International Telecommunication Union

# ITU-T

TELECOMMUNICATION
STANDARDIZATION SECTOR
OF ITU

# H.830.7

(04/2017)

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 7: Consent management: Health & Fitness Service sender

Recommendation ITU-T H.830.7

ITU-T
International Telecommunication Union

ITU-T H-SERIES RECOMMENDATIONS

**AUDIOVISUAL AND MULTIMEDIA SYSTEMS**

| | |
|---|---|
| CHARACTERISTICS OF VISUAL TELEPHONE SYSTEMS | H.100–H.199 |
| INFRASTRUCTURE OF AUDIOVISUAL SERVICES | |
| General | H.200–H.219 |
| Transmission multiplexing and synchronization | H.220–H.229 |
| Systems aspects | H.230–H.239 |
| Communication procedures | H.240–H.259 |
| Coding of moving video | H.260–H.279 |
| Related systems aspects | H.280–H.299 |
| Systems and terminal equipment for audiovisual services | H.300–H.349 |
| Directory services architecture for audiovisual and multimedia services | H.350–H.359 |
| Quality of service architecture for audiovisual and multimedia services | H.360–H.369 |
| Telepresence | H.420–H.429 |
| Supplementary services for multimedia | H.450–H.499 |
| MOBILITY AND COLLABORATION PROCEDURES | |
| Overview of Mobility and Collaboration, definitions, protocols and procedures | H.500–H.509 |
| Mobility for H-Series multimedia systems and services | H.510–H.519 |
| Mobile multimedia collaboration applications and services | H.520–H.529 |
| Security for mobile multimedia systems and services | H.530–H.539 |
| Security for mobile multimedia collaboration applications and services | H.540–H.549 |
| Mobility interworking procedures | H.550–H.559 |
| Mobile multimedia collaboration inter-working procedures | H.560–H.569 |
| BROADBAND, TRIPLE-PLAY AND ADVANCED MULTIMEDIA SERVICES | |
| Broadband multimedia services over VDSL | H.610–H.619 |
| Advanced multimedia services and applications | H.620–H.629 |
| Ubiquitous sensor network applications and Internet of Things | H.640–H.649 |
| IPTV MULTIMEDIA SERVICES AND APPLICATIONS FOR IPTV | |
| General aspects | H.700–H.719 |
| IPTV terminal devices | H.720–H.729 |
| IPTV middleware | H.730–H.739 |
| IPTV application event handling | H.740–H.749 |
| IPTV metadata | H.750–H.759 |
| IPTV multimedia application frameworks | H.760–H.769 |
| IPTV service discovery up to consumption | H.770–H.779 |
| Digital Signage | H.780–H.789 |
| E-HEALTH MULTIMEDIA SERVICES AND APPLICATIONS | |
| Personal health systems | H.810–H.819 |
| **Interoperability compliance testing of personal health systems (HRN, PAN, LAN, TAN and WAN)** | **H.820–H.859** |
| Multimedia e-health data exchange services | H.860–H.869 |

*For further details, please refer to the list of ITU-T Recommendations.*

# Recommendation ITU-T H.830.7

## Conformance of ITU-T H.810 personal health system: Services interface Part 7: Consent management: Health & Fitness Service sender


### Summary

Recommendation ITU-T H.830.7 provides a test suite structure (TSS) and the test purposes (TP) for consent management 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.830.7 is a transposition of Continua Test Tool DG2016, Test Suite Structure & Test Purposes, Services Interface; Part 7: Consent Management. HFS Sender (Version 1.5, 2017-03-14), that was developed by the Personal Connected Health Alliance. A number of versions of this specification existed before transposition.

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



### History

| Edition | Recommendation | Approval | Study Group | Unique ID* |
|---|---|---|---|---|
| 1.0 | ITU-T H.837 | 2015-01-13 | 16 | 11.1002/1000/12255 |
| 1.0 | ITU-T H.830.7 | 2015-01-13 | 16 | 11.1002/1000/12593 |
| 2.0 | ITU-T H.830.7 | 2016-07-14 | 16 | 11.1002/1000/12926 |
| 3.0 | ITU-T H.830.7 | 2017-04-13 | 16 | 11.1002/1000/13208 |

### Keywords

Conformance testing, Consent Management, Continua Design Guidelines, e-health, Health & Fitness Service sender, ITU-T H.810, personal connected health devices, 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.

## FOREWORD

The International Telecommunication Union (ITU) is the United Nations specialized agency in the field of telecommunications, information and communication technologies (ICTs). The ITU Telecommunication Standardization Sector (ITU-T) is a permanent organ of ITU. ITU-T is responsible for studying technical, operating and tariff questions and issuing Recommendations on them with a view to standardizing telecommunications on a worldwide basis.

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

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

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

## NOTE

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

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

## INTELLECTUAL PROPERTY RIGHTS

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

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

## Table of Contents

**Page**



**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 7: Consent Management. HFS Sender (Version 1.5, 2017-03-14), that was developed by the Continua 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 | 2012-10-05 | Initial release for Test Tool DG2011 based on the requirements in [b-CDG 2011]. |
| 1.1 | 2013-05-24 | Initial release for Test Tool DG2012. This uses "TSS&TP_DG2011_WAN_PART_7_(SEN CM)_v1.0" as a baseline and it adds minor modifications included in [b-CDG 2012] for consent management. |
| 1.1 | 2014-01-24 | Initial release for Test Tool DG2013. This is the same version as "TSS&TP_DG2012_WAN_PART_7_(SEN CM)_v1.1.doc" because new features included in [b-ITU-T H.810 (2013)]/ [b-CDG 2013] do not affect the test procedures specified in this document. |
| 1.2 | 2014-04-24 | TM Lite & Doc Enhancements (Test Tool v4.0 Maintenance Release 1). It uses "TSS&TP_DG2013_ WAN_PART_7_(SEN CM)_v1.1.doc" as baseline and it adds new features included in Documentation Enhancements:<br>• "Other PICS" row has been added |
| 1.3 | 2015-07-01 | Initial release for Test Tool DG2015:<br>• Test suite structure and applicability modified |
| 1.4 | 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. |
| 1.5 | 2017-03-14 | Editorial: added insulin pump and continuous glucose monitor specializations to the TSS list in clause 6. |

# Recommendation ITU-T H.830.7

## Conformance of ITU-T H.810 personal health system: Services interface Part 7: Consent management: Health & Fitness Service sender

### 1 Scope

The scope of this Recommendation[1] 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 7.

