HL7 Implementation Guide for CDA Release 2.0
Personal Healthcare Monitoring Report (PHMR)

(Danish profile – PHMR DK)

Release 1.3
March 31, 2014

Updated
March 2, 2020

Revision History			
Release	Author	Date	Notes
1.0	MedCom	2014.03.31	First version for trial implementation
	MedCom	2014.06.25	CONF-PHMR-DK-19: The type of ClinicalDocument/id attributes further specified.
1.1	MedCom	2016.09.20	OID's updated CONF-PHMR-2: Added for clarification CONF-PHMR-21: Changed to original wording CONF-PHMR-DK-1: Changed CONF-PHMR-DK-23: New CONF-PHMR-105: Added for clarification CONF-PHMR-76: Added for clarification CONF-PHMR-77: Added for clarification CONF-PHMR-78: Added for clarification CONF-PHMR-80: Added for clarification CONF-PHMR-DK-34: Added CONF-PHMR-DK-32: Deleted
1.2	MedCom	2016.11.04	CONF-PHMR-DK-35: Specification of eventCodeList entries in documentationOf added. The use of references to external documents added to Appendix F
1.3	MedCom	2017.11.28	CONF-PHMR-DK-36: Specification of Red and Yellow ReferenceRange added
1.3	MedCom	2018.04.24	CONF-PHMR-DK-28: Changed the wording for clarification
1.3	MedCom	2020.03.02	The cardinality of methodCode changed from 1..1 to 2..2 which is in accordance with test protocols and test examples

Table of Contents

Table of Figures

Table of Tables

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 for the use in the Danish healthcare sector (PHMR DK).

The PHMR DK is a document that carries personal healthcare monitoring information.

1.2 Scope

The Danish Reference Architecture for Collecting Health Data from Citizens[i] is partially based on the Continua Health Alliance Framework which profiles a number of existing standards for data communication from health monitoring devices.

The Continua Health Alliance Architecture is shown on Figure 1 below.
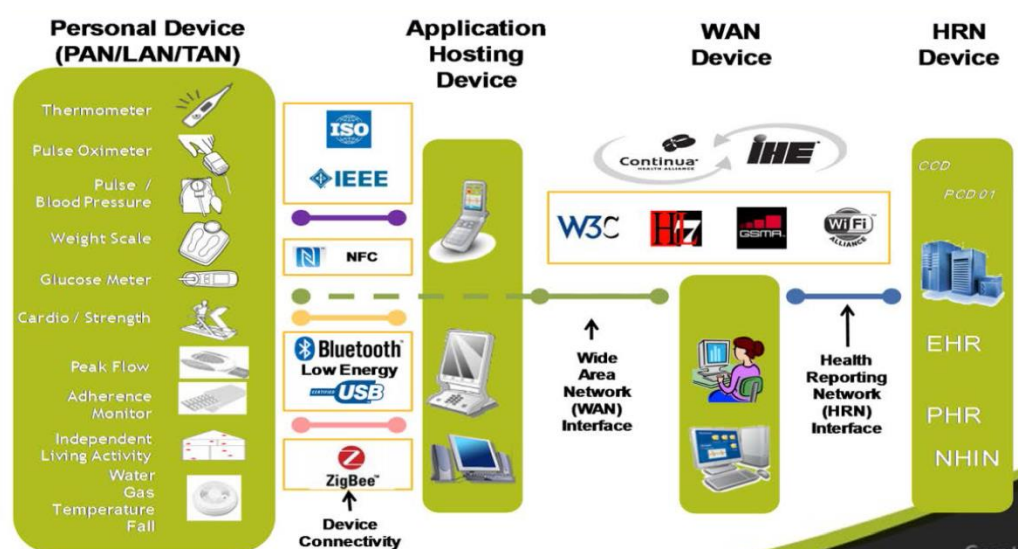
Figure 1: Continua Health Alliance Architecture

One of the standards is HL7 Personal Healthcare Monitoring Report (PHMR). The PHMR standard is used for communication between the WAN device and HRN Device.

---

[i] Reference Architecture for Collecting Health Data from Citizens. National eHealth Authority. June 2013.

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 9 of 89

This document does not describe the use of standards in the Personal Device and the Application Hosting Device.

1.3   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 DK documents created according to this specification.

1.4   Approach

Overall, the approach for the PHMR DK profile 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.

Wherever possible, the PHMR DK reuses templates already set forth by the HL7 Continuity of Care Document (CCD) and the HL7 Personal Healthcare Monitoring Report (PHMR).

This PHMR DK profile adds constraints to HL7's Personal Healthcare Monitoring Report (PHMR) through conformance statements that further define and restrict the CCD and PHMR objects and the vocabulary sets for coded elements.

The structured body of PHMR DK is intended to be compatible with CCD, although there are some differences in the CDA Header, most notably the demographic specifications, which are adjusted for the use in Denmark.

As the PHMR DK is the first version and also the first Danish CDA to be used on national level, it is important to note that not all area of the PHMR is included in this profile. The underlying basis for the specification has been the use cases, specified in appendix G. The use cases in appendix G are all based on real or planned implementation.

1.5   Use of Templates

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 10 of 89

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.

1.6   OID Representation

IN HL7 specifications an OID is represented as a sequence of non-negative integers separated by periods. They look like an IP address on steroids. For example, the OID fort HL7 appears as 2.16.840.1.113883. HL7 provides a publically available OID registry from which anyone can obtain their own use or look up OIDs used or assigned to others. This is available at http://www.hl7.org/oid/index.cfm.

As of March 18th, 2015 MedCom has changed from the HL7 OID registry to another public OID registry http://www.oid-info.com/, hence the MedCom root OID `2.16.840.1.113883.3.4208` has been retired and must not be used anymore. The new MedCom root OID `1.2.208.184` shall be used instead.

The HL7 Implementation Guide for Unique Object Identifiers informative specification is available from the HL7 website at http://www.hl7.org and provides information on how to use OIDs inside CDA documents.

In this profile as many as possible existing OID's have been reused. MedCom (as author for this profile) has created new OID's where required. A list of the OID's used in this profile is listed in appendix B.

1.7   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.

1.7.1   Keywords

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

- **SHALL:** an absolute requirement
- **SHALL NOT:** an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT:** best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT:** truly optional; can be included or omitted as the author decides with no implications

The keyword "SHALL" allows the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded.

1.7.2 Conformance Requirements

Where possible the original PHMR constraints are carried on by using the original PHMR conformance identification identifier (**CONF-PHMR-XX**).

New constraints in the PHMR DK are added by using the conformance identification identifier **CONF-PHMR-DK-XX.**

All conformance requirements are numbered sequentially.

1.7.3 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.

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" >
…
</ClinicalDocument >
```

Figure 2: XML code example

1.7.4 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.

1.8   CDA

The HL7 **Clinical Document Architecture** (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. The CDA standard doesn't specify how the documents should be transported.

CDA is a part of the HL7 version 3 standard and was developed using the HL7 Development Framework (HDF) and it is based on the HL7 Reference Information Model (RIM) and the HL7 Version 3 Data Types. CDA documents are persistent in nature.

1.8.1   Structure of a CDA Document

A CDA document is comprised of two parts.

The **document header** sets the context for the clinical document. It contains information such as when it was written, who wrote it, for what organisation, which patient it applies to, and the encounter for which it describes the healthcare services.

The **document body** contains the human readable narrative text. The body may also include machine-readable information called entries. The CDA standard has one restriction on the unstructured test. The format cannot be XML.

1.8.2   Levels of CDA

CDA includes the use of three levels. Each level introduced a higher degree of semantic interoperability into the exchange of the clinical documents.

At Level 1, the CDA provides a collection of metadata used to describe the clinical document, along with the human readable content in application specific or proprietary formats.

Level 2 introduces structures to convey the human readable content in a form similar to HTML, and to identify sections of that content using coded terms.
Finally, level 3 provides not only human readable semantics, but also machine readable semantic content.
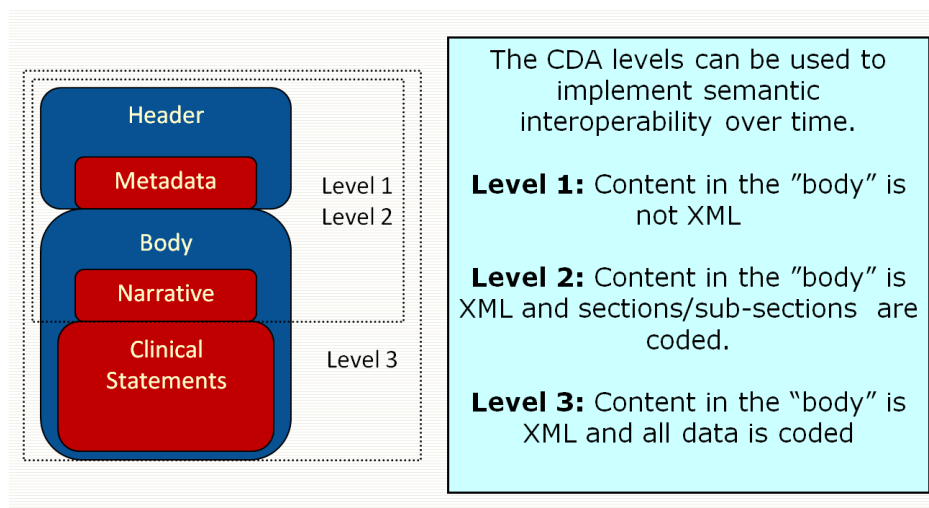
Figure 3: Levels of CDA

1.8.3 Persistence

According to the CDA standard, persistence is a characteristic of a clinical document. A CDA document continues to exist in an unaltered state, for a time period defined by regulatory requirements. Health care providers and provider organizations are required to retain documentation of care that has been provided for specific time periods.

1.8.4 Stewardship

Clinical documents are "maintained" by an organization entrusted with its care. This means that an organization must be able to produce the original of a clinical document, sometimes years after it was created.

The CDA format requires that the name of the organization be recorded as of the time the document was created. Over time, organizations may merge with other organizations, may be split off to other organizations. CDA does not require that the history of organizational changes be recorded and maintained. Instead, it assumes that knowledge of the original steward should be sufficient to locate any subsequent organization that would retain the original copy of the document.

The steward of a CDA document is known as its custodian. The CDA standard does not allow for individual persons to be stewards of documents, only organizations.

1.8.5 Potential for authentication

The potential for authentication of a clinical document refers to its ability to record or attest the signature of the legally responsible provider. This

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 14 of 89

legal authentication attests to the completeness and accuracy of the clinical information, and lends credibility to its content.

There may be different kinds of "signers" of a clinical document. Some signers are simply attesting that the content of the document is appears as they wrote it. Others are signing the document to assert that not only it is true, correct and complete, but also that they accept legally responsible for the care described in it.

The CDA standard supports the ability of the different types of authenticators to be recorded in the CDA document. It distinguishes between the legal authenticator (the person taking legal responsibility for the document content), and other authenticators.

Legal authentication is recorded in a CDA document a form that supports electronic signatures rather than digital signatures. When a paper document is signed, it is very clear that what is being signed is the information that appears on paper. When a CDA document records the signature of an authenticator, the standard does not make clear that it is the human readable content being authenticated. This is left to the local policy for implementation.

1.8.6   Human readability

Clinical documents are intended to communicate information between healthcare providers. Healthcare providers are humans so clinical documents must be human readable.

The CDA specifies that the content of the document consist of a mandatory textual part (which ensures human interpretation of the document and content) and optional structured parts (for software processing). The structured part relies on coding systems to represent concepts.

The human readability means that there must be a way to display the contents of the clinical document in a way that will allow a human to read it. This display can be through a separate application using proprietary formats such as a word processor, or it can be through the narrative format defined in the CDA standard.

1.8.7   Development process

This report has been prepared by the MedCom in collaboration with a workgroup composed by a number of partners from the health sector and suppliers of ICT solutions to the healthcare sector.

The work group held five workshops in the period from November 2013 to February 2014. The work group included:

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 specified for the use in Denmark and the needed adjustment for demographics information has been done. Special attention has been on the Danish use of Personal Identification, Address and Telephone Numbers as described in section 2.4.

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 profile does not require use of any specific namespace prefix. Instances should not include the `xsi:schemaLocation` element[ii].

CONF-PHMR-1:

The root of a PHM report **SHALL** be a `ClinicalDocument` element from the `urn:hl7-org:v3` namespace. This indicates conformance to the PHMR profile.

CONF-PHMR-DK- 3:

The `encoding` of a PHM report **SHALL** be a `UTF-8`. This indicates conformance to this profile.

2.2 ClinicalDocument/templateId

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

CONF-PHMR- 4:

A **`ClinicalDocument/templateId`** element SHALL be present where **`@root`** is `2.16.840.1.113883.10.20.9`. This indicates conformance to the PHMR profile.

CONF-PHMR-DK- 5:

[ii] 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.

A `ClinicalDocument/templateId` element **SHALL** be present where `@root` is `1.2.208.184.11.1`. This indicates conformance to this profile.

