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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia systems, 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 18: Personal Health Device Observation Upload (POU) Receive

Recommendation ITU-T H.830.18

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Recommendation ITU-T H.830.18

Conformance of ITU-T H.810 personal health system: Services interface Part 18: Personal Health Device Observation Upload (POU) Receiver

Summary

Recommendation ITU-T H.830.18 provides a test suite structure (TSS) and the test purposes (TPs) for the Personal Health Device Observation Upload (POU) receiver 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 (2019) 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.830.18 includes an electronic attachment with the protocol implementation conformance statements (PICSs) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

History

Edition	Recommendation	Approval	Study Group	Unique ID*
1.0	ITU-T H.830.18	2021-06-13	16	11.1002/1000/14688

Keywords

Capability exchange, conformance testing, continua design guidelines, e-health, health & fitness service, ITU-T H.810, personal connected health devices, POU, 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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Electronic attachment: This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICSs) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

Introduction

The table below shows the revision history of this test specification.

Version	Date	Revision history
1.0	2020-12-21	Initial release for the inclusion of Personal Health Device Observation Upload (POU) receiver.

Recommendation ITU-T H.830.18

Conformance of ITU-T H.810 personal health system: Services interface Part 18: Personal Health Device Observation Upload (POU) Receiver

1 Scope

The scope of this Recommendation[1] is to provide a test suite structure (TSS) and the test purposes (TPs) for the Services interface based on the requirements defined in the Continua Design Guidelines (CDG) [ITU-T H.810 (2019)]. The objective of this test specification is to provide a high probability of interoperability at this interface.

The TSS and TPs for the Services interface have been divided into the parts specified below. This Recommendation covers Part 18.

– 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
– Part 13: Capability Exchange. Health & Fitness Service sender
– Part 14: Capability Exchange. Health & Fitness Service receiver
– Part 15: FHIR Observation Upload. Health & Fitness Service sender
– Part 16: FHIR Observation Upload. Health & Fitness Service receiver.
– Part 17: POU. Health & Fitness Service sender.
– **Part 18: POU. 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 standalone document, the status of a Recommendation.

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

[ITU-T H.810 (2019)] Recommendation ITU-T H.810 (2019), *Interoperability design guidelines for personal health systems*: *Introduction*.

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
ATNA Audit Trail and Node Authentication
BLE Bluetooth Low Energy
BT HDP Bluetooth Health Device Profile
CDG Continua Design Guidelines
CGM Continuous Glucose Monitor
DOC Device Observation Consumer
DUT Device Under Test
FHIR Fast Healthcare Interoperability Resources
HFS Health & Fitness Service
HFSR Health & Fitness Service Receiver
HFSS Health & Fitness Service Sender
HL7 Health Level 7
HTTP Hypertext Transfer Protocol
IHE Integrating the Healthcare Enterprise
INR International Normalized Ratio
IP Insulin Pump
JSON JavaScript Object Notation
MDS Medical Device System
NFC Near Field Communication
PCD Patient Care Device
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

POU Personal Health Device Observation Upload

SABTE Sleep Apnoea Breathing Therapy Equipment

SCR Static Conformance Review

SOAP Simple Object Access Protocol

TLS Transport Level Security

TP Test Purpose

TSS Test Suite Structure

USB Universal Serial Bus

URI Uniform Resource Identifier

WS Web Service

WSI Web Services Interoperability

XDR Cross-Enterprise Document Reliable Interchange

XML extensible Markup Language

ZB Zigbee

5 Conventions

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

– 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 designations 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
2019	–	8.0	Release 2019 of the CDG including maintenance updates of the CDG 2017 and additional guidelines that cover new functionalities.	–
2017	–	7.0	Release 2017 of the CDG including maintenance updates of the CDG 2016 and additional guidelines that cover new functionalities.	–
2016 plus errata	[b-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 [ITU-T H.810] is split into eight parts in the ITU-T 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.	–
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

The test procedures (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 1.8: Capability Exchange (CE)
  - Subgroup 1.8.1: General (GEN)
  - Subgroup 1.8.2: hData record format (HRF)
- Group 1.9: FHIR Observation Upload (FHIR)
  - Subgroup 1.9.1: General (GEN)
  - Subgroup 1.9.2: FHIR Encoding Guidelines (ENC)
- Group 1.10: Personal Health Device Observation Upload (POU)
  - Subgroup 1.10.1: General (GEN)

– 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)
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  - Subgroup 2.8.1: General (GEN)
  - Subgroup 2.8.2: hData record format (HRF)
- Group 2.9: FHIR Observation Upload (FHIR)
  - Subgroup 2.9.1: General (GEN)
- **Group 2.10: Personal Health Device Observation Upload (POU)**
  - **Subgroup 1.10.1: General (GEN)**

7 Electronic attachment

The protocol implementation conformance statements (PICSs) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A can be downloaded from https://handle.itu.int/11.1002/2000/12067. See [b-HFSR PICS & PIXIT] and [b-HFSS PICS & PIXIT].

