ITU-T

H.830.12

TELECOMMUNICATION STANDARDIZATION SECTOR OF ITU (11/2015)

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 12: Questionnaires: Receiver

Recommendation ITU-T H.830.12



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#### Recommendation ITU-T H.830.12

# Conformance of ITU-T H.810 personal health devices: WAN interface Part 12: Questionnaires: Receiver

#### **Summary**

Recommendation ITU-T H.830.12 provides a test suite structure and the test purposes for the WAN interface (consent management; receiver) based on the requirements defined in Recommendation ITU-T H.810 (2015). The objective of this test specification is to provide a high probability of air interface interoperability between different devices.

This Recommendation is the transposition of Continua Test Tool DG2015, Test Suite Structure & Test Procedures, WAN Interface; Part 12: Questionnaires: Receiver (Version 1.0, 2015-07-01).

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.830.12	2015-11-29	16	11.1002/1000/12677

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<sup>\*</sup> 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, <a href="http://handle.itu.int/11.1002/1000/11830-en">http://handle.itu.int/11.1002/1000/11830-en</a>.

#### **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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**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 Test Tool DG2015, Test Suite Structure & Test procedures, WAN Interface; Part 12: Questionnaires: Receiver (Version 1.0, 2015-07-01), that was developed by the Personal Connected Health Alliance. A version of this specification that existed before transposition is indicated in the table below.

Version	Date	Revision history
1.0	2015-07-01	Initial Release for Test Tool DG2015

#### Recommendation ITU-T H.830.12

# Conformance of ITU-T H.810 personal health devices: WAN interface Part 12: Questionnaires: Receiver

#### 1 Scope

The scope of this Recommendation<sup>1</sup> is to provide a test suite structure and the test procedures (TSS & TP) for the WAN interface based on the requirements defined in Continua Specifications. 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 document have been divided into the 12 parts specified below. This Recommendation covers Part 12.

- 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
- Part 9: hData observation upload. Sender
- Part 10: hData observation upload. Receiver
- Part 11: Questionnaires. Sender
- Part 12: Questionnaires. 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.811] Recommendation H.811 (2015), Interoperability design guidelines for

personal health systems: PAN/LAN/TAN interface.

<sup>&</sup>lt;sup>1</sup> This Recommendation includes an electronic attachment with the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

[ITU-T H.812]	Recommendation H.812 (2015), Interoperability design guidelines for personal health systems: WAN interface: Common certified device class.
[ITU-T H.812.1]	Recommendation H.812.1 (2015), <i>Interoperability design guidelines for personal health systems: WAN interface: Observation upload certified device class.</i>
[ITU-T H.812.2]	Recommendation H.812.2 (2015), Interoperability design guidelines for personal health systems: WAN interface: Questionnaires.
[ITU-T H.812.3]	Recommendation H.812.3 (2015), Interoperability design guidelines for personal health systems: WAN interface: Capability exchange device class.
[ITU-T H.812.4]	Recommendation H.812.4 (2015), <i>Interoperability design guidelines for personal health systems: WAN interface: Authenticated persistent session device class.</i>
[ITU-T H.813]	Recommendation H.813 (2015), <i>Interoperability design guidelines for personal health systems: Health record network (HRN) interface.</i>
[HL7 CDA QFD]	Health Level Seven (2014), <i>HL7 Implementation Guide for CDA</i> , <i>Release 2: Questionnaire Form Definition Document, Release 1.</i> <a href="http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116">http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116</a>
[HL7 CDA QRD]	Health Level Seven (2014), <i>HL7 Implementation Guide for CDA</i> , <i>Release 2: Questionnaire Response Document, Release 1.</i> <a href="http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=117">http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=117</a>
[HL7 V3 HRF]	Health Level Seven (2014), <i>HL7 Version 3 Specification: hData Record Format, Release 1.</i> <a href="http://www.hl7.org/documentcenter/private/standards/v3/V3_ITS_HDATA_RF_R1_2014JUN.pdf">http://www.hl7.org/documentcenter/private/standards/v3/V3_ITS_HDATA_RF_R1_2014JUN.pdf</a> .
[IETF RFC 3339]	IETF RFC 3339 (2002), Date and Time on the Internet: Timestamps <a href="https://datatracker.ietf.org/doc/rfc3339/">https://datatracker.ietf.org/doc/rfc3339/</a> >

#### 3 Definitions

#### 3.1 Terms defined elsewhere

None.

#### 3.2 Terms defined in this Recommendation

None.

### 4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

ATS Abstract Test Suite

ATNA Audit Trail and Node Authentication

CDA Clinical Document Architecture

CDG Continua Design Guidelines

DUT Device Under Test

ebXML Electronic Business using extensible network interface

EHR Electronic Health Record

IHE Integrating the Healthcare Enterprise

**INR** International Normalized Ratio

**IUT** Implementation Under Test

**MDS** Medical Device System

**MTOM** Message Transmission Optimization Mechanism

**NFC Near Field Communication** 

Personal Connected Health Alliance **PCHA** 

**PCD** Patient Care Device

**PCT Protocol Conformance Testing** 

**PCO** Point of Control and Observation

Personal Healthcare Device PHD

**PHDC** Personal Healthcare Device Class

**PHM** Personal Health Manager

**PICS** Protocol Implementation Conformance Statement

**PIXIT** Protocol Implementation extra Information for Testing

S/MIME Secure/Multipurpose Internet Mail Extensions

**SABTE** Sleep Apnoea Breathing Therapy Equipment

**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 USB Universal Serial Bus

URI Uniform Resource Identifier

WAN Wide Area Network

Windows Driver Model **WDM** 

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.

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

CDG name	Transposed as	Version	Description	Designation
2015 plus errata	ITU-T H.810	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	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.	
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].	
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].	
1.0	-	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 2.7.1, 2.7.2 and 2.7.3 (shown in bold):

- Group 1: Sender (SEN)
  - Group 1.1: Web services interoperability (WSI)
    - Subgroup 1.1.1: Basic profile (BP)
    - O Subgroup 1.1.2: Basic security profile (BSP)
    - O Subgroup 1.1.3: Reliable messaging (RM)
  - Group 1.2: SOAP (SOAP)
    - O Subgroup 1.2.1: SOAP headers (HEAD)
  - Group 1.3: Audit (ATNA)
    - o Subgroup 1.3.1: General (GEN)
    - o Subgroup 1.3.2: PCD-01 (PCD-01)
    - o Subgroup 1.3.3: Consent management (CM)
  - Group 1.4: PCD-01 HL7 Messages (PCD-01-DATA)
    - O Subgroup 1.4.1: General (GEN)
    - o Subgroup 1.4.2: Design guidelines (DG)
    - O Subgroup 1.4.3: Pulse oximeter (PO)
    - Subgroup 1.4.4: Blood pressure monitor (BPM)
    - O Subgroup 1.4.5: Thermometer (TH)
    - O Subgroup 1.4.6: Weighing scales (WEG)
    - Subgroup 1.4.7: Glucose meter (GL)
    - O Subgroup 1.4.8: Cardiovascular fitness and activity monitor (CV)
    - Subgroup 1.4.9: Strength fitness equipment (ST)
    - O Subgroup 1.4.10: Independent living activity hub (HUB)
    - O Subgroup 1.4.11: Adherence monitor (AM)
    - O Subgroup 1.4.12: Peak expiratory flow monitor (PF)
    - O Subgroup 1.4.13: Body composition analyzer (BCA)
    - O Subgroup 1.4.14: Basic electrocardiograph (ECG)
    - O Subgroup 1.4.15: International normalized ratio (INR)
    - O Subgroup 1.4.16: Sleep apnoea breathing therapy equipment (SABTE)
  - Group 1.5: Consent management (CM)
    - O Subgroup 1.5.1: WAN XDR transaction (TRANS)
    - O Subgroup 1.5.2: WAN metadata validation (META)
    - O Subgroup 1.5.3: WAN consent directive validation (CDV)
  - Group 1.6: hData observation upload (HDATA)
    - o Subgroup 1.6.1: General (GEN)
  - Group 1.7: Questionnaires (QUE)
    - Subgroup 1.7.1: General (GEN)
    - o 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)
- o Subgroup 2.1.2: Basic security profile (BSP)
- o 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)
  - o Subgroup 2.3.2: PCD-01 (PCD-01)
  - o 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)
  - O Subgroup 2.4.4: Blood pressure monitor (BPM)
  - O Subgroup 2.4.5: Thermometer (TH)
  - O Subgroup 2.4.6: Weighing scales (WEG)
  - O Subgroup 2.4.7: Glucose meter (GL)
  - O Subgroup 2.4.8: Cardiovascular fitness and activity monitor (CV)
  - Subgroup 2.4.9: Strength fitness equipment (ST)
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- Group 2.5: Consent management (CM)
  - Subgroup 2.5.1: WAN XDR transaction (TRANS)
  - O Subgroup 2.5.2: WAN service validation (SER)
- Group 2.6: hData observation upload (HDATA)
  - O Subgroup 2.6.1: General (GEN)
  - Subgroup 2.6.2: hData record format (HRF)
- Group 2.7: Questionnaires (QUE)
  - Subgroup 2.7.1: General (GEN)
  - Subgroup 2.7.2: CDA validation (CDA)
  - 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 <a href="http://handle.itu.int/11.1002/2000/12067">http://handle.itu.int/11.1002/2000/12067</a>.

