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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Interoperability compliance testing of personal health systems (HRN, PAN, LAN, TAN and WAN)

Conformance of ITU-T H.810 personal health devices: WAN interface Part 7: Consent management: Sender

Recommendation ITU-T H.830.7

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Recommendation ITU-T H.830.7

Conformance of ITU-T H.810 personal health devices: WAN interface Part 7: Consent management: Sender

Summary

Recommendation ITU-T H.830.7 is a transposition of Continua Health Alliance Test Tool DG2013, Test Suite Structure & Test Purposes, WAN Interface; Part 7: Consent Management. Sender (Version 1.1, 2014-01-24), that was developed by the Continua Health Alliance. A number of versions of this specification existed before transposition.

This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

This Recommendation was initially approved as ITU-T H.837 (01/2015) and later renumbered, without further modifications, as ITU-T H.830.7 (01/2015) for consistency with the numbering of new WAN interface conformance testing specifications.

History

Edition	Recommendation	Approval	Study Group	Unique ID*
1.0	ITU-T H.837	2015-01-13	16	11.1002/1000/12255
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Keywords

Conformance testing, continua design guidelines, e-health, H.810, WAN interface, personal connected health devices, wide area network.

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* To access the Recommendation, type the URL http://handle.itu.int/ in the address field of your web browser, followed by the Recommendation's unique ID. For example, http://handle.itu.int/11.1002/1000/11830-en.

FOREWORD

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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/.

Table of Contents

Electronic attachment: This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

Introduction

This Recommendation is a transposition of Continua Health Alliance Test Tool DG2013, Test Suite Structure & Test Purposes, WAN Interface; Part 7: Consent Management. Sender (Version 1.1, 2014-01-24), that was developed by the Continua Health Alliance. A number of versions of this specification existed before transposition and these can be found in the table below.

Version	Date	Revision history
1.0	2012-10-05	Initial release for Test Tool DG2011
1.1	2013-05-24	Initial release for Test Tool DG2012. This uses "TSS&TP_DG2011_WAN_PART_7_(SEN CM)_v1.0" as a baseline and it adds minor modifications included in [b-CDG 2012] for consent management
1.2	2014-01-24	Initial release for Test Tool DG2013. This uses "TSS&TP_DG2012_WAN_PART_7_(SEN CM)_v1.1.doc" as a baseline because new features included in [b-ITU-T H.810 (2013)] do not affect the test procedures specified in this document

Recommendation ITU-T H.830.7

Conformance of ITU-T H.810 personal health devices: WAN interface Part 7: Consent management: Sender

1 Scope

The scope of this Recommendation[1] is to provide a test suite structure and the test purposes (TSS & TP) for the WAN interface based on the requirements defined in the Continua Design Guidelines (CDG) [ITU-T H.810 (2015)]. The objective of this test specification is to provide a high probability of air interface interoperability between different devices.

TSS & TP for the WAN interface have been divided into the eight parts specified below. This Recommendation covers Part 7.

– Part 1: Web services interoperability [ITU-T H.810 (2015)] Sender
– Part 2: Web services interoperability [ITU-T H.810 (2015] Receiver
– Part 3: SOAP/ATNA. Sender
– Part 4: SOAP/ATNA. Receiver
– Part 5: PCD-01 HL7 messages. Sender
– Part 6: PCD-01 HL7 messages. Receiver
– **Part 7: Consent management** [HL7 CDA IG] **Sender**
– Part 8: Consent management [HL7 CDA IG] Receiver

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 (2015)] Recommendation ITU-T H.810 (2015), *Interoperability design guidelines for personal health systems.*

[ITU-T H.810 (2016)] Recommendation ITU-T H.810 (2016), *Interoperability design guidelines for personal health systems.*

[HL7 CDA IG] Health Level Seven (2011), *HL7 Implementation Guide for Clinical Document Architecture, Release 2: Consent Directives, Release 1, HL7 Draft Standard for Trial Use.* <http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG%20_CONSENTDIR_DSTU_2011JAN.pdf>

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[1] This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

[IEEE 11073-20601A] IEEE 11073-20601A:2010, *IEEE Health informatics – Personal health device communication – Part 20601: Application profile – Optimized Exchange Protocol Amendment 1*.
<http://standards.ieee.org/findstds/standard/11073-20601a-2010.html>

[IHE ITI TF-2b] IHE IT TF-2b (2009), *IHE ITI Infrastructure Technical Framework, Volume 2b: Transactions Part B. Revision 6.0 Final Text.*
<www.ihe.net/technical_framework/upload/ihe_iti_tf_6-0_vol2b_ft_2009-08-10.pdf>

3 Definitions

3.1 Terms defined elsewhere

This Recommendation uses the following terms defined elsewhere:

3.1.1 agent [IEEE 11073-20601A]: A node that collects and transmits personal health data to an associated manager.

3.1.2 manager [IEEE 11073-20601A]: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

3.2 Terms defined in this Recommendation

None.

