

# CDA2 – PHMR – xml file template

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## GENERAL XML beginning

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```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="cda.xsl"?>
```

- cda.xsl is in the same folder as the xml file, so that Explorer can make the rendering

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## HEADER

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- 1- All documents begin with the **root element ClinicalDocument** which contains one or more attributes for namespace declarations.

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3
..\..\..\0.Standards\HL7\CCD\CDA\Schemas\cda\Schemas\CDA.xsd">
```

- **Namespace =** A namespace is a set of names in which all names are unique (for example: my family is a namespace because I want that all my children have different names; another family is another namespace because all children there will have unique names, too, but they can have the same name as one of my children, because they are different namespaces)
- **Xmlns =** xml namespace
- In this case the **namespace (xmlns:)** is **“urn:hl7-org:v3”** because PHMR Does not require any specific namespace
- **Xmlns:xsi =** namespace XMLSchema-Instance which contains several built-in attributes that can be used in any XML and XSD files with its location (**xsi:schemaLocation**)
- **Note that Instances should not include the xsi:schemaLocation1 element because of security issues.**

- 2- The **type.ID** is a technology-neutral explicit reference to the CDA, Release Two specification. The element has two attributes that must be valued as follows:

*root* = "2.16.840.1.113883.1.3" (which is the OID for HL7 Registered models);

*extension* = "POCD\_HD000040" (which is the unique identifier for the CDA, Release Two Hierarchical Description).

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

- **In typeId the root and extension are fixed**, but in most cases the root and extension are supplied by the application using internal OIDs or OIDs for an external organization such as HL7 or LOINC, or a third party that played some role in the event that is being documented, such as a lab, hospital, physicians office or other care setting.
- **OID** = ISO object identifiers (OIDs) uniquely specify the domain of a coded data value or an identifier for a person, organization, or other entity
- Together the **root and extension, when concatenated, result in a universally unique string** for identification of the document, person, or organization.

3- The ***ClinicalDocument/templateId*** element identifies the template that defines constraints on the content.

```
<templateId root="2.16.840.1.113883.10.20.9"/>
```

- root = 2.16.840.1.113883.**10.20.9**. This indicates conformance to the PHMR DSTU.
- Note that it is an OID

4- The ***id*** represents the unique instance identifier (UID) of a clinical document. The *id* element uniquely and universally distinguishes a document from all other documents. This allows documents to move among systems without ID collision within those systems. It has a root and an extension

```
<id root="db734647-fc99-424c-a864-7e3cda82e703"/>
```

- Root: usually the root should be the creating **organization's OID (or UUID in PHMR)** that has been assigned by an ISO assigning authority such as HL7 → the organization should ask HL7 to provide an OID (<http://www.hl7.org/oid/index.cfm>)
- Extension: is the **ID of the document within the organization**
- The combination of the two is unique

- 5- The **code element at the root level** of the document specifies the particular kind of document that is being created, such as a History and Physical, Discharge Summary, or Progress Note.

```
<code code="53576-5" codeSystem="2.16.840.1.113883.6.1"/>
```

- The value set is **drawn from LOINC**, and has a “Coding, With Extensions” (CWE) coding strength.
- **CWE** means that implementers should use the supplied code set, in this case from LOINC, but if none of the supplied set applies, a substitute code can be used.
- **Code =** contains the string indicating the type of document (53576-5" = "Personal Health Monitoring Report")
- **codeSystem** = OID of the organization that defined the string. (2.16.840.1.113883.6.1 LOINC®)
- For human-readability, the **optional elements** are codeSystemName and displayName

## 6- Title

```
<title>Good Health Personal Healthcare Monitoring Report</title>
```

- The title element must be present and specifies the local name used for the document in PHMR
- the title does not need to be the same as the display name provided with the document type code

- 7- The **effectiveTime** is the document creation time, when the document first came into being.

```
<effectiveTime value="20080501123333-0500"/>
```

- Where the CDA document is a transform from an original document in some other format, the effectiveTime is the time the original document is created.
- Date and times are coded per HL7 adoption of **ISO8601**.
- All **PHMR** documents authored by direct input to a computer system should record an effectiveTime that **should be (=optional) precise to the second**
- The effectiveTime shall include a **time zone** if more precise than to the day

8- **confidentialityCode** is a required contextual component of CDA and represents the level of confidentiality of the information in the document (see table or <http://wiki.hl7.de/index.php/2.16.840.1.113883.5.25>)

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

- the value expressed in the header holds true for the entire document, unless overridden by a nested value.
- The coding strength for this element is Coding With Extensions (CWE)
- The codeSystem refers to an HL7 OID that contains the code (<http://wiki.hl7.de/index.php/2.16.840.1.113883.5.25>)