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 (TP)

#### 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 procedure 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 procedure.
- **TP label:** This is the TP's title.
- **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 were included.
  - Testable iItem: 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 a 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 2.7.1: General (GEN)

TP Id TP			TP/WAN/REC/QUE/GEN/BV-000			
TP label		Questionnaire retrieval. Receiver.				
Coverage	Spec	[ITU-T H.812]				
	Testable items	RESTS	ec 7	RESTSec 8	CommonReq 5	
	Spec	[ITU-T H	1.812.2]	_		
	Testable items	Question	13	Question 4	Question 5	
Test purpos	se		nulated AHD applica	ation retrieves from the So-be-completed questionnaire	UT a list of to-be-completed document.	
Applicability	y	C_REC_	_000 AND C_REC_GE	N_004 AND C_REC_GEN_00	6	
Other PICS		C_REC_	_GEN_005			
Initial condi	nitial condition  The WAN receiver under test provides a list of to-be-completed questionnaires with one entry containing a link to an actual to-be-completed questionnaire document.					
Test procedure		<ol> <li>The simulated AHD application uses an HTTP GET request without query parameters at the URL representing the patient's questionnaire hData root section path (continua/questionnaires) using a secure hData connection in order to retrieve an atom feed containing a list of to-be-completed questionnaire documents containing at least one document.</li> </ol>				
		<ol> <li>The simulated AHD application retrieves the actual to-be-completed questionnaire document using the value of the "link" element contained in the atom feed retrieved in step 1. "Link" element may be a relative path to baseURL or a full path.</li> </ol>				
Pass/Fail cr	iteria	The WAN receiver under test supports capability exchange as specified in [ITU-T H.812.3].				
		<ul> <li>The WAN receiver under test provides a list of to-be-completed questionnaires with at least one entry.</li> </ul>				
		<ul> <li>The atom entry element of the questionnaire list shall contain the dueDate extension element in the Continua namespace, the content of which shall conform to the "date- time" production in [IETF RFC 3339].</li> </ul>				
		<ul> <li>The WAN receiver under test allows the retrieval of the actual to-be-completed questionnaire document using the content of the "link" element in the atom feed.</li> </ul>				
Notes						

TP ld		TP/WAN/REC/QUE/GEN/BV-001				
TP label		Questionnaire response submitting. Receiver.				
Coverage	Spec	[ITU-T H.812]	[ITU-T H.812]			
	Testable items	RESTSec 7	RESTSec 8	CommonReq 5		
<b>Spec</b> [ITU-T H.812.2]						

	Testable items	Question 6	Question 9	Question 13	
Test purpose			ation posts a questionnaire res	ponse document to the WAN	
Applicability		receiver under test.  C_REC_000 AND C_REC_0	SEN_004 AND C_REC_GEN_006		
Other PICS		C_REC_GEN_005			
Initial conditi	The WAN receiver under test is ready to receive a questionnaire response document from simulated AHD.				
Test procedu	Test procedure  1. The simulated AHD application uses HTTP POST with the following URL for a questionnaire response document to the WAN receiver under baseURL/continua/questionnaireResponse using a secure hData connection.			WAN receiver under test:	
Pass/Fail criteria		<ul> <li>The WAN receiver under test supports capability exchange as specified in [ITU-T H.812.3].</li> <li>Questionnaire Enabled WAN device validates the received document and sends the</li> </ul>			
Questionnaire Enabled WAN device validates the received document and HTTP 201 (Created) as a response.			erved document and sends the		
Notes					

TP Id	TP/WAN/REC/QUE/GEN/BV-002					
TP label Questionnaire HTTP responses. Receiver.			s. Receiver.			
Coverage	Spec	[ITU-T F	H.812]			
	Testable items	RESTS	ec 7	RESTSec 8	CommonReq 5	
	Spec	[ITU-T F	1.812.2]			
	Testable items	Questio	n 14	Question15	Question 16	
Test purpose	е	Check that:				
		The WAN receiver under test returns appropriate HTTP return codes to several HTTP operations.				
Applicability	,	C_REC_000 AND C_REC_GEN_004 AND C_REC_GEN_006				
Other PICS		C_REC_GEN_005				
Initial condit	ion	The que	estionnaire enabled WA	N receiver under test is ready to	receive HTTP operations.	
Test procedu	ure	<ol> <li>The questionnaire WAN receiver under test receives an HTTP POST request on questionnaire section path from the simulated AHD application.</li> </ol>				
		2.	<ol><li>The questionnaire WAN receiver under test receives an HTTP PUT request on questionnaire section path.</li></ol>			
		<ol> <li>The questionnaire WAN receiver under test receives an HTTP PUT request on questionnaire response section path.</li> </ol>				
		4.	<ol> <li>The questionnaire WAN receiver under test receives an HTTP DELETE request on questionnaire section path.</li> </ol>			
		5.	<ol> <li>The questionnaire WAN receiver under test receives an HTTP DELETE request on questionnaire response section path.</li> </ol>			

Pass/Fail criteria	The WAN receiver under test supports capability exchange as specified in [ITU-T H.812.3].
	<ul> <li>The questionnaire enabled WAN receiver under test does not support the creation of new questionnaire record via the hData interface and returns HTTP 405 Method Not Allowed as a response to HTTP POST request on questionnaire section path.</li> </ul>
	<ul> <li>The questionnaire enabled WAN receiver under test does not support the modification of an existing questionnaire or questionnaire response record and shall return HTTP 405 Method Not Allowed as a response to HTTP PUT request on questionnaire and questionnaire response section paths.</li> </ul>
	<ul> <li>The questionnaire enabled WAN receiver under test does not support the deletion of an existing questionnaire or questionnaire response record and shall return HTTP 405 Method Not Allowed as a response to HTTP DELETE request on questionnaire and questionnaire response section paths.</li> </ul>
Notes	

TP ld		TP/WAN/REC/QUE/GEN/BV-003			
TP label		Questionnaire response retrieval. Receiver.			
Coverage	overage Spec [ITU-T H.812]				
	Testable items	RESTSec	7	RESTSec 8	CommonReq 5
	Spec	[ITU-T H.8	12.2]		-
	Testable items	Question 7	7	Question 8	
Test purpos	e				of questionnaire responses and
Applicability	1	C_REC_0	00 AND C_REC_GE	N_004 AND C_REC_GEN_006	
Other PICS		C_REC_G	GEN_005		
Initial condit	The WAN receiver under test provides a list of questionnaire responses with at least one containing a link to an actual questionnaire response document.				
Test proced	<ol> <li>Test procedure         <ol> <li>The simulated AHD application uses an HTTP GET request without parameters at the URL representing the patient's questionnaire hData root path (continua/questionnaires) using a secure hData connection in order to an atom feed containing a list of to-be-completed questionnaire docuntaining at least one document.</li> </ol> </li> <li>The simulated AHD application retrieves the actual to-be-completed question document using the value of the "link" element contained in the atom feed retrieves.</li> </ol>		destionnaire hData root section connection in order to retrieve sted questionnaire documents to-be-completed questionnaire ined in the atom feed retrieved		
Pass/Fail criteria		• T a	The WAN receiver TU-T H.812.3]. The WAN receiver ur t least one entry. The WAN receiver uses the WAN receiver uses the WAN receiver uses the WAN receiver uses the way and the way are the	nder test provides a list of to-be	ty exchange as specified in -completed questionnaires with of the actual to-be-completed
Notes	lotes				