4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

ATNA Audit Trail and Node Authentication

ATS Abstract Test Suite

CDA Clinical Document Architecture

CDG Continua Design Guidelines

DUT Device Under Test

ebXML electronic business using extensible Markup Language

EHR Electronic Health Record

INR International Normalized Ratio

IUT Implementation Under Test

MDS Medical Device System

MTOM Message Transmission Optimization Mechanism

NFC Near Field Communication

PCD Patient Care Device

PCO Point of Control and Observation

PCT Protocol Conformance Testing

PHD Personal Healthcare Device

PHDC Personal Healthcare Device Class

PHM Personal Healthcare Monitoring (report)

PICS Protocol Implementation Conformance Statement

PIXIT Protocol Implementation extra Information for Testing

S/MIME Secure/Multipurpose Internet Mail Extensions

SDP Service Discovery Protocol

SABTE Sleep Apnoea Breathing Therapy Equipment

SOAP Simple Object Access Protocol

TCRL Test Case Reference List

TCWG Test and Certification Working Group

TP Test Purpose

TSS Test Suite Structure

URI Uniform Resource Identifier

USB Universal Serial Bus

WAN Wide Area Network

WDM Windows Driver Model

WS Web Service

WSDL Web Service Description Language

XDR cross-enterprise Document Reliable interchange

XDS.b cross-enterprise Document Sharing-b

XML extensible Markup Language

5 Conventions

The key words "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "MAY", "MAY NOT" in this Recommendation are to be interpreted as in [b-ETSI SR 001 262].

– SHALL is equivalent to 'must' or 'it is required to'.

– SHALL NOT is equivalent to 'must not' or 'it is not allowed'.

– SHOULD is equivalent to 'it is recommended to'.

– SHOULD NOT is equivalent to 'it is not recommended to'.

– MAY is equivalent to 'is permitted'.

– MAY NOT is equivalent to 'it is not required that'.

NOTE – The above-mentioned key words are capitalized for illustrative purposes only and they do not appear capitalized within this Recommendation.

Reference is made in the ITU-T H.800-series of Recommendations to different versions of the Continua Design Guidelines (CDG) by a specific designation. The list of terms that may be used in this Recommendation is provided in Table 1.

Table 1 – List of designations associated with the various versions of the CDG

CDG release	Transposed as	Version	Description	Designation
2016 plus errata	[ITU-T H.810 (2016)]	6.1	Release 2016 plus errata noting all ratified bugs [ITU-T H.810 (2016)].	–
2016	–	6.0	Release 2016 of the CDG including maintenance updates of the CDG 2015 and additional guidelines that cover new functionalities.	Iris
2015 plus errata	[ITU-T H.810 (2015)]	5.1	Release 2015 plus errata noting all ratified bugs [ITU-T H.810 (2015)].	–
2015	–	5.0	Release 2015 of the CDG including maintenance updates of the CDG 2013 and additional guidelines that cover new functionalities.	Genome
2013 plus errata	[ITU-T H.810 (2013)]	4.1	Release 2013 plus errata noting all ratified bugs [b-ITU-T H.810 (2013)].	–
2013	–	4.0	Release 2013 of the CDG including maintenance updates of the CDG 2012 and additional guidelines that cover new functionalities.	Endorphin
2012 plus errata	–	3.1	Release 2012 plus errata noting all ratified bugs [b-CDG 2012].	–
2012	–	3.0	Release 2012 of the CDG including maintenance updates of the CDG 2011 and additional guidelines that cover new functionalities.	Catalyst
2011 plus errata	–	2.1	CDG 2011 integrated with identified errata.	–
2011	–	2.0	Release 2011 of the CDG including maintenance updates of the CDG 2010 and additional guidelines that cover new functionalities [b-CDG 2011].	Adrenaline
2010 plus errata	–	1.6	CDG 2010 integrated with identified errata	–
2010	–	1.5	Release 2010 of the CDG with maintenance updates of the CDG Version 1 and additional guidelines that cover new functionalities [b-CDG 2010].	1.5
1.0	–	1.0	First released version of the CDG [b-CDG 1.0].	–

6 Test suite structure (TSS)

The test purposes (TPs) for the WAN interface have been divided into the main subgroups specified below. Annex A describes the TPs for subgroups 1.5.1 to 1.5.3 (shown in bold).

– Group 1: Sender (SEN)

  • Group 1.1: Web services interoperability (WSI)

    - Subgroup 1.1.1: Basic profile (BP)
    - Subgroup 1.1.2: Basic security profile (BSP)
    - Subgroup 1.1.3: Reliable messaging (RM)
  - Group 1.2: SOAP (SOAP)
    - Subgroup 1.2.1: SOAP headers (HEAD)
  - Group 1.3: Audit (ATNA)
    - Subgroup 1.3.1: General (GEN)
    - Subgroup 1.3.2: PCD-01 (PCD-01)
    - Subgroup 1.3.3: Consent management (CM)
  - Group 1.4: PCD-01 HL7 messages (PCD-01-DATA)
    - Subgroup 1.4.1: General (GEN)
    - Subgroup 1.4.2: Design guidelines (DG)
    - Subgroup 1.4.3: Pulse oximeter (PO)
    - Subgroup 1.4.4: Blood pressure monitor (BPM)
    - Subgroup 1.4.5: Thermometer (TH)
    - Subgroup 1.4.6: Weighing scales (WEG)
    - Subgroup 1.4.7: Glucose meter (GL)
    - Subgroup 1.4.8: Cardiovascular fitness and activity monitor (CV)
    - Subgroup 1.4.9: Strength fitness equipment (ST)
    - Subgroup 1.4.10: Independent living activity hub (HUB)
    - Subgroup 1.4.11: Adherence monitor (AM)
    - Subgroup 1.4.12: Peak expiratory flow monitor (PF)
    - Subgroup 1.4.13: Body composition analyser (BCA)
    - Subgroup 1.4.14: Basic electrocardiograph (ECG)
    - Subgroup 1.4.15: International normalized ratio (INR)
    - Subgroup 1.4.16: Sleep apnoea breathing therapy equipment (SABTE)
  - **Group 1.5: Consent management (CM)**
    - **Subgroup 1.5.1: WAN XDR transaction (TRANS)**
    - **Subgroup 1.5.2: WAN metadata validation (META)**
    - **Subgroup 1.5.3: WAN consent directive validation (CDV)**
  - Group 1.6: hData observation upload (HDATA)
    - Subgroup 1.6.1: General (GEN)
  - Group 1.7: Questionnaires (QUE)
    - Subgroup 1.7.1: General (GEN)
    - Subgroup 1.7.2: CDA validation (CDA)
- Group 2: Receiver (REC)
  - Group 2.1: Web service interoperability (WSI)
    - Subgroup 2.1.1: Basic profile (BP)
    - Subgroup 2.1.2: Basic security profile (BSP)
    - Subgroup 2.1.3: Reliable messaging (RM)
  - Group 2.2: SOAP (SOAP)

