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Implementation Guide for CDA Release 2.0 Personal Healthcare Monitoring Report (PHMR)

(International Realm)

Draft Standard for Trial Use

Release 1.1

October 2010

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This specification is a set of constraints on existing work, and the extent to which it can accommodate the expressive requirements of personal healthcare monitoring reporting is a function of the richness of the model on which it is built, the HL7 Reference Information Model (RIM) and the RIM document standard, and the Clinical Document Architecture Release 2 (CDA R2).

Many thanks to all those who have worked for over a decade to produce these fundamental specifications and special thanks to structured documents co-chairs Liora Alschuler, Bob Dolin, Keith Boone, and Calvin Beebe for their support of this project. A special thanks also to Gunter Schadow, Grahame Grieve, and George Marcini and the HL7 Healthcare Devices WG co-chairs Todd Cooper, Jack Harrington, and Melvin Reynolds.

Revision History

Release	Date	Notes
1	Nov 18, 2008	First release of the DSTU
2	August 31, 2010	Conformance Statement change: ▪ CONF_PHMR78 - Allow other device ID numbering spaces - and only recommend EUI-64 guideline in the example Editorial Corrections: ▪ Figure 25 – Corrected order of codes in the example : primary code should be MDC and translation shall be SNOMED CT as defined in the CONF_PHMR80 ▪ Figure 28 – corrected the MDC code in the example to MDC_ATTR_NU_RANGE_MSMT ▪ APPENDIX A – removed duplicated CCD conformance statements CONF-407…CONF-418 and updated that section title to include all applicable template ids ▪ Corrected the example file CombinedSampleCDAPHM.xml to comply with DSTU and use valid SNOMED CT codes

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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to describe constraints on the CDA Header and Body elements for Personal Healthcare Monitoring Report (PHMR) documents.

The 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.

A CDA-based format has been chosen to accommodate the wide variety of information available.

Wherever possible, the PHMR reuses templates already set forth by the HL7 Continuity of Care Document (CCD).

1.2 Audience

The audience for this document is software developers and other implementers of Personal Healthcare Monitoring (PHM) systems interfacing with Electronic Health Record (EHR) systems, Electronic Medical Record (EMR) systems, Personal Health Record (PHR) systems, and national health information exchange networks who wish to create and/or process PHMR documents created according to this specification.

1.3 Approach

Overall, the approach is consistent with balloted Implementation Guides (IGs) for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the RIM defined in the CDA R2 Refined Message Information Model (RMIM). Implementation Guides such as this and the CCD add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This Draft Standard for Trial Use (DSTU) is an extension of HL7's Continuity of Care Document (CCD) specification. The structured body of a PHMR is intended to be compatible with CCD, although there are some differences in the CDA Header, most notably the document type code (`ClinicalDocument/code`) and document template (`ClinicalDocument/templateId`). Tools that recognize CCD templates in the body of a document should be able to process CCD content from a PHMR document as they

would process content from a full CCD document. However, such tools would not be expected to process additional templates defined in this specification and not found in CCD without further enhancement.

The PHMR adds constraints to CCD through conformance statements that further define and restrict the CCD objects and the vocabulary sets for coded elements.

1.4 Use of Templates

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and assigning a unique template identifier (`templateId`) to the collection establishes a shorthand mechanism for the instance creator to assert conformance to those constraints. The `templateId` itself carries no semantics. Validation errors against a template must not be construed as anything other than failure to meet the exact requirements of the template, and absence of a `templateId` need not be construed as failure to meet the constraints required by the template.

1.5 Conventions Used in This Guide

This Implementation Guide is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this Implementation Guide is the HL7 Clinical Document Architecture, Release 2.0. As defined in that document, this Implementation Guide is both an annotation profile and a localization profile. Every aspect of the CDA R2 may not be described in this guide.

1.5.1 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.

1.5.2 Conformance Requirements

Conformance requirements for this DSTU are of two types: those that are collected within a published template of CDA/V3 conformance statements and those that are not associated with a published template.

Where not associated with a published template, conformance requirements are numbered sequentially and listed within the body of the DSTU as follows:

CONF-PHMR-1: This is an example conformance requirement original to this DSTU.

Where conformance requirements from another DSTU or IG are associated with a template, they are included through assertion of that `templateId` and listed in two ways:

- In the body of the DSTU, they are listed as follows (example of a foreign external constraint from the CDA4CDT History and Physical DSTU):

  CONF-HP-66: All constraints from this section are from the CCD Medications section. See Appendix A — CCD Constraints for CCD conformance

requirements. This section **SHALL** include the CCD `templateId` for the medications section (2.16.840.1.113883.10.20.1.8).

- In Appendix B — Template IDs, they are listed using the original numbering sequence from the source guide:

  Medications (`templateId: 2.16.840.1.113883.10.20.1.8`)

  CCD-CONF-299: CCD **SHOULD** contain exactly one and **SHALL NOT** contain …

1.5.3 Explanatory Statements

Text that clarifies and summarizes the conformance statement appears throughout the document.

1.5.4 Example XML Code

XML examples appear in various figures in this document in a `fixed-width font`. Portions of the XML content may be omitted from the content for brevity marked by an ellipsis (…) as shown in the example below.

Figure 1: XML code example

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Within the narrative, XML element and attribute names will appear in `this fixed character font`.

1.5.5 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism that will be familiar to developers for identifying parts of an XML document.

1.5.6 Vocabulary and Value Sets

Appendix D — Terminology, lists the terminology supported in this specification and, where applicable, its mappings to IEEE 11073, SNOMED, and LOINC®.

1.5.7 Content of the Implementation Guide Package

The implementation guide package contains the following files:

Table 1: Contents of the Implementation Guide Package

Filename	Description	Status
CDA-IG-PHM.doc	This guide in Microsoft Word format	DSTU
CombinedSampleCDAPHM.xml	A sample CDA document showing information reported from a variety of devices.	Informational
CDA.xsl	A display stylesheet for the sample XML document	Informational
wave1.jpg	Image used in sample document	Informational

2 CDA HEADER CONSTRAINTS

While the body of a Personal Healthcare Monitoring Report contains constrained CCD templates, the header does not follow those constraints.

The header constraints are adopted from the CDA4CDT specification, History and Physical Note (CDAR2_HPRPT_R1_D2_2007SEP). The H&P specification is US realm so applying the `templateId` from the H&P, 2.16.840.1.113883.10.20.3, is only acceptable if the document is being used in the US realm.

All of the H&P constraints, minus the realm restriction, are included in this DSTU along with additional PHM specific constraints.

2.1 ClinicalDocument

The namespace for CDA R2 is `urn:hl7-org:v3`. The appropriate namespace must be used in the XML instance of the Clinical Document. In the examples in this specification, all elements are shown unprefixed, assuming that the default namespace is declared to be `urn:hl7-org:v3`. This DSTU does not require use of any specific namespace prefix. Instances should not include the `xsi:schemaLocation`[1] element.

CONF-PHMR-1: The root of a PHM report **SHALL** be a `ClinicalDocument` element from the `urn:hl7-org:v3` namespace.

2.2 ClinicalDocument/templateId

The `ClinicalDocument/templateId` element identifies the template that defines constraints on the content.

CONF-PHMR-2: A `ClinicalDocument/templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9`. This indicates conformance to this DSTU. U.S. realm implementations **MAY** also include an additional `templateId` where `@root` is `2.16.840.1.113883.10.20.3`, indicating conformance to the general header constraints defined in the History and Physical Implementation Guide

Figure 2: ClinicalDocument/templateId example

```
<!-- Required: conforms to the DSTU -->
<templateId root="2.16.840.1.113883.10.20.9"/>

<!-- U.S. only: indicates conformance with H&P general header constraints -->
<templateId root="2.16.840.1.113883.10.20.3"/>
```

[1] The `xsi:schemaLocation` element is not recommended by the XML ITS because of security risks. Receivers who choose to perform validation should use a locally cached schema.

2.3 ClinicalDocument/code

CONF-PHMR-3: The `ClinicalDocument/code` element **SHALL** be present. The value for "`ClinicalDocument/code`" **SHALL** be "`53576-5`" "`Personal Health Monitoring Report`" 2.16.840.1.113883.6.1 LOINC® **STATIC**.

2.4 Name, Address, and Telephone Numbers

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

CONF-PHMR-4: All `patient`, `guardianPerson`, `assignedPerson`, `maintainingPerson`, `relatedPerson`, `intendedRecipient/informationRecipient`, `associatedPerson`, and `relatedSubject/subject` elements **SHALL** have a name.

CONF-PHMR-5: All `patientRole`, `assignedAuthor`, and `associatedEntity` elements **SHOULD** have `addr` and `telecom` elements.

CONF-PHMR-6: All `guardian`, `dataEnterer/assignedEntity`, `relatedEntity`, `intendedRecipient`, `relatedSubject`, and `participantRole` elements **SHOULD** have `addr` and `telecom` elements.

CONF-PHMR-7: All `guardianOrganization`, `providerOrganization`, `wholeOrganization`, `representedOrganization`, `representedCustodianOrganization`, `receivedOrganization`, `scopingOrganization`, and `serviceProviderOrganization` elements **SHALL** have `name`, `addr`, and `telecom` elements.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance 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 3: Various uses of nullFlavor

```
<assignedEntity>
  <id extension='3' root='2.16.840.1.113883.19'/>
  <addr nullFlavor='UNK'/>
  <telecom nullFlavor='ASKU' use='WP'/>
  <assignedPerson>
    <name nullFlavor='NAV'/>
  </assignedPerson>
</assignedEntity>
```

Events occurring at a single point in time that are represented in the Clinical Document Header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

CONF-PHMR-8: Times or time intervals found in the `ClinicalDocument/effectiveTime`, `author/time`, `dataEnterer/time`, `legalAuthenticator/time`, `authenticator/time` and `encompassingEncounter/effectiveTime` elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day[2], and **SHOULD** be precise to the second.

CONF-PHMR-9: Times or time intervals found in the `asOrganizationPartOf/effectiveTime`, `asMaintainedEntity/effectiveTime`, `relatedEntity/effectiveTime`, `serviceEvent/effectiveTime`, `ClinicalDocument/participant/time`, `serviceEvent/performer/time`, and `encounterParticipant/time` elements **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

In CDA-conformant documents, all telephone numbers are to be encoded using a restricted form of the `tel`: URL scheme (as described below).

The `telecom` element is used to provide a contact telephone number for the various participants that require it. The `value` attribute of this element is a URL that specifies the telephone number, as indicated by the `TEL data type`.

Within the specification, all telephone numbers are to be encoded using the grammar of Figure 4 below, which is a restriction on the `TEL data type` and RFC 2806[3]. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN subaddress, phone context, or other dialing parameters.

A telephone number used for voice calls begins with the URL scheme `tel`:. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.

Figure 4: Restricted URL grammar for telephone communications

```
telephone-url= telephone-scheme ':' telephone-subscriber
telephone-scheme = 'tel'
telephone-subscriber = global-phone-number  [ extension ]
global-phone-number = '+' phone-number
phone-number = digits
digits = phonedigit | digits phonedigit
phonedigit = DIGIT | visual-separator
extension = ';ext=' digits
visual-separator = '-' | '.' | '(' | ')'
```

CONF-PHMR-10: Telephone numbers **SHALL** match the regular expression pattern: `tel:\+?[-0-9().]+`

[2] The XML ITS precludes the use of time zone unless the precision of the timestamp is more than to the day.

[3] Note that RFC 3966 obsoletes RFC 2806, but is backwards-compatible. The restricted grammar is compatible with both RFC 3966 and RFC 2806 by virtue of Section 2.5.11 of RFC 2806, which provides for additional parameters; e.g., '`;ext=`', to be added as future extensions.

CONF-PHMR-11: At least one dialing digit **SHALL** be present in the phone number after visual separators are removed.

2.5 ClinicalDocument/typeId

The `clinicalDocument/typeId` identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier. The `@root` and `@extension` values of this element are specified as shown in the figure below.

Figure 5: ClinicalDocument/typeId example

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

2.6 ClinicalDocument/id

The `ClinicalDocument/id` element is an instance identifier data type. The `@root` attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The `@root` and `@extension` attributes uniquely identify the document.

OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.

CONF-PHMR-12: The `ClinicalDocument/id` element **SHALL** be present. The `ClinicalDocument/id/@root` attribute **SHALL** be a syntactically correct UUID or OID.

CONF-PHMR-13: UUIDs **SHALL** be represented in the form XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX, where each X is a character from the set `[A-Fa-f0-9]`.

CONF-PHMR-14: OIDs **SHALL** be represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form `([0-2])(.([1-9][0-9]*|0))+`

Figure 6: ClinicalDocument/id example

```
<id extension='999021'  root='2.16.840.1.113883.19'/>
```

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

2.7 ClinicalDocument/title

The `title` element must be present and specifies the local name used for the document.

