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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

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

Conformance of ITU-T H.810 personal health system: Conformity assessment test plan

Recommendation ITU-T H.820

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Recommendation ITU-T H.820

Conformance of ITU-T H.810 personal health system: Conformity assessment test plan

Summary

Recommendation ITU-T H.820 provides a top-level overview of the test specifications and test profiles used to verify product conformance to the Continua Design Guidelines (CDG) that are defined in the Recommendations of the ITU-T H.810 sub-series, of which Recommendation ITU-T H.810 (2017) is the base Recommendation. It outlines the scope of the conformance and interoperability tests, test suite structures (TSS) and test purposes (TP), the test case reference list and the Continua test tool, which in turn are specified in detail in the Recommendations of the ITU-T H.820-H.850 series.

History

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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.

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

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Introduction

This Recommendation provides an overview of the conformance and interoperability testing that is performed to ensure products conform to the Continua Design Guidelines [ITU-T H.810] and its underlying standards and demonstrate interoperability between conforming products.

Continua test descriptions are written in the form of test suite structure (TSS) and test procedures (TP) documents to guide execution of conformance tests using the Continua test tool (CTT) [b-Continua Test Tool]. These test descriptions also describe precisely the possible results of a given procedure such that the result is deterministic. Device profiles are employed to survey and describe features implemented on a product that are then used to configure the Continua test tool to execute all test cases applicable to that product's feature set.

Conformance testing verifies compliance with:

– Personal Health Devices interface (or PHD-IF) requirements for transport, exchange protocols, certified capability classes and device specializations;

– Services interface (or Services IF) requirements for web services interoperability, SOAP/ATNA, PCD-01 HL7 messages, consent management, hData observation upload and questionnaires;

– Health Information System interface (or HIS-IF) sender and receiver.

Interoperability testing verifies basic personal health device (PHD) and Services functionality of typical use cases for a device specialization against a test bed of Continua certified devices.

Test report templates are employed to document test results at detailed level and summary level. Detailed test reports are confidential to the product vendor. They may be presented to a customer to self-declare compliance to the Continua Design Guidelines (CDG) or provided to the Continua certification administrator (CertAdmin) as part of the Continua certification process [b-CDG Certification]. Summary level (passing) test results are available to the public. All Continua certified products are listed on the ITU Product Conformity Database at https://www.itu.int/net/itu-t/cdb/ConformityDB.aspx.

The Continua test tool provides a user interface by which product features are identified and mapped to the appropriate test cases to generate the test plan used to verify conformance to the Continua Design Guidelines and ISO/IEEE 11073-20601family of specifications.

The test specifications herein are published by the ITU as the ITU-T H.820-H.850 series of Recommendations "Conformance of ITU-T H.810 personal health systems" [ITU-T H.820-H.850].

Recommendation ITU-T H.820

Conformance of ITU-T H.810 personal health system: Conformity assessment test plan

1 Scope

The purpose of the conformity assessment test plan in this Recommendation is to provide an overview of the conformance and interoperability testing that is performed to ensure products conform to the Continua Design Guidelines (CDG) and its underlying standards and to demonstrate interoperability between conforming products.

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] Recommendation ITU-T H.810 (2017), *Interoperability design guidelines for personal connected health systems: Introduction*.

[ITU-T H.820-H.850] Recommendation ITU-T H.820-H.850 sub-series, *Conformance of ITU-T H.810 personal health devices*. List at http://itu.int/en/ITU-T/studygroups/2017-2020/16/Pages/rm/ehealth.aspx.

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[ISO/IEEE 11073-10404] ISO/IEEE 11073-10404:2010, *Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter*. https://www.iso.org/standard/54572.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10404-2010.html.

[ISO/IEEE 11073-10406] IEEE 11073-10406-2012, *Health informatics – Personal health device communication – Part 10406: Device specialization – Basic Electrocardiograph (ECG) (1 to 3-lead ECG).* https://www.iso.org/standard/61876.html. Same publication as http://standards.ieee.org/findstds/standard/11073-10406-2011.html.

[ISO/IEEE 11073-10407] ISO/IEEE 11073-10407:2010, *Health informatics – Personal health device communication – Part 10407: Device specialization – Blood pressure monitor.* https://www.iso.org/standard/54573.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10407-2010.html.