- Subgroup 2.2.1: SOAP headers (HEAD)
- Group 2.3: Audit (ATNA)
  - Subgroup 2.3.1: General (GEN)
  - Subgroup 2.3.2: PCD-01 (PCD-01)
  - Subgroup 2.3.3: Consent management (CM)
- Group 2.4: PCD-01 HL7 messages (PCD-01-DATA)
  - Subgroup 2.4.1: General (GEN)
  - Subgroup 2.4.2: Design guidelines (DG)
  - Subgroup 2.4.3: Pulse oximeter (PO)
  - Subgroup 2.4.4: Blood pressure monitor (BPM)
  - Subgroup 2.4.5: Thermometer (TH)
  - Subgroup 2.4.6: Weighing scales (WEG)
  - Subgroup 2.4.7: Glucose meter (GL)
  - Subgroup 2.4.8: Cardiovascular fitness and activity monitor (CV)
  - Subgroup 2.4.9: Strength fitness equipment (ST)
  - Subgroup 2.4.10: Independent living activity hub (HUB)
  - Subgroup 2.4.11: Adherence monitor (AM)
  - Subgroup 2.4.12: Peak expiratory flow monitor (PF)
  - Subgroup 2.4.13: Body composition analyser (BCA)
  - Subgroup 2.4.14: Basic electrocardiograph (ECG)
  - Subgroup 2.4.15: International normalized ratio (INR)
  - Subgroup 2.4.16: Sleep apnoea breathing therapy equipment (SABTE)
- Group 2.5: Consent management (CM)
  - Subgroup 2.5.1: WAN XDR transaction (TRANS)
  - Subgroup 2.5.2: WAN service validation (SER)
  - Subgroup 2.7.3: hData record format (HRF)

7 Electronic attachment

The protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A can be downloaded from http://handle.itu.int/11.1002/2000/12067.

In the electronic attachment, letters "C" and "I" in the column labelled "Mandatory" are used to distinguish between "PICS" and "PIXIT" respectively during testing. If the cell is empty, the corresponding PICS is "independent". If the field contains a "C", the corresponding PICS is dependent on other PICS, and the logical expression is detailed in the "SCR_Expression" field. The static conformance review (SCR) is used in the test tool to assert whether the PICS selection is consistent.

Annex A

Test purposes

(This annex forms an integral part of this Recommendation.)

A.1 TP definition conventions

The test purposes (TPs) are defined according to the following rules:

– **TP Id**: This is a unique identifier (TP/<TT>/<DUT>/<GR>/<SGR>/<XX> – <NNN>). It is specified according to the naming convention defined below:

- Each test purpose identifier is introduced by the prefix "TP".
- <TT>: This is the test tool that will be used in the test case.
  - WAN: Wide area network
- <DUT>: This is the device under test.
  - SEN: WAN observation sender
  - REC: WAN observation receiver
- <GR>: This identifies a group of test cases.
- <SGR>: This identifies a subgroup of test cases.
- <XX>: This identifies the type of testing.
  - BV: Valid behaviour test
  - BI: Invalid behaviour test
- <NNN>: This is a sequential number that identifies the test purpose (TP).

– **TP label**: This is the title of the TP.

– **Coverage**: This contains the specification reference and clause to be checked by the TP.

- Spec: This indicates the earliest version of the specification from which the testable items to be checked by the TP are included.
- Testable item: This contains testable items to be checked by the TP.

– **Test purpose**: This is a description of the requirements to be tested.

– **Applicability**: This contains the PICS items that define if the test case is applicable or not for a specific device. When a TP contains an "ALL" in this field it means that it applies to the device under test within that scope of the test (specialization, transport used, etc.).

– **Other PICS:** This contains additional PICS items (apart from the PICS specified in the Applicability row) which are used within the test case implementation and can modify the final verdict. When this row is empty, it means that only the PICS specified in the Applicability row are used within the test case implementation.

– **Initial condition**: This indicates the state to which the DUT needs to be moved at the beginning of TC execution.

– **Test procedure**: This describes the steps to be followed in order to execute the test case.

– **Pass/Fail criteria**: This provides criteria to decide whether the DUT passes or fails the test case.

