H.813 Healthcare Information System Interface

Version 2016

August 4, 2016

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0 Introduction

The Continua Design Guidelines (CDG) define a framework of underlying standards and criteria required to ensure the interoperability of devices used for applications monitoring personal health and wellness. It also contains additional design guidelines for interoperability that further clarify or reduce the options in underlying standards or specifications, or by adding a feature missing in an underlying standard or specification.

This guidelines document focuses on the following interfaces:

- **HIS-IF (Health Information System – Interface)** – Interface between Health and Fitness Services and Healthcare Information Systems

This guidelines document is one of the "H.810 Interoperability design guidelines for personal health systems" documents. See [H.810] for more details.

0.1 Organization

This Recommendation is organized in the following manner.
Clauses 0-5: Introduction and terminology – These clauses provide useful background information to help understand this design guideline.
Clause 6: HIS interface design guidelines - This clause is an overview of the HIS-IF architecture and design guidelines for Health and Fitness Services and Healthcare Information Systems implementing the HIS-IF.

0.2 Guideline releases and versioning

Information on releases and versioning of these guidelines can be found in Clause 0.2 of [H.810]

0.3 What's New

To see what is new in this release of the design guidelines refer to Clause 0.3 of [H.810]

1 Scope

This guidelines document focusses on the following interface:

- **HIS-IF** – Interface between Health and Fitness Services and Healthcare Information Systems

This interface is defined in the Continua architecture as described in [H.810]], Clause 6 as shown in Figure 1-1below.

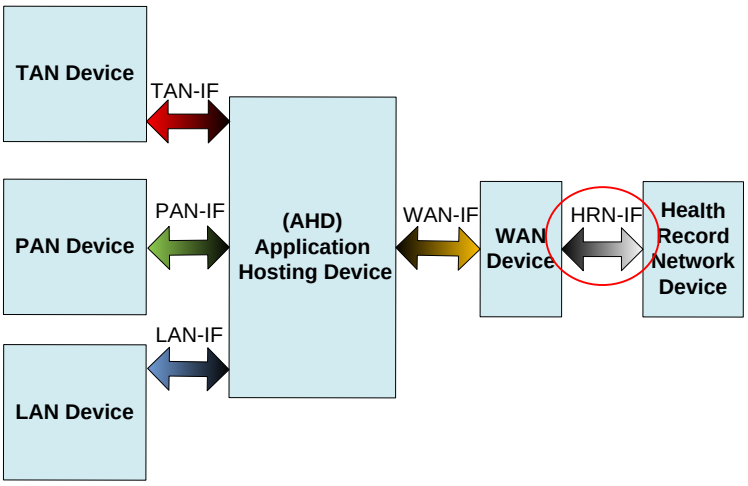

Figure 1-1 – HIS Interface in the Continua References

2 References

All referenced documents can be found in Clause 2 of [H.810]

3 Definitions

This guidelines document uses terms defined in [H.810]

4 Abbreviations and Acronyms

This guidelines document uses abbreviations and acronyms defined in [H.810]

5 Conventions

This guidelines document follows the conventions defined in [H.810]

6 HIS interface design guidelines

6.1 Architecture

6.1.1 Overview

The purpose of the HIS interface is to transfer patient information from a Continua Heath and Fitness Service (HIS Sender) to either another Heath and Fitness Service or an electronic health record device (HIS Receiver). The HIS Sender can be the Remote Patient Monitoring (RPM) server of a Disease Management service provider or the Application Server of an Ageing Independently or Health & Fitness service provider. The patient information for transfer may include a report summarizing the patient's current status, a detailed listing of specific patient results, readings from one or more personal health devices, or a combination of these. The electronic health record device may contain a hospital's Enterprise Health Record (EHR), a physician's Electronic Medical Record (EMR) or a Personal Health Record service (PHR) used by the patient.

Figure 6-1 represents the HIS interface relative to the Continua E2E architecture.

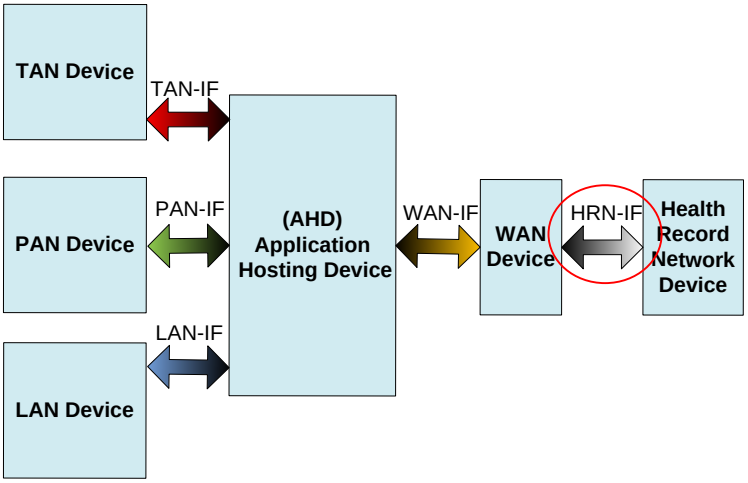

Figure 6-1 – HIS interface

At a high level, there are different functional blocks that make up the HIS interface. Figure 6-2 illustrates this view of the architecture.

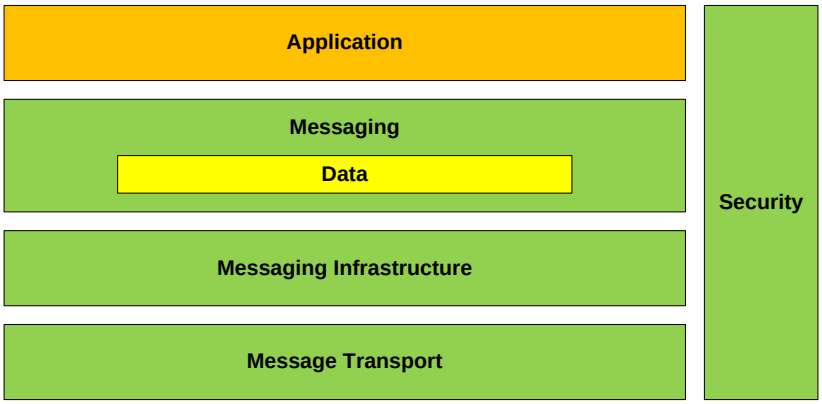

Figure 6-2 – HIS Functional Blocks

The applications block contains enterprise healthcare applications such as a Remote Patient Monitoring system hosted by a Disease Management service provider or an EMR system at a

physician's office. The data block contends with the format of the actual data transmitted between the applications. It may be in coded format, free-text, or a combination of both.

The messaging block handles how data is packaged to ensure consistency and readability across multiple transport methods. The messaging infrastructure deals with the infrastructure needed to transport this information model, such as MLLP, FTP, Web Services, and others. The message transport layer forms all the layers below the transport layer of the OSI stack. The security block ensures that the messages exchanged between applications are secure.

6.1.1.1 Scope

The scope of the HIS interface guidelines is to describe how Continua-certified HIS-IF devices can send patient information to other Continua-certified HIS-IF devices or to non-Continua EHR systems. Figure 6-3 is a high level picture of the scope for these guidelines.

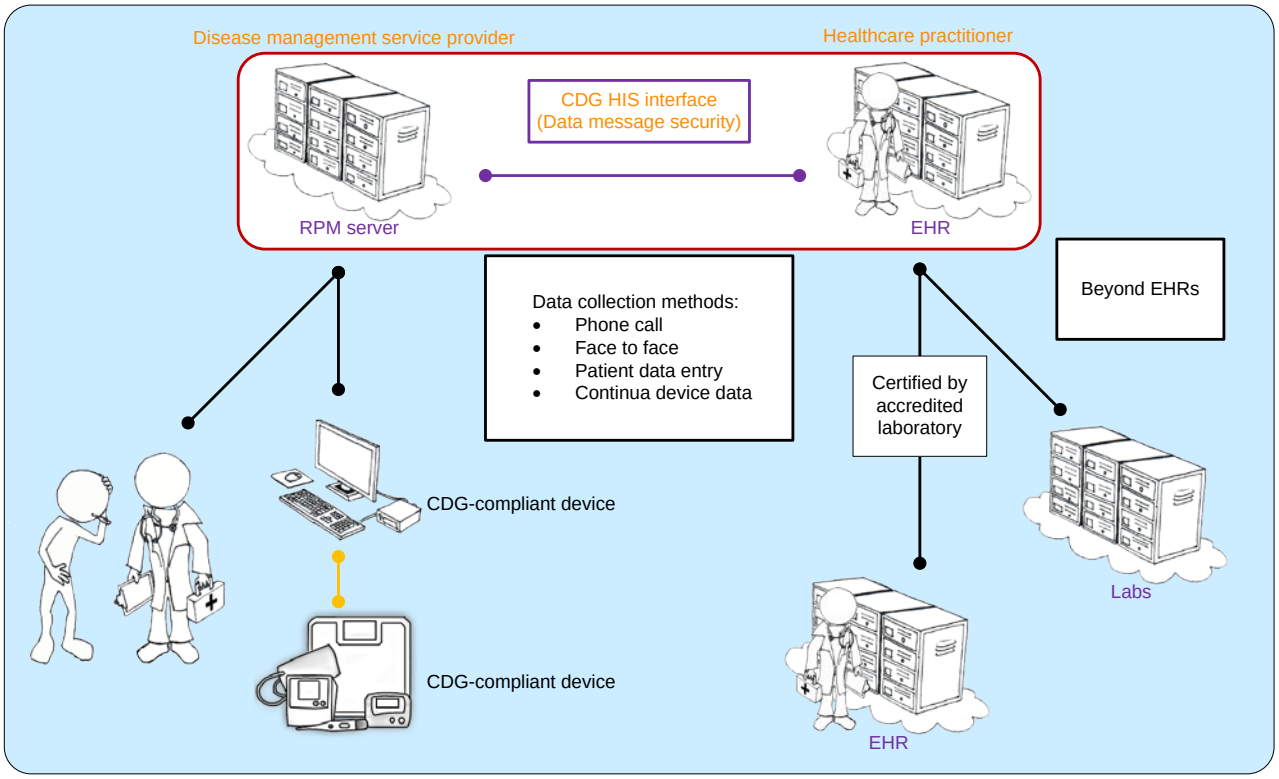

Figure 6-3 – HIS scope

The purpose of the guidelines is to establish the basic standards, rules and restrictions in the data, message, and transport protocols necessary to enable the transfer of pertinent information from a Heath and Fitness Service with an HIS-IF (HIS Sender) to another Heath and Fitness Service with an HIS-IF (HIS Receiver) or to a healthcare practitioner, system or setting (HIS Receiver). This pertinent information is obtained from the following sources:

Personal Healthcare Devices: This includes relevant vital measurements that the sending and receiving entities agree are relevant to the patient's condition.

Remote Patient Monitoring (RPM) Service Provider: This includes updates/notes/summary information that is sent by a remote monitoring service provider. The notes include information and progress updates relevant to the particular condition for which the patient is being monitored.

Patient data entry: This includes patient notes or notes interpreted by a nurse after talking to the patient.

Identification/Demographics: This may include patient identification information, device identification, and other registration information.

6.1.1.2 Chosen standards and profiles

Data: To facilitate the accurate transfer of both coded patient results from personal health devices and textual summary results from patient care-givers, the HL7 Personal Healthcare Monitoring Report document format standard was chosen.

NOTE - The Data Guidelines are based on the HL7 CDA R2 standard [HL7 CDA], profiled by the HL7 Personal Healthcare Monitoring (PHM) Implementation Guide.

Patient Identity: To ensure that HIS Senders and Receivers can correctly associate personal health data with the right patient, the Integrating the Healthcare Enterprise (IHE) Patient Identifier Cross-reference (PIX) profile was selected. This profile provides a standards-based interface for managing identifiers across organizational and political domains.

HIS Senders must implement the IHE Patient Identity Feed transaction in order to provide the necessary information for cross-referencing. This cross-referencing must then be performed from a Patient Identifier Cross-reference Manager either within the destination's domain of control, or shared between the Sending and Receiving entities—such as in the case of a Cross-Enterprise Document Sharing (XDS)-based Healthcare Information Exchange (HIE).

Using an IHE PIX Query of the Cross-reference Manager, Senders and Receivers are able to map between their local identifiers and those identifiers used for sharing/transfer.

The PIX profile is widely used in conjunction with the XDS family of specifications to implement integration scenarios within and between hospital enterprises, such as in the case of a Disease Management organization sending patient monitoring information to a Healthcare Information Exchange. However, the profile is also applicable in the ageing independently and health and fitness domains, when a particular organization's local identifiers must be mapped to a receiving system's identifiers, such as in the case of a physical therapy organization sharing fitness data with a member's primary care physician.

It is important to note, however, that in certain circumstances, the use of a patient identity cross-reference manager may not be required or appropriate. For instance, in cases where there is no party suited to perform the management of patient cross-references (as in certain Personal Health Record integration scenarios), the HIS Sender and Receiver must agree on a patient identification scheme that is suitable for their particular use case.

In general, PIX queries are most appropriately used for direct machine-to-machine interaction - where a system needs to locate a patient's global enterprise ID for reference against other clinical information stored against that ID. Here, the patient's ID assignment and device allocation is clearly known.

Patient Demographics Query (PDQ) queries are likely to be most appropriate for user-driven interactions such as a physician searching for a patient's history alongside recent monitoring data,

who may execute a search by name where a potential list of matches may be returned and then the physician drills further into each patient identity record to locate the exact match of information.

Messaging: A future is envisioned where patient information is sent between providers by various methods. These methods include: secure direct connection over the Internet, secure email, delivery on portable media (data stick, etc.), through a messaging hub, and through a data repository or RHIO / NHIN.

To facilitate this, a messaging standard capable of supporting all five transport methods with a minimal amount of rework was chosen. That is, once the first transport method was accomplished, incorporating additional transport methods require less work.

In addition, because this interface is used to communicate with non-Continua certified electronic health records, a messaging standard supported by others that certify electronic health record systems was chosen.

For these reasons, the IHE's XDS profile was chosen.

Transport Protocol: To accomplish secure direct communication of pertinent patient information between care-givers, the IHE XDR (Cross-Enterprise Document Reliable interchange) profile utilizes current standards such as SOAP 1.2 and MTOM.

To accomplish secure indirect communication of pertinent patient information between care-givers, the IHE Cross-Enterprise Document Media Interchange (XDM) profile utilizes current standards such as Zip and S-MIME.

NOTE - Because the HIS Sender and HIS Receiver are likely on separate local networks, the HIS Sender may send the patient information to the HIS Receiver across the public Internet. Therefore, both the HIS Sender and the HIS Receiver may require Internet access and the equipment (hardware and software) necessary to securely send the patient's information across the Internet using the transport method detailed in these guidelines. If the HIS Sender and HIS Receiver are on the same secure network, or if a secure network connection exists between their networks (i.e., a VPN connection), then Internet connectivity is not required.

6.1.1.3 Topology

The HIS interface defines a means of communication between an HIS Sender (client component) and an HIS Receiver (service component). The communication is initiated by the sender and the receiver acknowledges the receipt of the data (if the communication protocol allows, as XDR does).

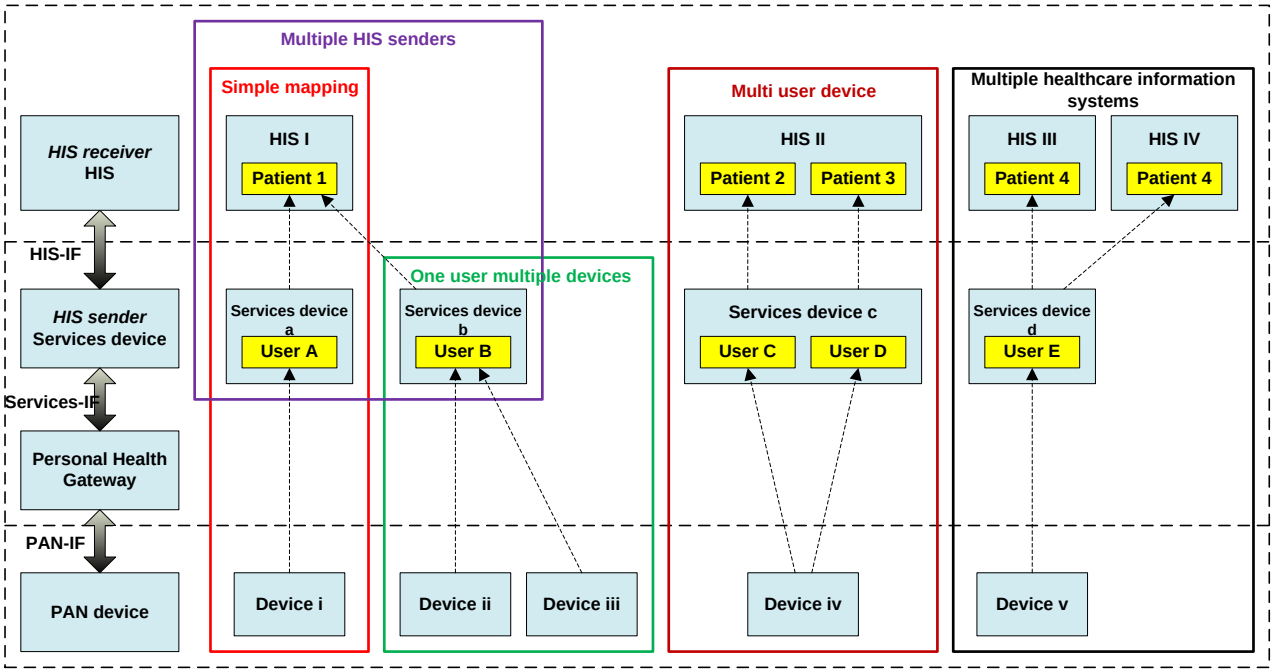

Figure 6-4 – HIS topology

Figure 6-4 displays the topology for the HIS interface communication. The context of communication is always related to a patient. The patient identification method is negotiated between the HIS Sender and the HIS Receiver through registration within a Patient Identity Cross Reference Manager utilizing the IHE Patient Identity Feed. It is important to note that the Patient identification is not necessarily globally unique, but rather it is specific to the particular instance of HIS communication. For example, the same person can be identified differently in distinct HIS Receiver systems and therefore, the appropriate patient identification should be used for each respective HIS interface communication. To this end, HIS Senders are required to implement the IHE Patient Identity Source actor, defined by transaction ITI-44: Patient Identity Feed HL7 V3 of the IHE IT Infrastructure (ITI) Technical Framework supplement, in order to provide HIS Receivers with the patient information needed to create and maintain accurate cross-referencing. As illustrated in the HIS Topology diagram, the HIS Sender and HIS Receiver must take into consideration the various scenarios when considering and communicating patient identification. These include (but are not limited to):

- **The Simple Mapping** – where one PHM Report containing data from a single device is sent to a single HIS Receiver. The patient identifier to be used is obtained via PIX Query, out-of-band agreement, and/or provided previously to the HIS Receiver via a Patient Identity Feed HL7 V3 message.
- **One User Multiple Devices** – similar to the simple mapping case, data from multiple devices for a single patient is transferred over the HIS protocol within a single PHM Report.
- **Multiple HIS Senders** – this case describes the situation where the HIS receiver accepts PHM Reports from multiple HIS Senders for the same patient. Each sender delivers independent messages with the patient properly identified and with data from devices specific to that HIS Sender.
- **Multi User Device** – the HIS Sender is delivering data for multiple patients in separate PHM Reports for each patient, even though the data originated from a single device.

