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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 11: Questionnaires: Sender

Recommendation ITU-T H.830.11

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Recommendation ITU-T H.830.11

Conformance of ITU-T H.810 personal health devices: WAN interface Part 11: Questionnaires: Sender

Summary

Recommendation ITU-T H.830.11 provides a test suite structure and the test purposes (TSS & TP) for the WAN interface (consent management; sender) 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 a transposition of Continua Test Tool DG2015, Test Suite Structure & Test Procedures, WAN Interface; Part 11: Questionnaires: Sender (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.830.11	2015-11-29	16	11.1002/1000/12676
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Keywords

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

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* To access the Recommendation, type the URL http://handle.itu.int/ in the address field of your web browser, followed by the Recommendation's unique ID. For example, http://handle.itu.int/11.1002/1000/11 830-en.

FOREWORD

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

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

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

NOTE

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

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

INTELLECTUAL PROPERTY RIGHTS

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

Table of Contents

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

Introduction

This Recommendation is a transposition of Continua Test Tool DG2015, Test Suite Structure & Test Procedures, WAN Interface; Part 11: Questionnaires: Sender (Version 1.0, 2015-07-01), that was developed by the Continua 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.830.11

Conformance of ITU-T H.810 personal health devices: WAN interface Part 11: Questionnaires: Sender

1   Scope

The scope of this Recommendation[1] is to provide a test suite structure and the test purposes (TSS & TP) for the WAN interface based on the requirements defined in Continua Specifications. 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 have been divided into the 12 parts specified below. This Recommendation covers Part 11.

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

[ITU-T H.811]   Recommendation ITU-T H.811 (2015), *Interoperability design guidelines for personal health systems: PAN/LAN/TAN interface*.

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

[ITU-T H.812]	Recommendation ITU-T H.812 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Common certified device class.*
[ITU-T H.812.1]	Recommendation ITU-T H.812.1 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Observation upload certified device class.*
[ITU-T H.812.2]	Recommendation ITU-T H.812.2 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Questionnaires.*
[ITU-T H.812.3]	Recommendation ITU-T H.812.3 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Capability exchange certified device class.*
[ITU-T H.812.4]	Recommendation ITU-T H.812.4 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Authenticated persistent session device class.*
[ITU-T H.813]	Recommendation ITU-T H.813 (2015), *Interoperability design guidelines for personal health systems: Health record network (HRN) interface.*
[HL7 CDA QFD]	Health Level Seven (2014), *HL7 Implementation Guide for CDA, Release 2: Questionnaire Form Definition Document, Release 1.* http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116
[HL7 CDA QRD]	Health Level Seven (2014), *HL7 Implementation Guide for CDA, Release 2: Questionnaire Response Document, Release 1.* http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=117

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:

AHD   Application Hosting Device

ATS   Abstract Test Suite

ATNA   Audit Trail and Node Authentication

DUT   Device Under Test

CDG   Continua Design Guidelines

GUI   Graphical User Interface

HL7   Health Level 7

HTTP   Hypertext Transfer Protocol

HTTPS   Hypertext Transfer Protocol Secure

IHE	Integrating the Healthcare Enterprise
INR	International Normalized Ratio
IUT	Implementation Under Test
MDS	Medical Device System
NFC	Near Field Communication
PCD	Patient Care Device
PCT	Protocol Conformance Testing
PCO	Point of Control and Observation
PHD	Personal Healthcare Device
PHDC	Personal Healthcare Device Class
PHM	Personal Health Manager
PICS	Protocol Implementation Conformance Statement
PIXIT	Protocol Implementation extra Information for Testing
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
TLS	Transport Level Security
TP	Test Purpose
TSS	Test Suite Structure
USB	Universal Serial Bus
URI	Uniform Resource Identifier
WAN	Wide Area Network
WDM	Windows Driver Model
WS	Web Service
WSDL	Web Service Description Language
XML	extensible Markup Language

5 Conventions

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

− SHALL is equivalent to 'must' or 'it is required to'.
− SHALL NOT is equivalent to 'must not' or 'it is not allowed'.
− SHOULD is equivalent to 'it is recommended to'.
− SHOULD NOT is equivalent to 'it is not recommended to'.
− MAY is equivalent to 'is permitted'.
− MAY NOT is equivalent to 'it is not required that'.