A.2 Subgroup 1.5.1: WAN XDR transaction (TRANS)

TP Id		TP/WAN/SEN/CM/TRANS/BV-000		
TP label		Provide and Register Document Set-b Transaction Request		
Coverage	**Spec**	[b-CDG 2012] - WAN interface requirements for consent management		
	Testable items	ConsentSender3; M		
	Spec	[IHE ITI TF-2b]		
	Testable items	ProvideProtocol12; M	ProvideProtocol13; M	ProvideProtocol2; M
		ProvideSource1; M		
Test purpose		Check that: Consent Enabled WAN Observation Sender shall send the consent document at least once to the WAN Observation Receiver [AND] The Document Source shall generate Provide and Register Document Set-b transactions in MTOM/XOP format. [AND] The Document Source shall accept the response message in MTOM/XOP format. [AND] The Provide and Register Document Set-b transaction shall use SOAP12 and MTOM with XOP encoding. [AND] An implementation of the Document Source actor shall be capable of submit one or more documents.		
Applicability		C_SEN_000 AND C_SEN_GEN_002		
Other PICS				
Initial condition		The WAN simulated receiver has a WebService enabled with a consent management service. The sender under test has a clinical document architecture (CDA) ready to be sent to the respective service according to its needs.		
Test procedure		1. The sender under test sends a "'Provide and Register Document Set-b Request"' message. 2. Check that: a. In the HTTP header: • action="urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b" • Content-Type = multipart/related • boundary element is a MIMEBoundary • type = "application/xop+xml" b. In the SOAP message • The namespace of the SOAP envelope is "http://www.w3.org/2003/05/soap-envelope" (SOAP 1.2) • There are one or more xsdb:Document elements in the SOAP Body. 3. The simulated receiver responds with a "Provide and Register Document Set-b Response" message 4. The sender under test accepts the message (it does not give any error message).		

Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

A.3 Subgroup 1.5.2: WAN metadata validation (META)

TP Id		TP/WAN/SEN/CM/META/BV-000		
TP label		Metadata Syntactic Validation		
Coverage	**Spec**	[IHE ITI TF-2b]		
	Testable items	ProvideScope1; M	ProvideProtocol9; M	
	Spec	[b-CDG 2012] - WAN interface requirements for consent management		
	Testable items	ConsentSender4; M	ConsentSender 5; M	
Test purpose		Check that: A Provide and Register Document Set-b transaction shall carry: - Metadata describing zero or more documents - Within metadata, one XDSDocumentEntry object per document - XDS Submission Set definition along with the linkage to new documents and references to existing documents - Zero or more XDS Folder definitions along with the linkage to new or existing documents - Zero or more documents [AND] The <ihe:ProvideAndRegisterDocumentSetRequest/> element is defined as: - One <lcm:SubmitObjectsRequest/> element that contains the submission set metadata - Zero or more <ihe:Document/> elements that contain the base64encoded data for the documents being submitted to the Document Repository. The <ihe:Document/> also includes the document id attribute (ihe:Document/@id) of type xsd:anyURI to match the document ExtrinsicObject id in the metadata and providing the necessary linkage [AND] The consent document transmitted by the Consent Enabled WAN Observation Sender shall contain the same Patient Identifier as the WAN Observation measurement message(s).		
Applicability		C_SEN_000 AND C_SEN_GEN_002		
Other PICS				
Initial condition		The WAN simulated receiver has a WebService enabled with a consent management service and a CommunicatePCDData service. The sender under test has a CDA ready to be sent to the respective service according to its needs.		
Test procedure		1. The sender under test sends a "Provide and Register Document Set-b Request" message to the consent management service and a "PCD-01" message to the CommunicatePCDData service. 2. Check that in the SOAP body: a. There is only one <ProvideAndRegisterDocumentSetRequest/> element, and that it contains: o Only one <lcm:SubmitObjectsRequest/> element, that contains: - A XDSDocumentEntry (ExtrinsicObject) element for each document		

	- An XDS Submission Set definition along with the linkage to new documents and references to existing documents (RegistryPackage element) - Zero or more XDS Folder definitions along with the linkage to new or existing documents. o Zero or more <ihe:Document/> elements. b. The PID-3 element of the "PCD-01" message is equal to SubmitObjectsRequest/RegistryObjectList/ExtrinsicObject/Slot[@name = sourcePatientId]/ValueList/Value element of the metadata, and: o Subfields CX-1 and CX-4 are present. o Subfield CX-5 is not present.
Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

TP Id		TP/WAN/SEN/CM/META/BV-001		
TP label		Metadata Submission Set Validation		
Coverage	**Spec**	[b-CDG 2012]		
	Testable items	WANXDSSub-1; O	WANXDSSub-2; M	WANXDSSub-3; M
		WANXDSSub-4; M	WANXDSSub-5; M	WANXDSSub-6; M
		WANXDSSub-7; O	WANXDSSub-8; M	WANXDSSub-9; O
		WANXDSSub-10; M	WANXDSSub-11; M	WANXDSSub-12; M
		WANXDSSub-13; M	WANXDSSub-14; M	WANXDSSub-15; M
Test purpose		Check that: availabilityStatus element MAY be present [AND] author element SHALL be equal to Consent Directive /ClinicalDocument/author [AND] authorInstitution element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization [AND] authorPerson element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson [AND] authorRole element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction [AND] authorSpecialty element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code [AND] comments element MAY be present [AND] contentTypeCode element SHALL be present [AND]		

