL^MDC^^1.1.0|

|532352^MDC\_REG\_CERT\_DATA\_CONTINUA\_VERSION^MDC^^5.0|

|532354^MDC\_REG\_CERT\_DATA\_CONTINUA\_REG\_STATUS^MDC^^regulated|

</manufacturerModelName>

</playingDevice>

<scopingEntity>

<id root="996d00e7-7b77-491e-b07b-233d3799817c"/>

<desc>PHMR Device Maker</desc>

</scopingEntity>

</participantRole>

</participant>

<component>

<!-- Here one can insert the Device Sampling Frequency Observation if there is one -->

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.10"/>

<!-- This entry is NOT from the MDC\_ATTR\_TIME\_PD\_SAMP attribute of an RTSA! That is part of the waveforms -->

<!-- This value cannot be obtained directly IEEE 11073 20601 devices but is an inferred behavior -->

<code code="67981" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="refId is MDC\_ATTR\_TIME\_PD\_SAMP"/>

<!-- Time units are always in milliseconds -->

<value xsi:type="PQ" value="125" unit="ms"/>

</observation>

</component>

<component>

<!-- Here one can insert the Device Resolution Observation if there is one -->

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.6"/>

<code code="17441009" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="device measurement resolution"/>

<!-- A value element shall be present whose data type is either PQ (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the device (though the units must still be a valid UCUM expression)-->

<!--Dimensionless units shall be indicated by 1-->

<value xsi:type="PQ" value="0.5" unit="hPa"/>

</observation>

</component>

<component>

<!-- Here one can insert the Device Measurement Range Observation if there is one -->

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.5"/>

<code code="67198" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="MDC\_ATTR\_NU\_RANGE\_MSMT (Measurement range)"/>

<!-- A value element shall be present whose data type is either IVL\_PQ (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the accuracy measurement (though the units must still be a valid UCUM expression)-->

<value xsi:type="IVL\_PQ">

<low value="2.5" unit="hPa"/>

<high value="300" unit="hPa"/>

</value>

</observation>

</component>

<component>

<!-- Here one can insert Device Accuracy Observation if there is one -->

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.3"/>

<code code="67194" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="MDC\_ATTR\_NU\_ACCUR\_MSMT (Measurement accuracy)"/>

<!-- A value element shall be present whose data type is either PQ (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the accuracy measurement (though the units must still be a valid UCUM expression)-->

<value xsi:type="PQ" value="0.05" unit="hPa"/>

</observation>

</component>

</organizer>

Device Measurement Range Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.5 (open)]

Table 14: Device Measurement Range Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Definition Organizer](#E_Device_Definition_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 15: Device Measurement Range Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.5) | | | | | |
| @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 |
| code | 1..1 | SHALL |  | [1141-1258](#C_1141-1258) |  |
| @code | 1..1 | SHALL |  | [1141-1280](#C_1141-1280) | 67198 |
| @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) |  |
| value | 0..1 | MAY | IVL\_PQ | [1141-1277](#C_1141-1277) |  |
| @unit | 1..1 | SHALL |  | [1141-1314](#C_1141-1314) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |
| low | 1..1 | SHALL |  | [1141-1283](#C_1141-1283) |  |
| high | 1..1 | SHALL |  | [1141-1284](#C_1141-1284) |  |
| value | 0..1 | MAY | ST | [1141-1285](#C_1141-1285) |  |

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).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.5" (CONF:1141-1271).
4. SHALL contain exactly one [1..1] code (CONF:1141-1258).
   1. This code SHALL contain exactly one [1..1] @code="67198" This is the code for MDC\_ATTR\_NU\_RANGE\_MSMT (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. MAY contain zero or one [0..1] value with @xsi:type="IVL\_PQ" (CONF:1141-1277).
   1. The value, if present, 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:1141-1314).
   2. The value, if present, SHALL contain exactly one [1..1] low (CONF:1141-1283).
   3. The value, if present, SHALL contain exactly one [1..1] high (CONF:1141-1284).
6. MAY contain zero or one [0..1] value with @xsi:type="ST" (CONF:1141-1285).
7. A value element **SHALL** be present either of data type IVL\_PQ  (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the device. The units, when expressed, **SHALL** be a valid UCUM expression (CONF:1141-1286).

Figure 8: Device Measurement Range Observation Example

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.5"/>

<code code="67198" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="MDC\_ATTR\_NU\_RANGE\_MSMT (Measurement range)"/>

<!-- A value element shall be present whose data type is either IVL\_PQ (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the accuracy measurement (though the units must still be a valid UCUM expression)-->

<value xsi:type="IVL\_PQ">

<low value="2.5" unit="hPa"/>

<high value="300" unit="hPa"/>

</value>

</observation>

Device PHMR Product Instance Template - Draft

[participantRole: identifier urn:oid:2.16.840.1.113883.10.20.36.9 (open)]

The Device PHMR Product Instance Template describes the properties of the medical device. Typically the device will be an IEEE medical device conforming to an IEEE 11073 medical device standard. This template defines the participantRole element of the Device Definition Organizer. Medical observations taken by the device described by this template that are present in this document reference this participant element.

However, there is more information provided by the device than easily mapped to CDA constructs. For example all the production specification and regulation certification attribute values have no matching element. What is done is to map these attribute values into the manufactureModelName element as a single string data type. To make the string parceable a sequence of CWE data types of PCD-01 has been used to format each entry. This CWE data type  provides sub-components for the numerical IEEE nomenclature code, reference id, coding system designator (always MDC) and a description which will be the value. The PCD-01 separator | is used to separate each CWE data type. The normative description of the formatting is given in the manufactureModelName element details.

Table 16: Device PHMR Product Instance Template Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| participantRole (identifier: urn:oid:2.16.840.1.113883.10.20.36.9) | | | | | |
| @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 |
| 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 | 1..1 | SHALL |  | [1141-1567](#C_1141-1567) |  |
| id | 1..\* | SHALL |  | [1141-1572](#C_1141-1572) |  |
| desc | 0..1 | SHOULD |  | [1141-1586](#C_1141-1586) |  |

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).
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. (e.g. @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 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).
         1. A display name describing the device type **SHOULD** be present, for example "Blood Pressure Monitor". One might also want to place the ref id MDC\_DEV\_SPEC\_PROFILE\_BP in the description (CONF:1141-1583).
      5. This code MAY contain zero or more [0..\*] translation (CONF:1141-1584).
         1. Translation elements may also be present giving an equivalent SNOMED CT code for the device type (CONF:1141-1587).
   2. This playingDevice SHALL contain exactly one [1..1] manufacturerModelName (CONF:1141-1585).
      1. This element **SHALL** contain the data items present in the Production Specification, System Model, and RegCertDataList attributes or equivalent (e.g Device Information Service characteristics of BTLE devices). To be machine readable this string entry **SHALL** be formatted as a CWE data type delineated by OR-bars (|) that would appear in OBX-3 of the corresponding OBX segment describing the value. CWE-1 **SHALL** contain the code, CWE-2 **SHALL** contain the nomenclature reference id in upper case, CWE-3 **SHALL** be 'MDC' and CWE-5 **SHALL** contain the actual component value. If the separator characters '|' , '^', '\', '~' or '&' appear in the value, they **SHALL** be escaped as \F\ ,\S\, \E\, \R\, and \T\, respectively . If there is no corresponding attribute entry value the entry **SHALL** be absent. For the regulation status the value **SHALL** be either 'unregulated-device' or 'regulated-device'. The entries appear as follows:  
         |531970^MDC\_ID\_MODEL\_MANUFACTURER^MDC^^value|  
         |531969^MDC\_ID\_MODEL\_NUMBER^MDC^^value|  
         |531971^MDC\_ID\_PROD\_SPEC\_UNSPECIFIED^MDC^^value|  
         |531972^MDC\_ID\_PROD\_SPEC\_SERIAL^MDC^^value|  
         |531973^MDC\_ID\_PROD\_SPEC\_PART^MDC^^value|  
         |531974^MDC\_ID\_PROD\_SPEC\_HW^MDC^^value|  
         |531975^MDC\_ID\_PROD\_SPEC\_SW^MDC^^value|  
         |531976^MDC\_ID\_PROD\_SPEC\_FW^MDC^^value|  
         |531977^MDC\_ID\_PROD\_SPEC\_PROTOCOL^MDC^^value|  
         |531978^MDC\_ID\_PROD\_SPEC\_GMDN^MDC^^value|  
         |532352^MDC\_REG\_CERT\_DATA\_CONTINUA\_VERSION^MDC^^value|  
         |532354^MDC\_REG\_CERT\_DATA\_CONTINUA\_REG\_STATUS^MDC^^value| (CONF:1141-1588).
6. SHALL contain exactly one [1..1] scopingEntity (CONF:1141-1567).
   1. This scopingEntity SHALL contain at least one [1..\*] id (CONF:1141-1572).
   2. This scopingEntity SHOULD contain zero or one [0..1] desc (CONF:1141-1586).
      1. The scopingEntity/desc element, if present **SHALL** contain the manufacturer's name. The element is present for backward compatibility, otherwise it is duplicated in the playingDevice/manufacturerModelName element (CONF:1141-1589).