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

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

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

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

6   Test suite structure (TSS)

The test purposes (TPs) for the WAN interface have been divided into the main subgroups specified below. Annex A describes the TPs for subgroups 1.7.1 and 1.7.2 (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 analyzer (BCA)
    - Subgroup 1.4.14: Basic electrocardiograph (ECG)
    - Subgroup 1.4.15: International normalized ratio (INR)
    - Subgroup 1.4.16: Sleep apnoea breathing therapy equipment (SABTE)
  - Group 1.5: Consent management (CM)
    - Subgroup 1.5.1: WAN XDR transaction (TRANS)
    - Subgroup 1.5.2: WAN metadata validation (META)
    - Subgroup 1.5.3: WAN consent directive validation (CDV)
  - Group 1.6: hData observation upload (HDATA)
    - Subgroup 1.6.1: General (GEN)
  - Group 1.7: Questionnaires (QUE)
    - **Subgroup 1.7.1: General (GEN)**
    - **Subgroup 1.7.2: CDA validation (CDA)**

- – Group 2: Receiver (REC)
  - • Group 2.1: Web service interoperability (WSI)
    - ○ Subgroup 2.1.1: Basic profile (BP)
    - ○ Subgroup 2.1.2: Basic security profile (BSP)
    - ○ Subgroup 2.1.3: Reliable messaging (RM)
  - • Group 2.2: SOAP (SOAP)
    - ○ Subgroup 2.2.1: SOAP headers (HEAD)
  - • Group 2.3: Audit (ATNA)
    - ○ Subgroup 2.3.1: General (GEN)
    - ○ Subgroup 2.3.2: PCD-01 (PCD-01)
    - ○ Subgroup 2.3.3: Consent management (CM)
  - • Group 2.4: PCD-01 HL7 messages (PCD-01-DATA)
    - ○ Subgroup 2.4.1: General (GEN)
    - ○ Subgroup 2.4.2: Design guidelines (DG)
    - ○ Subgroup 2.4.3: Pulse oximeter (PO)
    - ○ Subgroup 2.4.4: Blood pressure monitor (BPM)
    - ○ Subgroup 2.4.5: Thermometer (TH)
    - ○ Subgroup 2.4.6: Weighing scales (WEG)
    - ○ Subgroup 2.4.7: Glucose meter (GL)
    - ○ Subgroup 2.4.8: Cardiovascular fitness and activity monitor (CV)
    - ○ Subgroup 2.4.9: Strength fitness equipment (ST)
    - ○ Subgroup 2.4.10: Independent living activity hub (HUB)
    - ○ Subgroup 2.4.11: Adherence monitor (AM)
    - ○ Subgroup 2.4.12: Peak expiratory flow monitor (PF)
    - ○ Subgroup 2.4.13: Body composition analyzer (BCA)
    - ○ Subgroup 2.4.14: Basic electrocardiograph (ECG)
    - ○ Subgroup 2.4.15: International normalized ratio (INR)
    - ○ Subgroup 2.4.16: Sleep apnoea breathing therapy equipment (SABTE)
  - • Group 2.5: Consent management (CM)
    - ○ Subgroup 2.5.1: WAN XDR transaction (TRANS)
    - ○ Subgroup 2.5.2: WAN service validation (SER)
  - • Group 2.6: hData observation upload (HDATA)
    - ○ 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 http://handle.itu.int/11.1002/2000/12067.

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

Annex A

Test purposes

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

A.1 TP definition conventions

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

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

  Each test purpose identifier is introduced by the prefix "TP".

    - <TT>: This is the test tool that will be used in the test case.
        - WAN: Wide area network
    - <DUT>: This is the device under test.
        - SEN: WAN observation sender
        - REC: WAN observation receiver
    - <GR>: This identifies a group of test cases.
    - <SGR>: This identifies a subgroup of test cases.
    - <XX>: This identifies the type of testing.
        - BV: valid behaviour test
        - BI: invalid behaviour test
    - <NNN>: This is a sequential number that identifies the test purpose.
- **TP 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).
- **Other PICS**: This contains additional PICS items (apart from the PICS specified in the Applicability row) which are used within the test case implementation and can modify the final verdict. When this row is empty, it means that only the PICS specified in the Applicability row are used within the test case implementation.
- **Initial condition**: This indicates the state to which the DUT needs to be moved at the beginning of TC execution.
- **Test procedure**: This describes the steps to be followed in order to execute the test case.
- **Pass/Fail criteria**: This provides criteria to decide whether the DUT passes or fails the test case.