	contentTypeCodeDisplayName element MAY be present [AND] entryUUID element SHALL be equal to Consent Directive unique ID for submission set [AND] patientId element SHALL be mapped from /ClinicalDocument/recordTarget/patientRole/id [AND] sourceId element SHALL be present [AND] submissionTime element SHALL be present [AND] title element SHALL be equal to Consent Directive /ClinicalDocument/title [AND] uniqueId element SHALL be equal to Consent Directive /ClinicalDocument/id
Applicability	C_SEN_000 AND C_SEN_GEN_002
Other PICS	
Initial condition	The WAN simulated receiver has a WebService enabled with a consent management service. The sender under test has a CDA ready to be sent to the respective service according to its needs.
Test procedure	1. The sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body 2. Check the following elements of the "Metadata in Submission Set" section sent by the sender under test and its concordance with the clinical document: a. availabilityStatus element may be present b. author element is equal to Consent Directive /ClinicalDocument/author c. authorInstitution element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization d. authorPerson element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson e. authorRole element is equal to Consent Directive /ClinicalDocument/author/participationFunction f. authorSpecialty element Is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code g. comments element may be present h. contentTypeCode element Is present i. entryUUID element is equal to Consent Directive unique ID for submission set j. patientId element is mapped from /ClinicalDocument/recordTarget/patientRole/id k. sourceId element is present l. submissionTime element is present m. title element is equal to Consent Directive /ClinicalDocument/title n. uniqueId element is equal to Consent Directive /ClinicalDocument/id.
Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

TP Id		TP/WAN/SEN/CM/META/BV-002		
TP label		Metadata Document Entry Validation		
Coverage	**Spec**	[b-CDG 2012]		
	Testable items	WANXDSDocEntry-1; O	WANXDSDocEntry-2; M	WANXDSDocEntry-3; M
		WANXDSDocEntry-4; M	WANXDSDocEntry-5; M	WANXDSDocEntry-6; M
		WANXDSDocEntry-7; M	WANXDSDocEntry-8; O	WANXDSDocEntry-9; O
		WANXDSDocEntry-10; M	WANXDSDocEntry-11; M	WANXDSDocEntry-12; M
		WANXDSDocEntry-13; M	WANXDSDocEntry-14; M	WANXDSDocEntry-15; O
		WANXDSDocEntry-16; M	WANXDSDocEntry-17; O	WANXDSDocEntry-18; M
		WANXDSDocEntry-19; M	WANXDSDocEntry-20; M	WANXDSDocEntry-21; M
		WANXDSDocEntry-22; M	WANXDSDocEntry-23; M	WANXDSDocEntry-24; M
		WANXDSDocEntry-25; O	WANXDSDocEntry-26; O	WANXDSDocEntry-27; O
		WANXDSDocEntry-28; M	WANXDSDocEntry-29; M	WANXDSDocEntry-30; M
		WANXDSDocEntry-31; M	WANXDSDocEntry-32; M	WANXDSDocEntry-33; M
		WANXDSDocEntry-34; M	WANXDSDocEntry-35; M	WANXDSDocEntry-36; M
		WANXDSDocEntry-37; M	WANXDSDocEntry-38; M	WANXDSDocEntry-39; M
		WANXDSDocEntry-40; O	WANXDSDocEntry-41; M	WANXDSDocEntry-42; M
		WANXDSDocEntry-43; M		
Test purpose		Check that: availabilityStatus element MAY be present [AND] author element SHALL be equal to Consent Directive /ClinicalDocument/author [AND] authorInstitution element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization/name, id [AND] authorPerson element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson [AND] authorRole element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction/code [AND] authorSpecialty element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction [AND] classCode element SHALL be present and SHALL use the LOINC code 57016-8 [AND] classCodeDisplayName element MAY be present [AND]		

	Comments element MAY be present [AND] confidentialityCode element SHALL be equal to Consent Directive /ClinicalDocument/confidentialityCode [AND] confidentialityCodeDisplayName element SHALL be equal to Consent Directive /ClinicalDocument/confidentialityCode [AND] creationTime element SHALL be equal to Consent Directive /ClinicalDocument/effectiveTime [AND] entryUUID element SHALL be present [AND] eventCodeList element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/code [AND] eventCodeDisplayNameList element MAY be present [AND] formatCode element SHALL be present and equal to “urn:continua:cd:2011” [AND] formatCodeDisplayName element MAY be present [AND] hash element SHALL be present [AND] healthcareFacilityTypeCode element SHALL be present [AND] healthcareFacilityTypeCodeDisplayName element MAY be present [AND] languageCode element SHALL be equal to Consent Directive /ClinicalDocument/languageCode [AND] legalAuthenticator element SHALL be equal to Consent Directive /ClinicalDocument/legalAuthenticator [AND] mimeType element SHALL be equal to Consent Directive text/xml [AND] parentDocument element MAY come from /ClinicalDocument/relatedDocument/parentDocument [AND] parentDocumentId element MAY come from /ClinicalDocument/relatedDocument/parentDocument/id [AND] parentDocumentRelationship element MAY come from /ClinicalDocument/relatedDocument/typeId [AND] patientId element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id [AND]

	practiceSettingCode element SHALL be present [AND] practiceSettingCodeDisplayName element SHALL be present [AND] serviceStartTime element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low [AND] serviceStopTime element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high [AND] size element SHALL be present [AND] sourcePatientId element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id [AND] sourcePatientInfo element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id [AND] title element SHALL be equal to Consent Directive /ClinicalDocument/title [AND] typeCode element SHALL be equal to Consent Directive /ClinicalDocument/code/@code [AND] typeCodeDisplayName element SHALL be equal to Consent Directive /ClinicalDocument/code/@displayName [AND] uniqueId element SHALL be equal to Consent Directive /ClinicalDocument/id [AND] URI element MAY be present [AND] parentDocument element SHALL NOT be present [AND] parentDocumentId element SHALL NOT be present [AND] parentDocumentRelationship element SHALL NOT be present
Applicability	C_SEN_000 AND C_SEN_GEN_002
Other PICS	
Initial condition	The WAN simulated Receiver has a WebService enabled with a consent management service. The sender under test has a CDA ready to be sent to the respective service according to its needs.
Test procedure	1. The sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body 2. Check the following elements of the metadata in the "Document Entry" section sent by the sender under test and its concordance with the clinical document: a. availabilityStatus element may be present b. author element is equal to Consent Directive /ClinicalDocument/author c. authorInstitution element is equal to Consent Directive