- **Multiple Health Providers** – in this case, the HIS Sender delivers data for one patient from one (or more) device(s) to multiple HIS Receivers. Each HIS Receiver receives its own PHM Report for that patient. The pertinent information in these reports may be identical-however, each contains the patient identification agreed to and appropriate for the agreement between that HIS Sender and that HIS Receiver.

The above list describes some of the basic cases. The real world situation can be a combination of described cases. For example, one patient's data can be present in reports from multiple HIS Senders and submitted to several HIS Receivers.

6.1.2 Messaging infrastructure and transport standards

The messaging infrastructure guidelines describe how the messages will be transported between the HIS Sender and the HIS Receiver. They also describe the infrastructure that will be necessary to accomplish the selected transport method (see Figure 6-5).

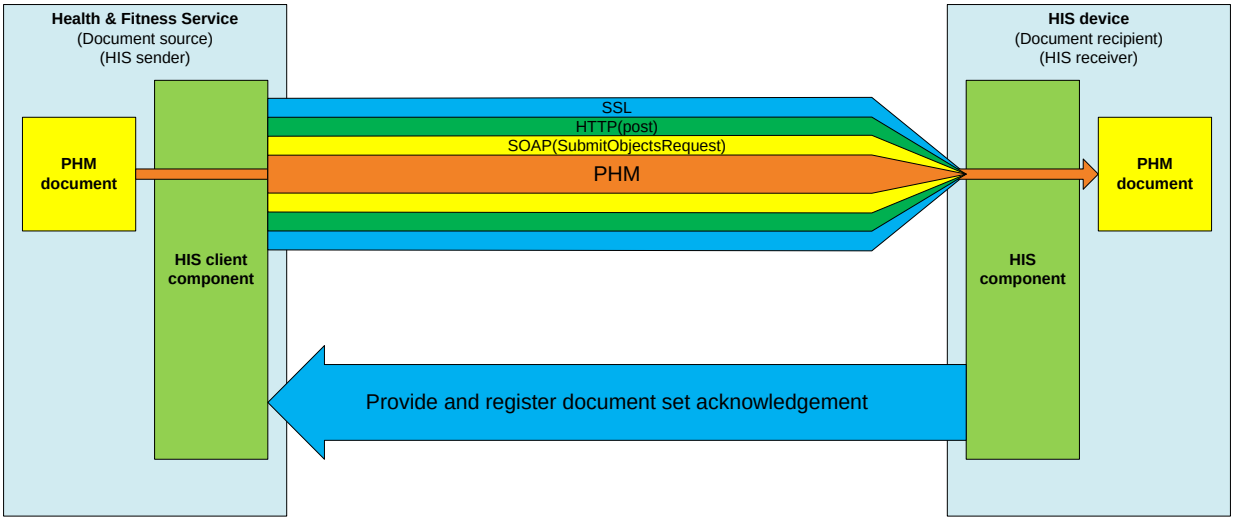

Figure 6-5 – Direct HIS messaging via XDR

For v1, the IHE's Cross-Enterprise Document Reliable Interchange (XDR) [IHE ITI TFS XDR] profile was selected as the transport method for direct communications across the HIS interface. This profile is a member of IHE's XDS family of profiles. As such, it uses the same HTTP, SOAP 1.2, ebXML, and MTOM standards set forth in IHE's XDS.b guidelines (for more details, see [IHE ITI TFS XDR]).

As noted in the overview above, special attention must be given to the infrastructure required to accomplish this transport method. The XDR profile contains no intermediate data repository or messaging hub. If the communication between the HIS Sender and the HIS Receiver will occur over the Internet, then the HIS Receiver will need to be Internet-facing. In other words, the system receiving the messages on the HIS interface will need to be reachable from the HIS Sender. If the HIS Sender is not on the same secure network as the HIS Receiver and a secure connection does not exist between their networks, then the HIS Receiver will need to be reachable from anywhere on the Internet and its IP address accessible to everyone on the Internet.
From an implementation standpoint, the HIS Receiver may be the provider's electronic health record system itself, or it may be a web-front-end system whose purpose is to securely carry the messages across the providers firewall boundary without exposing the electronic health record to the perils of the Internet. This second method provides additional security for the provider and patient data and therefore it should be duly considered by system integrators.

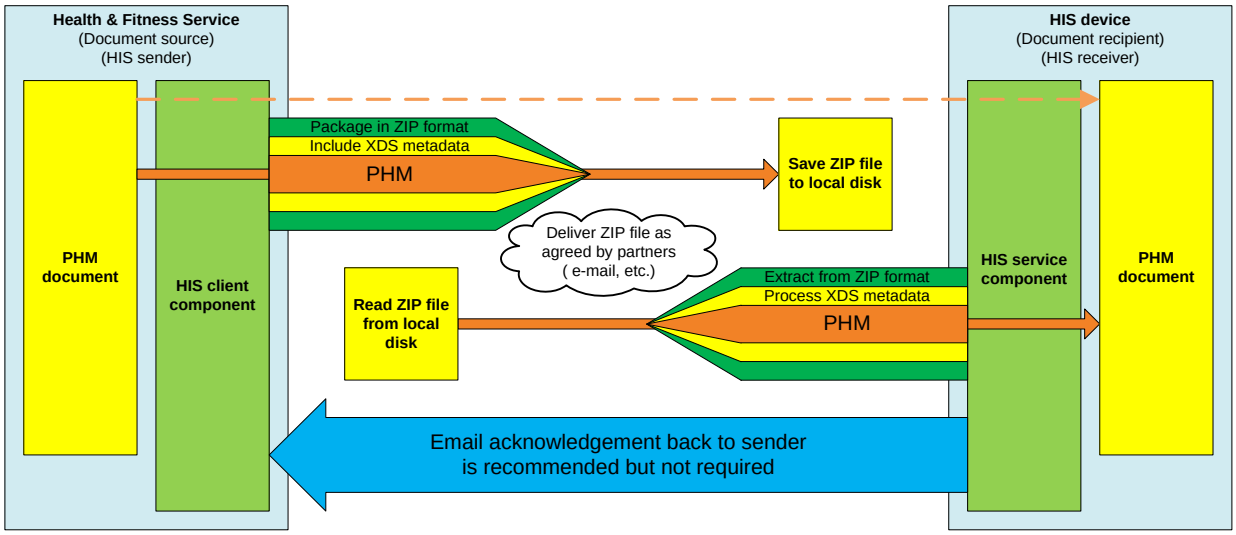

Figure 6-6 – Indirect HIS Messaging via XDM

IHE's Cross-Enterprise Document Media Interchange (XDM) profile [IHE ITI TFS XDM] was added in the 2013 CDG as the transport method for indirect communications (via email or physical media) across the HIS interface. This profile is a member of IHE's XDS family of profiles. For more details, see [IHE ITI TFS XDM].

The infrastructure required to accomplish XDM is different and likely to be less complicated than for XDR.

Selecting which transport method (XDR or XDM) to use is left up to the System Integrator. While XDR is clearly the more optimal choice because it provides faster communications, XDM can be much easier to implement, allowing the delivery of PHM reports to occur over an existing email infrastructure with little, if any, new equipment or software.

6.1.3 Messaging and selected standards

For messaging and transport, the HIS-IF utilizes as its base the Integrating the Healthcare Enterprise [IHE] Cross-Enterprise Document Sharing (XDS) family of profiles. This family of profiles thoroughly covers the spectrum of communication requirements for a large health information network such as a RHIO. In particular, the XDR and XDM profiles from this family are used because they explicitly target a simple point-to-point exchange of documents. When combined with the IHE Patient Identifier Cross-reference (PIX) profile, these profiles enable the safe transfer of a single document set against the correct patient identity.

An important aspect of the chosen standards is for a common set of meta-data that is specified and describes the PHM document being transmitted. This metadata is utilized by holders of the document to help determine how to handle the document without the need to open, resolve all referenced attached documents, parse, and examine the contents. Thus, the meta-data allows the holders to rapidly determine the best way to handle a document quickly and easily.

This metadata takes the form of a concretely defined list of required information. The metadata contains pertinent data such as authorship description (e.g., person, role, institution), document description (e.g., date, time, language), and patient identification and demographics (PID, name, address).

This information is then mapped to the appropriate form of the specific transport. In v1, this information takes the form of XML that will map to the ebXML that overlays the SOAP envelope. Thus, it is present in the SOAP header and body clauses where it is easily accessible on reception (see Figure 6-5). With the addition of XDM (sending data via email attachment or removable media) in this version of the guidelines, the meta-data is stored in the top-level directory of the exported file package that is created when the PHM document is exported for delivery via the XDM method. Because of this, the exported file package must first be opened or extracted before the meta-data can be accessed (see Figure 6-6). The particular file packaging format called out by XDM is the ZIP format. Applications and programming libraries to create and read ZIP files are widely available, and on many operating systems. Licensing costs will need to be confirmed; but may be covered by the purchasing of the application or library used to create or read the ZIP file.

6.1.4 Data and selected standards

The data transmitted from the HIS Sender can be either summary, raw data or both. The summarization may be a result of analysis by an authentic disease management service provider. The data has multiple characteristics that include:

1. Representation of measurements captured by devices.
2. Representation of notes, summary and other kinds of narrative information that are added by care givers or by the user themselves.
3. Representation of graphs that are added by intermediary devices that represent the trends of a user's health.
4. Patient information that allows endpoints to catalogue the aforementioned data against existing patient records.

To accommodate the wide variety of data characteristics, the HL7 Clinical Document Architecture (CDA) [HL7 CDA-PHMR] based format is chosen. The CDG specifies constraints on the CDA in accordance with requirements set forward by the HIS interface. These constraints are henceforth called the Personal Healthcare Monitoring (PHM) Report.

Wherever possible, the PHM report reuses the templates already set forth by an HL7 specification called Continuity of Care Document (CCD) [HL7 CDA-CCD]. The reasons for reusing the CCD templates are:

1. The CCD templates already contain a number of constraints that are needed by the HIS interface.
2. The CCD is a harmonized specification of CDA (based on HL7 V3 RIM) and ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR), (see [HL7 CDA-CCD]).
3. Since the CCD has gained relevance in the marketplace, it is best if the PHM Report is derived from the CCD so that it is a lesser burden to the EHR implementations that are designed to work with the CCD.

HL7 PHM Report Implementation Guide [HL7 CDA-PHMR] has an independent lifecycle under a project called "Personal Health Monitoring Report" under the HL7 Structured Documents Workgroup (SDWG).

6.1.5 Security

The five archetypal high-level areas of security requirements are a subset of 11.2.3 [b-ISO 27000] and are as follows:

- **Authorization -** Only fully identified and authenticated entities, equipped with access control credentials, should be able to avail themselves of services provided by systems.

- **Accountability -** Users should be fully accountable for (and unable to repudiate) their actions. It should be possible to determine, through a system's accountability features, who performed any given action and which actions have taken place in a specified interval.
- **Availability -** A system should be available for use when required for critical operations. Critical data should be available when required. The data and keys associated with encryption for the purposes of confidentiality should be recoverable.
- **Administration -** Responsible security policy authorities should have secure, usable interfaces for defining, maintaining, monitoring and modifying security policy information.
- **Assurance -** It should be possible to demonstrate to a sceptical observer that a system actually provides the claimed level of protection with periodic validation that the protection is still effective.

6.1.6 Transport security

The HL7 Clinical Document Architecture (CDA [HL7 CDA-PHMR], which is the basis for PHM report implementation, relies on the transport mechanism to implement security and authentication. The CDA does provide confidentiality status information to aid the application systems in managing access to sensitive data.

The IHE XDS profile family assumes that a suitable security and privacy environment was established and that the relevant threats are managed by agreements and implemented by generic security mechanisms not unique to XDS.

For direct communications, the transport security of the HIS interface is accomplished by the adoption of the security solution from the IHE XDR profile and its prerequisite industry standards. For indirect communications via the IHE XDM profile, the transport security depends on the final delivery method employed. If the exported file is delivered to the HIS Receiver via email (the recommended method), then S-MIME is used to ensure security. However, the cases in which the ZIP-packaged PHM report is further stored on removable media (i.e., USB, drive, CD-ROM, etc.) or transferred via FTP are not covered in this guideline and require their own security considerations.

In addition, the XDS profiles assume that implementers of the Document Source and Document Recipient have in place an agreement that defines when they interchange the PHM data and how to manage the inconsistencies between security policies in both organizations. The XDS profiles further require the reconciliation of patient identification upon import of the document.

The CDG specifications for the HIS Sender further narrow these framework provisions to allow reasonable Design Guidelines. However, it should be noted that the final security implementation must be designed by the communicating parties.

6.1.7 Document-level integrity, data origin authentication and non-repudiation

Integrity, data origin authentication and non-repudiation are important security properties for PHMR documents exchanged over the HIS-IF. Through the use of transport security (TLS, IHE ATNA) basic integrity and node authentication is realized. However, non-repudiation requires additional measures such as a signature over the documents. This also strengthens the integrity property as a signature can protect the integrity of the document independent of how it is exchanged and thereby provides end-to-end integrity if it is exchanged multiple times.

For the HIS-IF integrity, data origin authentication and non-repudiation are realized through the use of IHE Document Digital Signature Content Profile. IHE DSG allows signing of documents in a submission set exchanged using the protocols in [IHE ITI TF-1 XDM] and [IHE ITI TFS XDR].

Non-repudiation Enabled HIS Sender is an HIS Sender that deploys security operations to assure that data integrity, data origin authentication, and data origin non-repudiation properties are preserved when transmitting observation document. **Non-repudiation Enabled HIS Receiver** is an HIS Receiver that deploys security operations to assure that data integrity, data origin authentication, and data origin non-repudiation properties are preserved when receiving an observation document. In other words, these security operations are mandatory only for Non-repudiation Enabled HIS Senders and Receivers. This makes the decision to apply such measures a business decision based on risk assessments. It is a choice of an HIS Receiver to deploy these security constructs should the need arise to enable interoperability with Non-repudiation Enabled HIS Senders.

6.1.8 Consent management

Consent in healthcare includes concepts like opt-in, opt-out, secondary use and enables patients to regulate which care providers have access to which health information. Capturing consent in digital form increases consistency, compliance and efficiency for both patients and care providers.

Consent management at the HIS-IF supports scenarios where a patient holds a consent policy at a Heath and Fitness Service which should also be applied at an HIS service. An example is a scenario where a patient defines his consent at a disease management organization and a condition occurs that requires involvement of another doctor. In such a case a nurse may, if permitted by the consent policy, forward his record together with the consent document allowing the receiver to use the information in accordance with the patient's consent policy. In a variant, an HIS service may seek additional consent from the patient. Instead of Heath and Fitness Service to HIS exchanges, consent documents may also be exchanged from HIS to HIS services.

For the HIS-IF the scope is limited to the exchange of the consent documents between the HIS Sender and HIS Receiver. The creation and management of the consent documents is out of the scope of this design guideline. It is the assumption that patients have already given their consent, e.g., to a disease management organization.

The Consent Enabled HIS Sender is an HIS Sender that is capable of transmitting a patient consent document. The Consent Enabled HIS Receiver is an HIS Receiver that is capable of receiving a patient consent document. Support for consent management is mandatory for Consent Enabled HIS Senders and Receivers.

Consent management at the HIS-IF is based on HL7 CDA R2 Consent Directive [HL7 CDA IG] to capture patient consent in a CDA consent document. Two types of interaction are provided to exchange consent documents. The first extends the existing IHE XDR transaction to exchange the PHMR document by including the consent document in the submission set. Figure 6-7 provides an overview of this interaction. The IHE XDR profile is based on the ITI-41 Provider and Register document Set-b transaction. An exchange transaction here may concern a new consent document or update.

The second interaction follows a request/response structure to obtain the consent document separate from the PHMR document. This interaction may be used e.g., in cases where a reference to already shared consent documents suffices or situations where a consent document should be obtained

because is not available (anymore) for a particular patient or record. The HIS Receiver uses IHE XDS to send a request for a given consent document to the HIS Sender which then responds with the referenced consent document. Figure 6-8 provides an overview of this request-response interaction. The IHE XDS profile employs the ITI-43 Retrieve Document Set.b transaction and the ITI-18 Registry Stored Query transaction to facilitate lookup document identifiers and location URLs.

An HIS Sender has knowledge of the applicable patient consent for a PHMR document and signals this to an HIS Receiver using the ConfidentialityCode field in the PHRM document, which identifies the applicable consent document, thereby associating the consent document to the health data.

To properly authenticate the requester and personalize the PHMR and patient consent document, the actual user (care provider) is authenticated rather than an HIS Receiver device node. This allows for the selection and issuing of the appropriate consent, e.g., the consent based on or belonging to the functional role of a nurse or doctor. Such consent modified to the situation also allows for exceptions for particular users and records thereby tailoring the access to the record. The authentication uses IHE XUA to include an SAML token in the ITI-43 Retrieve Document Set.b request message (see Figure 6-9), which is used to request a consent document.