CONF-PHMR-15: `ClinicalDocument/title` **SHALL** be present.

Figure 7: ClinicalDocument/title example

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

Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "`Personal Health Monitoring Note`." The title can be localized, as appropriate (see Figure 7 above).

2.8 ClinicalDocument/effectiveTime

The `ClinicalDocument/effectiveTime` element must be present and specifies the creation time of the document. All PHMR documents authored by direct input to a computer system should record an `effectiveTime` that is precise to the second.

CONF-PHMR-16: `ClinicalDocument/effectiveTime` **SHALL** be present and **SHOULD** be precise to the second.

Figure 8: CinicalDocument/effectiveTime example

```
<effectiveTime value='20050303171504+0500'/>
```

2.9 ClinicalDocument/confidentialityCode

CDA R2 requires that the `ClinicalDocument/confidentialityCode` be present. It specifies the confidentiality assigned to the document. This DSTU provides no further guidance on documents with respect to the vocabulary used for `confidentialityCode`, nor treatment or implementation of confidentiality. A CDA R2-conforming example is shown below:

Figure 9: CinicalDocument/confidentialityCode example

```
<confidentialityCode code='N' codeSystem='2.16.840.1.113883.5.25'/>
```

2.10 ClinicalDocument/languageCode

The `ClinicalDocument/languageCode` specifies the language of the PHMR. PHMRs must be readable by medical practitioners, caregivers, and patients.

CONF-PHMR-17: `ClinicalDocument/languageCode` **SHALL** be present.

CONF-PHMR-18: `ClinicalDocument/languageCode` **SHALL** be in the form `nn`, or `nn-CC`.

CONF-PHMR-19: The nn portion of `ClinicalDocument/languageCode` **SHALL** be a legal ISO-639-1 language code in lower case.

CONF-PHMR-20: The CC portion `ClinicalDocument/languageCode`, if present, **SHALL** be an ISO-3166 country code in upper case.

Figure 10: ClinicalDocument/languageCode example with language only

```
<languageCode code='en'/>
```

Figure 11: ClinicalDocument/languageCode example with language and country

```
<languageCode code='en-US'/>
```

2.11 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.

CONF-PHMR-21: Both `ClinicalDocument/setId` and `ClinicalDocument/versionNumber` **SHALL** be present or both **SHALL** be absent.

CONF-PHMR-22: The `@extension` and/or `@root` of `ClinicalDocument/setId` and `ClinicalDocument/id` **SHALL** be different when both are present.

Figure 12: ClinicalDocument/setId and ClinicalDocument/versionNumber example

```
<setId extension='999021'  root='2.16.840.1.113883.19'/>
<versionNumber value='1'/>
```

2.12 ClinicalDocument/copyTime

The `ClinicalDocument/copyTime` element has been deprecated in CDA R2.

CONF-PHMR-23: A `ClinicalDocument/copyTime` element **SHALL NOT** be present.

2.13 Participants

This section describes the general constraints placed upon CDA participants.

The HL7 CDA Release 2.0 Specification, Section 4.2.2.13 describes various participant scenarios where a single person can participate in several ways. In these cases, the person needs to be listed for each type of participation.

Note that Authentication requires that the participant be able to verify the accuracy of the document and Legal Authentication requires that the participant has the privilege to legally authenticate the document. Patients or other persons, such as a guardian or parent may not have these privileges, depending upon local policy.

The participants are listed below in the order in which they appear in CDA R2.

2.13.1 recordTarget

The `recordTarget` element must be present. The `recordTarget` element records the patient or patients whose health information is described by the clinical document.

CONF-PHMR-24: At least one `recordTarget/patientRole` element **SHALL** be present.

CONF-PHMR-25: A `patient/birthTime` element **SHALL** be present. The `patient/birthTime` element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone.

CONF-PHMR-26: A `patient/administrativeGenderCode` element **SHALL** be present. Values for `administrativeGenderCode` **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.

CONF-PHMR-27: The `guardian` element **SHOULD** be present when the patient is a minor child.

CONF-PHMR-28: The `providerOrganization` element **MAY** be present.

Figure 13: recordTarget example

```
<recordTarget>
 <patientRole>
  <id extension='12345' root='2.16.840.1.113883.3.933'/>
  <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>
   </name>
   <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
   <birthTime value="19541125"/>
   <guardian>
    <id extension="23456" root="2.16.840.1.113883.19.5"/>
    <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" use="HP"/>
    <guardianPerson>
     <name>
      <given>Neville</given>
      <family>Nuclear</family>
     </name>
    </guardianPerson>
   </guardian>
  </patient>
  <providerOrganization>
   <id extension='M345' root='2.16.840.1.113883.19.5'/>
   <name>Good Health Hospital</name>
   <telecom value='tel:555-555-3004'/>
   <addr>
    <streetAddressLine>100 Hospital Lane</streetAddressLine>
    <city>Ann Arbor</city>
    <state>MI</state>
    <postalCode>99999</postalCode>
    <country>USA</country>
   </addr>
  </providerOrganization>
 </patientRole>
</recordTarget>
```

2.13.2 author

The `author` element represents the creator of the clinical document.

CONF-PHMR-29: The `author/time` element represents the start time of the author's participation in the creation of the clinical document. The `author/time` element **SHALL** be present.

CONF-PHMR-30: The `assignedAuthor/id` element **SHALL** be present.

CONF-PHMR-31: An `assignedAuthor` element **SHALL** contain at least one `assignedPerson` or `assignedAuthoringDevice` element.

CONF-PHMR-32: A Personal Healthcare Monitoring Report **SHOULD** contain one or more `ClinicalDocument/author` elements where `assignedAuthor/assignedPerson` is present, representing a person (such as a disease management professional) who finalized the document.

Figure 14: author example

```
<author>
 <time value='20050329224411+0500'/>
 <assignedAuthor>
  <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>
 </assignedAuthor>
</author>
```

2.13.3 dataEnterer

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.

CONF-PHMR-33: When `dataEnterer` is present, an `assignedEntity/assignedPerson` element **SHALL** be present.

CONF-PHMR-34: The `time` element **MAY** be present. If present, it represents the starting time of entry of the data.

Figure 15: dataEnterer example

```
<dataEnterer>
 <time value='20050329222451+0500'/>
 <assignedEntity>
  <id extension='2' root='2.16.840.1.113883.19'/>
  <assignedPerson>
   <name>
    <prefix>Mrs.</prefix>
    <given>Ellen</given>
    <family>Enter</family>
   </name>
  </assignedPerson>
 </assignedEntity>
</dataEnterer>
```

2.13.4 informant

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

CONF-PHMR-35: The `informant` element **MAY** be present.

CONF-PHMR-36: When `informant` is present, an `assignedEntity/assignedPerson` or `relatedEntity/relatedPerson` element **SHALL** be present.

2.13.5 custodian

Based on the CDA R2 constraints (HL7 Clinical Document Architecture, Release 2 Normative Web Edition, 2005), the `custodian` element is required and is the steward of the clinical document.

Figure 16: custodian example

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension='1' root='1.3.6.4.1.4.1.2835.3'/>
      <name>Good Health Hospital</name>
      <telecom value='tel:555-555-3004' use='WP'/>
      <addr>
        <streetAddressLine>1000 Hospital Lane</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

2.13.6 informationRecipient

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.

CONF-PHMR-37: The `ClinicalDocument/informationRecipient` element **MAY** be present[4]. When `informationRecipient` is used, at least one `informationRecipient/intendedRecipient/informationRecipient` or `informationRecipient/intendedRecipient/receivedOrganization` **SHALL** be present.

[4] Note that there are two elements in the CDA Release 2.0 schema that are named `informationRecipient`. The outermost of these elements is what is being discussed here. The second element with the same name may appear as a descendent of this one.

Figure 17: informationRecipient example

```
<informationRecipient>
 <intendedRecipient>
  <id extension='4' root='2.16.840.1.113883.19'/>
  <addr>
   <streetAddressLine>1001 Hospital Lane</streetAddressLine>
   <city>Ann Arbor</city>
   <state>MI</state>
   <postalCode>99999</postalCode>
   <country>USA</country>
  </addr>
  <telecom value='tel:555-555-1003' use='WP'/>
  <informationRecipient>
   <name>
    <prefix>Dr.</prefix>
    <given>Harold</given>
    <family>Hippocrates</family>
   </name>
  </informationRecipient>
  <receivedOrganization>
   <name>Good Health Hospital</name>
  </receivedOrganization>
 </intendedRecipient>
</informationRecipient>
```

2.13.7 legalAuthenticator

The `legalAuthenticator` element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that 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.

CONF-PHMR-38: The `assignedEntity/assignedPerson` and/or `assignedEntity/representedOrganization` element **SHALL** be present in `legalAuthenticator`.

Figure 18: legalAuthenticator example

```
<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>
```

2.13.8 authenticator

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

CONF-PHMR-39: An authenticator **MAY** be present. The `assignedEntity/assignedPerson` element **SHALL** be present in an `authenticator` element.

Figure 19: authenticator example

```
<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>
```

2.14 ClinicalDocument/serviceEvent

The main activity being described by a PHMR is the monitoring of a 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`.

CONF-PHMR-40: The `documentationOf/serviceEvent` element **SHALL** be present.

CONF-PHMR-41: The value for `ClinicalDocument/documentationOf/serviceEvent/@classCode` **SHALL** be `MPROT` (Monitoring Program) `2.16.840.1.113883.5.6` ActClass **STATIC**.

CONF-PHMR-42: A `serviceEvent/effectiveTime` element **SHALL** be present, and **SHALL** reflect the period of time for which the patient's health was monitored.

Figure 20: documentationOf/serviceEvent example

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

2.15 Rendering Header Information for Human Presentation

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)

3 BODY

3.1 General Body Constraints

CONF-PHMR-43: A Personal Healthcare Monitoring Report **SHALL** have a `structuredBody` element. The content of this element makes up the human-readable text of the document. This information **SHALL** be organized into sections and **MAY** have subsections.

CONF-PHMR-44: Except where specifically noted in this DSTU, the structured body of a Personal Healthcare Monitoring Report **SHALL** conform to the constraints of HL7's Continuity of Care Document (CCD) specification (published April 1, 2007), and all references to CCD `templateIds` apply to that initial release of CCD.

3.2 Section Descriptions

This Implementation Guide defines required and optional sections. In CCD, all sections are optional. This document constrains CCD by adding some section requirements and providing guidance on which sections are recommended for use with personal healthcare monitoring reports and how they should be used.

The following table summarizes required and recommended sections within this DSTU:

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.

All other CCD sections are allowed, but will typically not be used for transmitting structured data.

The ordering of sections is not constrained by this specification. However, from a reader's perspective, 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.

CONF-PHMR-45: All `section` elements in the body of the document **SHALL** have a `code` element.

CONF-PHMR-46: All `section` elements in the body of the document **SHALL** have some nonblank text or one or more subsections, even if the purpose of the text is only to indicate that information is unknown.

CONF-PHMR-47: A personal healthcare monitoring report **SHALL** contain a Medical Equipment section.

CONF-PHMR-48: A personal healthcare monitoring report **SHALL** contain either a Vital Signs section or Results section, and **MAY** contain both.

3.3 Required Sections

3.3.1 Medical Equipment 46264-8

CONF-PHMR-49: A Medical Equipment section **SHALL** contain two `templateIds`. CCD `templateId 2.16.840.1.113883.10.20.1.7` **SHALL** be present and the section **SHALL** conform to all the constraints specified in CCD for that template. An additional `templateId` **SHALL** be present where the value of `@root` is `2.16.840.1.113883.10.20.9.1`, indicating conformance to the constraints specified in this DSTU.

CONF-PHMR-50: One or more Device Definition Organizers (`templateId 2.16.840.1.113883.10.20.9.4`) (see section 3.5.2) **SHOULD** be present.

CONF-PHMR-51: If no medical devices are defined, this section **SHALL** contain a `text` element noting this fact.

Figure 21: Medical Equipment section example

```
<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>
  <!-- Device information -->
  <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>Acme</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>
    </tbody>
   </table>
  </text>
  <entry typeCode="COMP">
   <organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.9.4"/>
    <statusCode code="completed"/>
    <effectiveTime value="20070801"/>
    <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>
       <code code="32033000" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Arterial pressure monitor">
        <translation code="MDC_DEV_SPEC_PROFILE_BPM"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Blood Pressure
Monitor"/>
        <translation code="???" codeSystem="GMDN-OID">
         <!--move Production spec GMDN here from the manufacturerModelName-->
        </translation>
       </code>
       <manufacturerModelName>
        <!-- these will be unstructured, the text below is an example (no shalls for
the labels used below)-->
       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>Acme</desc>
      </scopingEntity>
     </participantRole>
    </participant>
    <component>
     <observation classCode="OBS" moodCode="EVN">
      <!--... all our device observations go here -->
      <code/>
     </observation>
    </component>
   </organizer>
  </entry>
</section>
```

3.3.2 Vital Signs 8716-3

The Vital Signs section is only required if there is no Results section.

