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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
system: Services interface Part 11:
Questionnaires: Health & Fitness Service
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 system: Services interface Part 11: Questionnaires: Health & Fitness Service sender

Summary

Recommendation ITU-T H.830.11 provides a test suite structure (TSS) and the test purposes (TP) for Questionnaires through the Health & Fitness Service (HFS) sender in the Services interface, based on the requirements defined in the Recommendations of the ITU-T H.810 sub-series, of which Recommendation ITU-T H.810 (2016) is the base Recommendation. The objective of this test specification is to provide a high probability of interoperability at this interface.

Recommendation ITU-T H.830.11 is a transposition of Continua Test Tool DG2016 Test Suite Structure & Test Purposes, Services Interface; Part 11: Questionnaires: HFS Sender (Version 1.2, 2017-03-14).

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* |
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Conformance testing, Continua Design Guidelines, e-health, Health & Fitness Service, ITU-T H.810, personal connected health devices, Questionnaires, Services interface.

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

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

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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 DG2016, Test Suite Structure & Test Purposes, Services Interface; Part 11: Questionnaires: HFS Sender (Version 1.21, 2017-03-14), that was developed by the Personal Connected Health Alliance. The table below shows the revision history of this test specification; it may contain versions that existed before transposition.

| Version | Date | Revision history |
|----------------|-------------|--|
| 1.0 | 2015-07-01 | Initial release for Test Tool DG2015 based on the requirements in [b-ITU-T H.810 (2015)]/[b-CDG 2015]. |
| 1.1 | 2016-09-20 | Initial release for Test Tool DG2016. It implements changes according to [ITU-T H.810 (2016)]/[b-CDG 2016] (Iris + Errata) refreshments. |
| 1.2 | 2017-03-14 | Editorial: added insulin pump and continuous glucose monitor specializations to the TSS list in clause 6. |

Recommendation ITU-T H.830.11

Conformance of ITU-T H.810 personal health system: Services interface Part 11: Questionnaires: Health & Fitness Service sender

1 Scope

The scope of this Recommendation¹ is to provide a test suite structure (TSS) and the test purposes (TP) for the Services interface based on the requirements defined in the Continua Design Guidelines (CDG) [ITU-T H.810 (2016)]. The objective of this test specification is to provide a high probability of interoperability at this interface.

The TSS and TP for the Services interface have been divided into the parts specified below. This Recommendation covers Part 11.

- Part 1: Web services interoperability. Health & Fitness Service sender
- Part 2: Web services interoperability. Health & Fitness Service receiver
- Part 3: SOAP/ATNA. Health & Fitness Service sender
- Part 4: SOAP/ATNA. Health & Fitness Service receiver
- Part 5: PCD-01 HL7 messages. Health & Fitness Service sender
- Part 6: PCD-01 HL7 messages. Health & Fitness Service receiver
- Part 7: Consent Management. Health & Fitness Service sender
- Part 8: Consent Management. Health & Fitness Service receiver
- Part 9: hData Observation Upload. Health & Fitness Service sender
- Part 10: hData Observation Upload. Health & Fitness Service receiver
- **Part 11: Questionnaires. Health & Fitness Service sender**
- Part 12: Questionnaires. Health & Fitness Service 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 (2016)] | Recommendation ITU-T H.810 (2016), <i>Interoperability design guidelines for personal health systems</i> . |
| [ITU-T H.811] | Recommendation ITU-T H.811 (2016), <i>Interoperability design guidelines for personal health systems: Personal health devices interface</i> . |

