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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia systems, services and applications – Personal health systems

Interoperability design guidelines for personal connected health systems: Health Information System interface

Recommendation ITU-T H.813

International Telecommunication Union

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Recommendation ITU-T H.813

Interoperability design guidelines for personal connected health systems: Health Information System interface

Summary

The Continua Design Guidelines (CDG) define a framework of underlying standards and criteria that ensure the interoperability of devices and data used for personal connected health services. The CDG also contain design guidelines (DGs) that further clarify underlying standards or specifications by reducing options or by adding missing features to improve interoperability.

ITU-T H.813 focuses on the following interface:

– HIS-IF – Interface between health & fitness services (HFSs) and the Healthcare Information System (HIS)

ITU-T H.813 is part of the "ITU-T H.810 interoperability design guidelines for personal connected health systems" subseries that covers the following areas:

– ITU-T H.810 – Interoperability design guidelines for personal connected health systems: Introduction

– ITU-T H.811 – Interoperability design guidelines for personal connected health systems: Personal Health Devices interface

– ITU-T H.812 – Interoperability design guidelines for personal connected health systems: Services interface

– ITU-T H.812.1 – Interoperability design guidelines for personal connected health systems: Services interface: Observation Upload capability

– ITU-T H.812.2 – Interoperability design guidelines for personal connected health systems: Services interface: Questionnaire capability

– ITU-T H.812.3 – Interoperability design guidelines for personal connected health systems: Services interface: Capability Exchange capability

– ITU-T H.812.4 – Interoperability design guidelines for personal connected health systems: Services interface: Authenticated Persistent Session Capability

– ITU-T H.813 – Interoperability design guidelines for personal connected health systems: Healthcare Information System interface design guidelines (this design guidelines document)

History

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CDG, Continua Design Guidelines, healthcare information systems, personal connected health systems, personal health devices, services.

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FOREWORD

The International Telecommunication Union (ITU) is the United Nations specialized agency in the field of telecommunications, information and communication technologies (ICTs). The ITU Telecommunication Standardization Sector (ITU-T) is a permanent organ of ITU. ITU-T is responsible for studying technical, operating and tariff questions and issuing Recommendations on them with a view to standardizing telecommunications on a worldwide basis.

The World Telecommunication Standardization Assembly (WTSA), which meets every four years, establishes the topics for study by the ITU-T study groups which, in turn, produce Recommendations on these topics.

The approval of ITU-T Recommendations is covered by the procedure laid down in WTSA Resolution 1.

In some areas of information technology which fall within ITU-T's purview, the necessary standards are prepared on a collaborative basis with ISO and IEC.

NOTE

In this Recommendation, the expression "Administration" is used for conciseness to indicate both a telecommunication administration and a recognized operating agency.

Compliance with this Recommendation is voluntary. However, the Recommendation may contain certain mandatory provisions (to ensure, e.g., interoperability or applicability) and compliance with the Recommendation is achieved when all of these mandatory provisions are met. The words "shall" or some other obligatory language such as "must" and the negative equivalents are used to express requirements. The use of such words does not suggest that compliance with the Recommendation is required of any party.

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As of the date of approval of this Recommendation, ITU had not received notice of intellectual property, protected by patents, which may be required to implement this Recommendation. However, implementers are cautioned that this may not represent the latest information and are therefore strongly urged to consult the TSB patent database at http://www.itu.int/ITU-T/ipr/.

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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 and data used for personal connected health services. The CDG also contain design guidelines (DGs) that further clarify the underlying standards or specifications by reducing options or by adding missing features to improve interoperability.

These design guidelines focus on the following interface:

– HIS-IF – Interface between Health & Fitness services (HFSs) and the Healthcare Information System (HIS).

These design guidelines are part of the "ITU-T H.810 interoperability design guidelines for personal health systems" subseries. See [ITU-T H.810] for more details.

0.1 Organization

This design guidelines document is organized in the following manner.

Clauses 0 to **5: Introduction and terminology** – These clauses provide useful background information to help understand the structure of the design specifications.

Clause 6: HIS interface design guidelines – This clause is an overview of the Healthcare Information System interface (HIS-IF) architecture and design guidelines (DGs) for the Health & Fitness services (HFSs and the Healthcare Information System (HIS) implementing the Healthcare Information System interface (HIS-IF).

0.2 Guideline releases and versioning

See clause 0.2 of [ITU-T H.810] for release and versioning information.

0.3 What's new

To see what is new in this release of the DGs, see clause 0.3 of [ITU-T H.810].

Recommendation ITU-T H.813

Interoperability design guidelines for personal connected health systems: Health Information System interface

1 Scope

This design guidelines document focuses on the following interface:

– HIS-IF – Interface between health and fitness services (HFSs) and the Healthcare Information System (HIS).

This interface is defined in the Continua architecture described in clause 6 of [ITU-T H.810] and illustrated in Figure 6-1 of [ITU-T H.810].

2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.

[ITU-T H.810] Recommendation ITU-T H.810 (2019), *Interoperability design guidelines for personal connected health systems: Introduction*.

[HL7 CDA CD (2017)] Health Level Seven International (2017). *HL7 CDA R2 implementation guide*: *Privacy consent directives,* Release 1. Available [viewed 2020-01-09] at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280

For all other referenced documents, see clause 2 of [ITU-T H.810].

3 Definitions

This design guidelines document uses terms defined in [ITU-T H.810].

4 Abbreviations and acronyms

This design guidelines document uses abbreviations and acronyms defined in [ITU-T H.810] and the following.

CD-ROM	Compact Disc-Read-Only Memory
DSG	Digital Signature
ID	Identifier
OID	Object Identifier
PDQ	Patient Demographic Query
PIX	Patient Identifier cross-reference
PKI	Public Key Infrastructure
RBAC	Role-Based Access Control
S/MIME	Secure/Multipurpose Internet Mail ExtensionsSMTP Simple Mail Transport Protocol
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms

URL Uniform Resource Locator

XSPA cross-Site Port Attack

5 Conventions

This design guidelines document follows the conventions defined in [ITU-T H.810].

6 HIS interface design guidelines

6.1 Architecture

6.1.1 Overview of the HIS-IF

The purpose of the HIS-IF is to transfer patient information from a Continua HFS (containing the HIS Sender) to either another HFS or another health information service (containing the HIS Receiver). The HFS can be the remote patient monitoring (RPM) server of a disease management service provider or the application server of an ageing independently or HFS provider. The 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 (PHDs), or a combination of these. The health information service may contain a hospital's enterprise health record, a physician's electronic medical record (EMR) or a personal health record (PHR) service used by the patient.

