# ITU-T

TELECOMMUNICATION STANDARDIZATION SECTOR OF ITU



# SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Interoperability compliance testing of personal health systems (HRN, PAN, LAN, TAN and WAN)

# Conformance of ITU-T H.810 personal health devices: WAN interface Part 10: hData observation upload: Receiver

Recommendation ITU-T H.830.10

1-DT



# ITU-T H-SERIES RECOMMENDATIONS AUDIOVISUAL AND MULTIMEDIA SYSTEMS

CHARACTERISTICS OF VISUAL TELEPHONE SYSTEMSH.100-H.199INFRASTRUCTURE OF AUDIOVISUAL SERVICESH.200-H.219GeneralH.200-H.219Transmission multiplexing and synchronizationH.220-H.229Systems aspectsH.230-H.239Communication proceduresH.240-H.259Coding of moving videoH.260-H.279Related systems aspectsH.280-H.299Systems and terminal equipment for audiovisual servicesH.300-H.349Directory services architecture for audiovisual and multimedia servicesH.350-H.359Quality of service architecture for audiovisual and multimedia servicesH.360-H.369
GeneralH.200–H.219Transmission multiplexing and synchronizationH.220–H.229Systems aspectsH.230–H.239Communication proceduresH.240–H.259Coding of moving videoH.260–H.279Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Transmission multiplexing and synchronizationH.220–H.229Systems aspectsH.230–H.239Communication proceduresH.240–H.259Coding of moving videoH.260–H.279Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Systems aspectsH.230–H.239Communication proceduresH.240–H.259Coding of moving videoH.260–H.279Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Communication proceduresH.240–H.259Coding of moving videoH.260–H.279Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Coding of moving videoH.260–H.279Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Related systems aspectsH.280–H.299Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Systems and terminal equipment for audiovisual servicesH.300–H.349Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
Directory services architecture for audiovisual and multimedia servicesH.350–H.359Quality of service architecture for audiovisual and multimedia servicesH.360–H.369
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 H.820–H.859 and WAN)
Multimedia e-health data exchange servicesH.860–H.869

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

#### **Recommendation ITU-T H.830.10**

#### Conformance of ITU-T H.810 personal health devices: WAN interface Part 10: hData observation upload: Receiver

#### Summary

Recommendation ITU-T H.830.10 provides a test suite structure and the test purposes (TSS & TPs) for the WAN interface (consent management; receiver) based on the requirements defined in Recommendation ITU-T H.810 (2015). The objective of this test specification is to provide a high probability of air interface interoperability between different devices.

This Recommendation is a transposition of Continua Test Tool DG2015, Test Suite Structure & Test Procedures, WAN interface; Part 10: hData observation upload: Receiver (Version 1.0, 2015-07-01).

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

#### History

Edition	Recommendation	Approval	Study Group	Unique ID*
1.0	ITU-T H.830.10	2015-11-29	16	11.1002/1000/12675
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#### Keywords

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

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

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#### **Table of Contents**

			0
1	Scope		1
2	Referen	ces	1
3	Definition	ons	2
	3.1	Terms defined elsewhere	2
	3.2	Terms defined in this Recommendation	2
4	Abbrevi	ations and acronyms	2
5	Convent	tions	3
6	Test sui	te structure (TSS)	4
7	Electron	ic attachment	6
Annex	A – Tes	t purposes	7
	A.1	TP definition conventions	7
	A.2	Subgroup 2.6.1: General (GEN)	8
	A.3	Subgroup 2.6.2: hData record format (HRF)	9
Biblio	graphy		11

**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.

Page

#### Introduction

This Recommendation is a transposition of Continua Test Tool DG2015, Test Suite Structure & Test Procedures, WAN Interface; Part 10: hData Observation Upload: Receiver (Version 1.0, 2015-07-01), that was developed by the Continua Health Alliance. A version of this specification that existed before transposition is indicated in the table below.