– 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), *Interoperability design guidelines for personal health systems.*

[ITU-T H.812] Recommendation ITU-T H.812 (2016), *Interoperability design guidelines for personal health systems: Services interface: Common certified capability class.*

---

[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.812.1] Recommendation ITU-T H.812.1 (2016), *Interoperability design guidelines for personal health systems: Services interface: Observation upload certified capability class.*

[ITU-T H.812.2] Recommendation ITU-T H.812.2 (2016), *Interoperability design guidelines for personal health systems: Services interface: Questionnaires certified capability class.*

[ITU-T H.812.3] Recommendation ITU-T H.812.3 (2016), *Interoperability design guidelines for personal health systems: Services interface: Capability exchange certified capability class.*

[ITU-T H.812.4] Recommendation ITU-T H.812.4 (2016), *Interoperability design guidelines for personal health systems: Services interface: Authenticated persistent session certified capability class.*

[HL7 CDA IG] Health Level Seven (2011), *HL7 Implementation Guide for Clinical Document Architecture, Release 2: Consent Directives, Release 1, HL7 Draft Standard for Trial Use.* http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG%20_CONSENTDIR_DSTU_2011JAN.pdf

[IHE ITI TF-2b] IHE IT TF-2b (2009), *IHE ITI Infrastructure Technical Framework, Volume 2b: Transactions Part B. Revision 6.0 Final Text.* www.ihe.net/technical_framework/upload/ihe_iti_tf_6-0_vol2b_ft_2009-08-10.pdf

## 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:

ATNA Audit Trail and Node Authentication

ATS Abstract Test Suite

CDA Clinical Document Architecture

CDG Continua Design Guidelines

CGM Continuous Glucose Monitor

DUT Device Under Test

GUI Graphical User Interface

ebXML electronic business using extensible Markup Language

EHR Electronic Health Record

HFS Health & Fitness Service

HFSS Health & Fitness Service Sender

HFSR Health & Fitness Service Receiver

| | |
|---|---|
| INR | International Normalized Ratio |
| IP | Insulin Pump |
| IUT | Implementation Under Test |
| MDS | Medical Device System |
| MTOM | Message Transmission Optimization Mechanism |
| NFC | Near Field Communication |
| PCD | Patient Care Device |
| PCO | Point of Control and Observation |
| PCT | Protocol Conformance Testing |
| PHD | Personal Health Device |
| PHDC | Personal Healthcare Device Class |
| PHG | Personal Health Gateway |
| PICS | Protocol Implementation Conformance Statement |
| PIXIT | Protocol Implementation extra Information for Testing |
| S/MIME | Secure/Multipurpose Internet Mail Extensions |
| SCR | Static Conformance Review |
| SDP | Service Discovery Protocol |
| SABTE | Sleep Apnoea Breathing Therapy Equipment |
| SOAP | Simple Object Access Protocol |
| TCRL | Test Case Reference List |
| TCWG | Test and Certification Working Group |
| TP | Test Purpose |
| TSS | Test Suite Structure |
| URI | Uniform Resource Identifier |
| USB | Universal Serial Bus |
| WAN | Wide Area Network |
| WDM | Windows Driver Model |
| WS | Web Service |
| WSDL | Web Service Description Language |
| XDR | cross-enterprise Document Reliable interchange |
| XDS.b | cross-enterprise Document Sharing-b |
| XML | extensible Markup Language |

## 5 Conventions

The key words "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "MAY", "MAY NOT" in this 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. | – |
| 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 | – |

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

| CDG release | Transposed as | Version | Description | Designation |
|---|---|---|---|---|
| 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 1.5.1 to 1.5.3 (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).

– **TP label**: This is the title of the TP.

– **Coverage**: This contains the specification reference and clause to be checked by the TP.
  - Spec: This indicates the earliest version of the specification from which the testable items to be checked by the TP are included.
  - Testable item: This contains testable items to be checked by the TP.

– **Test purpose**: This is a description of the requirements to be tested.

– **Applicability**: This contains the PICS items that define if the test case is applicable or not for a specific device. When a TP contains an "ALL" in this field it means that it applies to the device under test within that scope of the test (specialization, transport used, etc.).