## A.3 Subgroup 2.7.2: CDA validation (CDA)

TP Id		TP/WAN/REC/QUE/CD	A/BV-000	
TP label Questionnaire CDA syntatic and semantic validation. Receiver.		eceiver.		
Coverage Spec		[HL7 CDA QFD]		
	Testable	CONF-Q-1; M	CONF-Q-2;R	CONF-Q-3;M
	items	CONF-Q-4;M	CONF-Q-5;M	CONF-Q-6;M
		CONF-Q-7;M	CONF-Q-8;M	CONF-Q-10;M
		CONF-Q-13; R	CONF-Q-14;M	CONF-Q-15;M
		CONF-Q-16; M	CONF-Q-17;M	CONF-Q-18 ;M
		CONF-Q-19;M	CONF-Q-20;M	CONF-Q-21;M
		CONF-Q-22;M	CONF-Q-23 ;M	CONF-Q-24;M
		CONF-Q-25;M	CONF-Q-26;M	CONF-Q-27;M
		CONF-Q-28 ;M	CONF-Q-29;M	CONF-Q-30;R
		CONF-Q-31;M	CONF-Q-32;R	CONF-Q-33 ;M
		CONF-Q-34;M	CONF-Q-35;M	CONF-Q-36;M
		CONF-Q-37;M	CONF-Q-38 ;M	CONF-Q-39;M
		CONF-Q-40;M	CONF-Q-41;R	CONF-Q-42;M
		CONF-Q-43;M	CONF-Q-44;M	CONF-Q-45;M
		CONF-Q-46;M	CONF-Q-47;M	CONF-Q-48 ;M
		CONF-Q-49;M	CONF-Q-50;M	CONF-Q-51;M
		CONF-Q-52;M	CONF-Q-53 ;M	CONF-Q-54;M
		CONF-Q-55;R	CONF-Q-56;M	CONF-Q-57;M
		CONF-Q-58 ;M	CONF-Q-59;M	CONF-Q-60;M
		CONF-Q-61;M	CONF-Q-62;M	CONF-Q-63 ;R
		CONF-Q-64;M	CONF-Q-65;R	CONF-Q-66;M
		CONF-Q-67;M	CONF-Q-68 ;M	CONF-Q-69;M
		CONF-Q-70;M	CONF-Q-71;M	CONF-Q-72;M
		CONF-Q-73 ;M	CONF-Q-74;R	CONF-Q-75;M
		CONF-Q-76;M	CONF-Q-77;O	CONF-Q-78 ;M
		CONF-Q-79;M	CONF-Q-80;M	CONF-Q-81 ;M
		CONF-Q-82;M	CONF-Q-83 ;M	CONF-Q-84;M
		CONF-Q-85;M	CONF-Q-86;O	CONF-Q-87;M

CONE O 99 ·M	CONE O PO-M	CONE O 90 ·M
CONF-Q-88 ;M	CONF-Q-89;M	CONF-Q-90 ;M
CONF-Q-91;M	CONF-Q-92;O	CONF-Q-93 ;M
CONF-Q-94;M	CONF-Q-95;M	CONF-Q-96 ;M
CONF-Q-97;M	CONF-Q-98 ;M	CONF-Q-99;M
CONF-Q-100;M	CONF-Q-101;M	CONF-Q-102;M
CONF-Q-103 ;M	CONF-Q-104;M	CONF-Q-105 ;M
CONF-Q-106;M	CONF-Q-107;M	CONF-Q-108 ;M
CONF-Q-109;M	CONF-Q-110;R	CONF-Q-111 ;M
CONF-Q-112;M	CONF-Q-113 ;M	CONF-Q-114;M
CONF-Q-115;O	CONF-Q-116; M	CONF-Q-117;M
CONF-Q-118;M	CONF-Q-119; M	CONF-Q-120 ;M
CONF-Q-121;M	CONF-Q-122;M	CONF-Q-123 ;M
CONF-Q-124;M	CONF-Q-125;M	CONF-Q-126 ;M
CONF-Q-127;M	CONF-Q-128;M	CONF-Q-129 ;M
CONF-Q-130;M	CONF-Q-131;M	CONF-Q-132 ;M
CONF-Q-133;M	CONF-Q-134;M	CONF-Q-135 ;M
CONF-Q-136;M	CONF-Q-137;R	CONF-Q-138 ;R
CONF-Q-139;M	CONF-Q-140,M	CONF-Q-141 ;M
CONF-Q-142;M	CONF-Q-143;M	CONF-Q-144 ;M
CONF-Q-145;M	CONF-Q-146;M	CONF-Q-147 ;M
CONF-Q-148;R	CONF-Q-149;M	CONF-Q-150;M
CONF-Q-151;M	CONF-Q-152;M	CONF-Q-153;M
CONF-Q-154;M	CONF-Q-155;M	CONF-Q-156;M
CONF-Q-157;M	CONF-Q-158;R	CONF-Q-159;O
CONF-Q-160;M	CONF-Q-161;M	CONF-Q-162;M
CONF-Q-163;M	CONF-Q-164;M	CONF-Q-165;M
CONF-Q-166;R	CONF-Q-167;R	CONF-Q-168;M
CONF-Q-169;M	CONF-Q-70;M	CONF-Q-171;M
CONF-Q-172;M	CONF-Q-173;M	CONF-Q-174;M
CONF-Q-175;M	CONF-Q-176,M	CONF-Q-177;R
CONF-Q-178;M	CONF-Q-179;M	CONF-Q-180;M
CONF-Q-181;M	CONF-Q-182;M	CONF-Q-183;R
CONF-Q-184;M	CONF-Q-185;M	CONF-Q-186;M

1			
	CONF-Q-187;R	CONF-Q-188;M	CONF-Q-189;M
	CONF-Q-190;R	CONF-Q-191;M	CONF-Q-192;M
	CONF-Q-193;R	CONF-Q-194;M	CONF-Q-195;M
	CONF-Q-196;R	CONF-Q-197;M	CONF-Q-198;M
	CONF-Q-199;M	CONF-Q-200;R	CONF-Q-201;M
	CONF-Q-202;M	CONF-Q-203;M	CONF-Q-204;M
	CONF-Q-205;M	CONF-Q-206;R	CONF-Q-207;O
	CONF-Q-208;M	CONF-Q-209;M	CONF-Q-210;R
	CONF-Q-211;M	CONF-Q-212;M	CONF-Q-213;R
	CONF-Q-214;M	CONF-Q-215;M	CONF-Q-216;M
	CONF-Q-217;M	CONF-Q-218;M	CONF-Q-219;M
	CONF-Q-220;M	CONF-Q-221;M	CONF-Q-222;M
	CONF-Q-223;M	CONF-Q-224;M	CONF-Q-225;M
	CONF-Q-226;M	CONF-Q-227;M	CONF-Q-228;M
	CONF-Q-229;M	CONF-Q-230;M	CONF-Q-231;M
	CONF-Q-232;M	CONF-Q-233;O	CONF-Q-234;R
	CONF-Q-235;M	CONF-Q-236;M	CONF-Q-237;M
	CONF-Q-238;M	CONF-Q-239;M	CONF-Q-240;M
	CONF-Q-241;M	CONF-Q-242;R	CONF-Q-243;M
	CONF-Q-244;M	CONF-Q-245;M	CONF-Q-246;M
	CONF-Q-247;M	CONF-Q-248;M	CONF-Q-249;M
	CONF-Q-250;M	CONF-Q-251;M	CONF-Q-252;M
	CONF-Q-253;M	CONF-Q-254;R	CONF-Q-255;M
	CONF-Q-256;M	CONF-Q-257;M	CONF-Q-258;M
	CONF-Q-259;M	CONF-Q-260;R	CONF-Q-261;M
	CONF-Q-262;M	CONF-Q-263;R	CONF-Q-264;M
	CONF-Q-265;M	CONF-Q-266;M	
Applicability	C_REC_000 AND C_RE	C_GEN_004 AND C_REC_GE	N_006
Other PICS			
Initial condition  The questionnaire enabled WAN received document to the simulated AHD applic (TP/WAN/REC/QUE/GEN/BV-000 has be-		ated AHD application as a re	esponse to an HTTP GET operation
Test procedure  1. Make sure that TP/WAN/REC/QUE/GEN/BV-000 has been previously executhat the WAN receiver under test has already submitted a Questionnaire do to the simulated AHD application.			

- 2. Check the following elements of the Clinical Document sent by the SUT:
  - 1. ClinicalDocument element SHALL exactly one [1..1] realmCode.
  - 2. ClinicalDocument element SHOULD be selected from HL7 ValueSet BindingRealm [2.16.840.1.113883.1.11.20355] from codesystem hl7Realm [2.16.840.1.113883.5.1124] STATIC 2010-11-11.
  - 3. ClinicalDocument element SHALL contain exactly one [1..1]typeId.
    - This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3".
    - This typeId SHALL contain exactly one [1..1] @extension="POCD-HD-000040".
  - 4. ClinicalDocument SHALL contain at least one [1..\*] header-level templatedld such that it
    - This templateId SHALL contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.32"
  - 5. ClinicalDocument SHALL contain exactly one [1..1] id.
  - 6. ClinicalDocument SHALL contain exactly one [1..1] code.
  - 7. ClinicalDocument SHALL contain exactly one [1..1] title.
  - 8. ClinicalDocument SHALL contain exactly one [1..1] sdtc:statusCode.
    - This statusCode SHALL contain exactly one [1..1] @code="NEW" (CodeSystem: ActStatus 2.16.840.1.113883.5.14)
  - 9. ClinicalDocument SHALL contain exactly one [1..1] effectiveTime.
  - 10. ClinicalDocument SHALL contain exactly one [1..1] confidentialityCode, which SHALL be selected from ValueSet HL7 Basic ConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21.
  - 11. ClinicalDocument SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11523 DYNAMIC.
  - 12. ClinicalDocument SHALL contain exactly one [1..1] recordTarget.
    - Such recordTargets SHALL contain exactly one [1..1] patientRole.
      - 1. This patientRole SHALL contain exactly one [1..1] id.
        - a. The value of the recordTarget/patientRole/id/@NullFlavor" SHALL be "NI" "No Information" 2.16.840.1.113883.5.1008 NullFlavor STATIC
  - 13. ClinicalDocument SHALL contain at least one [1..\*] author.
    - Such authors SHALL contain exactly one [1..1] time.
    - Such authors SHALL contain exactly one [1..1] assignedAuthor.
      - 1. This assignedAuthor SHALL contain exactly one [1..1] id.
      - 2. This assignedAuthor SHALL contain at least one [1..\*] addr.
      - 3. This assignedAuthor SHALL contain at least one [1..\*] telecom.
      - 4. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice.
      - 5. This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson.
        - The assignedPerson, if present, SHALL contain at least one [1..\*] name
      - 6. This assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice
        - The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName
        - The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName
      - 7. This assignedAuthor SHALL contain exactly one [1..1] representedOrganization .
      - 8. If assignedAuthor has an associated representedOrganization and no assignedPerson or assignedAuthoringDevice, then the value for "ClinicalDocument/author/assignedAuthor/id/@NullFlavor" SHALL be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor STATIC.
  - 14. ClinicalDocument SHALL contain exactly one [1..1] custodian