Device Resolution Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.6 (open)]

Table 17: Device Resolution Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Definition Organizer](#E_Device_Definition_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 18: Device Resolution Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.6) | | | | | |
| @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 |
| 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 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1307](#C_1141-1307) | SNOMED CT |
| value | 0..1 | MAY | 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) |
| value | 0..1 | MAY | ST | [1141-1315](#C_1141-1315) |  |

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).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.6" (CONF:1141-1304).
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" (CONF:1141-1306).
   3. This code SHALL contain exactly one [1..1] @codeSystemName="SNOMED CT" (CONF:1141-1307).
5. MAY contain zero or one [0..1] value with @xsi:type="PQ" (CONF:1141-1303).
   1. The value, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1317).
   2. The value, if present, SHALL contain exactly one [1..1] @unit (ValueSet: [UnitsOfMeasureCaseSensitive](#UnitsOfMeasureCaseSensitive) urn:oid:2.16.840.1.113883.1.11.12839) (CONF:1141-1318).
      1. Dimensionless units **SHALL** be indicated by 1 (CONF:1141-1500).
6. MAY contain zero or one [0..1] value with @xsi:type="ST" (CONF:1141-1315).
7. A value element **SHALL** be present whose data type is either PQ  (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the device (though the units must still be a valid UCUM expression) (CONF:1141-1316).

Figure 9: Device Resolution Observation Example

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.6"/>

<code code="17441009" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="device measurement resolution"/>

<!-- A value element shall be present whose data type is either PQ (for a physical quantity) or ST (for a simple text description) for whatever units are appropriate for the device (though the units must still be a valid UCUM expression)-->

<!--Dimensionless units shall be indicated by 1-->

<value xsi:type="PQ" value="0.5" unit="hPa"/>

</observation>

Device Sampling Frequency Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.10 (open)]

Table 19: Device Sampling Frequency Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Device Definition Organizer](#E_Device_Definition_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 20: Device Sampling Frequency Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.10) | | | | | |
| @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 |
| code | 1..1 | SHALL |  | [1141-1288](#C_1141-1288) |  |
| @code | 1..1 | SHALL |  | [1141-1291](#C_1141-1291) | 67981 |
| @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) |  |
| 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).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.10" (CONF:1141-1290).
4. SHALL contain exactly one [1..1] code (CONF:1141-1288).
   1. This code SHALL contain exactly one [1..1] @code="67981" Ref id for this code is MDC\_ATTR\_TIME\_PD\_SAMP (CONF:1141-1291).  
      Note: Even though the MDC\_ATTR\_TIME\_PD\_SAMP IEEE 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. 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).

Figure 10: Device Sampling Frequency Observation Example

<observation classCode="OBS" moodCode="DEF">

<templateId root="2.16.840.1.113883.10.20.36.10"/>

<!-- This entry is NOT from the MDC\_ATTR\_TIME\_PD\_SAMP attribute of an RTSA! That is part of the waveforms -->

<!-- This value cannot be obtained directly IEEE 11073 20601 devices but is an inferred behavior -->

<code code="67981" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="refId is MDC\_ATTR\_TIME\_PD\_SAMP"/>

<!-- Time units are always in milliseconds -->

<value xsi:type="PQ" value="125" unit="ms"/>

</observation>

PHM Measurement Event Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.7 (open)]

Table 21: PHM Measurement Event Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) (optional) |  |

The PHM Event Observation describes the type of measurement reported from an enumeration metric object in an IEEE 11073 20601 PHM device. These measurements are typically represented as codes (on PHM devices these are MDC codes, ASN.1 codes, or ASN.1 bit settings where each bit represents something), or simply human readable strings.  Given the nature of this type of observation the code element describing the observation shall contain the MDC code, as that code is necessary in order to properly interpret all PHM observations that are reported as PHM events.

Table 22: PHM Measurement Event Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.7) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1148](#C_1141-1148) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1149](#C_1141-1149) | EVN |
| templateId | 1..1 | SHALL |  | [1141-1131](#C_1141-1131) |  |
| @root | 1..1 | SHALL |  | [1141-1150](#C_1141-1150) | 2.16.840.1.113883.10.20.36.7 |
| code | 1..1 | SHALL |  | [1141-1132](#C_1141-1132) |  |
| text | 0..1 | SHOULD |  | [1141-1135](#C_1141-1135) |  |
| reference | 0..1 | SHOULD |  | [1141-1136](#C_1141-1136) |  |
| @value | 0..1 | SHOULD |  | [1141-1137](#C_1141-1137) |  |
| statusCode | 1..1 | SHALL |  | [1141-1138](#C_1141-1138) |  |
| @code | 1..1 | SHALL |  | [1141-1155](#C_1141-1155) | completed |
| effectiveTime | 1..1 | SHALL |  | [1141-1134](#C_1141-1134) |  |
| value | 0..1 | MAY | CD | [1141-1139](#C_1141-1139) |  |
| @code | 1..1 | SHALL |  | [1141-1495](#C_1141-1495) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-1496](#C_1141-1496) | 2.16.840.1.113883.6.24 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1497](#C_1141-1497) | MDC |
| value | 0..1 | MAY | CD | [1141-1549](#C_1141-1549) |  |
| @code | 1..1 | SHALL |  | [1141-1550](#C_1141-1550) |  |
| @codeSystem | 1..1 | SHALL |  | [1141-1551](#C_1141-1551) | 2.16.840.1.113883.6.96 |
| @codeSystemName | 1..1 | SHALL |  | [1141-1552](#C_1141-1552) | SNOMED\_CT |
| value | 0..1 | MAY | ST | [1141-1381](#C_1141-1381) |  |
| value | 0..1 | MAY | INT | [1141-1379](#C_1141-1379) |  |
| author | 1..1 | SHALL |  | [1141-1165](#C_1141-1165) |  |
| assignedAuthor | 1..1 | SHALL |  | [1141-1207](#C_1141-1207) |  |
| id | 1..1 | SHALL |  | [1141-1208](#C_1141-1208) |  |
| assignedPerson | 0..1 | MAY |  | [1141-1213](#C_1141-1213) |  |
| name | 1..\* | SHALL |  | [1141-1214](#C_1141-1214) |  |
| assignedAuthoringDevice | 0..1 | MAY |  | [1141-1215](#C_1141-1215) |  |
| @classCode | 1..1 | SHALL |  | [1141-1217](#C_1141-1217) | DEV |
| @determinerCode | 1..1 | SHALL |  | [1141-1218](#C_1141-1218) | INSTANCE |
| entryRelationship | 0..\* | MAY |  | [1141-1542](#C_1141-1542) |  |
| observation | 1..1 | SHALL |  | [1141-1543](#C_1141-1543) |  |
| code | 1..1 | SHALL |  | [1141-1544](#C_1141-1544) |  |
| translation | 0..\* | SHOULD |  | [1141-1545](#C_1141-1545) |  |
| value | 0..\* | MAY |  | [1141-1547](#C_1141-1547) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1148).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-1149).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1131).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.7" (CONF:1141-1150).
4. SHALL contain exactly one [1..1] code (CONF:1141-1132).
   1. The coding system used in the event observation **SHALL** be  MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC) as this code is the only way to identify what the meaning of the measurement is when it is BITs integer. A translation element giving the corresponding SNOMED (CodeSystem: 2.16.840.1.113883.6.96) **SHOULD** be present. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-1151).
5. SHOULD contain zero or one [0..1] text (CONF:1141-1135).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-1136).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-1137).
         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:1141-1154).
6. SHALL contain exactly one [1..1] statusCode (CONF:1141-1138).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CONF:1141-1155).