– **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 1.5.1: HFS XDR transaction (TRANS)

| | | | | |
|---|---|---|---|---|
| **TP Id** | | TP/HFS/SEN/CM/TRANS/BV-000 | | |
| **TP label** | | Provide and Register Document Set-b Transaction Request | | |
| **Coverage** | **Spec** | [ITU-T H.812] | | |
| | **Testable items** | ConsentSender3; M | | |
| | **Spec** | [IHE ITI TF-2b] | | |
| | **Testable items** | ProvideProtocol12; M | ProvideProtocol13; M | ProvideProtocol2; M |
| | | ProvideSource1; M | | |
| **Test purpose** | | Check that:<br>Consent Enabled HFS sender shall send the consent document at least once to the HFS receiver<br>[AND]<br>The Document Source shall generate Provide and Register Document Set-b transactions in MTOM/XOP format.<br>[AND]<br>The Document Source shall accept the response message in MTOM/XOP format.<br>[AND]<br>The Provide and Register Document Set-b transaction shall use SOAP12 and MTOM with XOP encoding.<br>[AND]<br>An implementation of the Document Source actor shall be capable of submit one or more documents. | | |
| **Applicability** | | C_SEN_000 AND C_SEN_GEN_002 AND C_SEN_GEN_003 | | |
| **Other PICS** | | | | |
| **Initial condition** | | The HFS simulated receiver has a WebService enabled with a consent management service. The HFS sender under test has a clinical document architecture (CDA) ready to be sent to the respective service according to its needs. | | |
| **Test procedure** | | 1. The HFS sender under test sends a "'Provide and Register Document Set-b Request'" message.<br>2. Check that:<br>a. In the HTTP header:<br>• action="urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b"<br>• Content-Type = multipart/related<br>• boundary element is a MIMEBoundary<br>• type = "application/xop+xml"<br>b. In the SOAP message<br>• The namespace of the SOAP envelope is "http://www.w3.org/2003/05/soap-envelope" (SOAP 1.2)<br>• There are one or more xsdb:Document elements in the SOAP Body.<br>3. The simulated HFS receiver responds with a "Provide and Register Document Set-b Response" message<br>4. The HFS sender under test accepts the message (it does not give any error message). | | |

| | |
|---|---|
| **Pass/Fail criteria** | All steps are as specified within the test procedure above. |
| **Notes** | |

## A.3 Subgroup 1.5.2: HFS metadata validation (META)

| | | | | |
|---|---|---|---|---|
| **TP Id** | | TP/HFS/SEN/CM/META/BV-000 | | |
| **TP label** | | Metadata Syntactic Validation | | |
| **Coverage** | **Spec** | [IHE ITI TF-2b] | | |
| | **Testable items** | ProvideScope1; M | ProvideProtocol9; M | |
| | **Spec** | [ITU-T H.812] | | |
| | **Testable items** | ConsentSender4; M | ConsentSender 5; M | |
| **Test purpose** | | Check that:<br>A Provide and Register Document Set-b transaction shall carry:<br>- Metadata describing zero or more documents<br>- Within metadata, one XDSDocumentEntry object per document<br>- XDS Submission Set definition along with the linkage to new documents and references to existing documents<br>- Zero or more XDS Folder definitions along with the linkage to new or existing documents<br>- Zero or more documents<br>[AND]<br>The <ihe:ProvideAndRegisterDocumentSetRequest/> element is defined as:<br>- One <lcm:SubmitObjectsRequest/> element that contains the submission set metadata<br>- Zero or more <ihe:Document/> elements that contain the base64encoded data for the documents being submitted to the Document Repository. The <ihe:Document/> also includes the document id attribute (ihe:Document/@id) of type xsd:anyURI to match the document ExtrinsicObject id in the metadata and providing the necessary linkage<br>[AND]<br>The consent document transmitted by the Consent Enabled HFS sender shall contain the same Patient Identifier as the HFS Observation measurement message(s). | | |
| **Applicability** | | C_SEN_000 AND C_SEN_GEN_002 AND C_SEN_GEN_003 | | |
| **Other PICS** | | | | |
| **Initial condition** | | The simulated HFS receiver has a WebService enabled with a consent management service and a CommunicatePCDData service. The HFS sender under test has a CDA ready to be sent to the respective service according to its needs. | | |
| **Test procedure** | | 1. The HFS sender under test sends a "Provide and Register Document Set-b Request" message to the consent management service and a "PCD-01" message to the CommunicatePCDData service.<br>2. Check that in the SOAP body:<br>a. There is only one <ProvideAndRegisterDocumentSetRequest/> element, and that it contains:<br>o Only one <lcm:SubmitObjectsRequest/> element, that contains:<br>- A XDSDocumentEntry (ExtrinsicObject) element for each document<br>- An XDS Submission Set definition along with the linkage to new | | |

| | |
|---|---|
| | documents and references to existing documents (RegistryPackage element)<br>- Zero or more XDS Folder definitions along with the linkage to new or existing documents.<br>o Zero or more <ihe:Document/> elements.<br>b. The PID-3 element of the "PCD-01" message is equal to SubmitObjectsRequest/RegistryObjectList/ExtrinsicObject/Slot[@name = sourcePatientId]/ValueList/Value element of the metadata, and:<br>o Subfields CX-1 and CX-4 are present.<br>o Subfield CX-5 is not present. |
| **Pass/Fail criteria** | All steps are as specified within the test procedure above. |
| **Notes** | |

| | | | | |
|---|---|---|---|---|
| **TP Id** | | TP/HFS/SEN/CM/META/BV-001 | | |
| **TP label** | | Metadata Submission Set Validation | | |
| **Coverage** | **Spec** | [ITU-T H.812] | | |
| | **Testable items** | WANXDSSub-1; O | WANXDSSub-2; M | WANXDSSub-3; M |
| | | WANXDSSub-4; M | WANXDSSub-5; M | WANXDSSub-6; M |
| | | WANXDSSub-7; O | WANXDSSub-8; M | WANXDSSub-9; O |
| | | WANXDSSub-10; M | WANXDSSub-11; M | WANXDSSub-12; M |
| | | WANXDSSub-13; M | WANXDSSub-14; M | WANXDSSub-15; M |
| **Test purpose** | | Check that:<br>availabilityStatus element MAY be present<br>[AND]<br>author element SHALL be equal to Consent Directive /ClinicalDocument/author<br>[AND]<br>authorInstitution element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization<br>[AND]<br>authorPerson element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson<br>[AND]<br>authorRole element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction<br>[AND]<br>authorSpecialty element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code<br>[AND]<br>comments element MAY be present<br>[AND]<br>contentTypeCode element SHALL be present<br>[AND]<br>contentTypeCodeDisplayName element MAY be present | | |