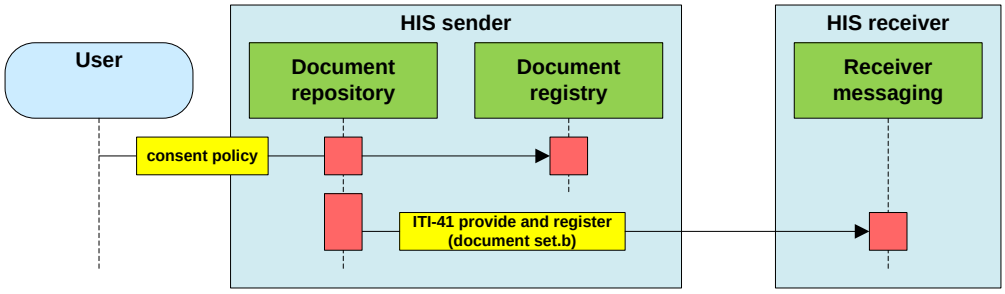

Figure 6-7 – Point-to-point interaction to exchange consent using IHE XDR at HIS-IF

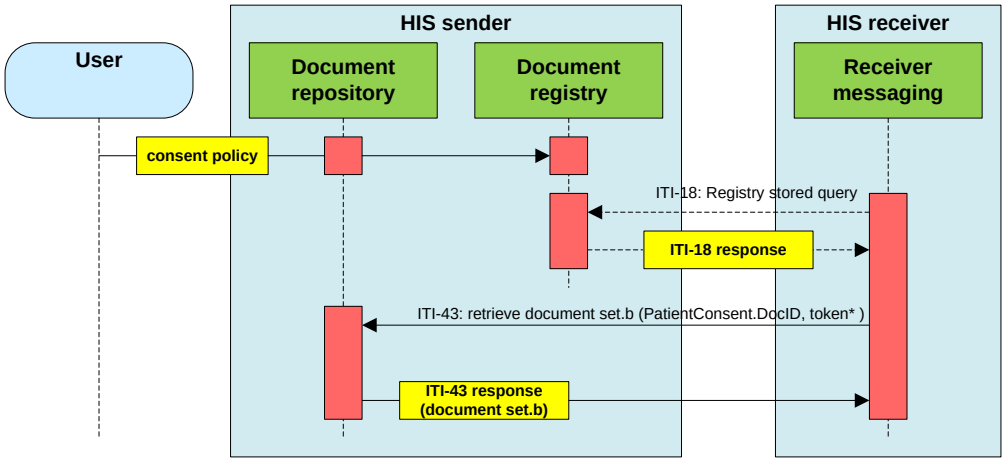

Figure 6-8 – Request-response interaction to obtain consent using IHE XDS at HIS-IF

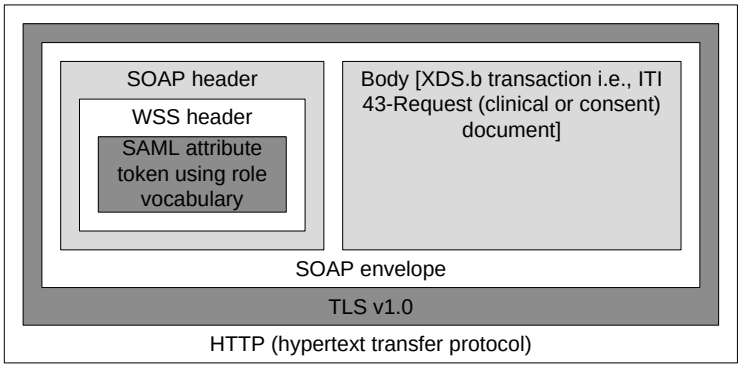

Figure 6-9 – SAML encapsulation and the overall protocol stack

6.1.9 Consent enforcement

The CDG enable the enforcement of patient consent through encryption on a Consent Enabled HIS device. The Consent Enabled HIS Sender is an HIS Sender that is capable of specifying patient consent according to HL7 CDA R2 Consent Directive [HL7 CDA IG], encrypting the PHMR document for a recipient(s) and transmitting them on the HIS-IF. The Consent Enabled HIS Receiver is an HIS Receiver that is capable of receiving patient consent document and encrypted PHMR document.

The IHE Document Encryption (DEN) profile is used to enable consent enforcement through encryption. IHE DEN enables encryption of a PHMR document for a specific recipient (e.g., doctor or nurse) at the Consent Enabled HIS Receiver. This protects the privacy of the patient in an efficient manner and makes sure that the PHMR document is viewed only by the intended recipient. This prevents the viewing of the PHMR document by other individuals who may be working in the same organization e.g., administrative staff.

Figure 6-10 provides an overview of different steps in order to exchange encrypted PHMR document(s) on the HIS-IF using IHE XDR profile. The only new feature that is added compared to Figure 12-7 (i.e., consent management guidelines) is the encryption of the PHMR document(s). The Consent Enabled HIS Sender has to at least support PKI based key management method from the IHE DEN profile. It means that the content encryption key is encrypted with the public key of the recipient. The Consent Enabled HIS Sender may also support other key management methods such as password based. However, the Consent Enabled HIS Receiver is required to support all key management methods specified in the IHE DEN profile. Before encrypting a PHMR document, the Consent Enabled HIS Sender has to construct the XDS metadata for the PHMR document. A submission set is created which consists of a encrypted PHMR document and patient consent document. The submission set is then transported using the IHE XDR profile (i.e., ITI-41 Provider and Register Document Set.b).

Figure 6-11 shows the application of the IHE DEN profile during the request/response interaction in order to enable patient consent enforcement. The requester is being authenticated and the patient consent is being evaluated. If the result of the authentication and the evaluation of patient consent are positive, then a personalized consent document is created based on the functional role of the requester. The PHMR document is then encrypted for the requester and a submission set is created which consists of a personalized consent document and encrypted PHMR document. The submission set is then being transported through an ITI-43 Response transaction.

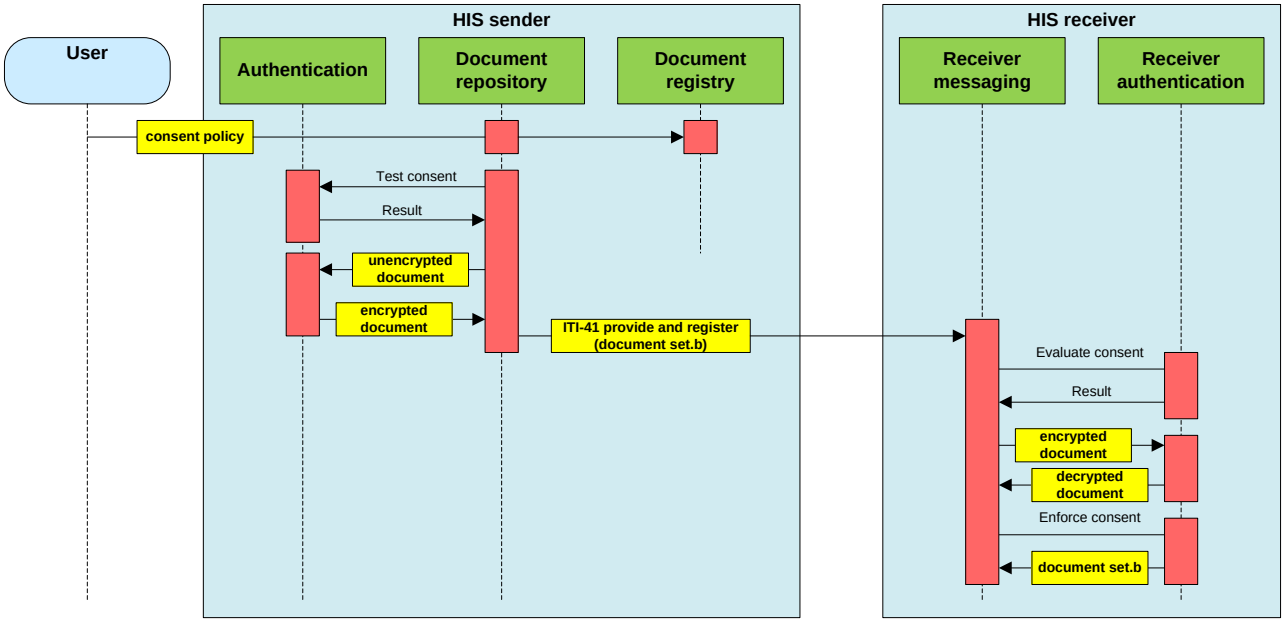

Figure 6-10 – Point-to-point interaction to exchange encrypted PHMR documents along with consent using IHE XDR at HIS-IF[1]

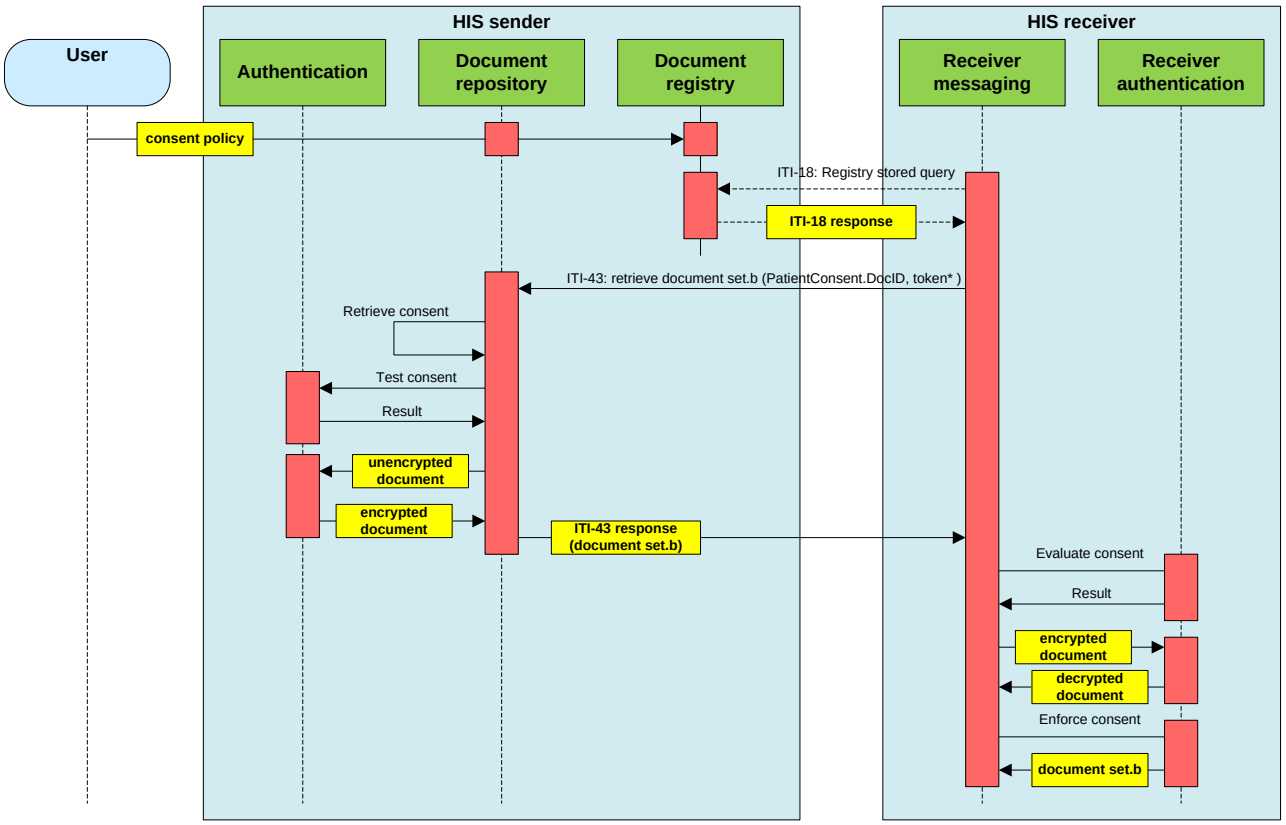

Figure 6-11 – Request-response interaction to obtain encrypted PHMR document along with consent document using IHE XDS at HIS-IF[2]

[1] The grey items have already been specified in previous version of the CDG.
[2] The grey items have already been specified in the previous version of the CDG.

6.1.10 Delivery of PHM information via ONC DIRECT

Guidance for implementations that elect to deliver CDG-compliant data from PHDs while meeting the United States' ONC's Meaningful Use requirements is found in clause V.1.

6.1.11 Certified device capabilities

Table 6-1 shows the Device Capabilities defined for the HIS-IF Interface Design Guidelines. At this time the Certification programme described in document H.810 only provides certification for software components implementing HIS Sender functionality. In contrast to the PHD interface, the HIS Sender certification can apply to just a software implementation and does not require integration into an entire system.

NOTE – HIS capability classes and respective guidelines for national and regional systems can be found in Appendix V.

Table 6-1 – HIS capability classes

	Network messaging
HIS Sender Device - Direct Communication	Yes
HIS Receiver Device - Direct Communication	Not certified
HIS Sender Device - Indirect Communication	Yes
HIS Receiver Device - Indirect Communication	Not Certified
Non-Repudiation Enabled HIS Sender Device	Yes
Non-Repudiation Enabled HIS Receiver Device	Not certified
Consent Enabled HIS Sender Device- XDR	Yes
Consent Enabled HIS Receiver Device- XDR	Not certified
Consent Enabled HIS Sender Device- XDS.b	Yes
Consent Enabled HIS Receiver Device- XDS.b	Not certified

The guidelines that are applicable for each of the HIS certified capability classes are shown in Table 6-2. Capability classes are referenced in Even though receivers on the HIS interface are not currently certified (see Clause 0.5), they can certainly be implemented by adhering to the appropriate guidelines indicated in table 12-2.

Table 6-2 – Guidelines for HIS capability classes

	Relevant Guidelines
HIS Receiver Device - Direct Communication	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1
HIS Sender Device - Direct Communication	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1
HIS Receiver Device - Indirect Communication	6.2.2.2, 6.2.3.2, 0, 6.2.4, 6.2.5.2
HIS Sender Device - Indirect Communication	6.2.2.2, 6.2.3.2, 0, 6.2.4, 6.2.5.2
Non-Repudiation Enabled HIS Sender Device	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.3

	Relevant Guidelines
Non-Repudiation Enabled HIS Receiver Device	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1 , Table 6-16
Consent Enabled HIS Sender Device- XDR	6.2.2.1**,** 6.2.3.1**,** 0, 6.2.4, 6.2.5.1, Table 6-17, Table 6-21
Consent Enabled HIS Receiver Device- XDR	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1, Table 6-18, Table 6-22
Consent Enabled HIS Sender Device- XDS.b	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1, Table 6-23
Consent Enabled HIS Receiver Device- XDS.b	6.2.2.1, 6.2.3.1, 0, 6.2.4, 6.2.5.1, Table 6-20, Table 6-24

6.2 Design guidelines

6.2.1 Introduction

The following clauses detail the specific rules, restrictions and guidelines for the Continua HIS interface.

In these requirements, the HIS Sender refers to a Continua HIS-IF client component, and the HIS Receiver refers to a Continua HIS-IF service component. The component naming was preserved for clarity.

6.2.2 Messaging infrastructure and transport guidelines

6.2.2.1 Requirements for direct communications via XDR

Table 6-3 – Requirements for HIS transport using XDR

Name	Description	Comments
HIS-Message-Infrastructure-Profile	Continua HIS Senders and Receivers **shall** use the IHE XDR profile, for the transfer of messages between the HIS Sender and HIS Receiver	
HIS-Message-Infrastructure-Protocol	Continua HIS Senders and Receivers **shall** use HTTP and SOAP 1.2 for Internet connectivity	

Name	Description	Comments
HIS-Message-Infrastructure-Init-Connection	A Continua HIS Sender **shall** initiate the connection to the HIS Receiver	
HIS-Message-Infrastructure-Internet	Continua HIS Receivers **shall** be reachable from their HIS Senders. Therefore, the HIS Receiver either **shall** be on the same secure network as the HIS Sender or **shall** be on a network connected to the HIS Senders network across a secure connection or **shall** be Internet-facing (i.e., reachable from the Internet)	
HIS-Message-Infrastructure-Sender-Topology	Continua HIS Senders **shall** connect to one or multiple HIS Receivers, sending only the relevant messages to each	This does not require connecting to multiple HIS Receivers at the same time
HIS-Message-Infrastructure-Receiver-Topology	Continua HIS Receivers **shall** be able to receive messages from multiple HIS Senders concurrently	
HIS-Messaging-Infrastructure-Transport-Mode-Supported	Continua HIS Senders and Receivers **shall** utilize the XDR "on-line" mode of operation	The "on-line" mode is the v1 methodology
HIS-Messaging-Infrastructure-Transport-Mode-Not-Supported	Continua HIS Senders and Receivers **shall not** utilize the XDR "off-line" mode of operation	The "off-line" mode is not supported for the v1 HIS interface

6.2.2.2 Requirements for indirect communications via XDM

Table 6-4 – Requirements for HIS transport using XDM

Name	Description	Comments
HIS-Indirect-Message-Infrastructure-Profile	Continua HIS Indirect Communication Senders and Receivers **shall** implement the IHE XDM integration profile, for the indirect transfer of messages between the HIS Sender and HIS Receiver	
HIS-Indirect-Message-Infrastructure-Protocol	Continua HIS Senders and Receivers **shall** implement the ZIP over Email transport option	
HIS-Indirect-Message-Infrastructure-Privacy	Continua HIS Senders and Receivers **should** implement the "Basic Patient Privacy Enforcement" option	
HIS-Indirect-Message-Infrastructure-Response	Continua HIS Senders and Receivers **may** implement the "Zip over Email Response" option	
HIS-Indirect-Message-Infrastructure-Init-Connection	A Continua HIS Sender **shall** initiate the communication with the HIS Receiver	
HIS-Indirect-Message-Infrastructure-Sender-Topology	Continua HIS Senders **shall** communicate with one or multiple HIS Receivers, sending only the relevant messages to each	This allows, but does not require, communicating with multiple HIS Receivers at the same time