	/ClinicalDocument/author/assignedAuthor/representedOrganization/name, id d. authorPerson element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson e. authorRole element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code f. authorSpecialty element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code/@code g. classCode element is equal to LOINC code 57016-8 h. classCodeDisplayName element may be present i. comments element may be present
	j. confidentialityCode element is equal to Consent Directive /ClinicalDocument/confidentialityCode k. confidentialityCodeDisplayName element is equal to Consent Directive /ClinicalDocument/confidentialityCode l. creationTime element is equal to Consent Directive /ClinicalDocument/effectiveTime m. entryUUID element is present n. eventCodeDisplayNameList element may be present o. formatCode element is equal to "urn:continua:cd:2011" p. formatCodeDisplayName element may be present q. hash element is present r. healthcareFacilityTypeCode element is present s. healthcareFacilityTypeCodeDisplayName element may be present t. languageCode element is equal to Consent Directive /ClinicalDocument/languageCode u. legalAuthenticator element is equal to Consent Directive /ClinicalDocument/legalAuthenticator v. mimeType element is equal to Consent Directive text/xml w. parentDocument element may come from /ClinicalDocument/relatedDocument/parentDocument x. parentDocumentId element may come from /ClinicalDocument/relatedDocument/parentDocument/id y. parentDocumentRelationship element may come from /ClinicalDocument/relatedDocument/typeId z. patientId element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id aa. practiceSettingCode element Is present bb. practiceSettingCodeDisplayName element Is present cc. serviceStartTime element is equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low dd. serviceStopTime element is equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high ee. size element is present ff. sourcePatientId element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id gg. sourcePatientInfo element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id hh. title element is equal to Consent Directive /ClinicalDocument/title ii. typeCode element is equal to Consent Directive /ClinicalDocument/code/@code

	jj. typeCodeDisplayName element is equal to Consent Directive /ClinicalDocument/code/@displayName kk. uniqueId element is equal to Consent Directive /ClinicalDocument/id II. URI element may be present
Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

A.4 Subgroup 1.5.3: WAN consent directive validation (CDV)

TP Id		TP/WAN/SEN/CM/CDV/BV-000		
TP label		Consent Directive Validation		
Coverage	**Spec**	[HL7 CDA IG]		
	Testable items	CONF-CD-1; M	CONF-CD-2; M	CONF-CD-2.2; M
		CONF-CD-3; M	CONF-CD-4; O	CONF-CD-4.2; O
		CONF-CD-4.3; O	CONF-CD-4.4; O	CONF-CD-5; O
		CONF-CD-6; O	CONF-CD-7; O	CONF-CD-8; O
		CONF-CD-9; O	CONF-CD-10; M	CONF-CD-11; M
		CONF-CD-12; O	CONF-CD-12.2; O	CONF-CD-13; M
		CONF-CD-14; M	CONF-CD-15; M	CONF-CD-16; M
		CONF-CD-17; M	CONF-CD-18; M	CONF-CD-19; R
		CONF-CD-20; R	CONF-CD-21; O	CONF-CD-22; R
		CONF-CD-23; R	CONF-CD-24; O	CONF-CD-25; M
		CONF-CD-26; M	CONF-CD-27; M	CONF-CD-28; O
		CONF-CD-29; R	CONF-CD-30; R	CONF-CD-31; O
		CONF-CD-32; O	CONF-CD-33; O	CONF-CD-34; M
		CONF-CD-35; O	CONF-CD-36; R	CONF-CD-37; O
		CONF-CD-38; R	CONF-CD-39; O	CONF-CD-41; C
		CONF-CD-42; O		
Test purpose		Check that: A document conforming to the CDA R2 General Header template shall include the ClinicalDocument/templateId “2.16.840.1.113883.10.20.3” [AND] ClinicalDocument/templateId element shall be present with the value “2.16.840.1.113883.3.445.1” [AND] Each Privacy Consent Directive must specify a healthcare client whose IIHI is affected by the privacy consent directive. [AND]		