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

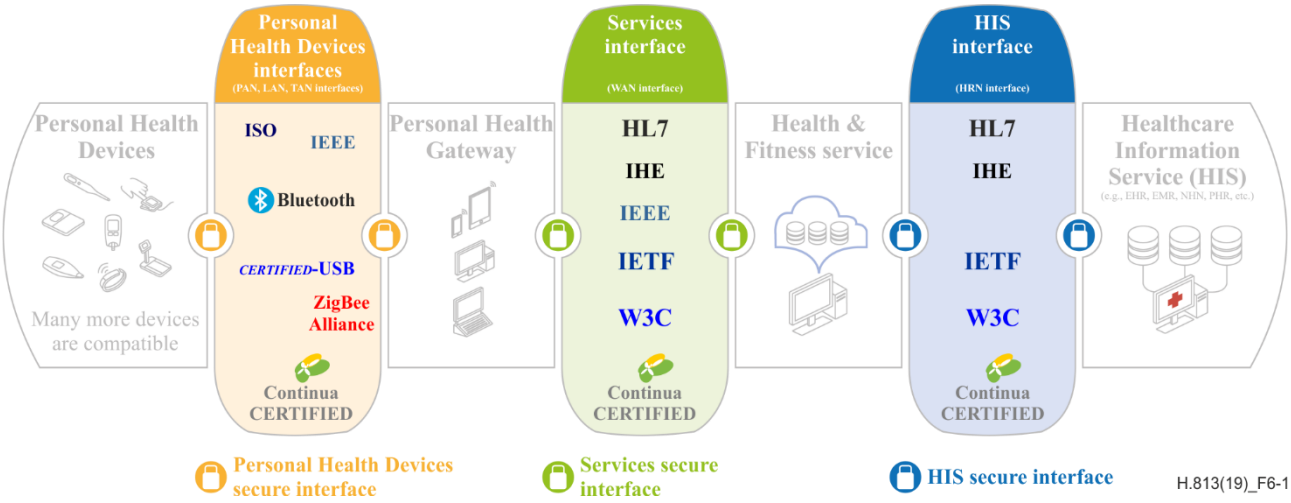

Figure 6-1 – HIS interface in the Continua E2E architecture

6.1.1.1 Coverage

The HIS interface guidelines determine how Continua-certified health information services can exchange patient information with other Continua-certified health information services or with non-Continua electronic health record (EHR) systems. Figure 6-2 is a high level view of the coverage of these guidelines.

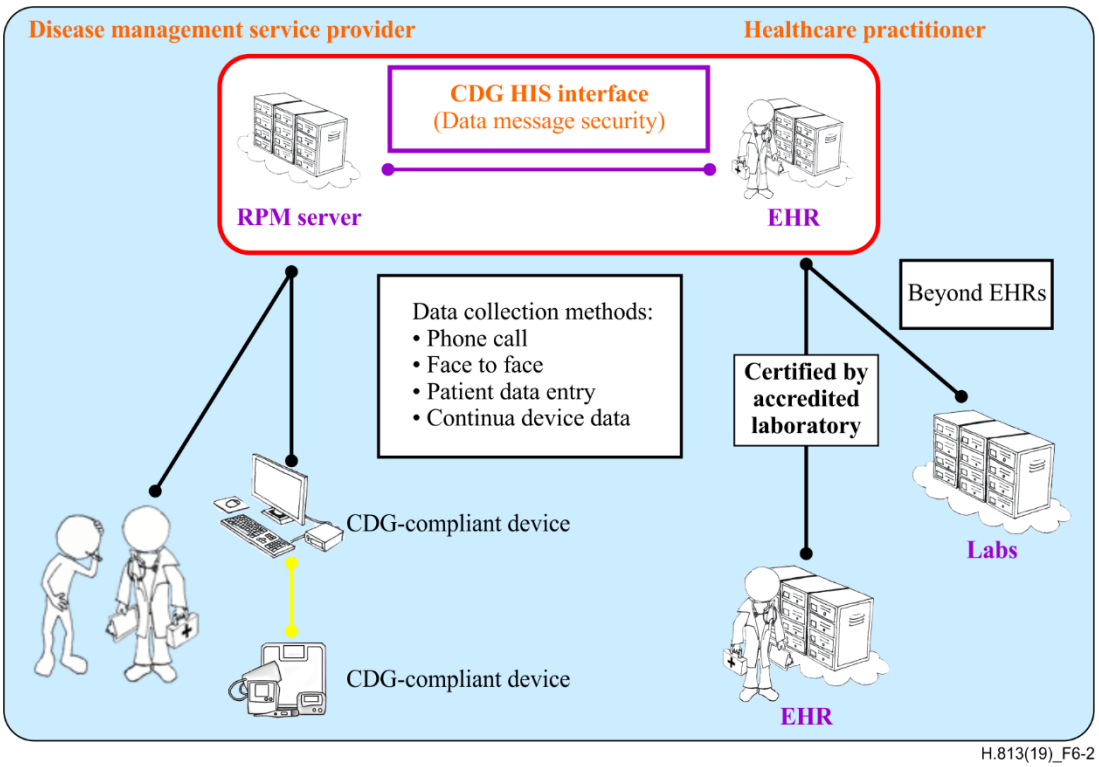

Figure 6-2 – User scenario for the HIS interface

The purpose of these guidelines is to establish basic specifications, rules and restrictions for the data, message and transport protocols necessary to enable the transfer of pertinent information from an HFS with an HIS-IF (HIS sender) to another HFS with an HIS-IF (HIS receiver). This pertinent information is typically obtained from the following sources:

PHDs: health observations, typically vital measurements generated by Continua complaint devices;

patient identification: additional information that is not generated by the PHD, but which entered out of band – often via manual configuration.

6.1.1.2 Chosen standards and profiles

Data: To facilitate the accurate transfer of coded patient results from PHDs, the HL7 Personal Healthcare Monitoring Report standard was chosen [HL7 CDA-PHMR].

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 [b-IHE ITI TF-V2x] 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 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 a healthcare information exchange (HIE) based on cross-enterprise document sharing (XDS).

Using an IHE PIX query of the cross-reference manager, senders and receivers can map between their local identifiers and those identifiers used for sharing or transfer.

The PIX profile is widely used in conjunction with the XDS [b-IHE ITI TF-3] family of specifications to implement integration scenarios within and between hospital enterprises, such as a disease management organization sending patient monitoring information to an HIE. However, the profile is also applicable in the ageing independently and HFS domains, when an organization’s local

identifiers must be mapped to a receiving system's identifiers, such as 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, if there is no party suited to perform the management of patient cross-references (as in certain PHR 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 identifier (ID) for reference against other clinical information stored against that ID. Here, the patient's ID assignment and device allocation is clearly known.

Patient demographic queries (PDQs) 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: Patient information is sent between providers by various methods. These methods include: secure direct connection over the Internet, secure e-mail, delivery on portable media (data stick, etc.), through a messaging hub and through a data repository or regional health information organization/nationwide health information network (RHIO/NHIN).

To facilitate this, a messaging standard capable of supporting multiple transport methods with a minimal amount of rework was chosen. That is, once the first transport method is accomplished, incorporating additional transport methods requires 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 cross-enterprise document sharing profile was chosen.

Transport protocol: To accomplish secure direct communication of pertinent patient information between care-givers, the IHE cross-enterprise document reliable interchange (XDR) [IHE ITI TF-1] profile is utilized.

To accomplish secure indirect communication of pertinent patient information between care-givers, the IHE cross-enterprise document media interchange (XDM) profile is utilized.

NOTE – This design guidelines *document* also profiles the use of XDR in the context of [b-Direct].

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 6-3).