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 measaurement 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.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-1134).
   1. Effective times containing accuracy greater than a day should contain the local time zone (CONF:1141-1153).
2. MAY contain zero or one [0..1] value with @xsi:type="CD" (CONF:1141-1139).
   1. The value, if present, SHALL contain exactly one [1..1] @code (CONF:1141-1495).
   2. The value, if present, SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.24" (CONF:1141-1496).
   3. The value, if present, SHALL contain exactly one [1..1] @codeSystemName="MDC" (CONF:1141-1497).
   4. This value element **SHALL** be present if the value is a code from a PHM device using the MDC code system (CodeSystem: 2.16.840.1.113883.6.24) or SNOMED (CodeSystem: 2.16.840.1.113883.6.96) code. A translation element **SHOULD** be present providing the MDC code if SNOMED is used or SNOMED if MDC is used. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-947) (CONF:1141-1498).
3. MAY contain zero or one [0..1] value with @xsi:type="CD" (CONF:1141-1549).
   1. The value, if present, SHALL contain exactly one [1..1] @code (CONF:1141-1550).
   2. The value, if present, SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CONF:1141-1551).
   3. The value, if present, SHALL contain exactly one [1..1] @codeSystemName="SNOMED\_CT" (CONF:1141-1552).
   4. This value element **SHALL** be present if the value is a code but not an MDC (CodeSystem: 2.16.840.1.113883.6.24) code. In that case the reported code **SHALL** use SNOMED (CodeSystem: 2.16.840.1.113883.6.96) code. A translation element **SHOULD** be present providing the MDC code. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-947) (CONF:1141-1553).
4. MAY contain zero or one [0..1] value with @xsi:type="ST" (CONF:1141-1381).
   1. This value element **SHALL** be present if the measurement reported by the PHM device is a human readable string. It **SHALL NOT** be present if the reported measurement is not a string (CONF:1141-1383).
5. MAY contain zero or one [0..1] value with @xsi:type="INT" (CONF:1141-1379).
   1. This value **SHALL** be present if the observation reported by the PHM device is an integer where each bit represents an item, event, or have some other defined meaning. For PHM devices the meaning of each bit in the integer is defined in the IEEE specialization document that defines the code present in the code element. This element **SHALL NOT** be present if the reported measurement is not an integer whose bits represent some item, event, or have some other defined meaning (CONF:1141-1384).
6. SHALL contain exactly one [1..1] author (CONF:1141-1165).
   1. This author SHALL contain exactly one [1..1] assignedAuthor (CONF:1141-1207).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF:1141-1208).
         1. The @root, @extension, and @assigningAuthorityName shall be taken from the equivalnet attributes of the Device PHMR Product Instance participantRole/id element (CONF:1141-1359).
      2. This assignedAuthor MAY contain zero or one [0..1] assignedPerson (CONF:1141-1213).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:1141-1214).
      3. This assignedAuthor MAY contain zero or one [0..1] assignedAuthoringDevice (CONF:1141-1215).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @classCode="DEV" (CONF:1141-1217).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @determinerCode="INSTANCE" (CONF:1141-1218).
      4. If the data in an observation was obtained directly from a PHM device, the observation **SHALL** include the assignedAuthoringDevice element and it **SHALL NOT** include the assignedPerson elelemt. If the data in an observation was entered manually, the observation **SHALL** include the assignedPerson element and **SHALL NOT** include the assignedAuthoringDevice element (CONF:1141-1216).
7. MAY contain zero or more [0..\*] entryRelationship (CONF:1141-1542).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] observation (CONF:1141-1543).
      1. This observation SHALL contain exactly one [1..1] code (CONF:1141-1544).
         1. This code SHOULD contain zero or more [0..\*] translation (CONF:1141-1545).
         2. The coding system used here **SHALL** be MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC) as this code is the only way to unambiguously identify the meaning of the the modification attribute. A translation element giving the corresponding SNOMED (CodeSystem: 2.16.840.1.113883.6.96) **SHOULD** be present. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-1546).
      2. This observation MAY contain zero or more [0..\*] value (CONF:1141-1547).
8. A single value element of either type CD, INT, or ST **SHALL** be present (CONF:1141-1380).
9. Some devices report attributes that modify the observation in some way, for example the Supplemental Types attribute of IEEE 11073 20601 devices. If there is a clear CDA equivalent for the concept, the CDA equivalent **MAY** be used, such as the targetSiteCode element for a measurement taken on a certain body location or the entryRelationship/procedure/specimen/targetSiteCode if the measurement was taken from a sample drawn at a certain body location, or the participant element if the attribute indicates something about how the measurement was taken (such as a tester, self, doctor, etc.). If no clear CDA equivalent can be found, the entryRelationship entry as described **SHALL** be used (CONF:1141-1548).

Figure 11: PHM Measurement Event Observation Example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.7"/>

<code code="8410916" displayName="MDC\_SABTE\_PATT\_EFFICACY\_CLS (SABTE Efficacy annotation events)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150322170922.86-0500"/>

<!-- This value is the ASN.1 MDER BITs value as an integer -->

<!-- It corresponds to 0x40000000 or 0100 0000 0000 0000 B -->

<value xsi:type="INT">1073741824</value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.7"/>

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150322170922.86-0500"/>

<!-- This value is itself an MDC code -->

<value code="8410895" displayName="MDC\_SABTE\_MODE\_THERAPY\_BPAP\_S\_AUTO (Bilevel positive air pressure therapy)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

PHM Measurement Numeric Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.8 (open)]

Table 23: PHM Measurement Numeric Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) (optional)  [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) (optional) |  |

The PHM Numeric Observation describes a measurement from a medical device. The technique used by the medical device to obtain the measurement may be equally as important in some medical situations as the measurement value. Thus the coding systems used to describe the measurement quantity in the PHM Numeric Observation are taken from MDC or SNOMED. The codes in these systems carry with it the method used by the device to obtain the measurement. For example, a heart rate can be obtained via an Electrocardiogram, a Pulseoximeter, or a non-invasive Blood Pressure cuff. In the SNOMED and MDC code systems, the heart rate for each of these devices is represented by a different code.

The Rosetta Terminology Mapping also provides a mapping between MDC and SNOMED.

Table 24: PHM Measurement Numeric Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.8) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-8](#C_1141-8) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-9](#C_1141-9) | EVN |
| templateId | 1..1 | SHALL |  | [1141-10](#C_1141-10) |  |
| @root | 1..1 | SHALL |  | [1141-11](#C_1141-11) | 2.16.840.1.113883.10.20.36.8 |
| templateId | 0..\* | MAY |  | [1141-944](#C_1141-944) |  |
| code | 1..1 | SHALL |  | [1141-12](#C_1141-12) |  |
| translation | 0..\* | SHOULD |  | [1141-1196](#C_1141-1196) |  |
| text | 0..1 | SHOULD |  | [1141-948](#C_1141-948) |  |
| reference | 0..1 | SHOULD |  | [1141-949](#C_1141-949) |  |
| @value | 0..1 | SHOULD |  | [1141-951](#C_1141-951) |  |
| statusCode | 1..1 | SHALL |  | [1141-971](#C_1141-971) |  |
| @code | 1..1 | SHALL |  | [1141-972](#C_1141-972) | completed |
| effectiveTime | 1..1 | SHALL |  | [1141-946](#C_1141-946) |  |
| value | 0..1 | MAY | PQ | [1141-973](#C_1141-973) |  |
| @value | 1..1 | SHALL |  | [1141-1300](#C_1141-1300) |  |
| @unit | 1..1 | SHALL |  | [1141-974](#C_1141-974) | urn:oid:2.16.840.1.113883.1.11.12839 (UnitsOfMeasureCaseSensitive) |
| value | 0..1 | MAY | IVL\_PQ | [1141-1513](#C_1141-1513) |  |
| low | 0..1 | MAY |  | [1141-1514](#C_1141-1514) |  |
| @value | 1..1 | SHALL |  | [1141-1519](#C_1141-1519) |  |
| @unit | 1..1 | SHALL |  | [1141-1520](#C_1141-1520) |  |
| high | 0..1 | MAY |  | [1141-1515](#C_1141-1515) |  |
| @value | 1..1 | SHALL |  | [1141-1521](#C_1141-1521) |  |
| @unit | 1..1 | SHALL |  | [1141-1522](#C_1141-1522) |  |
| value | 0..1 | MAY | PPD\_PQ | [1141-1516](#C_1141-1516) |  |
| @value | 1..1 | SHALL |  | [1141-1524](#C_1141-1524) |  |
| @unit | 1..1 | SHALL |  | [1141-1525](#C_1141-1525) |  |
| standardDeviation | 0..1 | MAY |  | [1141-1517](#C_1141-1517) |  |
| @value | 1..1 | SHALL |  | [1141-1526](#C_1141-1526) |  |
| @unit | 1..1 | SHALL |  | [1141-1527](#C_1141-1527) |  |
| author | 1..1 | SHALL |  | [1141-980](#C_1141-980) |  |
| assignedAuthor | 1..1 | SHALL |  | [1141-1173](#C_1141-1173) |  |
| id | 1..1 | SHALL |  | [1141-1177](#C_1141-1177) |  |
| assignedPerson | 0..1 | MAY |  | [1141-1193](#C_1141-1193) |  |
| name | 1..\* | SHALL |  | [1141-1194](#C_1141-1194) |  |
| assignedAuthoringDevice | 0..1 | MAY |  | [1141-1174](#C_1141-1174) |  |
| @classCode | 1..1 | SHALL |  | [1141-1175](#C_1141-1175) | DEV |
| @determinerCode | 1..1 | SHALL |  | [1141-1176](#C_1141-1176) | INSTANCE |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-8).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-9).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-10).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.8" (CONF:1141-11).
4. MAY contain zero or more [0..\*] templateId (CONF:1141-944).
   1. A Numeric Observation MAY also conform to other observation templates (such as a Result Observation or Vital Sign Observation). If so, it MAY also include the templateIds for those observation types (CONF:1141-945).
5. SHALL contain exactly one [1..1] code (CONF:1141-12).
   1. This code SHOULD contain zero or more [0..\*] translation (CONF:1141-1196).
   2. Observations from medical devices **SHALL** either be from SNOMED (CodeSystem: 2.16.840.1.113883.6.96)  or MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC). A translation element **SHOULD** be present providing the MDC code if SNOMED is used or SNOMED if MDC is used. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-947).
6. SHOULD contain zero or one [0..1] text (CONF:1141-948).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-949).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-951).
         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:1141-952).
7. SHALL contain exactly one [1..1] statusCode (CONF:1141-971).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CONF:1141-972).