In the electronic attachment, letters "C" and "I" in the column labelled "Mandatory" are used to distinguish between "PICSs" 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 PICSs, 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 procedures

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

A.1 Test purpose definition conventions

The 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 TP 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 TP.
- **TP label**: This is 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 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 DUT within that scope of the test (specialization, transport used, etc.).
- **Other PICSs**: 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 test case 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 1.10.1: General (GEN)

TP Id		TP/HFS/REC/POU/GEN/BV-000		
TP label		POU Profile – Actors and Transactions (DOC)		
Coverage	**Spec**	[b-IHE_PCD_Suppl_POU]		
	Testable items	IHETrans;M	DOCReq 2;M	POUActorTrans;M
		CommPCH-01MessSem 3;M		
Test purpose		Check that: To claim compliance with the POU, a Device Observation Consumer (DOC) supports all required transactions. 1. Communicate fast healthcare interoperability resources (FHIR) Personal Health Device (PHD) Data (PCH-01) 2. Communicate RESTful FHIR PHD Data (PCH-02) [AND] Supports one of the two transactions.		
Applicability		C_REC_000 AND C_REC_GEN_009 AND C_REC_GEN_010		
Other PICSs				
Initial condition		Simulated HFS supports POU Server and Capability Exchange Continua Certified Capability Classes, so it has an POU API that can accept a Personal Health Device Observation Upload (POU) that requires transport level security (TLS) and an authentication token. The HFS supports all available OAuth 2.0 authorization grant types (so they are listed in the grantTypes element of its OAuthDescriptor). Simulated HFS has no previously stored resources and supports both transactions: FHIR PHD data (PCH-01) and RESTful FHIR PHD Data (PCH-02).		
Test procedure		1. Ask the DOC under test to receive an observation resource as a complete package (FHIR PHD Data (PCH-01) transaction) from the simulated sender and wait for the response. 2. Ask the DOC under test to receive an observation resource as a complete package (RESTful FHIR PHD Data (PCH-02) transaction) from the simulated sender and wait for the response.		
Pass/fail criteria		• The first response uses transaction FHIR PHD Data (PCH-01). • The second response uses transaction RESTful FHIR PHD Data (PCH-02).		
Notes				

TP Id		TP/HFS/REC/POU/GEN/BV-001		
TP label		DOC Requirements. Transaction and bundle		
Coverage	**Spec**	[b-IHE_PCD_Suppl_POU]		
	Testable items	CommPCH-01ExpActions;M	A2.1PHD-PatientRes 2;M	
Test purpose		Check that: The DOC transfers the FHIR Bundle to a grouped Device Observation Reporter that dispatches the information using another Integrating the Healthcare Enterprise (IHE) transaction, for example, a PCD transaction containing a V2 message or any other IHE actor that can make use of this data and dispatch it to consumer actors.		

	[AND] The DOC does not reject such a resource due to the Patient resource reference. The referenced Patient resource is not accessible from the DOC.
Applicability	C_REC_000 AND C_REC_GEN_009
Other PICSs	
Initial condition	Simulated HFS supports POU Server and Capability Exchange Continua Certified Capability Classes, so it has an POU API that can accept a POU that requires TLS and an authentication token. The HFS supports all available OAuth 2.0 authorization grant types (so they are listed in the grantTypes element of its OAuthDescriptor). Simulated HFS has no previously stored resources and supports both transactions: FHIR PHD data PCH-01 and RESTful FHIR PHD Data (PCH-02).
Test procedure	1. Ask the DOC under test to upload an Observation resource as a complete bundle to the simulated Receiver using transaction PCH-01.
Pass/fail criteria	• The transaction of the FHIR Bundle is correct.
Notes	

TP Id		TP/HFS/REC/POU/GEN/BV-002		
TP label		DOC Requirements. TLS security and OAuth authentication		
Coverage	**Spec**	[b-IHE_PCD_Suppl_POU]		
	Testable items	CommPCH-02;M	DOCReq 1;M	CommPCH-01;M
Test purpose		Check that: The DOC Actor shall support TLS security and OAuth authentication for this IHE transaction.		
Applicability		C_REC_000 AND C_REC_GEN_009 AND C_REC_GEN_010 AND C_REC_GEN_011 AND C_REC_GEN_012		
Other PICSs				
Initial condition		Simulated HFS supports POU Server and Capability Exchange Continua Certified Capability Classes, so it has an POU API that can accept a POU that requires TLS and an authentication token. The HFS supports all available OAuth 2.0 authorization grant types (so they are listed in the grantTypes element of its OAuthDescriptor). Simulated HFS has no previously stored resources and supports both transactions: FHIR PHD data (PCH-01) and RESTful FHIR PHD Data (PCH-02).		
Test procedure		1. Ask the DOC under test to upload an Observation resource as a complete bundle to the simulated Receiver.		
Pass/fail criteria		• The DOC supports TLS security and OAuth authentication for this IHE transaction.		
Notes				

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