```
<!-- Required: Conforms to PHMR Danish profile -->
<templateId root="1.2.208.184.11.1"/>
```

Figure 4: ClinicalDocument/templateId example

2.3   ClinicalDocument/code

CONF-PHMR-DK- 6:

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.

2.4.1   Patient Identification

The Danish Personal Identification number (Danish: CPR-nummer or personnummer) is a national identification number, which is part of the personal information stored in the Civil Registration System.

It is a ten-digit number with the format DDMMYYSSSS, where DDMMYY is the date of birth and SSSS is a sequence number. The last digit of the sequence number is odd for males and even for females.

CONF-PHMR-DK- 7:

If the Danish Personal Identification number is unknown a validated replacement Danish Personal Identification[iii] number **SHALL** be used.

CONF-PHMR-DK- 8:

The `id` element **SHALL** be present and the value of the @extension holds a valid Danish Personal Identification number (cpr-nummer). The @codesystem value of this element **SHALL** be specified as shown in Figure 5 below.

[iii] https://cpr.dk/cpr-systemet/erstatningspersonnummer-i-eksterne-systemer/

```
<id extension="2512489996" root=" 1.2.208.176.1.2"/>
```

Figure 5: Danish Personal Identification example

2.4.2 DK (Patient) Name

The DK Patient Name datatype flavor is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. One or more middle names can be inserted between the first and last name. If a patient or person has only one name part (e.g., patient with first name only) then place the name part in the best matching field. Use the appropriate `nullFlavor`, "Not Applicable" (NA), in the other field.

CONF-PHMR-DK- 9:

SHALL contain exactly one [1..1] `family` element. In this profile the `@qualifier` is not used.

CONF-PHMR-DK- 10:

SHALL contain at least one [1..*] `given` element. In this profile the `@qualifier` is not used. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial.

```
<name>
  <given>Nancy</given>
  <given>Ann</given>
  <family>Berggren</family>
</name>
```

Figure 6: DK Name example

CONF-PHMR-DK- 11:

MAY contain one [0..1] `prefix` element, e.g. to include the tittle for a health professional. In this profile the `@qualifier` is not used.

```
<name>
  <prefix>Læge</prefix>
  <given>Anders</given>
  <family>Andersen</family>
</name>
```

Figure 7: DK prefix example

2.4.3 DK Address

This section describes constrains for a reusable "address" template, designed for use in DK PHMR CDA Header.

CONF-PHMR-DK- 12:

SHOULD contain exactly one [1..1] `@use`, which **SHALL** be selected from `ValueSet` PostalAddressUse in Table 1.

CONF-PHMR-DK- 13:

SHALL contain at least one and not more than 4 streetAddressLine.

CONF-PHMR-DK- 14:

SHALL contain exactly one [1..1] `postalcode`.

CONF-PHMR-DK- 15:

SHALL contain exactly one [1..1] `city`.

CONF-PHMR-DK- 16:

SHOULD contain zero or one [0..1] `country`, where the @code **SHALL** be selected from `ValueSet` PostalAddressUse in Table 1.

```
<addr use="H">
    <streetAddressLine>Skovvejen 12</streetAddressLine>
    <streetAddressLine>Landet</streetAddressLine>
    <postalCode>5700</postalCode>
    <city>Svendborg</city>
    <country>Danmark</country>
</addr>
```

Figure 8: DK Address example

Code	Code system	Print name
H	AddressUse	home address
WP	AddressUse	work place

Table 1: PostalAddressUse Value Set

2.4.4 DK Telecommunications Address

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 20 of 89

The telecommunications address or endpoint specifies how to contact someone or something using telecommunications equipment. That includes the telephone, a fax machine, e-mail, the web, instant messaging etc. All telecommunications addresses can be represented bu a URI.

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

E-mail addresses are represented using the `mailto:` URI scheme defined in RFC 2368. Technically, more than one e-mail address is permitted in the `mailto:` URI scheme.

Web site addresses are formatted using the `http:` and `https:` URI formats, which are described in RFC 2396.

Text messages are formatted using the `sms:` URI format, which are described in the RFC 5724.

The `use` attribute provides codes from PostalAddressUse as shown in Table 1, describing the type of communications endpoint.

CONF-PHMR-10:

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

```
<telecom value="tel:86121824" use="H"/>
<telecom value="mailto:info@medcom.dk" use="WP"/>
```

Figure 9: DK Telecommunication example

2.4.5   Support of communication

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-DK- 17:

All `patient` elements **SHALL** have a name.

CONF-PHMR-DK- 18:

All `patientRole` and `assignedAuthor` elements **SHOULD** have `addr` and `telecom` elements.

CONF-PHMR-DK- 19:

All `participantRole` elements **SHOULD** have `addr` and `telecom` elements.

CONF-PHMR-DK- 20:

All `providerOrganization` 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.

In this profile the HL7 NullFlavor vocabulary is constrained to the value set in Table 2 below.

NullFlavor	Explanation
NI	No information. This is the most general default null flavor
NA	Not applicable. Known to have no proper value (e.g. last menstrual period for a male)

<div align="center">

Table 2: PHMR DK NullFlavor Value Set

</div>

```
<signatureCode nullFlavor="NI"/>
```

<div align="center">

Figure 10: Example for the use of nullFlavor

</div>

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

CONF-PHMR-DK- 21:

Times or time intervals found in all elements e.g. `ClinicalDocument/effectiveTime`, `author/time`, `legalAuthenticator/time` **SHALL** be precise to the day, **SHALL** include a time zone and **SHALL** be precise to the second.

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.

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

Figure 11: ClinicalDocument/typeId example

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-DK- 22:

The `ClinicalDocument/id` element **SHALL** be present. The attribute `ClinicalDocument/id/@root` shall be an OID. The attribute `ClinicalDocument/id/@extension` **SHALL** be an UUID.

CONF-PHMR-DK- 23:

UUIDs **SHALL** be version 4 and represented in the form XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].

```
<id root="1.2.208.184 " extension="aa2386d0-79ea-11e3-981f-0800200c9a66" />
```

Figure 12: ClinicalDocument/id example

2.7 ClinicalDocument/title

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

CONF-PHMR-15:

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 23 of 89

`ClinicalDocument/title` **SHALL** be present.

CONF-PHMR-DK- 24:

The `ClinicalDocument/title` **SHALL** specify "Hjemmemonitorering for *cpr-number*", where *cpr-number* is a validated Danish cpr-numer.

<title>Hjemmemonitorering for 2512489996</title>

Figure 13: ClinicalDocument/title example

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-DK- 25:

`ClinicalDocument/effectiveTime` **SHALL** be present and **SHALL** be precise to the second.

<effectiveTime value="201401131000+0100"/>

Figure 14: ClinicalDocument/effectiveTime example

2.9   ClinicalDocument/confidentialityCode

CDA R2 requires that the `ClinicalDocument/confidentialityCode` be present. It specifies the confidentiality assigned to the document.

CONF-PHMR-DK- 26:

`ClinicalDocument/confidentialityCod`e **SHALL** be present and the `@code` and `@codesystem` values of this element **SHALL** be specified as shown in Figure 15 below.

<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-DK- 27:

`ClinicalDocument/languageCode` **SHALL** be in the form `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.

```
<languageCode code="da"/>
```

Figure 16: ClinicalDocument/languageCode example with language

```
<languageCode code="da-DK"/>
```

Figure 17: ClinicalDocument/languageCode example with language and country

2.11   ClinicalDocument/setId and ClinicalDocument/versionNumber

The `ClinicalDocument/setId` element uses the instance identifier (II) data type. The `@root` attribute is an 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.

CONF-PHMR-21:

Both `ClinicalDocument/setId` and `ClinicalDocument/versionNumber` **SHALL** be present or both **SHALL** be absent.

CONF-PHMR-22:

The `@extension` and `@root` of `ClinicalDocument/setId` and `ClinicalDocument/id` **SHALL** be different when both are present.

```
<setId extension="999021" root="2.16.840.1.113883.1.19"/>
<versionNumber value="1"/>
```

**Figure 18: ClinicalDocument/setId and
ClinicalDocument/versionNumber example**

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. Only participants, who are described in the examples (see appendix G) are included in the Danish profile.

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-DK- 28:

A `patient/birthTime` element **SHALL** be present. The `patient/birthTime` element **SHALL** be precise and include day, month and year, and **MAY** omit time zone. If the `patient/birthTime` is unknown, the null flavor **SHALL** be used as shown in Figure 19 below.

```
<!-- Known birthTime -->
<birthTime value="19481225000000+0000"/>


<!-- Unknown birthTime -->
<birthTime nullFlavor="NI"/>
```

Figure 19: Known and unknown patient/birthTime example

CONF-PHMR-26:

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

Code	Code system	Print name
F	AdministrativeGender	Female
M	AdministrativeGender	Male
UN	AdministrativeGender	Undifferentiated

Table 3: Administrative Gender (HL7) Value Set

```
<recordTarget typeCode="RCT" contextControlCode="OP">
  <patientRole classCode="PAT">
    <id extension="2512489996" root="1.2.208.176.1.2"
     assigningAuthorityName="CPR"/>
    <addr use="H">
      <streetAddressLine>Skovvejen 12</streetAddressLine>
      <streetAddressLine>Landet</streetAddressLine>
      <postalCode>5700</postalCode>
      <city>Svendborg</city>
      <country>Danmark</country>
    </addr>
    <telecom value="tel:65123456" use="H"/>
    <telecom value="mailto:nab@udkantsdanmark.dk" use="WP"/>
    <patient classCode="PSN" determinerCode="INSTANCE">
      <name>
        <given>Nancy</given>
        <given>Ann</given>
```

```
      <family>Berggren</family>
    </name>
    <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
    <birthTime value="19481225000000+0000"/>
  </patient>
 </patientRole>
</recordTarget>
```

Figure 20: recordTarget example

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-DK- 29:

An `assignedAuthor` element **SHALL** contain at least one `assignedPerson` 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.