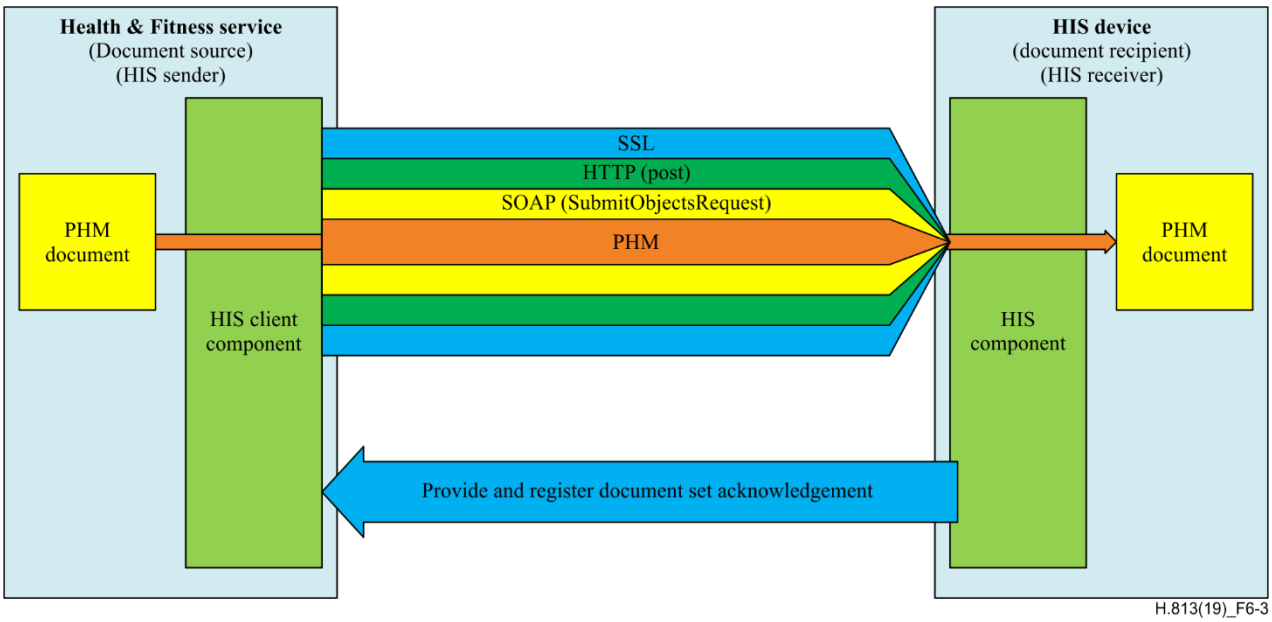

Figure 6-3 – Direct HIS messaging via XDR

The IHE's cross-enterprise document reliable interchange (XDR) [IHE ITI TF- 1] profile was selected as the transport method for direct communications across the HIS interface. This profile is a member of IHE XDS family. As such, it uses the same hypertext transfer protocol (HTTP), simple object access protocol (SOAP) 1.2, electronic business using extensible markup language (ebXML) and message transmission optimization mechanism (MTOM) standards set forth in the IHE XDS.b guidelines.

The XDR profile contains no intermediate data repository or messaging hub. If the communication between the HIS Sender and the HIS Receiver occurs over the Internet, then the HIS Receiver will need to be Internet-facing.

From an implementation standpoint, the HIS Receiver may be the provider's electronic health record system itself or a web-front-end system whose purpose is to securely carry the messages across the provider’s 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.

IHE's cross-enterprise document media interchange (XDM) profile [IHE ITI TFS XDM] is the specification used for indirect communications (via e-mail or physical media) across the HIS interface. This profile is a member of the IHE XDS family.

6.1.3 Messaging and selected standards

For messaging and transport, the HIS-IF utilizes as its base the IHE XDS family of profiles, which thoroughly covers the spectrum of communication requirements for a large health information network, such as an RHIO. 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 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 personal healthcare monitoring report (PHMR) being transmitted. This metadata is utilized by holders of the document to help determine how to handle it without the need to open, resolve all referenced attached documents, parse and examine the contents. Thus, the meta-data allows 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 (patient identifier (PID), name, address).

This information is then mapped to the appropriate form of the specific transport. This information takes the form of extensible markup language (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 6-3). In XDM (sending data via e-mail attachment or removable media), the meta-data is stored in the top-level directory of the exported file package that is created when the PHMR is exported for delivery. Because of this, the exported file package must first be opened or extracted before the meta-data can be accessed (see Figure 6-4). The set of files to be exchanged is archived using file compression (as ZIP files).

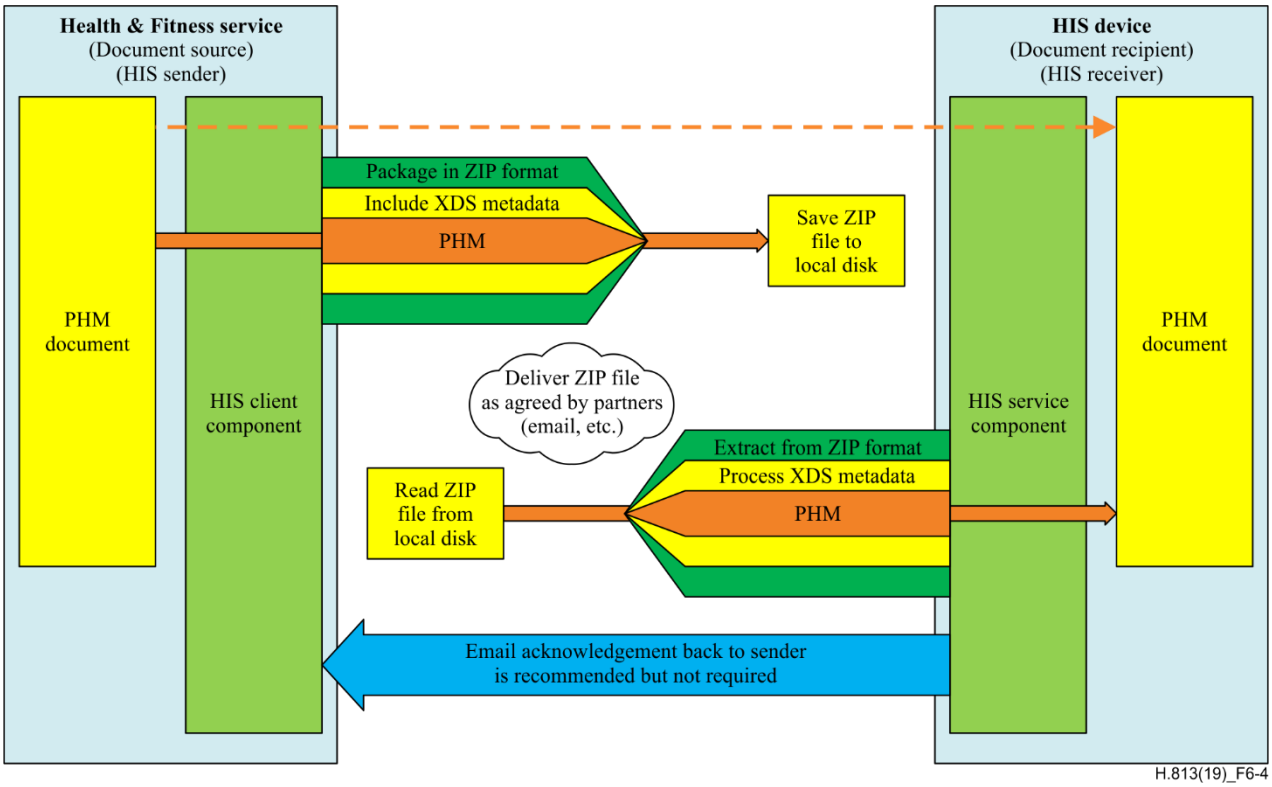

Figure 6-4 – Indirect HIS messaging via XDM

6.1.4 Data and selected standards

The data payload transmitted from the HIS sender is structured in accordance with the HL7 clinical document architecture (CDA) [HL7 CDA-PHMR]

6.1.5 Transport security

The HL7 CDA, which is the basis for the PHMR 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 e-mail (the recommended method), then secure/multipurpose internet mail extensions (S/MIME) are used to ensure security. However, the cases in which the ZIP-packaged PHMR is further stored on removable media (e.g., universal serial bus (USB), drive, compact disc-read-only memory (CD-ROM)) or transferred via the file transfer protocol (FTP) lie outside the scope of this Recommendation 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 PHMR 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 DGs. However, it should be noted that the final security implementation must be designed by the communicating parties.