CONF-PHMR-52: A Vital Signs section **SHALL** contain two templateIds. CCD templateId 2.16.840.1.113883.10.20.1.16 **SHALL** be present and the section **SHALL** conform to all the constraints specified in CCD for that template. An additional templateId **SHALL** be present where the value of @root is 2.16.840.1.113883.10.20.9.2, indicating conformance to the constraints specified in this DSTU.

CONF-PHMR-53: If the following values are present in the PHMR, they **SHOULD** be recorded in the Vital Signs section: blood pressure, temperature, O_2 saturation, respiratory rate, pulse. All other values **SHOULD** be recorded in the Results section.

CONF-PHMR-54: One or more Numeric Observations (templateId 2.16.840.1.113883.10.20.9.8) **SHOULD** be present inside entry elements.

CONF-PHMR-55: One or more Waveform Series Observations (templateId 2.16.840.1.113883.10.20.9.12) **MAY** be present inside entry elements.

CONF-PHMR-56: If no vital signs are recorded, this section **SHALL** contain a text element noting this fact.

Figure 22: Vital Signs section example

```
<section>
 <templateId root="2.16.840.1.113883.10.20.1.16"/>
 <templateId root="2.16.840.1.113883.10.20.9.2"/>
 <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
 <title>Vital Signs</title>
 <text>
  <paragraph>Thermometer Results</paragraph>
  <table border="1" width="100%">
   <tBody>
    <tr>
     <th>Date/Time</th>
     <th>Body Temp</th>
     <th>Finger Temp</th>
     <th>Oral Temp</th>
    </tr>
    <tr>
     <td>20080501104033</td>
     <td>99.9 deg F</td>
     <td>88.8 deg F</td>
     <td>37.5 deg C</td>
    </tr>
   </tBody>
  </table>
 </text>
 <entry typeCode="DRIV">
  <organizer classCode="CLUSTER" moodCode="EVN">
   <!-- Vital sign data/ Test Groups -->
   <!-- A VITAL SIGNS ORGANIZER IS USED TO GROUP RELATED  -->
   <templateId root="2.16.840.1.113883.10.20.1.35"/>
   <id root="b606a959-baab-4836-84a8-97c4e9857533"/>
   <code code="46680005" codeSystem="2.16.840.1.113883.6.96" displayName="Vital
signs"/>
```

```
    <statusCode code="completed"/>
    <component>
     <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.31"/>
      <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
       <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Body Temperature">
        <translation code="MDC_TEMP_BODY" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Body Temperature"/>
       </code>
      <statusCode code="completed"/>
      <effectiveTime value="20080501104033"/>
      <value xsi:type="PQ" value="99.9" unit="[degF]"/>
      <participant typeCode="DEV">
       <participantRole>
      <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64"
extension="1A-34-46-78-9A-BC-DE-F3"/>
       </participantRole>
      </participant>
     </observation>
    </component>
    <component>
     <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.31"/>
      <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
      <code code="MDC_TEMP_FINGER" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Finger Temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="20080501104033"/>
      <value xsi:type="PQ" value="88.8" unit="[degF]"/>
      <participant typeCode="DEV">
       <participantRole>
      <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64"
extension="1A-34-46-78-9A-BC-DE-F3"/>
       </participantRole>
      </participant>
     </observation>
    </component>
    <component>
     <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.31"/>
      <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
       <code code="415945006" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Oral Temperature">
        <translation code="MDC_TEMP_ORAL" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Oral Temperature"/>
       </code>
      <statusCode code="completed"/>
      <effectiveTime value="20080501104033"/>
      <value xsi:type="PQ" value="37.5" unit="Cel"/>
      <participant typeCode="DEV">
       <participantRole>
      <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64"
extension="1A-34-46-78-9A-BC-DE-F3"/>
       </participantRole>
      </participant>
     </observation>
    </component>
```

```
   </organizer>
  </entry>
</section>
```

3.3.3 Results 30954-2

The results section is only required if there is no Vital Signs section.

CONF-PHMR-57: A Results section **SHALL** contain two templateIds. CCD templateId 2.16.840.1.113883.10.20.1.14 **SHALL** be present and the section **SHALL** conform to all the constraints specified in CCD for that template. An additional templateId **SHALL** be present where the value of @root is 2.16.840.1.113883.10.20.9.14, indicating conformance to the constraints specified in this DSTU.

CONF-PHMR-58: One or more Numeric Observations (templateId 2.16.840.1.113883.10.20.9.8) **SHOULD** be present inside entry elements.

CONF-PHMR-59: One or more Waveform Series Observations (templateId 2.16.840.1.113883.10.20.9.12) **MAY** be present inside entry elements.

CONF-PHMR-60: If no results are recorded, this section **SHALL** contain a text element noting this fact.

Figure 23: Results section example

```
<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>
  <paragraph>Glucose Meter Results</paragraph>
  <table border="1" width="100%">
   <tbody>
    <tr>
     <th>Date/Time</th>
     <th>Value</th>
     <th>Measurement Condition</th>
     <th>Sample Location</th>
     <th>Tester</th>
    </tr>
    <tr>
     <td>2008/05/01 12:33:33</td>
     <td>104 mg/dL</td>
     <td>Post meal</td>
     <td>Ear lobe</td>
     <td>Patient</td>
    </tr>
   </tbody>
  </table>
 </text>
 <entry typeCode="COMP">
  <organizer classCode="CLUSTER" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.1.35"/>
   <id root="b606a959-baab-4836-84a8-97c4e9857533"/>
   <code code="15220000" codeSystem="2.16.840.1.113883.6.96" displayName="Tests"/>
   <statusCode code="completed"/>
   <component>
    <observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.1.31"/>
     <templateId root="2.16.840.1.113883.10.20.9.8"/>
     <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
     <code code="405176005" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Blood glucose status">
      <translation code="MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Blood Glucose
Level"/>
     </code>
     <statusCode code="completed"/>
     <effectiveTime value="20080501123333"/>
     <value xsi:type="PQ" value="104" unit="mg/dL"/>
     <targetSiteCode code="48800003" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Ear lobe">
      <translation nullFlavor="OTH">
       <originalText>3</originalText>
      </translation>
     </targetSiteCode>
     <participant typeCode="PRF">
      <participantRole>
       <id extension="996-756-495" root="2.16.840.1.113883.19.5"/>
       <code code="MDC_ATTR_TESTER" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Tester"/>
```

```
        </participantRole>
       </participant>
       <participant typeCode="DEV">
        <participantRole>
         <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-
64" extension="12-34-56-78-9A-BC-DE-F1"/>
        </participantRole>
       </participant>
       <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
         <code code="MDC_ATTR_MEASUREMENT_CONDITION"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Measurement
condition"/>
          <value xsi:type="CD" code="24863003" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="After meal">
           <translation nullFlavor="OTH">
            <originalText>1</originalText>
           </translation>
          </value>
        </observation>
       </entryRelationship>
     </observation>
    </component>
   </organizer>
  </entry>
</section>
```

3.4 Optional Sections

The following sections may optionally be present in a PHMR for activity, exercise, and medication monitoring. Currently, they are expressed as unconstrained CCD templates, although future releases of this specification may apply additional constraints.

3.4.1 Purpose 48764-5

CONF-PHMR-61: A Purpose section (CCD `templateId` `2.16.840.1.113883.10.20.1.13`) **MAY** be present, and if present **SHALL** conform to all the constraints specified in CCD.

3.4.2 Medications 10160-0

CONF-PHMR-62: A Medications section (CCD `templateId` `2.16.840.1.113883.10.20.1.8`) **MAY** be present, and if present **SHALL** conform to all the constraints specified in CCD.

3.4.3 Functional Status 30954-2

CONF-PHMR-63: A Functional Status section (CCD `templateId` `2.16.840.1.113883.10.20.1.5`) **MAY** be present, and if present **SHALL** conform to all the constraints specified in CCD.

3.5 Clinical Statement Constraints

3.5.1 General Clinical Statement Constrains

CONF-PHMR-64: Wherever clinical statement terminology conformance is left unspecified by CCD, SNOMED CT® or LOINC® (in the case of lab data) **SHOULD** be used, unless no SNOMED or LOINC term exists for a particular concept, in which case IEEE 11073-10101 MDC **SHOULD** be used (code system `2.16.840.1.113883.6.24`).

CONF-PHMR-65: If the data being reported came from a PHM-compliant device, and IEEE 11073-10101 is not used as the primary code, then a `translation` element **SHOULD** be present containing the equivalent IEEE 11073-10101 code. This constraint applies to the following elements: `act/code`, `encounter/code`, `observation/code`, `procedure/code`, `substanceAdministration/code`, `supply/code`, and `observation/value` if `value/@xsi:type` is `CD` or `CE`.

CONF-PHMR-66: If the data in an observation was obtained directly from a PHM device, the observation **SHALL** 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.

Devices sometimes report alerts. These are typically recorded using the `interpretationCode` element on an observation. Since many of the alerts are device specific and not defined in any code system, only in the device specs themselves, the human-readable equivalent of the alert is often the best information to communicate in the PHM report.

CONF-PHMR-67: When an observation is intended to convey that an alert threshold has been exceeded, the observation **SHOULD** 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. When an alert results in missing data, null flavors **SHOULD** be used on `observation/code` or `observation/value` where appropriate.

Data may be collected from devices that, due to manufacturing cost issues, do not implement time-zone information. The measurement is therefore stamped by a so-called "wall clock" set by the user. It will be the responsibility of the hosting system to append time-zone information where necessary before generating the CDA document.

CONF-PHMR-68: Observation time **SHOULD** incorporate the local time zone of the device into any `effectiveTime` elements with accuracy greater than the day in the resulting clinical statements.

3.5.2 Device Definition Organizer

CONF-PHMR-69: A Device Definition Organizer **SHALL** be represented with an organizer element where `@classCode` is `CLUSTER` and `@moodCode` is `EVN`.

CONF-PHMR-70: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.4`.

CONF-PHMR-71: A participant element where @typeCode is SBJ **SHALL** be present. It **SHALL** contain a single PHMR Product Instance template (templateId 2.16.840.1.113883.10.20.9.9).

CONF-PHMR-72: A single Sampling Frequency Observation (templateId 2.16.840.1.113883.10.20.9.10) **MAY** be present inside a component element.

CONF-PHMR-73: A single Device Measurement Range Observation (templateId 2.16.840.1.113883.10.20.9.5) **MAY** be present inside a component element.

CONF-PHMR-74: A single Device Resolution Observation (templateId 2.16.840.1.113883.10.20.9.6) **MAY** be present inside a component element.

CONF-PHMR-75: A single Device Accuracy Observation (templateId 2.16.840.1.113883.10.20.9.3) **MAY** be present inside a component element.

Figure 24: Device Definition Organizer example

```
<organizer classCode="CLUSTER" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.9.4"/>
 <statusCode code="completed"/>
 <effectiveTime value="20070801"/>
 <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"/>

   ...

  </participantRole>
 </participant>
 <component>

   ...

 </component>
</organizer>
```

3.5.3 PHMR Product Instance

CONF-PHMR-76: A PHMR Product Instance **SHALL** conform to the constraints of the CCD Product Instance template (CCD templateId 2.16.840.1.113883.10.20.1.52).

CONF-PHMR-77: A templateId **SHALL** be present where @root is 2.16.840.1.113883.10.20.9.9.

CONF-PHMR-78: An id element **SHALL** be present 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).

CONF-PHMR-79: A code element **MAY** be present 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").

CONF-PHMR-80: A playingDevice/code element **SHALL** be present indicating 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. Also, the value for ProdSpecGMDN from the Continua data model **MAY** be present as a translation. (See Appendix C — PHMR Data Model).

CONF-PHMR-81: A playingDevice/manufacturerModelName element **SHALL** be present. It **SHALL** contain the following data items from the Continua data model (See Appendix C — PHMR Data Model): Model, Unspecified, SerialNumber, PartNumber, HardwareRevision, SoftwareRevision, and ProtocolRevision. The manufacturerModelName may also contain device certification information. No constraints are placed on the ordering or formatting of those items.

CONF-PHMR-82: A scopingEntity/desc element **SHOULD** be present containing the manufacturer's name.