```
<author typeCode="AUT" contextControlCode="OP">
  <time value="20140113100000+0100"/>
  <assignedAuthor classCode="ASSIGNED">
   <id extension="241301000016007" root="1.2.208.176.1.1"
    assigningAuthorityName="SOR"/>
   <addr use="WP">
    <streetAddressLine>Hjertemedicinsk afdeling B</streetAddressLine>
    <streetAddressLine>Valdemarsgade 53</streetAddressLine>
    <postalCode>5700</postalCode>
    <city>Svendborg</city>
    <country>Danmark</country>
   </addr>
   <telecom value="tel:65112233" use="WP"/>
   <assignedPerson classCode="PSN" determinerCode="INSTANCE">
```

```
    <name>
      <given>Anders</given>
      <family>Andersen</family>
    </name>
  </assignedPerson>
  <representedOrganization classCode="ORG" determinerCode="INSTANCE">
    <name>Odense Universitetshospital - Svendborg Sygehus</name>
    <telecom nullFlavor="NI"/>
    <addr use="WP">
      <streetAddressLine nullFlavor="NI"/>
    </addr>
  </representedOrganization>
 </assignedAuthor>
</author>
```

Figure 21: author example

2.13.3   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.

CONF-PHMR-DK- 30:

The `assignedCustodian/representedCustodianOrganization` **SHALL**
be present.

```
<custodian typeCode="CST">
   <assignedCustodian classCode="ASSIGNED">
    <representedCustodianOrganization classCode="ORG" determinerCode="INSTANCE">
     <id extension="241301000016007" root="1.2.208.176.1.1" assigningAuthorityName="SOR"/>
     <name>Odense Universitetshospital - Svendborg Sygehus</name>
     <telecom value="tel:65223344" use="WP"/>
     <addr use="WP">
      <streetAddressLine>Hjertemedicinsk afdeling B</streetAddressLine>
      <streetAddressLine>Valdemarsgade 53</streetAddressLine>
      <postalCode>5700</postalCode>
      <city>Svendborg</city>
      <country>Danmark</country>
     </addr>
    </representedCustodianOrganization>
   </assignedCustodian>
 </custodian>
```

Figure 22: custodian example

2.13.4   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-DK-31:

If `legalAuthenticator` is present the `assignedEntity/assignedPerson` and `assignedEntity/representedOrganization` **SHALL** be present.

```xml
<legalAuthenticator typeCode="LA" contextControlCode="OP">
  <time value="20140113100000+0100"/>
  <signatureCode nullFlavor="NI"/>
  <assignedEntity classCode="ASSIGNED">
   <id extension="241301000016007" root="1.2.208.176.1.1" assigningAuthorityName="SOR"/>
   <addr use="WP">
    <streetAddressLine>Hjertemedicinsk afdeling B</streetAddressLine>
    <streetAddressLine>Valdemarsgade 53</streetAddressLine>
    <postalCode>5700</postalCode>
    <city>Svendborg</city>
    <country>Danmark</country>
   </addr>
   <telecom value="tel:65223344" use="WP"/>
   <assignedPerson classCode="PSN" determinerCode="INSTANCE">
    <name>
     <given>Anders</given>
     <family>Andersen</family>
    </name>
   </assignedPerson>
   <representedOrganization classCode="ORG" determinerCode="INSTANCE">
     <name>Odense Universitetshospital - Svendborg Sygehus</name>
     <telecom nullFlavor="NI"/>
     <addr use="WP">
       <streetAddressLine nullFlavor="NI"/>
     </addr>
   </representedOrganization>
  </assignedEntity>
</legalAuthenticator>
```

2.14   ClinicalDocument/documentationOf/serviceEvent

The main activity being described by a PHMR is the monitoring of a patient over a period of time.The 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.

Besides the period of time documentationOf also holds eventCodeList entries i.e measurement codes used to search for documents in the Danish XDS infrastructure, therefore:

CONF-PHMR-DK-35:

The first occurrence of documentationOf shall only contain information about start and end time of measurements recorded, as described in the three conformance statements above.

The following occurrences of documentationOf shall only contain information about measurement codes recorded, repeated once per unique measurement code.

A `serviceEvent/code` element **SHALL** be present, and **SHALL** reflect the measurement code used when the patient's health was monitored.

```xml
<documentationOf typeCode="DOC">
  <serviceEvent classCode="MPROT" moodCode="EVN">
   <effectiveTime>
    <low value="20140106080200+0100"/>
```

```
        <high value="20140110081500+0100"/>
      </effectiveTime>
    </serviceEvent>
  </documentationOf>

 <documentationOf typeCode="DOC">
   <serviceEvent classCode="MPROT" moodCode="EVN">
     <code code="NPU03011" codeSystem="1.2.208.176.2.1" displayName="O2 sat.;Hb(aB)"/>
   </serviceEvent>
  </documentationOf>

  <documentationOf typeCode="DOC">
   <serviceEvent classCode="MPROT" moodCode="EVN">
     <code code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme vægt; Pt"/>
   </serviceEvent>
  </documentationOf>
```

Figure 24: documentationOf/serviceEvent example

3   BODY

The codes for unambiguously representing measurement units in this profile are based on code systems which are used in other standards and profiles for the exchange of data in the eHealth sector in Denmark. More information on the code systems can be found in appendix C.

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 profile, 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

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 sections within this profile:

Section	LOINC code	Required (R)/Optional (O)
Vital Signs	8716-3	R (either Vital Signs or Results is required)
Purpose	48764-5	O (not used in the PHMR DK profile)
Medications	10160-0	O (not used in the PHMR DK profile)
Results	30954-2	R (either Vital Signs or Results is required)
Medical Equipment	46264-8	R

Table 4: Section Cardinality

In this profile all other CCD sections are not allowed.

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.

```xml
<component>
  <structuredBody>
   <component> <!-- Vital signs -->
    <section>
      <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
      <entry>
         :
      </entry>

      <entry>
         :
      </entry>
     </section>
    </component>

   <component> <!-- Results -->

     <section>
      <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
      <entry>
         :
      </entry>
     </section>
    </component>


   <component> <!—Medical equipment -->

     <section>
      <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"/>
      <entry>
         :
      </entry>
     </section>
```

```
      </component>
    </structuredBody>
  </component>
```

Figure 25: Generic XML-structure for the body

3.3   Required Sections

3.3.1   Vital Signs 8716-3

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

CONF-PHMR-DK- 32:

A Vital Signs section **SHALL** contain three `templateIds`. CCD `templateId`
`2.16.840.1.113883.10.20.1.16` and `2.16.840.1.113883.10.20.9.2`
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
`1.2.208.184.11.1`, indicating conformance to the constraints specified in
this profile.

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-DK-33:

All performed measurements **SHOULD** be identified by a unique ID (UUID)
of the instance identifier (II) data type, where the value of `@root` is an
OID and the value of `@extension` specifies the UUID.

CONF-PHMR-DK-36:

Observations **MAY** specify therapeutic reference ranges know in DK as
Red and Yellow reference ranges. If specified a templateId shall be
present where `@root` is `1.2.208.184.11.1.2`, and a `code` element

SHALL be present where @codeSystem is 1.2.208.184.100.1 MedCom Message Codes.

The reference ranges are specified as interval values where one and only one of the two attributes @low=low limit, @high=high limit **MAY** be left out.

In order to fulfill **CONF-PHMR-105** Numeric Observations which are identified by Danish code systems (e.g. NPU), shall be presented as a translation of either SNOMED CT (Dynamic) or MDC (Dynamic) codes.

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-56:

If no vital signs are recorded, this section **SHALL** contain a text element noting this fact.

```xml
<component typeCode="COMP">
 <section>
  <templateId root="2.16.840.1.113883.10.20.1.16"/>
  <templateId root="2.16.840.1.113883.10.20.9.2"/>
  <templateId root="1.2.208.184.11.1"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Vital Signs</title>
  <text> Vital Signs</text>
  <!-- Blood pressure only-->
  <entry typeCode="COMP">
   <organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.1.35"/>
    <statusCode code="Completed"/>
    <effectiveTime value="20140114094500+0100"/>
    <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="1.2.208.184" extension="fb6f8480-09f0-4ea3-86b8-          e7c08750f62a"
assigningAuthorityName="MedCom"/>
      <code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT">
       <translation code="DNK05472" codeSystem="1.2.208.176.2.1"
         displayName="Blodtryk systolisk;Arm" codeSystemName="NPU terminologien"/>
      </code>
      <value unit="mmHG" value="138" xsi:type="PQ"/>
      <methodCode code="POT" codeSystem="1.2.208.184.100.1" displayName="Målt af borger"
codeSystemName="MedCom Message Codes"/>
      <methodCode code="AUT" codeSystem="1.2.208.184.100.1" displayName="Måling
```

```
overført automatisk"
          codeSystemName="MedCom Message Codes"/>
        </observation>
      </component>
    </organizer>
  </entry>
 </section>
</component>
```

Figure 26: Vital Signs section example

3.3.2 Results 30954-2

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

CONF-PHMR-DK- 33:

A Results section **SHALL** contain three `templateIds`. CCD `templateId`
`2.16.840.1.113883.10.20.1.14` and
`2.16.840.1.113883.10.20.9.14` **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
`1.2.208.184.11.1`, indicating conformance to the constraints specified in
this profile.

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-DK-33:

All performed measurements **SHOULD** be identified by a unique ID (UUID)
of the instance identifier (II) data type, where the value of `@root` is an
OID and the value of `@extension` specifies the UUID.

CONF-PHMR-DK-36:

Observations **MAY** specify therapeutic reference ranges know in DK as
Red and Yellow reference ranges. If specified a templateId shall be
present where `@root` is `1.2.208.184.11.1.2`, and a `code` element
SHALL be present where `@codeSystem` is `1.2.208.184.100.1` MedCom
Message Codes.

The reference ranges are specified as interval values where one and only
one of the two attributes @low=low limit, @high=high limit **MAY** be left
out.

In order to fulfill **CONF-PHMR-105** Numeric Observations which are identified by Danish code systems (e.g. NPU), shall be presented as a translation of either SNOMED CT (Dynamic) or MDC (Dynamic) codes.

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-60:

If no results are recorded, this section **SHALL** contain a `text` element noting this fact.

```xml
<component typeCode="COMP" contextConductionInd="true">
    <section classCode="DOCSECT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.1.14"/>
    <templateId root="2.16.840.1.113883.10.20.9.14"/>
    <templateId root="1.2.208.184.11.1"/>
    <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
    <title>Results</title>
    <text>Results</text>
    <entry typeCode="COMP" contextConductionInd="true">
     <organizer classCode="CLUSTER" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.35"/>
      <statusCode code="completed"/>
      <effectiveTime value="20140106080200+0100"/>
      <component typeCode="COMP" contextConductionInd="true">
       <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="1.2.208.184" extension="23a44650-13f2-11e5-b939-0800200c9a66"
assigningAuthorityName="MedCom"/>
        <code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT">
         <translation code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme
vægt; Pt" codeSystemName="NPU terminologien"/>
        </code>
        <value unit="kg" value="77.5" xsi:type="PQ"/>
        <methodCode code="POT" codeSystem="1.2.208.184.100.1" displayName="Målt af borger"
          codeSystemName="MedCom Message Codes"/>
        <methodCode code="AUT" codeSystem="1.2.208.184.100.1" displayName="Måling
overført automatisk"
          codeSystemName="MedCom Message Codes"/>
       </observation>
      </component>
     </organizer>
    </entry>