6.1.6 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 (transport level security (TLS), IHE audit trail and node authentication (ATNA)) basic integrity and node authentication is realized. However, non-repudiation requires additional measures, such as a signature, over the documents. A signature can also strengthen the integrity of the document independently of how it is exchanged by providing E2E integrity if it is exchanged multiple times.

For HIS-IF integrity, data origin authentication and non-repudiation are realized through the use of an IHE document digital signature (DSG) content profile. IHE DSG allows signing of documents in a submission set exchanged using the protocols defined in [IHE ITI TF-1 XDM] and [IHE ITI TF-1].

A non-repudiation-enabled HIS sender is an HIS sender that deploys security operations to ensure that data integrity, data origin authentication and data origin non-repudiation properties are preserved when transmitting an observation document.

A non-repudiation-enabled HIS receiver is an HIS receiver that deploys security operations to ensure 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.

6.1.7 Consent management

Consent in healthcare includes concepts like opt-in, opt-out and 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 an HFS, which should also be applied at an HIS service. An example is a scenario where a patient defines his or her 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 HFS to HIS exchanges, consent documents may also be exchanged from HIS to HIS services.

For the HIS-IF, the coverage is limited to the exchange of the consent documents between the HIS sender and HIS receiver. The creation and management of the consent documents lies outside the

scope of these design guidelines. It is assumed that patients have already given their consent, e.g., to a disease management organization.

The consent-enabled HIS sender is a HIS sender that is capable of transmitting a patient consent document. The consent-enabled HIS receiver is a 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 the HL7 CDA R2 consent directive [HL7 CDA CD (2017)] 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 6-5provides 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 and response structure to obtain the consent document separately from the PHMR document. This interaction may be used, e.g., where a reference to already shared consent documents suffices or situations where a consent document should be obtained because it is no longer available 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 6-6 provides an overview of this request and 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 uniform resource locators (URLs).

A HIS sender has knowledge of the applicable patient consent for a PHMR document and signals this to a HIS receiver using the ConfidentialityCode field in the PHRM document, which identifies the applicable consent document, thereby associating the consent document with 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 a HIS receiver node. This allows for the selection and issue 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 cross-enterprise user assertion (XUA) to include a security assertion markup language (SAML) token in the ITI-43 Retrieve Document Set.b request message (see Figure 6-7), which is used to request a consent document.

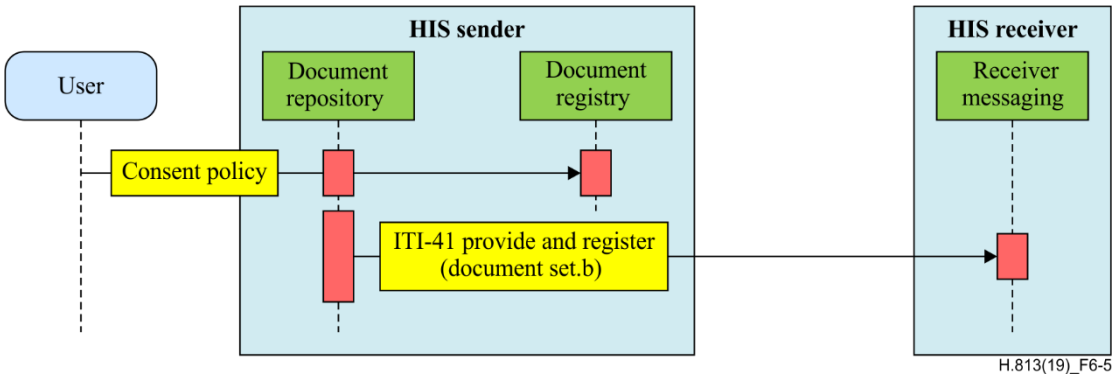

Figure 6-5 – Point-to-point interaction to exchange consent using IHE XDR at HIS-IF

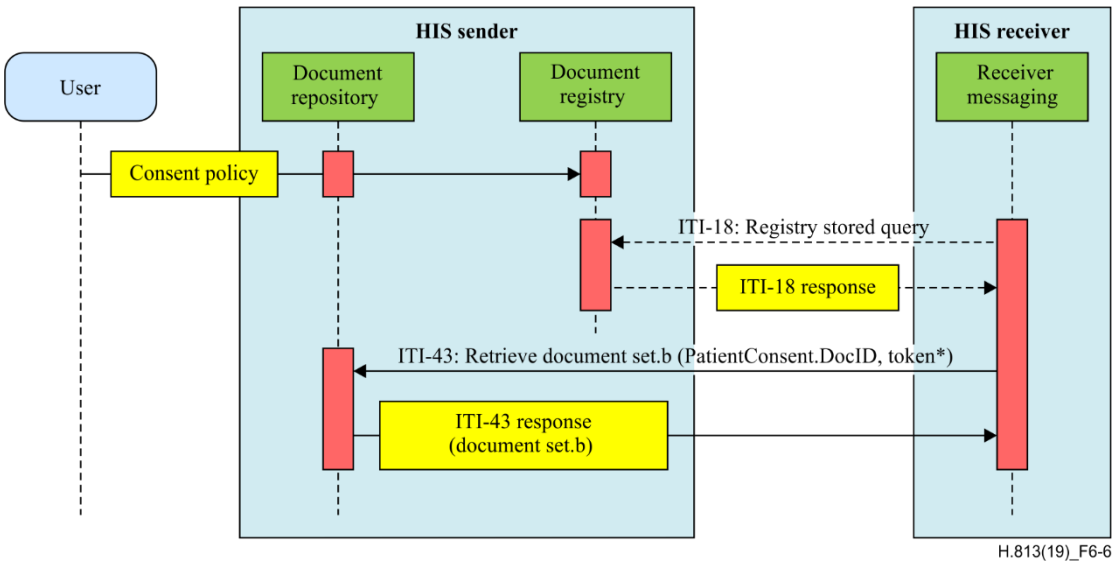

Figure 6-6 – Request and response interaction to obtain consent using IHE XDS at HIS-IF

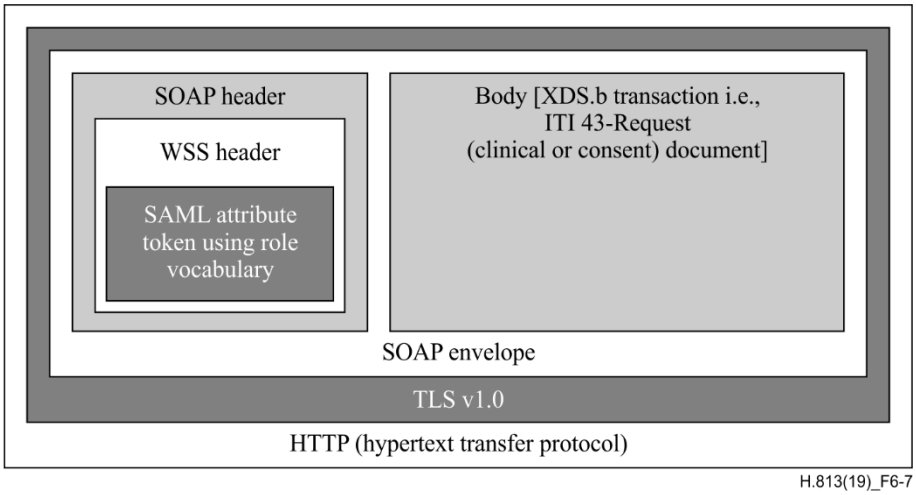

Figure 6-7 – SAML encapsulation and the overall protocol stack

6.1.8 Consent enforcement

The CDG enables the enforcement of patient consent through encryption on a consent-enabled HIS. The consent-enabled HIS sender is a HIS sender that is capable of specifying patient consent according to [HL7 CDA CD (2017)] directives, encrypting the PHMR document for a recipient(s) and transmitting them on the HIS-IF. The consent-enabled HIS receiver is a HIS receiver that is capable of receiving patient consent documents and encrypted PHMR documents.