Confidentiality		<p>Definition: Privacy metadata indicating the sender's sensitivity classification, which is based on an analysis of applicable privacy policies and the risk of harm that could result from unauthorized disclosure.</p> <p>Description: The confidentiality code assigned by a sender based on the information's sensitivity classification, which may convey a receiver's obligation to ensure that the information is not made available or redisclosed to unauthorized individuals, entities, or processes (security principals) per applicable policies.</p> <p>Map: Definition aligns with ISO 7498-2:1989 - Confidentiality is the property that information is not made available or disclosed to unauthorized individuals, entities, or processes.</p> <p>Usage Note: Confidentiality codes are used as metadata indicating the receiver responsibilities to ensure that the information is not made available or redisclosed to unauthorized individuals, entities, or processes (security principals) per applicable policies.</p>
.U	unrestricted	<p>Definition: Privacy metadata indicating that the information is not classified as sensitive.</p> <p>Examples: Includes publicly available information, e.g., business name, phone, email or physical address.</p> <p>Usage Note: This metadata indicates that the receiver has no obligation to consider additional policies when making access control decisions. Note that in some jurisdictions, personally identifiable information must be protected as confidential, so it would not be appropriate to assign a confidentiality code of "unrestricted" to that information even if it is publicly available.</p>
.L	low	<p>Definition: Privacy metadata indicating that the information has been de-identified, and there are mitigating circumstances that prevent re-identification, which minimize risk of harm from unauthorized disclosure. The information requires protection to maintain low sensitivity.</p> <p>Examples: Includes anonymized, pseudonymized, or non-personally identifiable information such as HIPAA limited data sets.</p> <p>Usage Note: This metadata indicates the receiver may have an obligation to comply with a data use agreement.</p> <p>No clear map to ISO 13606-4 Sensitivity Level (1) Care Management: RECORD_COMPONENTS that might need to be accessed by a wide range of administrative staff to manage the subject of care's access to health services.</p>
.M	moderate	<p>Definition: Privacy metadata indicating moderately sensitive information, which presents moderate risk of harm if disclosed without authorization.</p> <p>Examples: Includes allergies of non-sensitive nature used in food service; health information a patient authorizes to be used for marketing, released to a bank for a health credit card or savings account; or information in personal health record systems that are not governed under health privacy laws.</p> <p>Usage Note: This metadata indicates that the receiver may be obligated to comply with the receiver's terms of use or privacy policies.</p> <p>Partial Map to ISO 13606-4 Sensitivity Level (2) Clinical Management: Less sensitive RECORD_COMPONENTS that might need to be accessed by a wider range of personnel not all of whom are actively caring for the patient (e.g. radiology staff).</p>
.N	normal	<p>Definition: Privacy metadata indicating that the information is typical, non-stigmatizing health information, which presents typical risk of harm if disclosed without authorization.</p> <p>Examples: In the US, this includes what HIPAA identifies as the minimum necessary protected health information (PHI) given a covered purpose of use (treatment, payment, or operations). Includes typical, non-stigmatizing health information disclosed in an application for health, workers compensation, disability, or life insurance.</p> <p>Usage Note: This metadata indicates that the receiver may be obligated to comply with applicable jurisdictional privacy law or disclosure authorization.</p> <p>Partial Map to ISO 13606-4 Sensitivity Level (3) Clinical Care: Default for normal clinical care access (i.e. most clinical staff directly caring for the patient should be able to access nearly all of the EHR). Maps to normal confidentiality for treatment information but not to ancillary care, payment and operations</p>
.R	restricted	<p>Definition: Privacy metadata indicating highly sensitive, potentially stigmatizing information, which presents a high risk if disclosed without authorization. May be preempted by jurisdictional law, e.g., for public health reporting or emergency treatment.</p> <p>Examples: Includes information related to mental health, HIV, substance abuse, domestic violence, child abuse, genetic disease, and reproductive health. May be used to indicate proprietary or classified information that is not related to an individual, e.g., secret ingredients in a therapeutic substance; or the name of a manufacturer.</p> <p>Usage Note: This metadata indicates that the receiver may be obligated to comply with the information subject's consent directive or with organizational policies that are more stringent than jurisdictional privacy laws.</p> <p>Partial Map to ISO 13606-4 Sensitivity Level (4) Privileged Care: Access restricted to a small group of people caring intimately for the patient, perhaps an immediate care team or senior clinical party (the privileged clinical setting needs to be specified e.g. mental health).</p>
.V	very restricted	<p>Definition: Privacy metadata indicating extremely sensitive, likely stigmatizing information, which presents a very high risk if disclosed without authorization. This information must be kept in the highest confidence.</p> <p>Examples: Includes information about a victim of abuse, patient requested information sensitivity, and taboo subjects relating to health status that must be discussed with the patient by an attending provider before sharing with the patient. May also include information held under "legal lock" or attorney-client privilege.</p> <p>Usage Note: This metadata indicates that the receiver may not disclose this information except as directed by the information custodian, who may be the information subject.</p> <p>Partial Map to ISO 13606-4 Sensitivity Level (5) Personal Care: To be shared by the subject of care perhaps with only one or two other people whom they trust most, or only accessible to the subject of care (and to others by one-off authorizations).</p>

9- **LanguageCode**: PHMRs must be readable by medical practitioners, caregivers, and patients

<**languageCode** code="en-US"/>

- Form is: **nn-CC**

- **nn**: legal ISO-639-1 language code in lower case. ([http://en.wikipedia.org/wiki/List\\_of\\_ISO\\_639-1\\_codes](http://en.wikipedia.org/wiki/List_of_ISO_639-1_codes))
- **CC**: ISO-3166 country code in upper case. (<https://www.iso.org/obp/ui/#search>)