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 measaurement 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.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-946).
   1. Effective times containing accuracy greater than a day should contain the local time zone (CONF:1141-1099).
   2. If a device reports a single time stamp without a measurement duration, the time stamp **SHALL** appear in the value attribute or 'low' element. If a duration element is also present, the start time **SHALL** appear in the 'low' element and the finish time in the 'high' element and the value attribute **SHALL** be absent (CONF:1141-1512).
2. MAY contain zero or one [0..1] value with @xsi:type="PQ" (CONF:1141-973).
   1. The value, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1300).
   2. The value, if present, 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:1141-974).
   3. This value data type **SHALL** be used when the value is not a maximum or minimum or statistical value taken over a period of time (CONF:1141-1518).
3. MAY contain zero or one [0..1] value with @xsi:type="IVL\_PQ" (CONF:1141-1513).
   1. The value, if present, MAY contain zero or one [0..1] low (CONF:1141-1514).
      1. The low, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1519).
      2. The low, if present, SHALL contain exactly one [1..1] @unit (CONF:1141-1520).
   2. The value, if present, MAY contain zero or one [0..1] high (CONF:1141-1515).
      1. The high, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1521).
      2. The high, if present, SHALL contain exactly one [1..1] @unit (CONF:1141-1522).
   3. This value data type **SHALL** be used when the value is a maximum or minimum taken over a period of time. If the value is a maximum, it **SHALL** be reported in the high element. If the value is a minimum, it **SHALL** be reported in the low element (CONF:1141-1523).
4. MAY contain zero or one [0..1] value with @xsi:type="PPD\_PQ" (CONF:1141-1516).
   1. The value, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1524).
   2. The value, if present, SHALL contain exactly one [1..1] @unit (CONF:1141-1525).
   3. The value, if present, MAY contain zero or one [0..1] standardDeviation (CONF:1141-1517).  
      Note: IEEE 11073 20601 Personal HealthCare Devices do not report standard deviations
      1. The standardDeviation, if present, SHALL contain exactly one [1..1] @value (CONF:1141-1526).
      2. The standardDeviation, if present, SHALL contain exactly one [1..1] @unit (CONF:1141-1527).
   4. This value data type **SHALL** be used when the value is a average or standard deviation taken over a period of time. If the value is an average, it **SHALL** be reported in @value attibute. If the value is a standard deviation it **SHALL** be reported in the standardDeviation element (CONF:1141-1528).
5. SHALL contain exactly one [1..1] author (CONF:1141-980).
   1. This author SHALL contain exactly one [1..1] assignedAuthor (CONF:1141-1173).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF:1141-1177).
         1. The @root, @extension, and @assigningAuthorityName shall be taken from the equivalnet attributes of the Device PHMR Product Instance participantRole/id element (CONF:1141-1360).
      2. This assignedAuthor MAY contain zero or one [0..1] assignedPerson (CONF:1141-1193).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:1141-1194).
      3. This assignedAuthor MAY contain zero or one [0..1] assignedAuthoringDevice (CONF:1141-1174).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @classCode="DEV" (CONF:1141-1175).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @determinerCode="INSTANCE" (CONF:1141-1176).
      4. If the data in an observation was obtained directly from a PHM device, the observation **SHALL** include the assignedAuthoringDevice element and it **SHALL NOT** include the assignedPerson elelemt. If the data in an observation was entered manually, the observation **SHALL** include the assignedPerson element and **SHALL NOT** include the assignedAuthoringDevice element (CONF:1141-1195).
6. A value element **SHALL** be present (CONF:1141-1529).

Figure 12: PHM Measurement Numeric Observation Example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<!-- Supports C-CDA V2 vital signs observation template but will NOT support C-CDA V2 results observation template -->

<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2014-06-09"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="150364" displayName="MDC\_TEMP\_BODY (Body temperature)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC">

<translation code="386725007" displayName="Body temperature" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<translation code="8310-5" displayName="Body temperature" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

</code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#VitalSignsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="PQ" value="36.04" unit="Cel"/>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="90-59-AF-FF-FE-1D-F9-B5" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

<!-- Value is a MIN -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="8410949" displayName="MDC\_SABTE\_PRESS\_MIN (Minimum therapy pressure)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="IVL\_PQ">

<low value="10.4" unit="hPa"/>

</value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

<!-- Value is a MAX -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="8410950" displayName="MDC\_SABTE\_PRESS\_MAX (Maximum therapy pressure)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="IVL\_PQ">

<high value="25.4" unit="hPa"/>

</value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

<!-- Value is a MEAN -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="8410951" displayName="MDC\_SABTE\_PRESS\_MEAN (Mean therapy pressure)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="PPD\_PQ" value="15.4" unit="hPa">

<standardDeviation xsi:type="PQ" value="5.6" unit="hPa"/>

</value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

PHM Measurement Waveform Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.11 (open)]

Table 25: PHM Measurement Waveform Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) (optional) |  |

The PHM Waveform Observation is the entry that contains the actual waveform data. Three entries are typically used to describe waveform data from a device. The 'parent' entry is the PHM Waveform Series observation which contains an entry relationship that contains an observation that contains its own entry relationship that contains the PHM Waveform Sample Period observation as well as one or more entry relationships containing this observation. The PHM Waveform Sample Period observation contains the start time and the time between each sample contained in the PHM Waveform observation 'digits' element. The code in this PHM Waveform observation matches the code in the PHM Waveform Series observation. In both cases MDC or SNOMED shall be used, and it is recommended that a translation element to the code system NOT used be present, so both the MDC and SNOMED codes are available to the reader. It is also recommended that LOINC codes be present as a translation element.

Table 26: PHM Measurement Waveform Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.11) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1013](#C_1141-1013) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1014](#C_1141-1014) | EVN |
| templateId | 1..1 | SHALL |  | [1141-997](#C_1141-997) |  |
| @root | 1..1 | SHALL |  | [1141-1015](#C_1141-1015) | 2.16.840.1.113883.10.20.36.11 |
| code | 1..1 | SHALL |  | [1141-998](#C_1141-998) |  |
| translation | 0..\* | SHOULD |  | [1141-1022](#C_1141-1022) |  |
| text | 0..1 | SHOULD |  | [1141-1000](#C_1141-1000) |  |
| reference | 0..1 | SHOULD |  | [1141-1001](#C_1141-1001) |  |
| @value | 0..1 | SHOULD |  | [1141-1002](#C_1141-1002) |  |
| value | 1..1 | SHALL | SLIST\_PQ | [1141-1004](#C_1141-1004) |  |
| origin | 1..1 | SHALL |  | [1141-1023](#C_1141-1023) |  |
| @value | 0..1 | SHOULD |  | [1141-1557](#C_1141-1557) |  |
| @unit | 0..1 | MAY |  | [1141-1492](#C_1141-1492) |  |
| scale | 1..1 | SHALL |  | [1141-1024](#C_1141-1024) |  |
| @value | 0..1 | SHOULD |  | [1141-1558](#C_1141-1558) |  |
| @unit | 0..1 | MAY |  | [1141-1493](#C_1141-1493) |  |
| digits | 1..1 | SHALL |  | [1141-1025](#C_1141-1025) |  |
| entryRelationship | 0..\* | MAY |  | [1141-1530](#C_1141-1530) |  |
| observation | 1..1 | SHALL |  | [1141-1531](#C_1141-1531) |  |
| code | 1..1 | SHALL |  | [1141-1532](#C_1141-1532) |  |
| translation | 0..\* | SHOULD |  | [1141-1536](#C_1141-1536) |  |
| value | 1..1 | SHALL |  | [1141-1538](#C_1141-1538) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1013).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-1014).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-997).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.11" Device Waveform observation (CONF:1141-1015).
4. SHALL contain exactly one [1..1] code (CONF:1141-998).
   1. This code SHOULD contain zero or more [0..\*] translation (CONF:1141-1022).
   2. Waveform observations from medical devices **SHALL** either be from SNOMED (CodeSystem: 2.16.840.1.113883.6.96)  or MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC). A translation element **SHOULD** be present providing the MDC code if SNOMED is used or SNOMED if MDC is used. If the specific SNOMED code is not known, the generic code 363681001 (Waveform observable) may be used but only in the translation element. In that case the code element **SHALL** use the MDC codeing system. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1). The code element here **SHALL** match that used in the PHM Waveform Series Observation (CONF:1141-1016).
5. SHOULD contain zero or one [0..1] text (CONF:1141-1000).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-1001).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-1002).
         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:1141-1019).
6. SHALL contain exactly one [1..1] value with @xsi:type="SLIST\_PQ" (CONF:1141-1004).

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. This value SHALL contain exactly one [1..1] origin (CONF:1141-1023).
     1. This origin SHOULD contain zero or one [0..1] @value (CONF:1141-1557).
     2. This origin MAY contain zero or one [0..1] @unit (CONF:1141-1492).

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. This value SHALL contain exactly one [1..1] scale (CONF:1141-1024).
     1. This scale SHOULD contain zero or one [0..1] @value (CONF:1141-1558).
     2. This scale MAY contain zero or one [0..1] @unit (CONF:1141-1493).