[ISO/IEEE 11073-10408] ISO/IEEE 11073-10408:2010, *Health informatics – Personal health device communication – Part 10408: Device specialization – Thermometer*. https://www.iso.org/standard/54309.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10408-2010.html.

[ISO/IEEE 11073-10415] ISO/IEEE 11073-10415:2010, Health informatics – *Personal health device communication – Part 10415: Device specialization – Weighing scale*. https://www.iso.org/standard/54310.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10415-2010.html.

[ISO/IEEE 11073-10417] ISO/IEEE 11073-10417:2017, *Health informatics – Personal health device communication – Part 10417: Device specialization – Glucose meter*. https://www.iso.org/standard/70739.html. Same publication as http://standards.ieee.org/findstds/standard/11073-10417-2011.html.

[ISO/IEEE 11073-10418] ISO/IEEE 11073-10418-2011, *Health informatics – Personal health device communication – Part 10418: Device specialization – International Normalized Ratio (INR) monitor*. https://www.iso.org/standard/61897.html. Same publication as http://standards.ieee.org/findstds/standard/11073-10418-2011.html.

[ISO/IEEE 11073-10419] ISO/IEEE 11073-10419:2016, *Health informatics - Personal health device communication – Part 10419: Device specialization– Insulin pump*. https://www.iso.org/standard/69528.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10419-2015.html.

[ISO/IEEE 11073-10420] ISO/IEEE 11073-10420 (2012), *Health informatics – Personal health device communication – Part 10420: Device specialization – Body composition analyzer*. https://www.iso.org/standard/61055.html. Same publication as http://standards.ieee.org/findstds/standard/11073-10420-2010.html.

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[ISO/IEEE 11073-10424] ISO/IEEE 11073-10424:2016, *Health informatics – Personal health device communication – Part 10424: Device specialization – Sleep apnoea breathing therapy equipment (SABTE)*. https://www.iso.org/standard/68906.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10424-2014.html.

[ISO/IEEE 11073-10425] ISO/IEEE 11073-10425:2016, *Health informatics – Personal health device communication – Part 10425: Device specialization – Continuous glucose monitor (CGM)*. https://www.iso.org/standard/67821.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10425-2014.html.

[ISO/IEEE 11073-10427] ISO/IEEE 11073-10427:2018, *Health informatics – Personal health device communication – Part 10427: Device specialization – Power status monitor of personal health devices*. https://www.iso.org/standard/73759.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10427-2016.html.

[ISO/IEEE 11073-10441] ISO/IEEE 11073-10441:2015, *Health informatics – Personal health device communication – Part 10441: Device specialization – Cardiovascular fitness and activity monitor*. https://www.iso.org/standard/64868.html. Same publication as http://standards.ieee.org/findstds/standard/11073-10441-2013.html.

[ISO/IEEE 11073-10442] ISO/IEEE 11073-10442:2015, *Health informatics – Personal health device communication – Part 10442: Device specialization – Strength fitness equipment*. https://www.iso.org/standard/66212.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10442-2008.html.

[ISO/IEEE 11073-10471] ISO/IEEE 11073-10471:2010, *Health informatics – Personal health device communication – Part 10471: Device specialization – Independent living activity hub*. https://www.iso.org/standard/54328.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10471-2008.html.

[ISO/IEEE 11073-10472] ISO/IEEE 11073-10472:2012, *Health informatics – Personal health device communication – Part 10472: Device specialization – Medication Monitor*. https://www.iso.org/standard/54364.html. Same publication as https://standards.ieee.org/findstds/standard/11073-10472-2010.html.

3 Definitions

3.1 Terms defined elsewhere

This Recommendation uses the following terms defined elsewhere:

3.1.1 Continua Personal Health Devices interface (PHD-IF) [ITU-T H.810]: The Continua PHD-IF connects one or more Personal Health Device (e.g., sensor/actuator) client components to one or more Personal Health Device (sensor/actuator) service components using transport media such as USB, Bluetooth LE, Bluetooth BR/EDR, ZigBee or NFC. Examples of sensor service components include glucose meters, weighing scales and heart rate monitors.