10-The **recordTarget** represents the person whose chart this document belongs to. Typically this is the patient who is also the subject of the report, although the subject can be a tissue sample, fetus, etc.

```

<recordTarget>
  <patientRole>
    <id extension="996-756-495" root="2.16.840.1.113883.19.5"/>
    <!-- The following tag was modified in Release 2-->
    <addr>
      <streetAddressLine>6666 Home Street</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:555-555-5001"/>
    <patient>
      <name>
        <given>Ned</given>
        <family>Nuclear</family>
        <suffix/>
      </name>
      <administrativeGenderCode code="M"
codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19320924"/>
    </patient>
  </patientRole>
</recordTarget>

```

- **root and extension of the id** are supplied by the organization that is defining patient.
- **The patientRole in PHMR must have name, telecom, and address** to support communication between the receiver of the document and the patient or any other person or organization mentioned within it
- **Patient/Name:** given, family, suffix
- **Telecom:** form is “tel: +XX-digits-digits”
- **Address :** streetAddressLine, city, state, postalCode, country
- When name, address, or telecom **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.
- **patient/birthTime element** SHALL be present in PHMR

- **patient/administrativeGenderCode element** SHALL be present.
- **Guardian** needed if patient is a minor child

11-The **author** element represents the humans and/or machines that authored the document.

```

<author>
  <time value="20080501123333-0500"/>
  <assignedAuthor>
    <id extension="996-756-498" root="2.16.840.1.113883.19.5"/>
    <!-- The following tag was modified in Release 2-->
    <addr>
      <streetAddressLine>1002 Healthcare
Drive</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:555-555-1002" use="WP"/>
    <assignedPerson>
      <name>Dr. Henry Seven</name>
    </assignedPerson>
    <representedOrganization>
      <id root="8a54f393-8015-460c-abd2-f29aad15481c"/>
      <name>Good Health Disease Management</name>
      <telecom value="tel:(999)555-1212" use="DIR"/>
      <addr>
        <streetAddressLine>1002 Healthcare
Drive</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
    </representedOrganization>
  </assignedAuthor>
</author>

```

- Contains required child elements: **time and assignedAuthor**.
- **assignedAuthor** requires an id and **in PHMR must have name, telecom, and address** to support communication between the receiver of the document and the patient or any other person or organization mentioned within it
- The **Time** shall include a **time zone** if more precise than to the day **in PHMR**

- The **assignedPerson**, and **representedOrganization** are optional.
- In PHMR, **assignedAuthor** element **SHALL contain at least one assignedPerson or assignedAuthoringDevice** element
- **assignedPerson** contains a name, which in turn has child elements given, family and suffix. (maps the author if person)
- **representedOrganization** contains child element id and may have an optional name element and **in PHMR should (=optional) have name, telecom, and address**
- There can be one or more authors identified in the header. Their authorship applies to the full document unless overridden.

12-The **custodian** element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian.

```

<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="8a54f393-8015-460c-abd2-f29aad15481c"/>
      <name>Good Health Hospital</name>
      <telecom value="tel:(999)555-3004" use="DIR"/>
      <addr>
        <streetAddressLine>1000 Hospital
Lane</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>

```

- Contains required child element **assignedCustodian**.
- assignedCustodian requires a **representedCustodianOrganization**, which requires an **id** (root) **and must have name, addr, and telecom in PHMR.**

13- Other **optional** elements: **dataEnterer** and **informant**

- The **informant** element describes the source of the information in a medical document.
- When **informant** is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.

- The **dataEnterer** element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document subject to their own interpretation. The data enterer adds information to the electronic system. A person can participate as both author and data enterer.
- If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a data enterer.
- When **dataEnterer** is present, an assignedEntity/assignedPerson element SHALL be present and a time element MAY be present. If present, it represents the starting time of entry of the data

#### 14- *ClinicalDocument/setId and ClinicalDocument/versionNumber*

- The ClinicalDocument/setId element uses the instance identifier (II) data type. The @root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the @extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.
- **PHMR:** Both ClinicalDocument/setId and ClinicalDocument/versionNumber SHALL be present or both SHALL be absent.
- **PHMR:** The @extension and/or @root of ClinicalDocument/setId and ClinicalDocument/id SHALL be different when both are present.

15- The **informationRecipient** element records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart

```
<informationRecipient>
  <intendedRecipient>
    <id root="8a54f393-8015-460c-abd2-f29aad15481c"/>
    <addr>
      <streetAddressLine>1000 Hospital Lane</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(999)555-1212" use="DIR"/>
  </informationRecipient>
  <name>Good Health Hospital</name>
```



```
        </informationRecipient>
    </intendedRecipient>
</informationRecipient>
```

- **Not mandatory in PHMR**
- If present → **id, name, addr, telecom**

16-**legalAuthenticator** identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Another tag is the **authenticator** that identifies the participant who attested to the accuracy of the information in the document.

```
<legalAuthenticator>
  <time value='20050329224512+0500'/>
  <signatureCode code='S'/>
  <assignedEntity>
    <id extension='1' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>1002 Healthcare
      Drive</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:555-555-1002' use='WP'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Henry</given>
        <family>Seven</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

```
<authenticator>
  <time value='20050329224512+0500'/>
  <signatureCode code='S'/>
  <assignedEntity>
    <id extension='3' root='2.16.840.1.113883.19'/>
    <addr>
```