| | |
|---|---|
| | [AND]<br>entryUUID element SHALL be equal to Consent Directive unique ID for submission set<br>[AND]<br>patientId element SHALL be mapped from /ClinicalDocument/recordTarget/patientRole/id<br>[AND]<br>sourceId element SHALL be present<br>[AND]<br>submissionTime element SHALL be present<br>[AND]<br>title element SHALL be equal to Consent Directive /ClinicalDocument/title<br>[AND]<br>uniqueId element SHALL be equal to Consent Directive /ClinicalDocument/id |
| **Applicability** | C_SEN_000 AND C_SEN_GEN_002 AND C_SEN_GEN_003 |
| **Other PICS** | |
| **Initial condition** | The simulated HFS receiver has a WebService enabled with a consent management service. The HFS sender under test has a CDA ready to be sent to the respective service according to its needs. |
| **Test procedure** | 1. The HFS sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body<br>2. Check the following elements of the "Metadata in Submission Set" section sent by the HFS sender under test and its concordance with the clinical document:<br>a. availabilityStatus element may be present<br>b. author element is equal to Consent Directive /ClinicalDocument/author<br>c. authorInstitution element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization<br>d. authorPerson element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson<br>e. authorRole element is equal to Consent Directive /ClinicalDocument/author/participationFunction<br>f. authorSpecialty element Is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code<br>g. comments element may be present<br>h. contentTypeCode element Is present<br>i. entryUUID element is equal to Consent Directive unique ID for submission set<br>j. patientId element is mapped from /ClinicalDocument/recordTarget/patientRole/id<br>k. sourceId element is present<br>l. submissionTime element is present<br>m. title element is equal to Consent Directive /ClinicalDocument/title<br>n. uniqueId element is equal to Consent Directive /ClinicalDocument/id. |
| **Pass/Fail criteria** | All steps are as specified within the test procedure above. |
| **Notes** | |

| | |
|---|---|
| **TP Id** | TP/HFS/SEN/CM/META/BV-002 |
| **TP label** | Metadata Document Entry Validation |

| | | | | |
|---|---|---|---|---|
| **Coverage** | **Spec** | [ITU-T H.812] | | |
| | **Testable items** | WANXDSDocEntry-1; O | WANXDSDocEntry-2; M | WANXDSDocEntry-3; M |
| | | WANXDSDocEntry-4; M | WANXDSDocEntry-5; M | WANXDSDocEntry-6; M |
| | | WANXDSDocEntry-7; M | WANXDSDocEntry-8; O | WANXDSDocEntry-9; O |
| | | WANXDSDocEntry-10; M | WANXDSDocEntry-11; M | WANXDSDocEntry-12; M |
| | | WANXDSDocEntry-13; M | WANXDSDocEntry-14; M | WANXDSDocEntry-15; O |
| | | WANXDSDocEntry-16; M | WANXDSDocEntry-17; O | WANXDSDocEntry-18; M |
| | | WANXDSDocEntry-19; M | WANXDSDocEntry-20; M | WANXDSDocEntry-21; M |
| | | WANXDSDocEntry-22; M | WANXDSDocEntry-23; M | WANXDSDocEntry-24; M |
| | | WANXDSDocEntry-25; O | WANXDSDocEntry-26; O | WANXDSDocEntry-27; O |
| | | WANXDSDocEntry-28; M | WANXDSDocEntry-29; M | WANXDSDocEntry-30; M |
| | | WANXDSDocEntry-31; M | WANXDSDocEntry-32; M | WANXDSDocEntry-33; M |
| | | WANXDSDocEntry-34; M | WANXDSDocEntry-35; M | WANXDSDocEntry-36; M |
| | | WANXDSDocEntry-37; M | WANXDSDocEntry-38; M | WANXDSDocEntry-39; M |
| | | WANXDSDocEntry-40; O | WANXDSDocEntry-41; M | WANXDSDocEntry-42; M |
| | | WANXDSDocEntry-43; M | | |
| **Test purpose** | | Check that:<br>availabilityStatus element MAY be present<br>[AND]<br>author element SHALL be equal to Consent Directive /ClinicalDocument/author<br>[AND]<br>authorInstitution element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization/name, id<br>[AND]<br>authorPerson element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson<br>[AND]<br>authorRole element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction/code<br>[AND]<br>authorSpecialty element SHALL be equal to Consent Directive /ClinicalDocument/author/assignedAuthor/participationFunction<br>[AND]<br>classCode element SHALL be present and SHALL use the LOINC code 57016-8<br>[AND]<br>classCodeDisplayName element MAY be present<br>[AND]<br>Comments element MAY be present<br>[AND]<br>confidentialityCode element SHALL be equal to Consent Directive | | |