A.2 Subgroup 1.7.1: General (GEN)

TP Id	TP/WAN/SEN/QUE/GEN/BV-000
TP label	Questionnaire retrieval. Sender.

Coverage	Spec	[ITU-T H.812]		
	Testable items	RESTSec 3	RESTSec 4	RESTSec 5
		CommonReq 5		
	Spec	[ITU-T H.812.2]		
	Testable items	Question 1	Question 3	Question 5

Test purpose	Check that: SUT retrieves a list of to-be-completed questionnaires from simulated WAN application and an actual to-be-completed questionnaire document.
Applicability	C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006
Other PICS	C_SEN_GEN_005
Initial condition	The simulated WAN receiver provides a list of to-be-completed questionnaires with a single entry containing a link to an actual to-be-completed questionnaire document.
Test procedure	1. An 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 one document. 2. An 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 content will be a relative path to baseURL (WanReceiver). 3. An AHD application validates received document according to Questionnaire Form Definition Document [HL7 CDA QFD].
Pass/Fail criteria	• An AHD application under test supports capability exchange as specified in [ITU-T H.812.3]. • An AHD application successfully retrieves the list of to-be-completed questionnaires from the simulated WAN application. • An AHD application successfully retrieves the actual to-be-completed questionnaire document using the content of the "link" element in the atom feed. • An AHD application confirms that the questionnaire document has been validated.
Notes	

TP Id	TP/WAN/SEN/QUE/GEN/BV-001		
TP label	Questionnaire response submitting. Sender.		
Coverage	Spec	[ITU-T H.812]		
	Testable items	RESTSec 3	RESTSec 4	RESTSec 5
		CommonReq 5		
	Spec	[ITU-T H.812.2] Questionnaire Certified Device Class Guidelines		
	Testable items	Question 6		

Test purpose	Check that: SUT posts a questionnaire response document to the simulated WAN Receiver.

Applicability	C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006
Other PICS	C_SEN_GEN_005
Initial condition	The imulated WAN receiver is ready to receive a questionnaire response document from the AHD under test.
Test procedure	1. A questionnaire-enabled AHD under test uses HTTP POST with the following URL for posting a questionnaire response document to the simulated WAN device: baseURL/continua/questionnaireResponse. Connection uses TLSv1.1 and an Oauth2 bearer token.
Pass/Fail criteria	• An AHD application under test supports capability exchange as specified in [ITU-T H.812.3]. • An AHD application successfully posts a questionnaire response document to the WAN Receiver under test.
Notes	

TP Id	TP/WAN/SEN/QUE/GEN/BV-002		
TP label	Questionnaire response retrieval. Sender.		
Coverage	Spec	[ITU-T H.812]		
	Testable items	RESTSec 3	RESTSec 4	RESTSec 5
		CommonReq 5		
	Spec	[ITU-T H.812.2]		
	Testable items	Question 1	Question 7	Question 8
Test purpose	Check that: SUT retrieves a list of completed questionnaires from simulated WAN application and an actual questionnaire response document.		
Applicability	C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006		
Other PICS	C_SEN_GEN_005		
Initial condition	The imulated WAN receiver provides a list of completed questionnaires with a single entry containing a link to an actual questionnaire response document.		
Test procedure	1. An AHD application uses an HTTP GET request without query parameters at the URL representing the patient's questionnaire response hData path (continua/questionnaireResponses) using a secure REST connection in order to retrieve an atom feed containing a list of questionnaire response documents containing one single document. 2. An AHD application retrieves the questionnaire response document using the value of the "link" element contained in the atom feed retrieved in step 1. "Link" element content will be a relative path to baseURL (WanReceiver). 3. An AHD application validates received document according to Questionnaire Response Document [HL7 CDA QRD].		
Pass/Fail criteria	• An AHD application under test supports capability exchange as specified in [ITU-T H.812.3]. • An AHD application successfully retrieves the list of completed questionnaires from the simulated WAN application. • An AHD application successfully retrieves the actual questionnaire response		

		document using the content of the "link" element in the atom feed.
		• An AHD application confirms that the questionnaire response document has been validated.
Notes		

A.3 Subgroup 1.7.2: CDA validation (CDA)

