International Telecommunication Union

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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.837

International Telecommunication Union

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Recommendation ITU-T H.837

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

Summary

Recommendation ITU-T H.837 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.

History

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

* 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

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.

INTELLECTUAL PROPERTY RIGHTS

ITU draws attention to the possibility that the practice or implementation of this Recommendation may involve the use of a claimed Intellectual Property Right. ITU takes no position concerning the evidence, validity or applicability of claimed Intellectual Property Rights, whether asserted by ITU members or others outside of the Recommendation development process.

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: 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 [ITU-T H.810] do not affect the test procedures specified in this document

Recommendation ITU-T H.837

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]. The objective of this test specification is to provide a high probability of air interface interoperability between different devices.

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

– **Part 1:** Web services interoperability [ITU-T H.810] Sender
– **Part 2:** Web services interoperability [ITU-T H.810] 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] ITU-T H.810 (2013), *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>

[IHE ITI TF-2b] IHE IT TF-2b (2009) *IHE ITI Infrastructure Technical Framework, Volume 2b: Transactions Part B. Revision 6.0 Final Text.*

[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>

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

3 Definitions

3.1 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
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 document 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. Furthermore, the 2013 edition of the Continua design guidelines, which is published as [ITU-T H.810], is designated by "CDG 2013" as an extension of the designations indicated in the bibliography.

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

CDG name	Transposed as	Version	Description	Designation
2013 plus errata	ITU-T H.810	4.1	CDG 2013 plus errata noting all ratified bugs.	–
2013	–	4.0	Release 2013 of CDG including maintenance updates of the CDG 2012 and additional guidelines that cover new functionalities.	Endorphin
2012 plus errata	–	3.1	CDG 2012 plus errata noting all ratified bugs [b-CDG 2012].	–
2012	–	3.0	Release 2012 of the CDG including maintenance updates of CDG 2011 and additional guidelines that cover new functionalities.	Catalyst

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

CDG name	Transposed as	Version	Description	Designation
2011 plus errata	–	2.1	CDG 2011 integrated with identified errata.	–
2011	–	2.0	Release 2011 of 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 CDG with maintenance updates of 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 (TP) 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)
    - **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 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)
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        - Subgroup 2.4.9: Strength fitness equipment (ST)
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        - Subgroup 2.4.12: Peak expiratory flow monitor (PF)
        - Subgroup 2.4.13: Body composition analyser (BCA)
        - Subgroup 2.4.14: Basic electrocardiograph (ECG)
    - Group 2.5: Consent management (CM)
        - Subgroup 2.5.1: WAN XDR transaction (TRANS)
        - Subgroup 2.5.2: WAN service validation (SER)

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 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.).
- **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)

<table>
<tr><td colspan="2">TP Id</td><td colspan="3">TP/WAN/SEN/CM/TRANS/BV-000</td></tr>
<tr><td colspan="2">TP label</td><td colspan="3">Provide and Register Document Set-b Transaction Request</td></tr>
<tr><td rowspan="5">Coverage</td><td>Spec</td><td colspan="3">[b-CDG 2012] - WAN interface requirements for consent management</td></tr>
<tr><td>Testable items</td><td>ConsentSender3; M</td><td></td><td></td></tr>
<tr><td>Spec</td><td colspan="3">[IHE ITI TF-2b]</td></tr>
<tr><td rowspan="2">Testable items</td><td>ProvideProtocol12; M</td><td>ProvideProtocol13; M</td><td>ProvideProtocol2; M</td></tr>
<tr><td>ProvideSource1; M</td><td></td><td></td></tr>
<tr><td colspan="2">Applicability</td><td colspan="3">C_SEN_000 AND C_SEN_GEN_002</td></tr>
<tr><td colspan="2">Initial condition</td><td colspan="3">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.</td></tr>
<tr><td colspan="2">Test procedure</td><td colspan="3">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).</td></tr>
<tr><td colspan="2">Pass/Fail criteria</td><td colspan="3">All steps are as specified within the test procedure above.</td></tr>
<tr><td colspan="2">Notes</td><td colspan="3"></td></tr>
</table>

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	
Applicability		C_SEN_000 AND C_SEN_GEN_002		
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				

<table>
<tr><td colspan="2">TP Id</td><td colspan="3">TP/WAN/SEN/CM/META/BV-001</td></tr>
<tr><td colspan="2">TP label</td><td colspan="3">Metadata Submission Set Validation</td></tr>
<tr><td rowspan="7">Coverage</td><td>Spec</td><td colspan="3">[b-CDG 2012]</td></tr>
<tr><td rowspan="6">Testable items</td><td>WANXDSSub-1; O</td><td>WANXDSSub-2; M</td><td>WANXDSSub-3; M</td></tr>
<tr><td>WANXDSSub-4; M</td><td>WANXDSSub-5; M</td><td>WANXDSSub-6; M</td></tr>
<tr><td>WANXDSSub-7; O</td><td>WANXDSSub-8; M</td><td>WANXDSSub-9; O</td></tr>
<tr><td>WANXDSSub-10; M</td><td>WANXDSSub-11; M</td><td>WANXDSSub-12; M</td></tr>
<tr><td>WANXDSSub-13; M</td><td>WANXDSSub-14; M</td><td>WANXDSSub-15; M</td></tr>
<tr><td colspan="2">Applicability</td><td colspan="3">C_SEN_000 AND C_SEN_GEN_002</td></tr>
<tr><td colspan="2">Initial condition</td><td colspan="3">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.</td></tr>
<tr><td colspan="2">Test procedure</td><td colspan="3">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.</td></tr>
<tr><td colspan="2">Pass/Fail criteria</td><td colspan="3">All steps are as specified within the test procedure above.</td></tr>
<tr><td colspan="2">Notes</td><td colspan="3"></td></tr>
</table>