```

        <streetAddressLine>1002 Healthcare Drive </streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
    </addr>
    <telecom value='tel:555-555-1002' use='WP' />
    <assignedPerson>
        <name>
            <prefix>Dr.</prefix>
            <given>Henry</given>
            <family>Seven</family>
            <suffix>Sr.</suffix>
        </name>
    </assignedPerson>
</assignedEntity>
</authenticator>

```

- a clinical document that does not contain this element has not been legally authenticated.
- The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.
- Local policies may choose **to delegate the function of legal authentication to a device or system** that generates the clinical document. In these cases, the legal authenticator is a person or organization accepting responsibility for the document, **not the generating device or system.**
- **PHMR legalAuthenticator:** The assignedEntity/assignedPerson and/or assignedEntity/representedOrganization element SHALL be present in legalAuthenticator.
- **PHMR Authenticator:** CONF-PHMR-39: An authenticator MAY be present. The assignedEntity/assignedPerson element SHALL be present in an authenticator element.

*17-**documentationOf/serviceEvent** describes the encounter during which the subject was seen and may include a code to describe the encounter as well as identifying the provider, location, time.*

```

    <serviceEvent classCode="MPROT">
        <effectiveTime>
            <low value="20080501"/>
            <high value="20080531"/>
        </effectiveTime>
    </serviceEvent>

```

- **PHMR** is for monitoring the patient over a period of time. This is shown by setting the value of ClinicalDocument/documentationOf/serviceEvent/@classCode to **MPROT** (Monitoring Program) and **indicating the duration over** which the person's health was monitored in ClinicalDocument/documentationOf/serviceEvent/**effectiveTime**.
- **Mandatory** : ClinicalDocument/documentationOf/serviceEvent/@classCode SHALL be MPROT (Monitoring Program) 2.16.840.1.113883.5.6 ActClass STATIC.and ServiceEvent/effectiveTime element SHALL be present, and SHALL reflect the period of time for which the patient's health was monitored.

---

*Rendering Header Information for Human Presentation*

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Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR's user interface.

Best practice would recommend that the following also be present whenever a document is viewed:

- Document title and document date
- Service and encounter types and date ranges as appropriate
- All persons named along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Selected organizations named along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget(s)

---

*BODY <component>*

---

The CDA body (**component**) can be represented using a

1- **nonXMLBody** → the content is an external file such as a TIFF image, MS RTF document, etc

**<component>**

**<nonXMLBody>**

**<text mediaType="text/plain">**

```

        <reference value="patient.txt"/>
    </text>
</nonXMLBody>
</component>

```

- **nonXMLBody** contains a **text element**, which has an **optional mediaType attribute** which identifies the encoding of the encapsulated data and identifies a method to interpret or render the data. Preferred mediaType values include "image/gif", "image/tiff", "text/rtf", "application/pdf", "image/g3fax", "text/html", "image/jpeg", "image/png", and "text/plain".
- A text element may contain a **reference or thumbnail element**. The reference has a required attribute of value, which contains a **URL pointing to the external object**. It may also contain an **optional useablePeriod** that can declare the length of time the object will be available.

2- **structuredBody** → the content will be XML structured content. XML structured content is always inserted into the structuredBody element, never as an external file.

- **PHMR must be structured** → The content of this element makes up the human-readable text of the document.
- Organized in sections and subsections with no order constraints. it is generally useful to put **personal healthcare monitoring information such as vital signs first, and supporting information like medical equipment towards the end of the document**.
- Medical Equipment and one of Vital Signs or Result is needed
- Each **section must have a code** and some **nonblank text or one or more subsections**, even if the purpose of the text is only to indicate that information is unknown

Table 2: Section Cardinality

Section	LOINC® code	Required(R)/Optional(O)
Medical Equipment	46264-8	R
Vital Signs	8716-3	R*
Purpose	48764-5	O
Medications	10160-0	O
Results	30954-2	R*

\* See CONF-PHMR-48: either Vital Signs or Results is required.

- **Text** → what is displayed on the document (e.g., Table with all the info regarding devices)

```

<text>
  <table border="1" width="100%">
    <tbody>
      <tr>
        <th>System Type</th>
        <th>System Model</th>
        <th>System Manufacturer</th>
        <th>System ID</th>
        <th>Production Spec</th>
        <th>Regulated</th>
      </tr>
      <tr>
        <td>Blood Pressure Monitor</td>
        <td>Pulse Master 2000</td>
        <td>Nonin</td>
        <td>1F-3E-46-78-9A-BC-DE-F1</td>
        <td>
          Unspecified:
          Serial Number: 584216<br/>
          Part Number: 69854<br/>
          Hardware Revision: 2.1<br/>
          Software Revision: 1.1<br/>
          Protocol Revision: 1.0<br/>
          Prod Spec GMDN:
        </td>
        <td>Regulated</td>
      </tr>
      <tr>
        <td>Glucose Meter</td>
        <td>Diastar</td>
        <td>Roche</td>
        <td>12-34-56-78-9A-BC-DE-F1</td>
        <td>
          Unspecified:
          Serial Number: 123456789<br/>
          Part Number: 1234<br/>
          Hardware Revision: 1.1<br/>
          Software Revision: 1.5<br/>
          Protocol Revision: 1.0<br/>
          Prod Spec GMDN:
        </td>
        <td>Regulated</td>
      </tr>
    </tbody>
  </table>

```

</tbody>

<text>

- **Entries** → CDA entries represent structured content provided for further computer processing (e.g., decision-support applications). CDA entries typically encode content present in the narrative block of the same section.
- **Coding** → SNOMED (code system = 2.16.840.1.113883.6.96), LOINC (code system = 2.16.840.1.113883.6.1) or IEEE 11073-10101 MDC (code system = 2.16.840.1.113883.6.24)
- **Data from Personal Health Monitoring devices** → include an **entryRelationship** element containing a **Device Reference Act** identifying the device providing the data for the observation. If the data in an observation was entered manually, the observation SHALL NOT include a Device Reference Act.
- **Alerts from devices** → recorded using **the interpretationCode** element on an observation. Usually they are not coded, so the human-readable equivalent of the alert is often the best information to communicate in the PHM report.
- **Alerts for threshold exceeded** → include **an interpretationCode** element with an **appropriate code** (such as “A” for abnormal) from 2.16.840.1.113883.5.83 ObservationInterpretation (DYNAMIC) as well as an originalText element describing the alert reported by the device.
- **Alert from missing data** → use null flavors on observation/code or observation/value
- **Time zone data** → must be included in the effectiveTime even though the device does not implement them.
- These entries are **derived from classes in the RIM** and enable formal representation of clinical statements in the narrative:

### Observation