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. This value SHALL contain exactly one [1..1] digits (CONF:1141-1025).
  2. When units are required for the scale and origin elements, the units **SHALL** be drawn from the Unified Code for Units of Measure (UCUM).  For dimensionless data '1' **SHOULD** be used as the unit (CONF:1141-1494).

1. MAY contain zero or more [0..\*] entryRelationship (CONF:1141-1530).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] observation (CONF:1141-1531).
      1. This observation SHALL contain exactly one [1..1] code (CONF:1141-1532).
         1. This code SHOULD contain zero or more [0..\*] translation (CONF:1141-1536).
         2. The coding system used here **SHALL** be MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC) as this code is the only way to unambiguously identify the meaning of the the modification attribute. A translation element giving the corresponding SNOMED (CodeSystem: 2.16.840.1.113883.6.96) **SHOULD** be present. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-1151) (CONF:1141-1539).
      2. This observation SHALL contain exactly one [1..1] value (CONF:1141-1538).
   2. If the device reports an attribute that indicates something about how the measurement was taken (such as a tester, self, doctor, etc.) or otherwise modifies something about the observation (such as the MDC\_MODALITY\_SPOT value of the SupplementalTypes attribute) and no clear CDA equivalent can be found, this entryRelationship element **SHALL** be present (CONF:1141-1541).
2. Some devices report attributes that modify the observation in some way, for example the Supplemental Types attribute of IEEE 11073 20601 devices. If there is a clear CDA equivalent for the concept, the CDA equivalent **MAY** be used, such as the targetSiteCode element for a measurement taken on a certain body location or the entryRelationship/procedure/specimen/targetSiteCode if the measurement was taken from a sample drawn at a certain body location, or the participant element if the attribute indicates something about how the measurement was taken (such as a tester, self, doctor, etc.).  If no clear CDA equivalent can be found, the entryRelationship element as described using the observation element  **SHALL** be used (CONF:1141-1537).

Figure 13: PHM Measurement Waveform Observation Example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.11" />

<code code="8410948" displayName="MDC\_SABTE\_PRESS (SABTE Therapy pressure waveform)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value xsi:type="SLIST\_PQ">

<origin value="0.0" unit="hPa"/>

<scale value="0.1953125" unit="hPa" />

<digits>126 133 139 145 151 157 163 169 175 181 186 192 197 202 207 212 216 221 225 229 232 235 239 241 244 246 248 250 251 252 253 253 </digits>

</value>

</observation>

PHM Measurement Waveform Sample Period Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.13 (open)]

Table 27: PHM Measurement Waveform Sample Period Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) (optional) |  |

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 Waveform Series observation as one of the entry relationships describing structured data. That entry relationship contains a single observation element that contains multiple entry relationship elements. One of those entry relationship element must contain this sample period observation. All the other entry relationship elements in that observation contain the actual waveform data as PHM Waveform observations.

Table 28: PHM Measurement Waveform Sample Period Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.13) | | | | | |
| @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) | 2.16.840.1.113883.10.20.36.11 |
| 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).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.11" Device Waveform observation (CONF:1141-1033).
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).
      1. This head SHALL contain exactly one [1..1] @value (CONF:1141-1047).
         1. The head element shall contain the start time of the waveform data (CONF:1141-1051).

This value comes from the sample period attribute in the IEEE RTSA object

* 1. This value SHALL contain exactly one [1..1] increment (CONF:1141-1048).
     1. This increment SHALL contain exactly one [1..1] @value (CONF:1141-1049).
        1. This value shall be the time between each waveform sample (CONF:1141-1052).
     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).
        1. The unit shall indicate the time units of the interval; milliseconds, seconds, etc (CONF:1141-1053).

Figure 14: PHM Measurement Waveform Sample Period Observation Example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.13"/>

<code code="TIME\_ABSOLUTE" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" displayName="Absolute Time" />

<!-- This points to the Results or VitalSigns Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value>

<!-- The head element shall contain the start time of the waveform data.-->

<head value="20150322170922.86-0500"/>

<!-- This value shall be the time between each waveform sample.-->

<!-- The unit shall indicate the time units of the interval; milliseconds, seconds, etc.-->

<increment value="125" unit="ms"/>

</value>

</observation>

PHM Measurement Waveform Series Observation - Draft

[observation: identifier urn:oid:2.16.840.1.113883.10.20.36.12 (open)]

Table 29: PHM Measurement Waveform Series Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) (optional)  [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) (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. To fully describe the device waveform data two additional waveform observation entry types are present in the entry relationship elements of this observation, one entry describing the start time and period, and one of more 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 30: PHM Measurement Waveform Series Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.12) | | | | | |
| @classCode | 1..1 | SHALL |  | [1141-1070](#C_1141-1070) | OBSSER |
| @moodCode | 1..1 | SHALL |  | [1141-1071](#C_1141-1071) | EVN |
| templateId | 1..1 | SHALL |  | [1141-1054](#C_1141-1054) |  |
| @root | 1..1 | SHALL |  | [1141-1072](#C_1141-1072) | 2.16.840.1.113883.10.20.36.12 |
| code | 1..1 | SHALL |  | [1141-1055](#C_1141-1055) |  |
| translation | 0..\* | SHOULD |  | [1141-1092](#C_1141-1092) |  |
| text | 0..1 | SHOULD |  | [1141-1057](#C_1141-1057) |  |
| reference | 0..1 | SHOULD |  | [1141-1058](#C_1141-1058) |  |
| @value | 0..1 | SHOULD |  | [1141-1059](#C_1141-1059) |  |
| statusCode | 1..1 | SHALL |  | [1141-1060](#C_1141-1060) |  |
| @code | 1..1 | SHALL |  | [1141-1077](#C_1141-1077) | completed |
| effectiveTime | 1..1 | SHALL |  | [1141-1075](#C_1141-1075) |  |
| low | 1..1 | SHALL |  | [1141-1104](#C_1141-1104) |  |
| @value | 0..1 | MAY |  | [1141-1563](#C_1141-1563) |  |
| high | 0..1 | SHALL |  | [1141-1105](#C_1141-1105) |  |
| @value | 0..1 | MAY |  | [1141-1564](#C_1141-1564) |  |
| author | 1..1 | SHALL |  | [1141-1197](#C_1141-1197) |  |
| assignedAuthor | 1..1 | SHALL |  | [1141-1198](#C_1141-1198) |  |
| id | 1..1 | SHALL |  | [1141-1202](#C_1141-1202) |  |
| assignedPerson | 0..1 | MAY |  | [1141-1219](#C_1141-1219) |  |
| name | 1..\* | SHALL |  | [1141-1220](#C_1141-1220) |  |
| assignedAuthoringDevice | 0..1 | MAY |  | [1141-1199](#C_1141-1199) |  |
| @classCode | 1..1 | SHALL |  | [1141-1221](#C_1141-1221) | DEV |
| @determinerCode | 1..1 | SHALL |  | [1141-1222](#C_1141-1222) | INSTANCE |
| entryRelationship | 0..\* | SHOULD |  | [1141-1466](#C_1141-1466) |  |
| @typeCode | 1..1 | SHALL |  | [1141-1468](#C_1141-1468) | COMP |
| observation | 1..1 | SHALL |  | [1141-1467](#C_1141-1467) |  |
| @classCode | 1..1 | SHALL |  | [1141-1469](#C_1141-1469) | OBSCOR |
| @moodCode | 1..1 | SHALL |  | [1141-1470](#C_1141-1470) | EVT |
| code | 1..1 | SHALL |  | [1141-1490](#C_1141-1490) |  |
| @nullFlavor | 1..1 | SHALL |  | [1141-1491](#C_1141-1491) | NA |
| entryRelationship | 1..1 | SHALL |  | [1141-1471](#C_1141-1471) |  |
| @typeCode | 1..1 | SHALL |  | [1141-1475](#C_1141-1475) | COMP |
| observation | 1..1 | SHALL |  | [1141-1472](#C_1141-1472) | [PHM Measurement Waveform Sample Period Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.13](#E_PHM_Measurement_Waveform_Sample_Perio) |
| entryRelationship | 1..\* | SHALL |  | [1141-1473](#C_1141-1473) |  |
| @typeCode | 1..1 | SHALL |  | [1141-1478](#C_1141-1478) | COMP |
| observation | 1..1 | SHALL |  | [1141-1479](#C_1141-1479) | [PHM Measurement Waveform Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.11](#E_PHM_Measurement_Waveform_Observation) |
| entryRelationship | 0..\* | SHOULD |  | [1141-1474](#C_1141-1474) |  |
| @typeCode | 1..1 | SHALL |  | [1141-1480](#C_1141-1480) | COMP |
| observationMedia | 1..1 | SHALL |  | [1141-1481](#C_1141-1481) |  |
| @classCode | 1..1 | SHALL |  | [1141-1485](#C_1141-1485) | OBS |
| @moodCode | 1..1 | SHALL |  | [1141-1486](#C_1141-1486) | EVT |
| id | 0..\* | SHOULD |  | [1141-1482](#C_1141-1482) |  |
| @root | 0..1 | SHOULD |  | [1141-1487](#C_1141-1487) |  |
| value | 1..1 | SHALL |  | [1141-1483](#C_1141-1483) |  |
| @mediaType | 1..1 | SHOULD |  | [1141-1488](#C_1141-1488) |  |
| reference | 1..\* | SHALL |  | [1141-1484](#C_1141-1484) |  |
| @value | 1..1 | SHALL |  | [1141-1489](#C_1141-1489) |  |