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

#### **Recommendation ITU-T H.830.10**

#### Conformance of ITU-T H.810 personal health devices: WAN interface Part 10: hData observation upload: Receiver

#### 1 Scope

The scope of this Recommendation<sup>1</sup> is to provide a test suite structure (TSS) and the test purposes for the WAN interface based on the requirements defined in the Continua Design Guidelines (CDG). The objective of this test specification is to provide a high probability of air interface interoperability between different devices.

TSS & TP for the WAN interface have been divided into the 12 parts specified below. This Recommendation covers Part 10.

- **Part 1:** Web Services Interoperability. Sender
- **Part 2:** Web Services Interoperability. Receiver
- **Part 3:** SOAP/ATNA. Sender
- **Part 4:** SOAP/ATNA. Receiver
- **Part 5:** PCD-01 HL7 messages. Sender
- **Part 6:** PCD-01 HL7 messages. Receiver
- **Part 7:** Consent management. Sender
- **Part 8:** Consent management. Receiver
- **Part 9:** hData observation upload. Sender
- Part 10: hData observation upload. Receiver
- **Part 11:** Questionnaires. Sender
- **Part 12:** Questionnaires. Receiver

#### 2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.

[ITU-T H.810 (2015)]	Recommendation ITU-T H.810 (2015), Interoperability design guidelines for personal health systems.
[ITU-T H.810 (2016)]	Recommendation ITU-T H.810 (2016), Interoperability design guidelines for personal health systems.
[ITU-T H.811]	Recommendation ITU-T H.811 (2015), Interoperability design guidelines for personal health systems: PAN/LAN/TAN interface.

<sup>&</sup>lt;sup>1</sup> 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.

1

[ITU-T H.812]	Recommendation ITU-T H.812 (2015), Interoperability design guidelines for personal health systems: WAN interface: Common certified device class.
[ITU-T H.812.1]	Recommendation ITU-T H.812.1 (2015), Interoperability design guidelines for personal health systems: WAN interface: Observation upload certified device class.
[ITU-T H.812.2]	Recommendation ITU-T H.812.2 (2015), Interoperability design guidelines for personal health systems: WAN interface: Questionnaires.
[ITU-T H.812.3]	Recommendation ITU-T H.812.3 (2015), Interoperability design guidelines for personal health systems: WAN interface: Capability exchange device class.
[ITU-T H.812.4]	Recommendation ITU-T H.812.4 (2015), Interoperability design guidelines for personal health systems: WAN interface: Authenticated persistent session device class.
[ITU-T H.813]	Recommendation ITU-T H.813 (2015), Interoperability design guidelines for personal health systems: Health record network (HRN) interface.
[HL7 V3 HRF]	Health Level Seven (2014), <i>HL7 Version 3 Specification: hData Record</i> <i>Format, Release 1.</i> < <u>http://www.hl7.org/documentcenter/private/standards/v3/V3_ITS_HDATA_RF_R1_2014JUN.pdf&gt;</u>

#### **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
- CDA Clinical Document Architecture
- CDG Continua Design Guidelines
- DUT Device Under Test
- GUI Graphical User Interface
- HL7 Health Level 7
- HTTP Hypertext Transfer Protocol
- HTTPS Hypertext Transfer Protocol Secure
- IHE Integrating the Healthcare Enterprise
- INR International Normalized Ratio
- PCHA Personal Connected Health Alliance
- PCD Patient Care Device

#### 2 Rec. ITU-T H.830.10 (07/2016)

PCHA	Personal Connected Health Alliance
PICS	Protocol Implementation Conformance Statement
PIXIT	Protocol Implementation eXtra Information for Testing
SABTE	Sleep Apnoea Breathing Therapy Equipment
SOAP	Simple Object Access Protocol
TLS	Transport Level Security
TP	Test Purpose
TSS	Test Suite Structure
WAN	Wide Area Network
WS	Web Service
WSI	Web Services Interoperability
XDR	Cross-Enterprise Document Reliable Interchange
УMI	evtensible Markun Language