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 (2016), <i>Interoperability design guidelines for personal health systems: Services interface: Common certified capability class.</i> |
| [ITU-T H.812.1] | Recommendation ITU-T H.812.1 (2016), <i>Interoperability design guidelines for personal health systems: Services interface: Observation upload certified capability class.</i> |
| [ITU-T H.812.2] | Recommendation ITU-T H.812.2 (2016), <i>Interoperability design guidelines for personal health systems: Services interface: Questionnaires certified capability class.</i> |
| [ITU-T H.812.3] | Recommendation ITU-T H.812.3 (2016), <i>Interoperability design guidelines for personal health systems: Services interface: Capability exchange certified capability class.</i> |
| [ITU-T H.812.4] | Recommendation ITU-T H.812.4 (2016), <i>Interoperability design guidelines for personal health systems: Services interface: Authenticated persistent session certified capability class.</i> |
| [ITU-T H.813] | Recommendation ITU-T H.813 (2016), <i>Interoperability design guidelines for personal health systems: Healthcare information system interface.</i> |
| [HL7 CDA QFD] | Health Level Seven (2014), <i>HL7 Implementation Guide for CDA, Release 2: Questionnaire Form Definition Document, Release 1.</i> http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=116 |
| [HL7 CDA QRD] | Health Level Seven (2014), <i>HL7 Implementation Guide for CDA, Release 2: Questionnaire Response Document, Release 1.</i> 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 |
| CGM | Continuous Glucose Monitor |
| GUI | Graphical User Interface |
| HFS | Health & Fitness Service |
| HFSS | Health & Fitness Service Sender |

| | |
|-------|---|
| HFSR | Health & Fitness Service ReceiverHL7 Health Level 7 |
| HTTP | Hypertext Transfer Protocol |
| HTTPS | Hypertext Transfer Protocol Secure |
| INR | International Normalized Ratio |
| IP | Insulin Pump |
| 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 Health Device |
| PHDC | Personal Healthcare Device Class |
| PHG | Personal Health Gateway |
| PICS | Protocol Implementation Conformance Statement |
| PIXIT | Protocol Implementation extra Information for Testing |
| SABTE | Sleep Apnoea Breathing Therapy Equipment |
| SCR | Static Conformance Review |
| 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 |
| WSI | Web Services Interoperability |
| XDR | Cross-Enterprise Document Reliable Interchange |
| 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 [b-CDG 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 | [b-ITU-T H.810 (2015)] | 5.1 | Release 2015 plus errata noting all ratified bugs [b-CDG 2015]. The 2013 edition of H.810 is split into eight parts in the H.810-series. | – |
| 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 | [b-ITU-T H.810 (2013)] | 4.1 | Release 2013 plus errata noting all ratified bugs [b-CDG 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. | – |

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

| CDG release | Transposed as | Version | Description | Designation |
|------------------|---------------|---------|--|-------------|
| 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 Services 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: HFS sender (HFSS)
 - 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: Simple object access protocol (SOAP)
 - Subgroup 1.2.1: SOAP headers (HEAD)
 - Group 1.3: Audit trail and node authentication (ATNA)
 - Subgroup 1.3.1: General (GEN)
 - Subgroup 1.3.2: PCD-01 (PCD-01)
 - Subgroup 1.3.3: Consent Management (CM)
 - Group 1.4: PCD-01 HL7 messages (PCD-01-DATA)
 - Subgroup 1.4.1: General (GEN)
 - Subgroup 1.4.2: Design guidelines (DG)
 - Subgroup 1.4.3: Pulse oximeter (PO)
 - Subgroup 1.4.4: Blood pressure monitor (BPM)
 - Subgroup 1.4.5: Thermometer (TH)
 - Subgroup 1.4.6: Weighing scales (WEG)
 - Subgroup 1.4.7: Glucose meter (GL)
 - Subgroup 1.4.8: Cardiovascular fitness and activity monitor (CV)
 - Subgroup 1.4.9: Strength fitness equipment (ST)
 - Subgroup 1.4.10: Independent living activity hub (HUB)
 - Subgroup 1.4.11: Adherence monitor (AM)
 - Subgroup 1.4.12: Peak expiratory flow monitor (PF)