Figure 25: PHMR product instance example

```
<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>
  <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>
  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):
   Certified for blood pressure monitoring by Acme Inc. (ACME_OID)
  </manufacturerModelName>
 </playingDevice>
 <scopingEntity>
  <desc>Acme</desc>
 </scopingEntity>
</participantRole>
```

3.5.4 PHMR Product Instance Reference

A PHMR Product Instance Reference is used to refer to a PHMR Product Instance defined in the Device Definition Organizer for the device.

Note: Per SDWG recommendations, there is no `templateId` for a device reference act. The guidance for any act reference is to include only the ID of the source act, and the minimal number of elements and attributes required as defined by the CDA schema.

CONF-PHMR-83: A PHMR Product Instance Reference **SHALL** be represented with the `participant` element where `@typeCode` is `SBJ`.

CONF-PHMR-84: A `participantRole` element containing only a single `id` element **SHALL** be present. The `id` element **SHALL** contain the same values for `@root` and `@extension` as the PHMR Product Instance that it references.

CONF-PHMR-85: All other elements **SHALL NOT** be present.

Note: Some information regarding the device (device accuracy, et cetera) is found in the Device Definition Organizer, not the PHMR Product Instance. Therefore, someone following a PHMR Product Instance Reference may need to traverse to the Device Definition Organizer `parent` element to retrieve all related device information.

Figure 26: PHMR product instance reference example

```
<participant typeCode="SBJ">
 <participantRole>
  <id .../>
 </participantRole>
</participant>
```

3.5.5 Sampling Frequency Observation

The sampling period (frequency) of the device may be communicated in the PHMR. However, it will not be automatically derived from device data, i.e., it may be manually entered.

CONF-PHMR-86: A Sampling Frequency Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `DEF`.

CONF-PHMR-87: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.10`.

CONF-PHMR-88: A `code` element **SHALL** be present where `@code` is `MDC_ATTR_TIME_PD_SAMP` and `@codeSystem` is `2.16.840.1.113883.6.24 IEEE 11073` (**STATIC**)

CONF-PHMR-89: A `value` element **SHALL** be present where `@xsi:type` is `PQ` containing the sampling period in milliseconds (`@unit= "ms"`).

Figure 27: Sampling Frequency Observation example

```
<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>
```

3.5.6 Device Measurement Range Observation

The measurement range of the device may be communicated in the PHMR (for example, a thermometer may report values between 0 and 100 degrees Celsius). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

CONF-PHMR-90: A Device Measurement Range Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `DEF`.

CONF-PHMR-91: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.5`.

CONF-PHMR-92: A code element **SHALL** be present where `@code` is MDC_ATTR_NU_RANGE_MSMT and `@codeSystem` is 2.16.840.1.113883.6.24 `IEEE 11073` (**STATIC**)

CONF-PHMR-93: A `value` element **SHALL** be present where `@xsi:type` is `IVL_PQ` (for a range of physical quantities) or `ST` (for a simple text description) describing the resolution of the device.

Figure 28: Device measurement range observation example

```
<observation classCode="OBS" moodCode="DEF">
 <templateId root=" 2.16.840.1.113883.10.20.9.5"/>
 <code code="MDC_ATTR_NU_RANGE_MSMT" displayName="Device Measurement Range"
codeSystemName="LOINC" codeSystem="2.16.840.1.113883.6.1"/>
 <value xsi:type="IVL_PQ">
  <low value="0" unit="Cel"/>
  <high value="100" unit="Cel"/>
 </value>
</observation>
```

3.5.7 Device Resolution Observation

The reporting resolution of the device may be communicated in the PHMR (for example, a thermometer may have a resolution of 0.1 degrees Celsius). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

CONF-PHMR-94: A Device Resolution Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `DEF`.

CONF-PHMR-95: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.6`.

CONF-PHMR-96: A code element **SHALL** be present where @code is 17441009 and @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (**STATIC**).

CONF-PHMR-97: A value element **SHALL** be present 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).

Figure 29: Device resolution observation example

```
<observation classCode="OBS" moodCode="DEF">
 <templateId root="2.16.840.1.113883.10.20.9.6"/>
 <code code="17441009" codeSystem="2.16.840.1.113883.6.96" displayName="Resolution
threshold (observable entity)"/>
 <value xsi:type="PQ" value=".1" unit="Cel"/>
</observation>
```

3.5.8 Device Accuracy Observation

The accuracy of the device may be reported in the PHM report (for example, the values reported by a device may be within +/- 3% of the actual value). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

CONF-PHMR-98: A Device Accuracy Observation **SHALL** be represented with an observation element where @classCode is OBS and @moodCode is DEF.

CONF-PHMR-99: A templateId element **SHALL** be present where @root is 2.16.840.1.113883.10.20.9.3.

CONF-PHMR-100: A code element **SHALL** be present where @code is MDC_ATTR_NU_ACCUR_MSMT and @codeSystem is 2.16.840.1.113883.6.24 IEEE 11073 (**STATIC**).

CONF-PHMR-101: A value element **SHALL** be present where @xsi:type is PQ (for a physical quantity) or ST (for a simple text description) describing the processing accuracy of the device.

Figure 30: Device accuracy observation example

```
<observation classCode="OBS" moodCode="DEF">
 <templateId root="2.16.840.1.113883.10.20.9.3"/>
 <code code="MDC_ATTR_NU_ACCUR_MSMT" codeSystem="2.16.840.1.113883.6.24"/>
 <value xsi:type="PQ" value="3" unit="%"/>
</observation>
```

3.5.9 Numeric Observation

Most devices will report data consisting of a code identifying the type of data being reported, a numeric value, and a unit.

CONF-PHMR-102: A Numeric Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-PHMR-103: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.8`.

CONF-PHMR-104: A Numeric Observation **MAY** also conform to another CCD observation template (such as a Result Observation). If so, it **SHOULD** also include the CCD `templateId` for that observation type.

CONF-PHMR-105: A `code` element **SHALL** be present where `@codeSystem` is `2.16.840.1.113883.6.96 SNOMED CT` (**DYNAMIC**) or `2.16.840.1.113883.6.24 MDC` (**DYNAMIC**).

CONF-PHMR-106: A `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.

CONF-PHMR-107: A `participant` element **SHOULD** be present conforming to the constraints of a PHMR Product Instance Reference.

Figure 31: Numeric observation example

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.1.31"/>
 <templateId root="2.16.840.1.113883.10.20.9.8"/>
 <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
  <code code="386725007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
CT" displayName="Body Temperature">
   <translation code="MDC_TEMP_BODY" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Body Temperature"/>
  </code>
 <statusCode code="completed"/>
 <effectiveTime value="20080501104033"/>
 <value xsi:type="PQ" value="99.9" unit="[degF]"/>
 <participant typeCode="DEV">
  <participantRole>
 <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" assigningAuthorityName="EUI-64"
extension="1A-34-46-78-9A-BC-DE-F3"/>
  </participantRole>
 </participant>
</observation>
```

3.5.10 Waveform Series Observation

Some devices, such as the pulse oximeter, report a series of equidistant time-spaced observations that can be represented as a waveform.

CONF-PHMR-108: A Waveform Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBSSER` and `@moodCode` is `EVN`.

CONF-PHMR-109: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.12`.

CONF-PHMR-110: A code element **SHALL** be present 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**).

Table 3 below lists some suggested codes from the Waveform-observable hierarchy for reference (please refer to SNOMED CT® for a full listing of possible codes).

Table 3: SNOMED CT® Waveform observation code suggestions

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

CONF-PHMR-111: An effectiveTime element **SHALL** be present 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.

CONF-PHMR-112: A participant element **SHOULD** be present conforming to the constraints of a PHMR Product Instance Reference.

CONF-PHMR-113: An entryRelationship element **SHOULD** be present containing an observableMedia element. If present, the observableMedia element **SHALL** include a reference to a displayable graphic containing a graphic representation of the data in the waveform.

CONF-PHMR-114: An entryRelationship element where @typeCode is COMP **SHOULD** be present containing an observation element where @classCode is OBSCOR, @moodeCode is EVN, representing a container for series of correlated observations.

CONF-PHMR-115: The correlated observation container **SHALL** contain an entryRelationship where @typeCode is COMP containing a Waveform Sample Period Observation (templateId 2.16.840.1.113883.10.20.9.13). Only one Waveform Sample Period Observation **SHALL** be present within the correlated observation container.

CONF-PHMR-116: The correlated observation container **SHALL** contain one or more entryRelationship elements where @typeCode is COMP each containing a Waveform Observation (templateId 2.16.840.1.113883.10.20.9.11).

Figure 32: Waveform series observation example

```
<observation classCode="OBSSER" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.9.12"/>
 <id root="f37a5e13-aae6-4f9c-8afc-af7a9ab087e0"/>
 <code code="277923006" 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"/>
  <high value="20071206121000.99"/>
 </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="wave1.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>

   ...entryRelationships to Waveform Observations go here.

  </observation>
 </entryRelationship>
</observation>
```

3.5.11 Waveform Sample Period Observation

CONF-PHMR-117: A Waveform Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-PHMR-118: A templateId element **SHALL** be present where @root is 2.16.840.1.113883.10.20.9.13.

CONF-PHMR-119: A code element **SHALL** be present where @code is TIME_ABSOLUTE from 2.16.840.1.113883.5.4 ActCode (**STATIC**).

CONF-PHMR-120: A value element **SHALL** be present 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).

Figure 33: Waveform sample period observation example

```
<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>
```

3.5.12 Waveform Observation

CONF-PHMR-121: A Waveform Observation **SHALL** be represented with an observation element where @classCode is OBS and @moodCode is EVN.

CONF-PHMR-122: A templateId element **SHALL** be present where @root is 2.16.840.1.113883.10.20.9.11.

CONF-PHMR-123: A code element **SHALL** be present 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**).

Table 3: SNOMED CT® Waveform observation code suggestions, lists some suggested codes from the Waveform-observable hierarchy for reference (please refer to SNOMED CT® for a full listing of possible codes).

CONF-PHMR-124: A value element **MAY** be present. If present, it **SHALL** be expressed 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.

Figure 34: Waveform observation example

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.9.11"/>
 <code code="277923006" 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>
```

3.5.13 Event Observation

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.

CONF-PHMR-125: An Event Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-PHMR-126: A `templateId` element **SHALL** be present where `@root` is `2.16.840.1.113883.10.20.9.7`.

CONF-PHMR-127: A `code` element **SHALL** be present containing an appropriate event code from `2.16.840.1.113883.6.24 MDC` **DYNAMIC**.

CONF-PHMR-128: A `value` element **SHALL** be present 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).

CONF-PHMR-129: A `participant` element where `@typeCode` is `SBJ` **SHOULD** be present conforming to the constraints of a PHMR Product Instance Reference.

Figure 35: Event observation example

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.1.31"/>
 <templateId root="2.16.840.1.113883.10.20.9.7"/>
 <id root="5d186d6a-40c8-4d2d-9187-069ddf08e288"/>
 <code code="MDC_PULS_OXIM_PULS_CHAR" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Pulse characteristics Event"/>
 <statusCode code="completed"/>
 <effectiveTime value="20071206125500.66"/>
 <value xsi:type="ST">Maximal inrush of the pulsatile event has been detected</value>
 <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>
</observation>
```

3.6 Additional Body Constraints

3.6.1 Remote Monitoring 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.

CONF-PHMR-130: Any section **MAY** contain notes that add additional information not transmitted by the device. If present, such notes **SHALL** be in the `text` element of a section and **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.

Figure 36: Coded remote monitoring note example

```
<section>
 ...
 <text>
  <paragraph>
   <content ID="note1">Patient was found dead in bed</content>
  </paragraph>
 </text>
 <entry>
  <observation classCode="OBS" moodCode="EVN">
   <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
   <text><reference value="#note1"/></text>
   <value xsi:type="CD" code="300990005" codeSystem="2.16.840.1.113883.6.96"
displayName="Found dead in bed"/>
  </observation>
 </entry>
</section>
```

Figure 37: Uncoded remote monitoring note example