```
classCode*: <= OBS
moodCode*: <= x_ActMoodDocumentObservation
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ObservationType
negationInd: BL [0..1]
derivationExpr: ST [0..1]
text: ED [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
priorityCode: CE CWE [0..1] <= ActPriority
repeatNumber: IVL<INT> [0..1]
languageCode: CS CNE [0..1] <= HumanLanguage
value: ANY [0..1]
interpretationCode: SET<CE> CNE [0..*]
methodCode: SET<CE> CWE [0..*]
targetSiteCode: SET<CD> CWE [0..*]
```

### RegionOfInterest

**classCode\***: <= *ROIIOVL*  
**moodCode\***: <= *EVN*  
**id\***: SET<II> [1..\*]  
**code\***: CS CNE [1..1] <= *ROIOverlayShape*  
**value\***: LIST<INT> [1..\*]

### ObservationMedia

**classCode\***: <= *OBS*  
**moodCode\***: <= *EVN*  
**id**: SET<II> [0..\*]  
**languageCode**: CS CNE [0..1] <= *HumanLanguage*  
**value\***: ED [1..1]

### SubstanceAdministration

**classCode\***: <= *SBADM*  
**moodCode\***: <= *x\_DocumentSubstanceMood*  
**id**: SET<II> [0..\*]  
**code**: CD CWE [0..1] <= *SubstanceAdministrationActCode*  
**negationInd**: BL [0..1]  
**text**: ED [0..1]  
**statusCode**: CS CNE [0..1] <= *ActStatus*  
**effectiveTime**: GTS [0..1]  
**priorityCode**: CE CWE [0..1] <= *ActPriority*  
**repeatNumber**: IVL<INT> [0..1]  
**routeCode**: CE CWE [0..1] <= *RouteOfAdministration*  
**approachSiteCode**: SET<CD> CWE [0..\*] <= *ActSite*  
**doseQuantity**: IVL<PQ> [0..1]  
**rateQuantity**: IVL<PQ> [0..1]  
**maxDoseQuantity**: RTO<PQ,PQ> [0..1]  
**administrationUnitCode**: CE CWE [0..1] <= *AdministrableDrugForm*

### Supply

**classCode\***: <= SPLY  
**moodCode\***: <= x\_DocumentSubstanceMood  
id: SET<II> [0..\*]  
code: CD CWE [0..1] <= ActCode  
text: ED [0..1]  
statusCode: CS CNE [0..1] <= ActStatus  
effectiveTime: GTS [0..1]  
priorityCode: SET<CE> CWE [0..\*] <= ActPriority  
repeatNumber: IVL<INT> [0..1]  
independentInd: BL [0..1]  
quantity: PQ [0..1]  
expectedUseTime: IVL<TS> [0..1]

### Procedure

**classCode\***: <= PROC  
**moodCode\***: <= x\_DocumentProcedureMood  
id: SET<II> [0..\*]  
code: CD CWE [0..1]  
negationInd: BL [0..1]  
text: ED [0..1]  
statusCode: CS CNE [0..1] <= ActStatus  
effectiveTime: IVL<TS> [0..1]  
priorityCode: CE CWE [0..1] <= ActPriority  
languageCode: CS CNE [0..1] <= HumanLanguage  
methodCode: SET<CE> CWE [0..\*]  
approachSiteCode: SET<CD> CWE [0..\*]  
targetSiteCode: SET<CD> CWE [0..\*]

### Encounter

**classCode\***: <= ENC  
**moodCode\***: <= x\_DocumentEncounterMood  
id: SET<II> [0..\*]  
code: CD CWE [0..1] <= ActEncounterCode  
text: ED [0..1]  
statusCode: CS CNE [0..1] <= ActStatus  
effectiveTime: IVL<TS> [0..1]  
priorityCode: CE CWE [0..1] <= ActPriority



**Organizer**  
classCode\*: <= x\_ActClassDocumentEntryOrganizer  
moodCode\*: <= EVN  
id: SET<I|> [0..\*]  
code: CD CWE [0..1] <= ActCode  
statusCode\*: CS CNE [1..1] <= ActStatus  
effectiveTime: IVL<TS> [0..1]

**Act**  
classCode\*: <= x\_ActClassDocumentEntryAct  
moodCode\*: <= x\_DocumentActMood  
id: SET<I|> [0..\*]  
code\*: CD CWE [1..1] <= ActCode  
negationInd: BL [0..1]  
text: ED [0..1]  
statusCode: CS CNE [0..1] <= ActStatus  
effectiveTime: IVL<TS> [0..1]  
priorityCode: CE CWE [0..1] <= ActPriority  
languageCode: CS CNE [0..1] <= HumanLanguage

## MEDICAL EQUIPMENT

- Needs **2 templateId, one for PHMR and one for CCD Medical Equipment Section**, the **code is 46264-8 (LOINC)**, title is **Medical Equipment**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.1.7"/>
  <templateId root="2.16.840.1.113883.10.20.9.1"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Medical Equipment</title>

  <text>...</text>

  <entry> ...</entry>
</section>
```