- Subgroup 1.4.13: Body composition analyser (BCA)
- Subgroup 1.4.14: Basic electrocardiograph (ECG)
- Subgroup 1.4.15: International normalized ratio (INR)
- Subgroup 1.4.16: Sleep apnoea breathing therapy equipment (SABTE)
- Subgroup 1.4.17: Insulin pump (IP)
- Subgroup 1.4.18: Continuous glucose monitor (CGM)
- Group 1.5: Consent Management (CM)
 - Subgroup 1.5.1: HFS XDR transaction (TRANS)
 - Subgroup 1.5.2: HFS metadata validation (META)
 - Subgroup 1.5.3: HFS 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: HFS receiver (HFSR)
 - Group 2.1: Web service interoperability (WSI)
 - Subgroup 2.1.1: Basic profile (BP)
 - Subgroup 2.1.2: Basic security profile (BSP)
 - Subgroup 2.1.3: Reliable messaging (RM)
 - Group 2.2: SOAP (SOAP)
 - Subgroup 2.2.1: SOAP headers (HEAD)
 - Group 2.3: Audit (ATNA)
 - Subgroup 2.3.1: General (GEN)
 - Subgroup 2.3.2: PCD-01 (PCD-01)
 - Subgroup 2.3.3: Consent Management (CM)
 - Group 2.4: PCD-01 HL7 messages (PCD-01-DATA)
 - Subgroup 2.4.1: General (GEN)
 - Subgroup 2.4.2: Design guidelines (DG)
 - Subgroup 2.4.3: Pulse oximeter (PO)
 - Subgroup 2.4.4: Blood pressure monitor (BPM)
 - Subgroup 2.4.5: Thermometer (TH)
 - Subgroup 2.4.6: Weighing scales (WEG)
 - Subgroup 2.4.7: Glucose meter (GL)
 - Subgroup 2.4.8: Cardiovascular fitness and activity monitor (CV)
 - Subgroup 2.4.9: Strength fitness equipment (ST)
 - Subgroup 2.4.10: Independent living activity hub (HUB)
 - Subgroup 2.4.11: Adherence monitor (AM)
 - Subgroup 2.4.12: Peak expiratory flow monitor (PF)
 - Subgroup 2.4.13: Body composition analyser (BCA)
 - Subgroup 2.4.14: Basic electrocardiograph (ECG)

- Subgroup 2.4.15: International normalized ratio (INR)
- Subgroup 2.4.16: Sleep apnoea breathing therapy equipment (SABTE)
- Subgroup 2.4.17: Insulin pump (IP)
- Subgroup 2.4.18: Continuous glucose monitor (CGM)
- Group 2.5: Consent Management (CM)
 - Subgroup 2.5.1: HFS XDR transaction (TRANS)
 - Subgroup 2.5.2: HFS 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.
 - HFS: Health & Fitness Services Interface
 - <DUT>: This is the device under test.
 - SEN: HFS sender
 - REC: HFS 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 item: This contains testable items to be checked by the TP.
- **Test purpose:** This is a description of the requirements to be tested.
- **Applicability:** This contains the PICS items that define if 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/HFS/SEN/QUE/GEN/BV-000 | | | |
| TP label | Questionnaire retrieval. HFS Sender. | | | |
| Coverage | Spec | [ITU-T H.812] | | |
| | Testable items | RESTSec 3;M | RESTSec 4;M | RESTSec 5;M |
| | | CommonReq 5;M | | |
| | Spec | [ITU-T H.812.2] | | |
| Testable items | Question 1;M | Question 3;M | Question 5;M | |
| Test purpose | <p>Check that:</p> <p>SUT retrieves a list of to-be-completed questionnaires from simulated HFS application and an actual to-be-completed questionnaire document.</p> | | | |
| Applicability | C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006 | | | |
| Other PICS | C_SEN_GEN_005 | | | |
| Initial condition | The simulated HFS 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 | <ol style="list-style-type: none"> 1. An HFS 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 HFS 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 HFS application validates received document according to Questionnaire Form Definition Document [HL7 CDA QFD]. | | | |
| Pass/Fail criteria | <ul style="list-style-type: none"> • An HFS application under test supports capability exchange as specified in [ITU-T H.812.3]. • An HFS application successfully retrieves the list of to-be-completed questionnaires from the simulated HFS application. • An HFS application successfully retrieves the actual to-be-completed questionnaire document using the content of the "link" element in the atom feed. • An HFS application confirms that the questionnaire document has been validated. | | | |
| Notes | | | | |

| | | | | |
|-----------------|--|-----------------|-------------|-------------|
| TP Id | TP/HFS/SEN/QUE/GEN/BV-001 | | | |
| TP label | Questionnaire response submitting. HFS Sender. | | | |
| Coverage | Spec | [ITU-T H.812] | | |
| | Testable items | RESTSec 3;M | RESTSec 4;M | RESTSec 5;M |
| | | CommonReq 5;M | | |
| | Spec | [ITU-T H.812.2] | | |