TP Id		TP/WAN/SEN/QUE/CDA/BV-000		
TP label		Questionnaire Response CDA syntactic and semantic validation. Sender.		
Coverage	**Spec**	[HL7 CDA QRD]		
	Testable items	CONF-QR-1; M	CONF-QR-2;R	CONF-QR-3;M
		CONF-QR-4;M	CONF-QR-5;M	CONF-QR-6;M
		CONF-QR-7;M	CONF-QR-8;M	CONF-QR-9;M
		CONF-QR-11;M	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
		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
Test purpose		Check that: SUT has submitted a syntactically correct questionnaire response document , so that: ClinicalDocument element SHALL contain exactly one [1..1] realmCode. [AND] 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. [AND] ClinicalDocument element SHALL contain exactly one [1..1] typeId. [AND] ClinicalDocument/typeId element SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3". [AND] ClinicalDocument/typeId element SHALL contain exactly one [1..1] @extension="POCD_HD000040".		

	[AND]
	ClinicalDocument SHALL contain at least one [1..*] header-level templateId.
	[AND]
	ClinicalDocument/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.29" .
	[AND]
	ClinicalDocument/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33" .
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] id.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] code.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] title.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] effectiveTime.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] confidentialityCode, which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] recordTarget.
	[AND]
	Such recordTargets SHALL contain exactly one [1..1] patientRole.
	[AND]
	This patientRole SHALL contain at least one [1..*] id.
	[AND]
	This patientRole SHALL contain at least one [1..*] addr.
	[AND]
	This patientRole SHALL contain at least one [1..*] telecom.
	[AND]
	This patientRole SHALL contain exactly one [1..1] patient.
	[AND]
	This patient SHALL contain exactly one [1..1] name.
	[AND]
	This patient SHALL contain exactly one [1..1] administrativeGenderCode.
	[AND]
	This patient SHALL contain exactly one [1..1] birthTime.
	[AND]
	Patient/birthTime SHALL be precise to year.
	[AND]
	Patient/birthTime SHOULD be precise to day.
	[AND]

ClinicalDocument SHALL contain at least one [1..*] author.

[AND]

Such authors SHALL contain exactly one [1..1] time.

[AND]

Such authors SHALL contain exactly one [1..1] assignedAuthor.

[AND]

Author/assignedAuthor SHALL contain exactly one [1..1] id.

[AND]

Author/assignedAuthor/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

[AND]

Author/assignedAuthor, when the author is a person, this assignedAuthor SHALL contain exactly one [1..1] code.

[AND]

Author/assignedAuthor SHALL contain exactly one [1..1] @code, which SHOULD be selected from the Personal And Legal Relationship Role Type 2.16.840.1.113883.11.20.12.1.

[AND]

Author/assignedAuthor SHALL contain at least one [1..*] addr.

[AND]

Author/assignedAuthor SHALL contain at least one [1..*] telecom.

[AND]

Author/assignedAuthor There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice.

[AND]

Author/assignedAuthor SHOULD contain zero or one [0..1] assignedPerson.

[AND]

Author/assignedAuthor/assignedPerson if present, SHALL contain at least one [1..*] name.

[AND]

Author/assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice.

[AND]

Author/assignedAuthor/assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName.

[AND]

Author/assignedAuthor/assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName.

[AND]

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

[AND]

ClinicalDocument MAY contain zero or one [0..1] dataEnterer.

[AND]

DataEnterer , if present, SHALL contain exactly one [1..1] assignedEntity.

[AND]

DataEnterer/assignedEntity SHALL contain at least one [1..*] id.

[AND]