- This custodian SHALL contain exactly one [1..1] assignedCustodian
  - 1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization.
    - a. This representedCustodianOrganization SHALL contain at least one [1..\*] id.
    - b. This representedCustodianOrganization SHOULD contain exactly one [1..1] name.
    - c. This representedCustodianOrganization SHALL contain exactly one [1..1] telecom.
    - d. This representedCustodianOrganization SHALL contain exactly one [1..1] addr.
- 15. ClinicalDocument SHALL conform to the Universal Realm Questionnaire Form Definition Document Header template (templateId: 2.16.840.1.113883.10.20.32)
- 16. ClinicalDocument SHALL contain exactly one [1..1] templated such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.1.1"
- 17. ClinicalDocument SHALL contain exactly one [1..1] component such that it
  - SHALL contain exactly one [1..1] Questionnaire Form Definition Section template (templateId: 2.16.840.1.113883.10.20.32.2.1)
  - SHALL contain exactly one [1..1] Copy Right Section template (templateld: 2.16.840.1.113883.10.20.32.2.2)
- 18. Questionnaire Form Definition Section SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.2.1"
- 19. Questionnaire Form Definition Section SHALL contain exactly one [1..1] code.
- 20. Questionnaire Form Definition SHOULD contain zero or one [0..1] title
- 21. Questionnaire Form Definition Section SHALL contain exactly one [1..1] text
- 22. Questionnaire Form Definition Section SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 23. Questionnaire Form Definition Section SHALL contain at least one [1..\*] entry (CONF:58) such that it
  - SHALL contain exactly one [1..1] @typeCode="DRIV"
  - SHALL contain exactly one [1..1] Questions Organizer template(templateld: 2.16.840.1.113883.10.20.32.4.1)
- 24. Copy Right Section SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.2.2"
- 25. Copy Right Section SHOULD contain zero or one [0..1] title
- 26. Copy Right Section SHALL contain exactly one [1..1] text
- 27. Copy Right Section SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 28. Copy Right Section SHALL contain at least one [1..\*] entry such that it
  - 1. SHALL contain exactly one [1..1] @typeCode="DRIV"
  - 2. SHALL contain exactly one [1..1] Copy Right Pattern Observation template (templateId: 2.16.840.1.113883.10.20.32.4.21)
- 29. Questions Organizer SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 30. Questions Organizer SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 31. Questions Organizer SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.1" (CONF:72).
- 32. Questions Organizer SHALL contain at least one [1..\*] id
- 33. Questions Organizer SHOULD contain zero or one [0..1] code
- 34. Questions Organizer SHALL contain exactly one [1..1] statusCode
  - 1. This statusCode SHALL contain exactly one [1..1] @code="COMPLETED" (CodeSystem: ActStatus 2.16.840.1.113883.5.14)
- 35. Questions Organizer MAY contain zero or more [0..\*] Precondition Pattern templates (templateld 2.16.840.1.113883.10.20.32.4.4) or

- sdtc:precondition(templateId 2.16.840.1.113883.10.20.32.4.12)
- 36. Questions Organizer SHALL contain at least one [1..\*] component such that it
  - SHALL contain exactly one [1..1] squenceNumber
  - SHALL contain exactly one [1..1] of the following templates
    - 1. Numeric Question Pattern Observation template(templateld: 2.16.840.1.113883.10.20.32.4.7)
    - 2. Multiple Choice Question Pattern Observation template(templateld: 2.16.840.1.113883.10.20.32.4.8)
    - 3. Text Question Pattern Observation template(templateld: 2.16.840.1.113883.10.20.32.4.9)
    - 4. Analog Slider Question Pattern Observation template(templateld: 2.16.840.1.113883.10.20.32.4.10)
    - 5. Discrete Slider Question Pattern Observation template(templateld: 2.16.840.1.113883.10.20.32.4.11)
- 37. Question Media Pattern SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 38. Question Media Pattern SHALL contain exactly one [1..1] @moodCode="DEF" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 39. Question Media Pattern SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.2"
- 40. Question Media Pattern SHALL contain exactly one [1..1] value
- 41. Criterion Pattern SHALL contain exactly one [1..1] templated such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.3"
- 42. Criterion Pattern SHALL contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 43. Criterion Pattern SHALL contain exactly one [1..1] @moodCode="EVN.CRT" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 44. Criterion Pattern SHALL contain exactly one [1..1] code
- 45. Criterion Pattern SHALL contain exactly one [1..1] value
- 46. Precondition Pattern SHALL contain exactly one [1..1] @typeCode="PRCN"
- 47. Precondition Pattern SHALL contain exactly one [1..1] template such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.4".
- 48. Precondition Pattern SHALL contain exactly one [1..1] Criterion Pattern template templateld 2.16.840.1.113883.10.20.32.4.3)
- 49. Question Text Help SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 50. Question Text Help SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 51. Question Text Help SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.19".
- 52. Question Text Help SHALL contain exactly one [1..1] code
  - This code SHALL contain exactly one [1..1] @code="48767-8" Annotation Comment.
  - 2. This code SHALL contain exactly one [1..1] (@CodeSystem: 2.16.840.1.113883.6.1"
- 53. Question Text Help SHALL contain [1..1] value so that itSHALL contain [1..1] @xsi:type="ST"
- 54. Question Text Help SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 55. Question Reference Range Pattern SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
- 56. Question Reference Range Pattern SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.5".
- 57. Question Reference Range Pattern SHALL contain exactly one [1..1] observationRange so that it
  - 1. MAY contain zero or one [0..1] text
  - 2. SHALL contain exactly one [1..1] value so that it SHALL contain

- exactly one [1..1] @xsi:type, SHALL contain exactly one [1..1] low and SHALL contain exactly one [1..1] high.
- 58. Question Options Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 59. Question Options Pattern Observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 60. Question Options Pattern Observation SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.20".
- 61. Question Options Pattern Observation SHALL contain exactly one [1..1] code
  - 1. This code SHALL contain exactly one [1..1] @code="74467-2" Number of Options
  - This code SHALL contain exactly one [1..1] @CodeSystem:=" 2.16.840.1.113883.6.1".
- 62. Question Options Pattern Observation SHALL contain exactly one [1..1] value
  - 1. SHALL contain exactly one [1..1] @xsi:type="IVL\_INT"
  - 2. SHALL contain exactly one [1..1] low.
  - 3. SHALL contain exactly one [1..1] high
- 63. Question Feedback Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 64. Question Feedback Pattern Observation SHALL contain exactly one [1..1] @moodCode="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 65. Question Feedback Pattern Observation SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.6".
- 66. Question Feedback Pattern Observation SHALL contain exactly one [1..1] code
- 67. Question Feedback Pattern Observation SHALL contain exactly one [1..1] value
- 68. Question Feedback Pattern Observation SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 69. Question Feedback Pattern Observation SHOULD contain zero or more [0..\*] Precondition Pattern template(templateId 2.16.840.1.113883.10.20.32.4.4) or sdtc:precondition(templateId 2.16.840.1.113883.10.20.32.4.12)
- 70. Copy Right Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 71. Copy Right Pattern Observation SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 72. Copy Right Pattern Observation SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.21".
- 73. Copy Right Pattern Observation SHALL contain exactly one [1..1] code
  - 1. This code SHALL contain exactly one [1..1] @code="COPY"
  - 2. This code SHALL contain exactly one [1..1] @CodeSystem="2.16.840.1.113883.5.4".
- 74. Copy Right Pattern Observation SHALL contain [1..1] value so that it SHALL contain [1..1] @xsi:type="ST"
- 75. Copy Right Pattern Observation SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 76. Numeric Question Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 77. Numeric Question Pattern Observation SHALL contain exactly one [1..1] @moodCode="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001