1. SHALL contain exactly one [1..1] @classCode="OBSSER" (CONF:1141-1070).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CONF:1141-1071).
3. SHALL contain exactly one [1..1] templateId (CONF:1141-1054).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.36.12" (CONF:1141-1072).
4. SHALL contain exactly one [1..1] code (CONF:1141-1055).
   1. This code SHOULD contain zero or more [0..\*] translation (CONF:1141-1092).
   2. Waveform observations from medical devices **SHALL** either be from SNOMED (CodeSystem: 2.16.840.1.113883.6.96)  or MDC (CodeSystem: 2.16.840.1.113883.6.24 DYNAMIC). A translation element **SHOULD** be present providing the MDC code if SNOMED is used or SNOMED if MDC is used. If the specific SNOMED code is not known, the generic code 363681001 (Waveform observable) may be used but only in the translation element. In that case the code element **SHALL** use the MDC codeing system. An additional translation element **SHOULD** be present providing the code from LOINC (CodeSystem: 2.16.840.1.113883.6.1) (CONF:1141-1073).
5. SHOULD contain zero or one [0..1] text (CONF:1141-1057).
   1. The text, if present, SHOULD contain zero or one [0..1] reference (CONF:1141-1058).
      1. The reference, if present, SHOULD contain zero or one [0..1] @value (CONF:1141-1059).
         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:1141-1076).
6. SHALL contain exactly one [1..1] statusCode (CONF:1141-1060).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CONF:1141-1077).

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 measaurement 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.

1. SHALL contain exactly one [1..1] effectiveTime (CONF:1141-1075).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:1141-1104).
      1. This low MAY contain zero or one [0..1] @value (CONF:1141-1563).
      2. This timestamp shall be the time of the first data point in the waveform (CONF:1141-1109).
   2. This effectiveTime SHALL contain zero or one [0..1] high (CONF:1141-1105).
      1. The high, if present, MAY contain zero or one [0..1] @value (CONF:1141-1564).
      2. This timestamp shall be the time of the last data point in the waveform (CONF:1141-1110).
   3. Effective times containing accuracy greater than a day should contain the local time zone (CONF:1141-1100).
2. SHALL contain exactly one [1..1] author (CONF:1141-1197).
   1. This author SHALL contain exactly one [1..1] assignedAuthor (CONF:1141-1198).
      1. This assignedAuthor SHALL contain exactly one [1..1] id (CONF:1141-1202).
         1. The @root, @extension, and @assigningAuthorityName shall be taken from the equivalnet attributes of the Device PHMR Product Instance participantRole/id element (CONF:1141-1361).
      2. This assignedAuthor MAY contain zero or one [0..1] assignedPerson (CONF:1141-1219).
         1. The assignedPerson, if present, SHALL contain at least one [1..\*] name (CONF:1141-1220).
      3. This assignedAuthor MAY contain zero or one [0..1] assignedAuthoringDevice (CONF:1141-1199).
         1. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @classCode="DEV" (CONF:1141-1221).
         2. The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] @determinerCode="INSTANCE" (CONF:1141-1222).
      4. If the data in an observation was obtained directly from a PHM device, the observation **SHALL** include the assignedAuthoringDevice element and it **SHALL NOT** include the assignedPerson elelemt. If the data in an observation was entered manually, the observation **SHALL** include the assignedPerson element and **SHALL NOT** include the assignedAuthoringDevice element (CONF:1141-1201).
3. SHOULD contain zero or more [0..\*] entryRelationship (CONF:1141-1466).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-1468).
   2. The entryRelationship, if present, SHALL contain exactly one [1..1] observation (CONF:1141-1467).
      1. This observation SHALL contain exactly one [1..1] @classCode="OBSCOR" (CONF:1141-1469).
      2. This observation SHALL contain exactly one [1..1] @moodCode="EVT" (CONF:1141-1470).
      3. This observation SHALL contain exactly one [1..1] code (CONF:1141-1490).
         1. This code SHALL contain exactly one [1..1] @nullFlavor="NA" (CONF:1141-1491).
      4. This observation SHALL contain exactly one [1..1] entryRelationship (CONF:1141-1471).
         1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-1475).
         2. This entryRelationship SHALL contain exactly one [1..1] [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) (identifier: urn:oid:2.16.840.1.113883.10.20.36.13) (CONF:1141-1472).
      5. This observation SHALL contain at least one [1..\*] entryRelationship (CONF:1141-1473).
         1. Such entryRelationships SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-1478).
         2. Such entryRelationships SHALL contain exactly one [1..1] [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.11) (CONF:1141-1479).
4. SHOULD contain zero or more [0..\*] entryRelationship (CONF:1141-1474).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:1141-1480).
   2. The entryRelationship, if present, SHALL contain exactly one [1..1] observationMedia (CONF:1141-1481).
      1. This observationMedia SHALL contain exactly one [1..1] @classCode="OBS" (CONF:1141-1485).
      2. This observationMedia SHALL contain exactly one [1..1] @moodCode="EVT" (CONF:1141-1486).
      3. This observationMedia SHOULD contain zero or more [0..\*] id (CONF:1141-1482).
         1. The id, if present, SHOULD contain zero or one [0..1] @root (CONF:1141-1487).
      4. This observationMedia SHALL contain exactly one [1..1] value (CONF:1141-1483).
         1. This value SHOULD contain exactly one [1..1] @mediaType (CONF:1141-1488).
         2. This value SHALL contain at least one [1..\*] reference (CONF:1141-1484).
            1. Such references SHALL contain exactly one [1..1] @value (CONF:1141-1489).

Figure 15: PHM Measurement Waveform Series Observation Example

<observation classCode="OBSSER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.12"/>

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150323190039">

<!-- This timestamp shall be the time of the first data point in the waveform-->

<low value="20150322170922.86-0500"/>

<!-- This timestamp shall be the time of the last data point in the waveform-->

<high value="20150322170923.86-0500"/>

</effectiveTime>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

<entryRelationship typeCode="COMP">

<observation classCode="OBSCOR" moodCode="EVT">

<code nullFlavor="NA"/>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.13"/>

<code code="TIME\_ABSOLUTE" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" displayName="Absolute Time" />

<!-- This points to the Results or VitalSigns Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value>

<!-- The head element shall contain the start time of the waveform data.-->

<head value="20150322170922.86-0500"/>

<!-- This value shall be the time between each waveform sample.-->

<!-- The unit shall indicate the time units of the interval; milliseconds, seconds, etc.-->

<increment value="125" unit="ms"/>

</value>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.11" />

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value xsi:type="SLIST\_PQ">

<origin value="0.0" unit="hPa"/>

<scale value="0.1953125" unit="hPa" />

<digits>126 133 139 145 151 157 163 169 175 181 186 192 197 202 207 212 216 221 225 229 232 235 239 241 244 246 248 250 251 252 253 253 </digits>

</value>

</observation>

</entryRelationship>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP"></entryRelationship>

</observation>

PHMR Result Organizer (V2) - Draft

[organizer: identifier urn:oid:2.16.840.1.113883.10.20.36.16 (open)]

Table 31: PHMR Result Organizer (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Results Section (entries optional) (V2)](#S_PHMR_Results_Section_entries_optional) (optional) | [PHM Measurement Event Observation](#E_PHM_Measurement_Event_Observation)  [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation)  [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) |

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 32: PHMR Result Organizer (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:oid:2.16.840.1.113883.10.20.36.16) | | | | | |
| @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 |
| id | 1..\* | SHALL |  | [1141-1408](#C_1141-1408) |  |
| code | 1..1 | SHALL |  | [1141-1400](#C_1141-1400) |  |
| 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 Measurement Numeric Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.8](#E_PHM_Measurement_Numeric_Observation) |
| component | 0..\* | MAY |  | [1141-1417](#C_1141-1417) |  |
| observation | 1..1 | SHALL |  | [1141-1419](#C_1141-1419) | [PHM Measurement Waveform Series Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.12](#E_PHM_Measurement_Waveform_Series_Obser) |
| component | 0..\* | MAY |  | [1141-1418](#C_1141-1418) |  |
| observation | 1..1 | SHALL |  | [1141-1420](#C_1141-1420) | [PHM Measurement Event Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.7](#E_PHM_Measurement_Event_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).
4. SHALL contain at least one [1..\*] id (CONF:1141-1408).
5. SHALL contain exactly one [1..1] code (CONF:1141-1400).
   1. **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) **OR** SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). For PHM devices it may often be appropriate to repeat the PHMR Results Section code of 30954-2 since the observations being grouped are coming from a single device and not a battery of devices (CONF:1141-1409).