	DataEnterer/assignedEntity SHALL contain at least one [1..*] addr.
	[AND]
	DataEnterer/assignedEntity SHALL contain at least one [1..*] telecom.
	[AND]
	DataEnterer/assignedEntity SHALL contain exactly one [1..1] assignedPerson.
	[AND]
	DataEnterer/assignedEntity/assignedPerson SHALL contain at least one [1..*] name.
	[AND]
	DataEnterer/assignedEntity/assignedPerson MAY contain zero or one [0..1] code to encode the relationship of the person to the recordTarget.
	[AND]
	ClinicalDocument MAY contain zero or more [0..*] informant.
	[AND]
	ClinicalDocument/informant SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity.
	[AND]
	This assignedentity or relatedentity SHOULD contain at least one [1..*] addr.
	[AND]
	This assignedentity or relatedentity SHALL contain exactly one [1..1] assignedPerson OR exactly one [1..1] relatedPerson.
	[AND]
	This assignedentity or relatedentity SHALL contain at least one [1..*] name.
	[AND]
	This assignedEntity MAY contain zero or one [0..1] code.
	[AND]
	This assignedentity or relatedentity SHOULD contain zero or more [0..*] id.
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] custodian.
	[AND]
	This custodian SHALL contain exactly one [1..1] assignedCustodian.
	[AND]
	This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization which may be the person when the document is not maintained by an organization.
	[AND]
	This representedCustodianOrganization SHALL contain at least one [1..*] id.
	[AND]
	This representedCustodianOrganization SHALL contain exactly one [1..1] name.
	[AND]
	This representedCustodianOrganization SHALL contain exactly one [1..1] telecom.
	[AND]
	This telecom SHOULD contain exactly one [1..1] @use.
	[AND]
	This representedCustodianOrganization SHALL contain at least one [1..*] addr.
	[AND]
	MAY contain zero or more [0..*] informationRecipient.

	[AND]
	The informationRecipient, if present, SHALL contain exactly one [1..1] intendedRecipient.
	[AND]
	This intendedRecipient SHOULD contain atleast one [1..*] id.
	[AND]
	This intendedRecipient MAY contain zero or one [0..1] informationRecipient.
	[AND]
	The informationRecipient, if present, SHALL contain at least one [1..*] name.
	[AND]
	This intendedRecipient MAY contain zero or one [0..1] receivedOrganization.
	[AND]
	The receivedOrganization, if present, SHALL contain exactly one [1..1] name.
	[AND]
	ClinicalDocument SHOULD contain zero or one [0..1] legalAuthenticator.
	[AND]
	The legalAuthenticator, if present, SHALL contain exactly one [1..1] time.
	[AND]
	The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode.
	[AND]
	This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89).
	[AND]
	The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] id.
	[AND]
	This assignedEntity MAY contain zero or one [0..1] code.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] addr.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] telecom.
	[AND]
	This assignedEntity SHALL contain exactly one [1..1] assignedPerson.
	[AND]
	This assignedPerson SHALL contain at least one [1..*] name.
	[AND]
	ClinicalDocument MAY contain zero or more [0..*] authenticator.
	[AND]
	The authenticator, if present, SHALL contain exactly one [1..1] time.
	[AND]
	The authenticator, if present, SHALL contain exactly one [1..1] signatureCode.
	[AND]
	This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89).

	[AND]
	The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] id.
	[AND]
	This assignedEntity MAY contain zero or one [0..1] code.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] addr.
	[AND]
	This assignedEntity SHALL contain at least one [1..*] telecom.
	[AND]
	Such telecoms SHOULD contain exactly one [1..1] @use.
	[AND]
	This assignedEntity SHALL contain exactly one [1..1] assignedPerson.
	[AND]
	This assignedPerson SHALL contain at least one [1..*] name.
	[AND]
	ClinicalDocument MAY contain zero or more [0..*] participant.
	[AND]
	The participant, if present, MAY contain zero or one [0..1] time.
	[AND]
	Such participants, if present, SHALL have an associatedPerson or scopingOrganization element under participant/associatedEntity.
	[AND]
	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.
	[AND]
	ClinicalDocument SHOULD contain zero or one [0..1] inFulfillmentOf.
	[AND]
	The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order.
	[AND]
	This order SHALL contain at least one [1..*] id.
	[AND]
	ClinicalDocument MAY contain zero or one [0..1] componentOf.
	[AND]
	The componentOf, if present, SHALL contain exactly one [1..1] encompassingEncounter.
	[AND]
	This encompassingEncounter SHALL contain at least one [1..*] id.
	[AND]
	This encompassingEncounter SHALL contain exactly one [1..1] effectiveTime.
	[AND]
	ClinicalDocument SHALL conform to the Universal Realm Questionnaire Response Document Header template (templateId: 2.16.840.1.113883.10.20.33).
	[AND]