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 6-8 provides an overview of different steps employed in order to exchange encrypted PHMR document(s) on the HIS-IF using the IHE XDR profile. The only new feature that is added compared to Figure 6-5 (i.e., consent management guidelines) is the encryption of the PHMR document(s). The consent-enabled HIS sender has to at least support the key management method based on the public key infrastructure (PKI) from the IHE DEN profile. This 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 key management methods. 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 that consists of an encrypted PHMR document and a 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 6-9 shows the application of the IHE DEN profile during the request and response interaction in order to enable patient consent enforcement. The requester is being authenticated and 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 that consists of a personalized consent document and an encrypted PHMR document. The submission set is then transported through an ITI-43 Response transaction.

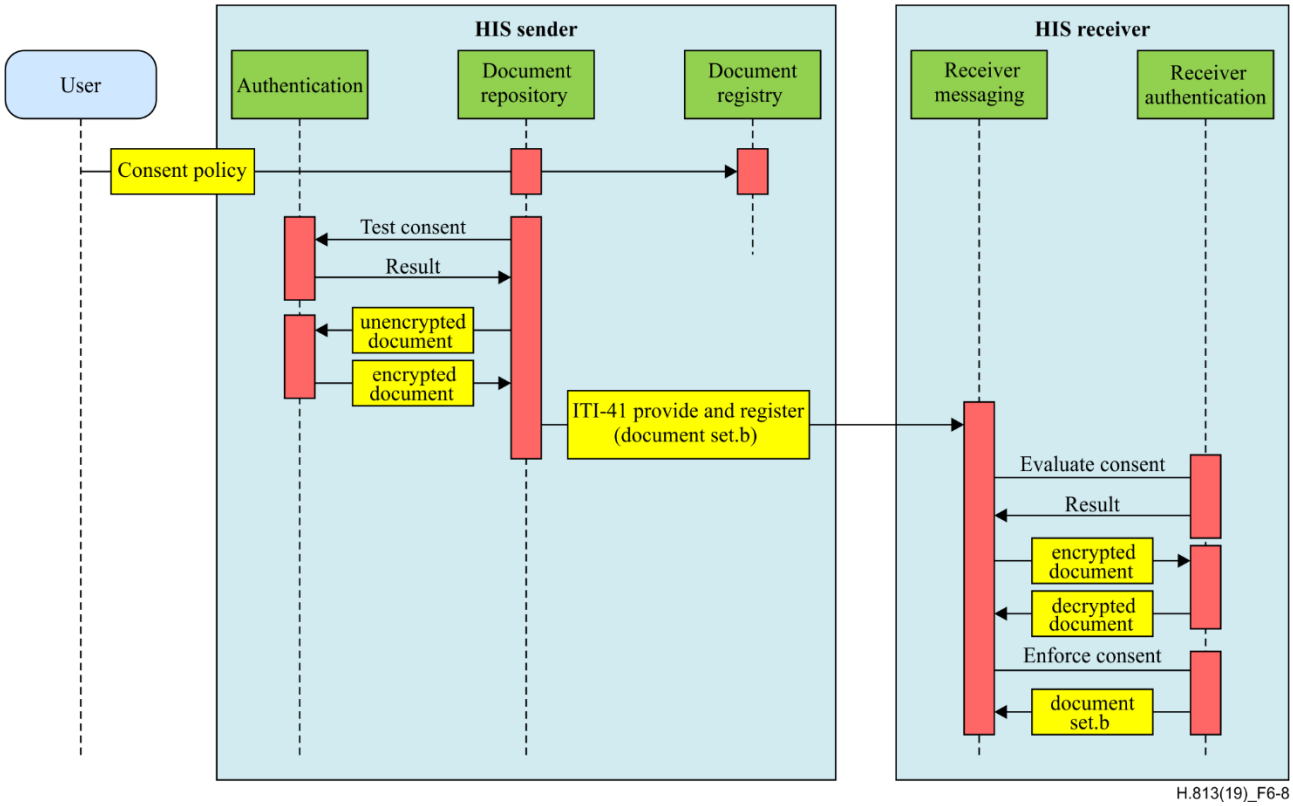

Figure 6-8 – Point-to-point interaction to exchange encrypted PHMR documents along with consent using IHE XDR at HIS-IF[1]