6.2.3 Messaging guidelines

6.2.3.1 Messaging guidelines for direct communications via XDR

Table 6-5 – General messaging guidelines

Name	Description	Comments
HIS-Messaging-Document-Source-Standard	Continua HIS Senders **shall** implement the Document Source Actor of the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile for sending PHM data	Primary v1 messaging/transport is based on IHE XDR profile and its referenced standards
HIS-Messaging-Document-Recipient-Standard	Continua HIS Receivers **shall** implement the Document Recipient Actor of the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile for receiving PHM data	Primary v1 messaging/transport is based on IHE XDR profile and its referenced standards
HIS-Messaging-Mode-Supported	Continua HIS Senders and Receivers **shall** utilize the XDR "on-line" mode of operation	The "on-line" mode is the methodology
HIS-Messaging-Mode-Not-Supported	Continua HIS Senders and Receivers **shall not** utilize the XDR "off-line" mode of operation	The "off-line" mode is not supported for the HIS interface
HIS-Messaging-Transport-Exclusivity	Continua HIS Senders and Receivers **shall** utilize the transport mechanisms as defined in the XDR profile for all PHM exchanges	

Name	Description	Comments
HIS-Messaging-Message-Scope	The Continua HIS Sender application **should not** include information that is not present within the PHM Report	This requirement is necessary since the primary usage of message is designed to only transmit PHM information
HIS-Messaging-Meta-Data	The Continua HIS Sender XDR meta-data **shall** be consistent with the included PHM Report and its attachments	This is to ensure that any preprocessing based on the XDR meta-data is consistent with the PHM payload. Of primary concern are the patient ID, the document ID, and the originator ID
HIS-Messaging-Atomic-Transaction	The Continua HIS Sender and Receiver exchange of the PHM document transaction **shall** be atomic in that it may only succeed or be "rolled back" in its entirety if it fails	The state and condition of both the sender and the receiver must be maintained in a consistent manner regardless of the success of the exchange. This also means that this transaction is complete and not dependent on another transaction to send the intended data

6.2.3.2 Messaging guidelines for indirect communications via XDM

Table 6-6 – General messaging guidelines

Name	Description	Comments
HIS-Indirect-Message-Sender	The Continua HIS Sender **shall** implement the Portable Media Creator actor of the XDM profile	
HIS-Indirect-Message-Receiver	The Continua HIS Receiver **shall** implement the Portable Media Importer actor of the XDM profile	
HIS-Indirect-Messaging-Document-Source-Standard	Continua HIS Indirect Communication Senders **shall** implement the Portable Media Creator of the Cross-Enterprise Document Media Interchange (XDM) Integration Profile for sending PHM data	
HIS-Indirect-Messaging-Message-Scope-One-Report	The Continua HIS Sender **shall** include exactly one Submission Set, including one PHM Report document and associated metadata in the "Zip over Email" attachment	XDM allows for multiple documents and multiple patients to be sent. The CDG further restrains this to one PHM document on one patient, with all related attachments
HIS-Indirect-Messaging-Message-Scope	The contents of the submission set sent by the Continua HIS Sender **shall** be related to the same patient	XDM Distribute Document Set on Media Transaction does not require that all the submission sets included in the media are relative to the same patient

Name	Description	Comments
HIS-Indirect-Messaging-Document-Source-Directory-Structure	The Continua HIS Sender **shall** name the Submission Set directory that includes PHM Report "SUBSET01"	
HIS-Indirect-Messaging-Attachment-Scope-Allowed-Content	The Continua HIS Sender application **shall** include in the submission set ZIP file only the information that is relevant to the information within the PHM Report	This requirement is necessary since the primary usage of message is designed to only transmit PHM information
HIS-Indirect-Messaging-Message-Scope-Allowed-Content	The Continua HIS Sender **shall** only include in the submission set files and directories that are required to transfer the submission set containing the PHM report and optional XML style sheet used to render the PHM report	There should not be contents that the HIS Receiver would have to ignore. Especially, the attachment shall not include any executable files
HIS-Indirect-Messaging-Message-Scope-Restricted-Content	The Continua HIS Sender **shall not** include in the submission set executable files and files that are configured to start automatically	Security related (executable files are allowed by XDM) Even when the PHM Report would reference such a file, and thus it would be allowed in the submission set – this is restricted and shall not be submitted

Name	Description	Comments
HIS-Indirect-Messaging-Meta-Data	The Continua HIS Sender XDM meta-data **shall** be consistent with the included PHM Report and its attachments	This is to ensure that any preprocessing based on the XDM meta-data is consistent with the PHM payload. Of primary concern are the patient ID, the document ID, and the originator ID
HIS-Indirect-Messaging-Meta-Data-Compatibility	The Continua HIS Indirect Sender XDM **shall** include all information in the XDM meta data that is required by the HIS Direct Sender XDR	This means Register Document Set-b [ITI-42] metadata as required by the XDR specification in [IHE ITI TFS XDR]. The XDM would allow also the Register Document Set [ITI-14] of [IHE ITI TFS XDR], which may not be XDR compatible
HIS-Indirect-Messaging-Atomic-Transaction	The Continua HIS Sender and Receiver exchange of the PHM document transaction **shall** be atomic in that the included PHM report is complete and that none of the content relies on content from other messages in order to be understood	

Name	Description	Comments
HIS-Indirect-Message-Infrastructure-Internet	A Continua HIS Sender **shall** either export the PHM "Zip over E-Mail" media as a one ZIP file or create an email with the PHM report attached as a ZIP file using internal E-Mail processing	This gives the sender flexibility to either create the email with the attachment or export the ZIP package for manual attachment to an email
HIS-Indirect-Message-Infrastructure-Internet-Email	If the Continua HIS Sender exports the "Zip over E-Mail" it **shall** include the PHM report in the media that comply with the requirements of the XDM media format as a single-file ZIP package that can be attached to an email message	
HIS-Indirect-Message-Infrastructure-Internet-Attachment	If the Continua HIS Sender creates an email with the XDM submission set attached, the submission set **shall** contain the PHM report in the prescribed format	
HIS-Indirect-Message-Infrastructure-Manual-Auditing	If a Continua HIS Sender is used by a person manually creating the XDM "Zip over E-Mail" media, the HIS Sender **shall** maintain an audit log of PHM documents exported for delivery that adheres to the IHE ATNA Auditing related clauses as defined for XDM	Auditing ATNA "Export" is required for the XDM. See the link in Clause 0 for more details on ATNA [OASIS WS-I RM].The manual E-Mail option could skip the auditing step. This would not be a compliant or complete implementation

Name	Description	Comments
HIS-Indirect-Messaging-Infrastructure-Acknowledgement-Receiver	Continua HIS Receivers **may** send the HIS Sender an indirect acknowledgement that the HIS Sender message was received and processed using the "Zip over Email Response" option	This corresponds to the protocol option Zip over Email Response. For XDM, acknowledgement are recommended, but never required
HIS-Indirect-Messaging-Infrastructure-Acknowledgement-Sender	If the Zip over Email Response" option is used the Continua HIS Senders **should** send the document ID in the email subject line in addition to the required subject XDM/1.0/DDM in the format: XDM/1.0/DDM/DocumentID	The document ID format is ASCII text. There is no failure handling mechanism beyond what standard email provides, and no consistent time-out standard is possible due to variability of how people read email. Any concerns over if a message was received should be handled manually
HIS-Indirect-Messaging-Infrastructure-Acknowledgement-Subject	If the Continua HIS Receiver sends indirect acknowledgement using the Zip over Email Response" option, the response message **should** include the subject line of the original email message	The acknowledgment email subject should contain the exact contents of the original email's subject, prefixed by "RE:" (the way typical email replies are handled) NOTE: Email return receipt only assures that the email was correct, not that the attachment was readable or successfully imported. These require a further acknowledgement from the importer

6.2.3.3 Messaging guidelines applicable to both direct and indirect communications

Table 6-7 – PHM attachments guidelines

Name	Description	Comments
HIS-PHM-Attachments-Attachment-Completeness	Continua HIS Senders **shall** communicate all attachments referenced or contained in the PHM Report document	
HIS-PHM-Attachments-Message-Completeness	Continua HIS Senders **shall** communicate all attachments specified in the PHM Report in the same message	

Table 6-8 – Patient identity mapping guidelines

Name	Description	Comments
HIS-Patient-Identity-Mapping	Continua HIS Senders **shall** implement the Patient Identity Source actor of IHE ITI-44: Patient Identity Feed HL7 V3 in order to submit new patient identifiers to the HIS receiver or third party exchanges	
HIS-Device-Registration	Continua HIS Senders **may** implement the Patient Identity Source actor of IHE ITI-44: Patient Identity Feed HL7 V3 in order to submit new device registration to the HIS receiver or third party exchanges	
HIS-Patient-Identity-Query	Continua HIS Senders and Receivers **may** implement the Patient Identifier Cross-reference Consumer actor of the IHE ITI-45: PIXV3 Query transaction in order to map between their local identifiers and the identifiers used for exchange	

Name	Description	Comments
HIS-Patient-Demographics-Query	Continua HIS Receivers **may** implement the Patient Demographics Consumer actor of the IHE ITI-47: Patient Demographics Query HL7 V3 transaction, using the patient name and demographics in order to correlate the record with its own local identifiers	

Table 6-9 – Quality of service guidelines

Name	Description	Comments
HIS-Transport-QoS-Best.Veryhigh	Continua HIS Senders and Receivers **shall** implement the Continua *best.veryhigh* QoS bin using TCP as specified in Clause 2, Basic Functionality of [IETF RFC 4614], Clause 2: 1. [IETF RFC 793] 2. [IETF RFC 1122] 3. [IETF RFC 2460] 4. [IETF RFC 2581] 5. [IETF RFC 2873] 6. [IETF RFC 2988]	

6.2.4 Data guidelines

Table 6-10 – General data format guidelines

Name	Description	Comments
HIS-Data-Standard	Continua HIS Sender and Receiver data format **shall** comply with [HL7 CDA-PHM]	

Name	Description	Comments
HIS-Data-Subject-Identity	Continua HIS Senders **shall** uniquely identify patient within for the HIS Receiver domain in the `/ClinicalDocument/recordTarget` element	Assuring that Patient ID is understood in the receiver
HIS-Data-Receiver-Identity	A Continua HIS Sender **shall** identify HIS Receiver within the `/ClinicalDocument/informationRecipient` element	
HIS-Data-Receiver-As-Custodian	A Continua HIS Sender **shall** specify `/ClinicalDocument/custodian` element	The receiver becomes a custodian of the document (Element Required in CDA)
HIS-Data-Author-Organization-Identity	Continua HIS Senders **shall** identify the organization associated with HIS Sender as the author of the PHM document in the `/ClinicalDocument/author/assignedAuthor/representedOrganization` element	
HIS-Data-Author-Device-Identity	Continua HIS Senders **should** identify the Personal Health Gateway/ Heath and Fitness Service in the role of HIS Sender in the `/ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice` element	

Name	Description	Comments
HIS-Data-Document-Identity	Continua HIS Senders **shall** assign the document unique identifier in the `/ClinicalDocument/id` element according to guidelines for HL7 CDA documents [HL7 CDA]	CDA specification uses II (instance identifier) composed of a root and extension
HIS-Data-Measurement-Units	Continua HIS Sender data format **shall** interpret the UCUM Units of measure according to mapping in Tables V-1, V-2 and V-3.	
HIS-Data-Original-Data-Authoring-Device-Identity	For all original data, Continua HIS Senders **shall** include a reference to originating personal health device identified by Unique Device Identifier	To comply with the in recommendation [b-CHA UI]. Continua devices use EUI-64 device identifier
HIS-Data-Processed-Data-Author-Identity	For processed data, Continua HIS Senders **should** include a reference to the device that processed the data	NOTE - This may propagate up to the authoring device as defined in HIS-Data-author-device-identity Recommended by [b-CHA UI]
HIS-Data-Coding-Snomed	Continua HIS sender **shall** use SNOMED CT coding for device data as identified in, Tables V-1, V-2 and V-3.	The effort was made to map all clinical data types and most events / alerts into SNOMED CT

Name	Description	Comments
HIS-Data-Coding-Mdc	Continua HIS sender **shall** use original MDC coding for device data that does not have identified SNOMED CT code in Tables V-1, V-2 and V-3.	Some events and alerts
HIS-Data-Coding-Unencoded-Bitmaps	Continua HIS sender **should** use local coding agreed upon with HIS receiver for device data that does not have either identified MDC or SNOMED CT code in Tables V-1, V-2 and V-3.	For example bitmap coded device data, manufacturer-specific error codes. HIS sender may also choose not to send such data. HIS receiver must gracefully handle cases when the coding is not supported
HIS-Data-Coding-Legacy-And-Manual-Data	Continua HIS sender **shall** transfer data from devices that do not provide MDC codes and manually entered data using SNOMED CT coding, and if available using codes in the SNOMED-CT mapping in Tables V-1, V-2 and V-3.	To allow data from devices that do not provide MDC codes still to be transferred using SNOMED CT as if they were manual entries

6.2.4.1 Data guidelines for devices related to medication delivery

Table 6-11 – General medication delivery guidelines

Name	Description	Comments
HIS-Data-Medication-Section	If medication delivery data is communicated, the Continua HIS Sender **shall** report the medication delivery in Medications section (CCD templateId 2.16.840.1.113883.10.20.1.8)	The HL7 PHM Report [HL7 CDA-PHMR] covers the Vital Signs and Results. This section adds the medication delivery guidelines. Based on HL7 PHM Report: This section if present SHALL conform to all the constraints specified in CCD
HIS-Data-Medication-Exclusive-Section	If Continua HIS Sender is only submitting medication data and not submitting data in the Vital Signs nor the Result Sections, the HIS Sender **shall** include an empty "Vital Signs" section that contains a text element noting this fact	To comply with the HL7 PHM Report guideline [HL7 CDA-PHMR].
HIS-Data-Medication-Substance-Administration	The Continua HIS Sender **shall** represent the medication delivery activity as the SubstanceAdministration	CCD Section 3.9.2.1.1 Medication activity [HL7 CDA-CCD].
HIS-Data-Medication-Substance-Administration-Event	In the Continua HIS Sender submitted data the value for "SubstanceAdministration / @moodCode" in a medication activity **shall** be "EVN"	

Name	Description	Comments
HIS-Data-Medication-Consumable	In the Continua HIS Sender submitted data the medication definition **shall** be implemented as `SubstanceAdministration /consumable`, the target of which is a product template in accordance with the PHM Report specification	To comply with the CCD template. The coding system shall be based on regional needs of the HIS Sender and Receiver. There is no universal medication coding
HIS-Data-Medication-Substance-Administration-Code	In the Continua HIS Sender submitted data the value for the `SubstanceAdministration /code` **shall** contain the original MDC code if code is reported from the device	
HIS-Data-Medication-Device-Specific-Attributes	The Continua HIS Sender **shall** transmit a device-specific attribute with no semantic CDA equivalent, as an entryRelationship containing an observation where observation/code contains the attribute type and observation/value contains the attribute value	An example is fast bolus delivery vs. slow bolus delivery. An attribute "fast" can be added using an observation linked via entryRelationship to a Substance administration

Name	Description	Comments
HIS-Data-Medication-Originating-Device-Specification	The Continua HIS Sender **shall** represent the medication delivery device as the participant element of the Substance Administration conforming to the constraints of a PHMR Product Instance Reference	PHM Report IG: Chapter 3.5.4 PHMR Product Instance Reference Also to comply with guideline: HIS-Data-original-data-authoring-device-identity [HL7 CDA-PHMR]

Table 6-12 – Adherence monitor specific guidelines (separate from general medication guidelines)

Name	Description	Comments
HIS-Data-Coding-Dosage-Dispensed	Continua HIS Sender and Receiver data format **shall** contain SubstanceAdministration/effectiveTime, SubstanceAdministration/doseQuantity, SubstanceAdministration/consumable, and SubstanceAdministration/routeCode elements at a minimum	
HIS-Data-Medication-Delivery-Route	In the Continua HIS Sender submitted data, the value for "SubstanceAdministration / routeCode" in a medication activity **shall** be one of the delivery routes From the HL7 RouteOfAdministration (2.16.840.1.113883.5.112) code system	For example, ingestion by swallowing orally is "PO" (internalId: 14735)
HIS-Data-Coding-Dosages-Scheduled-(Regimen)	Continua HIS Sender and Receiver data format **shall** use an HL7 substanceAdministration entry with a classCode of "SBADM" and a moodCode of "INT" for encoding dosage dispensed events in the PHRM	Restriction on the CCD template

Name	Description	Comments
HIS-Data-Coding-Question-Responses	Continua HIS Sender and Receiver data format **shall** comply with [HL7 CDAR2-QA] (Universal Realm) for encoding question and response events in the PHRM	
HIS-Data-Coding-Question-Responses-Code-Systems	Continua HIS Sender and Receiver Observation/code **may** be selected from LOINC codeSystem 2.16.840.1.113883.6.1, or SNOMED CT codeSystem 2.16.840.1.113883.6.96, or International Classification of Functioning, Disability and Health (ICF) codeSystem 2.16.840.1.113883.6.254, and/or a local code system that identifies the question/response in a manner that is agreed to by the collaborating parties	Preference is for reuse of existing question/response code schemes, but allowance is made for rapid expansion and local schemes. This guideline is relaxed with the Framework for Questionnaire Assessments specification

6.2.5 Security guidelines

6.2.5.1 Security guidelines for direct communications via XDR

Table 6-13 – General security guidelines

Name	Description	Comments
HIS-Security-Communication	Continua HIS Senders and Receivers **shall** ensure all direct communication is done via specified XDR secure mechanism	
HIS-Security-Authentication	Continua HIS Senders and Receivers **shall** use a prior agreed upon XDR mechanism to ensure authentication	
HIS-Security-Auditing1	Continua HIS Senders and Receivers **shall** implement and adhere to Audit Trail and Node Identification (ATNA) clauses of the XDR profile	
HIS-Security-Cipher	Continua HIS Senders and Receivers **should** use an encryption cipher suite of TLS-RSA-WITH-AES-128-CBC-SHA	

6.2.5.2 Security guidelines for indirect communications via XDM

Table 6-14 – General security guidelines

Name	Description	Comments
HIS-Security-Communication	The secure communication between Continua Sender and Receiver is guided by: **HIS-Indirect-Message-Infrastructure-privacy** guideline (see Table 6-4)	
HIS-Security-Authentication	Continua HIS Senders and Receivers **shall** use a prior agreed upon mechanism to ensure authentication	Authentication is of both sender and receiver
HIS-Security-Auditing	The auditing of interaction between Continua HIS Sender and Receiver is guided by: HIS-Indirect-Message-Infrastructure-manual-auditing guideline (see Table 6-6)	

6.2.5.3 Security guidelines for integrity, data origin authentication and non-repudiation

NOTE - Other guidelines that are applicable for the Non-Repudiation Enabled HIS Sender and Receiver are mentioned in Table 6-2.