- Has to be present → otherwise, text saying “no device” or something else noting this fact
- Text** → contains the table for the information visualized by the user
- Entries** → each medical device is coded through a **Device Definition Organizer (type code = “COMP”, classCode = “CLUSTER”, moodCode = “EVN”, templateId @root is 2.16.840.1.113883.10.20.9.4)**

```
<entry typeCode="COMP">
  <organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.9.4"/>
    <id root="5a2ddd7e-f725-40f7-94f4-35d99218e587"/>
    <statusCode code="completed"/>
    <effectiveTime value="200708011348-0500"/>
  </organizer>
</entry>
```

```

<participant typeCode="SBJ">
  <participantRole classCode="MANU">
    <templateId root="2.16.840.1.113883.10.20.1.52"/>
    <templateId root="2.16.840.1.113883.10.20.9.9"/>
    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
assigningAuthorityName="EUI-64" extension="1F-3E-46-78-9A-BC-DE-
F1"/>
    <code nullFlavor="OTH">
      <originalText>Regulated Device</originalText>
    </code>
    <playingDevice>
      <!-- The following tag was modified in Release 2 - code was
corrected-->
      <code code="MDC_DEV_SPEC_PROFILE_BP"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"
displayName="BloodPressure Monitor">
        <translation code="32033000"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
CT" displayName="Arterial pressure monitor"/>
      </code>
      <manufacturerModelName>
        <!-- free text, could be any format -->
          Model: Pulse Master 2000
          Serial number:584216
          Part number: 69854
          Hardware revision: 2.1
          Software revision: 1.1
          Protocol revision: 1.0
          Unspecified (free text comment):
        </manufacturerModelName>
      </playingDevice>
    <scopingEntity>
      <desc>Nonin</desc>
    </scopingEntity>
  </participantRole>
</participant>
<component>
  <!-- sampling frequency observation -->
  <observation classCode="OBS" moodCode="DEF">
    <templateId root="2.16.840.1.113883.10.20.9.10"/>
    <code code="MDC_ATTR_TIME_PD_SAMP"
codeSystem="2.16.840.1.113883.6.24"/>
    <value xsi:type="PQ" value="10" unit="ms"/>
  </observation>
</component>
</organizer>
</entry>

```

- **Device definition Organizer** → must contain a “**participant**” with typeCode “SBJ” that contains the PHMD instance (templateId 2.16.840.1.113883.10.20.9.9)
- **Participant** → it is the “Product Instance Reference”. It contains a **participantRole with classCode = “MANU”** that is the Product Instance and has:
  - **two templateID**; CCD Product Instance template (CCD templateId 2.16.840.1.113883.10.20.1.52) and the other one where @root is 2.16.840.1.113883.10.20.9.9.
  - **id** element where @root is OID of device numbering space and @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);
  - **code** element where @nullFlavor is OTH (other) containing an originalText element describing the regulatory status of the device in plain text (e.g., "Regulated Device " or " Unregulated Device");
  - **playingDevice/code** element indicates the type of device, where @code SHALL be drawn from code system 2.16.840.1.113883.6.24 MDC DYNAMIC. An equivalent SNOMED CT® code MAY be used as a translation.
  - **A playingDevice/manufacturerModelName** that contains data items from the Continua data model (no constraints on the formatting, is plain text): Model, Unspecified, SerialNumber, PartNumber, HardwareRevision, SoftwareRevision, and ProtocolRevision. The manufacturerModelName may also contain device certification information.
  - **scopingEntity/desc** contains the manufacturer's name.
- Other components in the device definition organizer (one per device) →
  - **Sampling Frequency Observation** (templateId 2.16.840.1.113883.10.20.9.10) → **observation** element where @classCode is OBS and @moodCode is DEF; **templateId** element where @root is 2.16.840.1.113883.10.20.9.10; **code** element where @code is MDC\_ATTR\_TIME\_PD\_SAMP and @codeSystem is 2.16.840.1.113883.6.24 IEEE 11073 (STATIC); **value** element where @xsi:type is PQ containing the sampling period in milliseconds (@unit= “ms”).
  - **Device Measurement Range Observation** (templateId 2.16.840.1.113883.10.20.9.5) → **observation** element where @classCode is OBS and @moodCode is DEF; **templateId** where @root is 2.16.840.1.113883.10.20.9.5; **code** element where @code is MDC\_ATTR\_NU\_RANGE\_MSMT and @codeSystem is 2.16.840.1.113883.6.24 IEEE 11073 (STATIC); **value** element @xsi:type is IVL\_PQ (for a range of physical quantities) or ST (for a simple text description) describing the resolution of the device.
  - **Device Resolution Observation** (templateId 2.16.840.1.113883.10.20.9.6) → **observation** element where @classCode is OBS and @moodCode is DEF; **templateId** element where @root is 2.16.840.1.113883.10.20.9.6; **code** element where @code is 17441009 and @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (STATIC); **value** element where @xsi:type is PQ (for a physical quantity) or ST (for a simple text description) describing the resolution of the device, in whatever units are appropriate for the device in question (though units must still be a valid UCUM expression).