- STATIC)
- 78. Numeric Question Pattern Observation SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.7".
- 79. Numeric Question Pattern Observation SHALL contain at least one [1..\*] id
- 80. Numeric Question Pattern Observation SHALL contain exactly one [1..1] code
  - 1. This code SHALL contain exactly one [1..1] @code
  - 2. This code SHALL contain exactly one [1..1] @codeSystem"
  - 3. This code SHALL contain exactly one [1..1] originalText
- 81. Numeric Question Pattern Observation SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 82. Numeric Question Pattern Observation MAY contain zero or one [0..1] entryRelationship
  - 1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL contain exactly one [1..1] Question Help Text Pattern
    Observation template (templateId
    2.16.840.1.113883.10.20.32.4.19)
- 83. Numeric Question Pattern Observation SHOULD contain zero or one [0..1] entryRelationship
  - 1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType2.16.840.1.113883.5.1002)
  - 2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2)
  - 3. SHALL conform to the Question Feedback Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.6)
- 84. Numeric Question Pattern Observation SHOULD contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) or sdtc:precondition(templateId 2.16.840.1.113883.10.20.32.4.12)
- 85. Numeric Question Pattern Observation SHOULD contain zero or more [0..\*]

  Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5)
- 86. Multiple Choice Question Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 87. Multiple Choice Question Pattern Observation SHALL contain exactly one [1..1] @moodCode="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 88. Multiple Choice Question Pattern Observation SHALL contain exactly one [1..1] templateId such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.8"
- 89. Multiple Choice Question Pattern Observation SHALL contain at least one [1..\*] id
- Multiple Choice Question Pattern Observation SHALL contain exactly one [1..1]
   code
  - 1. This code SHALL contain exactly one [1..1] @code
  - 2. This code SHALL contain exactly one [1..1] @codeSystem"
  - 3. This code SHALL contain exactly one [1..1] originalText
- 91. Multiple Choice Question Pattern Observation SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526
- 92. Multiple Choice Question Pattern Observation SHALL contain at least two or more [2..\*] value
  - 1. SHALL contain exactly one [1..1] @xsi:type="CE"
  - 2. This code SHALL contain exactly one [1..1] @code
  - 3. This code SHALL contain exactly one [1..1] @CodeSystem
  - 4. This code SHALL contain exactly one [1..1] @displayName

- 93. Multiple Choice Question Pattern Observation SHOULD contain zero or many [0..\*] entryRelationship
  - 1. SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL contain exactly one [1..1] Question Help Text Pattern
    Observation template (templateId
    2.16.840.1.113883.10.20.32.4.19)
  - 3. SHALL contain exactly one [1..1] Question Options Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.20)
- 94. Multiple Choice Question Pattern Observation SHOULD contain zero or one [0..1] entryRelationship
  - 1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2)
- 95. Multiple Choice Question Pattern Observation SHOULD contain zero or one [0..\*] entryRelationship
  - 1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL conform to the Question Feedback Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.6)
- 96. Multiple Choice Question Pattern Observation SHOULD contain zero or one [0..1] entryRelationship
  - 1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL conform to the Text Question Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.9)
- 97. Multiple Choice Question Pattern Observation SHOULD contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) or sdtc:precondition(templateId 2.16.840.1.113883.10.20.32.4.12)
- 98. Text Question Pattern Observation SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)
- 99. Text Question Pattern Observation SHALL contain exactly one [1..1] @moodCode="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)
- 100.Text Question Pattern Observation SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.6"
- 101. Text Question Pattern Observation SHALL contain at least one [1..\*] id
- 102. Text Question Pattern Observation SHALL contain exactly one [1..1] code
  - 1. This code SHALL contain exactly one [1..1] @code
  - 2. This code SHALL contain exactly one [1..1] @codeSystem"
  - 3. This code SHALL contain exactly one [1..1] originalText
- 103.Text Question Pattern Observation SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC
- 104.Text Question Pattern Observation MAY contain zero or one [0..1] entryRelationship
  - 1. The @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL contain exactly one [1..1] Question Help Text Pattern
    Observation template (templateId
    2.16.840.1.113883.10.20.32.4.19)
- 105.Text Question Pattern Observation SHOULD contain zero or one [0..1]

- entryRelationship
  - The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL conform to the Question Media Pattern template (templateId 2.16.840.1.113883.10.20.32.4.2)
- 106.Text Question Pattern Observation SHOULD contain zero or more [0..\*] Precondition Pattern templates (templateId 2.16.840.1.113883.10.20.32.4.4) or sdtc:precondition(templateId 2.16.840.1.113883.10.20.32.4.12)
- 107.Analog Slider Question Pattern Observation SHALL conform to the Numeric Question Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.7)
- 108. Analog Slider Question Pattern Observation SHALL NOT contain Question Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.5)
- 109.Analog Slider Question Pattern Observation SHALL contain exactly one [1..1] templateId such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.10"
- 110.Analog Slider Question Pattern Observation SHALL contain exactly one [1..1] referenceRange
  - 1. SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002)
  - 2. SHALL contain exactly one [1..1] observationRange so that it SHALL contain exactly one [1..1] value, so that
    - a. SHALL contain exactly one [1..1] @xsi:type="GLIST\_PQ"
    - b. SHALL contain exactly one [1..1] head
    - c. SHALL contain exactly one [1..1] increment
    - d. SHALL contain exactly one [1..1] denominator
- 111.Discrete Slider Question Pattern SHALL confirm to Multiple Choice Question Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.8)
- 112.Discrete Slider Question Pattern SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.11"
- 113.The value of entryRelationship/observation/value/high/@value SHALL be set to "1" in the Question Options Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.20)
- 114. Precondition extension pattern
- 115.Precondition extension pattern SHALL contain exactly one [1..1] @typeCode="PRCN"
- 116.Precondition extension pattern SHALL contain exactly one [1..1] templateld such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.12"
- 117.Precondition extension pattern SHOULD contain zero or one [0..1] conjunctionCode
- 118.Precondition extension pattern SHALL contain exactly one [1..1] Criterion Pattern template or one of the following grouper templates
  - 1. AllTrue Pattern template (templateld 2.16.840.1.113883.10.20.32.4.13)
  - 2. AllFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.14)
  - 3. AtLeastOneTrue Pattern template (templateId 2.16.840.1.113883.10.20.32.4.15)
  - 4. AtLeastOneFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.16)
  - 5. OnlyOneTrue Pattern template (templateId 2.16.840.1.113883.10.20.32.4.17)
  - 6. OnlyOneFalse Pattern template (templateId 2.16.840.1.113883.10.20.32.4.18)
- 119.Precondition extension pattern SHOULD contain zero or one [0..1] negationInd 120.AllTrue Pattern SHALL contain exactly one [1..1] templateld such that it SHALL

Notes	
Pass/Fail criteria	The submitted questionnaire document is compliant with HL7 Implementation Guide for CDA R2: Questionnaire Form Definition, Release 1 as described above.
	contain exactly one [11] @root="2.16.840.1.113883.10.20.32.4.13"  121.AllTrue Pattern SHALL contain exactly one [11] id  122.AllTrue Pattern SHALL contain at least one [1*] sdtc:precondition template (templateld 2.16.840.1.113883.10.20.32.4.12)  123.AllFalse Pattern SHALL contain exactly one [11] templateld such that it SHALL contain exactly one [11] @root=" 2.16.840.1.113883.10.20.32.4.14"  124.AllFalse Pattern SHALL contain exactly one [11] id  125.AllFalse Pattern SHALL contain at least one [1*] sdtc:precondition template (templateld 2.16.840.1.113883.10.20.32.4.12)  126.AtLeastOneFalsePattern SHALL contain exactly one [11] templateld such that it SHALL contain exactly one [11] @root=" 2.16.840.1.113883.10.20.32.4.16"  127.AtLeastOneFalsePattern SHALL contain exactly one [11] id  128.AtLeastOneFalsePattern SHALL contain at least one [1*] sdtc:precondition template (templateld 2.16.840.1.113883.10.20.32.4.12)  129.OnlyOneTrue Pattern SHALL contain exactly one [11] id  131.OnlyOneTrue Pattern SHALL contain exactly one [11] id  131.OnlyOneTrue Pattern SHALL contain exactly one [11] id  131.OnlyOneTrue Pattern SHALL contain at least one [1*] sdtc:precondition template (templateld 2.16.840.1.113883.10.20.32.4.12)  132.OnlyOneFalse Pattern SHALL contain exactly one [11] it  SHALL contain exactly one [11] @root=" .16.840.1.113883.10.20.32.4.18"  133.OnlyOneFalse Pattern SHALL contain exactly one [11] id  134.OnlyOneFalse Pattern SHALL contain exactly one [11] id
	contain eyactly one [1, 1] @root="2.16.8/0.1.113883.10.20.32.7.13"