3.1.2 Personal Health Devices interface (PHD-IF) [ITU-T H.810]: Interface between a Personal Health Device (PHD) and Personal Health Gateway (PHG). See Continua PHD interface.

3.2 Terms defined in this Recommendation

This Recommendation defines the following terms:

3.2.1 CDG certification: The process by which a certification body verifies, through conformance testing, that a personal health device complies with the ITU-T H.810 Continua Design Guidelines (CDG) and specifications and is able to interoperate with other personal health devices compliant with the ITU-T H.810 CDG. A certification body may provide a certificate of compliance and/or a logo to provide proof of certification. There are four types of certification:

– Type A: certification of a totally new product;

– Type D: certification of a derivative product;

– Type U: certification of an updated product; and

– Type O: certification of a Type A or Type D certified product relabelled by a second vendor.

3.2.2 Certified Capability Class: Entity in the ITU-T H.810 Continua end-to-end (E2E) architecture for which a complete set of guidelines has been defined such that a device or application can be certified to comply with that set of guidelines via the Continua certification programme.

3.2.3 CDG compliance: The state of being in accordance with [ITU-T H.810] Continua Design Guidelines (CDG). Compliance with the CDG and specifications is assessed through conformance testing performed during the certification process.

3.2.4 CDG component: A logical entity in the Continua Design Guidelines (CDG) ecosystem. In general, for any *Interface*, there is a service component, with a well-defined set of functions depending on its type, on one side of the interface and one (or more) client components on the other side. Each component is realized within a physical device.

3.2.5 CDG conformance: An affirmative indication, through testing, that a personal health device (PHD) was built and functionally behaves according to a certification body's interoperability specifications and Continua Design Guidelines (CDG). Conformance with a certification body interoperability guidelines and specifications is assessed via conformance testing performed during the certification process.

3.2.6 device: A physical entity (box) and contains one or more functional components and capabilities.

3.2.7 interoperability: The ability of a client component in a device to communicate and share data with a variety of server components in an unambiguous and predictable manner, to exchange data accurately, effectively and consistently and to understand and use the information that is exchanged. The ITU-T H.820-H.850 series is used to certify devices and specifies the technical scope and requirements by which a device is considered compliant with interoperability.

3.2.8 Personal Health Gateway (PHG): A Continua reference capability class that contains a number of client components that use Personal Health Devices interfaces (PHD-IFs) and Service interfaces (Service-IFs) to access one or more services on other devices to coordinate data collection, data analysis, data sharing and alerting.

3.2.9 plugfest: An organized event for product vendors to gather together and implement the cross-vendor interoperability test.

3.2.10 product vendor: Product vendors are creators of personal health devices (PHDs).

3.2.11 Services interface (Services IF): An interface between Personal Health Gateway (e.g., smart phone, tablet and dedicate hub) and Health & Fitness Service applications (e.g., disease management service, ageing independently service and wellness service). The Health & Fitness Service application could be hosted in the cloud. IP based connectivity is assumed between the Personal Health Gateway and the Health & Fitness Service application and Continua focuses on defining the behaviour of the OSI layers above IP.

4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

AG Agent

ATNA Audit Trail and Node Authentication

BLE Bluetooth Low Energy

CertAdmin	Certification Administrator
CDG	Continua Design Guidelines
CTT	Continua Test Tool
DIM	Device Information Model
E2E	End-to-End
EPL	End Product Listing
HF	Health & Fitness
HFS	Health & Fitness Service
HIS	Healthcare Information System
HIS-IF	Health Information System Interface
ICT	Information and Communications Technology
PCD	Patient Care Device
PHD	Personal Health Devices
PHD-IF	Personal Health Devices Interface
PHG	Personal Health Gateway
PLT	PAN-LAN-TAN
SOAP	Simple Object Access Protocol
TP	Test Purpose
TSS	Test Suite Structure
USB	Universal Serial Bus

5 Conventions

None.

6 Application

This Recommendation familiarizes the reader with device profiles, test descriptions, conformance and interoperability test specifications, test report formats and the Continua test tool (CTT) as they are used to verify product conformance and compliance.