	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).
	[AND]
	Clinicians generated Questionnaire Response Document in US Realm SHOULD conform to the US C-CDA General Header template (templateId: 2.16.840.1.113883.10.20.22.1.1).
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] templateId.
	[AND]
	ClinicalDocument/tempalteId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.1.1".
	[AND]
	ClinicalDocument SHALL contain exactly one [1..1] component.
	[AND]
	ClinicalDocument/component SHALL contain exactly one [1..1] structuredBody.
	[AND]
	ClinicalDocument/component/structureBody SHALL contain at least one [1..*] component .
	[AND]
	ClinicalDocument/component/structureBody/component SHALL contain exactly one [1..1] Questionnaire Response Section template(templateId: '2.16.840.1.113883.10.20.33.1.1').
	[AND]
	ClinicalDocument/component/structureBody/component SHALL contain exactly one [1..1] Copy Right Section template (templateId:2.16.840.1.113883.10.20.32.2.2).
	[AND]
	This section SHALL contain exactly one [1..1] templateId .
	[AND]
	Section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.2.1".
	[AND]
	This section SHALL contain exactly one [1..1] code.
	[AND]
	This section SHOULD contain zero or one [0..1] title.
	[AND]
	This section SHALL contain exactly one [1..1] text.
	[AND]
	This 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.
	[AND]
	This section SHALL contain at least one [1..*] entry .
	[AND]
	This section/entry SHALL contain exactly one [1..1] @typeCode="DRIV".
	[AND]
	This section/entry SHALL contain exactly one [1..1] Responses Organizer template(templateId: 2.16.840.1.113883.10.20.33.4.1).
	[AND]
	This section SHALL contain exactly one [1..1] @classCode="BATTERY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).

[AND]

This section SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).

[AND]

This section SHALL contain exactly one [1..1] templateId.

[AND]

This section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.1".

[AND]

This section SHALL contain at least one [1..*] id.

[AND]

This section SHOULD contain zero or one [0..1] code.

[AND]

This section SHALL contain exactly one [1..1] statusCode.

[AND]

This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

[AND]

This section SHALL contain at least one [1..*] component such that it

[AND]

This section/component SHALL contain exactly one [1..1] sequenceNumber.

[AND]

This section/component SHALL contain exactly one [1..1] of the following templates:

 -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).

 -Text Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.6).
-Analog Slider Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.7).   -Discrete Slider Response Pattern Observation template(templateID: 2.16.840.1.113883.10.20.33.4.8).

[AND]

This section SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)

[AND]

This section SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).

[AND]

This section SHALL contain exactly one [1..1] templateId .

[AND]

This section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.2".

[AND]

This section SHALL contain exactly one [1..1] value.

[AND]

This section SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This section SHALL contain exactly one [1..1] templateId (CONF:150) such that it.

[AND]

This section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.3".

[AND]

The referenceRange SHALL contain exactly one [1..1] observationRange.

[AND]

This observationRange MAY contain zero or one [0..1] text.

[AND]

This observationRange SHALL contain exactly one [1..1] value .

[AND]

This value SHALL contain exactly one [1..1] @xsi:type.

[AND]

This value SHALL contain exactly one [1..1] low.

[AND]

This value SHALL contain exactly one [1..1] high.

[AND]

This section SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).

[AND]

This section SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC),.

[AND]

This section SHALL contain exactly one [1..1] templateId .

[AND]

This section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4",

[AND]

This section SHALL contain at least one [1..*] id.

[AND]

This section SHALL contain exactly one [1..1] code.

[AND]

This code SHALL contain exactly one [1..1] @code.

[AND]

This code SHALL contain exactly one [1..1] @CodeSystem.

[AND]

This code SHALL contain exactly one [1..1] originalText.

[AND]

This 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.

[AND]

This section SHALL contain exactly one [1..1] statusCode.

[AND]

This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) .

[AND]

This section SHALL contain exactly one [1..1] value.

[AND]

This section SHALL contain exactly one [1..1] @xsi:type, where the value of @xsi:type could be "INT", "REAL" or "TS".

[AND]

This section MAY contain zero or one [0..1] entryRelationship.

[AND]

The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This entryRelationship SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).

[AND]

This section SHOULD contain zero or one [0..1] entryRelationship.

[AND]

The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This entryRelationship SHALL conform to the Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).

[AND]

This section SHOULD contain zero or more [0..*] Response Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.33.4.3).

[AND]

This section SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).

[AND]

This section SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).

[AND]

This section SHALL contain exactly one [1..1] templateId.