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		
Applicability		C_SEN_000 AND C_SEN_GEN_002		
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		
Applicability		C_SEN_000 AND C_SEN_GEN_002		
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:
   - /templateId = "2.16.840.1.113883.3.445.2"
   - /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:
   - id element may be present
   - effectiveTime element may be present
   - effectiveTime/low/@value element may be present
   - effectiveTime/high/@value element may be present
   - code/@code attribute is present
   - code/@codeSystem attribute is present
   - 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" o 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 o 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 o component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.16" o 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	

Bibliography

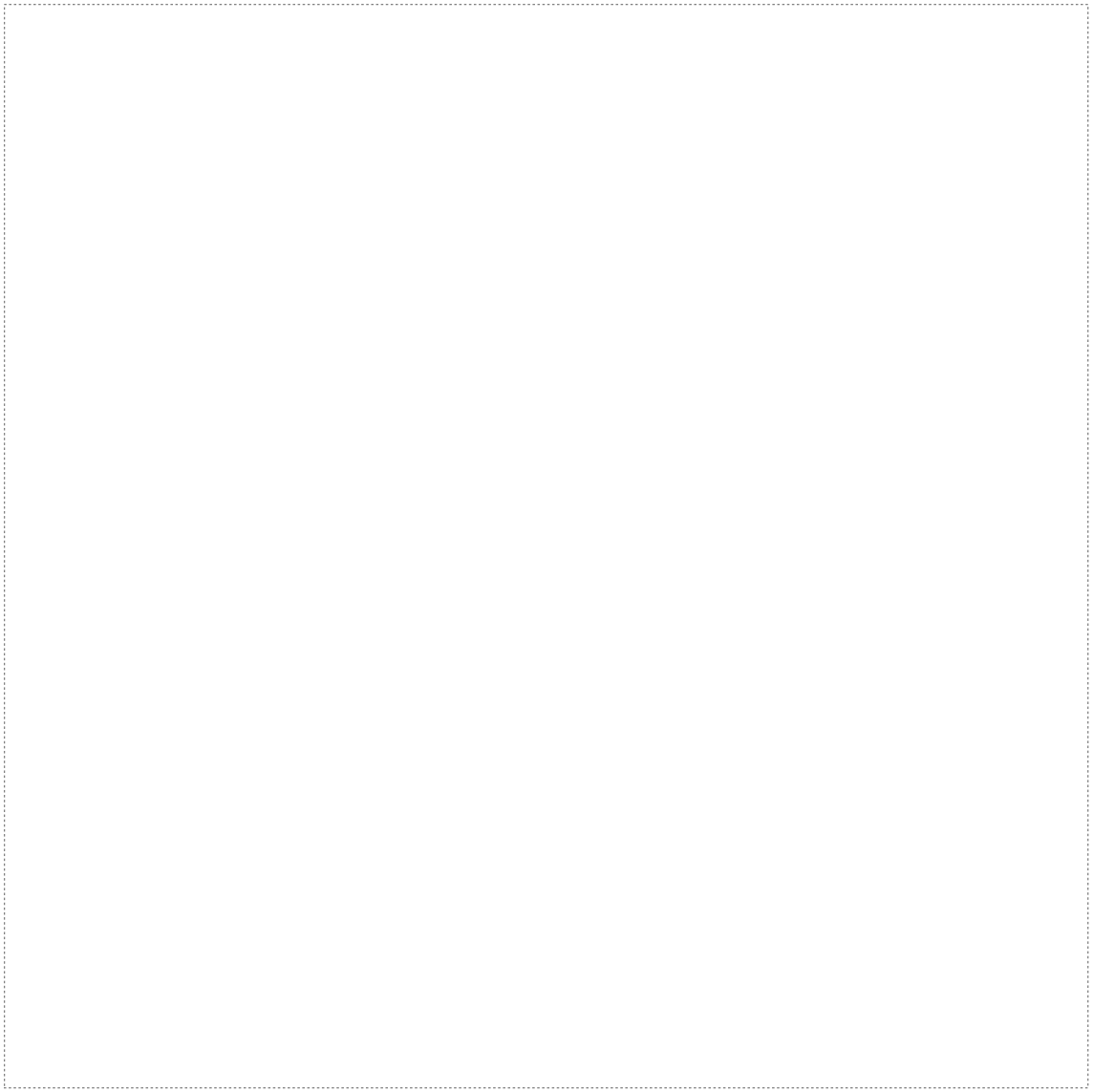
[b-CDG 1.0] Continua Health Alliance Continua Design Guidelines v1.0. (2008), *Continua Design Guidelines*.

[b-CDG 2010] Continua Health Alliance Continua Design Guidelines v1.5_ (2010), *Continua Design Guidelines*.

[b-CDG 2011] Continua Health Alliance Continua Design Guidelines (2011) "Adrenaline", *Continua Design Guidelines.*

[b-CDG 2012] Continua Health Alliance CDG, Continua Design Guidelines (2012), "Catalyst", *Continua Design Guidelines*.

[b-ETSI SR 001 262] ETSI SR 001 262 v1.8.1 (2003): *ETSI drafting rules*.



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