7 Test case reference list

A list of all test cases is to be maintained with traceability back to the CDG. For each test case, this reference list contains applicability logic to determine mandatory and optional test cases based on product features, the date the test case becomes active, test specifications and test tool versions and any bug fixes addressed by that release. This reference list is available as part of the Continua test tool (CTT) for download [b-Continua Test Tool].

8 Device profile

A device profile is a document used to describe a device under test (DUT). The profile is a survey of features implemented on a device. It is created using the certification web site. The user fills in a form indicating the features of the device under test. The tool then generates an XML device profile document. The device profile document contains enough information to determine every part of the

specification that applies to the DUT. This device profile document is used for multiple purposes in Continua.

– Used by the CTT to select test suites and test cases that are applicable to the DUT.
– Used in the certified device database as a record of what the certified device implements for features.
– Used as part of the certification documentation so that third parties can determine what other devices will be interoperable with this device.
– Used by Continua to create reports of which features of the Continua products are present in certified products.

9 Test descriptions

Continua test descriptions are created to guide execution of conformance tests that are part of a test suite implemented in the CTT. Interoperability procedures may be divergent from this format.

Test descriptions provide documentation for both the test developer and the executer of the test. Test descriptions are written such that a person with an architectural understanding of the network protocols involved can follow the discussion and procedure. Test descriptions are always written for black box testing. A test description contains at a minimum the following elements:

Test label	A title for the document. This often has taxonomic information embedded. For example, a suggested syntax could be 20601.Scanner.Buf-Scan-Report-Var.1 where the notation includes from left to right the standard name, the test spec name, the subsection of the test spec and a test number.
Device type	A label indicating the type of Certified Capabilities Class this test case applies to (see clause 6.1.3 of [ITU-T H.810] "Reference capability classes and system topology").
Compliance classifier	Indicates the requirement level as stated in the Continua interoperability test suite. Either Mandatory, Recommended or Optional.
Purpose	An executive summary of the requirement.
Discussion	Narrative text that outlines the requirement and the approach to testing. This statement should include the reasoning of the test designer for choosing the approach for testing and mention other approaches that were not taken and why. This section can also mention possible problems in the specification or in the procedure.
References	References to the relevant external specifications being tested in this test procedure.
Configuration	Assumptions about the topology of the network and configuration of the devices necessary before beginning the procedure.
Procedure	A testing procedure written in outline form that details the behaviour of the testing tool as well as the expected behaviour for the device under test.
Observable results	A table mapping possible outcomes of the procedure with a result (see clause 9.1). The observable results table should try to enumerate all possible reasons for exiting the procedure. Logged results from the test tool should be indexed in the observable results table to aid in failure isolation.
Device under test (DUT)	The vendor product being tested. It is a common shorthand used in black box testing and in test descriptions.

9.1 Results system

Test description documents describe precisely the possible results of a given procedure such that the results are deterministic. A requirement is considered to have a mandatory, recommended, optional or optional normative requirement level. This system provides sufficient variation to identify the outcome of any test for each of the requirement levels as compliant or non-compliant. Further it creates added value in the test suites by giving the developer information about what features are implemented on their device. Finally, compliance for certification purposes can still be easily determined, by applying the rule that "Compliant devices must not **FAIL** any mandatory tests."

The six result system is enumerated as follows:

PASS Compliance with the requirement is demonstrated by the DUT exhibiting the expected behaviour.

FAIL Non-compliance with the requirement is demonstrated by the DUT failing to exhibit a required behaviour or exhibiting an incorrect behaviour.

INCONC (inconclusive) Test tool is unable to determine if DUT PASSed or FAILed the test procedure. INCONCs shall be evaluated by the test lab to determine whether the test procedure has PASSed or FAILed. The test lab may need to use special tools, such as sniffers, manual procedures, or reference devices to determine whether the test procedure has PASSed or FAILed. Continua test lab personnel and Continua Certified Experts maintain a document that outlines the alternative approaches to achieve a conclusive verdict.

ERROR There is an error in the test harness (transport, drivers, operating system, etc.) and the test case is not able to be run.

NA The requirement does not apply to the DUT.

NT The recommended or optional behaviour could be not invoked when testing the DUT. This is not a valid result for mandatory items.