| | | | | |
|---------------------------|--|--------------|--|--|
| | Testable items | Question 6;M | | |
| Test purpose | Check that: SUT posts a questionnaire response document to the simulated HFS receiver. | | | |
| Applicability | C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006 | | | |
| Other PICS | C_SEN_GEN_005 | | | |
| Initial condition | The simulated HFS receiver is ready to receive a questionnaire response document from the HFS sender under test. | | | |
| Test procedure | 1. A questionnaire-enabled HFS sender under test uses HTTP POST with the following URL for posting a questionnaire response document to the simulated HFS Device: baseURL/continua/questionnaireResponse. Connection uses TLSv1.1 and an Oauth2 bearer token. | | | |
| Pass/Fail criteria | <ul style="list-style-type: none"> An HFS application under test supports capability exchange as specified in [ITU-T H.812.3]. An HFS application successfully posts a questionnaire response document to the HFS receiver under test. | | | |
| Notes | | | | |

| | | | | |
|--------------------------|--|-----------------|--------------|-------------|
| TP Id | TP/HFS/SEN/QUE/GEN/BV-002 | | | |
| TP label | Questionnaire response retrieval. HFS Sender. | | | |
| Coverage | Spec | [ITU-T H.812] | | |
| | Testable items | RESTSec 3;M | RESTSec 4;M | RESTSec 5;M |
| | | CommonReq 5;M | | |
| | Spec | [ITU-T H.812.2] | | |
| Testable items | Question 1;M | Question 7;M | Question 8;M | |
| Test purpose | Check that: SUT retrieves a list of completed questionnaires from simulated HFS 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 simulated HFS receiver provides a list of completed questionnaires with a single entry containing a link to an actual questionnaire response document. | | | |
| Test procedure | <ol style="list-style-type: none"> An HFS 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. An HFS 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). An HFS application validates received document according to Questionnaire Response Document [HL7 CDA QRD]. | | | |

| | |
|---------------------------|---|
| Pass/Fail criteria | <ul style="list-style-type: none"> • An HFS application under test supports capability exchange as specified in [ITU-T H.812.3]. • An HFS application successfully retrieves the list of completed questionnaires from the simulated HFS application. • An HFS application successfully retrieves the actual questionnaire response document using the content of the "link" element in the atom feed. • An HFS application confirms that the questionnaire response document has been validated. |
| Notes | |

A.3 Subgroup 1.7.2: CDA validation (CDA)

| | | | |
|-----------------|---|----------------|---------------|
| TP Id | TP/HFS/SEN/QUE/CDA/BV-000 | | |
| TP label | Questionnaire Response CDA syntactic and semantic validation. HFS 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 | | <p>Check that:</p> <p>SUT has submitted a syntactically correct questionnaire response document , so that:</p> <p>ClinicalDocument element SHALL contain exactly one [1..1] realmCode.</p> <p>[AND]</p> <p>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.</p> <p>[AND]</p> <p>ClinicalDocument element SHALL contain exactly one [1..1] typeld.</p> <p>[AND]</p> <p>ClinicalDocument/typeld element SHALL contain exactly one [1..1]</p> | | |

@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]