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

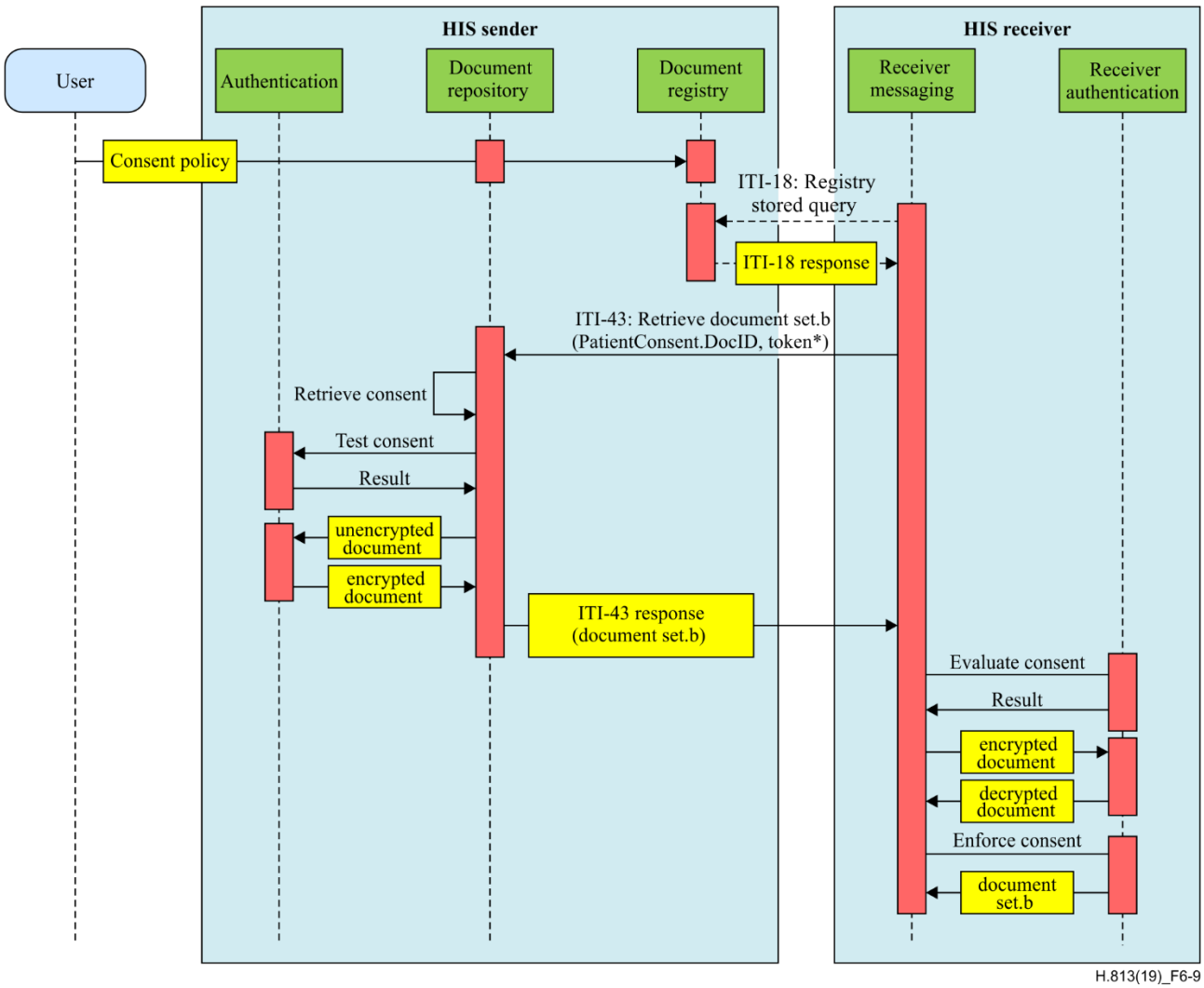

Figure 6-9 – Request and response interaction to obtain an encrypted PHMR document along with a consent document using IHE XDS at HIS-IF[2]

6.1.9 Delivery of PHMR data via ONC Direct

Guidance for implementations that elect to deliver CDG-compliant data from PHDs while meeting the meaningful use requirements of [b-Direct] is found in clause V.1.

6.1.10 Certified capability classes

Table 6-1 shows the HIS certified capability classes defined for the HIS-IF interface DGs. At this time, the programme described in [ITU-T H.810] only provides certification for software components implementing HIS sender functionality. In contrast to the PHD interface, the HIS sender certification can just apply to a software implementation and does not require integration into an entire system.

NOTE – For HIS capability classes and respective guidelines for national and regional systems, see Appendix V.

2 The grey items have already been specified in a previous version of the CDG.

Table 6-1 – HIS capability classes

Capability classes	Network messaging
HIS sender – Direct Communication	Yes
HIS receiver – Direct Communication	Not certified
HIS sender – Indirect Communication	Yes
HIS receiver – Indirect Communication	Not certified
HIS sender – ONC_DIRECT	Yes
HIS receiver – ONC_DIRECT	Not Certified
Non-repudiation-Enabled HIS sender	Yes
Non-repudiation-Enabled HIS receiver	Not certified
Consent-Enabled HIS sender – XDR	Yes
Consent-Enabled HIS receiver – XDR	Not certified
Consent-Enabled HIS sender – XDS.b	Yes
Consent-Enabled HIS receiver – XDS.b	Not certified

Certification of HIS capability classes are shown in Table 6-2. Capability classes are referenced even though receivers on the HIS interface are not currently certified (see clause 0.5); they can be implemented by adhering to the appropriate guidelines (clause numbers) indicated in Table 6-2.

Table 6-2 – Guidelines for HIS capability classes

Capability classes	Relevant guidelines
HIS receiver – Direct Communication	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1
HIS sender – Direct Communication	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1
HIS receiver – Indirect Communication	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS sender – Indirect Communication	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS receiver – ONC_DIRECT	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
HIS sender – ONC_DIRECT	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2
Non-repudiation-Enabled HIS sender	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.3
Non-repudiation-Enabled HIS receiver	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1,Table 6-13
Consent-Enabled HIS sender – XDR	6.2.2.1**,** 6.2.3.1**,** 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-14, Table 6-18
Consent-Enabled HIS receiver – XDR	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-15, Table 6-19
Consent-Enabled HIS sender – XDS.b	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-20
Consent-Enabled HIS receiver – XDS.b	6.2.2.1, 6.2.3.1, 6.2.3.3, 6.2.4, 6.2.5.1, Table 6-17, Table 6-21

6.2 Design guidelines

6.2.1 Introduction

Clauses 6.2.2 to 6.2.7 detail the specific rules, restrictions and guidelines for the Continua HIS interface.

In these guidelines, 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 has been preserved for clarity.

6.2.2 Messaging infrastructure and transport guidelines

6.2.2.1 Requirements for direct communications via XDR

See Table 6-3.

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	

6.2.2.2 Requirements for indirect communications via XDM

See Table 6-4.

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	

6.2.3 Messaging guidelines

6.2.3.1 Messaging guidelines for direct communications via XDR

See Table 6-5.

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 PHMR 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 PHMR data	Primary v1 messaging/transport is based on IHE XDR profile and its referenced standards
HIS_Messaging_Transport_ Exclusivity	Continua HIS senders and receivers **shall** utilize the transport mechanisms as defined in the XDR profile for all PHMR exchanges	
HIS_Messaging_Message_Scope	The Continua HIS sender application **should not** include information that is not present within the PHMR	This requirement is necessary since the primary usage of message is designed to only transmit PHMR data
HIS_Messaging_Meta_Data	The Continua HIS sender XDR meta-data **shall** be consistent with the included PHMR and its attachments	This is to ensure that any preprocessing based on the XDR meta-data is consistent with the PHMR payload. Of primary concern are the patient ID, the document ID and the originator ID

6.2.3.2 Messaging guidelines for indirect communications via XDM

See Table 6-6.

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 PHMR data	

Table 6-6 – General messaging guidelines

Name	Description	Comments
HIS_Indirect_Messaging_ Message_Scope_One_Report	The Continua HIS sender **shall** include exactly one submission set, including one PHMR 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 PHMR 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	The 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
HIS_Indirect_Messaging_ Document_Source_Directory_ Structure	The Continua HIS sender **shall** name the submission set directory that includes PHMR "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 PHMR	This requirement is necessary since the primary usage of the message is designed to only transmit PHMR data
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 PHMR and optional XML style sheet used to render the PHMR	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 PHMR would reference such a file and thus it would be allowed in the submission set – this is restricted and shall not be submitted
HIS_Indirect_Messaging_Meta_ Data	The Continua HIS sender XDM meta-data **shall** be consistent with the included PHMR and its attachments	This is to ensure that any preprocessing based on the XDM meta-data is consistent with the PHMR 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].

Table 6-6 – General messaging guidelines

Name	Description	Comments
		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 PHMR document transaction **shall** be atomic in that the included PHMR is complete and that none of the content relies on content from other messages in order to be understood	
HIS_Indirect_Message_ Infrastructure_Internet	A Continua HIS sender **shall** either export the PHMR "Zip over E-Mail" media as a one ZIP file or create an e-mail with the PHMR attached as a ZIP file using internal e-mail processing	This gives the sender flexibility to either create the e-mail with the attachment or export the ZIP package for manual attachment to an e-mail
HIS_Indirect_Message_ Infrastructure_Internet_Email	If the Continua HIS sender exports the "Zip over E-Mail" it **shall** include the PHMR 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 e-mail message	
HIS_Indirect_Message_ Infrastructure_Internet_ Attachment	If the Continua HIS sender creates an e-mail with the XDM submission set attached, the submission set **shall** contain the PHMR 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 PHMR 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 [IHE ITI TF-1] for more details on ATNA. The manual e-mail option could skip the auditing step. This would not be a compliant or complete implementation
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 is 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 e-mail subject line in	The document ID format is American standard code for information interchange (ASCII) text.