TP ld		TP/WAN/REC/QUE/CDA/BV-001		
TP label Questionnaire Response CDA syntatic and semantic validation. Receiver.		idation. Receiver.		
Coverage	Spec	[HL7 CDA QRD]	-	
	Testable	CONF-QR-1; M	CONF-QR-2;R	CONF-QR-3;M
	items	CONF-QR-4;M	CONF-QR-5;M	CONF-QR-6;M
		CONF-QR-7;M	CONF-QR-8;M	CONF-QR-10;M
		CONF-QR-13 ; R	CONF-QR-14;M	CONF-QR-15;M
		CONF-QR-16; M	CONF-QR-17;M	CONF-QR-18 ;M
		CONF-QR-19;M	CONF-QR-20;M	CONF-QR-21;M
		CONF-QR-22;M	CONF-QR-23 ;M	CONF-QR-24;M
		CONF-QR-25;M	CONF-QR-26;M	CONF-QR-27;M
		CONF-QR-28 ;M	CONF-QR-29;M	CONF-QR-30;M
		CONF-QR-31;M	CONF-QR-32;M	CONF-QR-33 ;R
		CONF-QR-34;M	CONF-QR-35;M	CONF-QR-36;M
		CONF-QR-37;M	CONF-QR-38 ;M	CONF-QR-39;R
		CONF-QR-40;M	CONF-QR-41;R	CONF-QR-42;M

CONF-QR-43;M	CONF-QR-44;M	CONF-QR-45;O
CONF-QR-46;M	CONF-QR-47;M	CONF-QR-48 ;M
CONF-QR-49;M	CONF-QR-50;M	CONF-QR-51;M
CONF-QR-52;O	CONF-QR-53 ;O	CONF-QR-54;M
CONF-QR-55;R	CONF-QR-56;M	CONF-QR-57;M
CONF-QR-58 ;O	CONF-QR-59;R	CONF-QR-60;M
CONF-QR-61;M	CONF-QR-62;M	CONF-QR-63 ;M
CONF-QR-64;M	CONF-QR-65;M	CONF-QR-66;R
CONF-QR-67;M	CONF-QR-68 ;O	CONF-QR-69;M
CONF-QR-70;R	CONF-QR-71;O	CONF-QR-72;M
CONF-QR-73 ;O	CONF-QR-74;M	CONF-QR-75;R
CONF-QR-76;M	CONF-QR-77;M	CONF-QR-78 ;M
CONF-QR-79;M	CONF-QR-80;M	CONF-QR-81 ;O
CONF-QR-82;M	CONF-QR-83 ;M	CONF-QR-84;M
CONF-QR-85;M	CONF-QR-86;O	CONF-QR-87;M
CONF-QR-88 ;M	CONF-QR-89;M	CONF-QR-90 ;M
CONF-QR-91;M	CONF-QR-92;O	CONF-QR-93 ;M
CONF-QR-94;M	CONF-QR-95;R	CONF-QR-96 ;R
CONF-QR-97;M	CONF-QR-98 ;O	CONF-QR-99;O
CONF-QR-100;M	CONF-QR-101;M	CONF-QR-102;R
CONF-QR-103 ;M	CONF-QR-104;M	CONF-QR-105 ;O
CONF-QR-106;M	CONF-QR-107;M	CONF-QR-108 ;M
CONF-QR-109;M	CONF-QR-110;R	CONF-QR-111 ;R
CONF-QR-112;M	CONF-QR-113 ;M	CONF-QR-114;M
CONF-QR-115;M	CONF-QR-116;	CONF-QR-117;M
CONF-QR-118;M	CONF-QR-119;	CONF-QR-120 ;M
CONF-QR-121;M	CONF-QR-122;R	CONF-QR-123 ;M
CONF-QR-124;R	CONF-QR-125;M	CONF-QR-126 ;M
CONF-QR-127;M	CONF-QR-128;M	CONF-QR-129 ;M
CONF-QR-130;M	CONF-QR-131;M	CONF-QR-132 ;M
CONF-QR-133;R	CONF-QR-134;M	CONF-QR-135 ;M
CONF-QR-136;M	CONF-QR-137;M	CONF-QR-138 ;M
CONF-QR-139;M	CONF-QR-140,M	CONF-QR-141 ;M

	1	
CONF-QR-142;M	CONF-QR-143;M	CONF-QR-144 ;M
CONF-QR-145;M	CONF-QR-146;M	CONF-QR-147 ;M
CONF-QR-148;M	CONF-QR-149;M	CONF-QR-150;M
CONF-QR-151;M	CONF-QR-152;M	CONF-QR-153;O
CONF-QR-154;M	CONF-QR-155;M	CONF-QR-156;M
CONF-QR-157;M	CONF-QR-158;M	CONF-QR-159;M
CONF-QR-160;M	CONF-QR-161;M	CONF-QR-162;M
CONF-QR-163;M	CONF-QR-164;M	CONF-QR-165;M
CONF-QR-166;M	CONF-QR-167;R	CONF-QR-168;M
CONF-QR-169;M	CONF-QR-170;M	CONF-QR-171;M
CONF-QR-172;O	CONF-QR-173;M	CONF-QR-174;M
CONF-QR-175;R	CONF-QR-176,M	CONF-QR-177;M
CONF-QR-178;R	CONF-QR-179;M	CONF-QR-180;M
CONF-QR-181;M	CONF-QR-182;M	CONF-QR-183;M
CONF-QR-184;M	CONF-QR-185;M	CONF-QR-186;M
CONF-QR-187;M	CONF-QR-188;M	CONF-QR-189;M
CONF-QR-190;M	CONF-QR-191;M	CONF-QR-192;M
CONF-QR-193;M	CONF-QR-194;M	CONF-QR-195;M
CONF-QR-196;R	CONF-QR-197;M	CONF-QR-198;M
CONF-QR-199;M	CONF-QR-200;R	CONF-QR-201;M
CONF-QR-202;M	CONF-QR-203;M	CONF-QR-204;M
CONF-QR-205;M	CONF-QR-206;M	CONF-QR-207;M
CONF-QR-208;M	CONF-QR-209;M	CONF-QR-210;M
CONF-QR-211;M	CONF-QR-212;M	CONF-QR-213;R
CONF-QR-214;M	CONF-QR-215;M	CONF-QR-216;M
CONF-QR-217;M	CONF-QR-218;M	CONF-QR-219;M
CONF-QR-220;M	CONF-QR-221;R	CONF-QR-222;M
CONF-QR-223;M	CONF-QR-224;M	CONF-QR-225;M
CONF-QR-226;M	CONF-QR-227;M	CONF-QR-228;M
CONF-QR-229;M	CONF-QR-230;M	CONF-QR-231;M
CONF-QR-232;M	CONF-QR-233;M	CONF-QR-234;M
CONF-QR-235;M	CONF-QR-236;M	CONF-QR-237;M
CONF-QR-238;M	CONF-QR-239;M	CONF-QR-240;M

Applicability	C_REC_000 AND C_REC_GEN_004 AND C_REC_GEN_006			
Other PICS				
Initial condition	The questionnaire enabled WAN receiver under test has previously submitted a Questionnaire Response document to the simulated AHD application as a response to an HTTP GET operation (TP/WAN/REC/QUE/GEN/BV-003 has been previously executed).			
Test procedure	<ol> <li>Make sure that TP/WAN/REC/QUE/GEN/BV-001 has been previously executed, so that the AHD under test has already received a Questionnaire Response document from the WAN receiver under test.</li> </ol>			
	2. Check the following elements of the Clinical Document sent by the Sender under test:  1. ClinicalDocument element SHALL exactly one [11] realmCode.  2. ClinicalDocument element SHOULD be selected from HL7 ValueSet BindingRealm [2.16.840.1.113883.1.11.20355] from codesystem hl7Realm [2.16.840.1.113883.5.1124] STATIC 2010-11-11.  3. ClinicalDocument element SHALL contain exactly one [11] @root="2.16.840.1.113883.1.3".  • This typeld SHALL contain exactly one [11] @cxtension="POCD-HD-000040".  4. ClinicalDocument SHALL contain at least one [11] header-level templatedld such that it  • This templateld SHALL contain exactly one [11] @root="2.16.840.1.113883.10.20.29".  • This templateld SHALL contain exactly one [11] id.  ClinicalDocument SHALL contain exactly one [11] id.  6. ClinicalDocument SHALL contain exactly one [11] id.  ClinicalDocument SHALL contain exactly one [11] title.  8. ClinicalDocument SHALL contain exactly one [11] ittle.  8. ClinicalDocument SHALL contain exactly one [11] effectiveTime.  9. ClinicalDocument SHALL contain exactly one [11] assic ConfidentialityCode, which SHALL be selected from ValueSet HL7 Basic ConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21.  10. ClinicalDocument SHALL contain exactly one [11] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11523 DYNAMIC.  11. ClinicalDocument SHALL contain exactly one [11] patientRole.  1. This patientRole SHALL contain at least one [11] addr.  3. This patientRole SHALL contain at least one [11] addr.  3. This patientRole SHALL contain at least one [11] addr.  3. This patientRole SHALL contain exactly one [11] patient.  a. This patientRole SHALL contain exactly one [11] patient.  a. This patientRole SHALL contain exactly one [11] patient.  a. This patient SHALL contain exactly one [11] patient.  a. This patient SHALL contain exactly one [11] patient.			
	➤ SHALL be precise to year.  ➤ SHOULD be precise to day.  12. ClinicalDocument SHALL contain at least one [1*] author.  • Such authors SHALL contain exactly one [11] time.			
	Such authors SHALL contain exactly one [11] assignedAuthor.  1. This assignedAuthor SHALL contain exactly one [11] id such that it.  a. The id SHOULD utilize the combined @root and @extension attributes to record the person's or the device's identity in a secure, trusted, and unique way.  2. When the author is a person, this assignedAuthor SHALL contain			
	exactly one [11] code.  • The code, SHALL contain exactly one [11]  @code, which SHOULD be selected from the			

Personal And Legal Relationship Role Type 2.16.840.1.113883.11.20.12.1.