- **Device Accuracy Observation** (templateId 2.16.840.1.113883.10.20.9.3) → **observation** element where @classCode is OBS and @moodCode is DEF; **templateId** where @root is 2.16.840.1.113883.10.20.9.3; **code** element where @code is MDC\_ATTR\_NU\_ACCUR\_MSMT and @codeSystem is 2.16.840.1.113883.6.24 IEEE 11073 (STATIC); **value** element @xsi:type is PQ (for a physical quantity) or ST (for a simple text description) describing the processing accuracy of the device

## VITAL SIGNS

- Required only if there are no results

```

<section>
  <templateId root="2.16.840.1.113883.10.20.1.16"/>
  <templateId root="2.16.840.1.113883.10.20.9.2"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Vital Signs</title>

  <text>...</text>

  <entry> ...</entry>

</section>

```

- Needs **2 templateId, one for PHMR and one for CCD Medical Equipment Section, the code is 8716-3 (LOINC), title is Vital Signs**
- Vital Signs include → **Blood pressure, temperature, O2 saturation, respiratory rate, pulse**. All other values SHOULD be recorded in the Results section.
- **Text:** if empty → text to say it is empty
- **Entries type** →
  - **Numeric Observations** (templateId 2.16.840.1.113883.10.20.9.8) → **observation** element where @classCode is OBS and @moodCode is EVN; **templateId** where @root is 2.16.840.1.113883.10.20.9.8; **code** element where @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (DYNAMIC) or 2.16.840.1.113883.6.24 MDC (DYNAMIC); **value** element SHALL be present where @xsi:type is PQ (physical quantity) and the unit of measure is expressed using a valid Unified Code for Units of Measure (UCUM) expression; **participant** element conforming to the constraints of a PHMR Product Instance Reference.

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.31"/>
  <templateId root="2.16.840.1.113883.10.20.9.8"/>
  <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
  <!-- The following tag was modified in Release 2 - code and translation code
corrected-->

```

```

    <code code="433588001" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Temperature of digit of hand">
      <translation code="MDC_TEMP_FINGER"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"
displayName="Finger Temperature"/>
    </code>
    <statusCode code="completed"/>
    <effectiveTime value="20080501104033-0500"/>
    <value xsi:type="PQ" value="88.8" unit="[degF]"/>
    <participant typeCode="DEV">
      <participantRole>
        <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
      </participantRole>
    </participant>
  </observation>

```

- **Waveform Series Observations** (templateId 2.16.840.1.113883.10.20.9.12) → **observation** element where @classCode is OBSSER and @moodCode is EVN; templateId where @root is 2.16.840.1.113883.10.20.9.12; **code** element where @code is either 364681001 Waveform-observable or from the Waveform-observable hierarchy in SNOMED CT®, and @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (DYNAMIC); **effectiveTime** element containing low and high elements, where low represents the time of the first data point on the waveform, and high represents the time of the last data point; participant element conforming to the constraints of a PHMR Product Instance Reference; **entryRelationship element contains an observableMedia** element that includes a reference to a displayable graphic containing a graphic representation of the data in the waveform; correlated observations: **entryRelationship** element where @typeCode is COMP containing an observation element where @classCode is OBSCOR, @moodCode is EVN, **representing a container for series of correlated observations**; the correlated observations container contains ONLY ONE entryRelationship where @typeCode is COMP containing a **Waveform Sample Period Observation** (templateId 2.16.840.1.113883.10.20.9.13); the correlated observation container contains one or more entryRelationship elements where @typeCode is COMP each containing a **Waveform Observation** (templateId 2.16.840.1.113883.10.20.9.11).
  - **Waveform Sample Period Observation** → observation element where @classCode is OBS and @moodCode is EVN; templateId element where @root is 2.16.840.1.113883.10.20.9.13; code element where @code is TIME\_ABSOLUTE from 2.16.840.1.113883.5.4 ActCode (STATIC); value element where @xsi:type is GLIST\_TS containing a **head element which stores the time of the first data point**

**waveform, and an increment element showing the sample period**  
(the time between data points).

- **Waveform Observation** → **observation** element where @classCode is OBS and @moodCode is EVN; templateId element where @root is 2.16.840.1.113883.10.20.9.11; **code** element where @code is either 364681001 Waveform-observable or from the Waveform-observable hierarchy in SNOMED CT®, and @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (DYNAMIC); **value** element where @xsi:type is SLIST\_PQ containing origin, scale, and digits elements, where origin represents the **origin of the waveform (typically 0), scale is the scaling factor (typically 1), and digits contains a list of space-separated digits representing discrete data points on the waveform**. Where required as attributes on origin and scale, unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. For dimensionless values, “1” SHOULD be used as the unit.
- Table of suggested SNOMED codes

Concept ID	Description
364681001	Waveform-observable
250864000	Plethysmograph waveform
277923006	Pulse oximetry waveform