[AND]

This section/templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.5".

[AND]

This section SHALL contain at least one [1..*] id.

[AND]

This section SHALL contain exactly one [1..1] code.

[AND]

This code SHALL contain exactly one [1..1] @code.

[AND]

This code SHALL contain exactly one [1..1] @CodeSystem.

[AND]

This code SHALL contain exactly one [1..1] originalText.

[AND]

This 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.

[AND]

This section SHALL contain exactly one [1..1] statusCode.

[AND]

This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

[AND]

This section SHALL contain at least one [1..*] value

[AND]

This section/value SHALL contain exactly one [1..1] @xsi:type="CE".

[AND]

This section/value SHALL contain exactly one [1..1] @code.

[AND]

This section/value SHALL contain exactly one [1..1] @CodeSystem.

[AND]

This section/value SHALL contain exactly one [1..1] @displayName.

[AND]

This section SHOULD contain zero or many [0..*] entryRelationship.

[AND]

This section/entryRelationship SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This section/entryRelationship SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).

[AND]

This section/entryRelationship SHALL contain exactly one [1..1] Question Options Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.20).

[AND]

This section SHOULD contain zero or one [0..*] entryRelationship.

[AND]

The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This entryRelationship SHALL contain exactly one [1..1] Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).

[AND]

This entryRelationship SHALL contain exactly one [1..1] Text Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.33.4.6.

[AND]

This section SHALL contain exactly one [1..1] Text Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.33.4.6.

[AND]

This section SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).

[AND]

This section SHALL contain exactly one [1..1] templateId.

[AND]

This section/templateId SHALL contain exactly one [1..1]

| | @root="2.16.840.1.113883.10.20.33.4.4".

[AND]

This section SHALL contain at least one [1..1] id.

[AND]

This section SHALL contain exactly one [1..1] code.

[AND]

This code SHALL contain exactly one [1..1] @code.

[AND]

This code SHALL contain exactly one [1..1] @CodeSystem.

[AND]

This code SHALL contain exactly one [1..1] originalText.

[AND]

This 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.

[AND]

This section SHALL contain exactly one [1..1] statusCode.

[AND]

This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

[AND]

This section SHALL contain exactly one [1..1] value.

[AND]

This value SHALL contain exactly one [1..1] @xsi:type="ST".

[AND]

This section MAY contain zero or one [0..1] entryRelationship.

[AND]

The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This entryRelationship SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.19).

[AND]

This section SHOULD contain zero or one [0..1] entryRelationship.

[AND]

The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).

[AND]

This entryRelationship SHALL contain exactly one [1..1] Response Media Pattern template (templateId 2.16.840.1.113883.10.20.33.4.2).

[AND]

This section SHALL conform to the Numeric Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.6).

[AND]

This section SHALL NOT contain Response Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.4).

[AND]

This section SHALL contain exactly one [1..1] templateId.

	[AND] This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.9". [AND] This section SHALL contain exactly one [1..1] referenceRange. [AND] This referenceRange SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002). [AND] The referenceRange SHALL contain exactly one [1..1] observationRange. [AND] This observationRange SHALL contain exactly one [1..1] value. [AND] This value SHALL contain exactly one [1..1] @xsi:type="GLIST_PQ". [AND] This value SHALL contain exactly one [1..1] head. [AND] This value SHALL contain exactly one [1..1] increment. [AND] This value SHALL contain exactly one [1..1] denominator. [AND] This section SHALL conform to Multiple Choice Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.7). [AND] This section SHALL contain exactly one [1..1] templateId. [AND] This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.10". [AND] This section SHALL contain exactly one [1..1] value. [AND] 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).
Applicability	C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006
Other PICS	N/A
Initial condition	An AHD application under test has previously submitted a Questionnaire Response document to the simulated WAN receiver (TP/WAN/SEN/QUE/GEN/BV-001 has been previously executed).

Test procedure	1. Make sure that TP/WAN/SEN/QUE/GEN/BV-001 has been previously executed, so that the AHD under test has already submitted a Questionnaire Response document to the simulated WAN receiver.
	
	2. Check the following elements of the clinical document sent by the sender under test:
	
	    1. ClinicalDocument element SHALL contain 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 templatedId such that:

- This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.29".

- This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33".

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] effectiveTime.

9. 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.