| | |
|---|---|
| | /ClinicalDocument/confidentialityCode<br>[AND]<br>confidentialityCodeDisplayName element SHALL be equal to Consent Directive /ClinicalDocument/confidentialityCode<br>[AND]<br>creationTime element SHALL be equal to Consent Directive /ClinicalDocument/effectiveTime<br>[AND]<br>entryUUID element SHALL be present<br>[AND]<br>eventCodeList element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/code<br>[AND]<br>eventCodeDisplayNameList element MAY be present<br>[AND]<br>formatCode element SHALL be present and equal to “urn:continua:cd:2011”<br>[AND]<br>formatCodeDisplayName element MAY be present<br>[AND]<br>hash element SHALL be present<br>[AND]<br>healthcareFacilityTypeCode element SHALL be present<br>[AND]<br>healthcareFacilityTypeCodeDisplayName element MAY be present<br>[AND]<br>languageCode element SHALL be equal to Consent Directive /ClinicalDocument/languageCode<br>[AND]<br>legalAuthenticator element SHALL be equal to Consent Directive /ClinicalDocument/legalAuthenticator<br>[AND]<br>mimeType element SHALL be equal to Consent Directive text/xml<br>[AND]<br>parentDocument element MAY come from /ClinicalDocument/relatedDocument/parentDocument<br>[AND]<br>parentDocumentId element MAY come from /ClinicalDocument/relatedDocument/parentDocument/id<br>[AND]<br>parentDocumentRelationship element MAY come from /ClinicalDocument/relatedDocument/typeId<br>[AND]<br>patientId element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>[AND]<br>practiceSettingCode element SHALL be present<br>[AND]<br>practiceSettingCodeDisplayName element SHALL be present |

| | |
|---|---|
| | [AND]<br>serviceStartTime element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low<br>[AND]<br>serviceStopTime element SHALL be equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high<br>[AND]<br>size element SHALL be present<br>[AND]<br>sourcePatientId element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>[AND]<br>sourcePatientInfo element SHALL be equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>[AND]<br>title element SHALL be equal to Consent Directive /ClinicalDocument/title<br>[AND]<br>typeCode element SHALL be equal to Consent Directive /ClinicalDocument/code/@code<br>[AND]<br>typeCodeDisplayName element SHALL be equal to Consent Directive /ClinicalDocument/code/@displayName<br>[AND]<br>uniqueId element SHALL be equal to Consent Directive /ClinicalDocument/id<br>[AND]<br>URI element MAY be present<br>[AND]<br>parentDocument element SHALL NOT be present<br>[AND]<br>parentDocumentId element SHALL NOT be present<br>[AND]<br>parentDocumentRelationship element SHALL NOT be present |
| **Applicability** | C_SEN_000 AND C_SEN_GEN_002 AND C_SEN_GEN_003 |
| **Other PICS** | |
| **Initial condition** | The simulated HFS receiver has a WebService enabled with a consent management service. The HFS sender under test has a CDA ready to be sent to the respective service according to its needs. |
| **Test procedure** | 1. The HFS sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body<br>2. Check the following elements of the metadata in the "Document Entry" section sent by the HFS sender under test and its concordance with the clinical document:<br>a. availabilityStatus element may be present<br>b. author element is equal to Consent Directive /ClinicalDocument/author<br>c. authorInstitution element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/representedOrganization/name, id<br>d. authorPerson element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/assignedPerson |

| | |
|---|---|
| | e. authorRole element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code<br>f. authorSpecialty element is equal to Consent Directive /ClinicalDocument/author/assignedAuthor/code/@code<br>g. classCode element is equal to LOINC code 57016-8<br>h. classCodeDisplayName element may be present<br>i. comments element may be present<br>j. confidentialityCode element is equal to Consent Directive /ClinicalDocument/confidentialityCode<br>k. confidentialityCodeDisplayName element is equal to Consent Directive /ClinicalDocument/confidentialityCode<br>l. creationTime element is equal to Consent Directive /ClinicalDocument/effectiveTime<br>m. entryUUID element is present<br>n. eventCodeDisplayNameList element may be present<br>o. formatCode element is equal to "urn:continua:cd:2011"<br>p. formatCodeDisplayName element may be present<br>q. hash element is present<br>r. healthcareFacilityTypeCode element is present<br>s. healthcareFacilityTypeCodeDisplayName element may be present<br>t. languageCode element is equal to Consent Directive /ClinicalDocument/languageCode<br>u. legalAuthenticator element is equal to Consent Directive /ClinicalDocument/legalAuthenticator<br>v. mimeType element is equal to Consent Directive text/xml<br>w. parentDocument element may come from /ClinicalDocument/relatedDocument/parentDocument<br>x. parentDocumentId element may come from /ClinicalDocument/relatedDocument/parentDocument/id<br>y. parentDocumentRelationship element may come from /ClinicalDocument/relatedDocument/typeId<br>z. patientId element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>aa. practiceSettingCode element Is present<br>bb. practiceSettingCodeDisplayName element Is present<br>cc. serviceStartTime element is equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low<br>dd. serviceStopTime element is equal to Consent Directive /ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high<br>ee. size element is present<br>ff. sourcePatientId element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>gg. sourcePatientInfo element is equal to Consent Directive /ClinicalDocument/recordTarget/patientRole/id<br>hh. title element is equal to Consent Directive /ClinicalDocument/title<br>ii. typeCode element is equal to Consent Directive /ClinicalDocument/code/@code<br>jj. typeCodeDisplayName element is equal to Consent Directive /ClinicalDocument/code/@displayName<br>kk. uniqueId element is equal to Consent Directive /ClinicalDocument/id<br>ll. URI element may be present |

| | |
|---|---|
| **Pass/Fail criteria** | All steps are as specified within the test procedure above. |
| **Notes** | |