	ClinicalDocument/author element shall be present and specify a templateId if "2.16.840.1.113883.3.445.2" [AND] ClinicialDocument/author/functionCode/ may be present to specify function/relationship of the author to the client who is the record target. This element may be used to specify the client's relationship to the Substitute Decision Maker – if one is involved in the creation of the privacy consent directive [AND] Information Recipient is used to specify the recipients of the Privacy Consent Directive. In the case of consultations and referrals, the Privacy Consent Directive recipient may be the same person/entity as the intended recipient of the client IIHI that is disclosed as a result of the persimission granted using the Privacy Consent Directive. [AND] The legalAuthenticator is as defined in CDA. For a Privacy Consent Document this element may be either the client or their Substitute Decision Maker. If necessary, the Signatures section may provide the signature associated with the consenter's signature. [AND] In some cases, a Privacy Consent Document may identify and record the signature of a person who witnessed the consenter's signature. This may occur if the authenticator/consenter makes a mark instead of a signature. [AND] ClinicalDocument/documentationOf/serviceEvent/ element with a templateId of "2.16.840.1.113883.3.445.3" may be present [AND] ClinicalDocument/documentationOf/serviceEvent/id element may be present [AND] ClinicalDocument/documentationOf/serviceEvent/effectiveTime element may be present [AND] ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low/@value element may be present. It may be different than the value of the ClinicalDocument/documentationOf/serviceEvent/effectiveTime/@value and represents the first time the Privacy Consent Directive takes effect [AND] ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high/@value element may be present to specify the date/time when the Privacy Consent Directives expires [AND] ClinicalDocument/documentationOf/serviceEvent/code/@code attribute shall be present and indicates the OID of the externally identified and defined privacy policy corresponding to the "Privacy Policy Acknowledgement Document" [AND] ClinicalDocument/documentationOf/serviceEvent/code/@codeSystem attribute shall be present and indicates the assigning authority of the externally identified and defined privacy policy corresponding to the "Privacy Policy Acknowledgement Document" [AND] ClinicalDocument/documentationOf/serviceEvent/code/@codeSystemName attribute may be present and be a descriptive text of the privacy policy being acknowledged. [AND] A Privacy Consent Directive may replace a previous (revoked) or expired Privacy Consent Directive. [AND] /ClinicalDocument/confidentialityCode/@code SHALL be present and SHALL be equal to "R" [AND]

	/ClinicalDocument/confidentialityCode/@codeSystem SHALL be present and SHALL be equal to 2.16.840.1.113883.5.25 [AND] If present, /ClinicalDocument/confidentialityCode/@codeSystemName SHALL be equal to "Confidentiality" [AND] If present, /ClinicalDocument/confidentialityCode/@displayName SHALL be equal to "Restricted"[AND] A Privacy Consent Directive shall have a structuredBody element [AND] A Privacy Consent Directive shall contain a Privacy Consent Directive Details section [AND] This section shall include the templateId for the Privacy Consent Directive section with the value "2.16.840.1.113883.3.445.17" and a title of "Privacy Consent Directive Details". [AND] This section shall include an entry element with templateId of "2.16.840.1.113883.3.445.4" and a typeCode of "COMP" to organize the structure of a Privacy Consent Directive entry. [AND] This entry element shall include an act element with templateId of "2.16.840.1.113883.3.445.5" and a moodCode of "DEF" to specify the execution of a Privacy Consent Directive. [AND] The act element shall include a code element to specify the purpose of use for which the privacy consent is applicable [AND] This section should include one or more entry/act/informant/[@typeCode='CST'] elements with a templateId of "2.16.840.1.113883.3.445.6" to represent the custodian of the referenced IIHI. This may be different than the custodian of the Privacy Consent Directive document identified in the header. Note, if the informant is different from the custodian of the IIHI, then the informant is re-disclosing, which typically is not allowed. [AND] This section should include one or more entry/act/participant/[@typeCode='IRCP'] elements with a templateId of "2.16.840.1.113883.3.445.7" to represent the provider organization or person intended to use, access, collect information as allowed or prevented by the action specified in this privacy consent directive. [AND] The participant element may include participantRole/codeSystem specification of "2.16.840.1.113883.11.19682" corresponding to the receiving provider's role [DYNAMIC]. [AND] The participantRole element should include playingEntity element corresponding to the organization or provider intended to receive the information specified in this Privacy Consent Directive document. [AND] This section should include one or more entry/act/participant/ elements to represent the provider organization or person intended to use, access, collect information, as allowed or prevented by the action specified in this privacy consent directive. [AND] This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.8" to represent the action allowed and problem associated with the information allowed by the Privacy Consent Directive. [AND] This entryRelationship shall include an act element with default classCode="ACT" and moodCode="DEF".

	[AND] This act element should include a @negationId attribute with a default value of “false” indicating that the action specified is enabled, and a value of “true” if the action is not allowed by the Privacy Consent Directive. When the negationInd attribute is not transmitted, the receiver must assume the default (specified action is enabled). [AND] The act element shall include a code element with default of codeSystem=”2.16.840.1.113883.5.4” to specify the Privacy Consent Directive operation or action [DYNAMIC]. [AND] This section may include an entry/act/entryRelationship/ with a templateId of “2.16.840.1.113883.3.445.9” to represent the entire set of protected information (IIHI) including specific attributes of that information (e.g., category type, related diagnosis, sensitivity/confidentiality). [AND] The observation element should include one or more organizer/component/observation[@moodCode=’DEF’]/ elements with a templateId of “2.16.840.1.113883.3.445.10” to specify each information type (IIHI) included in the authorization contained in the Privacy Consent Directive document. [AND] The observation element should include a code element to specify the code corresponding to the information type (IIHI) included in the authorization contained in the Privacy Consent Directive document. [AND] The observation element may include a precondition[@typeCode=”PRCN”]/ element with a templateId of “2.16.840.1.113883.3.445.11” to specify the diagnosis or problem associated with the information. [AND] The observation element may include a precondition[@typeCode=”PRCN”]/ element with a templateId of “2.16.840.1.113883.3.445.12” to specify the sensitivity of the protected information (IIHI) specified in Privacy Consent Directive. [AND] This section may include an entry/act/entryRelationship with a templateId of “2.16.840.1.113883.3.445.13” to represent references to Privacy Policies on which the Privacy Consent Directive is based along with the information recipient Obligation. [AND] The component element shall include an act/code element to specify the Privacy Policy or regulation that is basis for requesting the authorizations specified in the Privacy Consent Directive. [AND] The component element may include a precondition element with a templateId of “2.16.840.1.113883.3.445.14” and an element of @typeCode=”PRCN” to specify any additional obligations imposed on the recipient of the IIHI referenced in the Privacy Consent Directive. [AND] The component element should include a criterion[classCode=”OBS”]/code element to specify the coded obligations imposed on the recipient of the IIHI referenced in the Privacy Consent Directive. [AND] This section may include an entry/act/entryRelationship with a templateId of “2.16.840.1.113883.3.445.15” to include a scanned image of the paper-based Privacy Consent Directive. [AND] The entryRelationship element should include an observationMedia[@classCode=”OBS”] element to embed a scanned document representation of the Privacy Consent Directive including