Table 6-15 – Integrity, data origin authentication and non-repudiation HIS sender guidelines

Name	Description	Comments
HIS-Sender-Sign	Non-repudiation Enabled HIS Sender **shall** sign PHMR document(s) according to IHE Document Digital Signature Content Profile	
HIS-Sender-Signature-Algorithm	Non-repudiation Enabled HIS Sender **shall** use RSA-SHA256 as the signature algorithm	[FIPS PUB 180-4] (using the cyphers compatible with [b-FIPS PUB 180-2])

Table 6-16 – Integrity, data origin authentication and non-repudiation HIS receiver guidelines

Name	Description	Comments
HIS-Receiver-Verify	Non-repudiation Enabled HIS Receiver **shall** verify PHMR document(s) according to the IHE Documents Digital Signature Content Profile and only accept documents that pass the signature verification	
HIS-Receiver-Verification-Algorithm	Non-repudiation Enabled HIS Receiver **shall** support RSA-SHA256 signature algorithm	

6.2.6 Consent management guidelines

NOTE - Other guidelines that are applicable for the Consent Enabled HIS Sender and Receiver are mentioned in Table 6-2.

6.2.6.1 Security guidelines for consent management

Table 6-17 – Consent management guidelines for consent enabled HIS sender via XDR

Name	Description	Comments
HIS-Sender-Consent-Document-Format-XDR	Consent enabled HIS Sender **shall** comply with [HL7 CDA IG] to represent patient consent in a consent document	
HIS-Sender-Consent-Clinical-Document(s)-ConfidentialityCode-XDR	Consent Enabled HIS Sender **shall** set the confidentiality code value to "R" in the header of the PHMR document	

Name	Description	Comments
HIS-Sender-Consent-Clinical-Document(s)-Association-XDR	To associate PHMR documents(s) with the patient consent document, Consent Enabled HIS Sender **shal**l use the translation element of the Confidentiality code system as defined in Table I-8	Consult Table I-6 for the elements of the confidentiality code system Consult Table I-7 for the elements of the Continua consent directive code system Consult Table I-9 for the Continua assigned OIDs
HIS-Sender-Consent-Transport-XDR	Consent Enabled HIS Sender **shall** use IHE XDR profile to send a consent document along with PHMR document(s)	The consent document and PHMR document(s) could be sent in the same submission set of the ITI-41 Provider and Register Document Set.b transaction
HIS-Sender-Consent-Personlization-XDR	Consent Enabled HIS Sender **may** personalize permissions in the consent document based on the identity or roles of the requester and/or jurisdictional and organizational security policies	The roles are indicated by an SAML attribute token. An example of personalization is the creation of a modified consent document with the permissions and authorizations based on the role of requester (e.g., doctor or nurse)
HIS-Sender-Audit-log-XDR	Consent Enabled HIS Sender **should** create audit events and send to audit repository using IHE ATNA in case of the occurrence of the following events: Release of PHMR document(s) Release of consent document(s)	IHE ATNA is covered by HIS Security guideline named as: HIS-Security-Auditing1

Table 6-18 – Consent management guidelines for consent enabled HIS receiver via XDR

Name	Description	Comments
HIS-Receiver-Consent-Format-XDR	Consent Enabled HIS Receiver **shall** be able to receive, interpret and enforce HL7 CDA R2 Consent Directive patient consent document(s) [HL7 CDA IG]	
HIS-Receiver-Consent-Transport-XDR	Consent Enabled HIS Receiver **shall** use the IHE XDR profile to receive a consent document	The consent document could be received through the ITI-41 Provider and Register Document Set.b transaction alone or with the PHMR document(s) in the same submission set

Table 6-19 – Consent management guidelines for consent enabled HIS sender via XDS.b

Name	Description	Comments
HIS-Sender-Consent-Document-Format-XDS.b	Consent enabled HIS Sender **shall** comply with [HL7 CDA IG] to represent patient consent in a consent document	
HIS-Sender-Source-Actor	Consent Enabled HIS Sender **shall** implement the document source actor of the IHE XDS.b profile	The source actor consequently supports the ITI-41 Provider and Register Document Set.b transaction
HIS-Sender-Repository-Actor	Consent Enabled HIS Sender **shall** implement the document repository actor of the IHE XDS.b profile	

Name	Description	Comments
HIS-Sender-Registry-Actor	Consent Enabled HIS Sender **shall** implement the document registry actor of the IHE XDS.b profile	Enables query and lookup of PHMR and consent documents through IHE ITI-18 registry stored query transaction
HIS-Sender-Consent-Clinical-Document(s)-ConfidentialityCode-XDS.b	Consent Enabled HIS Sender **shall** set the confidentiality code value to "R" in the header of the PHMR document	
HIS-Sender-Consent-Clinical-Document(s)-Association-XDS.b	To associate PHMR documents(s) with the patient consent document, Consent Enabled HIS Sender **shall** use the translation element of the Confidentiality code system as defined in Table I-8	Consult Table I-6 for the elements of the confidentiality code system Consult Table I-7 for the Continua consent directive code system Consult Table I-9 for the Continua assigned OIDs
HIS-Sender-Publishing-Repository	Consent Enabled HIS Sender **shall** make consent documents available in the document repository	See also HIS-Sender-Repository-Actor guideline
HIS-Sender-Publishing-Registry	Consent Enabled HIS Sender **shall** publish the XDS metadata for the published consent documents in the document registry	See also HIS-Sender-Registry-Actor guideline. This enables the search of the PHMR documents for a specific patient

Name	Description	Comments
HIS-Sender-Authentication	Consent Enabled HIS Sender **shall** authenticate the document consumer using the token as specified by IHE XUA in the request message	It facilitates the authentication of the user rather than the node and enables the personalization of consent documents. The authentication functionality is part of the document repository actor implemented on the HIS Sender. IHE XUA profile (ITI-18 Provide X-User Assertion) uses SAML token for authentication
HIS-Sender-Attribute-Authentication-	Consent Enabled HIS Sender **may** authenticate the document consumer actor based on attribute token as specified by IHE XUA++ profile	This is to support roles and RBAC (Role Based Access Control) IHE XUA++ profile uses SAML Attribute token. XUA++ refers to OASIS XSPA profile of SAML for healthcare
HIS-Sender-Response-Successful	Consent Enabled HIS Sender **shall** return patient consent document after successful authentication of the document consumer and successful verification that sending the document satisfies the patient consent policies	This is the positive response of the document repository actor after the reception of the retrieve document request according to ITI-43 Retrieve Document Set.b transaction

Name	Description	Comments
HIS-Sender-Response-Fail	Consent Enabled HIS Sender **shall** return a failure message if the document consumer fails to authenticate or document consumer fails to satisfy patient consent policies	This is a negative response from the document repository actor after the reception of the retrieve document request according to ITI-43 Retrieve Document Set.b transaction
HIS-Sender-Consent-Personlization-XDS.b	Consent Enabled HIS Sender **may** personalize permissions in the consent document based on the identity or roles of the requester and/or jurisdictional and organizational security policies	The roles are indicated by the SAML attribute token. An example of personalization is the creation of a modified consent document with the permissions and authorizations based on the role of requester (e.g., doctor or nurse)
HIS-Sender-Audit-log-XDS.b	Consent Enabled HIS Sender **should** create audit events and send to audit repository using IHE ATNA in case of the occurrence of the following events: Successful authentication Authentication failure Release of PHMR document(s) Release of consent document(s)	IHE ATNA is covered by HIS Security guideline named as: HIS-Security-Auditing1

Table 6-20 – Consent management guidelines for consent enabled HIS receiver via XDS.b

Name	Description	Comments
HIS-Receiver-Consent-Format-XDS.b	Consent Enabled HIS Receiver **shall** be able to receive, interpret and enforce [HL7 CDA IG] patient consent document(s)	
HIS-Receiver-Consumer-Actor	Consent Enabled HIS Receiver **shall** implement document consumer actor of IHE XDS profile for retrieving consent documents from the document repository of the Continua HIS Sender	ITI-43 Retrieve Document Set.b a transaction is used to retrieve the document set from the repository
HIS-Receiver-Registry-Query	Consent Enabled HIS Receiver **shall** use ITI-18 Registry Stored Query transaction to retrieve unique identifier(s) of a patient consent document	Use if the identifier and URL of the repository are unknown
HIS-Receiver-Authentication	Consent Enabled HIS Receiver **shall** authenticate to the Continua HIS Sender using a token as specified by IHE XUA (cross-enterprise user assertion) profile	Token is sent in ITI-43 Retrieve Document Request for PHMR and/or consent document. The token is placed in the SOAP header. IHE XUA profile uses SAML token for authentication

Name	Description	Comments
HIS-Receiver-Attribute-Authentication	Consent Enabled HIS Receiver **may** authenticate to the Continua HIS Sender using the attribute token as specified by IHE XUA++ profile	This is to realize role based access control IHE XUA++ uses SAML Attribute token. IHE XUA++ refers to the OASIS XSPA profile of SAML for healthcare

6.2.7 Consent enforcement design guidelines

NOTE - Other guidelines that are applicable for the Consent Enabled HIS Sender and Receiver are mentioned in Table 6-2.

6.2.7.1 Security guidelines for consent enforcement

Table 6-21 – Consent enforcement guidelines for consent enabled HIS sender via XDR

Name	Description	Comments
HIS-Sender-Content-Encryption-Actor-XDR	Consent Enabled HIS Sender **shall** encrypt PHMR document(s) in compliance with IHE Document Encryption (DEN) Profile	IHE DEN is based on CMS (Cryptographic Message Syntax) standard
HIS-Sender-Content-Encryption-Algorithm-XDR	Consent Enabled HIS Sender **shall** use AES-128 CBC for encryption of the document(s)	The algorithm used is identified through the ContentEncryptionAlgorithmIdentifier in CMS (Cryptographic Message Syntax)
HIS-Sender-Encryption-Recipient-Binding-PKI-XDR	Consent Enabled HIS Sender **shall** implement PKI based key management method from IHE DEN Profile	PKI based content key management method uses KeyTransRecipientInfo as CMS RecipientInfoType. This point to the public key or x.509 v3 certificate of the recipient

Name	Description	Comments
HIS-Sender-Encryption-Recipient-Binding-Other-XDR	Consent Enabled HIS Sender **may** implement other key management methods from IHE DEN Profile	

Table 6-22 – Consent enforcement guidelines for consent enabled HIS receiver via XDR

Name	Description	Comments
HIS-Receiver-Consent-Evaluation-XDR	Consent Enabled HIS Receiver **shall** evaluate consent before decrypting the encrypted PHMR document(s)	E.g., determining that the recipient is using a document for the purpose authorized by the consent document and/or required infrastructure is available for the consent enforcement
HIS-Receiver-Content-Decryption-Actor-XDR	Consent Enabled HIS Receiver **shall** comply with Content Consumer Actor of IHE DEN Profile to decrypt document(s)	
HIS-Sender-Encryption-Recipient-Binding-XDR	Consent Enabled HIS Receiver **shall** support all key management methods specified by the IHE DEN Profile	
HIS-Receiver-Content-Decryption-Algorithm-XDR	Consent Enabled HIS Receiver **shall** use AES-128 CBC decryption algorithm	The algorithm used is identified through the ContentEncryptionAlgorithmIdentifier in CMS (Cryptographic Message Syntax)
HIS-Receiver-Consent-Enforcement-XDR	Consent Enabled HIS Receiver **shall** enforce consent preferences expressed in the consent document	E.g., prevents further disclosure of the content to the unauthorized entities

Table 6-23 – Consent enforcement guidelines for consent enabled HIS sender via XDS.b

Name	Description	Comments
HIS-Sender-Publishing-PHMR-Repository-XDS.b	Consent Enabled HIS Sender **shall** make PHMR document(s) available in the document repository	
HIS-Sender-Publishing-Registry-XDS.b	Consent Enabled HIS Sender **shall** publish the XDS metadata for the published PHMR document(s) in the document registry	
HIS-Sender-Content-Encryption-Actor-XDS.b	Consent Enabled HIS Sender **shall** encrypt PHMR document(s) in compliance with IHE DEN Profile	
HIS-Sender-Response-Successful	Consent Enabled HIS Sender **shall** return encrypted PHMR document(s) after successful authentication of the document consumer and successful verification that sending the document satisfies the patient consent policies	The related consent management guidelines are: HIS-Sender-Authentication, HIS-Sender-Attribute-Authentication, HIS-Sender-Response-Successful and HIS-Sender-Response-Fail

Name	Description	Comments
HIS-Sender-Content-Encryption-Algorithm-XDS.b	Consent Enabled HIS Sender **shall** use AES-128 CBC for encryption of the PHMR document(s)	The algorithm used is identified through the ContentEncryptionAlgorithmIdentifier in CMS (cryptographic message syntax)
HIS-Sender-Encryption-Recipient-Binding-PKI-XDS.b	Consent Enabled HIS Sender **shall** implement a PKI based key management method from the IHE DEN profile	PKI based content key management method uses KeyTransRecipientInfo as CMS RecipientInfoType. This points to the public key or x.509 v3 certificate of the recipient
HIS-Sender-Encryption-Recipient-Binding-Other-XDS.b	Consent Enabled HIS Sender **may** implement other key management methods from the IHE DEN profile	

Table 6-24 – Consent enforcement guidelines for consent enabled HIS receiver via XDS.b

Name	Description	Comments
HIS-Receiver-Registry-Query-XDS.b	Consent Enabled HIS Receiver **shall** use ITI-18 Registry Stored Query transaction to retrieve unique identifier(s) of a patient PHMR document(s)	The ITI-18 has already been specified in the consent management guidelines. See the guidelines HIS-Sender-Registry-Actor and HIS-Receiver-Registry-Query
HIS-Receiver-Re-Query-XDS.b	Consent Enabled HIS Receiver **shall** use ITI-43 Retrieve Document Set.b transaction to retrieve PHMR document(s)	ITI-43 has already been specified in the consent management guidelines. See the guideline HIS-Receiver-Consumer-Actor

Name	Description	Comments
HIS-Receiver-Consent-Evaluation-XDS.b	Consent Enabled HIS Receiver **shall** evaluate consent before decrypting an encrypted PHMR document	E.g., determining that the recipient is using the document for the purpose authorized by the consent document and/or required infrastructure is available for the consent enforcement
HIS-Receiver-Content-Decryption-Actor-XDS.b	Consent Enabled HIS Receiver **shall** comply with Content Consumer Actor of the IHE Document Encryption Profile to decrypt PHMR document(s)	
HIS-Sender-Encryption-Recipient-Binding-XDS.b	Consent Enabled HIS Receiver **shall** support all key management methods specified by the IHE DEN Profile	
HIS-Receiver-Content-Decryption-Algorithm-XDS.b	Consent Enabled HIS Receiver **shall** use AES-128 CBC decryption algorithm	
HIS-Receiver-Consent-Enforcement-XDS.b	Consent Enabled HIS Receiver **shall** enforce the consent preferences expressed in the consent document	E.g., prevents further disclosure of the content to the unauthorized entities

Appendix I Messaging implementation and technology

(This appendix does not form an integral part of this Recommendation)

I.1 Overview

The XDR transaction (used for direct communication on the HIS interface) consists of the document source actor (HIS Sender) transmitting a SOAP message to the document recipient actor (HIS Receiver). Upon receipt, the document recipient actor replies by transmitting back an acknowledgement SOAP message.

For indirect HIS interface communication, XDM is used. XDM does not require the HIS Receiver to send back an acknowledgement. However, an indirect, non-technical acknowledgement of each XDM communication is **strongly recommended**. Furthermore, in the case of auto-generated email messages (where the HIS Sender creates an email message and attaches the ZIP file to it), it is **strongly recommended** that the subject of the message include a unique message identifier (not the patient ID) that can be included in the email acknowledgement and identify which message is being acknowledged. Regardless of the media delivery method employed (email, ftp, USB, CD-ROM, etc.), this non-technical acknowledgement **may** come in the form of an email (or email reply, if email was the original media delivery method), telephone call or other method acceptable to both communicating partners. If the message is sent via email, email acknowledgement is preferred. The unique message identifier can be as simple as a counter that starts with 1 on the first XDM message ever sent and increments from there with each new XDM message from that XDM Sender. It need not be unique across all XDM Senders, only for that one XDM Sender.

I.2 XDR and XDM metadata

The IHE profiles XDR and XDS organize their requirements based on concepts from the XDS family of profiles (of which XDR and XDM are members). Fundamentally, for the metadata, there are two primary pieces, the XDS Submission Set piece and the XDSDocumentEntry piece. The tables below show the HIS required entries for a conformant HIS transaction.

NOTE - While the profile discussions are in the terms below, when the actual SOAP envelope is constructed (for XDR messages); these terms are encoded in ebXML terms for electronic transfer.
References:

- Primary background is the IHE ITI TF-2 Clause 4.1 [b-IHE ITI TF 2 R4] IHE PCC working group mapping [b-IHE PCC TF 2]
- Implementation Guide for PHM Report Release 1.0 [HL7 CDA-PHMR]

Table I-1 – Element requirement

Code	Meaning
R	Required
R2	Required if known
O	Optional
N	Not Allowed

Table I-2 – XDS submission set metadata

NOTE - For the HIS-IF, the submission set may only contain a single PHM document.

