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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 8: Consent Management: Receiver

Recommendation ITU-T H.838

International Telecommunication Union

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Recommendation ITU-T H.838

Conformance of ITU-T H.810 personal health devices: WAN interface Part 8: Consent Management: Receiver

Summary

This Recommendation is a transposition of Continua Health Alliance Test Tool DG2013, Test Suite Structure & Test Purposes, WAN Interface; Part 8: Consent Management. Receiver (Version 1.0, 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.838	2015-01-13	16	11.1002/1000/12256

* 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 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.

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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 8: Consent Management. Receiver (Version 1.0, 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_DG2012_WAN_PART_8 (REC CM) v1.0.doc" as a baseline as new features included in [b-CDG 2012] do not affect the test procedures specified in this document.
1.2	2014-01-24	Initial release for Test Tool DG2013. This uses "TSS&TP_DG2012_WAN_PART_8 (REC CM) v1.0.doc" as a baseline as new features included in [ITU-T H.810] do not affect the test procedures specified in this document.

Recommendation ITU-T H.838

Conformance of ITU-T H.810 personal health devices: WAN interface Part 8: Consent Management: Receiver

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 8.

– **Part 1:** Web services interoperability Sender
– **Part 2:** Web services interoperability 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 Sender
– **Part 8:** Consent management 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*.

[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-2] IHE ITI TF 2 (2009), *IHE IT Infrastructure Technical Framework, Volume 2* (ITI TF-2), Revision 6.0. It comprises three sub-volumes: 2a (Transactions Part A), 2b (Transactions Part B) and 2x (Appendices).
<http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2a_FT_2009-08-10.pdf>
<http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2b_FT_2009-08-10.pdf>
<http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2x_FT_2009-08-10.pdf>

[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 [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 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 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 2.5.1 and 2.5.2 (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)
- 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)

• 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 (TP) 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 2.5.1: WAN XDR Transaction (TRANS)

TP Id		TP/WAN/REC/CM/TRANS/BV-000		
TP label		Provide and Register Document Set-b Transaction Response		
Coverage	**Spec**	[b-CDG 2012], WAN interface requirements for consent management		
	Testable items	ConsentReceiver1; M		
	Spec	[IHE ITI TF-2], Volume 2b		
	Testable items	ProvideResponse1; M	ProvideResponse2; M	ProvideProtocol2; M
		ProvideProtocol10; M	ProvideProtocol11; M	
Applicability		C_REC_000 AND C_REC_GEN_002		
Initial condition		The receiver under test has published the document recipient service and is ready to receive a "Provide and Register Document Set-b Request" sent by the simulated sender.		
Test procedure		The simulated sender sends a "Provide and Register Document Set-b Request" with a clinical document architecture (CDA) using MTOM/XOP. The receiver under test responds with a "Provide and Register Document Set-b Response" with status = "urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success" using SOAP12 [b-SOAP 1.2].		
Pass/Fail criteria		All steps are as specified within the test procedure above.		
Notes				

A.3 Subgroup 2.5.2: WAN Service Validation (SER)

TP Id		TP/WAN/REC/CM/SER/BV-000		
TP label		Service WSDL		
Coverage	**Spec**	[IHE ITI TF-2], Volume 2b		
	Testable items	ProvideProtocol3; M	ProvideProtocol4; M	ProvideProtocol5; M
		ProvideProtocol6; M	ProvideProtocol7; M	ProvideProtocol8; M
Applicability		C_REC_000 AND C_REC_GEN_002		
Initial condition		The receiver under test has published its WSDL description for a consent management service		
Test procedure		Look up the WSDL description using the corresponding URL given by the receiver under test (I_REC_CM_001). Check that: There are two xsd:import elements in the definitions/types section for which the namespaces are: namespace="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0" namespace="urn:ihe:iti:xds-b:2007" /definitions/message/part/@element = "ihe:ProvideAndRegisterDocumentSetRequest" for the "Provide and Register Document Set-b Request" /definitions/message/part/@element = " ihe:RegistryResponse " for the "Provide and Register Document Set-b Response" /definitions/portType/operation/input/@wsaw:Action = "urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b" for the "Provide and Register Document Set-b Request" /definitions/portType/operation/input/@wsaw:Action = "urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-bResponse" for the "Provide and Register Document Set-b Response" /definitions/portType/operation/soap12:operation/@soapAction = "urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b"		
Pass/Fail criteria		All steps are as specified within the test procedure above.		
Notes				

TP Id		TP/WAN/REC/CM/SER/BV-001		
TP label		Service Metadata Validation		
Coverage	**Spec**	[IHE ITI TF-2], Volume 2b		
	Testable items	ProvideRecipient3; M	ProvideRecipient5; O	ProvideRecipient7; C
Applicability		C_REC_000 AND C_REC_GEN_002		
Initial condition		The receiver under test has published the document recipient service and is ready to receive a "Provide and Register Document Set-b Request" sent by the simulated sender.		

Test procedure	The Simulated Sender sends a "Provide and Register Document Set-b Request" message including XDSSubmissionSet.sourceId, XDSDocumentEntry.uniqueId, XDSDocumentEntry.hash and XDSDocumentEntry.size elements with correct values. The Receiver under test responds with a "Provide and Register Document Set-b Response" with status Success The simulated sender sends a "Provide and Register Document Set-b Request" message including an XDSDocumentEntry.hash element with a wrong value The receiver under test responds with a "Provide and Register Document Set-b Response" with status Success The simulated sender sends a "Provide and Register Document Set-b Request" message including an XDSDocumentEntry.size element with a wrong value The receiver under test responds with a "Provide and Register Document Set-b Response" with status Success The simulated sender sends a "Provide and Register Document Set-b Request" message including a different XDSSubmissionSet.sourceId element The receiver under test may accept or may not accept the message.
Pass/Fail criteria	All steps are as specified within the test procedure above.
Notes	

TP Id		TP/WAN/REC/CM/SER/BV-002		
TP label		Multiple Documents and Errors		
	Spec	[IHE ITI TF-2], Volume 2b		
	Testable items	ProvideReqActions3; M	ProvideRecipient1; M	
Applicability		C_REC_000 AND C_REC_GEN_002		
Initial condition		The receiver under test has published the document recipient service and is ready to receive a "Provide and Register Document Set-b Request" sent by the simulated sender.		
Test procedure		The simulated sender sends a "Provide and Register Document Set-b Request" with two documents using MTOM/XOP The receiver under test responds with a "Provide and Register Document Set-b Response" with status = "urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success" The simulated sender sends a "Provide and Register Document Set-b Request" without attaching a document using MTOM/XOP The receiver under test responds with a "Provide and Register Document Set-b Response" with status = "urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Failure".		
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.*

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

[b-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>

[b-SOAP 1.2] W3C SOAP 1.2 (2007), SOAP Version 1.2 (Second Edition). <http://www.w3.org/TR/soap/>

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