    <entry typeCode="COMP">
     <organizer classCode="CLUSTER" moodCode="EVN">
```

```
            <templateId root="2.16.840.1.113883.10.20.1.35"/>
            <statusCode code="completed"/>
            <effectiveTime value="20140108074500+0100"/>
            <component typeCode="COMP" contextConductionInd="true">
             <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 extension="cf9b8f40-13f2-11e5-b939-0800200c9a66" root="1.2.208.184"/>
              <code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT">
                <translation code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme
vægt; Pt" codeSystemName="NPU terminologien"/>
              </code>
              <value unit="kg" value="77.0" xsi:type="PQ"/>
              <methodCode code="POT" codeSystem="1.2.208.184.100.1" displayName="Målt af borger"
                codeSystemName="MedCom Message Codes"/>
              <methodCode code="AUT" codeSystem="1.2.208.184.100.1" displayName="Måling
overført automatisk"
                codeSystemName="MedCom Message Codes"/>
             </observation>
            </component>
          </organizer>
        </entry>
        <entry typeCode="COMP">
         <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.1.35"/>
          <statusCode code="completed"/>
          <effectiveTime value="20140110081500+0100"/>
          <component typeCode="COMP" contextConductionInd="true">
           <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 extension="cf9b8f41-13f2-11e5-b939-0800200c9a66" root="1.2.208.184"/>
            <code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT">
              <translation code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme
vægt; Pt" codeSystemName="NPU terminologien"/>
            </code>
            <value unit="kg" value="77.2" xsi:type="PQ"/>
                  <methodCode code="POT" codeSystem="1.2.208.184.100.1" displayName="Målt
af borger"
              codeSystemName="MedCom Message Codes"/>
            <methodCode code="AUT" codeSystem="1.2.208.184.100.1" displayName="Måling
overført automatisk"
              codeSystemName="MedCom Message Codes"/>
           </observation>
          </component>
         </organizer>
        </entry>
      </section>
    </component>
```

Figure 27. Results section XML example

3.3.3 Medical Equipment 46264-8

CONF-PHMR-DK- 34:

A Medical Equipment section **SHALL** contain three `templateIds`. CCD `templateId` `2.16.840.1.113883.10.20.1.7` and `2.16.840.1.113883.10.20.9.1` **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 `1.2.208.184.11.1` indicating conformance to the constraints specified in this profile.

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-DK- 35:**~~

~~One or more Device Definition Organizers (~~`templateId`
~~`1.2.208.184.100.2`~~~~) **SHOULD** be present.~~

CONF-PHMR-DK-34:

A playingDevice shall be identified by a `@code` drawn from the code system `1.2.208.184.100.3` MedCom Instrument Codes.

In order to fulfill CONF-PHMR-80 the playingDevice/code drawn from MedCom Instrument Codes **SHALL** be presented as a translation of either MDC (Dynamic) or SNOMED CT codes.

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.

CONF-PHMR-51:

If no medical devices are defined, this section **SHALL** contain a `text` element noting this fact.

```xml
<component typeCode="COMP" contextConductionInd="true">
 <section classCode="DOCSECT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.7"/>
  <templateId root="2.16.840.1.113883.10.20.9.1"/>
  <templateId root="1.2.208.184.11.1"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Medical Equipment</title>
  <text>Medical Equipment</text>
  <entry typeCode="COMP">
   <organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.9.4"/>
    <statusCode code="completed"/>
    <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="1.2.208.184.100.3" extension="MCI00001" assigningAuthorityName="MedCom"/>
       <playingDevice classCode="DEV" determinerCode="INSTANCE">
                <code code="NI" codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC
Dynamic">
          <translation code=" MCI00001" codeSystem="1.2.208.184.100.3" displayName="Weight"
codeSystemName="MedCom Instrument Codes"/>
         </code>
         <manufacturerModelName>Manufacturer: AD Company / Model:
6121ABT1</manufacturerModelName>
         <softwareName>SerialNr: 6121ABT1-987 Rev. 3 / SW Rev. 20144711</softwareName>
        </playingDevice>
       </participantRole>
      </participant>
     </organizer>
    </entry>
   </section>
  </component>
```

Figure 28: Medical Equipment section example

3.4   Optional Sections

The content of optional section in the PHMR (International Realm), October 2011 has not been included in the PHMR DK profile

The content in optional section will be considered based on requirements from new use cases.

4   APPENDIX A. GOVERNANCE

MedCom[iv] contributes to the development, testing, dissemination and quality assurance of electronic communication and information in the Danish healthcare sector. MedCom solves problems with a focus to support efficient performance and a gradual expansion of the national eHealth infrastructure, which is necessary for a safe and coherent access to relevant data and communication across regions, municipalities, and general practitioners.

MedCom is the owner of the PHMR DK profile and as such also have the responsibility to maintain and update the profile.

MedCom will continuous collect information on the use and possible new requirements for the profile. A regular update is not planned as this depends on the user needs and requirements, within the scope of this profile. However, MedCom will once a year assess the collected information and decide if an update process will be initiated. In case it is decided to update the profile, MedCom will assemble a group, representing the needed stakeholders, to take part in the work.

[iv] http://www.medcom.dk

5   APPENDIX B. OBJECT IDENTIFIERS (OID'S)

The table below includes a list of the Object Identifier's used in this profile.

Description	OID	Responsible organization
SOR codes codesystem	1.2.208.176.1.1	SDS
NPU codes codesystem root	1.2.208.176.2.1	SDS
Provider register	1.2.208.176.1.4	Region Midtjylland managed by SDS
Danish Health Authorisation register	1.2.208.176.1.3	SDS
CPR-number codesystem root	1.2.208.176.1.2	Indenrigsministeriet
HL7 PHMR typeID root	2.16.840.1.113883.1.3	HL7
HL7 PHMR Medical Equipment templateId	2.16.840.1.113883.10.20.1.7	HL7
HL7 PHMR Results Section templateID	2.16.840.1.113883.10.20.1.14	HL7
HL7 PHMR Vital Signs Section templateId	2.16.840.1.113883.10.20.1.16	HL7
HL7 PHMR Result Observation templateID	2.16.840.1.113883.10.20.1.31	HL7
HL7 PHMR Vital Signs Organizer templateID	2.16.840.1.113883.10.20.1.35	HL7
HL7 PHMR Device Definition organizer	2.16.840.1.113883.10.20.9.4	HL7
HL7 PHMR Numeric Observation templateID	2.16.840.1.113883.10.20.9.8	HL7
HL7 PHMR Product Instance templateId	2.16.840.1.113883.10.20.9.9	HL7
HL7 administrativeGenderCode CodeSystem	2.16.840.1.113883.5.1	HL7
HL7 confidentialityCode codeSystem	2.16.840.1.113883.5.25	HL7
LOINC PHMR codes codesystem	2.16.840.1.113883.6.1	LOINC
Data Acquisition codes	1.2.208.184.100.8	DAK-e/MedCom
MedCom root	1.2.208.184	MedCom
MedCom CDA External Document Resolution root type	1.2.208.184.5	MedCom
MedCom External Document Reference templateId	1.2.208.184.6.1	MedCom
PHMR-DK TemplateId	1.2.208.184.11.1	MedCom
PHMR-DK Therapeutic Reference Values templateId	1.2.208.184.11.1.2	MedCom
MedCom Message Codes	1.2.208.184.100.1	MedCom
MedCom Prompt Table	1.2.208.184.100.2	MedCom
MedCom Instrument Codes	1.2.208.184.100.3	MedCom

6 APPENDIX C. TERMINOLOGY

6.1 NPU codes

The NPU terminology is a coding system and terminology for identification and communication of examination results from clinical laboratories in the health area.

The NPU terminology is supported by the IFCC-IUPAC (Sub) committee on Nomenclature for Properties and Units, which is jointly supported by the International Union of Pure and Applied Chemistry (IUPAC) and the International Federation of Clinical Chemistry (IFCC).

It is in national use in Denmark, for communication and recording of clinical laboratory information.

The basic principles and structures were published by IFCC and IUPAC in 1995. The system has since then been continually widening its technical basis in clinical laboratory sciences, closely aligned with international standardization work in the area of health informatics. It holds today 16,000 active codes, covering areas of clinical chemistry, clinical immunology and blood banking, clinical microbiology, allergology, thrombosis and hemostasis, molecular biology and genetics, reproduction and fertility, toxicology and clinical pharmacology.

The Danish version of the NPU terminology[v] has been translated and published for national use since 2001. Today The National eHealth Authority serves as the National NPU Release Center for Denmark, and as the daily manager and repository for the International version of NPU Terminology. The terminology and its coding system were accepted right away by the clinical chemistry labs as the main identifier for laboratory result items. Its use is now spreading into other laboratory fields.

6.1.1 NPU codes for device measurements

The NPU terminology defines individual types of examination results. However, they are less readable and take up much space when many results are presented together on a screen. In Denmark, National Short Names (NKN)[vi] are developed for use in result overviews on a screen. Their purpose is to give the user a general understanding of the meaning of the examination results.

NKN are not unique, and cannot alone identify the individual types of an examination result. For that reason, when displaying examination results,

---

[v] http://www.labterm.dk
[vi] National Short Names *translated to Danish* = Nationale Kort Navne (NKN)

the user must have access to the defined NPU definition for further clarification.

The maximum length for a NKN is 35 characters.

NPU code	NKN	Unit
NPU03804	Legeme masse; Pt	Kg
DNK05473	Blodtryk diastolisk; Arm	mmHg
DNK05472	Blodtryk systolisk; Arm	mmHg
NPU03958	Protein; U	g/L

6.2 MedCom codes

The table below includes a list of MedCom codes used in this profile.

Description	Code	CodeSystem	DisplayName in Danish lang.	Responsible organization	Type
Measurement transferred electronically	AUT	1.2.208.184.100.1	Måling overført automatisk	MedCom	MedCom Message Code
Measurement performed by citizen	POT	1.2.208.184.100.1	Målt af borger	MedCom	MedCom Message Code
Measurement performed by healthcareprofessional	PNT	1.2.208.184.100.1	Målt af aut. sundhedsperson	MedCom	MedCom Message Code
Measurement performed by caregiver	PCG	1.2.208.184.100.1	Målt af anden omsorgsperson	MedCom	MedCom Message Code
Measurement typed in by citizen	TPD	1.2.208.184.100.1	Indtastet af borger	MedCom	MedCom Message Code
Measurement typed in by citizen relative	TPR	1.2.208.184.100.1	Indtastet af pårørende	MedCom	MedCom Message Code
Measurement typed in by healthcareprofessional	TPH	1.2.208.184.100.1	Indtastet af aut. sundhedsperson	MedCom	MedCom Message Code
Measurement typed in by caregiver	TPC	1.2.208.184.100.1	Indtastet af anden omsorgsperson	MedCom	MedCom Message Code
Yellow alert on therapeutic reference value	GAL	1.2.208.184.100.1	Terapeutiske grænseværdier for GUL alarm	MedCom	MedCom Message Code
Red alert on therapeutic reference value	RAL	1.2.208.184.100.1	Terapeutiske grænseværdier for RØD alarm	MedCom	MedCom Message Code

6.3 LOINC codes

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 46 of 89

Logical Observation Identifiers Names and Codes (LOINC[vii]) is a database and universal standard for identifying medical laboratory observations. It was developed and is maintained by the Regenstreif Institute, a US non-profit medical research organization, in 1994. LOINC was created in response to the demand for an electronic database for clinical care and management and is publicly available at no cost.

Several standards, such as IHE or HL7, use LOINC to electronically transfer results from different reporting systems to the appropriate healthcare networks.

In the PHMR DK profile the use of LOINC is not used for the coding of clinical observations. However, LOINC codes which are maintained by HL7 are re-used. For example LOINC codes to identify that the health observation is a medical device, a vital signs or a results is used in this profile.

[vii] http://loinc.org

7 APPENDIX D. HL7 DATA TYPES

7.1 Text and multimedia

ST STRING	String Data is left justified with trailing blanks optional. Any printable ASCII characters are allowed. An empty string must send a flavor of null.

7.2 Demographic Data

ADXP Address Part	Postal addresses can be parsed into a collection of different parts. Each of these parts identifies a geographic or political boundary at some level of detail. **\<streetAddressLine\>** The \<streetAddressLine\> element is intended to record a physical address. This address may be used to deliver correspondence or to physically locate the destination. The CDA standard allows this element to be repeated as many times as needed. **\<city\>** The \<city\> element records the city, town or municipality associated with the address. **\<postalCode\>** The \<postalCode\> element records codes used and defines by the delivery agent to identify the delivery or street address. **\<country\>** The \<country\> element records the country. HL7 Data Type Release 2 will allow the country can be bound to a list of legal values. ISO 3166 Part 1 defines one such list of country codes.
AD Address	The Address data type is used to record the postal addresses. They are modeled as a collection of geographical or political boundaries at various levels of detail and are used to deliver mail or packages. The CDA standard treats and address as an arbitrary list of address parts elements (see the ADXP data type) and text. According to the XML schema, each of the different parts of the \<addr\> element can appear as many times as necessary. However, it does not make sense for an address to have two \<postalCode\> elements. The same is true for several other elements. Almost all components should appear only once with the exception of the \<streeAddressLine\> or \<deliveryAddressLine\> element.
ON Organization Name	Organization names are a list of \<prefix\>, \<suffix\>, \<delimiter\> and \<name\> elements and text that represent the name of an organization.
PN Person Name	Person names are a list of \<prefix\>, \<given\>, \<family\>, \<suffix\> and \<delimiter\> elements and text. The PN data type is found in the \<name\> element of the \<assignedPerson\>, \<associatedPerson\>, \<guardianPerson\>, \<informationRecipient\>, \<maintainingPerson\>, \<relatedPerson\>, \<playingEntitry\>, \<specimenPlayingEntity\> and

	<subject> elements. The PN data type is derived from the EN data type and so also supports the use attribute and the <validTime> element of that data type.

II **Instance Identifier**	The II data type is used to identify different instances of a kind of thing. The data type is used extensively in the CDA specification to identify persons, things, actions, roles etc. The II data type most commonly appears in the <id> elements found in the CDA schema. It is also used by the <setId>, <templateId> and <typeId> elements.

TEL **Telecommunications Address**	A telecommunications address or endpoint specifies how to contact someone or something using telecommunications equipment. That includes the telephone, a fax machine, e-mail, the web, instant messaging, et cetera. All telecommunications address can be represented by a URI. **Value** The value attribute of a <telecom> data element provides the URI identifying the communication endpoint. **Use** The use attribute provides codes describing the type of communication endpoint.

7.3   Codes

CE **Coded with eqivalents**	The CE data type is used to exchange coded concepts that are not permitted to contain qualifiers and so do not allow for codes to be created compositionally using post-coordination.

CS **Coded simple**	The CS data type is used to convey codes that have a fixed value for codeSystem. It is used in the CDA specification for coded values where there is only one choice for the codeSystem according to the standard.

7.4   Dates and Times

TS **Time Stamp**	The representation of the HL7 time stamp data type is based upon the ISO 8601 standard for representations of time. The representation of time uses two digits each to represent the century, year within century, month, day, hour, minute and second. The second can be be followed by a decimal point and fractional parts of a second. Finally, the time may include a + or − sign followed by up to four digits representing the offset in hours and minutes from Universal Coordinated Time (UTC). The format for time is: YYYYMMDDhhmmss.SSS±ZZzz YYYY The year of the event MM The month in the full year

	DD	The day in the month and year
	hh	The hour in the day
	mm	The minute in the hour
	ss	The second in the minute
	.SSS	Fraction of a second
	±	Direction of offset from UTC
	ZZ	Hours offset from UTC
	Zz	Minutes offset from UTC

9   APPENDIX E. CDA HEADER ELEMENTS

9.1   ClinicalDocument (DK header)