Element	Req.	HIS PHM report mapping	Comments
availabilityStatus	(O)		See comment in the XDSDocumentEntry table
author	(R2)	/ClinicalDocument/author	See comment in the XDSDocumentEntry table
authorInstitution	(R2)	/ClinicalDocument/author/assignedAuthor/representedOrganization	
authorPerson	(O)	/ClinicalDocument/author/assignedAuthor/assignedPerson	
authorRole	(R2)	/ClincicalDocument/author/participationFunction	
authorSpecialty	(R2)	/ClinicalDocument/author/assignedAuthor/code	
comments	(O)		
contentTypeCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
contentTypeCodeDisplayName	(O)	"Subsequent evaluation" (R if contentTypeCode present)	The value of this element can be any value agreed upon by the two transaction participants
entryUUID	(R)	unique ID for submission set	
patientId	(R)	Mapped from /ClinicalDocument/recordTarget/patientRole/id	
sourceId	(R)	Unique OID assigned to the system that is submitting the submission set	
submissionTime	(R)	Message submission time	
title	(O)	/ClinicalDocument/title	
uniqueId	(R)	/ClinicalDocument/id	

Table I-3 – XDSDocumentEntry metadata

Element	Req.	HIS PHM report mapping	Comments
availabilityStatus	(O)		XDR and XDM are subsets of XDS that do not have Registry/Repository actors. Therefore, the requirement level is defined as "optional"

Element	Req.	HIS PHM report mapping	Comments
author	(R2)	/ClinicalDocument/author	Composed of sub-elements (defined below): - authorInstitution - authorPerson - authorRole - authorSpeciality
authorInstitution	(R2)	/ClinicalDocument/author/assignedAuthor/representedOrganization	
authorPerson	(R2)	/ClinicalDocument/author/assignedAuthor/assignedPerson	
authorRole	(R2)	/ClinicalDocument/author/assignedAuthor/code	
authorSpecialty	(R2)	/ClincicalDocument/author/participationFunction	
classCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
classCodeDisplayName	(O)		(R if classCode present) The value of this element can be any value agreed upon by the two transaction participants
Comments	(O)		
confidentialityCode	(R)	/ClinicalDocument/confidentialityCode	
confidentialityCodeDisplayName	(O)	/ClinicalDocument/confidentialityCode (R if confidentialityCode present)	
creationTime	(R)	/ClinicalDocument/effectiveTime	
entryUUID	(R)	unique ID for documentEntry	
eventCodeList	(O)	/ClinicalDocument/documentationOf/serviceEvent/code	
eventCodeDisplayNameList	(O)	(R if eventCodeList present)	
formatCode	(R)	"urn:continua:phm:2008"	
formatCodeDisplayName	(O)		
hash	(R)		
healthcareFacilityTypeCode	(R)		The value of this element can be any value agreed upon by the two transaction participants

Element	Req.	HIS PHM report mapping	Comments
healthcareFacilityTypeCodeDisplayName	(R)		(R if healthcareFacilityTypeCode present) The value of this element can be any value agreed upon by the two transaction participants
intendedRecipient	(O)	ClinicalDocument/intendedRecipient	
languageCode	(R)	/ClinicalDocument/languageCode	
legalAuthenticator	(O)	/ClinicalDocument/legalAuthenticator	Additional transformation is required as it is described in the mapping table
mimeType	(R)	text/xml	
parentDocument	(N)		Optional encoding, may come from[3]/ClinicalDocument/relatedDocument/parentDocument
parentDocumentId	(N)		Optional encoding may come from /ClinicalDocument/relatedDocument/parentDocument/id
parentDocumentRelationship	(N)		Optional encoding may come from /ClinicalDocument/relatedDocument/typeId
patientId	(R)	/ClinicalDocument/recordTarget/patientRole/id	
practiceSettingCode	(R)		The value of this element can be any value agreed upon by the two transaction participants
practiceSettingCodeDisplayName	(R)		(R if practiceSettingCode present) The value of this element can be any value agreed upon by the two transaction participants
serviceStartTime	(O)	/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low	Contained in PHM data
serviceStopTime	(O)	/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high	Contained in PHM data
size	(R)		

[3] What gets stored in the application may not be what gets sent. For example, version 1 is sent, version 2 is created but not sent, version 3 is created and sent. In this case, version 3 replaces version 1 in the "exchange", but version 2 in the application!

Element	Req.	HIS PHM report mapping	Comments
sourcePatientId	(R)	/ClinicalDocument/recordTarget/patientRole/id	
sourcePatientInfo	(R)	/ClinicalDocument/recordTarget/patientRole/id	
title	(O)	/ClinicalDocument/title	
typeCode	(R)	/ClinicalDocument/code/@code	
typeCodeDisplayName	(R)	/ClinicalDocument/code/@displayName	
uniqueId	(R)	/ClinicalDocument/id	
URI	(O)		Not used for HIS as there is no expectation of document retrieval

Table I-4 – XDS submission set metadata for the consent directive document

There are no additional constraints for the XDS submission set metadata for the consent directive document on the top of Table I-2

XDSDocumentEntry metadata requirements for consent directive documents are the same as those mentioned in Table I-3 for PHM documents, however with the exceptions in Table III-5.

Table I-5 – XDSDocumentEntry metadata for the consent directive document

Element	Req.	HIS PHM Report Mapping	Comments
classCode	(R)	57016-8	
codeSystem	(R)	2.16.840.1.113883.6.1	
codeSystemName	(R)	LOINC	
classCodeDisplayName	(O)	"Privacy Policy Acknowledgment Document"	
formatCode	(R)	"urn:continua:cd:2011"	

Table I-6 – The elements of the confidentiality code system

Name	Value	Comments
Code	"R"	
codeSystem	2.16.840.1.113883.5.25	
codeSystemName	"Confidentiality"	
displayName	"Restricted"	

Table I-7 – The elements of the Continua Consent Directive code system

Name	Value	Comments
Code	The value **shall** be the same as specified by [HL7 CDA IG].	
codeSystem	2.16.840.1.113883.3.1817 .1.2.1	

Name	Value	Comments
codeSystemName	"Continua Consent Directive"	
displayName	ID of the consent document	

Table I-8 – The translation of the Confidentiality code system to the Continua Consent Directive code system

Name	Value	Comments
Code	"R"	
codeSystem	2.16.840.1.113883.5.25	
codeSystemName	"Confidentiality"	
displayName	"Restricted"	
translation	code="<ID of the consent document>" codeSystem=2.16.840.1.113883.3.1817.1.2.1 codeSystemName="Continua Consent Directive" displayName=ID of the consent document	"<> " is a place holder for the ID of the consent document. Consult Table III-7 for the elements of the Continua Consent Directive code system. For further information about translation construct, consult: <http://dwidgis02.salud.gob.mx/forohl7/html/infrastructure/datatypes_r2/datatypes_r2.htm#dtdl-introduction>

Table I-9 – OID Distribution for Continua Health Alliance

OID	Description	Comments
2.16.840.1.113883.3.1817	Organization OID: Continua Health Alliance	
2.16.840.1.113883.3.1817.1	Root OID for the Continua E2E Architecture	
2.16.840.1.113883.3.1817.1.2	Root OID for the E2E Security and Privacy	
2.16.840.1.113883.3.1817.1.3	Root OID for the Personal Health Device -IF	
2.16.840.1.113883.3.1817.1.4	Root OID for the ZigBee Personal Health Device-IF	
2.16.840.1.113883.3.1817.1.5	Root OID for the NFC Personal Health Device-IF	
2.16.840.1.113883.3.1817.1.6	Root OID for the Heath and Fitness Service -IF	
2.16.840.1.113883.3.1817.1.7	Root OID for the HIS-IF	
2.16.840.1.113883.3.1817	E2E Security and Privacy: OID for the Continua Consent	

OID	Description	Comments
.1.2.1	Directive code system	

I.3 Document source SOAP request/response messages

I.3.1 SOAP request message

The SOAP request message consists of several parts:

1) SOAP Header
   a) The header is used for WS-Addressing information as in the following Example XDR SOAP request message sent by document source actor [IHE ITI TFS XDR][8].
   b) This information is useful for the identification of transmission source, target and desired processing.
2) SOAP Body
   a) The body contains the ebXML compatible mapping of the document meta-data in the form of a "ProvideAndRegisterDocumentSetRequest" message.
   b) The meta-data is useful in quickly determining the ultimate document dispensation without actually examining the document.
   c) The meta-data is constructed by encoding the XDS meta-data into the underlying ebXML transaction.
3) PHM document
   a) The PHM document (and any other required files referenced by the PHM) would appear in the same message transmission as the SOAP envelope but separated in an MTOM compatible manner.

I.3.2 SOAP response message

The SOAP response consists of two simple parts:

1) SOAP header
   a) The header is used for WS-Addressing information as in the following example below.
   b) This information is useful for matching the response to the corresponding request.
2) SOAP body
   a) The body contains the ebXML compatible response.

Example XDR SOAP request message sent by document source actor[4]

```
<s:Envelope xmlns:s= "http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
   <s:Header>
      <a:Action
         s:mustUnderstand="1">urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b</a:Action>
      <a:MessageID>urn:uuid:6d296e90-e5dc-43d0-b455-7c1f3eb35d83</a:MessageID>
      <a:ReplyTo>
         <a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
      </a:ReplyTo>
      <a:To s:mustUnderstand="1">
         http://localhost:2647/XdsService/IHEXDSRepository.svc
      </a:To>
   </s:Header>
   <s:Body>
      <ProvideAndRegisterDocumentSetRequest
         xsi:schemaLocation="urn:ihe:iti:xds-b:2007 ../schema/IHE/XDS.b_DocumentRepository.xsd"
```

[4] Example supplied by IHE. IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE) International. Copies of this standard may be retrieved from the IHE at http://www.ihe.net.

```
         xmlns="urn:ihe:iti:xds-b:2007" xmlns:xsi= "http://www.w3.org/2001/XMLSchema-instance"
         xmlns:lcm="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0"
xmlns:rim="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
         xmlns:rs="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0">
        <lcm:SubmitObjectsRequest>
           <rim:RegistryObjectList>
              <rim:ExtrinsicObject id="Document01" mimeType="text/xml"
objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">
                 <rim:Slot name="creationTime">
                  <rim:ValueList>
                     <rim:Value>20051224</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Slot name="languageCode">
                  <rim:ValueList>
                     <rim:Value>en-us</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Slot name="serviceStartTime">
                  <rim:ValueList>
                     <rim:Value>200412230800</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Slot name="serviceStopTime">
                  <rim:ValueList>
                     <rim:Value>200412230801</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Slot name="sourcePatientId">
                  <rim:ValueList>
                     <rim:Value>ST-1000^^^&amp;amp;1.3.6.1.4.1.21367.2003.3.9&amp;amp;ISO</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Slot name="sourcePatientInfo">
                  <rim:ValueList>
                     <rim:Value>PID-3|ST-1000^^^&amp;amp;1.3.6.1.4.1.21367.2003.3.9&amp;amp;ISO</rim:Value>
                        <rim:Value>PID-5|Doe^John^^^</rim:Value>
                     <rim:Value>PID-7|19560527</rim:Value>
                        <rim:Value>PID-8|M</rim:Value>
                        <rim:Value>PID-11|100 Main St^^Metropolis^Il^44130^USA</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="Physical"/>
                  </rim:Name>
                  <rim:Description/>
                  <rim:Classification id="cl01" classificationScheme="urn:uuid:93606bcf-9494-43ec-
9b4e-a7748d1a838d"
                     classifiedObject="Document01">
                     <rim:Slot name="authorPerson">
                        <rim:ValueList>
                           <rim:Value>Gerald Smitty</rim:Value>
                        </rim:ValueList>
                     </rim:Slot>
                     <rim:Slot name="authorInstitution">
                        <rim:ValueList>
                           <rim:Value>Cleveland Clinic</rim:Value>
                           <rim:Value>Parma Community</rim:Value>
                        </rim:ValueList>
                     </rim:Slot>
                     <rim:Slot name="authorRole">
                        <rim:ValueList>
                           <rim:Value>Attending</rim:Value>
                        </rim:ValueList>
                     </rim:Slot>
                     <rim:Slot name="authorSpecialty">
                        <rim:ValueList>
                           <rim:Value>Orthopedic</rim:Value>
                        </rim:ValueList>
                     </rim:Slot>
                  </rim:Classification>
               <rim:Classification id="cl02" classificationScheme="urn:uuid:41a5887f-8865-4c09-adf7-
e362475b143a"
                     classifiedObject="Document01" nodeRepresentation="History and Physical">
                     <rim:Slot name="codingScheme">
                        <rim:ValueList>
```

```
                        <rim:Value>Connect-a-thon classCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="History and Physical"/>
                  </rim:Name>
               </rim:Classification>
               <rim:Classification id="cl03" classificationScheme="urn:uuid:f4f85eac-e6cb-4883-
b524-f2705394840f"
                  classifiedObject="Document01"
nodeRepresentation="1.3.6.1.4.1.21367.2006.7.101">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>Connect-a-thon confidentialityCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="Clinical-Staff"/>
                  </rim:Name>
               </rim:Classification>
               <rim:Classification id="cl04" classificationScheme="urn:uuid:a09d5840-386c-46f2-
b5ad-9c3699a4309d"
                  classifiedObject="Document01" nodeRepresentation="CDAR2/IHE 1.0">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>Connect-a-thon formatCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="CDAR2/IHE 1.0"/>
                  </rim:Name>
               </rim:Classification>
               <rim:Classification id="cl05" classificationScheme="urn:uuid:f33fb8ac-18af-42cc-
ae0e-ed0b0bdb91e1"
                  classifiedObject="Document01" nodeRepresentation="Outpatient">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>Connect-a-thon healthcareFacilityTypeCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="Outpatient"/>
                  </rim:Name>
               </rim:Classification>
               <rim:Classification id="cl06" classificationScheme="urn:uuid:cccf5598-8b07-4b77-
a05e-ae952c785ead"
                  classifiedObject="Document01" nodeRepresentation="General Medicine">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>Connect-a-thon practiceSettingCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="General Medicine"/>
                  </rim:Name>
               </rim:Classification>
               <rim:Classification id="cl07" classificationScheme="urn:uuid:f0306f51-975f-434e-
a61c-c59651d33983"
                  classifiedObject="Document01" nodeRepresentation="34108-1">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>LOINC</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="Outpatient Evaluation And Management"/>
                  </rim:Name>
               </rim:Classification>
               <rim:ExternalIdentifier id="ei01" registryObject="Document01"
                  identificationScheme="urn:uuid:58a6f841-87b3-4a3e-92fd-a8ffeff98427"
                  value="SELF-5^^^&amp;1.3.6.1.4.1.21367.2005.3.7&amp;ISO">
                  <rim:Name>
                     <rim:LocalizedString value="XDSDocumentEntry.patientId"/>
                  </rim:Name>
               </rim:ExternalIdentifier>
               <rim:ExternalIdentifier id="ei02" registryObject="Document01"
```

```
                  identificationScheme="urn:uuid:2e82c1f6-a085-4c72-9da3-8640a32e42ab"
value="1.3.6.1.4.1.21367.2005.3.9999.32">
                  <rim:Name>
                     <rim:LocalizedString value="XDSDocumentEntry.uniqueId"/>
                  </rim:Name>
               </rim:ExternalIdentifier>
            </rim:ExtrinsicObject>
            <rim:RegistryPackage id="SubmissionSet01">
               <rim:Slot name="submissionTime">
                  <rim:ValueList>
                     <rim:Value>20041225235050</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
               <rim:Name>
                  <rim:LocalizedString value="Physical"/>
               </rim:Name>
               <rim:Description>
                  <rim:LocalizedString value="Annual physical"/>
               </rim:Description>
               <rim:Classification id="cl08" classificationScheme="urn:uuid:a7058bb9-b4e4-4307-
ba5b-e3f0ab85e12d"
                  classifiedObject="SubmissionSet01">
                  <rim:Slot name="authorPerson">
                     <rim:ValueList>
                        <rim:Value>Sherry Dopplemeyer</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Slot name="authorInstitution">
                     <rim:ValueList>
                        <rim:Value>Cleveland Clinic</rim:Value>
                        <rim:Value>Berea Community</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Slot name="authorRole">
                     <rim:ValueList>
                        <rim:Value>Primary Surgon</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Slot name="authorSpecialty">
                     <rim:ValueList>
                        <rim:Value>Orthopedic</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
               </rim:Classification>
               <rim:Classification id="cl09" classificationScheme="urn:uuid:aa543740-bdda-424e-
8c96-df4873be8500"
                  classifiedObject="SubmissionSet01" nodeRepresentation="History and Physical">
                  <rim:Slot name="codingScheme">
                     <rim:ValueList>
                        <rim:Value>Connect-a-thon contentTypeCodes</rim:Value>
                     </rim:ValueList>
                  </rim:Slot>
                  <rim:Name>
                     <rim:LocalizedString value="History and Physical"/>
                  </rim:Name>
               </rim:Classification>
               <rim:ExternalIdentifier id="ei03" registryObject="SubmissionSet01"
                  identificationScheme="urn:uuid:96fdda7c-d067-4183-912e-bf5ee74998a8"
value="1.3.6.1.4.1.21367.2005.3.9999.33">
                  <rim:Name>
                     <rim:LocalizedString value="XDSSubmissionSet.uniqueId"/>
                  </rim:Name>
               </rim:ExternalIdentifier>
               <rim:ExternalIdentifier id="ei04" registryObject="SubmissionSet01"
                  identificationScheme="urn:uuid:554ac39e-e3fe-47fe-b233-965d2a147832"
value="3670984664">
                  <rim:Name>
                     <rim:LocalizedString value="XDSSubmissionSet.sourceId"/>
                  </rim:Name>
               </rim:ExternalIdentifier>
               <rim:ExternalIdentifier id="ei05" registryObject="SubmissionSet01"
                  identificationScheme=
                     "urn:uuid:6b5aea1a-874d-4603-a4bc-96a0a7b38446" value="SELF-
5^^^&amp;1.3.6.1.4.1.21367.2005.3.7&amp;ISO">
                  <rim:Name>
                     <rim:LocalizedString value="XDSSubmissionSet.patientId"/>
```

```
                  </rim:Name>
               </rim:ExternalIdentifier>
            </rim:RegistryPackage>
            <rim:Classification id="cl10" classifiedObject="SubmissionSet01"
               classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-b4633d873bdd"/>
            <rim:Association id="as01" associationType="HasMember" sourceObject="SubmissionSet01"
targetObject="Document01">
               <rim:Slot name="SubmissionSetStatus">
                  <rim:ValueList>
                     <rim:Value>Original</rim:Value>
                  </rim:ValueList>
               </rim:Slot>
            </rim:Association>
         </rim:RegistryObjectList>
      </lcm:SubmitObjectsRequest>
      <Document id="Document01">UjBsR09EbGhjZ0dTQUxNQUFBUUNBRU1tQ1p0dU1GUXhEUzhi</Document>
   </ProvideAndRegisterDocumentSetRequest>
</s:Body>
</s:Envelope>
```

Example XDR SOAP response message sent by document recipient actor[5]

```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
   <s:Header>
      <a:Action s:mustUnderstand="1">urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-
bResponse</a:Action>
      <a:RelatesTo>urn:uuid:6d296e90-e5dc-43d0-b455-7c1f3eb35d83</a:RelatesTo>
   </s:Header>
   <s:Body>
      <rs:RegistryResponse xsi:schemaLocation="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0
../schema/ebRS/rs.xsd"
         status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success"
xmlns:rs="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
         xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
   </s:Body>
</s:Envelope>
```

[5] Example supplied by IHE

Appendix II Security Recommendations

(This appendix does not form an integral part of this design guideline.)