For IEEE 11073 20602 devices this would most likely be 'completed'

1. SHALL contain exactly one [1..1] statusCode (CONF:1141-1401).
   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).
2. 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).
3. MAY contain zero or more [0..\*] component (CONF:1141-1398) such that it
   1. SHALL contain exactly one [1..1] [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.8) (CONF:1141-1403).
4. MAY contain zero or more [0..\*] component (CONF:1141-1417) such that it
   1. SHALL contain exactly one [1..1] [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) (identifier: urn:oid:2.16.840.1.113883.10.20.36.12) (CONF:1141-1419).
5. MAY contain zero or more [0..\*] component (CONF:1141-1418) such that it
   1. SHALL contain exactly one [1..1] [PHM Measurement Event Observation](#E_PHM_Measurement_Event_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.7) (CONF:1141-1420).

Figure 16: PHMR Result Organizer Example

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.16"/>

<id root="d2c3ce7d-0895-40fc-91e0-105d73669837"/>

<!-- Selected from LOINC or SNOMED CT and may be selected from CPT-4 For PHM devices it may often be appropriate to repeat the PHMR Results Section code of 30954-2 since the observations being grouped are coming from a single device and not a battery of devices.-->

<code code="30954-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Results"/>

<statusCode code="completed"/>

<effectiveTime>

<!-- The low and high time could be equal if there is no effective time range -->

<low value="20150322170922.86-0500"/>

<high value="20150322170923.86-0500"/>

</effectiveTime>

<component>

<!-- Here one can insert the Phm Numeric Observation if there is one -->

<observation classCode="OBS" moodCode="EVN">

---------------------------

</observation>

</component>

<component>

<!-- Here one can insert the Phm Waveform Series Observation if there is one -->

<observation classCode="OBSSER" moodCode="EVN">

---------------------------

</observation>

</component>

<component>

<!-- Here one can insert the Phm Event Observation if there is one -->

<observation classCode="OBS" moodCode="EVN">

---------------------------

</observation>

</component>

</organizer>

<!-- Full example with observation content -->

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.16"/>

<id root="d2c3ce7d-0895-40fc-91e0-105d73669837"/>

<!-- Selected from LOINC or SNOMED CT and may be selected from CPT-4 For PHM devices it may often be appropriate to repeat the PHMR Results Section code of 30954-2 since the observations being grouped are coming from a single device and not a battery of devices.-->

<code code="30954-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Results"/>

<statusCode code="completed"/>

<effectiveTime>

<!-- The low and high time could be equal if there is no effective time range -->

<low value="20150322170922.86-0500"/>

<high value="20150322170923.86-0500"/>

</effectiveTime>

<component>

<!-- Here one can insert the Phm Numeric Observation if there is one -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="8410951" displayName="MDC\_SABTE\_PRESS\_MEAN (Mean therapy pressure)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="PPD\_PQ" value="15.4" unit="hPa">

<standardDeviation xsi:type="PQ" value="5.6" unit="hPa"/>

</value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

</component>

<component>

<!-- Here one can insert the Phm Waveform Series Observation if there is one -->

<observation classCode="OBSSER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.12"/>

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150323190039">

<!-- This timestamp shall be the time of the first data point in the waveform-->

<low value="20150322170922.86-0500"/>

<!-- This timestamp shall be the time of the last data point in the waveform-->

<high value="20150322170923.86-0500"/>

</effectiveTime>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

<entryRelationship typeCode="COMP">

<observation classCode="OBSCOR" moodCode="EVT">

<code nullFlavor="NA"/>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.13"/>

<code code="TIME\_ABSOLUTE" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" displayName="Absolute Time" />

<!-- This points to the Results or VitalSigns Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value>

<!-- The head element shall contain the start time of the waveform data.-->

<head value="20150322170922.86-0500"/>

<!-- This value shall be the time between each waveform sample.-->

<!-- The unit shall indicate the time units of the interval; milliseconds, seconds, etc.-->

<increment value="125" unit="ms"/>

</value>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.11" />

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<value xsi:type="SLIST\_PQ">

<origin value="0.0" unit="hPa"/>

<scale value="0.1953125" unit="hPa" />

<digits>126 133 139 145 151 157 163 169 175 181 186 192 197 202 207 212 216 221 225 229 232 235 239 241 244 246 248 250 251 252 253 253 </digits>

</value>

</observation>

</entryRelationship>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP"></entryRelationship>

</observation>

</component>

<component>

<!-- Here one can insert the Phm Event Observation if there is one -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.7"/>

<code code="8410888" displayName="MDC\_SABTE\_MODE\_THERAPY\_SET (SABTE Therapy mode)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></code>

<!-- This points to the Results Section text element containing the observation data -->

<text>

<reference value="#ResultsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150322170922.86-0500"/>

<!-- This value is itself an MDC code -->

<value code="8410895" displayName="MDC\_SABTE\_MODE\_THERAPY\_BPAP\_S\_AUTO (Bilevel positive air pressure therapy)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"></value>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="EC-DE-3D-00-00-00-00-01" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

</component>

</organizer>

PHMR Vital Signs Organizer (V2) - Draft

[organizer: identifier urn:oid:2.16.840.1.113883.10.20.36.2 (open)]

Table 33: PHMR Vital Signs Organizer (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [PHMR Vital Signs Section (entries optional) (V2)](#S_PHMR_Vital_Signs_Section_entries_opti) (optional) | [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation)  [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) |

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 34: PHMR Vital Signs Organizer (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| organizer (identifier: urn:oid:2.16.840.1.113883.10.20.36.2) | | | | | |
| @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 |
| id | 1..\* | SHALL |  | [1141-1434](#C_1141-1434) |  |
| code | 0..1 | MAY |  | [1141-1428](#C_1141-1428) |  |
| @code | 1..1 | SHALL |  | [1141-1438](#C_1141-1438) | 74728-7 |
| @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 Measurement Numeric Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.8](#E_PHM_Measurement_Numeric_Observation) |
| component | 0..\* | MAY |  | [1141-1440](#C_1141-1440) |  |
| observation | 1..1 | SHALL |  | [1141-1441](#C_1141-1441) | [PHM Measurement Waveform Series Observation (identifier: urn:oid:2.16.840.1.113883.10.20.36.12](#E_PHM_Measurement_Waveform_Series_Obser) |

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).
4. SHALL contain at least one [1..\*] id (CONF:1141-1434).
5. MAY contain zero or one [0..1] code (CONF:1141-1428).
   1. The code, if present, SHALL contain exactly one [1..1] @code="74728-7" Vital signs, weight, height, head circumference, oximetry, BMI, and BSA panel - HL7.CCDAr1.1 (CONF:1141-1438).
   2. The code, if present, SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1 " LOINC (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.
8. MAY contain zero or more [0..\*] component (CONF:1141-1425) such that it
   1. SHALL contain exactly one [1..1] [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation) (identifier: urn:oid:2.16.840.1.113883.10.20.36.8) (CONF:1141-1429).
9. MAY contain zero or more [0..\*] component (CONF:1141-1440) such that it
   1. SHALL contain exactly one [1..1] [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) (identifier: urn:oid:2.16.840.1.113883.10.20.36.12) (CONF:1141-1441).
10. At least one component **SHALL be present** (CONF:1141-1461).

Figure 17: PHMR Vital Signs Organizer Example

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.2"/>

<id root="4a0f4ac0-0475-4eb0-8331-cb5dc96dd964"/>

<!-- Always uses the LOINC code for vital signs.-->

<code code="74728-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Vital Signs"/>

<statusCode code="completed"/>

<effectiveTime>

<!-- The low and high time could be equal if there is no effective time range. This entry is optional -->

<low value="20150321183730.86-0400"/>

<high value="20150321183730.86-0400"/>

</effectiveTime>

<component>

<!-- Here one can insert the Phm Numeric Observation if there is one -->

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.36.8"/>

<!-- Supports C-CDA V2 vital signs observation template but will NOT support C-CDA V2 results observation template -->

<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2014-06-09"/>

<id root="76c133be-fb37-4cb6-9307-84ef8326cc88"/>

<code code="150364" displayName="MDC\_TEMP\_BODY (Body temperature)" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC">

<translation code="386725007" displayName="Body temperature" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<translation code="8310-5" displayName="Body temperature" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

</code>

<!-- This points to the id of the text element in the parent section element -->

<text>

<reference value="#VitalSignsSection"/>

</text>

<statusCode code="completed" />

<effectiveTime value="20150321183730.86-0400"/>

<value xsi:type="PQ" value="36.04" unit="Cel"/>

<author>

<assignedAuthor>

<!-- This contains the same information found in the PHMR Product Instance id element -->

<id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" extension="90-59-AF-FF-FE-1D-F9-B5" assigningAuthorityName="EUI-64"/>

<assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE"/>

</assignedAuthor>

</author>

</observation>

</component>

<component>

<!-- Here one can insert the Phm Waveform Series Observation if there is one. For PHM devices this entry is rare; might be a heart rate or SpO2 trace. -->