| | |
|--|---|
| | <p>Patient/birthTime SHALL be precise to year.</p> <p>[AND]</p> <p>Patient/birthTime SHOULD be precise to day.</p> <p>[AND]</p> <p>ClinicalDocument SHALL contain at least one [1..*] author.</p> <p>[AND]</p> <p>Such authors SHALL contain exactly one [1..1] time.</p> <p>[AND]</p> <p>Such authors SHALL contain exactly one [1..1] assignedAuthor.</p> <p>[AND]</p> <p>Author/assignedAuthor SHALL contain exactly one [1..1] id.</p> <p>[AND]</p> <p>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</p> <p>[AND]</p> <p>Author/assignedAuthor, when the author is a person, this assignedAuthor SHALL contain exactly one [1..1] code.</p> <p>[AND]</p> <p>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.</p> <p>[AND]</p> <p>Author/assignedAuthor SHALL contain at least one [1..*] addr.</p> <p>[AND]</p> <p>Author/assignedAuthor SHALL contain at least one [1..*] telecom.</p> <p>[AND]</p> <p>Author/assignedAuthor There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice.</p> <p>[AND]</p> <p>Author/assignedAuthor SHOULD contain zero or one [0..1] assignedPerson.</p> <p>[AND]</p> <p>Author/assignedAuthor/assignedPerson if present, SHALL contain at least one [1..*] name.</p> <p>[AND]</p> <p>Author/assignedAuthor SHOULD contain zero or one [0..1] assignedAuthoringDevice.</p> <p>[AND]</p> <p>Author/assignedAuthor/assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] manufacturerModelName.</p> <p>[AND]</p> <p>Author/assignedAuthor/assignedAuthoringDevice, if present, SHALL contain exactly one [1..1] softwareName.</p> <p>[AND]</p> <p>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</p> <p>[AND]</p> <p>ClinicalDocument MAY contain zero or one [0..1] dataEnterer.</p> <p>[AND]</p> <p>DataEnterer , if present, SHALL contain exactly one [1..1] assignedEntity.</p> |
|--|---|

[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]

| | |
|--|--|
| | <p>ClinicalDocument SHALL conform to the Universal Realm Questionnaire Response Document Header template (templated: 2.16.840.1.113883.10.20.33).</p> <p>[AND]</p> <p>Patient generated Questionnaire Response Document in US Realm SHOULD conform to the US Realm Patient Generated Document Header template (templated: 2.16.840.1.113883.10.20.29.1).</p> <p>[AND]</p> <p>Clinicians generated Questionnaire Response Document in US Realm SHOULD conform to the US C-CDA General Header template (templated: 2.16.840.1.113883.10.20.22.1.1).</p> <p>[AND]</p> <p>ClinicalDocument SHALL contain exactly one [1..1] templated.</p> <p>[AND]</p> <p>ClinicalDocument/templated SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.1.1".</p> <p>[AND]</p> <p>ClinicalDocument SHALL contain exactly one [1..1] component.</p> <p>[AND]</p> <p>ClinicalDocument/component SHALL contain exactly one [1..1] structuredBody.</p> <p>[AND]</p> <p>ClinicalDocument/component/structureBody SHALL contain at least one [1..*] component .</p> <p>[AND]</p> <p>ClinicalDocument/component/structureBody/component SHALL contain exactly one [1..1] Questionnaire Response Section template(templated: '2.16.840.1.113883.10.20.33.1.1').</p> <p>[AND]</p> <p>ClinicalDocument/component/structureBody/component SHALL contain exactly one [1..1] Copy Right Section template (templated:2.16.840.1.113883.10.20.32.2.2).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] templated .</p> <p>[AND]</p> <p>Section/templated SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.2.1".</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] code.</p> <p>[AND]</p> <p>This section SHOULD contain zero or one [0..1] title.</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] text.</p> <p>[AND]</p> <p>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.</p> <p>[AND]</p> <p>This section SHALL contain at least one [1..*] entry .</p> <p>[AND]</p> <p>This section/entry SHALL contain exactly one [1..1] @typeCode="DRIV".</p> <p>[AND]</p> <p>This section/entry SHALL contain exactly one [1..1] Responses Organizer template(templated: 2.16.840.1.113883.10.20.33.4.1).</p> |
|--|--|

[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]