```

<observation classCode="OBSSER" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.9.12"/>
  <id root="f37a5e13-aae6-4f9c-8afc-af7a9ab087e0"/> <!--
The following tag was modified in Release 2 - code was corrected-->
  <code code="250864000" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Pulse oximetry waveform">
  <translation code="MDC_PULS_OXIM_PLETH"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Pulse
Oximeter Plethysmograph"/>
  </code>
  <effectiveTime>
    <low value="20071206121000.00-0400"/>
    <high value="20071206121000.99-0400"/>
  </effectiveTime>
  <participant typeCode="DEV">
    <participantRole>
      <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
assigningAuthorityName="EUI-64" extension="1A-3E-41-78-9A-BC-DE-42"/>
    </participantRole>
  </participant>
  <entryRelationship typeCode="COMP">
    <observationMedia classCode="OBS" moodCode="EVN"
ID="waveSeries1">

```

```

        <id root="d122a5e9-823e-403a-b49e-2c6daa150110"/>
        <value mediaType="image/jpeg">
            <reference value="wavel.jpg"/>
        </value>
    </observationMedia>
</entryRelationship>
<entryRelationship typeCode="COMP">
    <observation classCode="OBSCOR" moodCode="EVN">
        <code nullFlavor="NA"/>
        <entryRelationship typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.9.13"/>
                <code code="TIME_ABSOLUTE" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode" displayName="Absolute Time"/>
                <value xsi:type="GLIST_TS">
                    <head value="20071206121000.00"/>
                    <!-- The sample period is 13.375 ms -->
                    <increment value="0.013375" unit="s"/>
                </value>
            </observation>
        </entryRelationship>
    <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.9.11"/>

            <!-- The following tag was modified in Release 2 - code was corrected-->
            <code code="250864000" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Pulse oximetry waveform">
                <translation code="MDC_PULS_OXIM_PLETH"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Pulse
Oximeter Plethysmograph"/>
            </code>
            <statusCode code="completed"/>
            <value xsi:type="SLIST_PQ">
                <origin value="0" unit="1"/>
                <scale value="1" unit="1"/>
                <digits>94 92 92 91 90 90 89 88 86 85 84 82 81 80 79 78 77 77 77 76 77
77 77 78 78</digits>
            </value>
        </observation>
    </entryRelationship>
<entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        ....
    </observation>
</observation>

```

## RESULTS

- Required only if there are no vital signs

```
<section>
  <templateId root="2.16.840.1.113883.10.20.1.14"/>
  <templateId root="2.16.840.1.113883.10.20.9.14"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Results</title>

  <text>...</text>

  <entry> ...</entry>
</section>
```

- Needs **2 templateId, one for PHMR and one for CCD Medical Equipment Section, the code is 30954-2 (LOINC), title is Results**
- Results include → All values **except** Blood pressure, temperature, O2 saturation, respiratory rate, pulse (Vital Signs)
- **Entries type** → Numeric Observations (templateId 2.16.840.1.113883.10.20.9.8) and/or Waveform Series Observations (templateId 2.16.840.1.113883.10.20.9.12)
- If empty → text to say it is empty

## OPTIONAL SECTIONS

- Can be used to record medications, activity, exercise.
- Optional, unconstrained
- **Purpose** → code is 48764-5, CCD templateId 2.16.840.1.113883.10.20.1.13. the specific reason for which the report is created
- **Medications** → code is 10160-0, CCD templateId 2.16.840.1.113883.10.20.1.8. From LOINC: History of medication use defines a patient's current medications and history of pertinent medications. This term may also include a patient's prescription and dispense history.
- **Functional Status** → code is 30954-2, CCD templateId 2.16.840.1.113883.10.20.1.5.

## DEVICE-REPORTED EVENT OBSERVATIONS

- Sometimes devices report events that are not related to the health of the patient, but are necessary to properly perform remote monitoring.
- Events can be present directly inside a section/entry, organizer/component, or related to any other clinical statement via **an entryRelationship** element.
- **observation** element where @classCode is OBS and @moodCode is EVN
- **templateId** where @root is 2.16.840.1.113883.10.20.9.7.
- **code** element containing an appropriate event code from 2.16.840.1.113883.6.24 MDC DYNAMIC.



- **value** element where @xsi:type is CS or ST describing the event. Note that the codes reported by the devices are typically arbitrary values defined in device specific specifications, and are currently not part of any code system; thus it is often most useful to translate such a code into a human readable string (thus the ST datatype).
- **participant** element where @typeCode is SBJ SHOULD be present conforming to the constraints of a PHMR Product Instance Reference.

## NOTES

- Sometimes it is necessary to add **additional information to a PHM report that was not derived from device data**. Such information would typically be inserted by a disease management professional who is monitoring the patient before the document is finalized and sent to the ultimate recipient.
- any section MAY contain notes that add additional information not transmitted by the device in the **text element of a section**
- may also be present as a clinical statement entry of any type, in which case a reference element SHOULD be present linking the narrative text and the entry.

## REPORTING SUMMARIES

- aimed to send only **a summary of the information**, such as the maximum blood pressure encountered during the reporting period, or the person's average weight after several measurements.
- **Minimum or maximum** → **observation/value has @xsi:type is IVL PQ**, and the min or max values SHALL be reported using high and low elements respectively
- **Average** → average of values over a period of time (such as mean and standard deviation), **observation/value has @xsi:type is PPD PQ**, mean is expressed in @value, and standard deviation is expressed in standardDeviation/@value.