Table 6-6 – General messaging guidelines

Name	Description	Comments
	addition to the required subject XDM/1.0/DDM in the format: XDM/1.0/DDM/DocumentID	There is no failure-handling mechanism beyond that provided by standard e-mail and no consistent time-out standard is possible due to variability of how people read e-mail. Any concerns over whether 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 e-mail message	The acknowledgment e-mail subject should contain the exact contents of the original e-mail's subject, prefixed by "RE:" (the way typical e-mail replies are handled) NOTE – An e-mail return receipt only confirms that the e-mail was opened, 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 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[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[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 [ONC-DIRECT-X].	

6.2.3.4 Messaging guidelines applicable to both direct and indirect communications

See Table 6-7 and Table 6-8.

Table 6-7 – PHMR attachments guidelines

Name	Description	Comments
HIS_PHMR_Attachments_Attachment_ Completeness	Continua HIS senders **shall** communicate all attachments referenced or contained in the PHMR document	
HIS_PHMR_Attachments_Message_ Completeness	Continua HIS senders **shall** communicate all attachments specified in the PHMR 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_Registration	Continua HIS senders **may** implement the patient identity source actor of IHE ITI-44: Patient Identity Feed HL7 V3 in order to submit a 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	
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	

6.2.4 Data guidelines

See Table 6-9.

Table 6-9 – General data format guidelines

Name	Description	Comments
HIS_Data_Standard	Continua HIS sender and receiver data format **shall** comply with [HL7 CDA-PHMR]	
HIS_Data_Subject_ Identity	Continua HIS senders **shall** uniquely identify a 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 a 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 PHMR document in the `/ClinicalDocument/author/assignedAuthor/representedOrganization` element	
HIS_Data_Authoring_ PHD_Identity	Continua HIS senders **should** identify the personal health gateway/health & fitness service in the role of HIS sender in the `/ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice` element	
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]	
HIS_Data_Processed_ Data_Author_Identity	For processed data, Continua HIS senders **should** include a reference to the PHD that processed the data	NOTE – This may propagate up to the authoring PHD as defined in HIS_Data_ authoring_ PHD__identity

6.2.5 Security guidelines

6.2.5.1 Security guidelines for direct communications via XDR

See Table 6-10.

Table 6-10 – 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_Auditing1	Continua HIS senders and receivers **shall** implement and adhere to 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

See Table 6-11.

Table 6-11 – General security guidelines

Name	Description	Comments
None.		

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

See Table 6-12 and Table 6-13.

NOTE – Other guidelines that are applicable for the non-repudiation-enabled HIS sender and receiver are mentioned in Table 6-2.

Table 6-12 – 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 6-13 – 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

See Table 6-14, Table 6-15, Table 6-16 and Table 6-17.

Table 6-14 – 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 CD (2017)] directives 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	
HIS_Sender_Consent_Clinical_ Document(s)_Association_XDR	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 elements of the Continua Consent Directive code system Consult Table I.9 for the assigned object identifiers (OIDs)

Table 6-14 – Consent management guidelines for consent-enabled HIS sender via XDR

Name	Description	Comments
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 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 6-15 – 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 CD (2017)]	
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 6-16 – 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 CD (2017)] 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	
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 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
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

Table 6-16 – Consent management guidelines for consent-enabled HIS sender via XDS.b

Name	Description	Comments
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 role-based access control (RBAC) IHE XUA++ profile uses SAML attribute token. XUA++ refers to OASIS Cross-Site Port Attack (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
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 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 6-17 – 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 CD (2017)] 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 or consent document. The token is placed in the SOAP header. IHE XUA profile uses SAML token for authentication
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 RBAC 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

See Table 6-18, Table 6-19, Table 6-20 and Table 6-21.

Table 6-18 – 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 DEN profile	IHE DEN is based on cryptographic message syntax (CMS) 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
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 points to the public key or x.509 v3 certificate of the recipient
HIS_Sender_Encryption_ Recipient_Binding_Other_XDR	Consent-enabled HIS sender **may** implement other key management methods from IHE DEN profile	

Table 6-19 – 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 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
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 6-20 – 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
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
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 6-21 – 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
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 an acknowledgement SOAP message.

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. Tables I.1 to I.9 show the entries required for a conforming 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 clause 4.1 of [b-IHE ITI TF-3]

– IHE PCC working group mapping [b-IHE PCC TF-1]

– Implementation Guide for PHMR 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

Element	Req.	HIS PHMR mapping	Comments
availabilityStatus	(O)		See comment in the XDS DocumentEntry table
author	(R2)	/ClinicalDocument/author	See comment in the XDS DocumentEntry 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	

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

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR 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"

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR mapping	Comments
author	(R2)	/ClinicalDocument/author	Composed of sub-elements (defined in subsequent rows): – 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	
confidentialityCode DisplayName	(O)	/ClinicalDocument/ confidentialityCode (R if confidentialityCode present)	
creationTime	(R)	/ClinicalDocument/effectiveTime	
entryUUID	(R)	unique ID for documentEntry	
eventCodeList	(O)	/ClinicalDocument/ documentationOf/serviceEvent/ code	
eventCodeDisplay NameList	(O)	(R if eventCodeList present)	
formatCode	(R)	"urn:continua:phm:2008"	
formatCodeDisplay Name	(O)		
hash	(R)		
healthcareFacilityTypeCode	(R)		The value of this element can be any value agreed upon by the two transaction participants

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR 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 described in the mapping table of [b-IHE PCC TF-2]
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 PHMR data
serviceStopTime	(O)	/ClinicalDocument/ documentationOf/serviceEvent/ effectiveTime/high	Contained in PHMR data
size	(R)		
sourcePatientId	(R)	/ClinicalDocument/recordTarget/ patientRole/id	

[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.

Table I.3 – XDSDocumentEntry metadata

Element	Req.	HIS PHMR mapping	Comments
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

Apart from those constraints listed in Table I.2, there are no additional constraints for the XDS submission set metadata for the consent directive document.

XDSDocumentEntry metadata requirements for consent directive documents are the same as those mentioned in Table I.3 for PHMR documents; however, exceptions are listed in Table I.5.

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

Element	Req.	HIS PHMR 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 CD (2017)].	
codeSystem	2.16.840.1.113883.3.1817.1.2.1	
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	
codeSystem Name	"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 placeholder for the ID of the consent document. Consult Table I.7 for the elements of the Continua Consent Directive code system.

Table I.9 – OID distribution for Personal Connected 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 Health and Fitness Service-IF	
2.16.840.1.113883.3.1817.1.7	Root OID for the HIS-IF	
2.16.840.1.113883.3.1817.1.2.1	E2E security and privacy: OID for the Continua Consent Directive code system	
NOTE – The OIDs defined in this table may change for subsequent versions of this Specification.		

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 [b-IHE IT-1].

b) This information is useful for the identification of transmission source, target and desired processing.

2) SOAP body

c) The body contains the ebXML compatible mapping of the document meta-data in the form of a "ProvideAndRegisterDocumentSetRequest" message.

d) The meta-data is useful in quickly determining the ultimate document dispensation actually examining the document.

e) The meta-data is constructed by encoding the XDS meta-data into the underlying ebXML transaction.

3) PHMR document

f) The PHMR document (and any other required files referenced by the PHMR) 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.

b) This information is useful for matching the response to the corresponding request.

2) SOAP body

c) 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"
     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>
```

[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.