	required signatures. [AND] This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.16" to represent an alternative representation of the Privacy Consent Directive (e.g.,ODRL, XrML, XACML). [AND] If included, this section shall include the templateId for the Signatures section "2.16.840.1.113883.3.445.18" and a title of "Signatures". [AND] This section may include the entry/observationMedia for each signature (e.g.,legalAuthenticator, authenticator) or a scanned version of the entire privacy consent directive form including the signatures.
Applicability	C_SEN_000 AND C_SEN_GEN_002
Other PICS	
Initial condition	The WAN simulated receiver has a webservice enabled with a consent management service. The sender under test has a CDA ready to be sent to the respective service according to its needs.
Test procedure	1. The sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body 2. Check the following elements of the Clinical Document sent by the sender under test: a. A templateId = "2.16.840.1.113883.10.20.3" b. Another templateId = "2.16.840.1.113883.3.445.1" c. code attribute of the confidentialityCode element is present and equal to "R". d. codeSystem attribute of the confidentialityCode element is present and equal to 2.16.840.1.113883.5.25. e. If present, codeSystemName of the confidentialityCode element is present and equal to "Confidentiality". f. If present, displayName attribute of the confidentialityCode element is equal to "Restricted". g. recordTarget element is present h. author element: o /templateId = "2.16.840.1.113883.3.445.2" o /functionCode may be present i. intendedRecipient element: the Privacy Consent Directive recipient may be the same person/entity as the intended recipient j. legalAuthenticator element may be either the client or their Substitute Decision Maker and if necessary, the Signatures section may provide the signature associated with the consenter's signature k. authenticator element may be present l. documentationOf/serviceEvent/ element with a templateId of "2.16.840.1.113883.3.445.3" may be present and within this element: o id element may be present o effectiveTime element may be present o effectiveTime/low/@value element may be present o effectiveTime/high/@value element may be present o code/@code attribute is present o code/@codeSystem attribute is present o code/@codeSystemName attribute may be present

m. relatedDocument element may be present

n. component/structuredBody element is present and within this element:

- component/section with templateId = "2.16.840.1.113883.3.445.17" is present
- component/section/title = Privacy Consent Directive Details
- component/section/entry is present
- component/section/entry/templateId = "2.16.840.1.113883.3.445.4"
- component/section/entry/@typeCode = "COMP"
- component/section/entry/act/templateId = "2.16.840.1.113883.3.445.5"
- component/section/entry/act/@moodcode ="DEF"
- component/section/entry/act/code is present
- component/section/entry/act/informant/@typeCode = 'CST'
- one or more component/section/entry/act/participant should be present
- one or more component/section/entry/act/participant/@typeCode = 'IRCP' and component/section/entry/act/participant/templateId = "2.16.840.1.113883.3.445.7" should be present
- component/section/entry/act/participant/participantRole/code/@codeSystem = "2.16.840.1.113883.11.19682" may be present
- component/section/entry/act/participant/participantRole should include a playingEntity element
- component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.8" and if it is present:
  - /act element is present with classCode = "ACT" and moodCode = "DEF"
  - /act/@negationId with a value of "false" or "true" should be present
  - /act/code/@codeSystem = "2.16.840.1.113883.5.4" is present
- component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.9" and if it is present:
  - it should include one or more /organizer/component/observation/@moodCode = 'DEF' with a templateId = "2.16.840.1.113883.3.445.10"
  - /organizer/component/observation should include a code element
  - /organizer/component/observation may include a precondition/@typeCode = "PRCN" element with a templateId = "2.16.840.1.113883.3.445.11"
  - /organizer/component/observation may include a precondition/@typeCode = "PRCN" element with a templateId = "2.16.840.1.113883.3.445.12"
- component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.13" and if it is present:
  - /act/code is present
  - /act/precondition may be present with templateId = "2.16.840.1.113883.3.445.14" and @typeCode = "PRCN"
  - /act/precondition/criterion/[@classCode = "OBS"]/code should be present
- component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.15" and if it is present:
  - /observationMedia/@classCode = "OBS" should be present
- component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.16"
- component/section with templateId = "2.16.840.1.113883.3.445.18" and a title of "Signatures" may be present, and if present this section may include the entry/observationMedia for each signature

Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

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http://handle.itu.int/11.1002/2000/12067

[b-Sender PICS & PIXIT] WAN Sender DG2013 PICS and PIXIT excel sheet v1.3
http://handle.itu.int/11.1002/2000/12067

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