- 3. This assignedAuthor SHALL contain at least one [1..\*] addr.
- 4. This assignedAuthor SHALL contain at least one [1..\*] telecom.
- 5. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice.
- This assignedAuthor SHOULD contain zero or one [0..1] assignedPerson.
  - The assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName.
  - The assignedAuthoringDevice, if present,SHALL contain exactly one [1..1] softwareName.
- 7. If assignedAuthor has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for "ClinicalDocument/author/assignedAuthor/id/@NullFlavor" SHALL be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor STATIC.
- 13. ClinicalDocument MAY contain zero or one [0..1] dataEnterer.
  - The dataEnterer, if present, SHALL contain exactly one [1..1] assignedEntity.
    - 1. This assignedEntity SHALL contain at least one [1..\*] id.
    - 2. This assignedEntity SHALL contain at least one [1..\*] addr.
    - 3. This assignedEntity SHALL contain at least one [1..\*] telecom.
    - I. This assignedEntity SHALL contain exactly one [1..1] assignedPerson.
      - a. This assigned Person SHALL contain at least one [1..\*] name.
    - 5. This assignedEntity MAY contain zero or one [0..1] code to encode the relationship of the person to the recordTarget.
- 14. ClinicalDocument MAY contain zero or more [0..\*] informant.
  - SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity.
    - 1. SHOULD contain at least one [1..\*] addr.
    - 2. SHALL contain exactly one [1..1] assignedPerson OR exactly one [1..1] relatedPerson.
      - a. SHALL contain at least one [1..\*] name.
    - 3. This assignedEntity MAY contain zero or one [0..1] code.
    - 4. SHOULD contain zero or more [0..\*] id
- 15. ClinicalDocument SHALL contain exactly one [1..1] custodian.
  - This custodian SHALL contain exactly one [1..1] assignedCustodian.
    - 1. This assigned custodian SHALL contain exactly one [1..1] represented Custodian Organization which may be the person when the document is not maintained by an organization.
      - a. This representedCustodianOrganization SHALL contain at least one [1..\*] id.
      - b. This representedCustodianOrganization SHALL contain exactly one [1..1] name.
      - This representedCustodianOrganization SHALL contain exactly one [1..1] telecom.
        - This telecom SHOULD contain exactly one [1..1] @use.
      - d. This representedCustodianOrganization SHALL contain at least one [1..\*] addr.
- 16. ClinicalDocument MAY contain zero or more[0..\*] informationRecipient.
  - The informationRecipient, if present, SHALL contain exactly one [1..1] intendedRecipient.
    - 1. This intendedRecipient SHOULD contain atleast one [1..\*] id.
    - 2. This intendedRecipient MAY contain zero or one [0..1] informationRecipient.
      - a. The informationRecipient, if present, SHALL contain at least one [1..\*] name.
    - 3. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization.

- a. The informationRecipient, if present, SHALL contain at least one [1..\*] name.
- 4. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization.
  - a. The receivedOrganization, if present, SHALL contain exactly one [1..1] name.
- 17. ClinicalDocument SHOULD contain zero or one [0..1] legalAuthenticator.
  - The legalAuthenticator, if present, SHALL contain exactly one [1..1] time.
  - The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode.
    - 1. This signatureCode SHALL contain exactly one [1..1] signatureCode.
      - a. This signatureCode SHALL exactly one [1..1] @code="S"(CodeSystem: Participationsignature 2.16.840.1.113883.5.89).
  - The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity.
    - 1. This assignedEntity SHALL contain at least one [1..\*] id.
    - 2. This assignedEntity MAY contain zero or one [0..1] code.
    - 3. This assignedEntity SHALL contain at least one [1..\*] addr.
    - 4. This assignedentity SHALL contain at least one [1..\*] telecom.
      - This assignedEntity SHALL contain exactly one [1..1] assignedPerson.
        - a. This assignedPerson SHALL contain at least one [1..\*] name.
- 18. ClinicalDocument MAY contain zero or more [0..\*] authenticator.
  - The authenticator, if present, SHALL contain exactly one [1..1] time.
  - The authenticator, if present, SHALL contain exactly one [1..1] signatureCode.
    - 1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89).
  - The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity.
    - 1. This assignedEntity SHALL contain at least one [1..\*] id.
    - 2. This assignedEntity MAY contain zero or one [0..1] code.
    - 3. This assignedEntity SHALL contain at least one [1..\*] addr.
    - 4. This assignedEntity SHALL contain at least one [1..\*] telecom.
      - a. Such telecoms SHOULD contain exactly one [1..1] @use.
    - 5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson.
      - a. This assignedPerson SHALL contain at least one [1..\*] name.
- 19. ClinicalDocument MAY contain zero or more [0..\*] participant.
  - The participant, if present, MAY contain zero or one [0..1] time.
  - Such participants, if present, SHALL have an associatedPerson or scopingOrganization element under participant/associatedEntity.
  - Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode SHALL be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes STATIC 2011-09-30.
- 20. ClinicalDocument SHOULD contain zero or one [0..1] inFulfillmentOf.
  - $\bullet$  The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order.
    - 1. This order SHALL contain at least one [1..\*] id.
- 21. ClinicalDocument MAY contain zero or one [0..1] componentOf.
  - The componentOf, if present, SHALL contain exactly one [1..1] encompassingEncounter.
    - 1. This encompassingEncounter SHALL contain at least one [1..\*] id.
    - This encompassingEncounter SHALL contain exactly one [1..1] effectiveTime.
- 22. SHALL conform to the Universal Realm Questionnaire Response Document Header template (templateld: 2.16.840.1.113883.10.20.33).
- 23. Patient generated Questionnaire Response Document in US Realm SHOULD conform to the US Realm Patient Generated Document Header template (templateId: 2.16.840.1.113883.10.20.29.1).
- 24. Clinicians generated Questionnaire Response Document in US realm SHOULD conform to the US C-CDA General Header template (templateld:

- 2.16.840.1.113883.10.20.22.1.1).
- 25. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.1.1".
- 26. SHALL contain exactly one [1..1] component.
  - SHALL contain exactly one [1..1] structuredBody.
    - This structuredBody SHALL contain at least one [1..\*] component such that it.
      - a. SHALL contain exactly one [1..1] Questionnaire Response Section template (templateld: '2.16.840.1.113883.10.20.33.1.1').
      - b. SHALL contain exactly one [1..1] Copy Right Section template (templateld: 2.16.840.1.1113883.10.20.32.2.2).
- 27. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] code.
- 28. SHALL contain exactly one [1..1] code.
- 29. SHOULD contain zero or one [0..1] title.
- 30. SHALL contain exactly one [1..1] text.
- 31. SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSetLanguage 2.16.840.1..113883.1.11.11523 DYNAMIC.
- 32. SHALL contain at least one [1..\*] entry such that it.
  - SHALL contain exactly one [1..1] @typeCode="DRIV".
  - SHALL contain exactly one [1..1] Responses Organizer template (templateld: 2.16.840.1.113883.10.20.33.4.1).
- 33. SHALL contain exactly one [1..1] @classCode="BATTERY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 34. SHALL contain exactly one [1..1] @moodcode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 35. SHALL contain exactly one [1..1] templateld such that it .

   SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.1".
- 36. SHALL contain at least one [1..\*] id.
- 37. SHOULD contain zero or one [0..1] code.
- 38. SHALL contain exactly one [1..1] statusCode.
  - This statusCode SHALL contain exactly one [1..1] @code="completed"(CodeSystem: ActStatus 2.16.840.1.11383.5.14).
- 39. SHALL contain at least one [1..\*] component such that it.
  - SHALL contain exactly one [1..1] sequenceNumber.
  - SHALL contain exactly one [1..1] of the following template (templateID: 2.16.840.1.113883.10.20.33.4.5).
    - 1. Numeric Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.4).
    - Multiple Choice Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.5).
    - 3. Text Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.6).
    - 4. Analog Slider Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.7).
    - 5. Discrete Slider Resposne Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.8).
- 40. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 41. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 42. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.2".
- 43. SHALL contain exactly one [1..1] value.
- 44. SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
- 45. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.3".
- 46. The referenceRange SHALL contain exactly one [1..1] observationRange.