XML extensible Markup Language

#### 5 Conventions

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

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

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

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

CDG release	Transposed as	Version	Description	Designation
2016 plus errata	[ITU-T H.810 (2016)]	6.1	Release 2016 plus errata noting all ratified bugs [ITU-T H.810 (2016)].	—
2016	_	6.0	Release 2016 of the CDG including maintenance updates of the CDG 2015 and additional guidelines that cover new functionalities.	Iris
2015 plus errata	[ITU-T H.810 (2015)]	5.1	Release 2015 plus errata noting all ratified bugs [ITU-T H.810 (2015)].	_
2015	_	5.0	Release 2015 of the CDG including maintenance updates of the CDG 2013 and additional guidelines that cover new functionalities.	Genome

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

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

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

#### 6 Test suite structure (TSS)

The test purposes (TPs) for the WAN interface have been divided into the main subgroups specified below. Annex A describes the TPs for subgroups 2.6.1 and 2.6.2 (shown in bold):

- Group 1: Sender (SEN)
  - Group 1.1: Web services interoperability (WSI)
    - Subgroup 1.1.1: Basic profile (BP)
    - Subgroup 1.1.2: Basic security profile (BSP)
    - Subgroup 1.1.3: Reliable messaging (RM)
  - Group 1.2: SOAP (SOAP)
    - Subgroup 1.2.1: SOAP headers (HEAD)
  - Group 1.3: Audit (ATNA)
    - Subgroup 1.3.1: General (GEN)
    - Subgroup 1.3.2: PCD-01 (PCD-01)
  - Subgroup 1.3.3: Consent management (CM)• Group 1.4: PCD-01 HL7 Messages (PCD-01-DATA)
    - Subgroup 1.4.1: General (GEN)
    - Subgroup 1.4.2: Design guidelines (DG)

- Subgroup 1.4.3: Pulse oximeter (PO)
- Subgroup 1.4.4: Blood pressure monitor (BPM)
- Subgroup 1.4.5: Thermometer (TH)
- Subgroup 1.4.6: Weighing scales (WEG)
- Subgroup 1.4.7: Glucose meter (GL)
- Subgroup 1.4.8: Cardiovascular fitness and activity monitor (CV)
- Subgroup 1.4.9: Strength fitness equipment (ST)
- Subgroup 1.4.10: Independent living activity hub (HUB)
- Subgroup 1.4.11: Adherence monitor (AM)
- Subgroup 1.4.12: Peak expiratory flow monitor (PF)
- Subgroup 1.4.13: Body composition 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)
- Group 1.5: Consent management (CM)
  - Subgroup 1.5.1: WAN XDR transaction (TRANS)
  - Subgroup 1.5.2: WAN metadata validation (META)
  - Subgroup 1.5.3: WAN consent directive validation (CDV)
- Group 1.6: hData observation upload (HDATA)
  - Subgroup 1.6.1: General (GEN)
- Group 1.7: Questionnaires (QUE)
  - Subgroup 1.7.1: General (GEN)
  - Subgroup 1.7.2: CDA validation (CDA)
- Group 2: Receiver (REC)
  - Group 2.1: Web service interoperability (WSI)
    - Subgroup 2.1.1: Basic profile (BP)
    - Subgroup 2.1.2: Basic security profile (BSP)
    - Subgroup 2.1.3: Reliable messaging (RM)
  - Group 2.2: SOAP (SOAP)
    - Subgroup 2.2.1: SOAP headers (HEAD)
  - Group 2.3: Audit (ATNA)
    - Subgroup 2.3.1: General (GEN)
    - Subgroup 2.3.2: PCD-01 (PCD-01)
    - Subgroup 2.3.3: Consent management (CM)
  - Group 2.4: PCD-01 HL7 Messages (PCD-01-DATA)
    - Subgroup 2.4.1: General (GEN)
    - Subgroup 2.4.2: Design guidelines (DG)
    - Subgroup 2.4.3: Pulse oximeter (PO)
    - Subgroup 2.4.4: Blood pressure monitor (BPM)
    - Subgroup 2.4.5: Thermometer (TH)
    - Subgroup 2.4.6: Weighing scales (WEG)