XDR and XDM have security considerations that require participant attention. The primary considerations are ensuring that the node to which the HIS Sender is transmitting is the correct/authorized node and that the document is not intercepted/examined/altered while in transmission.

As XDR and XDM are the simplified members of the XDS family of profiles, they have some simplifying assumptions that make this more straightforward.

CONF-PHMR-1: The base consideration is that this movement of personal health information is not ad hoc. That is, the document source and document recipient have a prior knowledge of each other and have each reached a comfort level that the other is a satisfactory partner in this transaction with all its social, business and legal ramifications.

CONF-PHMR-2: An additional consideration is that this transaction is a point-to-point private transaction between the two parties with no other parties involved.

The first assumption allows for the participants to work out specifics of the transfer (such as transport method, IP address, key certificates, email addresses, etc.) as part of their formal arrangements. The second assumption allows for common cryptographic techniques to supply the rest of the puzzle.

XDR requires the usage of Transport Level Security (TLS) as the minimum transmission security. In server environments, this is quite often the underlying technology already operational at the participant's site HTTPS implementation. Thus, by utilizing HTTPS for the SOAP message exchange, the security requirements are met. A cipher suite of TLS_RSA_WITH_AES_128_CBC_SHA is recommended.

For XDM, transmission security depends on the exact delivery method chosen. For email transfers, S-MIME is required.

Appendix III ISO/IEEE 11073-10101 to SNOMED CT and UCUM

(This appendix does not form an integral part of this design guideline)

III.1 Observation types mapping to SNOMED CT

NOTE - Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not been all finalized at the present time, the following table provides adequate guidance to map IEEE device terminology into SNOMED CT.

Table III-1 – Observation types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_CAPILLARY_PLASMA 2::29116	434911002	2774413018	Plasma glucose concentration	2774414012	122554006 | Capillary blood specimen (specimen)	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_VENOUS_PLASMA 2::29124	434911002	2774413018	Plasma glucose concentration	2774414012	122555007 | Venous blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_ARTERIAL_PLASMA 2::29132	434911002	2774413018	Plasma glucose concentration	2774414012	122552005 | Arterial blood specimen (specimen)	
Plasma Glucose Level (-10417)	CONC_GLU_UNDETERMINED_PLASMA 2::29296	434911002	2774413018	Plasma glucose concentration	2774414012	N/A	

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Blood Glucose Level (-10417)	MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD 2::29112	434912009	2774415013	Blood glucose concentration	2774416014	122554006 | Capillary blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	
Blood Glucose Level (-10417)	MDC_CONC_GLU_VENOUS_WHOLEBLOOD 2::29120	434912009	2774415013	Blood glucose concentration	2774416014	122555007 | Venous blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	
Blood Glucose Level (-10417)	MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD 2::29128	434912009	2774415013	Blood glucose concentration	2774416014	122552005 | Arterial blood specimen (specimen) 119298005 | Mixed venous blood specimen (specimen)	
Plasma Glucose Level (-10417)	MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD 2::29292	434912009	2774415013	Blood glucose concentration	2774416014	N/A	
Glucose Control Measurement (-10417)	MDC_CONC_GLU_CONTROL 2::29136	434913004	2774417017	Glucose concentration in quality control reagent	2774418010		

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Interstitial Fluid Glucose level (-10417)	MDC_CONC_GLU_ISF 2::29140	434910001	2774412011	Interstitial fluid glucose concentration	2774411016		
Haemoglobin A1C finding (-10417)	MDC_CONC_HBA1C 2::29148	365845005	489331011	Haemoglobin A1C - diabetic control finding	772274010		
Coagulation ratio - INR (-10418)	MDC_RATIO_INR_COAG 2::29188	165581004	257472014	international normalised ratio	165581004		
Prothrombin time (-10418)	MDC_TIME_PD_COAG 2::29192	396451008	1776384018	prothrombin time			
Coagulation quick value (-10418)	MDC_QUICK_VALUE_COAG 2::29196						
International Sensitivity Index - ISI (-10418)	MDC_ISI_COAG 2::29200						
INR Control Measurement (-10418)	MDC_COAG_CONTROL 2::29204						

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body mass (weight) (-20601)	MDC_MASS_BODY_ACTUAL 2::57664	27113001	45352010	Body weight	757644016		
Body height (-10415)	MDC_LEN_BODY_ACTUAL 2::57668	50373000	495662010	Body height measure	788154012		
Body mass index (-10415)	MDC_RATIO_MASS_BODY_LEN_SQ 2::57680	60621009	100716012	Body mass index	799594012		
Systolic Pressure (-10407)	MDC_PRESS_BLD_NONINV_SYS 2::18949	271649006	106507015	Systolic blood pressure	664067013		
Diastolic Pressure (-10407)	MDC_PRESS_BLD_NONINV_DIA 2::18950	271650006	406508013	Diastolic blood pressure	664068015		
Mean Arterial Pressure (-10407)	MDC_PRESS_BLD_NONINV_MEAN 2::18951	6797001	500884018	Mean blood pressure	807753012	NOTE: Must be rendered as mean blood press not mean arterial pressure	
Pulse (-10407)	MDC_PULS_RATE_NON_INV 2::18474	78564009	130365016	Pulse rate	819518016		
Body Water (-10420)	MDC_BODY_WATER	251837008	375163013	Total body water (observable entity)			

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body Fat (-10420)	MDC_BODY_FAT	248361005	370758016	Total body fat (observable entity)			
Body Fat Free (-10420)	MDC_BODY_FAT_FREE	248363008	370760019	Fat-free Mass (observable entity)			
Heart Rate (-10406)	MDC_ECG_HEART_RATE	364075005	487210016	Heart Rate (observable entity)			
Body Temperature (-10408)	MDC_TEMP_BODY 2::19292	386725007	1480858013	Body Temperature	1460904011		
Body Temperature (Finger) (-10408)	MDC_TEMP_FINGER 2::57360	433588001	*2771281010*	Temperature of digit of hand	*2760794019*		
Body Temperature (Ear) (-10408)	MDC_TEMP_EAR 2::57356	415974002	2534421019	Tympanic temperature	2530951014		
Body Temperature (Toe) (-10408)	MDC_TEMP_TOE 2::57376	433776001	*2768039016*	Temperature of toe	*2745011013*		

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Body Temperature (Gastro) (-10408)	MDC_TEMP_GIT 2::57384	431598003	*2769062014 (US)*	Temperature of esophagus	*2747764015*	*2769063016 (UK) Temperature of oesophagus*	
Body Temperature (Armpit) (-10408)	MDC_TEMP_AXILLA 2::57380	415882003	2534419012	Auxiliary temperature	2530949010		
Body Temperature (Oral) (-10408)	MDC_TEMP_ORAL 2::57352	415945006	2534418016	Oral temperature	253094019		
Body Temperature (Rectal) (-10408)	MDC_TEMP_RECT 2::57348	307047009	450211011	Rectal temperature	703520017		
Body Temperature (Tympanic) (-10408)	MDC_TEMP_TYMP 2::19320	415974002	2534421019	Tympanic temperature	2530951014		
SpO2 (-10404)	MDC_PULS_OXIM_SAT_O2 2::19384	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*2767654013* | SpO2 - saturation of peripheral oxygen	

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Pulse Rate (-10404)	MDC_PULS_OXIM_PULS_RATE 2::18458	78564009	130365016	Pulse rate	819518016		
Pulse amplitude (-10404)	MDC_PULS_OXIM_PERF_REL 2::19376 Or MDC_SAT_O2_QUAL 2::19248	431591009	*2769937011*	Pulse waveform amplitude using pulse oximetry	*2736894010*		
Plethysmographic waveform (-10404)	MDC_PULS_OXIM_PLETH 2::19380	250864000	373962018	Plethysmograph waveform	*641309010*		
Peak Expiratory Flow (-10421)	MDC_FLOW_AWAY_EXP_FORCED_PEAK 2::21512	251940009	375280019	Serial peak expiratory flow rate	*642506016*		
Personal Best of PEF (-10421)	MDC_FLOW_AWAY_EXP_FORCED_PEAK_PB 2::21513	251936000	375276012	Best ever peak expiratory flow rate	*642501014*		

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Preferred term description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Forced Expiratory Volume over 1 second (-10421)	MDC_VOL_AWAY_EXP_FORCED_1S 2::21514	59328004	498401010	Forced expired volume in 1 second	*798158012*		
Forced Expiratory Volume over 6 seconds (-10421)	MDC_VOL_AWAY_EXP_FORCED_EXP_6S 2::21515	165041004	256687019	Forced expired volume	*546438012*	The duration shall express 6s interval	New SNOMED concept is needed for MDC code.

III.2 Events and attributes types mapping to SNOMED CT

NOTE - Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not been all finalized at the present time, the following table provides adequate guidance to map IEEE device terminology into SNOMED CT.

Table III-2 – Events and attributes types mapping to SNOMED CT

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Sample Location (-10417)	MDC_CTXT_GLU_SAMPLE LOCATION 128:29236						
Sample Location Attribute (-10417)	Finger MDC_CTXT_GLU_SAMPLE LOCATION_FINGER 128::29240	125685002	473565013	Digit of hand structure	729542015		
Sample Location Attribute (-10417)	Alternative Site Testing (AST) MDC_CTXT_GLU_SAMPLE LOCATION_AST 128::29244						
Sample Location Attribute (-10417)	Earlobe MDC_CTXT_GLU_SAMPLE LOCATION_EARLOBE 128::29248	113327001	383219015	Pinna structure	648683014		

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Control Solution Indicator Attribute (-10417)	Control Solution MDC_CTXT_GLU_SAMPLE LOCATION_CTRLSOLUTIO N 128::29252						Mapped via Observation of type: MDC_CONC_GLU_CO NTROL
Measurement Condition (-10417)	MDC_CTXT_GLU_MEAL 128:29256						
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_P REPRANDIAL Pre-Prandial (or Pre-Meal) 128::29260	307165006	450357011	Before meal	703654021		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_P OSTPRANDIAL Post-Prandial (or Post-Meal) 128::29264	225758001	339227016	After food	613042015		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_F ASTING 128::29268	16985007	478017015	Fasting	744117012		
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_B EDTIME 128::29300	307155000	450339010	Before sleeping	703641017		Bedtime

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
Measurement Condition Attribute (-10417)	MDC_CTXT_GLU_MEAL_CASUAL 128::29272	255226008	380387010	Random	646234012		
Tester (-10417)	MDC_CTXT_GLU_TESTER 128:29276						
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_SELF 128::29280						Mapped via HL7 CDA Information Model
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_HCP 128::29284						Mapped via HL7 CDA Information Model
Tester Attribute (-10417)	MDC_CTXT_GLU_TESTER_LAB 128::29288						Mapped via HL7 CDA Information Model
SpO2 – fast-response (-10404)	MDC_MODALITY_FAST 2::19508	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	*NOTE - This must be used in conjunction with 277748003 Fast (qualifier value)*	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."

Description	ISO/IEEE 11073-10101			SNOMED CT			Notes
		Concept ID	Description ID	Description text	Fully specified name ID	Supplemental concept ID (Description ID – text)	
SpO2 – slow-response (-10404)	MDC_MODALITY_SLOW 2::19512	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	*NOTE - This must be used in conjunction with 255361000 Slow (qualifier value)*	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."
SpO2 – spot-check (-10404)	MDC_MODALITY_SPOT 2::19516	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*2767654013* | SpO2 – saturation of peripheral oxygen	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."
SpO2 – precise pulse (-10404)	MDC_TRIG_BEAT_MAX_INRUSH 2::53259						The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time."

III.3 Events and attributes not mapped to SNOMED CT

NOTE - Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not been all finalized at the present time, the following table provides an indication of IEEE device terminology that was not mapped into SNOMED CT.

Table III-3 – Events and attributes not mapped to SNOMED CT

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

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
Pulse characteristics Event (-10404)	Event: MDC_PULS_OXIM_PULS_CHAR 2::19512				
Pulse characteristics Event (-10404)	Value for attribute MDC_PULS_OXIM_PULS_CHAR Attributes (Not Coded) Perfusion or quality of the detected pulse is marginal – pulse-qual-marginal Perfusion or quality of the detected pulse is minimal – pulse-qual-minimal Perfusion or quality of the detected pulse is unacceptable – pulse-qual-unacceptable				Bit values will need local coding
Pulse device and sensor conditions (-10404)	Event: MDC_PULS_OXIM_DEV_STATUS 2::19532				
Pulse device and sensor conditions (-10404)	Value for attribute MDC_PULS_OXIM_DEV_STATUS Attributes: Agent reports that the sensor is disconnected from the instrument. – sensor-disconnected Agent reports that the sensor is malfunctioning or faulting. – sensor-malfunction				Bit values will need local coding

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
	Agent reports that the sensor is not properly attached or has been dislodged, preventing accurate measurement. – sensor-displaced An unsupported sensor is connected to the Agent – sensor-unsupported Agent reports that sensor is not connected to the user – sensor-off Signal analysis is currently in progress prior to measurement availability – sensor-searching Agent reports that there is interference due to ambient light or electrical phenomena – sensor-interference Agent determines that a questionable pulse is detected – signal-pulse-questionable Agent detects a non-pulsatile signal – signal-non-pulsatile Agent reports that the signal is erratic or is not plausible – signal-erratic Agent reports a consistently low perfusion condition exists – signal-low-perfusion Agent reports a poor signal exists, possibly affecting accuracy – signal-poor Agent reports that the incoming signal cannot be analyzed or is inadequate for producing a meaningful result. – signal-				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
	inadequate Agent has determined that some irregularity has been detected while processing the signal. – signal-processing-irregularity A general device fault has occurred in the Agent – device-equipment-malfunction An Extended Display Update is currently active – device-extended-update				
Medication (insulin) event (-10417)	Event: MDC_CTXT_MEDICATION 128::29188				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_RAPIDACTING 128::29192 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_SHORTACTING 128::29196 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_INTERMEDIATEACTING 128::29200 Value for attribute MDC_CTXT_MEDICATION				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_LONGACTING 128::29204 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_PREMIX 128::29208 Value for attribute MDC_CTXT_MEDICATION				
Subjective Health Event (-10417)	Event: MDC_CTXT_GLU_HEALTH 128::29212				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_MINOR 128::29216 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_MAJOR 128::29220 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_MENSES 128::29224 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_STRESS 128::29228 Value for attribute				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
	MDC_CTXT_GLU_HEALTH				
Subjective Health Event (-10417)	MDC_CTXT_GLU_HEALTH_NONE 128::29232 Value for attribute MDC_CTXT_GLU_HEALTH				
Exercise Activity (-10417)	MDC_CTXT_GLU_EXERCISE 128::29152				
Dietary Intake Event (-10417)	Event: MDC_CTXT_GLU_CARB 128::29156				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_BREAKFAST 128::29160 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_LUNCH 128::29164 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_DINNER 128::29168 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_SNACK 128::29172 Value for attribute MDC_CTXT_GLU_CARB				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_DRINK 128::29176 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_SUPPER 128::29180 Value for attribute MDC_CTXT_GLU_CARB				
Dietary Intake Event (-10417)	MDC_CTXT_GLU_CARB_BRUNCH 128::29184 Value for attribute MDC_CTXT_GLU_CARB				
Meter Status (-10417)	MDC_GLU_METER_DEV_STATUS 128::29144				
Fixed Medication Dispensed Event (-10472)	MDC_AI_MED_DISPENSED_FIXED 130::13312				Mapped via the HL7 CDA Medication Section
Variable Medication Dispensed Event (-10472)	MDC_AI_MED_DISPENSED_VARIABLE 130::13313				Mapped via the HL7 CDA Medication Section [ANSI/HL7 CDA]
User Feedback Event (-10472)	MDC_AI_MED_FEEDBACK 130::13315				Mapped via the HL7 Framework for Questionnaire Assessments (Universal Realm)