- MAY contain zero or one [0..1] text.
- SHALL contain exactly one [1..1] value such that it.
  - 1. SHALL contain exactly one [1..1] @xsi:type.
  - 2. SHALL contain exactly one [1..1] low.
  - 3. SHALL contain exactly one [1..1] high.
- 47. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 48. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 49. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4".
- 50. SHALL contain at least one [1..\*] id.
- 51. SHALL contain exactly one [1..1] code.
  - This code SHALL contain exactly one [1..1] @code.
  - This code SHALL contain exactly one [1..1] @CodeSystem.
  - This code SHALL contain exactly one [1..1] originalText.
- 52. SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC.
- 53. SHALL contain exactly one [1..1] statusCode.
  - This statuscode SHALL contain exactly one [1..1] @code="completed"(CodeSystem: ActStatus 2.16.840.1.113883.5.14).
- 54. SHALL contain exactly one [1..1] value.
  - SHALL contain exactly one [1..1] @xsi:type,where the value of @xsi:type could be "INT", "REAL" or "TS".
- 55. MAY contain zero or one [0..1] entryRelationship.
  - The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).
- 56. SHOULD contain zero or one [0..1] entryRelationship.
  - The entryRelationship, if present, SHALL contain exactly one [1..1]
     @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - SHALL conform to the Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).
- 57. SHOULD contain zero or more [0..\*] Response Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.33.4.3).
- 58. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 59. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 60. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.5".
- 61. SHALL contain at least one [1..\*]] id.
- 62. SHALL contain exactly one [1..1] code.
  - This code SHALL contain exactly one [1..1] @code.
  - This code SHALL contain exactly one [1..1] @CodeSystem.
  - This code SHALL contain exactly one [1..1] originalText.
- 63. SHOULD contain zero or one [0..1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC.
- 64. SHALL contain exactly one [1..1] statusCode.
  - This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
- 65. SHALL contain at least one [1..\*] value.
  - SHALL contain exactly one [1..1] @xsi:type="CE".
  - SHALL contain exactly one [1..1] @code.
  - SHALL contain exactly one [1..1] @CodeSystem.
  - SHALL contain exactly one [1..1] @displayName such that it.

- 66. SHOULD contain zero or many [0..\*] entryRelationship such that it.
  - SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).
  - SHALL contain exactly one [1..1] Question Options Pattern Observation template (templateId 2.16.840.1.113883.1020.32.4.20).
- 67. SHOULD contain zero or one [0..\*] entryRelationship.
  - The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - SHALL contain exactly one [1..1] Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).
  - SHALL contain exactly one [1..1] Text Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.33.4.6).
- 68. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7A ctClass 2.16.840.1.113883.5.6 STATIC).
- 69. SHALL CONTAIN EXACTLY ONE [1..1] @moodcode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 70. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4".
- 71. SHALL contain at least one [1..1] id.
- 72. SHALL contain exactly one [1..1] code.
  - This code SHALL contain exactly one 1..1] @code.
  - This code SHALL contain exactly one [1..1] @CodeSystem.
  - This code SHALL contain exactly one [1..1] originalText.
- 73. SHOULD contain zero or one [0.1] languageCode which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC.
- 74. SHALL contain exactly one [1..1] statusCode.
  - This Statuscode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.11388.5.14).
- 75. SHALL contain exactly one [1..1] value.
  - SHALL contain exactly one [1..1] @xsi:type="ST".
- 76. MAY contain zero or one [0..1] entryRelationship.
  - The entryRelationship, if present, SHALL contain exactly one [1..1]
     @typeCode="SUBJ" (CodeSystem: HL7ActrelationshipType 2.16.840.1.113883.5.1002).
  - SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).
- 77. SHOULD contain zero or one [0..1] entryRelationship.
  - The entryRelationship,if present, SHALL contain exactly one [1..1]
     @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - SHALL contain exactly one [1..1] Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).
- 78. SHALL conform to the Numeric Response Pattern Observation template(templateId 2.16.840.1.113883.10.20.32.4.6).
- 79. SHALL NOT contain Response Reference Range Pattern template (template 2.16.840.1.113883.10.20.32.4.6).
- 80. SHALL contain exactly one [1..1] templateld such that it.
  - SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.9".
- 81. SHALL contain exactly one [1..1] referenceRange.
  - SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
  - The referenceRange SHALL contain exactly one [1..1] observationRange.
    - 1. SHALL contain exactly one [1..1] value such that it.
      - a. SHALL contain exactly one [1..1] @xsi:type="GLIST\_PQ".
      - b. SHALL contain exactly one [1..1] head.
      - c. SHALL contain exactly one [1..1] increment.

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	d. SHALL contain exactly one [11] denominator.		
	82. SHALL conform to Multiple Choice Response Pattern Observation template		
	(templateld 2.16.840.1.113883.10.20.32.4.7).		
	83. SHALL contain exactly one [11] templateld such that it.		
	• SHALL contain exactly one [11] @root="2.16.840.1.113883.10.20.32.4.10".		
	84. SHALL contain exactly one [11] value.		
	85. The value of entryRelationship/observation/value/high/@value SHALL be set to		
	"1" in the Question Options Pattern Observation template (templateId		
	2.16.840.1.113883.10.20.32.4.20)		
Pass/Fail criteria	<ul> <li>The submitted Questionnaire Response is compliant with HL7 Implementation Guide for CDA R2: Questionnaire Response Document, Release 1 [HL7 CDA QRD] as described above.</li> </ul>		
Notes			

## A.4 Subgroup 2.7.3: hData record format (HRF)

TP Id		TP/WAN/REC/QUE/HRF/BV-000			
TP label		Questionnaire. Root file elements.			
Coverage	Spec	[ITU-T H.812]			
	Testable items	CommonReq 5			
	Spec	[ITU-T H.812.2]			
	Testable items	Question 11 Question 12			
	Spec	[HL7 V3 HRF]			
	Testable	Root 9	Root 10	Root 11	
	items	Root 12	Root 13	Root 14	
		Root 15	Root 16	Root 18	
		Root 19	Root 20	Root 22	
Applicability		C_REC_000 AND C_REC_GEN_004 AND C_REC_GEN_006			
Other PICS		C_REC_GEN_005			
Initial condition  The simulated AHD application using hData observation upload Questionnaire capabilities declared in its root file. The SUT has URL.					

Test procedure	<ol> <li>The simulated AHD application performs an HTTP GET of root.xml using TLS v.1.1. OAuth 2.0 token is not required.</li> </ol>					
	<ol><li>The simulated AHD application obtains and check required Questionnaire capabilities in root.xml file.</li></ol>					
Pass/Fail criteria	<ul> <li>The WAN application under test supports capability exchange as specified in [ITU-T H.812.3].</li> </ul>					
	The WAN application provides root.xml file.					
	• Root.xml shows the capability elements for questionnaire as shown: 1.profile     a. id="questionnaire"     b. reference=http://www.continuaallia					
	nce.org/hData/Questionnaire/2015 /01/H.812.2.pdf					
	2.section					
	<pre>a. path="questionnaires" b. profileID= "questionnaire"</pre>					
	c. resourceTypeId=" questionnaire"					
	3.resourceType					
	<pre>a. resourceTypeId=" questionnaire" b.</pre>					
	<pre>reference="http://www.hl7.org/dstucomments/showdetail.cfm?d stuid =116"</pre>					
	<pre>c. representation    i. mediaType="application/xml"</pre>					
	<ul> <li>Additionally, the simulated AHD application checks that questionnaire response capability elements are as shown:</li> <li>1.profile</li> </ul>					
	a. id="questionnaireResponse" b.					
	reference=http://www.continuaalliance.org/hData/Questionnaire/2015 /01/H.812.2.pdf					
	2.section					
	<ul><li>a. path="questionnaireResponses"</li><li>b. profileID="questionnaireResponse"</li></ul>					
	c. resourceTypeId="questionnaireResponse"					
	<pre>3.resourceType     a. resourceTypeId="questionnaireResponse"</pre>					
	b.					
	<pre>reference="http://www.hl7.org/dstucomments/showdetail.cfm?d stuid =117"</pre>					
	c. representation i. mediaType="application/xml"					
Notes						

## **Bibliography**

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[b-CDG 1.0]	Continua Health Alliance, Continua Design Guidelines v1.0 (2008), <i>Continua Design Guidelines</i> .
[b-CDG 2010]	Continua Health Alliance, Continua Design Guidelines v1.5 (2010), <i>Continua Design Guidelines</i> .
[b-CDG 2011]	Continua Health Alliance, Continua Design Guidelines (2011), "Adrenaline", <i>Continua Design Guidelines</i> .
[b-CDG 2012]	Continua Health Alliance CDG, Continua Design Guidelines (2012), "Catalyst", <i>Continua Design Guidelines</i> .
[b-CDG 2013]	Continua Design Guidelines 2013 (Endorphin). November 23, 2012
[b-CDG 2015]	Personal Connected Health Alliance CDG, Continua Design Guidelines (2015/07) "Genome", <i>Continua Design Guidelines</i> .
[b-ETSI SR 001 262]	ETSI SR 001 262 v1.8.1 (2003), ETSI drafting rules.

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