<observation classCode="OBSSER" moodCode="EVN">

--------------------------------------

</observation>

</component>

</organizer>

# Template Ids in This Guide

Table 35: Template List

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) | document | urn:oid:2.16.840.1.113883.10.20.36 |
| [Universal Realm Header](#D_Universal_Realm_Header) | document | urn:oid:2.16.840.1.113883.10.20.29 |
| [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) | section | urn:oid:2.16.840.1.113883.10.20.36.1 |
| [PHMR Results Section (entries optional) (V2)](#S_PHMR_Results_Section_entries_optional) | section | urn:oid:2.16.840.1.113883.10.20.36.14 |
| [PHMR Vital Signs Section (entries optional) (V2)](#S_PHMR_Vital_Signs_Section_entries_opti) | section | urn:oid:2.16.840.1.113883.10.20.36.15 |
| [Device Accuracy Observation](#E_Device_Accuracy_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.3 |
| [Device Definition Organizer](#E_Device_Definition_Organizer) | entry | urn:oid:2.16.840.1.113883.10.20.36.4 |
| [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.5 |
| [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template) | entry | urn:oid:2.16.840.1.113883.10.20.36.9 |
| [Device Resolution Observation](#E_Device_Resolution_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.6 |
| [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.10 |
| [PHM Measurement Event Observation](#E_PHM_Measurement_Event_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.7 |
| [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.8 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.11 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:oid:2.16.840.1.113883.10.20.36.13 |
| [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) | entry | urn:oid:2.16.840.1.113883.10.20.36.12 |
| [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) | entry | urn:oid:2.16.840.1.113883.10.20.36.16 |
| [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) | entry | urn:oid:2.16.840.1.113883.10.20.36.2 |

Table 36: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [Personal Healthcare Monitoring Report 1.2](#Personal_Healthcare_Monitoring_Report_1) | document | urn:oid:2.16.840.1.113883.10.20.36 |
| [PHMR Medical Equipment Section (Entries Optional)](#S_PHMR_Medical_Equipment_Section_Entrie) | section | urn:oid:2.16.840.1.113883.10.20.36.1 |
| [Device Definition Organizer](#E_Device_Definition_Organizer) | entry | urn:oid:2.16.840.1.113883.10.20.36.4 |
| [Device Accuracy Observation](#E_Device_Accuracy_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.3 |
| [Device Measurement Range Observation](#E_Device_Measurement_Range_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.5 |
| [Device Resolution Observation](#E_Device_Resolution_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.6 |
| [Device Sampling Frequency Observation](#E_Device_Sampling_Frequency_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.10 |
| [PHMR Results Section (entries optional) (V2)](#S_PHMR_Results_Section_entries_optional) | section | urn:oid:2.16.840.1.113883.10.20.36.14 |
| [PHMR Result Organizer (V2)](#E_PHMR_Result_Organizer_V2) | entry | urn:oid:2.16.840.1.113883.10.20.36.16 |
| [PHM Measurement Event Observation](#E_PHM_Measurement_Event_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.7 |
| [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.8 |
| [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) | entry | urn:oid:2.16.840.1.113883.10.20.36.12 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.11 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:oid:2.16.840.1.113883.10.20.36.13 |
| [PHMR Vital Signs Section (entries optional) (V2)](#S_PHMR_Vital_Signs_Section_entries_opti) | section | urn:oid:2.16.840.1.113883.10.20.36.15 |
| [PHMR Vital Signs Organizer (V2)](#E_PHMR_Vital_Signs_Organizer_V2) | entry | urn:oid:2.16.840.1.113883.10.20.36.2 |
| [PHM Measurement Numeric Observation](#E_PHM_Measurement_Numeric_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.8 |
| [PHM Measurement Waveform Series Observation](#E_PHM_Measurement_Waveform_Series_Obser) | entry | urn:oid:2.16.840.1.113883.10.20.36.12 |
| [PHM Measurement Waveform Observation](#E_PHM_Measurement_Waveform_Observation) | entry | urn:oid:2.16.840.1.113883.10.20.36.11 |
| [PHM Measurement Waveform Sample Period Observation](#E_PHM_Measurement_Waveform_Sample_Perio) | entry | urn:oid:2.16.840.1.113883.10.20.36.13 |
| [Universal Realm Header](#D_Universal_Realm_Header) | document | urn:oid:2.16.840.1.113883.10.20.29 |
| [Device PHMR Product Instance Template](#E_Device_PHMR_Product_Instance_Template) | entry | urn:oid:2.16.840.1.113883.10.20.36.9 |

# Value Sets In This Guide

Table 37: 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 38: Marital Status

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Marital Status urn:oid:2.16.840.1.113883.1.11.12212  Marital Status is the domestic partnership status of a person.  Value Set Source: <http://www.hl7.org> | | | |
| Code | Code System | Code System OID | Print Name |
| A | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Annulled |
| D | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Divorced |
| T | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Domestic partner |
| I | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Interlocutory |
| L | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Legally Separated |
| M | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Married |
| S | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Never Married |
| P | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Polygamous |
| W | MaritalStatus | urn:oid:2.16.840.1.113883.5.2 | Widowed |

Table 39: Religious Affiliation

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Religious Affiliation urn:oid:2.16.840.1.113883.1.11.19185  A value set of codes that reflect spiritual faith affiliation.  Value Set Source: <http://www.hl7.org/v3ballotarchive_temp_16B8D83E-1C23-BA17-0CBFC625BE7BA72F/v3ballot/html/infrastructure/vocabulary/vocabulary.html#voc-sets> | | | |
| Code | Code System | Code System OID | Print Name |
| 1001 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Adventist |
| 1002 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | African Religions |
| 1003 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Afro-Caribbean Religions |
| 1004 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Agnosticism |
| 1005 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Anglican |
| 1006 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Animism |
| 1007 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Atheism |
| 1008 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Babi & Baha'I faiths |
| 1009 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Baptist |
| 1010 | ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 | Bon |
| ... | | | |

Table 40: Race

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Race urn:oid:2.16.840.1.113883.1.11.14914  Concepts in the race value set include the 5 minimum categories for race specified by OMB along with a more detailed set of race categories used by the Bureau of Census.  Value Set Source: <http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=1000-9> | | | |
| Code | Code System | Code System OID | Print Name |
| 1002-5 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | American Indian or Alaska Native |
| 2028-9 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Asian |
| 2054-5 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Black or African American |
| 2076-8 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Native Hawaiian or Other Pacific Islander |
| 2106-3 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | White |
| 1006-6 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Abenaki |
| 1579-2 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Absentee Shawnee |
| 1490-2 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Acoma |
| 2126-1 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Afghanistani |
| 1740-0 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Ahtna |
| ... | | | |

Table 41: EthnicityGroup

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: EthnicityGroup urn:oid:2.16.840.1.114222.4.11.837  Code System: Race & Ethnicity - CDC 2.16.840.1.113883.6.238  Value Set Source: <http://phinvads.cdc.gov/vads/ViewValueSet.action?id=35D34BBC-617F-DD11-B38D-00188B398520> | | | |
| Code | Code System | Code System OID | Print Name |
| 2135-2 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Hispanic or Latino |
| 2186-5 | Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 | Not Hispanic or Latino |

Table 42: 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 43: Country

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Country urn:oid:2.16.840.1.113883.3.88.12.80.63  This identifies the codes for the representation of names of countries, territories and areas of geographical interest.  Value Set Source: <http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm> | | | |
| Code | Code System | Code System OID | Print Name |
| AW | Country | urn:oid:2.16.840.1.113883.3.88.12.80.63 | Aruba |
| IL | Country | urn:oid:2.16.840.1.113883.3.88.12.80.63 | Israel |
| ... | | | |

Table 44: 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.ietf.org/rfc/rfc4646.txt](http://www.ietf.org/rfc/rfc4646.txt%20) | | | |
| 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 45: 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> | | | |
| 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 46: LanguageAbilityProficiency

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: LanguageAbilityProficiency urn:oid:2.16.840.1.113883.1.11.12199  Value Set Source: <http://www.hl7.org> | | | |
| 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 47: Administrative Gender (HL7 V3)

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Administrative Gender (HL7 V3) urn:oid:2.16.840.1.113883.1.11.1  Administrative Gender based upon HL7 V3 vocabulary. This value set contains only male, female and undifferentiated concepts.  Value Set Source: <http://www.hl7.org> | | | |
| Code | Code System | Code System OID | Print Name |
| F | AdministrativeGender | urn:oid:2.16.840.1.113883.5.1 | Female |
| M | AdministrativeGender | urn:oid:2.16.840.1.113883.5.1 | Male |
| UN | AdministrativeGender | urn:oid:2.16.840.1.113883.5.1 | Undifferentiated |

Table 48: 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 49: Result Status

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Result Status urn:oid:2.16.840.1.113883.11.20.9.39  Value Set Source: <http://www.hl7.org> | | | |
| 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 50: 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 |
| AdministrativeGender | urn:oid:2.16.840.1.113883.5.1 |
| 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 |
| MaritalStatus | urn:oid:2.16.840.1.113883.5.2 |
| Participationsignature | urn:oid:2.16.840.1.113883.5.89 |
| Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 |
| ReligiousAffiliation | urn:oid:2.16.840.1.113883.5.1076 |
| 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 |