NOTE – To ensure consistency in the case of INCONC results, the procedure used by the test lab to generate a conclusive result will be shared with all other test labs. This is typically done by modifying the test tool and/or test procedures to generate a conclusive result. Information is typically communicated via email and sent to the Certification Administrator (CertAdmin) and other test labs for use in future certifications.

9.2 Acceptance results

The test descriptions are the primary source of documentation for the test tool. Because of this relationship they are written primarily by the test tool vendor. The certification body reviews the test descriptions written by the test tool vendor on a regular interval before the test descriptions are implemented. This process has multiple benefits. First, it fulfils the requirement of an acceptance process. Second, it will bring to light omissions, ambiguities or common misunderstandings in the specification in a timely manner. This prevents implementation of test cases that might perpetuate misinterpretations and prevent a duplication of effort if the standards or test descriptions need to be changed.

10 Conformance assessment test specification

This document provides a test plan for each Certified Capability Class in the Continua Design Guidelines (CDG). Devices applying for certification must demonstrate successful completion of the test plan, by providing test logs for the test suites indicated in this document. Additionally, this document lists supplemental information that must be submitted as part of the application for certification. The certification body CertAdmin verifies compliance with the requirements of this

document. Certified test labs adhere to the test plans contained in this document. Applicants should use this test plan to prepare an application and coordinate testing needs with a test lab.

10.1 Transport test requirements

This clause contains requirements for personal health devices (PHDs) implementing transport technologies for passing CDG data. Products applying for certification must test all transport interfaces that will carry CDG data. There are test suites that are specific to each transport technology. Test logs must be submitted for each interface.

10.1.1 Required transport test suites

USB Design Guidelines (TP/PAN/PHD/TR/UDG/* for Personal Health Devices (PHDs), TP/PAN/PHG/TR/UDG/* for Personal Health Gateways (PHGs))

USB Host Test Suite (TP/PHDC/HOS/* for PHGs)

Bluetooth Design Guidelines (TP/PAN/PHD/TR/BDG/* for PHDs, TP/PAN/PHG/TR/BDG/* for PHGs)

Bluetooth Low Energy Design Guidelines (TP/PAN/PHD/TR/BLEDG/* for PHDs, TP/PAN/PHG/TR/BLEDG/* for PHGs)

ZigBee Design Guidelines (TP/LAN/PHD/TR/ZDG/* for PHDs, TP/LAN/PHG/TR/ZDG/* for PHGs)

10.2 IEEE 11073-20601 features test requirements

All devices must implement the required elements of [ISO/IEEE 11073-20601-2016], which is a framework specification of features and mechanisms, and the device specialization documents select which features of the framework to use to synthesize a device class. All devices must also implement the applicable CDG that apply to ISO/IEEE 11073-20601 as well as the applicable general design guidelines. The test suites corresponding to these required features are listed in the following clauses.

10.2.1 Required test suites for ISO/IEEE 11073-20601 features

Design Guidelines: Common (TP/PLT/AG/TR/DGC/* for Agents, TP/PLT/MAN/TR/DGC/* for Managers)

PHD Domain Information Model (TP/PLT/AG/OXP/DIM/* for Agents, TP/PLT/MAN/OXP/DIM/* for Managers)

PHD Service Model (TP/PLT/AG/OXP/SER/* for Agents, TP/PLT/MAN/OXP/SER/* for Managers)

PHD Communication Model (TP/PLT/AG/OXP/COM/* for Agents, TP/PLT/MAN/OXP/COM/* for Managers)

10.3 Certified Capability Class test requirements

This clause contains the certification requirements for each Certified Capability Class. A device must implement one or more Certified Capability Classes at the time it applies for a Type A Certification, as required in the CDG. If a device implements multiple certifiable device classes, then the test plan for all device classes must be executed.