```
<section>
 ...
 <text>
  <paragraph>Patient was found dead in bed</paragraph>
 </text>
</section>
```

3.6.2 Device-specific Attributes

Some devices may have attributes that can modify an observation in some way. At the time this IG was being written, not all device-specific attributes were known, so it was not possible to create individual mappings for each attribute.

CONF-PHMR-131: If a device-specific attribute has a CDA equivalent element as a direct child of an observation, the specific CDA element **SHALL** be used. Some examples are shown below:

Table 4: Examples of Some Device-specific Attributes Mapped to CDA Elements

Device	Attribute	CDA Equivalent (XPath from observation)
Blood Glucose Meter	MDC_ATTR_TESTER	participant
	MDC_ATTR_SAMPLE_LOCATION	entryRelationship/procedure[specimen]/targetSiteCode

CONF-PHMR-132: If a device-specific attribute has no CDA equivalent, an `entryRelationship` **SHALL** be used containing an observation where `observation/code` contains the attribute `type` and `observation/value` contains the attribute `value`. An example of this would be the

MDC_ATTR_MEASUREMENT_CONDITION attribute from the blood glucose meter specification.

Figure 38: Blood glucose meter custom attribute mapping example

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.1.31"/>
 <templateId root="2.16.840.1.113883.10.20.9.8"/>
 <id root="975c2f3b-2bd4-4e45-aed1-84af9ff51b10"/>
 <code code="405176005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Blood glucose status">
   <translation code="MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Blood Glucose
Level"/>
 </code>
 <statusCode code="completed"/>
 <effectiveTime value="20080501123333"/>
 <value xsi:type="PQ" value="104" unit="mg/dL"/>
 <specimen typeCode="SPC">
  <specimenRole classCode="SPEC">
   <id root="ab3bde0e-46f3-4508-9b2c-a5bf7c6a6cbd"/>
   <specimenPlayingEntity>
    <code code="87612001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
CT" displayName="Blood"/>
   </specimenPlayingEntity>
  </specimenRole>
 </specimen>
 ...
 <entryRelationship typeCode="COMP">
  <procedure classCode="PROC" moodCode="EVN">
   <templateId root="1.3.6.1.4.1.19376.1.3.1.8"/>
   <effectiveTime value="20080404000000.0000-0400"/>
   <targetSiteCode code="48800003" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Ear lobe">
    <translation nullFlavor="OTH">
     <!-- The original value sent from the device (no IEEE code, it is device
dependent) -->
      <originalText>3</originalText>
    </translation>
   </targetSiteCode>
   <specimen typeCode="SPC">
    <specimenRole classCode="SPEC">
     <id root="ab3bde0e-46f3-4508-9b2c-a5bf7c6a6cbd"/>
    </specimenRole>
   </specimen>
  </procedure>
 </entryRelationship>
 ...
</observation>
```

3.6.3 Reporting Summary Information

Typically, a PHMR will contain all the relevant device information over a period of time as a series of discrete observations. However, it is sometimes desirable 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.

CONF-PHMR-133: When reporting minimum and/or maximum values recorded over a period of time, `observation/value` **SHALL** be used where `@xsi:type` is `IVL_PQ`, and the `min` or `max` values **SHALL** be reported using `high` and `low` elements respectively.

Figure 39: Expressing min/max values over a period of time example

```
<value xsi:type="IVL_PQ">
 <low value="36" unit="Cel"/>
 <high value="38.3" unit="Cel"/>
</value>
```

CONF-PHMR-134: When reporting an average of values over a period of time (such as mean and standard deviation), `observation/value` **SHALL** be used where `@xsi:type` is `PPD_PQ`, mean is expressed in `@value`, and standard deviation is expressed in `standardDeviation/@value`.

Figure 40: Expressing mean and standard deviation example

```
<observation classCode="OBS" moodCode="EVN">
  <code />
  <statusCode code="completed"/>
  <effectiveTime value="20080730"/>
  <value xsi:type="PPD_PQ" value="80" unit="kg">
    <standardDeviation value="2" unit="kg"/>
  </value>
</observation>
```

APPENDIX A — CCD CONSTRAINTS

Introduction

This appendix lists all of the CCD conformance statements from templates referenced from the body of this document. These constraints are provided for reference only. For a complete description of these constraints of CCD, please refer to the original specification.

Medical Equipment (CCD templateId 2.16.840.1.113883.10.20.1.7)

CONF-371: CCD SHOULD contain exactly one and SHALL NOT contain more than one Medical Equipment section (templateId 2.16.840.1.113883.10.20.1.7). The Medical Equipment section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more supply activities (templateId 2.16.840.1.113883.10.20.1.34) and MAY include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24).

CONF-372: The medical equipment section SHALL contain Section / code.

CONF-373: The value for “Section / code” SHALL be “46264-8” “History of medical device use” 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-374: The medical equipment section SHALL contain Section / title.

CONF-375: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing “equipment”.

Medication activity (CCD templateId 2.16.840.1.113883.10.20.1.24)

CONF-304: A medication activity (templateId 2.16.840.1.113883.10.20.1.24) SHALL be represented with SubstanceAdministration.

CONF-305: The value for “SubstanceAdministration / @moodCode” in a medication activity SHALL be “EVN” or “INT” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-306: A medication activity SHALL contain at least one SubstanceAdministration / id.

CONF-307: A medication activity SHOULD contain exactly one SubstanceAdministration / statusCode.

CONF-308: A medication activity SHOULD contain one or more SubstanceAdministration / effectiveTime elements, used to indicate the actual or intended start and stop date of a medication, and the frequency of administration. (See section 5.4.1 Dates and Times for additional details about time representation).

CONF-309: A medication activity SHOULD contain exactly one SubstanceAdministration / routeCode.

CONF-310: The value for “SubstanceAdministration / routeCode” in a medication activity SHOULD be selected from the HL7 RouteOfAdministration

CONF-311: A medication activity SHOULD contain exactly one SubstanceAdministration / doseQuantity or SubstanceAdministration / rateQuantity.

CONF-312: A medication activity MAY contain exactly one SubstanceAdministration / maxDoseQuantity, which represents a maximum dose limit.

CONF-313: A medication activity MAY contain one or more SubstanceAdministration / performer, to indicate the person administering a substance.

CONF-314: A medication activity MAY have one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent.

CONF-315: A medication activity SHALL contain one or more sources of information, as defined in section 5.2 Source.

Supply activity (CCD templateId 2.16.840.1.113883.10.20.1.34)

CONF-316: A supply activity (templateId 2.16.840.1.113883.10.20.1.34) SHALL be represented with Supply.

CONF-317: The value for "Supply / @moodCode" in a supply activity SHALL be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-318: A supply activity SHALL contain at least one Supply / id.

CONF-319: A supply activity SHOULD contain exactly one Supply / statusCode.

CONF-320: A supply activity SHOULD contain exactly one Supply / effectiveTime, to indicate the actual or intended time of dispensing.

CONF-321: A supply activity MAY contain exactly one Supply / repeatNumber, to indicate the number of fills. (Note that Supply / repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").

CONF-322: A supply activity MAY contain exactly one Supply / quantity, to indicate the actual or intended supply quantity.

CONF-323: A supply activity MAY contain one or more Supply / author, to indicate the prescriber.

CONF-324: A supply activity MAY contain one or more Supply / performer, to indicate the person dispensing the product.

CONF-325: A supply activity MAY contain exactly one Supply / participant / @typeCode = "LOC", to indicate the supply location.

CONF-326: A supply activity SHALL contain one or more sources of information, as defined in section 5.2 Source.

Indications

CONF-327: A medication activity MAY contain one or more SubstanceAdministration / precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met.

CONF-328: A medication activity MAY contain one or more SubstanceAdministration / entryRelationship, whose value for "entryRelationship / @typeCode" SHALL be "RSON"

"Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, where the target of the relationship represents the indication for the activity.

CONF-329: SubstanceAdministration / entryRelationship / @typeCode="RSON" in a medication activity SHALL have a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement.

Patient instructions (CCD templateId 2.16.840.1.113883.10.20.1.49)

CONF-330: A medication activity MAY contain one or more patient instructions.

CONF-331: A patient instruction (templateId 2.16.840.1.113883.10.20.1.49) SHALL be represented with Act.

CONF-332: The value for "Act / @moodCode" in a patient instruction SHALL be "INT" "Intent" 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-333: The value for "entryRelationship / @typeCode" in a relationship to a patient instruction SHALL be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

Fulfillment instructions (CCD templateId 2.16.840.1.113883.10.20.1.43)

CONF-334: A supply activity MAY contain one or more fulfillment instructions.

CONF-335: A fulfillment instruction (templateId 2.16.840.1.113883.10.20.1.43) SHALL be represented with Act.

CONF-336: The value for "Act / @moodCode" in a fulfillment instruction SHALL be "INT" "Intent" 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-337: The value for "entryRelationship / @typeCode" in a relationship between a supply activity and fulfillment instruction SHALL be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

Medication series number observation (CCD templateId 2.16.840.1.113883.10.20.1.46)

CONF-338: A medication activity MAY contain exactly one medication series number observations.

CONF-339: The value for "entryRelationship / @typeCode" in a relationship between a medication activity and medication series number observation SHALL be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

CONF-340: A medication series number observation (templateId 2.16.840.1.113883.10.20.1.46) SHALL be represented with Observation.

CONF-341: The value for "Observation / @classCode" in a medication series number observation SHALL be "OBS" 2.16.840.1.113883.5.6 ActClass STATIC.

CONF-342: The value for "Observation / @moodCode" in a medication series number observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-343: A medication series number observation SHALL include exactly one Observation / statusCode.

CONF-344: A medication series number observation SHALL contain exactly one Observation / code.

CONF-345: The value for “Observation / code” in a medication series number observation SHALL be “30973-2” “Dose number” 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-346: A medication series number observation SHALL contain exactly one Observation / value.

CONF-347: The data type for “Observation / value” in a medication series number observation SHALL be INT (integer).

Reaction observations and interventions

CONF-348: A medication activity MAY contain one or more reaction observations (templateId 2.16.840.1.113883.10.20.1.54), each of which MAY contain exactly one severity observation (templateId 2.16.840.1.113883.10.20.1.55) AND/OR one or more reaction interventions.

CONF-349: The value for “entryRelationship / @typeCode” in a relationship between a medication activity and reaction observation SHALL be “CAUS” “Is etiology for” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

Representation of “status” values (CCD templateId 2.16.840.1.113883.10.20.1.47)

CONF-350: A medication activity MAY contain exactly one medication status observation.

CONF-351: A supply activity MAY contain exactly one medication status observation.

CONF-352: A medication status observation (templateId 2.16.840.1.113883.10.20.1.47) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 “Type” and “Status” values).

CONF-353: The value for “Observation / value” in a medication status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode STATIC 20061017.

Representation of a product (CCD templateId 2.16.840.1.113883.10.20.1.53)

CONF-354: A medication activity SHALL contain exactly one SubstanceAdministration / consumable, the target of which is a product template.

CONF-355: A supply activity MAY contain exactly one Supply / product, the target of which is a product template.

CONF-356: A product (templateId 2.16.840.1.113883.10.20.1.53) SHALL be represented with the ManufacturedProduct class.

CONF-357: A ManufacturedProduct in a product template SHALL contain exactly one manufacturedProduct / manufacturedMaterial.

CONF-358: A manufacturedMaterial in a product template SHALL contain exactly one manufacturedMaterial / code.

CONF-359: The value for “manufacturedMaterial / code” in a product template SHOULD be selected from the RxNorm (2.16.840.1.113883.6.88) code system for

medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations , or MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode STATIC 20061017.

CONF-360: The value for “manufacturedMaterial / code” in a product template MAY contain a precoordinated product strength, product form, or product concentration (e.g. “metoprolol 25mg tablet”, “amoxicillin 400mg/5mL suspension”).

CONF-361: If manufacturedMaterial / code contains a precoordinated unit dose (e.g. “metoprolol 25mg tablet”), then SubstanceAdministration / doseQuantity SHALL be a unitless number that indicates the number of products given per administration.

CONF-362: If manufacturedMaterial / code does not contain a precoordinated unit dose (e.g. “metoprolol product”), then SubstanceAdministration / doseQuantity SHALL be a physical quantity that indicates the amount of product given per administration.

CONF-363: A manufacturedMaterial in a product template SHALL contain exactly one Material / code / originalText, which represents the generic name of the product.

CONF-364: A manufacturedMaterial in a product template MAY contain exactly one Material / name, which represents the brand name of the product.

CONF-365: A ManufacturedProduct in a product template MAY contain exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material.

CONF-366: A ManufacturedProduct in a product template MAY contain one or more manufacturedProduct / id, which uniquely represent a particular kind of product.

CONF-367: If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct SHOULD also contain manufacturedProduct / manufacturerOrganization.

CONF-368: A medication activity MAY contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section 3.14.2.2 Procedure related products), to identify a particular product instance.

CONF-369: A supply activity MAY contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section 3.14.2.2 Procedure related products), to identify a particular product instance.

CONF-370: Supply / participant / participantRole / id SHOULD be set to equal a [Act | Observation | Procedure] / participant / participantRole / id (see section 3.14.2.2 Procedure related products) to indicate that the Supply and the Procedure are referring to the same product instance.

Vital Signs (CCD templateId 2.16.840.1.113883.10.20.1.16)

CONF-381: CCD SHOULD contain exactly one and SHALL NOT contain more than one Vital signs section (templateId 2.16.840.1.113883.10.20.1.16). The Vital signs section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more vital signs organizers (templateId 2.16.840.1.113883.10.20.1.35), each of which SHALL contain one or more result observations (templateId 2.16.840.1.113883.10.20.1.31).