| | |
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| | <p>This section SHALL contain exactly one [1..1] statusCode.</p> <p>[AND]</p> <p>This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) .</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] value.</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] @xsi:type, where the value of @xsi:type could be "INT", "REAL" or "TS".</p> <p>[AND]</p> <p>This section MAY contain zero or one [0..1] entryRelationship.</p> <p>[AND]</p> <p>The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).</p> <p>[AND]</p> <p>This entryRelationship SHALL contain exactly one [1..1] Question Help Text Pattern Observation template (templated 2.16.840.1.113883.10.20.32.4.19).</p> <p>[AND]</p> <p>This section SHOULD contain zero or one [0..1] entryRelationship.</p> <p>[AND]</p> <p>The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).</p> <p>[AND]</p> <p>This entryRelationship SHALL conform to the Response Media Pattern template (templated 2.16.840.1.113883.10.20.33.4.2).</p> <p>[AND]</p> <p>This section SHOULD contain zero or more [0..*] Response Reference Range Pattern template (templated 2.16.840.1.113883.10.20.33.4.3).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] templated.</p> <p>[AND]</p> <p>This section/templated SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.5".</p> <p>[AND]</p> <p>This section SHALL contain at least one [1..*] id.</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] code.</p> <p>[AND]</p> <p>This code SHALL contain exactly one [1..1] @code.</p> <p>[AND]</p> <p>This code SHALL contain exactly one [1..1] @CodeSystem.</p> |
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[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 (templated 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 (templated 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 (templated 2.16.840.1.113883.10.20.33.4.2).

[AND]

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

[AND]

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

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| | <p>[AND]</p> <p>This section SHALL NOT contain Response Reference Range Pattern template (templateId 2.16.840.1.113883.10.20.32.4.4).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] templateId.</p> <p>[AND]</p> <p>This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.9".</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] referenceRange.</p> <p>[AND]</p> <p>This referenceRange SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).</p> <p>[AND]</p> <p>The referenceRange SHALL contain exactly one [1..1] observationRange.</p> <p>[AND]</p> <p>This observationRange SHALL contain exactly one [1..1] value.</p> <p>[AND]</p> <p>This value SHALL contain exactly one [1..1] @xsi:type="GLIST_PQ".</p> <p>[AND]</p> <p>This value SHALL contain exactly one [1..1] head.</p> <p>[AND]</p> <p>This value SHALL contain exactly one [1..1] increment.</p> <p>[AND]</p> <p>This value SHALL contain exactly one [1..1] denominator.</p> <p>[AND]</p> <p>This section SHALL conform to Multiple Choice Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.7).</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] templateId.</p> <p>[AND]</p> <p>This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.10".</p> <p>[AND]</p> <p>This section SHALL contain exactly one [1..1] value.</p> <p>[AND]</p> <p>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).</p> |
| Applicability | C_SEN_000 AND C_SEN_GEN_004 AND C_SEN_GEN_006 |
| Other PICS | |
| Initial condition | An HFS application under test has previously submitted a Questionnaire Response document to the simulated HFS receiver (TP/HFS/SEN/QUE/GEN/BV-001 has been previously executed). |
| Test procedure | <ol style="list-style-type: none"> 1. Make sure that TP/HFS/SEN/QUE/GEN/BV-001 has been previously executed, so that the HFS sender under test has already submitted a Questionnaire Response document to the simulated HFS receiver. 2. Check the following elements of the clinical document sent by the HFS sender under test: |

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| | <ol style="list-style-type: none"> 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. <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • This templatedId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.29". • This templatedId 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. <ul style="list-style-type: none"> • Such recordTargets SHALL contain exactly one [1..1] patientRole. <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. <ul style="list-style-type: none"> ➤ SHALL be precise to year. ➤ SHOULD be precise to day. 12. ClinicalDocument SHALL contain at least one [1..*] author. <ul style="list-style-type: none"> • Such authors SHALL contain exactly one [1..1] time. • Such authors SHALL contain exactly one [1..1] assignedAuthor. <ol style="list-style-type: none"> 1. This assignedAuthor SHALL contain exactly one [1..1] id such that it. <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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. |
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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 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 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 at least 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.