```xml
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:hl7-org:v3 ../Schema/CDA_SDTC.xsd" xmlns="urn:hl7-org:v3"
  classCode="DOCCLIN" moodCode="EVN">
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <templateId root="2.16.840.1.113883.10.20.9"/>
    <templateId root="1.2.208.184.11.1"/>
    <id extension="aa2386d0-79ea-11e3-981f-0800200c9a66" root="1.2.208.184"
assigningAuthorityName="MedCom"/>
    <code code="53576-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Personal Health Monitoring Report"/>
    <title>Hjemmemonitorering for 2512489996</title>
    <effectiveTime value="20140113100000+0100"/>
    <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
    <languageCode code="da-DK"/>
```

Figure 29. ClinicalDocument (DK Header) XML example

/ClinicalDocument

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 0..1	Clinical Document
Description	The @classCode and @moodCode values of this element are specified as shown in the example below.	
Example	<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 http://svn.medcom.dk/svn/drafts/Standarder/HL7/PHMR/Schema/CDA_SDTC.xsd" xmlns="urn:hl7-org:v3" classCode="DOCCLIN" moodCode="EVN"> : : </ClinicalDocument>	

/ClinicalDocument/typeId

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	II

Description	The element 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 example below.
Example	<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>

/ClinicalDocument/templateId

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	II
Description	The templateId element identifies the template for the PHMR DK profile. The @root value of this element is specified as shown in the example below.	
Example	<templateId root="1.2.208.184.11.1"/>	

/clinicalDocument/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	II
Description	The /ClinicalDocument/id is a globally unique identifier for the document. The PHMR DK-profile has constrained the @extension attribute to be an UUID. The @root and @extension attributes identifies the document.	
Example	<id extension="aa2386d0-79ea-11e3-981f-0800200c9a66" root="1.2.208.184"/>	

/ClinicalDocument/code

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CE
Description	The /ClinicalDocument/code specifies the particular kind of the clinical document (Personal Health Monitoring Report). The /ClinicalDocument/code shall be set in accordance to the Master value catalog, tab classCodes.	
Example	<code code="53576-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Personal Health Monitoring Report"/>	

/ClinicalDocument/title

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..1	ST
Description	The /ClinicalDocument/title should be presented and specifies the display name. The /ClinicalDocument/title shall specify "Hjemmemonitorering for DDMMYYSSSS", where DDMMYYSSSS is the Danish patient identifier (cpr-nummer).	
Example	<title>Hjemmemonitorering for 2512489996</title>	

/ClinicalDocument/effectiveTime

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	TS
Description	The /ClinicalDocument/effectiveTime element specifies the creation time of the document. The /ClinicalDocument/effectiveTime shall be precise to the second including an offset from UTC.	
Example	<effectiveTime value="201401131000+0100"/>	

/ClinicalDocument/confidentialityCode

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CE
Description	The @code value is selected from ValueSet HL7 BasicConfidentialityKind. The @code value of this element in the DK profile is constrained to "N" (Normal). Other values are not allowed.	
Example	<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>	

Code	Code system	Print name
N	Confidentiality Code	Normal
R	Confidentiality Code	Restricted
V	Confidentiality Code	Very Restricted

Table 5. Basic Confidentiality Kind Value Set

/ClinicalDocument/launguageCode

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..1	CS
Description	The /ClinicalDocument/languageCode element specifies the language of the report which shall be selected from ValueSet Language. The @code value of this element in the DK profile is constrained to "da-DK". Other values are not allowed
Example	<languageCode code="da-DK"/>

9.2   RecordTarget

The recordTarget element must be present. It records the patient whose health information is described in the clinical document.

```
<recordTarget typeCode="RCT" contextControlCode="OP">
 <patientRole classCode="PAT">
  <id extension="2512489996" root="1.2.208.176.1.2"
assigningAuthorityName="CPR"/>
   <addr use="H">
    <streetAddressLine>Skovvejen 12</streetAddressLine>
    <streetAddressLine>Landet</streetAddressLine>
    <postalCode>5700</postalCode>
    <city>Svendborg</city>
    <country>Danmark</country>
   </addr>
   <telecom value="tel:65123456" use="H"/>
   <telecom value="mailto:nab@udkantsdanmark.dk" use="WP"/>
   <patient classCode="PSN" determinerCode="INSTANCE">
    <name>
     <given>Nancy</given>
     <given>Ann</given>
     <family>Berggren</family>
    </name>
    <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
    <birthTime value="19481225000000+0000"/>
   </patient>
  </patientRole>
 </recordTarget>
```

Figure 30. recordTarget XML example

/ClinicalDocument/recordTarget

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	SET <RecordTarget>
Description	The recordTarget records the patient whose health information is described by the clinical document. The value for the @typeCode and the @contextControlCode shall be as shown in the example below.	
Example	<recordTarget typeCode="RCT" contextControlCode="OP"> : : </recordTarget>	

/ClinicalDocument/recordTarget/patientRole

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	PatientRole
Description	Shall contain exactly one [1..1] patientRole. The value for the @classCode shall be as shown in the example below.	
Example	<patientRole classCode="PAT"> : : </patientRole>	

/ClinicalDocument/recordTarget/patientRole/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	SET <II>
Description	This id element holds the Personal Identifier for the patient. The DK profile is constrained to hold only a validated Danish patient identifier (cpr-nummer). The @extension value holds the Danish patient identification (cpr-nummer), the @root is the associated OID for the National Danish patient registry (cpr) and the assigningAuthorityName shall be set to "CPR".	
Example	<id extension="2512489996" root="1.2.208.176.1.22" assigningAuthorityName="CPR""/>	

/ClinicalDocument/recordTarget/patientRole/addr

Variable/ Fixed	Required/Cardinality	Data Type

Variable	R 0..*	SET <AD>
Description	This element holds the patient address. The content of the `addr` element and the @use attribute shall be conformant to DK Address (see 2.4.3).	
Example	<addr use="H"> <streetAddressLine>Skovvejen 12</streetAddressLine> <streetAddressLine>Landet</streetAddressLine> <postalCode>5700</postalCode> <city>Svendborg</city> <country>Danmark</country> </addr>	

/ClinicalDocument/recordTarget/patientRole/telecom

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..*	SET <TEL>
Description	At least one telecom element shall be present. When unknown use appropriate Null Flavor. Multiple telecoms are supported. The content of the @use value shall be conformant to section 2.4.4.	
Example	<telecom value="tel:65123456" use="H"/> <telecom value="mailto:nab@udkantsdanmark.dk" use="WP"/>	

/ClinicalDocument/recordTarget/patientRole/patient

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..1	Patient
Description	Shall contain exactly one [1..1] patient. The value of the @classCode and @determinerCode shall be as shown in the example below.	
Example	<patient classCode="PSN" determinerCode="INSTANCE"> : : </patient>	

/ClinicalDocument/recordTarget/patientRole/patient/name

Variable/ Fixed	Required/Cardinality	Data Type

Variable	R 1..*	SET <PN>
Description	The element shall contain exactly one [1..1] name. The content of the name shall be conformant to DK name (see 2.4.2).	

Example	`<name>`
	  `<given>Nancy</given>`
	  `<given>Ann</given>`
	  `<family>Berggren</family>`
	`</name>`	

/ClinicalDocument/recordTarget/patientRole/patient/administrativeGender Code

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	O 0..*	CE
Description	The `administrativeGenderCode` should be present. The `@code` values to be used are specified in section 2.13.1.	
Example	`<administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>`	

/ClinicalDocument/recordTarget/patientRole/patient/birthTime

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..1	TS
Description	The `birthTime` should be present The content of the `@value` value shall be on the format YYYYMMDD000000+0000.	
Example	`<birthTime value="19481225000000+0000"/>`	

9.3   Author

The `author` element represents the creator of the clinical document and must be present.