CONF-382: The vital signs section SHALL contain Section / code.

CONF-383: The value for “Section / code” SHALL be “8716-3” “Vital signs” 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-384: The vital signs section SHALL contain Section / title.

CONF-385: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing “vital signs”.

Vital signs organizer (CCD templateId 2.16.840.1.113883.10.20.1.35)

CONF-386: A vital signs organizer (templateId 2.16.840.1.113883.10.20.1.35) SHALL be a conformant results organizer (templateId 2.16.840.1.113883.10.20.1.32).

CONF-387: A vital signs organizer SHALL contain one or more sources of information, as defined in section 5.2 Source.

Result organizer (CCD templateId 2.16.840.1.113883.10.20.1.32)

CONF-393: A result organizer (templateId 2.16.840.1.113883.10.20.1.32) SHALL be represented with Organizer.

CONF-394: The value for “Organizer / @moodCode” in a result organizer SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-395: A result organizer SHALL contain at least one Organizer / id.

CONF-396: A result organizer SHALL contain exactly one Organizer / statusCode.

CONF-397: A result organizer SHALL contain exactly one Organizer / code.

CONF-398: The value for “Organizer / code” in a result organizer 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) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC.

CONF-399: A result organizer SHOULD include one or more Organizer / specimen if the specimen isn't inherent in Organizer / code.

CONF-400: Organizer / specimen SHALL NOT conflict with the specimen inherent in Organizer / code.

CONF-401: Organizer / specimen / specimenRole / id SHOULD be set to equal a Procedure / specimen / specimenRole / id (see section 3.14 Procedures) to indicate that the Results and the Procedure are referring to the same specimen.

CONF-402: A result organizer SHALL contain one or more Organizer / component.

CONF-403: The target of one or more result organizer Organizer / component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn’t inherent in Organizer / code or if there is a need to further specialize the Organizer / code value.

CONF-404: A result organizer Organizer / component / procedure MAY be a reference to a procedure described in the Procedure section. (See section 5.3 InternalCCRLink for more on referencing within CCD).

CONF-405: The target of one or more result organizer Organizer / component relationships SHALL be a result observation.

CONF-406: A result organizer SHALL contain one or more sources of information, as defined in section 5.2 Source.

Result observation (CCD templateId 2.16.840.1.113883.10.20.1.31)

CONF-407: A result observation (templateId 2.16.840.1.113883.10.20.1.31) SHALL be represented with Observation.

CONF-408: The value for “Observation / @moodCode” in a result observation SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-409: A result observation SHALL contain at least one Observation / id.

CONF-410: A result observation SHALL contain exactly one Observation / statusCode.

CONF-411: A result observation SHOULD contain exactly one Observation / effectiveTime, which represents the biologically relevant time (e.g. time the specimen was obtained from the patient).

CONF-412: A result observation SHALL contain exactly one Observation / code.

CONF-413: The value for “Observation / code” in a result observation 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).

CONF-414: A result observation MAY contain exactly one Observation / methodCode if the method isn't inherent in Observation / code or if there is a need to further specialize the method in Observation / code.

CONF-415: Observation / methodCode SHALL NOT conflict with the method inherent in Observation / code.

CONF-416: A result observation SHALL contain exactly one Observation / value.

CONF-417: Where Observation / value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression.

CONF-418: A result observation SHOULD contain exactly one Observation / interpretationCode, which can be used to provide a rough qualitative interpretation of the observation, such as “N” (normal), “L” (low), “S” (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.

CONF-419: A result observation SHOULD contain one or more Observation / referenceRange to show the normal range of values for the observation result.

CONF-420: A result observation SHALL NOT contain Observation / referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.

CONF-421: A result observation SHALL contain one or more sources of information, as defined in section 5.2 Source.

Purpose (CCD templateId 2.16.840.1.113883.10.20.1.13)

CONF-15: CCD MAY contain exactly one and SHALL NOT contain more than one Purpose section (templateId 2.16.840.1.113883.10.20.1.13). The Purpose section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more purpose activities (templateId 2.16.840.1.113883.10.20.1.30).

CONF-16: The purpose section SHALL contain Section / code.

CONF-17: The value for "Section / code" SHALL be "48764-5" "Summary purpose" 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-18: The purpose section SHALL contain Section / title.

CONF-19: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "purpose".\

Purpose activity (CCD templateId 2.16.840.1.113883.10.20.1.30)

CONF-20: A purpose activity (templateId 2.16.840.1.113883.10.20.1.30) SHALL be represented with Act.

CONF-21: The value for "Act / @classCode" in a purpose activity SHALL be "ACT" 2.16.840.1.113883.5.6 ActClass STATIC.

CONF-22: The value for "Act / @moodCode" in a purpose activity SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-23: A purpose activity SHALL contain exactly one Act / statusCode.

CONF-24: The value for "Act / statusCode" in a purpose activity SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC.

CONF-25: A purpose activity SHALL contain exactly one Act / code, with a value of "23745001" "Documentation procedure" 2.16.840.1.113883.6.96 SNOMED CT STATIC.

CONF-26: A purpose activity SHALL contain exactly one Act / entryRelationship / @typeCode, with a value of "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate the reason or purpose for creating the CCD.

CONF-27: The target of Act / entryRelationship / @typeCode in a purpose activity SHALL be an Act, Encounter, Observation, Procedure, SubstanceAdministration, or Supply.

Functional Status (CCD templateId 2.16.840.1.113883.10.20.1.5)

CONF-123: CCD SHOULD contain exactly one and SHALL NOT contain more than one Functional status section (templateId 2.16.840.1.113883.10.20.1.5). The Functional status section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more problem acts (templateId 2.16.840.1.113883.10.20.1.27) and/or result organizers (templateId 2.16.840.1.113883.10.20.1.32).

CONF-124: The functional status section SHALL contain Section / code.

CONF-125: The value for "Section / code" SHALL be "47420-5" "Functional status assessment" 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-126: The functional status section SHALL contain Section / title.

CONF-127: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing “functional status”.

Problem act (CCD templateId 2.16.840.1.113883.10.20.1.27)

CONF-145: A problem act (templateId 2.16.840.1.113883.10.20.1.27) SHALL be represented with Act.

CONF-146: The value for “Act / @classCode” in a problem act SHALL be “ACT” 2.16.840.1.113883.5.6 ActClass STATIC.

CONF-147: The value for “Act / @moodCode” in a problem act SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-148: A problem act SHALL contain at least one Act / id.

CONF-149: The value for “Act / code / @NullFlavor” in a problem act SHALL be “NA” “Not applicable” 2.16.840.1.113883.5.1008 NullFlavor STATIC.

CONF-150: A problem act MAY contain exactly one Act / effectiveTime, to indicate the timing of the concern (e.g. the interval of time for which the problem is a concern).

CONF-151: A problem act SHALL contain one or more Act / entryRelationship.

CONF-152: A problem act MAY reference a problem observation, alert observation (see section 3.8 Alerts) or other clinical statement that is the subject of concern, by setting the value for “Act / entryRelationship / @typeCode” to be “SUBJ” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

CONF-153: The target of a problem act with Act / entryRelationship / @typeCode=“SUBJ” SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section, see section 3.8 Alerts), but MAY be some other clinical statement.

Problem observation (CCD templateId 2.16.840.1.113883.10.20.1.28)

CONF-154: A problem observation (templateId 2.16.840.1.113883.10.20.1.28) SHALL be represented with Observation.

CONF-155: The value for “Observation / @moodCode” in a problem observation SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-156: A problem observation SHALL include exactly one Observation / statusCode.

CONF-157: The value for “Observation / statusCode” in a problem observation SHALL be “completed” 2.16.840.1.113883.5.14 ActStatus STATIC.

CONF-158: A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).

CONF-159: The value for “Observation / code” in a problem observation MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017.

CONF-160: The value for “Observation / entryRelationship / @typeCode” in a problem observation MAY be “SUBJ” “Subject” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).

CONF-161: A problem observation SHALL contain one or more sources of information, as defined in section 5.2 Source.

Problem status observation (CCD templateId 2.16.840.1.113883.10.20.1.50)

CONF-162: A problem observation MAY contain exactly one problem status observation.

CONF-163: A problem status observation (templateId 2.16.840.1.113883.10.20.1.50) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 “Type” and “Status” values).

CONF-164: The value for “Observation / value” in a problem status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017.

CONF-165: A problem observation MAY contain exactly one problem healthstatus observation.

Problem healthstatus observation (CCD templateId 2.16.840.1.113883.10.20.1.51)

CONF-166: A problem healthstatus observation (templateId 2.16.840.1.113883.10.20.1.51) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 “Type” and “Status” values), except that the value for “Observation / code” in a problem healthstatus observation SHALL be “11323-3” “Health status” 2.16.840.1.113883.6.1 LOINC STATIC.

CONF-167: The value for “Observation / value” in a problem healthstatus observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017.

Results organizer (CCD templateId 2.16.840.1.113883.10.20.1.32)

CONF-393: A result organizer (templateId 2.16.840.1.113883.10.20.1.32) SHALL be represented with Organizer.

CONF-394: The value for “Organizer / @moodCode” in a result organizer SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC.

CONF-395: A result organizer SHALL contain at least one Organizer / id.

CONF-396: A result organizer SHALL contain exactly one Organizer / statusCode.

CONF-397: A result organizer SHALL contain exactly one Organizer / code.

CONF-398: The value for “Organizer / code” in a result organizer 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) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC.

CONF-399: A result organizer SHOULD include one or more Organizer / specimen if the specimen isn't inherent in Organizer / code.

CONF-400: Organizer / specimen SHALL NOT conflict with the specimen inherent in Organizer / code.

CONF-401: Organizer / specimen / specimenRole / id SHOULD be set to equal a Procedure / specimen / specimenRole / id (see section 3.14 Procedures) to indicate that the Results and the Procedure are referring to the same specimen.

CONF-402: A result organizer SHALL contain one or more Organizer / component.

CONF-403: The target of one or more result organizer Organizer / component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in Organizer / code or if there is a need to further specialize the Organizer / code value.

CONF-404: A result organizer Organizer / component / procedure MAY be a reference to a procedure described in the Procedure section. (See section 5.3 InternalCCRLink for more on referencing within CCD).

CONF-405: The target of one or more result organizer Organizer / component relationships SHALL be a result observation.

CONF-406: A result organizer SHALL contain one or more sources of information, as defined in section 5.2 Source.

Result observation, Result organizer, Problem act and Problem observation (CCD templateId 2.16.840.1.113883.10.20.1.31, 2.16.840.1.113883.10.20.1.32, 2.16.840.1.113883.10.20.1.27 and 2.16.840.1.113883.10.20.1.28)

CONF-128: A problem observation or result observation in the functional status section SHALL contain exactly one observation / code.

CONF-129: The value for "Observation / code" in a problem observation or result observation in the functional status section MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.6 FunctionalStatusTypeCode STATIC 20061017.

CONF-130: If the functional status was collected using a standardized assessment instrument, then the instrument itself SHOULD be represented in the "Organizer / code" of a result organizer, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) .

CONF-131: If the functional status was collected using a standardized assessment instrument, then the question within that instrument SHOULD be represented in the "Observation / code" of a result observation, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96).

CONF-132: If the functional status was collected using a standardized assessment instrument containing questions with enumerated values as answers, then the answer SHOULD be represented in the "Observation / value" of a result observation.

CONF-133: If Observation / value in a result observation in the functional status section is of data type CE or CD, then it SHOULD use the same code system used to code the question in Observation / code.

CONF-134: Observation / value in a result observation in the functional status section MAY be of datatype CE or CD and MAY contain one or more Observation / value / translation, to represent equivalent values from other code systems.

CONF-135: A problem observation or result observation in the functional status section MAY use codes from the International Classification of Functioning, Disability, and Health (ICF, http://www.who.int/classifications/icf/en/) (codeSystem 2.16.840.1.113883.6.254).

CONF-136: A problem observation in the functional status section SHALL contain exactly one status of functional status observation.

CONF-137: A result observation in the functional status section SHALL contain exactly one status of functional status observation.

CONF-138: A status of functional status observation (templateId 2.16.840.1.113883.10.20.1.44) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 “Type” and “Status” values).

CONF-139: The value for “Observation / value” in a status of functional status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.5 StatusOfFunctionalStatusCode STATIC 20061017.