10. ClinicalDocument SHALL contain exactly one [1..1] languageCode, which SHALL be selected from ValueSet Language 2.16.840.1.113883.1.11.11523 DYNAMIC.

11. ClinicalDocument SHALL contain exactly one [1..1] recordTarget.

- Such recordTargets SHALL contain exactly one [1..1] patientRole.

  1. This patientRole SHALL contain at least one [1..*] id.

  2. This patientRole SHALL contain at least one [1..1] addr.

  3. This patientRole SHALL contain at least one [1..*] telecom.

  4. This patientRole SHALL contain exactly one [1..1] patient.

     a. This patient SHALL contain exactly one [1..1] name.

     b. This patient SHALL contain exactly one [1..1] administrativeGenderCode.

     c. This patient SHALL contain exactly one [1..1] birthTime.

        ➢ 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 [1..1] time.

- Such authors SHALL contain exactly one [1..1] assignedAuthor.

  1. This assignedAuthor SHALL contain exactly one [1..1] 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 [1..1] code.

     - The code, SHALL contain exactly one [1..1] @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. |

6. 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.

4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson.

a. This assignedPerson 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..*] informants.

- 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 leas 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 assignedcustodian SHALL contain exactly one [1..1] representedCustodianOrganization 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.

c. 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.

<table>
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<td></td>
<td></td>
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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 contain 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.

  5. 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..*] participants.

- 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.

</td>
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- 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.

        2. This encompassingEncounter SHALL contain exactly one [1..1] effectiveTime.

22. SHALL conform to the Universal Realm Questionnaire Response Document Header template (templateId: 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 (templateId: 2.16.840.1.113883.10.20.22.1.1).

25. SHALL contain exactly one [1..1] templateId 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.

        1. This structuredBody SHALL contain at least one [1..*] component such that it.

            a. SHALL contain exactly one [1..1] Questionnaire Response Section template (templateId: '2.16.840.1.113883.10.20.33.1.1').

            b. SHALL contain exactly one [1..1] Copy Right Section template (templateId: 2.16.840.1.1113883.10.20.32.2.2).

27. SHALL contain exactly one [1..1] templateId 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 (templateId: 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] templateId 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).

   2. 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] templateId 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] templateId 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] templateId 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 templates (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] templateId 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 2.16.840.1.1020.32.4.20).

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).

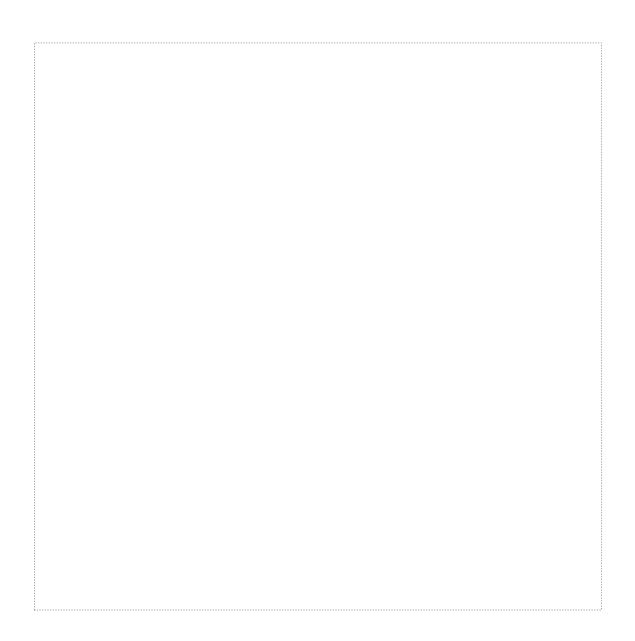|	
	• SHALL contain exactly one [1..1] Text Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.33.4.6).
	68. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
	69. SHALL CONTAIN EXACTLY ONE [1..1] @moodcode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
	70. SHALL contain exactly one [1..1] templateId 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] templateId 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.
	d. SHALL contain exactly one [1..1] denominator.
	82. SHALL conform to Multiple Choice Response Pattern Observation template

	(templateId 2.16.840.1.113883.10.20.32.4.7).
	83. 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".
	84. SHALL contain exactly one [1..1] 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	• The submitted questionnaire response is compliant with HL7 Implementation Guide for CDA R2: Questionnaire Response Document, Release 1 [HL7 CDA QRD] as described above.
Notes	

Bibliography

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