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| | <p>3. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization.</p> <p>a. The informationRecipient, if present, SHALL contain at least one [1..*] name.</p> <p>4. This intendedRecipient MAY contain zero or one [0..1] receivedOrganization.</p> <p>a. The receivedOrganization, if present, SHALL contain exactly one [1..1] name.</p> <p>17. ClinicalDocument SHOULD contain zero or one [0..1] legalAuthenticator.</p> <ul style="list-style-type: none"> • The legalAuthenticator, if present, SHALL contain exactly one [1..1] time. • The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode. <ol style="list-style-type: none"> 1. This signatureCode SHALL contain exactly one [1..1] signatureCode. <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> a. This assignedPerson SHALL contain at least one [1..*] name. <p>18. ClinicalDocument MAY contain zero or more [0..*] authenticator.</p> <ul style="list-style-type: none"> • The authenticator, if present, SHALL contain exactly one [1..1] time. • The authenticator, if present, SHALL contain exactly one [1..1] signatureCode. <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> a. Such telecoms SHOULD contain exactly one [1..1] @use. 5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson. <ol style="list-style-type: none"> a. This assignedPerson SHALL contain at least one [1..*] name. <p>19. ClinicalDocument MAY contain zero or more [0..*] participants.</p> <ul style="list-style-type: none"> • 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. <p>20. ClinicalDocument SHOULD contain zero or one [0..1] inFulfillmentOf.</p> <ul style="list-style-type: none"> • The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order. <ol style="list-style-type: none"> 1. This order SHALL contain at least one [1..*] id. |
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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: 2.16.840.1.113883.10.20.32.2.2).
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:

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| | <p>2.16.840.1.113883.10.20.33.4.5).</p> <ol style="list-style-type: none"> 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). <p>40. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).</p> <p>41. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).</p> <p>42. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.2". <p>43. SHALL contain exactly one [1..1] value.</p> <p>44. SHALL contain exactly one [1..1] @typeCode="REFV" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).</p> <p>45. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.3". <p>46. The referenceRange SHALL contain exactly one [1..1] observationRange.</p> <ul style="list-style-type: none"> • MAY contain zero or one [0..1] text. • SHALL contain exactly one [1..1] value such that it. <ol style="list-style-type: none"> 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. <p>47. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).</p> <p>48. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).</p> <p>49. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4". <p>50. SHALL contain at least one [1..*] id.</p> <p>51. SHALL contain exactly one [1..1] code.</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>53. SHALL contain exactly one [1..1] statusCode.</p> <ul style="list-style-type: none"> • This statuscode SHALL contain exactly one [1..1] @code="completed"(CodeSystem: ActStatus 2.16.840.1.113883.5.14). <p>54. SHALL contain exactly one [1..1] value.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @xsi:type, where the value of @xsi:type could be "INT" , "REAL" or "TS". <p>55. MAY contain zero or one [0..1] entryRelationship.</p> |
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- 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 2.16.840.1.113883.10.20.32.4.20).
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

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| | <p>2.16.840.1.113883.5.6 STATIC).</p> <p>69. SHALL CONTAIN EXACTLY ONE [1..1] @moodcode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).</p> <p>70. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.33.4.4". <p>71. SHALL contain at least one [1..1] id.</p> <p>72. SHALL contain exactly one [1..1] code.</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>74. SHALL contain exactly one [1..1] statusCode.</p> <ul style="list-style-type: none"> • This Statuscode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.11388.5.14). <p>75. SHALL contain exactly one [1..1] value.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @xsi:type="ST". <p>76. MAY contain zero or one [0..1] entryRelationship.</p> <ul style="list-style-type: none"> • 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). <p>77. SHOULD contain zero or one [0..1] entryRelationship.</p> <ul style="list-style-type: none"> • 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). <p>78. SHALL conform to the Numeric Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.6).</p> <p>79. SHALL NOT contain Response Reference Range Pattern template (template 2.16.840.1.113883.10.20.32.4.6).</p> <p>80. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.9". <p>81. SHALL contain exactly one [1..1] referenceRange.</p> <ul style="list-style-type: none"> • 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. <ol style="list-style-type: none"> 1. SHALL contain exactly one [1..1] value such that it. <ol style="list-style-type: none"> 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. <p>82. SHALL conform to Multiple Choice Response Pattern Observation template (templateId 2.16.840.1.113883.10.20.32.4.7).</p> <p>83. SHALL contain exactly one [1..1] templateId such that it.</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.32.4.10". |
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| | <p>84. SHALL contain exactly one [1..1] value.</p> <p>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)</p> |
| Pass/Fail criteria | <ul style="list-style-type: none"> 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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- [b-CDG 2016] Personal Connected Health Alliance, Continua Design Guidelines (2016), "Iris", *Continua Design Guidelines*.
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