5

- 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)
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- Subgroup 2.4.16: Sleep apnoea breathing therapy equipment (SABTE)
- Group 2.5: Consent management (CM)
  - Subgroup 2.5.1: WAN XDR transaction (TRANS)
  - Subgroup 2.5.2: WAN service validation (SER)
- Group 2.6: hData observation upload (HDATA)
  - Subgroup 2.6.1: General (GEN)
  - Subgroup 2.6.2: hData record format (HRF)
- Group 2.7: Questionnaires (QUE)
  - Subgroup 2.7.1: General (GEN)
  - Subgroup 2.7.2: CDA validation (CDA)
  - Subgroup 2.7.3: hData record format (HRF)

#### 7 Electronic attachment

The protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A can be downloaded from <a href="http://handle.itu.int/11.1002/2000/12067">http://handle.itu.int/11.1002/2000/12067</a>.

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

#### Annex A

#### **Test purposes**

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

#### A.1 TP definition conventions

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

- **TP Id:** This is a unique identifier (TP/<TT>/<DUT>/<GR>/<SGR>/<XX> <NNN>). It is specified according to the naming convention defined below:
  - Each test purpose identifier is introduced by the prefix "TP".
  - <TT>: This is the Test Tool that will be used in the test case.
    - WAN: Wide area network
  - <DUT>: This is the device under test.
    - SEN: WAN observation sender
    - REC: WAN observation receiver
  - <GR>: This identifies a group of test cases.
  - <SGR>: This identifies a subgroup of test cases.
  - <XX>: This identifies the type of testing.
    - BV: valid behaviour test
    - BI: Invalid behaviour test
  - <NNN>: This is a sequential number that identifies the 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 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 protocol implementation conformance statement (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 device under test (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.

TP ld		TP/WAN/REC/HDATA/GEN/BV-000				
TP label		hData Observation Upload. WAN Receiver				
Coverage	Spec	[ITU-T H.812]				
Testak items		RESTSec 7	RESTSec 8	CommonReq 5		
	Spec	[ITU-T H.812.1]				
	Testable items	hData 6	hData 9	hData 10		
Test purpos	se	Check that: SUT accepts an hData observation upload using TLS 1.1 and using a provided Oauth v2.0 bearer token for authorization.				
Applicabilit	у	C_REC_000 AND C_	REC_GEN_004			
Other PICS		C_REC_GEN_005				
Initial condi	ition	Simulated AHD application using hData observation upload has a PCD-01 message ready to be sent to the SUT using TLS 1.1 and an Oauth 2.0 bearer token provided by the SUT.				
Test procedure		<ol> <li>Simulated AHD application requests a beater OAuth 2.0 token using the URL provided by the SUT, the authorization grant type specified in PIXIT I_REC_OAUTH_001, and the required parameters specified in the test tool general parameters for the specific grant type, using a TLS 1.1 connection.</li> </ol>				
		<ol> <li>Simulated AHD application uses the provided bearer token to send a PCD-01 message to the URL provided by the SUT using TLS 1.1 connection.</li> </ol>				
		3. Simulated AHD application also sends an HTTP DELETE request on the observation upload URL.				
Pass/Fail cr	iteria	• WAN application under test supports capability exchange as specified in [ITU-T H.812.3].				
		• WAN device providing the authorization server returns an authorization token of type "bearer" after validating the access token request.				
		• WAN device providing the authorization server includes "refresh token" in the response to the access token request.				
		<ul> <li>WAN application under test returns an <http 201=""> response when the PCD-01 message is received.</http></li> </ul>				
		<ul> <li>WAN application returns an <http 405=""> (Method not allowed) response to an HTTP DELETE request on the observation upload URL.</http></li> </ul>				
Notes						