APPENDIX B — TEMPLATE IDS

The following table lists PHMR `templateIds` and their descriptions:

Table 5: Template IDs

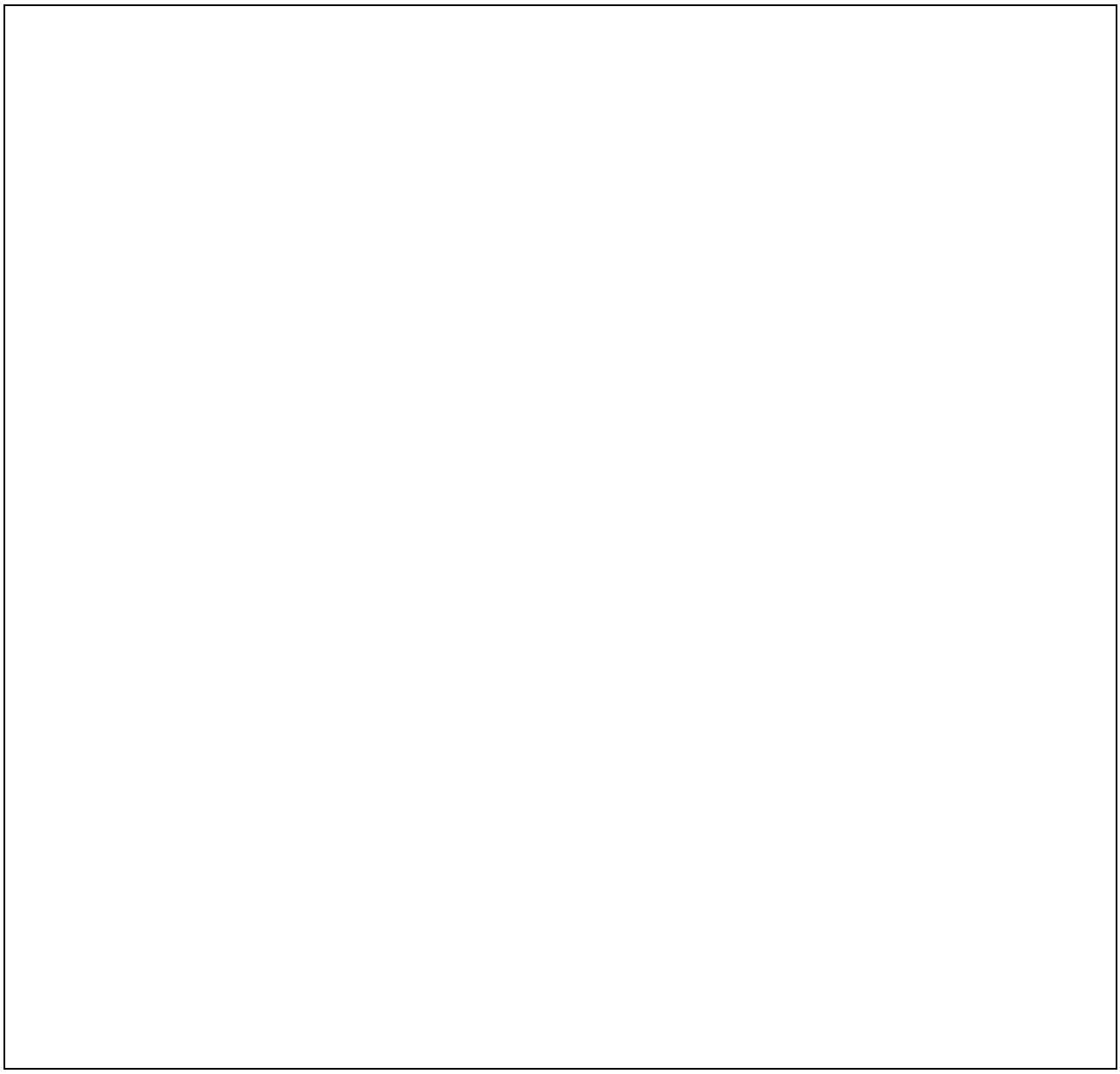
TemplateId	Description
2.16.840.1.113883.10.20.9	Template ID for Personal Healthcare Monitoring Reports
Section Templates	
2.16.840.1.113883.10.20.9.1	Medical Equipment 46264-8
2.16.840.1.113883.10.20.9.2	Vital Signs 8716-3
2.16.840.1.113883.10.20.9.14	Results 30954-2
Clinical Statement Templates	
2.16.840.1.113883.10.20.9.3	Device Accuracy Observation
2.16.840.1.113883.10.20.9.4	Device Definition Organizer
2.16.840.1.113883.10.20.9.5	Device Measurement Range Observation
2.16.840.1.113883.10.20.9.6	Device Resolution Observation
2.16.840.1.113883.10.20.9.7	Event Observation
2.16.840.1.113883.10.20.9.8	Numeric Observation
2.16.840.1.113883.10.20.9.9	PHMR Product Instance
2.16.840.1.113883.10.20.9.10	Sampling Frequency Observation
2.16.840.1.113883.10.20.9.11	Waveform Observation
2.16.840.1.113883.10.20.9.12	Waveform Series Observation
2.16.840.1.113883.10.20.9.13	Waveform Sample Period Observation

APPENDIX C — PHMR DATA MODEL

PHMR Device Data Model

The following diagram[5] shows the PHMR device data model:

Figure 41: PHMR device data model



[5] Continua Design Guidelines, Version 1.0, Copyright (c) 2008 Continua Health Alliance, October 2008.

PHMR Data Model to CDA Mapping

The following table shows how items in the PHMR data model are mapped to constructs in this PHMR CDA specification. Please refer to the relevant sections in this document, the CCD specification, or the CDA specification for further details and constraints. This table is meant to serve as a quick reference, not a complete set of constraints.

Note: All XPath statements reference elements in the CDA namespace; for readability no namespace prefixes are shown.

Table 6: PHMR Data Model to CDA Mapping

Class	Attribute	CDA XPath	Comments
PHMReport	Creation Data/Time	/ClinicalDocument/effectiveTime	
	Document Identifier	/ClinicalDocument/id	
	Document Code	/ClinicalDocument/code[@code="53576-5"][@codeSystem="2.16.840.1.113883.6.1"]	
	Language	/ClinicalDocument/languageCode	
	Version	/ClinicalDocument/versionNumber	If versionNumber is specified then setId should also be specified.
Actors and Identification	Authorized Source	/ClinicalDocument/author	
	Authorized Destination	/ClinicalDocument/ informationRecipient	
	Document Author	/ClinicalDocument/author	
	Custodian	/ClinicalDocument/custodian	
Subject	Name	/ClinicalDocument/recordTarget/ patientRole/name	
	Patient id	/ClinicalDocument/recordTarget/ patientRole/id	
	Demographics	/ClinicalDocument/recordTarget/ patientRole/…	Various elements in the recordTarget can store demographic information. Refer to the CDA specification for guidance.
Purpose	Narrative Description	//section[templateId/@root="2.16.840.1.113883.10.20.1.13"]/text	Maps to the CCD purpose section.
	Code	//section[templateId/@root="2.16.840.1.113883.10.20.1.13"]/code	
	Title	//section[templateId/@root="2.16.840.1.113883.10.20.1.13"]/title	
Remote Monitoring Notes		//section/text	Can be present in any section in the document.

Class	Attribute	CDA XPath	Comments
Functional Status		//section[templateId/@root="2.16.840.1.113883.10.20.1.5"]	Maps to the CCD functional status section.
PHM Section		//component/section	Maps to generic CDA section. Not expected to be used directly, rather use a subclass such as Vital Signs, etc.
Vital Signs		//section[templateId/@root="2.16.840.1.113883.10.20.1.16"]	Maps to the CCD Vital Signs section.
Results		//section[templateId/@root="2.16.840.1.113883.10.20.1.14"]	Maps to the CCD Results section.
Medications		//section[templateId/@root="2.16.840.1.113883.10.20.1.8"]	Maps to the CCD Medications section.
Exercise		//section[templateId/@root="2.16.840.1.113883.10.20.1.5"]	Maps to the Functional Status section.
Activity		//section[templateId/@root="2.16.840.1.113883.10.20.1.5"]	Maps to the Functional Status section.
Device	Device Id	//participant[templateId/@root="2.16.840.1.113883.10.20.9.9"]/id	The root attribute of the id will be "1.2.840.10004.1.1.1.0.0.1.0.0.1.2680" and the extension will be the actual EUI-64 id.
	System Type	//participant[templateId/@root="2.16.840.1.113883.10.20.9.9"]/participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/code	
	Manufacturer	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/scopingEntity/desc	
	Model	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
Production Spec	Unspecified	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
	Serial Number	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
	Part Number	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
	Hardware Revision	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
	Software Revision	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/p	Note 1

Class	Attribute	CDA XPath	Comments
		layingDevice/manufacturerModelName	
	Protocol Revision	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
	Prod Spec MDN	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/playingDevice/manufacturerModelName	Note 1
Regulatory Information	Regulatory Status	//participantRole[templateId/@root="2.16.840.1.113883.10.20.9.9"]/code[@nullFlavor="OTH"]/originalText	The originalText element will contain a simple free text description of the regulatory status, such as "Regulated Device" or "Unregulated Device".
Technical Attributes	Sampling Frequency	//observation[templateId/@root="2.16.840.1.113883.10.20.9.10"]/interpretationCode	Note 2
	Measurement Range	//observation[templateId/@root="2.16.840.1.113883.10.20.9.5"]/interpretationCode	Note 2
	Resolution	//observation[templateId/@root="2.16.840.1.113883.10.20.9.6"]/interpretationCode	Note 2
	Accuracy	//observation[templateId/@root="2.16.840.1.113883.10.20.9.3"]/interpretationCode	Note 2
Observation	Observation Type	//observation/code	
	Date Time Stamp	//observation/effectiveTime	
	Units	//observation/value[xsi:type="PQ"]/@unit	Only applicable for value elements containing physical quanities.
Attribute	type	See 0: Device-specific Attributes.	
	value	See 0: Device-specific Attributes.	
Value		//observation	Will either be a numeric observation or a waveform observation.
	Units	//observation/value[xsi:type="PQ"]/@unit	
	Accuracy	//observation[templateId/@root="2.16.840.1.113883.10.20.9.3"]	Reference from an observation using an entryRelationship.
AlertFlag		//observation/interpretationCode	
Numeric	NumericValue	//observation[templateId/@root="2.16.840.1.113883.10.20.9.8	

Class	Attribute	CDA XPath	Comments
		"]/value[xsi:type="PQ"]/@value	
Waveform	Sample Period	//observation[templateId/@root="2.16.840.1.113883.10.20.9.13"]	
	ValueSet	//observation[templateId/@root="2.16.840.1.113883.10.20.9.11"]/value	
Event	Event Code	//observation[templateId/@root="2.16.840.1.113883.10.20.9.7"]/value	Referenced from any observation type

Notes:

1. The manufacturer `ModelName` field will contain the model name as well as the production spec and regulatory information in structured text.
2. Reference from a Device Definition Organizer using an `entryRelationship`.

APPENDIX D — TERMINOLOGY

The following tables list the vocabulary supported by this specification, as well as appropriate mappings to IEEE 11073, SNOMED CT®, and UCUM.

Note: The ISO/IEEE Std 11073 Reference IDs and numeric code assignments have not been finalized at the time of publication of this DSTU, however, the following table provides adequate guidance to map IEEE device terminology into SNOMED CT.

Observation Types

For SNOMED CT®, some of the concepts require qualifiers to completely describe the term. These are listed under the Supplemental Concept ID column.