```
<author typeCode="AUT" contextControlCode="OP">
  <time value="20140113100000+0100"/>
  <assignedAuthor classCode="ASSIGNED">
    <id extension="241301000016007" root="1.2.208.176.1.1"
assigningAuthorityName="SOR"/>
      <addr use="WP">
        <streetAddressLine>Hjertemedicinsk afdeling B</streetAddressLine>
        <streetAddressLine>Valdemarsgade 53</streetAddressLine>
        <postalCode>5700</postalCode>
        <city>Svendborg</city>
        <country>Danmark</country>
      </addr>
      <telecom value="tel:65112233" use="WP"/>
      <assignedPerson classCode="PSN" determinerCode="INSTANCE">
        <name>
          <given>Anders</given>
          <family>Andersen</family>
        </name>
      </assignedPerson>
      <representedOrganization classCode="ORG" determinerCode="INSTANCE">
        <name>Odense Universitetshospital - Svendborg Sygehus</name>
        <telecom nullFlavor="NI"/>
        <addr use="WP">
          <streetAddressLine nullFlavor="NI"/>
        </addr>
      </representedOrganization>
  </assignedAuthor>
</author>
```

Figure 31. Author XML example

/ClinicalDocument/author

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	SET <author>
Description	The element shall contain one or more [1..*] authors. In most cases the element includes exactly one author. The value for the @typeCode and the @contextControlCode shall be as shown in the example below.	
Example	<author typeCode="AUT" contextControlCode="OP"> : : </author>	

/ClinicalDocument/author/time

Variable/ Fixed	Required/Cardinality	Data Type

Variable	R 1..1	TS
Description	The author/time element represents the start time of the author's participation in the creation of the clinical document.	
Example	<time value="20140113100000+0100"/>	

/ClinicalDocument/author/assignedAuthor

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	AssignedAuthor
Description	The element shall contain exactly one [1..1] assignedAuthor. The value for the @classCode shall be as shown in the example below.	
Example	<assignedAuthor classCode="ASSIGNED"> : : </assignedAuthor>	

/ClinicalDocument/author/assignedAuthor/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..*	SET <II>
Description	The id element holds the identifier for the author organization. The @extension value of this element shall be set to the code for the health organization. The @root is the associated OID for Sundhedsvæsenets Organisations Register (SOR) and the @assignedAuthorityName shall be set to "SOR"	
Example	<id extension="241301000016007" root="1.2.208.176.1.1"/>	

/ClinicalDocument/author/assignedAuthor/addr

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..*	SET <AD>
Description	The element should contain at least one [1..*] addr.	
Example	<addr use="WP"> <streetAddressLine>	

	Hjertemedicinsk afdeling B</streetAddressLine> <streetAddressLine>Valdemarsgade 53</streetAddressLine> <postalCode>5700</postalCode> <city>Svendborg</city> <country>Danmark</country> </addr>

/ClinicalDocument/author/assignedAuthor/telecom

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..*	SET <TEL>
Description	At least one telecom element shall be present. When unknown use appropriate Null Flavor.	
Example	<telecom value="tel:65112233"/>	

/ClinicalDocument/author/assignedAuthor/assignedPerson

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	assignedPerson
Description	The element shall exactly one [1..1] assignedPerson. The value of the @classCode shall be as shown in the example below.	
Example	<assignedPerson classCode="PSN"> : : </assignedPerson>	

/ClinicalDocument/author/assignedAuthor/assignedPerson/name

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	SET <PN>
Description	The element shall contain exactly one [1..1] name. The content of the name shall be conformant to DK name (see 2.4.2).	
Example	<name> <prefix>Læge</prefix> <given>Anders</given> <family>Andersen</family> </name>	

/ClinicalDocument/author/assignedAuthor/representedOrganization

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	O 0..*	representedOrganisation
Description	The element should contain exactly one [1..1] representedOrganization. The value for the @classCode and @determinercode shall be as shown in the example below.	
Example	<representedOrganization classCode="ORG" determinerCode="INSTANCE"> : </representedOrganization>	

/ClinicalDocument/author/assignedAuthor/representedOrganization/name

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	ON
Description	The representedOrganization shall contaion exactly one [1..1] name for the author organization.	
Example	<name>Odense Universitetshospital - Svendborg Sygehus</name>	

9.4 Custodian

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

```
 <custodian typeCode="CST">
  <assignedCustodian classCode="ASSIGNED">
   <representedCustodianOrganization classCode="ORG"
determinerCode="INSTANCE">
     <id extension="241301000016007" root="1.2.208.176.1.1"
assigningAuthorityName="SOR"/>
    <name>Odense Universitetshospital - Svendborg Sygehus</name>
    <telecom value="tel:65223344" use="WP"/>
    <addr use="WP">
     <streetAddressLine>Hjertemedicinsk afdeling B</streetAddressLine>
     <streetAddressLine>Valdemarsgade 53</streetAddressLine>
     <postalCode>5700</postalCode>
     <city>Svendborg</city>
     <country>Danmark</country>
    </addr>
   </representedCustodianOrganization>
  </assignedCustodian>
 </custodian>
```

Figure 32. Custodian XML example.

/ClinicalDocument/custodian

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	Custodian
Description	The element shall contain exactly one [1..1] custodian. The value for the @typeCode shall be as shown in the example below.	
Example	`<custodian typeCode="CST">` : : `</custodian>`	

/ClinicalDocument/custodian/assignedCustodian

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	AssignedCustodian
Description	The element shall contain exactly one [1..1] custodian. The value for the @classCode shall be as shown in the example below.	
Example	`<assignedCustodian classCode="ASSIGNED">` :	

| | : |
| | </assignedCustodian> |

/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	representedCustodianOrganization
Description	The element shall contain exactly one [1..1] custodian. The value for the @classCode and determinerCode shall be as shown in the example below.	
Example	<representedCustodianOrganization classCode="ORG" determinerCode="INSTANCE"> : : </representedCustodianOrganization>	

/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..*	SET <II>
Description	The id element holds the identifier for the Custodian Organization. The @extension value of this element shall be set to code for health organization. The @root is the associated OID for Sundhedsvæsenets Organisations Register (SOR) and the @assignedAuthorityName shall be "SOR"	
Example	<id extension="241301000016007" root="1.2.208.176.1.1" assigningAuthorityName="SOR"/>	

/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization/name

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..1	ON
Description	The representedCustodianOrganization should contaion exactly one [1..1] name for the Custodian Organization.	

Example	<name>Odense Universitetshospital - Svendborg Sygehus</name>

/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization/telecom

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..1	TEL
Description	One telecom element shall be present. When unknown use appropriate Null Flavor.	
Example	<telecom value="tel:65223344"/>	

/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization/addr

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..1	AD
Description	The element should contain one [1..1] addr.	
Example	<addr> <streetAddressLine> Hjertemedicinsk afdeling B</streetAddressLine> <streetAddressLine>Valdemarsgade 53</streetAddressLine> <postalCode>5700</postalCode> <city>Svendborg</city> <country>Danmark</country> </addr>	

9.5   legalAuthenticator

/ClinicalDocument/legalAuthenticator

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	legalAuthenticator
Description	The legalAuthenticator element identifies the legal authenticator of the document and must be present. The value for the @typeCode and @contextControlcode shall be as shown in the example below.	

Example	<legalAuthenticator typeCode="LA" contextControlCode="OP">
	:
	:
	</legalAuthenticator>

/ClinicalDocument/legalAuthenticator/time

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	TS
Description	The /ClinicalDocument/legalAuthenticator/time element specifies the time for the authentication of the document. The /ClinicalDocument/legalAuthenticator/time shall be precise to the second including an offset from UTC.	
Example	<time value="201401131000+0100"/>	

/ClinicalDocument/legalAuthenticator/signatureCode

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CS
Description	The /ClinicalDocument/legalAuthenticator/signaturCode element shall be present and the value shall be nullFlavor="NI".	
Example	<signatureCode nullFlavor="NI"/>	

/ClinicalDocument/legalAuthenticator/assignedEntity

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	assignedEntity
Description	The assignedEntity element must be present. The value of the @classCode shall be as shown in the example below.	
Example	<assignedEntity classCode="ASSIGNED"> : : </assignedEntity>	

/ClinicalDocument/legalAuthenticator/assignedEntity/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..*	II
Description	The id element holds the identifier for the legalAuthenticator organization. The @extension value of this element shall be set to code for health organization. The @root is the associated OID for Sundhedsvæsenets Organisations Register (SOR)	
Example	<id extension="241301000016007" root="1.2.208.176.1.1"/>	

/ClinicalDocument/legalAuthenticator/assignedEntity/addr

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..1	AD
Description	The element should contain one [1..1] addr.	

Example	<addr>
	  <streetAddressLine>
	          Hjertemedicinsk afdeling B</streetAddressLine>
	  <streetAddressLine>Valdemarsgade 53</streetAddressLine>
	  <postalCode>5700</postalCode>
	  <city>Svendborg</city>
	  <country>Danmark</country>
	</addr>	

/ClinicalDocument/legalAuthenticator/assignedEntity/telecom

Variable/ Fixed	Required/Cardinality	Data Type
Variable	O 0..*	TEL
Description	One telecom element should be present. When unknown use appropriate Null Flavor.	
Example	<telecom value="tel:65223344"/>	

/ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson

Variable/ Fixed	Required/Cardinality	Data Type

Fixed	R 1..1	assignedPerson
Description	The assignedPerson element must be present. The value of the @classCode and @determinerCode shall be as shown in the example below.	
Example	<assignedPerson classCode="PSN" determinerCode="INSTANCE"> : : </assignedPerson>	

/ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson/name

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	SET <PN>
Description	The element shall contain exactly one [1..1] name. The content of the name shall be conformant to DK name (see 2.4.2).	

Example	<name>
	  <prefix>Læge</prefix>
	  <given>Anders</given>
	  <family>Andersen</family>
	</name>	

/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganisation

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	representedOrganisation
Description	The representedOrganisation element must be present. The value of the @classCode and @determinerCode is shown in the example below	
Example	<representedOrganization classCode="ORG" determinerCode="INSTANCE"> : : </representedOrganization>	

/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganisation/name

Variable/ Fixed	Required/Cardinality	Data Type

Variable	O 0..1	ON
Description	The representedCustodianOrganization should contaion exactly one [1..1] name for the Custodian Organization.	
Example	`<name>`Odense Universitetshospital - Svendborg Sygehus`</name>`	

10   APPENDIX F. CDA BODY ELEMENTS

The structure of the CDA Body elements is shown on the figure below.

```
<documentationOf>
  <serviceEvent>
    <effectiveTime>
      ….
    </effectiveTime>
  </serviceEvent>
</documentationOf>

<documentationOf>
  <serviceEvent>
    <code>
      ….
    </code
  </serviceEvent>
</documentationOf>

<component>
  <structuredBody>

    <component>
      <section>
        …
      </section>
    </component>

    <component>
      <section>
        …
      </section>
    </component>

    <component>
      <section>
        …
      </section>
    </component>

  </structuredBody>
</component>
```

Figure 33: Structure of the CDA Body elements

The attributes for the documentationOf, serviceEvent, component, structuredBody and section shall be as shown on the above Figure 33.

The use of element documentationOf and element section is described below.

10.1 documentationOf

The documentationOf is holds information about the start and end time for the vital signs and/or results recorded. It also holds eventCodeList entries i.e measurement codes used to search for documents in the Danish XDS infrastructure.

The first occurrence of documentationOf shall only contain information about start and end time of measurements recorded.

The next occurrences of documentationOf shall only contain information about measurement codes recorded, repeated once per unique measurement code.