## A.2 Subgroup 2.6.1: General (GEN)

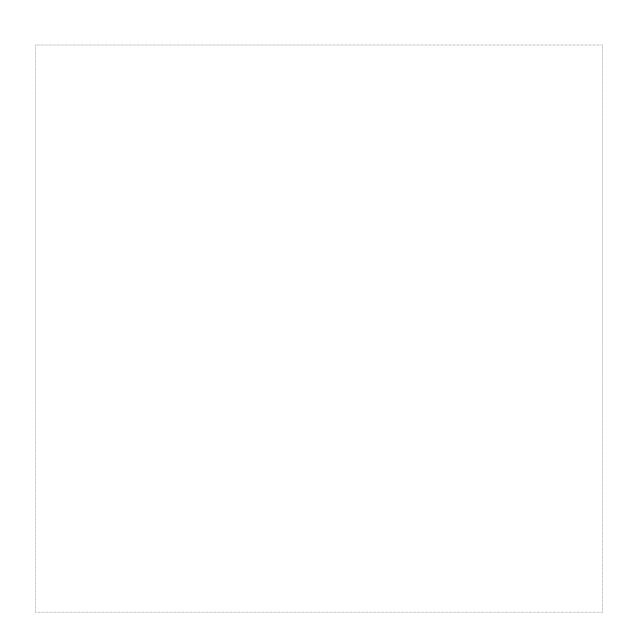
TP ld		TP/WAN/REC/HDATA/HRF/BV-000				
TP label		hData Observation Upload. Root file elements				
Coverage Spec		[ITU-T H.812]				
	Testable items	CommonReq 5				
	Spec	[ITU-T H.812.1]				
	Testable items	hData 6	hData 7	hData 8		
	Spec	[HL7 V3 HRF]				
	Testable	Root 9	Root 10	Root 11		
	items	Root 12	Root 13	Root 14		
		Root 15	Root 16	Root 18		
		Root 19	Root 20	Root 22		
Applicability	/	SUT declares required and recommended observation upload capabilities in its root file according to hData Record Format.				
Other PICS		C_REC_GEN_005				
Initial condition		Simulated AHD application using hData observation upload is ready to check the SUT hData observation upload capabilities declared in its root file. SUT has previously provided a base URL.				
Test procedure		<ol> <li>Simulated AHD application performs an HTTP GET of root.xml using TLS v.1.1. OAuth 2.0 token is not required.</li> <li>Simulated AHD application obtains and check required and recommended observation upload capabilities in root.xml file.</li> </ol>				
Pass/Fail cr	iteria	• WAN application under test supports capability exchange as specified in [ITU-T H.812.3].				
		WAN application provides root.xml file.				
		• Root.xml shows the capability elements for observation upload applications supporting hData as shown:				
		<profile> <id>observation-upload-hData</id> <reference></reference></profile>				
			int/11.1002/3000/h	Data/Upload/2015/01/H.812.1.pdf		
		<section></section>				

## A.3 Subgroup 2.6.2: hData record format (HRF)

	<path>path/to/payload/post for hData</path>
	<profileid>observation-upload-hData</profileid>
	<resourcetypeid>observation</resourcetypeid>
	<resourcetype></resourcetype>
	<id>observation</id>
	<reference></reference>
	http://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol2.pdf
	<representation></representation>
	<mediatype><b>application/txt</b></mediatype>
	<ul> <li>Additionally, simulated AHD application checks that Oauth2 authentication server support capability (recommended) is as shown:</li> </ul>
	<profile></profile>
	<id>oAUTH</id>
	<reference></reference>
	http://handle.itu.int/11.1002/3000/hData/Upload/2015/01/H.812.1.pdf
	<section></section>
	<path>path/to/post for oAUTH token</path>
	<profileid>oAUTH</profileid>
	<resourcetype></resourcetype>
	<id>oAUTH-Bearer</id>
	<reference></reference>
	http://tools.ietf.org/html/rfc6750
	<representation></representation>
	<pre>- <mediatype>application/json</mediatype></pre>
Notes	

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[b-CDG 2012]	Continua Health Alliance, Continua Design Guidelines (2012), "Catalyst", <i>Continua Design Guidelines</i> .
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[b-Receiver PICS & PIXIT]	WAN Receiver DG2013 PICS and PIXIT excel sheet v1.2 http://handle.itu.int/11.1002/2000/12067
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