## A.4 Subgroup 1.5.3: HFS consent directive validation (CDV)

| | | | | |
|---|---|---|---|---|
| **TP Id** | | TP/HFS/SEN/CM/CDV/BV-000 | | |
| **TP label** | | Consent Directive Validation | | |
| **Coverage** | **Spec** | [HL7 CDA IG] | | |
| | **Testable items** | CONF-CD-1; M | CONF-CD-2; M | CONF-CD-2.2; M |
| | | CONF-CD-3; M | CONF-CD-4; O | CONF-CD-4.2; O |
| | | CONF-CD-4.3; O | CONF-CD-4.4; O | CONF-CD-5; O |
| | | CONF-CD-6; O | CONF-CD-7; O | CONF-CD-8; O |
| | | CONF-CD-9; O | CONF-CD-10; M | CONF-CD-11; M |
| | | CONF-CD-12; O | CONF-CD-12.2; O | CONF-CD-13; M |
| | | CONF-CD-14; M | CONF-CD-15; M | CONF-CD-16; M |
| | | CONF-CD-17; M | CONF-CD-18; M | CONF-CD-19; R |
| | | CONF-CD-20; R | CONF-CD-21; O | CONF-CD-22; R |
| | | CONF-CD-23; R | CONF-CD-24; O | CONF-CD-25; M |
| | | CONF-CD-26; M | CONF-CD-27; M | CONF-CD-28; O |
| | | CONF-CD-29; R | CONF-CD-30; R | CONF-CD-31; O |
| | | CONF-CD-32; O | CONF-CD-33; O | CONF-CD-34; M |
| | | CONF-CD-35; O | CONF-CD-36; R | CONF-CD-37; O |
| | | CONF-CD-38; R | CONF-CD-39; O | CONF-CD-41; C |
| | | CONF-CD-42; O | | |
| **Test purpose** | | Check that:<br>A document conforming to the CDA R2 General Header template shall include the ClinicalDocument/templateId “2.16.840.1.113883.10.20.3”<br>[AND]<br>ClinicalDocument/templateId element shall be present with the value “2.16.840.1.113883.3.445.1”<br>[AND]<br>Each Privacy Consent Directive must specify a healthcare client whose IIHI is affected by the privacy consent directive.<br>[AND]<br>ClinicalDocument/author element shall be present and specify a templateId if “2.16.840.1.113883.3.445.2”<br>[AND]<br>ClinicialDocument/author/functionCode/ may be present to specify function/relationship of the author to the client who is the record target. This element may be used to specify the client’s relationship to the Substitute Decision Maker – if one is involved in the creation of the privacy | | |

| | |
|---|---|
| | consent directive<br><br>[AND]<br><br>Information Recipient is used to specify the recipients of the Privacy Consent Directive. In the case of consultations and referrals, the Privacy Consent Directive recipient may be the same person/entity as the intended recipient of the client IIHI that is disclosed as a result of the persimission granted using the Privacy Consent Directive.<br><br>[AND]<br><br>The legalAuthenticator is as defined in CDA. For a Privacy Consent Document this element may be either the client or their Substitute Decision Maker. If necessary, the Signatures section may provide the signature associated with the consenter's signature.<br><br>[AND]<br><br>In some cases, a Privacy Consent Document may identify and record the signature of a person who witnessed the consenter's signature. This may occur if the authenticator/consenter makes a mark instead of a signature.<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/ element with a templateId of "2.16.840.1.113883.3.445.3" may be present<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/id element may be present<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/effectiveTime element may be present<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low/@value element may be present. It may be different than the value of the ClinicalDocument/documentationOf/serviceEvent/effectiveTime/@value and represents the first time the Privacy Consent Directive takes effect<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high/@value element may be present to specify the date/time when the Privacy Consent Directives expires<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/code/@code attribute shall be present and indicates the OID of the externally identified and defined privacy policy corresponding to the "Privacy Policy Acknowledgement Document"<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/code/@codeSystem attribute shall be present and indicates the assigning authority of the externally identified and defined privacy policy corresponding to the "Privacy Policy Acknowledgement Document"<br><br>[AND]<br><br>ClinicalDocument/documentationOf/serviceEvent/code/@codeSystemName attribute may be present and be a descriptive text of the privacy policy being acknowledged.<br><br>[AND]<br><br>A Privacy Consent Directive may replace a previous (revoked) or expired Privacy Consent Directive.<br><br>[AND]<br><br>/ClinicalDocument/confidentialityCode/@code SHALL be present and SHALL be equal to "R"<br><br>[AND]<br><br>/ClinicalDocument/confidentialityCode/@codeSystem SHALL be present and SHALL be equal to 2.16.840.1.113883.5.25<br><br>[AND]<br><br>If present, /ClinicalDocument/confidentialityCode/@codeSystemName SHALL be equal to "Confidentiality" |

| | |
|---|---|
| | [AND]<br>If present, /ClinicalDocument/confidentialityCode/@displayName SHALL be equal to "Restricted"[AND]<br>A Privacy Consent Directive shall have a structuredBody element<br>[AND]<br>A Privacy Consent Directive shall contain a Privacy Consent Directive Details section<br>[AND]<br>This section shall include the templateId for the Privacy Consent Directive section with the value "2.16.840.1.113883.3.445.17" and a title of "Privacy Consent Directive Details".<br>[AND]<br>This section shall include an entry element with templateId of "2.16.840.1.113883.3.445.4" and a typeCode of "COMP" to organize the structure of a Privacy Consent Directive entry.<br>[AND]<br>This entry element shall include an act element with templateId of "2.16.840.1.113883.3.445.5" and a moodCode of "DEF" to specify the execution of a Privacy Consent Directive.<br>[AND]<br>The act element shall include a code element to specify the purpose of use for which the privacy consent is applicable<br>[AND]<br>This section should include one or more entry/act/informant/[@typeCode='CST'] elements with a templateId of "2.16.840.1.113883.3.445.6" to represent the custodian of the referenced IIHI. This may be different than the custodian of the Privacy Consent Directive document identified in the header. Note, if the informant is different from the custodian of the IIHI, then the informant is re-disclosing, which typically is not allowed.<br>[AND]<br>This section should include one or more entry/act/participant/[@typeCode='IRCP'] elements with a templateId of "2.16.840.1.113883.3.445.7" to represent the provider organization or person intended to use, access, collect information as allowed or prevented by the action specified in this privacy consent directive.<br>[AND]<br>The participant element may include participantRole/codeSystem specification of "2.16.840.1.113883.11.19682" corresponding to the receiving provider's role [DYNAMIC].<br>[AND]<br>The participantRole element should include playingEntity element corresponding to the organization or provider intended to receive the information specified in this Privacy Consent Directive document.<br>[AND]<br>This section should include one or more entry/act/participant/ elements to represent the provider organization or person intended to use, access, collect information, as allowed or prevented by the action specified in this privacy consent directive.<br>[AND]<br>This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.8" to represent the action allowed and problem associated with the information allowed by the Privacy Consent Directive.<br>[AND]<br>This entryRelationship shall include an act element with default classCode="ACT" and moodCode="DEF".<br>[AND]<br>This act element should include a @negationId attribute with a default value of "false" indicating that the action specified is enabled, and a value of "true" if the action is not allowed by the Privacy Consent Directive. When the negationInd attribute is not transmitted, the receiver must assume the default (specified action is enabled). |