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
					[HL7 CDAR2_QA]
Status Reporter Event (-10472)	Value for attribute MDC_AI_MED_STATUS 130::13314				
Body Fat (-10420)	MDC_BODY_FAT 2::57676				
Body Water (-10420)	MDC_BODY_WATER 2::57692				
Fat Free Mass (-10420)	MDC_MASS_BODY_FAT_FREE 2::57684				
Soft Lean Mass (-10420)	MDC_MASS_BODY_SOFT_LEAN 2::57688				
Heart Rate (-10406)	MDC_ECG_HEART_RATE 2::16770				
Instantaneous Heart Rate (-10406)	MDC_ECG_HEART_RATE_INSTANT 128::21982				
R-R Interval (-10406)	MDC_ECG_TIME_PD_RR_GL 2::16168				
ECG Lead Unspecified (-10406)	MDC_ECG_ELEC_POTL 2::256				
ECG Lead Augmented voltage foot (aVF) (-10406)	MDC_ECG_ELEC_POTL_AVF 2::320				
ECG Lead Augmented voltage left	MDC_ECG_ELEC_POTL_AVL				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
(aVL) (-10406)	2::319				
ECG Lead Augmented voltage right (aVR) (-10406)	MDC_ECG_ELEC_POTL_AVR 2::318				
ECG Lead I (-10406)	MDC_ECG_ELEC_POTL_I 2::257				
ECG Lead II (-10406)	MDC_ECG_ELEC_POTL_II 2::258				
ECG Lead III (-10406)	MDC_ECG_ELEC_POTL_III 2::317				
ECG Lead V1 (-10406)	MDC_ECG_ELEC_POTL_V1 2::259				
ECG Lead V2 (-10406)	MDC_ECG_ELEC_POTL_V2 2::260				
ECG Lead V3 (-10406)	MDC_ECG_ELEC_POTL_V3 2::261				
ECG Lead V4 (-10406)	MDC_ECG_ELEC_POTL_V4 2::262				
ECG Lead V5 (-10406)	MDC_ECG_ELEC_POTL_V5 2::263				
ECG Lead V6 (-10406)	MDC_ECG_ELEC_POTL_V6 2::264				
ECG Device Status (-10406)	Event: MDC_ECG_DEV_STAT				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
	128::21976				
ECG Device Status (-10406)	Value for attribute MDC_ECG_DEV_STAT Attributes: Agent reports loss of lead wire or electrode connection (lead unspecified). – leadwire-loss Agent reports loss of lead signal (lead unspecified). – leadsignal-loss Agent reports loss of lead wire or electrode connection (first lead). – leadwire-loss-first-lead Agent reports loss of lead signal (first lead). – leadsignal-loss-first-lead Agent reports loss of lead wire or electrode connection (second lead). – leadwire-loss-second-lead Agent reports loss of lead signal (second lead). – leadsignal-loss-second-lead Agent reports loss of lead wire or electrode connection (third lead). – leadwire-loss-third-lead Agent reports loss of lead signal (third lead). – leadsignal-loss-third-lead				
ECG Context Data Trigger Event (-10406)	Event: MDC_ECG_EVT_CTXT_GEN 128:: 21977				

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
ECG Context Data Trigger Event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_USER 128::21978				
ECG Context Data Trigger Event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_PERIODIC 128::21979				
ECG Context Data Trigger Event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_DETECTED 128::21980				
ECG Context Data Trigger Event (-10406)	Value for attribute MDC_ECG_EVT_CTXT_GEN MDC_ECG_EVT_CTXT_EXTERNAL 128::21981				

III.4 ISO/IEEE 11073-10101 Unit elements mapping to UCUM

Table III-4 – ISO/IEEE 11073-10101 Unit elements (MDC_PART_DIM) mapping to UCUM

11073 Reference ID	Symbol (informative)	UCUM Unit Code (case sensitive)
MDC_DIM_PERCENT	%	%
MDC_DIM_BEAT_PER_MIN	Bpm	{beat }/min
MDC_DIM_MMHG	mmHg	mm[Hg]
MDC_DIM_KILO_PASCAL	kPa	kPa
MDC_DIM_DEGC	˚C	Cel
MDC_DIM_FAHR	˚F	[degF]
MDC_DIM_KILO_G	kg	kg
MDC_DIM_LB	lb	[lb_av]
MDC_DIM_CENTI_M	cm	cm
MDC_DIM_INCH	in	[in_i]
MDC_DIM_KG_PER_M_SQ	kg/m^2	kg/m2
MDC_DIM_MILLI_MOLE_PER_L	mmol/L	mmol/L
MDC_DIM_KCAL	Cal	[Cal]
MDC_DIM_MILLI_G_PER_DL	mg/dL	mg/dL
MDC_DIM_DIMLESS		1
MDC_DIM_MILLI_L	mL	mL
MDC_DIM_MILLI_G	mg	mg
MDC_DIM_INTL_UNIT	IU	[iU]
MDC_DIM_L_PER_MIN	L/min	L/min

11073 Reference ID	Symbol (informative)	UCUM Unit Code (case sensitive)
MDC_DIM_L	L	L
MDC_DIM_MICRO_SEC	us	us
MDC_DIM_MILLI_SEC	ms	ms
MDC_DIM_MILLI_VOLT	mV	mV
MDC_DIM_PER_SEC	s-1	/s
MDC_DIM_TICK	tick	

Appendix IV Mapping from the Continua WAN to the HL7 Personal Health Monitoring Report object model (Informative)

(This appendix does not form an integral part of this design guideline)

IV.1 Introduction

The Continua HIS Interface utilizes the Personal Healthcare Monitoring Report (PHMR) [HL7 CDA-PHMR] document to convey information to HR systems. As the PHMR is meant to be a report detailing a wide assortment of patient-centred information, the information conveyed could be from a myriad of data sources. These data sources may be in-home devices but they can also be information gathered at other points in the complete health care spectrum.

This document is based on the HL7 V3 architecture and is a derivative of the Clinical Document Architecture Release 2 (CDA R2). As such, it is a structured XML based file that has specified clauses for various types of health information.

Placing the data derived from Heath and Fitness Service Interface messages (PCD-01) entails placing the data in specific document clauses in their proper format. Along with any desired data from other sources, this total set of information would comprise a single PHMR document.

The discussion that follows centres on the Heath and Fitness Service interface and only gives guidance on how to place Heath and Fitness Service interface derived data in the report.

IV.2 Base mapping strategy

At a high level, information is split up and reported in various clauses of the PHRM depending on the type of data and the type of device.

IV.3 Device information

Information on the device itself is placed in the *Medical Equipment* Clause of the PHMR. This device information should be formatted into *Device Definition Organizer* element. At a minimum, the data should include the system type, system model, system manufacturer, system ID, production spec, and whether the device is regulated.

IV.4 Observation information

The PHRM specifies that the blood pressure, temperature, o2 saturation, respiratory rate, and pulse observation data be conveyed in the *Vital Signs* clause. All other information is conveyed in the *Results* clause.

For Continua HIS usage, the CDG place some additional constraints on the data reported. The guidelines contain a table of mappings from IEE MDC codes to SNOMED codes.

If the value being reported is contained in this guideline mapping table, then the measurement must be reported using the SNOMED code *and* there should be a *translation code* element that specifies the corresponding (probably original) IEEE MDC code.
If the value being reported is not contained in the guideline mapping table, then the observation is simply reported using the IEEE MDC code.

IV.5 Device information

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  <templateId root="2.16.840.1.113883.10.20.9.1"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Medical Equipment</title>
  <text>
     <!-- Device information -->
     <table border="1" width="100%">
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                    <th>System Type</th>
                    <th>System Model</th>
                    <th>System Manufacturer</th>
                    <th>System ID</th>
                    <th>Production Spec</th>
                    <th>Regulated</th>
               </tr>
               <tr>
                    <td>Blood Pressure Monitor</td>
                    <td>Pulse Master 2000</td>
                    <td>Acme</td>
                    <td>1F-3E-46-78-9A-BC-DE-F1</td>
                    <td>
                            Unspecified:
                             Serial Number: 584216<br/>
                             Part Number: 69854<br/>
                             Hardware Revision: 2.1<br/>
                             Software Revision: 1.1<br/>
                             Protocol Revision:  1.0<br/>
                             Prod Spec GMDN:
                    </td>
                    <td>Regulated</td>
               </tr>
          </tbody>
     </table>
  </text>
  <entry typeCode="COMP">
     <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.9.4"/>
          <statusCode code="completed"/>
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          <participant typeCode="SBJ">
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                    <templateId root="2.16.840.1.113883.10.20.9.9"/>
                    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
                    <code nullFlavor="OTH">
```

```
                    <originalText>Regulated Device</originalText>
                </code>
                <playingDevice>
                    <code code="MDC_DEV_SPEC_PROFILE_BPM"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Blood
Pressure Monitor">
                        <translation code="32033000"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Arterial pressure monitor"/>
                        <translation code="???" codeSystem="GMDN-OID">
                            <!--move Production spec GMDN here from
the manufacturerModelName-->
                        </translation>
                    </code>
<code code="MDC_DEV_SPEC_PROFILE_BPM" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Blood Pressure Monitor">
                        <translation code="32033000"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Arterial pressure monitor"/>
                        </translation>
                    </code>
                    <manufacturerModelName>
                        <!-- these will be unstructured, the text below is
an example (no shalls for the labels used below)-->
                        Model: Pulse Master 2000
                        Serial number:584216
                        Part number: 69854
                        Hardware revision: 2.1
                        Software revision: 1.1
                        Protocol revision: 1.0
                        Unspecified (free text comment):
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                </playingDevice>
                <scopingEntity>
                    <desc>Acme</desc>
                </scopingEntity>
            </participantRole>
        </participant>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <!--... all our device observations go here -->
                <code/>
            </observation>
        </component>
    </organizer>
  </entry>
</section>
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IV.6 Observation information

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  <text>
     <paragraph>Thermometer Results</paragraph>
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                    <th>Finger Temp</th>
                    <th>Oral Temp</th>
               </tr>
               <tr>
                    <td>20080501104033</td>
                    <td>99.9 deg F</td>
                    <td>88.8 deg F</td>
                    <td>37.5 deg C</td>
               </tr>
          </tBody>
     </table>
  </text>
  <entry typeCode="DRIV">
     <organizer classCode="CLUSTER" moodCode="EVN">
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          <!-- A VITAL SIGNS ORGANIZER IS USED TO GROUP RELATED  -->
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displayName="Vital signs"/>
          <statusCode code="completed"/>
          <component>
               <observation classCode="OBS" moodCode="EVN">
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                    <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Body Temperature">
                         <translation code="MDC_TEMP_BODY"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Body
Temperature"/>
                    </code>
                    <statusCode code="completed"/>
                    <effectiveTime value="20080501104033-0600"/>
                    <value xsi:type="PQ" value="99.9" unit="[degF]"/>
                    <participant typeCode="DEV">
                         <participantRole>
                    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
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```
assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
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                    </participant>
                </observation>
            </component>
            <component>
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codeSystemName="SNOMED CT" displayName="Temperature of digit of hand">
                        <translation code="MDC_TEMP_FINGER"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Finger
Temperature"/>
                    </code>
                    <statusCode code="completed"/>
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assigningAuthorityName="EUI-64" extension="1A-34-46-78-9A-BC-DE-F3"/>
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                    </participant>
                </observation>
                </component>
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                    <templateId root="2.16.840.1.113883.10.20.9.8"/>
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codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Oral
Temperature">
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codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" displayName="Oral
Temperature"/>
                        </code>
                    <statusCode code="completed"/>
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                        <participantRole>
                    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
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                        </participantRole>
                    </participant>
                </observation>
            </component>
        </organizer>
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  </entry>
</section>
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Appendix V
Delivery of PHMR data within national and regional contexts

V.1 Delivery of PHMR data via ONC DIRECT

The DIRECT project of the United States Department of Health and Human Services – Health Information Technology – defines a mechanism to securely exchange health data between trusted parties using electronic mail. The purpose of ONC's (Office of the National Coordinator for Health Information Technology of the United States) DIRECT project is outlined in [b-DIRECT].
Within Continua the use of ONC's DIRECT aligns the Continua Guidelines with those of the ONC's Meaningful Use directives. Thus a product that wishes to deliver Continua data from PHDs while meeting the United States' ONC's Meaningful Use requirements can follow the guidelines for an HIS Sender – ONC_DIRECT.
This clause documents a certified capability class that builds on top of the existing HIS Sender capability class (HIS Sender – Indirect Communication). The capability class is named HIS Sender -ONC_DIRECT. It defines how the ZIP package created using the HIS Sender – Indirect communication capability class is to be sent when using email. The HIS Sender ONC_DIRECT certified capability class specifies three items:

1. Generate the ZIP package to be exchanged in accordance with HIS Sender – Indirect Communications.
2. Send the ZIP package using the Simple Mail Transport Protocol [b-IETF RFC 5321].
3. When sending the ZIP package using SMTP follow the specifications of ONC's DIRECT.

See [b-ONC-DIRECT-AS] for additional details.
The relevant certified capabilities class and messaging guidelines are given in the Table V.1 and Table V.2.

Table V.1 – HIS certified capability classes and guidelines for ONC_DIRECT

	Network messaging	Relevant guidelines
HIS Sender – ONC_DIRECT	Yes	6.2.2.2, 6.2.3.2, 0, 6.2.4, 6.2.5.2
HIS Receiver – ONC_DIRECT	Not Certified	6.2.2.2, 6.2.3.2, 0, 6.2.4, 6.2.5.2

Table V.2 – Messaging guidelines applicable to ONC_DIRECT

Name	Description	Comments
HIS-ONC-DIRECT-CONFORM-APPLICABILITY	A HIS Sender -ONC-DIRECT and an HIS receiver -ONC-DIRECT **shall** conform to the requirements specified in the Applicability Statement for Secure Health Transport[b-ONC-DIRECT-AS]	
HIS-ONC-DIRECT-CONFORM-XDM	A HIS Sender -ONC-DIRECT and an HIS receiver -ONC-DIRECT **shall** conform to the XDR and XDM for Direct Messaging Specification[b-ONC-DIRECT-X]	
HIS-SENDER-ONC-DIRECT	A HIS Sender– ONC-DIRECT **shall** support the interaction pattern of a RFC 5322 + XDM sender as defined in the table on page 6 of [b-ONC-DIRECT-X].	

Bibliography

[b-ISO/IEEE 11073-10101] ISO/IEEE 11073-10101: 2004, *Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature*.

[b-IEEE 11073-20601 (2008)] IEEE 11073-20601-2008, *Health informatics — Personal health device communication — Application profile – Optimized exchange profile*. <http://standards.ieee.org/findstds/standard/11073-20601-2008.html>.

[b-CHA UI] Continua Health Alliance (2007-12), *Recommendations for Proper User Identification in Continua Version 1—PAN and xHR interfaces, Version 1.0*. <https://cw.continuaalliance.org/document/dl/download/3734>

[b-CHA USB-PHDC] Continua Health Alliance (2012-03), *Recommendations for Continua USB PHDC Device Driver Interoperability Version 1.0*. <http://www.continuaalliance.org/sites/default/files/WP_ContinuaUSB-PHDC_Interop.pdf>.

[b-Bluetooth Discovery] Bluetooth SIG (2008), *Bluetooth Discovery White Paper, Version 1.0*. <https://www.bluetooth.org/Technical/Specifications/whitepapers.htm>

[b-Bluetooth SSP UT] Bluetooth SIG (2007), *Bluetooth Secure Simple Pairing User Terminology White Paper, Version 1.0*. <https://www.bluetooth.org/Technical/Specifications/whitepapers.htm>

[b-Bluetooth SSP UI] Bluetooth SIG (2007), *Bluetooth User Interface Flow Diagrams for Bluetooth Secure Simple Pairing Devices White Paper, Version 1.0*. <https://www.bluetooth.org/Technical/Specifications/whitepapers.htm>

[b-Bluetooth SSP UM] Bluetooth SIG (2007), *Bluetooth Secure Simple Pairing Usability Metric White Paper, Version 1.0*. <https://www.bluetooth.org/Technical/Specifications/whitepapers.htm>

[b-CHA CMG] Continua Health Alliance (2012-10), *Implementation Guidelines for Cellular Modems Embedded into Medical Devices 1.0*.

[b-DIRECT] US Department of Health and Human Services Health Information Technolgy DIRECT Project <http://www.healthit.gov/policy-researchers-implementers/direct-project> <http://www.continuaalliance.org/sites/default/files/Implementation_Guidelines_for_Cellular_Modems_Embedded_into_Medical_Devices.pdf>

[b-IETF RFC 2119] IETF RFC 2119 (1997), *Key words for use in RFCs to Indicate Requirement Levels*.

[b-ISO 27000] ISO 27000 (2012), *Information technology - Security techniques - Information security management systems - Overview and vocabulary*.

[b-IETF RFC 2437] IETF RFC 2437 (1998), *PKCS #1: RSA Cryptography Specifications Version 2.0*.

[b-IETF RFC 3370] IETF RFC 3370 (2002), *Cryptographic Message Syntax (CMS) Algorithms*.

[b-IHE ITI TF 2 R4] IHE ITI TF 2 R4 (2007), *IT Infrastructure Technical Framework 10 Volume 2 (ITI TF-2) Transactions Revision 4.0*, Final Text. <http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_4.0_Vol2_FT_2007-08-22.pdf>

[b-IHE PCC TF 2] IHE PCC TF-2/Bindings, *IHE Patient Care Coordination Bindings*. <http://wiki.ihe.net/index.php?title=PCC_TF-2/Bindings>

[b-IEEE 11073-30200] ISO/IEEE 11073-30200-2004, *Health informatics – Pont-of-care medical device communication – Part 30200: Transport profile – Cable connected*.

[b-IEEE 802.15.4] IEEE Std 802.15.4 (2011), *IEEE Standard for Local and metropolitan area networks, Part 15.4: Low-Rate Wireless Personal Area Networks (LR-WPANs)*. <http://standards.ieee.org/getieee802/download/802.15.4-2011.pdf>

[b-SNOMED CT] International Health Terminology Standards Development Organization, *SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms)*. <http://www.ihtsdo.org/>.

[b-UCUM] *The Unified Code for Units of Measure*, Gunther Schadow, Clement J. McDonald, 1998-2008. < http://unitsofmeasure.org/trac/>.

[b-FIPS PUB 180-2] NIST FIPS PUB 180-2 (2002-08), *Secure Hash Signature Standard (SHS)*. <http://csrc.nist.gov/publications/fips/fips180-2/fips180-2withchangenotice.pdf>

[b-IHE ITI TF-1 PDQ] IHE TF-1 PDQ (2009), *IHE Patient Demographic Query (PDQ) profile*. <http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2b_FT_2009-08-10.pdf>