```xml
<documentationOf typeCode="DOC">
  <serviceEvent classCode="MPROT" moodCode="EVN">
    <effectiveTime>
      <low value="20140106080200+0100"/>
      <high value="20140110081500+0100"/>
    </effectiveTime>
  </serviceEvent>
</documentationOf>

<documentationOf typeCode="DOC">
  <serviceEvent classCode="MPROT" moodCode="EVN">
    <code code="NPU03011" codeSystem="1.2.208.176.2.1" displayName="O2
sat.;Hb(aB)"/>
  </serviceEvent>
</documentationOf>

<documentationOf typeCode="DOC">
  <serviceEvent classCode="MPROT" moodCode="EVN">
    <code code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme
vægt; Pt"/>
  </serviceEvent>
</documentationOf>
```

Figure 34: documentationOf XML-example

/ClinicalDocument/documentationOf

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	documentationOf
Description	The element shall contain at least one [1..*] documentationOf. The value of the @typeCode shall be as shown in the example below.	

Example
<documentationOf typeCode="DOC"> : : </documentationOf>

/ClinicalDocument/documentationOf[1]/serviceEvent (First occurrence)

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	serviceEvent
Description	The element shall contain exactly one [1..1] serviceEvent. The @classCode value shall be set to "MPROT" and the @moodCode shall be set to "EVN"	
Example	<serviceEvent classCode="MPROT" moodCode="EVN"> : : </serviceEvent>	

/ClinicalDocument/documentationOf/serviceEvent/effectiveTime

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	effectiveTime
Description	The element shall contain exactly one [1..1] effectiveTime.	
Example	<effectiveTime> : : </effectiveTime>	

/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	TS
Description	The element shall contain exactly one [1..1] effectiveTime. The value for low is the time for the first vital sign or result recorded.	
Example	<low value="20140106080200+0100"/>	

/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high

Variable/ Fixed	Required/Cardinality	Data Type

Variable	R 1..1	TS
Description	The element shall contain exactly one [1..1] effectiveTime. The value for high is the time for the last vital sign or result recorded.	
Example	<high value="20140110081500+0100"/>	

/ClinicalDocument/documentationOf[n]/serviceEvent (following occurrences)

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	serviceEvent
Description	The element shall contain exactly one [1..1] serviceEvent. The @classCode value shall be set to "MPROT" and the @moodCode shall be set to "EVN"	
Example	<serviceEvent classCode="MPROT" moodCode="EVN"> : : </serviceEvent>	

/ClinicalDocument/documentationOf[n]/code

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	code
Description	The element shall contain exactly one [1..1] code. The value for @code shall be the measurement code i.e. NPU-code specified by labterm.dk or MCS-code specified in the MedCom table **oversigtoverhjemmemålinger.xlsx[viii]**. The value for @codesystem shall be the OID for the codesystem i.e. 1.2.208.176.2.1 (NPU-terminology) The value for @displayName shall be as specified by labterm.dk or in MedCom table **oversigtoverhjemmemålinger.xlsx**.	
Example	<code code="NPU03011" codeSystem="1.2.208.176.2.1" displayName= "Legeme vægt; Pt"/> </code>	

[viii] Located at http://svn.medcom.dk/svn/releases/Standarder/POCT-Hjemmemonitorering/

10.2 section

A section holds information about vital signs, results, external references
and medical equipment.

```xml
<section classCode="DOCSECT" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.1.14"/>
   <templateId root="2.16.840.1.113883.10.20.9.14"/>
   <templateId root="1.2.208.184.11.1"/>
   <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
   <title>Results</title>
   <text>Results</text>
   <entry typeCode="COMP" contextConductionInd="true">
    <organizer classCode="CLUSTER" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.20.1.35"/>
     <statusCode code="completed"/>
     <effectiveTime value="20140106080200+0100"/>
     <component typeCode="COMP" contextConductionInd="true">
      <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 extension="23a44650-13f2-11e5-b939-0800200c9a66"
root="1.2.208.184" assigningAuthorityName="MedCom"/>
       <code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT">
         <translation code="NPU03804" codeSystem="1.2.208.176.2.1"
displayName="Legeme masse; Pt" codeSystemName="NPU terminologien"/>
       </code>
       <statusCode code="completed"/>
       <value xsi:type="PQ" value="77.5" unit="kg"/>
       <methodCode code="POT" codeSystem="1.2.208.184.100.1"
displayName="Målt af borger"
          codeSystemName="MedCom Message Codes"/>
       <methodCode code="AUT" codeSystem="1.2.208.184.100.1"
displayName="Måling overført automatisk"
          codeSystemName="MedCom Message Codes"/>
      </observation>
     </component>
    </organizer>
   </entry>
</section>
```

Figure 35: section XML example

/ClinicalDocument/component/structuredBody/component/section

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	component
Description	May contain one or more [1..*] component. See the above Figure 33. The value of the @typeCode and @contectConductionInd shall be as shown in the example below.	
Example	<component typeCode="COMP" contextConductionInd="true"> : : </component>	

/ClinicalDocument/component/structuredBody/component/section

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	section
Description	The element shall contain exactly one [1..1] section. The value of the @typeCode and @contectConductionInd shall be as shown in the example below.	
Example	<section classCode="DOCSECT" moodCode="EVN"> : : </section>	

/ClinicalDocument/component/structuredBody/component/section/templateId

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	II

Description	A Vital Signs, a result or a medical equipment section **SHALL** contain three `templateId`'s. The @root values are shown below.
	
	`Vital signs:`
	`2.16.840.1.113883.10.20.1.16 (CCD template)`
	`2.16.840.1.113883.10.20.9.2 (DSTU template)`
	`1.2.208.184.11.1 (this profile)`
	
	`Results:`
	`2.16.840.1.113883.10.20.1.14 (CCD template)`
	`2.16.840.1.113883.10.20.9.14 (DSTU template)`
	`1.2.208.184.11.1 (this profile)`	

	Medical equipment:
	`2.16.840.1.113883.10.20.1.7 (CCD template)`
	`2.16.840.1.113883.10.20.9.1 (DSTU template)`
	`1.2.208.184.11.1 (this profile)`

Example	`<templateId root="2.16.840.1.113883.10.20.1.14"/>` `<templateId root="1.2.208.184.11.1"/>`

/ClinicalDocument/component/structuredBody/component/section/code

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	II
Description	The code element shall be present. The @code value indicates the content in the section: Vital signs: @code="8716-3" Results: @code="30954-2" Medical equipment: @code="46264-8" The @codeSystem="2.16.840.1.113883.6.1" is the OID for LOINC.
Example	`<code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>`

/ClinicalDocument/component/structuredBody/component/section/title

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 0..1	ST
Description	The tittle should be present and contain the text: Vital signs, Results or Medical equipment depending on the value of the @code attribute in the code element.
Example	`<title>Results</title>`

/ClinicalDocument/component/structuredBody/component/section/entry

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	SET <entry>
Description	May contain one or more [1..*] entry. The value of the @typeCode and @contectConductionInd shall be as shown in the example below.

Example	<entry typeCode="COMP" contextConductionInd="true"> : : </entry>

/ClinicalDocument/component/structuredBody/component/section/entry/organizer

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	organizer
Description	Shall contain exactly one [1..1] organizer. The value of the @typeCode and @contectConductionInd shall be as shown in the example below.	
Example	<organizer classCode="CLUSTER" moodCode="EVN"> : : </organizer>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/templateId

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	II
Description	Shall contain exactly one [1..1] templateId. The value of the @root shall be as shown in the example below.	
Example	<templateId root="2.16.840.1.113883.10.20.1.35"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/statusCode

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CS
Description	Shall contain exactly one [1..1] statusCode. The value for the @code shall be set to "completed" or "nullified". The use of @code="nullified" is shown in example 4.	
Example	<statusCode code="completed"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/effectiveTime

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	TS
Description	Shall contain exactly one [1..1] effectiveTime.	
Example	<effectiveTime value="20140106080200+0100"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	component
Description	Shall contain exactly one [1..1] component. The value of the @typeCode and @contectConductionInd shall be as shown in the example below.	
Example	<component typeCode="COMP" contextConductionInd="true"> : : </component>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	observation
Description	Shall contain exactly one [1..1] observation. The value of the @classCode and @moodCode shall be as shown in the example below.	
Example	<observation classCode="OBS" moodCode="EVN">: : </observation>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/templateId

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	II

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 77 of 89

Description	**SHALL** contain two `templateId`'s:
	
	`2.16.840.1.113883.10.20.1.31 (Observation)`
	`2.16.840.1.113883.10.20.9.8 (Numerical)`

Example	\<templateId root="2.16.840.1.113883.10.20.1.31"/> \<templateId root="2.16.840.1.113883.10.20.9.8"/>

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/id

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	II
Description	**SHALL** contain exactly one [1..1] id (UUID) The /ClinicalDocument/../observation/id is a globally unique identifier for the observation i.e. the performed measurement. The PHMR DK-profile has constrained the @extension attribute to be an UUID. The @root and @extension attributes identifies the observation.	
Example	\<id extension="23a44650-13f2-11e5-b939-0800200c9a66" root="1.2.208.184" assigningAuthorityName="MedCom"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/code

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	**SHALL** contain exactly one [1..1] code The appropriate values for @code, @codesystem, @displayname and codeSystemName shall be used	
Example	\<code nullFlavor="NI" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"> \<translation code="NPU03804" codeSystem="1.2.208.176.2.1" displayName="Legeme masse; Pt" codeSystemName="NPU terminologien"/> \</code>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/value

Variable/ Fixed	Required/Cardinality	Data Type

Fixed	R 1..1	CD
Description	**SHALL** contain exactly one [1..1] value The appropriate values for @unit and @xsi:type shall be used	
Example	<value unit="kg" value="77.5" xsi:type="PQ"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/methodCode

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 2..2	CD
Description	**SHALL** contain exactly two [2..2] methodCode The appropriate values for @code, @codeSystem, @displayName and codeSystemName shall be used	

Example	<methodCode code="POT" codeSystem=" 1.2.208.184.100.1" displayName="Målt af borger"
	          codeSystemName="MedCom Message Codes"/>
	<methodCode code="AUT" codeSystem="1.2.208.184.100.1" displayName="Måling overført automatisk"
	          codeSystemName="MedCom Message Codes"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/referenceRange

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	O 0..2	CD
Description	**MAY** contain zero, one or two [0..2] referenceRange elements These elements may specify therapeutic reference values in DK known as Red low and high, and Yellow low and high	
Example	<!-- Reference range defined as RED low and RED high --> <referenceRange> <observationRange classCode="OBS" moodCode="EVN.CRT"> <templateId root="1.2.208.184.11.1.2"/> <code code="RAL" displayName="Terapeutiske grænseværdier for RØD alarm" codeSystem="1.2.208.184.100.1" codeSystemName="MedCom Message Codes"/> <value xsi:type="IVL_PQ"> <low value="50" inclusive="true"/> <high value="130" inclusive="true"/>	