– IEEE 11073-10415 – Weighing scale [ISO/IEEE 11073-10415]
– IEEE 11073-10417 – Glucose meter [ISO/IEEE 11073-10417]
– IEEE 11073-10404 – Pulse oximeter [ISO/IEEE 11073-10404]
– IEEE 11073-10406 – Basic electrocardiograph [ISO/IEEE 11073-10406]

– IEEE 11073-10407 – Blood pressure monitor [ISO/IEEE 11073-10407]
– IEEE 11073-10408 – Thermometer [ISO/IEEE 11073-10408]
– IEEE 11073-10472 – Body composition analyser [ISO/IEEE 11073-10472]
– IEEE 11073-10421 – Peak expiratory flow monitor [ISO/IEEE 11073-10421]
– IEEE 11073-10441 – Cardiovascular [ISO/IEEE 11073-10441]
– IEEE 11073-10442 – Strength [ISO/IEEE 11073-10442]
– IEEE 11073-10471 – Activity hub [ISO/IEEE 11073-10471]
– IEEE 11073-10472 – Adherence monitor [ISO/IEEE 11073-10472]
– IEEE 11073-10418 – INR monitor [ISO/IEEE 11073-10418]
– IEEE 11073-10424 – Sleep apnoea breathing therapy equipment (SABTE) [ISO/IEEE 11073-10424]
– IEEE 11073-10419 – Insulin pump [ISO/IEEE 11073-10419]
– IEEE 11073-10425 – Continuous glucose monitor [ISO/IEEE 11073-10425]
– IEEE 11073-10427 – Power status monitor [ISO/IEEE 11073-10427]

10.4 PHD test suite structure and test purposes specification

The scope of the ITU-T H.840-series set is to provide test suite structure and test purposes (TSS & TP) for Personal Health Devices interfaces based on the requirements defined in Continua specifications. The objective is to provide a high probability of air interface interoperability between different devices.

TSS & TP for the Personal Health Devices Interface document set includes the following ten parts:

– Part 1: Optimized Exchange Protocol Personal Health Device
– Part 2: Optimized Exchange Protocol Personal Health Gateway
– Part 3: Continua Design Guidelines Personal Health Device
– Part 4: Continua Design Guidelines Personal Health Gateway
– Part 5: Device Specializations Personal Health Device
– Part 6: Device Specializations Personal Health Gateway
– Part 7: Continua Design Guidelines Personal Health Device BLE
– Part 8: Continua Design Guidelines Personal Health Gateway BLE
– Part 9: Personal Health Devices Transcoding White paper Personal Health Device
– Part 10: Personal Health Devices Transcoding White paper Personal Health Gateway

10.5 USB host test suite structure and test purposes specification

The scope of [ITU-T H.840] is to provide test suite structure and test purposes (TSS & TP) for USB Host based on the requirements defined in USB Personal Healthcare Device Class specification that has been selected for the PHD interface (see [ITU-T H.810].

Group 1 Descriptors (DESC)

Group 2 Meta-Data, Message Preamble, (MDMP)

10.6 Services test suite structure & test purposes specification

The scope of the ITU-T H.830 series is to provide test suite structure and test purposes (TSS & TP) for the Services interface based on the requirements defined in Continua Specifications. The objective is to provide a high probability of air interface interoperability between different devices.

TSS & TP for the Services interface document set includes the following 16 parts:

– Part 1: Web Services Interoperability. HFS sender
– Part 2: Web Services Interoperability. HFS receiver
– Part 3: SOAP/ATNA. HFS sender
– Part 4: SOAP/ATNA. HFS receiver
– Part 5: PCD-01 HL7 Messages. HFS sender
– Part 6: PCD-01 HL7 Messages. HFS receiver
– Part 7: Consent Management. HFS sender
– Part 8: Consent Management. HFS receiver
– Part 9: hData Observation Upload. HFS sender
– Part 10: hData Observation Upload. HFS receiver
– Part 11: Questionnaires. HFS sender
– Part 12: Questionnaires. HFS 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: HIR Observation Upload: Health & Fitness Service receiver

10.7 HIS test suite structure and test purposes specification

The scope of [ITU-T H.821] is to provide test suite structure and test purposes (TSS & TP) for the healthcare information system (HIS) interface based on the requirements defined in Continua Specifications. The objective is to provide a high probability of air interface interoperability between different devices via the healthcare information system (HIS) interface to transfer patient information from a Health & Fitness Service (HIS sender) to a healthcare information system (HIS receiver).