| | |
|---|---|
| | [AND]<br><br>The act element shall include a code element with default of codeSystem="2.16.840.1.113883.5.4" to specify the Privacy Consent Directive operation or action [DYNAMIC].<br><br>[AND]<br><br>This section may include an entry/act/entryRelationship/ with a templateId of "2.16.840.1.113883.3.445.9" to represent the entire set of protected information (IIHI) including specific attributes of that information (e.g., category type, related diagnosis, sensitivity/confidentiality).<br><br>[AND]<br><br>The observation element should include one or more organizer/component/observation[@moodCode='DEF']/ elements with a templateId of "2.16.840.1.113883.3.445.10" to specify each information type (IIHI) included in the authorization contained in the Privacy Consent Directive document.<br><br>[AND]<br><br>The observation element should include a code element to specify the code corresponding to the information type (IIHI) included in the authorization contained in the Privacy Consent Directive document.<br><br>[AND]<br><br>The observation element may include a precondition[@typeCode="PRCN"]/ element with a templateId of "2.16.840.1.113883.3.445.11" to specify the diagnosis or problem associated with the information.<br><br>[AND]<br><br>The observation element may include a precondition[@typeCode="PRCN"]/ element with a templateId of "2.16.840.1.113883.3.445.12" to specify the sensitivity of the protected information (IIHI) specified in Privacy Consent Directive.<br><br>[AND]<br><br>This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.13" to represent references to Privacy Policies on which the Privacy Consent Directive is based along with the information recipient Obligation.<br><br>[AND]<br><br>The component element shall include an act/code element to specify the Privacy Policy or regulation that is basis for requesting the authorizations specified in the Privacy Consent Directive.<br><br>[AND]<br><br>The component element may include a precondition element with a templateId of "2.16.840.1.113883.3.445.14" and an element of @typeCode="PRCN" to specify any additional obligations imposed on the recipient of the IIHI referenced in the Privacy Consent Directive.<br><br>[AND]<br><br>The component element should include a criterion[classCode="OBS"]/code element to specify the coded obligations imposed on the recipient of the IIHI referenced in the Privacy Consent Directive.<br><br>[AND]<br><br>This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.15" to include a scanned image of the paper-based Privacy Consent Directive.<br><br>[AND]<br><br>The entryRelationship element should include an observationMedia[@classCode="OBS"] element to embed a scanned document representation of the Privacy Consent Directive including required signatures.<br><br>[AND]<br><br>This section may include an entry/act/entryRelationship with a templateId of "2.16.840.1.113883.3.445.16" to represent an alternative representation of the Privacy Consent Directive (e.g.,ODRL, XrML, XACML). |

| | |
|---|---|
| | [AND]<br>If included, this section shall include the templateId for the Signatures section “2.16.840.1.113883.3.445.18” and a title of “Signatures”.<br>[AND]<br>This section may include the entry/observationMedia for each signature (e.g.,legalAuthenticator, authenticator) or a scanned version of the entire privacy consent directive form including the signatures. |
| **Applicability** | C_SEN_000 AND C_SEN_GEN_002 AND C_SEN_GEN_003 |
| **Other PICS** | |
| **Initial condition** | The simulated HFS receiver has a webservice enabled with a consent management service. The HFS sender under test has a CDA ready to be sent to the respective service according to its needs. |
| **Test procedure** | 1. The HFS sender under test sends a "Provide and Register Document Set-b Request" message containing a CDA referenced in its body<br>2. Check the following elements of the Clinical Document sent by the HFS sender under test:<br>a. A templateId = "2.16.840.1.113883.10.20.3"<br>b. Another templateId = "2.16.840.1.113883.3.445.1"<br>c. code attribute of the confidentialityCode element is present and equal to "R".<br>d. codeSystem attribute of the confidentialityCode element is present and equal to 2.16.840.1.113883.5.25.<br>e. If present, codeSystemName of the confidentialityCode element is present and equal to "Confidentiality".<br>f. If present, displayName attribute of the confidentialityCode element is equal to "Restricted".<br>g. recordTarget element is present<br>h. author element:<br>o /templateId = "2.16.840.1.113883.3.445.2"<br>o /functionCode may be present<br>i. intendedRecipient element: the Privacy Consent Directive recipient may be the same person/entity as the intended recipient<br>j. legalAuthenticator element may be either the client or their Substitute Decision Maker and if necessary, the Signatures section may provide the signature associated with the consenter's signature<br>k. authenticator element may be present<br>l. documentationOf/serviceEvent/ element with a templateId of "2.16.840.1.113883.3.445.3" may be present and within this element:<br>o id element may be present<br>o effectiveTime element may be present<br>o effectiveTime/low/@value element may be present<br>o effectiveTime/high/@value element may be present<br>o code/@code attribute is present<br>o code/@codeSystem attribute is present<br>o code/@codeSystemName attribute may be present<br>m. relatedDocument element may be present<br>n. component/structuredBody element is present and within this element:<br>o component/section with templateId = "2.16.840.1.113883.3.445.17" is present<br>o component/section/title = Privacy Consent Directive Details |