```
            </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;amp;1.3.6.1.4.1.21367.2005.3.7&amp;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

Mapping of [b-ISO/IEEE 11073-10101] to the Systematized Nomenclature of Medicine – Clinical Terms [b-SNOMED CT]

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

II.1 Observation types mapping to SNOMED CT

NOTE – Even though the final ISO/IEEE 11073 Reference IDs and numeric code assignments have not all been finalized at the present time(2008), Table II.1 provides adequate guidance to map ISO/IEEE device terminology into SNOMED CT.

Table II.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	

Table II.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)	
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		
Interstitial fluid glucose level (-10417)	MDC_CONC_GLU_ISF 2::29140	434910001	2774412011	Interstitial fluid glucose concentration	2774411016		

Table II.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)	
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						
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		

Table II.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)	
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)			
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		

Table II.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)	
Body temperature (Finger) (-10408)	MDC_TEMP_FINGER 2::57360	433588001	*2771281010*	Temperature of digit of hand	*2760794019*		
Body temperature (Ear) (-10408)	MDC_TEMP_EAR 2::57356	415974002	2534421019	Tympanic temperature	2530951014		
Body temperature (Toe) (-10408)	MDC_TEMP_TOE 2::57376	433776001	*2768039016*	Temperature of toe	*2745011013*		
Body temperature (Gastro) (-10408)	MDC_TEMP_GIT 2::57384	431598003	*2769062014 (US)*	Temperature of oesophagus	*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		

Table II.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)	
Body temperature (Tympanic) (-10408)	MDC_TEMP_TYMP 2::19320	415974002	2534421019	Tympanic temperature	2530951014		
SpO2 (-10404)	MDC_PULS_OXIM_SAT_O2 2::19384	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*2767654013* | SpO2 – saturation of peripheral oxygen	
Pulse rate (-10404)	MDC_PULS_OXIM_PULS_RATE 2::18458	78564009	130365016	Pulse rate	819518016		
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*		

Table II.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)	
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.

II.2 Events and attribute 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, Table II.2 provides adequate guidance to map IEEE device terminology into SNOMED CT.

Table II.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		
Control solution indicator attribute (-10417)	Control Solution MDC_CTXT_GLU_SAMPLE LOCATION_CTRLSOLUTIO N 128::29252						Mapped via observation of type: MDC_CONC_GLU_CONT ROL
Measurement condition (-10417)	MDC_CTXT_GLU_MEAL 128:29256						

Table II.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)	
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_PREPRANDIAL Pre-Prandial (or Pre-Meal) 128::29260	307165006	450357011	Before meal	703654021		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_POSTPRANDIAL Post-Prandial (or Post-Meal) 128::29264	225758001	339227016	After food	613042015		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_FASTING 128::29268	16985007	478017015	Fasting	744117012		
Measurement condition attribute (-10417)	MDC_CTXT_GLU_MEAL_BEDTIME 128::29300	307155000	450339010	Before sleeping	703641017		Bedtime
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

Table II.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)	
Tester attribute (-10417)	MDC_CTXT_GLU_TESTER_LAB 128::29288						Mapped via HL7 CDA information model
SpO2 – fast-response (-10404)	MDC_MODALITY_FAST 2::19508	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	NOTE – This must be used in conjunction with 277748003 Fast (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.
SpO2 – slow-response (-10404)	MDC_MODALITY_SLOW 2::19512	433204000	*2768695014*	Rate of sampling of peripheral oxygen saturation by device	*2743645015*	NOTE – This must be used in conjunction with 255361000 Slow (qualifier value)	The final IEEE 11073 ReferenceIDs and numeric code assignments have not been assigned at the present time.
SpO2 – spot-check (-10404)	MDC_MODALITY_SPOT 2::19516	431314004	*2772010012*	Peripheral oxygen saturation	*2735642016*	*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.

II.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 all been finalized at the present time, Table II.3 provides an indication of IEEE device terminology that was not mapped into SNOMED CT.

Table II.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				

Table II.3 – Events and attributes not mapped to SNOMED CT

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				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
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 faulty. – sensor-malfunction Agent reports that the sensor is not properly attached or has been dislodged, preventing accurate measurement. – sensor-displaced An unsupported sensor is connected to the Agent – sensor-unsupported 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 analysed or is inadequate for producing a meaningful result. – signal-inadequate Agent has determined that some irregularity has been detected while processing the signal. – signal-processing-irregularity A general device fault has occurred in the Agent – device-equipment-malfunction An Extended Display Update is currently active – device-extended-update				Bit values will need local coding

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Medication (insulin) event (-10417)	Event: MDC_CTXT_MEDICATION 128::29188				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_RAPIDACTING 128::29192 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_SHORTACTING 128::29196 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_INTERMEDIATEACTING 128::29200 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_LONGACTING 128::29204 Value for attribute MDC_CTXT_MEDICATION				
Medication (insulin) event (-10417)	MDC_CTXT_MEDICATION_PREMIX 128::29208 Value for attribute MDC_CTXT_MEDICATION				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Subjective health event (-10417)	Event: MDC_CTXT_GLU_HEALTH 128::29212				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MINOR 128::29216 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MAJOR 128::29220 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_MENSES 128::29224 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_STRESS 128::29228 Value for attribute MDC_CTXT_GLU_HEALTH				
Subjective health event (-10417)	MDC_CTXT_GLU_HEALTH_NONE 128::29232 Value for attribute MDC_CTXT_GLU_HEALTH				
Exercise activity (-10417)	MDC_CTXT_GLU_EXERCISE 128::29152				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
Dietary intake event (-10417)	Event: MDC_CTXT_GLU_CARB 128::29156				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_BREAKFAST 128::29160 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_LUNCH 128::29164 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_DINNER 128::29168 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_SNACK 128::29172 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_DRINK 128::29176 Value for attribute MDC_CTXT_GLU_CARB				
Dietary intake event (-10417)	MDC_CTXT_GLU_CARB_SUPPER 128::29180 Value for attribute MDC_CTXT_GLU_CARB				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101	SNOMED CT			Notes
		Concept ID	Description ID	Description text	
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) [HL7 CDA R2 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				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
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 (aVL) (-10406)	MDC_ECG_ELEC_POTL_AVL 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				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
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 128::21976				

Table II.3 – Events and attributes not mapped to SNOMED CT

Description	ISO/IEEE 11073-10101		SNOMED CT		Notes
		Concept ID	Description ID	Description text	
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				

Table II.3 – Events and attributes not mapped to SNOMED CT

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				

Appendix III

Delivery of PHMR data within national and regional contexts

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

III.1 Delivery of PHMR data via ONC Direct

The Direct project of the Office of the National Coordinator (ONC) of the United States Department of Health and Human Services – Health Information Technology – establishes 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 ONC's meaningful use requirements can follow the guidelines for a HIS Sender – ONC_DIRECT.

This appendix documents a certified capability class that builds on 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 communication.
2. Send the ZIP package using the simple mail transport protocol (SMTP) [b-IETF RFC 5321].
3. When sending the ZIP package using SMTP, follow the specifications of [b-Direct].

See [b-ONC-DIRECT-AS] for additional details.

The relevant certified capability classes and messaging guidelines are given in the Table III.1 and Table III.2.

Table III.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, 6.2.3.3, 6.2.4, 6.2.5.2
HIS Receiver – ONC_DIRECT	Not Certified	6.2.2.2, 6.2.3.2, 6.2.3.3, 6.2.4, 6.2.5.2

Table III.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].	

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For all other referenced documents, see the bibliography of [ITU-T H.810].

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