This document only focuses on the TSS & TP for HIS sender because, at this moment, HIS Receiver is out of the scope of Continua Certification Program.

The set of HIS interface test purposes includes two groups:

Group 1 HIS sender

Group 2 HIS receiver

10.8 Non-Continua hardware/software test requirements

In general, changes to non-Continua hardware or software are considered Type U (changes are superficial, or identification related not requiring software or hardware modifications). However, if the size or format of the data changes, the timing changes, the CPU changes or the message changes, then retesting for such changes is required.

10.9 PHD interfaces

This clause defines retesting certification procedures.

10.10 Inconclusive results

All devices going through testing are required to receive passing results for the Certified Device Classes claimed and for each applicable test within the test plan. A waiver may be pursued if a device does not receive a PASS verdict (instead it receives either an INCONC or FAIL) yet the member believes they are compliant with the respective standard, guideline or specialization.

10.11 Self-testing

Members should provide the XML output from running the test procedure for all applicable test procedures. If a test procedure does not apply, the reason why it does not should be included in the Statement of Compliance (for self-declaration) or provided to the CertAdmin (for Certification by a certification body).

11 Interoperability assessment test specification

In general, the set of interoperability procedures that are used for certification is a subset of the set of procedures that are used at a plugfest. The interoperability procedures used for certification are designed around the basic functionality of typical use cases for a device specialization. This is in contrast to interoperability procedures for plugfests, which may exercise error paths, simulate error conditions or try to cause devices to exhibit non-compliant behaviour (known as negative testing).

Interoperability testing for conformity assessment is conducted by test labs. Test labs are required to keep a test bed of certified Continua devices. Test labs conducting interoperability testing will perform the interoperability procedures specified in the certification specification using the DUT and each of the three pair devices. The DUT must pass all the required test cases when paired with each of the devices.

In the case where an interoperability procedure fails, the test lab will need to determine if the DUT or the paired device is at fault. If the paired device is at fault, the test lab must report the failure to the CertAdmin. The CertAdmin will notify the device manufacturer and help guide them to take appropriate corrective action.

If at the time of the certification there are not three certified Continua devices for a device specialization, the test lab will run interoperability pair testing against all available certified devices (if any).

Note that the interoperability program against certified Continua devices will not go into effect until:

1) Approved interoperability procedures exist for the DUT, and
2) The test lab or the plugfest program has certified Continua devices that can pair with the DUT.

11.1 Personal Health Devices interface functional test procedures

The following test procedures document a process that starts by having an application that is controlling a manager issue a request to enter the *Unassociated* state defined within Figure 10 of [ISO/IEEE 11073-20601-2016] (Manager state machine diagram). If the application does not have explicit control over this process, it should use a power on sequence to reach this state.

– General procedures
– Temporary measurements
– PM store
– Scanner

11.2 Services interface functional test procedures

The following Services interface test procedures document a process that starts by having an application, the Health & Fitness Service (HFS) sender, which typically resides on a personal health gateway (PHG) and is responsible for sending the appropriate HL7 messaging representing the desired measurements taken. The HFS sender then transmits the measurements to a HFS receiver, which typically resides on a HFS hosting server and is responsible for receiving and handling the desired measurements and performing any further and more intelligent processes.

– General procedures
– Batch measurements
– Continuous measurements
– Multiple connections – HFS receivers

12 Test reports

Both detailed and summary test reports are used to communicate results of conformity assessment tests. These reports follow the requirements of ISO/IEC regarding test report content.

12.1 Detailed test report

The detailed test report states the results of each test and is confidential between the test lab and the vendor providing the product under test. This report is provided to the CertAdmin when applying for Continua Certification.

12.2 Summary test report

The summary test report documents and highlights test results sufficiently to clearly qualify and document the Certified Capability Classes being declared compliant to the Continua Design Guidelines and identify the product under test. This report is intended to be made public but is made so at the discretion of the vendor.

13 Continua test tool

A Continua test tool provides two major functions: user interface and test case database.

A user manual is useful to provide a detailed description of the usage and features of the test tool and to guide the test operator through all the steps: parameters, test execution and result reporting.

The Continua test tool also contains a database of test cases from which product specific test procedures are generated based on PIX/PICIT.

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