Table 7: Terminology Mapping for Observation Types

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	**Preferred Term Description ID**	**Description Text**	**Fully Specified Name ID**	**Supplemental Concept ID (Description ID – Text)**	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_CAPILLARY_PLASMA 2::29116	434911002	2774413018	Plasma glucose concentration	2774414012	122554006 | Capillary blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT
Plasma Glucose Level (-10417)	MDC_CONC_GLU_VENOUS_PLASMA 2::29124	434911002	2774413018	Plasma glucose concentration	2774414012	122555007 | Venous blood specimen (specimen)119298005 | Mixed venous blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_ARTERIAL_PLASMA 2::29132	434911002	2774413018	Plasma glucose concentration	2774414012	122552005 | Arterial blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT
Blood Glucose Level (-10417)	MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD 2::29112	434912009	2774415013	Blood glucose concentration	2774416014	122554006 | Capillary blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT
Blood Glucose Level (-10417)	MDC_CONC_GLU_VENOUS_WHOLEBLOOD 2::29120	434912009	2774415013	Blood glucose concentration	2774416014	122555007 | Venous blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Blood Glucose Level (-10417)	MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD 2::29128	434912009	2774415013	Blood glucose concentration	2774416014	122552005 | Arterial blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT
Glucose Control Measurement (-10417)	MDC_CONC_GLU_CONTROL 2::29136	434913004	2774417017	Glucose concentration in quality control reagent	2774418010		Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT
Interstitial Fluid Glucose level (-10417)	MDC_CONC_GLU_ISF 2::29140	434910001	2774412011	Interstitial fluid glucose concentration	2774411016		Not yet released. Will be distributed as part of the January 2009 International Release of SNOMED CT

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Hemoglobin A1C finding (-10417)	MDC_CONC_HBA1C 2::29148	365845005	489331011	Hemoglobin A1C - diabetic control finding	772274010		
Body mass (weight) (-20601)	MDC_MASS_BODY_ACTUAL 2::57664	27113001	45352010	Body weight	757644016		
Body height (-10415)	MDC_LEN_BODY_ACTUAL 2::57668	50373000	495662010	Body height measure	788154012		
Body mass index (-10415)	MDC_RATIO_MASS_BODY_LEN_SQ 2::57680	60621009	100716012	Body mass index	799594012		
Systolic Pressure (-10407)	MDC_PRESS_BLD_NONINV_SYS 2::18949	271649006	106507015	Systolic blood pressure	664067013		
Diastolic Pressure (-10407)	MDC_PRESS_BLD_NONINV_DIA 2::18950	271650006	406508013	Diastolic blood pressure	664068015		
Mean Arterial Pressure (-10407)	MDC_PRESS_BLD_NONINV_MEAN 2::18951	6797001	500884018	Mean blood pressure	807753012	Note: Must be rendered as mean blood press not mean arterial pressure	

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Pulse (-10407)	MDC_PULS_RATE_NON_INV 2::18474	78564009	130365016	Pulse rate	819518016		
Body Temperature (-10408)	MDC_TEMP_BODY 2::19292	386725007	1480858013	Body Temperature	1460904011		
Body Temperature (Finger) (-10408)	MDC_TEMP_FINGER 2::57360	433588001	2771281010	Temperature of digit of hand	2760794019		
Body Temperature (Ear) (-10408)	MDC_TEMP_EAR 2::57356	415974002	2534421019	Tympanic temperature	2530951014		
Body Temperature (Toe) (-10408)	MDC_TEMP_TOE 2::57376	433776001	2768039016	Temperature of toe	2745011013		
Body Temperature (Gastro) (-10408)	MDC_TEMP_GIT 2::57384	431598003	2769062014 (US)	Temperature of esophagus	2747764015	2769063016 (UK) Temperature of oesophagus	
Body Temperature (Armpit) (-10408)	MDC_TEMP_AXILLA 2::57380	415882003	2534419012	Auxiliary temperature	2530949010		

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Body Temperature (Oral) (-10408)	MDC_TEMP_ORAL 2::57352	415945006	2534418016	Oral temperature	253094019		
Body Temperature (Rectal) (-10408)	MDC_TEMP_RECT 2::57348	307047009	450211011	Rectal temperature	703520017		
Body Temperature (Tympanic) (-10408)	MDC_TEMP_TYMP 2::19320	415974002	2534421019	Tympanic temperature	2530951014		
SpO2 (-10404)	MDC_PULS_OXIM_SAT_O2 2::19384	431314004	2772010012	Peripheral oxygen saturation	2735642016	2767654013 | SpO2 - saturation of peripheral oxygen	
Pulse Rate (-10404)	MDC_PULS_OXIM_PULS_RATE 2::18458	78564009	130365016	Pulse rate	819518016		

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Preferred Term Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Pulse amplitude (-10404)	MDC_PULS_OXIM_PERF_REL 2::19376 Or MDC_SAT_O2_QUAL 2::19248	431591009	2769937011	Pulse waveform amplitude using pulse oximetry	2736894010		
Plethysmographic waveform (-10404)	MDC_PULS_OXIM_PLETH 2::19380	250864000	373962018	Plethysmograph waveform	641309010		

Events and Attributes

Table 8: Terminology for Events and Attributes

Description	**ISO/IEEE Std 11073-10101**	**SNOMED CT**					**Notes**
		Concept ID	**Description ID**	**Description Text**	**Fully Specified Name ID**	**Supplemental Concept ID (Description ID – Text)**	
Sample Location (-10417)	MDC_CTXT_GLU_SAMPLELOCATION 128:29236						
Sample Location Attribute (-10417)	Finger MDC_CTXT_GLU_SAMPLELOCATION_FINGER 128::29240	125685002	473565013	Digit of hand structure	729542015		
Sample Location Attribute (-10417)	Alternative Site Testing (AST) MDC_CTXT_GLU_ SAMPLELOCATION_AST 128::29244						
Sample Location Attribute (-10417)	Earlobe MDC_CTXT_GLU_ SAMPLELOCATION_EARLOBE 128::29248	113327001	383219015	Pinna structure	648683014		
Control Solution Indicator Attribute (-10417)	Control Solution MDC_CTXT_GLU_ SAMPLELOCATION_CTRLSOLUTION 128::29252						Mapped via Observation of type: MDC_CONC_GLU_CONTROL

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Measurement Condition (-10417)	MDC_CTXT_GLU_MEAL 128:29256						
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_PREPRANDIAL Pre-Prandial (or Pre-Meal) 128::29260	307165006	450357011	Before meal	703654021		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_POSTPRANDIAL Post-Prandial (or Post-Meal) 128::29264	225758001	339227016	After food	613042015		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_FASTING 128::29268	16985007	478017015	Fasting	744117012		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_CASUAL 128::29272	255226008	380387010	Random	646234012		
Tester (-10417)	MDC_CTXT_GLU_TESTER 2:29276						
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_SELF 128::29280						Mapped via HL7 CDA Information Model
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_HCP 128::29284						Mapped via HL7 CDA Information Model

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_LAB 128::29288						Mapped via HL7 CDA Information Model
SpO2 – fast-response (-10404)	MDC_MODALITY_FAST 2::19508	433204000	2768695014	Rate of sampling of peripheral oxygen saturation by device	2743645015	Note: this must be used in conjunction with 277748003 Fast (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."
SpO2 – slow-response (-10404)	MDC_MODALITY_SLOW 2::19512	433204000	2768695014	Rate of sampling of peripheral oxygen saturation by device	2743645015	Note: this must be used in conjunction with 255361000 Slow (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."
SpO2 – spot-check (-10404)	MDC_MODALITY_SPOT 2::19516	431314004	2772010012	Peripheral oxygen saturation	2735642016	276765 4013 | SpO2 - saturation of peripheral oxygen	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."

Description	ISO/IEEE Std 11073-10101	SNOMED CT					Notes
		Concept ID	Description ID	Description Text	Fully Specified Name ID	Supplemental Concept ID (Description ID – Text)	
SpO2 – precise pulse (-10404)	MDC_TRIG_BEAT_MAX_INRUSH 2::53259						The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."

Unmapped Events and Attributes

Currently there is no SNOMED CT mapping of IEEE-11073 for these values.

Table 9: Unmapped Events and Attributes

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
Pulse Events (-10404)	MDC_TRIG 2::53250				
Pulse Events (-10404)	MDC_TRIG_BEAT 2::53251 Value for attribute MDC_TRIG				
Compound Blood Pressure Measurement (-10407)	MDC_PRESS_BLD_NONINV 2::18948				
SpO2 Threshold Conditions (-20601)	MDC_ATTR_MSMT_STAT 1::2375				
Alarm Condition (-10404)	MDC_ATTR_AL_COND 1::2476				
SpO2 Threshold Conditions (-10404)	MDC_ATTR_AL_OP_STAT 1::2310				
SpO2 Threshold Conditions (-10404)	MDC_ATTR_LIMIT_CURR 1::2356				
SpO2 Threshold Conditions (-10404)	MDC_ATTR_AL_OP_TEXT_STRING 1::2478				
Pulse Event Placeholder (-10404)	MDC_METRIC_NOS 2::61439				
Pulse characteristics Event (-10404)	Event: MDC_PULS_OXIM_PULS_CHAR 2::19512				

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
Pulse characteristics Event (-10404)	Value for attribute MDC_PULS_OXIM_PULS_CHAR Attributes (Not Coded) Perfusion or quality of the detected pulse is marginal – pulse-qual-marginal Perfusion or quality of the detected pulse is minimal – pulse-qual-minimal Perfusion or quality of the detected pulse is unacceptable – pulse-qual-unacceptable				Bit values will need local coding
Pulse device and sensor conditions (-10404)	Event: MDC_PULS_OXIM_DEV_STATUS 2::19532				
Pulse device and sensor conditions (-10404)	Value for attribute MDC_PULS_OXIM_DEV_STATUS Attributes: Agent reports that the sensor is disconnected from the instrument. – sensor-disconnected Agent reports that the sensor is malfunctioning or faulting. – sensor-malfunction Agent reports that the sensor is not properly attached or has been dislodged, preventing accurate measurement. – sensor-displaced An unsupported sensor is connected to the Agent – sensor-unsupported				Bit values will need local coding

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
	Agent reports that sensor is not connected to the user – sensor-off Signal analysis is currently in progress prior to measurement availability – sensor-searching Agent reports that there is interference due to ambient light or electrical phenomena – sensor-interference Agent determines that a questionable pulse is detected – signal-pulse-questionable Agent detects a non-pulsatile signal – signal-non-pulsatile Agent reports that the signal is erratic or is not plausible – signal-erratic Agent reports a consistently low perfusion condition exists – signal-low-perfusion Agent reports a poor signal exists, possibly affecting accuracy – signal-poor Agent reports that the incoming signal cannot be analyzed or is inadequate for producing a meaningful result. – signal-inadequate Agent has determined that some irregularity has been detected while processing the signal. – signal-processing-irregularity A general device fault has occurred in the Agent – device-equipment-malfunction				

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
	An Extended Display Update is currently active – device-extended-update				
Medication (insulin) event (-10417)	Event: MDC_CTXT_MEDICATION 128::29188				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_RAPIDACTING 128::29192 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_SHORTACTING 128::29196 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_INTERMEDIATEACTING 128::29200 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_LONGACTING 128::29204 Value for attribute MDC_CTXT_MEDICATION				

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_PREMIX 128::29208 Value for attribute MDC_CTXT_MEDICATION				
Subjective Health Event (-10417)	Event: MDC_CTXT_GLU_HEALTH 128::29212				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_MINOR 128::29216 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_ GLU_HEALTH_MAJOR 128::29220 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_ GLU_HEALTH_MENSES 128::29224 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_ GLU_HEALTH_STRESS 128::29228 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_ GLU_HEALTH_NONE 128::29232 Value for attribute MDC_CTXT_GLU_HEALTH				

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
Exercise Activity (-10417)	MDC_CTXT_GLU_EXERCISE 128::29152				
Dietary Intake Event (-10417)	Event: MDC_CTXT_GLU_CARB 128::29156				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_BREAKFAST 128::29160 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_LUNCH 128::29164 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_DINNER 128::29168 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_SNACK 128::29172 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_DRINK 128::29176 Value for attribute MDC_CTXT_GLU_CARB				

Description	ISO/IEEE Std 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description Text	
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_SUPPER 128::29180 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_BRUNCH 128::29184 Value for attribute MDC_CTXT_GLU_CARB				
Meter Status (-10417)	MDC_GLU_METER_DEV_STATUS 128::29144				

UCUM Unit Mapping

Table 10: UCUM Unit Mapping

11073 Reference ID	Symbol (informative)	UCUM Unit Code (case sensitive)
MDC_DIM_PERCENT	%	%
MDC_DIM_BEAT_PER_MIN	bpm	{beat }/min
MDC_DIM_MMHG	mmHg	mm[Hg]
MDC_DIM_KILO_PASCAL	kPa	kPa
MDC_DIM_BEAT_PER_MIN	bpm	{beat}/min
MDC_DIM_DEGC	˚C	Cel
MDC_DIM_FAHR	˚F	[degF]
MDC_DIM_KILO_G	kg	kg
MDC_DIM_LB	lb	[lb_av]
MDC_DIM_CENTI_M	cm	cm
MDC_DIM_INCH	in	[in_i]
MDC_DIM_KG_PER_M_SQ	kg/m2	kg/m2
MDC_DIM_MILLI_MOLE_PER_L	mmol/L	mmol/L
MDC_DIM_KCAL	Cal	[Cal]
MDC_DIM_MILLI_G_PER_DL	mg/dL	mg/dL
MDC_DIM_DIMLESS		1

Common Object Identifiers (OIDs)

The following table lists the code systems and identifier namespaces referenced in this IG along with their object identifiers (OIDs):

Table 11: Common Object Identifiers (OIDs)

Code System	Object Identifier (OID)
IEEE 11073 (aka MDC)	2.16.840.1.113883.6.24
SNOMED CT®	2.16.840.1.113883.6.96
LOINC®	2.16.840.1.113883.6.1
EUI-64	2.16.840.1.113883.6.24
GMDN	2.16.840.1.113883.6.276