```
        </value>
      </observationRange>
    </referenceRange>

<!-- Reference range defined as YELLOW low and YELLOW
high -->
<referenceRange>
    <observationRange classCode="OBS"
moodCode="EVN.CRT">
        <templateId root="1.2.208.184.11.1.2"/>
        <code code="GAL" displayName="Terapeutiske
grænseværdier for GUL alarm" codeSystem="1.2.208.184.100.1"
codeSystemName="MedCom Message Codes"/>
        <value xsi:type="IVL_PQ">
            <low value="60" inclusive="true"/>
            <high value="110" inclusive="true"/>
        </value>
    </observationRange>
</referenceRange>
```

/ClinicalDocument/component/structuredBody/component/section/entry/o
rganizer/component/observation/referenceRange/observationRange

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CD
Description	**SHALL** contain exactly one [1..1] observationRange The values of @classCode and @moodCode shall be as specified in the example below	
Example	`<observationRange classCode="OBS" moodCode="EVN.CRT">`	

/ClinicalDocument/component/structuredBody/component/section/entry/o
rganizer/component/observation/referenceRange/observationRange/templ
ateId

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	II
Description	**SHALL** contain exactly one `templateId`: `1.2.208.184.11.1.2 (PHMR-DK Therapeutic Reference Values templateId)`	
Example	`<templateId root="1.2.208.184.11.1.2"/>`	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/referenceRange/observationRange/code

Variable/Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	**SHALL** contain exactly one [1..1] code The appropriate values for @code, @codesystem, @displayname and @codeSystemName shall be used @code="RAL" indicates Red reference values @code="GAL" indicates Yellow reference values
Example	\<code code="GAL" displayName="Terapeutiske grænseværdier for GUL alarm" codeSystem="1.2.208.184.100.1" codeSystemName="MedCom Message Codes"/>

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/referenceRange/observationRange/value

Variable/Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	CD
Description	**SHALL** contain exactly one [1..1] value The value of @xsi:type shall correspond to that of the performed measurement inside the observation i.e. if the xsi:type of the measured value is "PQ" (Physical Quantity) the xsi:type of this value must be "IVL_PQ" (Physical Quantity interval) @low and @high expresses the limits of the reference interval, one of these may be omitted. @inclusive="true" is the default.

Example	\<value xsi:type="IVL_PQ">
	   \<low value="60" inclusive="true"/>
	   \<high value="110" inclusive="true"/>
	\</value>

10.3   External references

This paragraph outlines how to handle references to external documents in the Danish XDS infrastructure using Document Sharing Service (DDS)

as well as how to handle references to specific observations in external documents.

A document describing external references in CDA documents[ix] was made during the MaTis project and is available on MedCom SVN: http://svn.medcom.dk/svn/drafts/Standarder/HL7/CDA-XREF/

The rest of this paragraph describes which elements, templateId's, codes etc. to use when referencing is necessary.

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	CD
Description	May contain one or more [1..*] reference elements The reference can be to external documents and/or external observations. The value of @typeCode must be "REFR"	
Example	<reference typeCode="REFR"> … </reference>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/templateId

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..1	II
Description	If the reference is made to an external document or an external observation one templateId shall be specified indicating conformance with the rules for cross references in the Danish XDS infrastructure. The value of @root shall be 1.2.208.184.6.1	
Example	<templateId root="1.2.208.184.6.1"/>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalDocument

---

[ix] Notat-KrydsreferencermellemCDAdokumenter-6.pdf

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	When the reference is made to an external document externalDocument shall be specified with the attribute @typeCode="DOC".	
Example	\<externalDocument classCode="DOC"\> … \</externalDocument/\>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalDocument/Id

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	II
Description	When the reference is made to an external document two id's shall be specified: One id specifying the root and UUID of the external document. One id specifying the reference resolver type where @root=1.2.208.184.5 and: @extension="1" equals unique DDS XDS reference @extension="2" equals link-resolver reference	
Example	\<id root="1.2.208.184" extension="23a44650-13f2-11e5-b939-0800200c9a66"/\> \<id root="1.2.208.184.5" extension="1"	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalDocument/code

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	When the reference is made to an external document the type of the external document shall be specified by the appropriate LOINC code.	
Example	\<code code="74465-6" codeSystem="2.16.840.1.113883.6.1" displayName="Questionnaire Response Document"/\>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalObservation

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	When the reference is made to an external observation externalObservation shall be specified with the attribute @typeCode="OBS".	
Example	\<externalObservation classCode="OBS"\> … \</externalObservation/\>	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalObservation/Id

Variable/ Fixed	Required/Cardinality	Data Type
Fixed	R 1..*	II
Description	When the reference is made to an external observation three id's shall be specified: One id specifying the root and UUID of the external document. One id specifying the root and UUID of the external observation. One id specifying the reference resolver type where @root=1.2.208.184.5 and: @extension="1" equals unique DDS XDS reference @extension="2" equals link-resolver reference	
Example	\<id root="1.2.208.184" extension="23a44650-13f2-11e5-b939-0800200c9a66"/\> \<id root="1.2.208.184" extension="45a44650-13f3-11e5-b939-0800200c9a66"/\> \<id root="1.2.208.184.5" extension="1"	

/ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/observation/reference/externalObservation/code

Variable/ Fixed	Required/Cardinality	Data Type
Variable	R 1..1	CD
Description	When the reference is made to an external observation the type of the external document shall be specified by the appropriate LOINC code.	
Example	\<code code="74465-6" codeSystem="2.16.840.1.113883.6.1" displayName="Questionnaire Response Document"/\>	

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 84 of 89

11 APPENDIX G. XML EXAMPLES

11.1 Example 1: Weight measurement

11.1.1 Use case

By the end of 2013, Nancy Ann Berggren was diagnosed with a heart failure and treated at Odense Universitetshospital Svendborg sygehus, Hjertemedicinsk afdeling B. After the discharge she was referred to the outpatient clinic at Svendborg Hospital, for further rehabilitation.
As a part of the rehabilitation plan, Dr. Hans Hansen prescribed Home Monitoring of the weight in the morning – 3 times per. week. A weighing Scale, type xxx was installed in the Nancy Ann Berggren's house.

The following measures were taken: 6. January 2014, 08:02: 77,5 kg. 8. January 2014: 07:45: 77,0 kg. 10. January 2014: 8:15: 77,2 kg.

The first transfer of the weight was done the 12. January 2014 at 22.00, to the Home monitoring server in the Region of South Denmark.

The data was viewed at by Dr. Anders Andersen at Svendborg Hospital, Hjertemedicinsk afdeling B the 13. January 2014 at 10.00. Dr. Anders Andersen approved the 3 weight.

The data was now stored at the Home Monitoring Server in the Region of South Denmark as a Clinical Document (persistent). Finally a copy of the Clinical document was transferred to the National Home Monitoring repository.

11.1.2 XML example
Filename: Ex1-Weight_measurement.xml

11.2 Example 2: Assisted data capture and typing error

11.2.1 Use case

On January 20th 2014, Nancy as usual performs her weighing in the morning, and a measurement of 77,3 kg is automatically transmitted to the home monitoring device at 7:53. In the afternoon the same day, a home nurse (hjemmesygeplejerske) Mathilde Christensen visits Nancy and performs a blood pressure measurement using a non-digital device. It

shows 153 mm Hg systolic and 86 mm Hg diastolic. She enters these values manually into Nancy's home monitoring device's blood pressure screen but erroneously enters the systolic value as 253 mm Hg. Next, she requests immediate upload to the Home monitoring server.

The data is again viewed at by Dr. Anders Andersen at Svendborg Hospital, Hjertemedicinsk afdeling B the 21th January 2014. He can see that the weight measurement is made by the patient herself and electronically transmitted whereas the blood pressure is measured aided by a home carer and manually entered which makes him suspect the alarmingly high systolic blood pressure is due to a typing error. Dr. Andersen thus does not approves the latter measurement but notes a question about the potential typing error for a later conference with the home nurse.

11.2.2   XML example
Filename: Ex2-Typing_error.xml

11.3   Example 3: Preeclampsia

11.3.1   Use case
Ellen is expecting her second child. During her first pregnancy she was diagnosed with pre-eclampsia and was attending extra clinic visits at the outpatient clinic at the Department of Obstetrics and Gynaecology at Aarhus University Hospital, 60 km from home, before she was hospitalized until the birth of her child four weeks premature. This time she and her husband feel insecure and stressed because of the risk of pre-eclampsia in this pregnancy and the time and energy they have to spend on extra clinic visits. Because of her pre-eclampsia, she is referred to the outpatient clinic at the Department of Obstetrics and Gynaecology at Aarhus University by her general practitioner after her first pregnancy consultation in week 8.

During her first visit at the outpatient clinic doctor Peter Petersen prescribes home monitoring of weight, blood pressure, urine and cardiotocography (CTG) supplemented with a questionnaire asking questions about i.a. headache, dizziness and her general condition. Midwife Sarah Andersen introduces her to the home monitoring set up and device – a tablet, a weighing scale, a sphygmomanometer, uristix for urine analysis of protein and a device for fetal monitorering (Monica). Ellen is instructed to do the home monitoring twice weekly in the morning between 8 am and 10 am. The home monitoring replaces most doctor consultations at the outpatient clinic.

As prescribing doctor, Peter Petersen is responsible for Ellen's home monitoring programme. During the period of home monitoring midwife

Sarah Andersen approves all normal measurements. Does she detect any irregularities, doctor Peter Andersen is contacted and he is then responsible to decide whether to take action or not – either by means of a phone call to Ellen from the midwife, himself or by means of a physical consultation at the outpatient clinic.

The following measures are taken on 14th of January 2014 at 09:45 am:
Weight: 75 kg
Blood pressure: 138/91
Urine (protein): neg
CTG: normal
At the same time the questionnaire is completed showing no irregularities or subjective signs of pre-eclampsia.

As soon as Ellen has completed the measures and the questionnaire the transfer of data is done to the Home monitoring server in for the Region of Central Jutland. On the tablet Ellen receives a feedback reply: "submission of data completed". The data is viewed at by midwife Sarah Andersen, the Department of Obstetrics and Gynaecology at Aarhus University, at 10.00 am. She approves the measurements and Ellen receives a text message on her tablet saying: "Data has been looked at and approved". Sarah adds a note in the electronic patient record once weekly and when irregularities are detected.

11.3.2 XML example

Filename: Ex3-Preeclampsia.xml

11.4 Example 4: COPD

11.4.1 Use case

In of 2013, Janus Berggren was diagnosed with chronic obstructive lung decease (COPD) and treated at Odense University Hospital, Odense, Lungemedicinsk Afdeling J. After being initially treated and his treatment was adjusted he was discharged to his home. He was instructed to follow up in the Out-patient Clinic and enrolled in a home monitoring program in order to facilitate early detection and prevention unwanted changes in his health condition.
At his home a home monitoring equipment was installed in order for him to measure lung function and oxygen saturation according to a schedule managed by the Specialist Dr. Lars Olsen in the hospital. Dr. Olsen prescribed measurements taken every morning.

Janus Berggren conducted these measurements:

HL7 Implementation Guide for CDA R2.
Personal HealthCare Monitoring Report (PHMR DK). Danish Profile.
Release 1.3. 31. March 2014. Updated 2. March 2020.

Side 88 of 89

Date	Time	Type	Result	Unit
11/2 2013	09:11	SAT	92	%
11/2 2013	09:14	FVC	2,5	Liter
12/2 2013	08:45	SAT	91	%
12/2 2013	08:50	FVC	2,4	Liter
13/2 2013	09:15	SAT	94	%
13/2 2013	09:21	FVC	2,9	Liter
14/2 2013	09:45	SAT	95	%
14/2 2013	09:50	FVC	3,1	Liter
15/2 2013	07:01	SAT	90	%
15/2 2013	07:10	FVC	2,2	Liter
16/2 2013	11:10	SAT	94	%
16/2 2013	11:14	FVC	3,0	Liter

The measurements were reviewed by Dr. M. Madsen Monday 17/2 at 09:15. The measurements were approved and a note was added to the measurement sample: "The COPD condition seems to be stable".

The data was now stored at the Home Monitoring Server in the Region of South Denmark as a Clinical Document (persistent). Finally a copy of the Clinical document was transferred to the National Home Monitoring repository.

11.4.2   XML example
Filename: Ex4-COPD.xml

11.5   Other examples

11.5.1   XML example showing documentationOf
Filename: PHMR_KOL_Example_1_MaTIS__documentationOf_text.xml

11.5.2   XML example showing External references
Filename: QRD_KOL_Example_1_MaTIS_with_extended_references.xml

11.5.3   XML example showing therapeutic reference ranges
Filename:
PHMR_KOL_Example_4_MaTIS_Validated_Devices_Reference_RED_YELLOW.xml