| | |
|---|---|
| | ○ component/section/entry is present<br>○ component/section/entry/templateId = "2.16.840.1.113883.3.445.4"<br>○ component/section/entry/@typeCode = "COMP"<br>○ component/section/entry/act/templateId = "2.16.840.1.113883.3.445.5"<br>○ component/section/entry/act/@moodcode ="DEF"<br>○ component/section/entry/act/code is present<br>○ component/section/entry/act/informant/@typeCode = 'CST'<br>○ one or more component/section/entry/act/participant should be present<br>○ one or more component/section/entry/act/participant/@typeCode = 'IRCP' and component/section/entry/act/participant/templateId = "2.16.840.1.113883.3.445.7" should be present<br>○ component/section/entry/act/participant/participantRole/code/@codeSystem = "2.16.840.1.113883.11.19682" may be present<br>○ component/section/entry/act/participant/participantRole should include a playingEntity element<br>○ component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.8" and if it is present:<br>- /act element is present with classCode = "ACT" and moodCode = "DEF"<br>- /act/@negationId with a value of "false" or "true" should be present<br>- /act/code/@codeSystem = "2.16.840.1.113883.5.4" is present<br>○ component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.9" and if it is present:<br>- it should include one or more /organizer/component/observation/@moodCode = 'DEF' with a templateId = "2.16.840.1.113883.3.445.10"<br>- /organizer/component/observation should include a code element<br>- /organizer/component/observation may include a precondition/@typeCode = "PRCN" element with a templateId = "2.16.840.1.113883.3.445.11"<br>- /organizer/component/observation may include a precondition/@typeCode = "PRCN" element with a templateId = "2.16.840.1.113883.3.445.12"<br>○ component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.13" and if it is present:<br>- /act/code is present<br>- /act/precondition may be present with templateId = "2.16.840.1.113883.3.445.14" and @typeCode = "PRCN"<br>- /act/precondition/criterion/[@classCode = "OBS"]/code should be present<br>○ component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.15" and if it is present:<br>- /observationMedia/@classCode = "OBS" should be present<br>○ component/section/entry/act/entryRelationship may be present with a templateId = "2.16.840.1.113883.3.445.16"<br>○ component/section with templateId = "2.16.840.1.113883.3.445.18" and a title of "Signatures" may be present, and if present this section may include the entry/observationMedia for each signature |
| **Pass/Fail criteria** | All steps are as specified within the test procedure above. |
| **Notes** | |

# Bibliography


[b-ITU-T H.810 (2013)] Recommendation ITU-T H.810 (2013), *Interoperability design guidelines for personal health systems*.

[b-ITU-T H.810 (2015)] Recommendation ITU-T H.810 (2015), *Interoperability design guidelines for personal health systems*.

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

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

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

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

[b-CDG 2013] Continua Health Alliance, Continua Design Guidelines (2013), "Endorphin", *Continua Design Guidelines*.

[b-CDG 2015] Continua Health Alliance, Continua Design Guidelines (2015), "Genome", *Continua Design Guidelines*.

[b-CDG 2016] Personal Connected Health Alliance, Continua Design Guidelines (2016), "Iris", *Continua Design Guidelines*.

[b-ETSI SR 001 262] ETSI SR 001 262 v1.8.1 (2003), *ETSI drafting rules*. https://docbox.etsi.org/MTS/MTS/10-PromotionalMaterial/MBS-20111118/Referenced%20Documents/Drafting%20Rules.pdf

[b-HFSR PICS & PIXIT] Services HFS Receiver DG2016 PICS and PIXIT excel sheet v1.7 http://handle.itu.int/11.1002/2000/12067

[b-HFSS PICS & PIXIT] Services HFS Sender DG2016 PICS and PIXIT excel sheet v1.7 http://handle.itu.int/11.1002/2000/12067

## SERIES OF ITU-T RECOMMENDATIONS

| | |
|---|---|
| Series A | Organization of the work of ITU-T |
| Series D | Tariff and accounting principles and international telecommunication/ICT economic and policy issues |
| Series E | Overall network operation, telephone service, service operation and human factors |
| Series F | Non-telephone telecommunication services |
| Series G | Transmission systems and media, digital systems and networks |
| **Series H** | **Audiovisual and multimedia systems** |
| Series I | Integrated services digital network |
| Series J | Cable networks and transmission of television, sound programme and other multimedia signals |
| Series K | Protection against interference |
| Series L | Environment and ICTs, climate change, e-waste, energy efficiency; construction, installation and protection of cables and other elements of outside plant |
| Series M | Telecommunication management, including TMN and network maintenance |
| Series N | Maintenance: international sound programme and television transmission circuits |
| Series O | Specifications of measuring equipment |
| Series P | Telephone transmission quality, telephone installations, local line networks |
| Series Q | Switching and signalling, and associated measurements and tests |
| Series R | Telegraph transmission |
| Series S | Telegraph services terminal equipment |
| Series T | Terminals for telematic services |
| Series U | Telegraph switching |
| Series V | Data communication over the telephone network |
| Series X | Data networks, open system communications and security |
| Series Y | Global information infrastructure, Internet protocol aspects, next-generation networks, Internet of Things and smart cities |
| Series Z | Languages and general software aspects for telecommunication systems |

Printed in Switzerland
Geneva, 2017