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SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Personal health systems

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Interoperability design guidelines for personal health systems

Recommendation ITU-T H.810

ITU-T

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Recommendation ITU-T H.810

Interoperability design guidelines for personal health systems

Summary

The Continua Design Guidelines (CDG) defines a framework of underlying standards and criteria required to ensure the interoperability of devices and data used for personal connected health. It also contains design guidelines (DGs) that further clarify the underlying standards or specifications by reducing options or by adding a missing feature to improve interoperability. These guidelines focus on the following interfaces:

– TAN-IF – Interface between touch area network (TAN) health devices and application hosting devices (AHDs)

– PAN-IF – Interface between personal area network (PAN) health devices and AHDs

– LAN-IF – Interface between local area network (LAN) health devices and AHDs

– WAN-IF – Interface between AHDs and wide area network (WAN)

HRN-IF – Interface between WAN health devices and health record network (HRN).

Recommendation ITU-T H.810 is part of the "ITU-T H.810 interoperability design guidelines for personal health systems" subseries, as follows:

Mapping of CDG 2013, ITU-T H.810 and restructured ITU-T H.810-series

Part	Elements	Clauses in the 2013 CDG "Endorphin"	Clauses in ITU-T H.810 (2013)	Restructured ITU-T H.810-series (2015)
Part 0	System overview	Up to clause 3, plus Annex A and Appendix G	Up to clause 6, plus Annex A and Appendix V	ITU-T H.810 – System overview
Part 1	TAN/ PAN/LAN	Clauses 4 to 7, Appendices C, D, M	Clauses 7 to 10, Appendices I, II, XI	ITU-T H.811 – TAN-PAN-LAN Interface
Part 2	WAN	Clause 8, Appendices H, I, J, K	Clause 11; Appendices VI, VII, VIII, IX	ITU-T H.812 – WAN interface ITU-T H.812.1 – Observation upload ITU-T H.812.2 – Questionnaires ITU-T H.812.3 – Capability exchange ITU-T H.812.4 – Authenticated persistent session
Part 3	HRN	Clause 9, Appendices E, F, L	Clause 12, Appendices III, IV, X	ITU-T H.813 – HRN interface

History

Edition	Recommendation	Approval	Study Group	Unique ID*
1.0	ITU-T H.810	2013-12-14	16	11.1002/1000/12067
2.0	ITU-T H.810	2015-11-29	16	11.1002/1000/12651

* 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.

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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/.

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0 Introduction

The Continua Design Guidelines (CDG) define a framework of underlying standards and criteria that are required to ensure the interoperability of devices and data used for personal connected health. They also contain design guidelines (DGs) that further clarify the underlying standards or specifications by reducing options or by adding missing features to improve interoperability. These guidelines focus on the following interfaces:

– TAN-IF – Interface between touch area network (TAN) health devices and AHDs.

– PAN-IF – Interface between personal area network (PAN) health devices and AHDs.

– LAN-IF – Interface between local area network (LAN) health devices and AHDs.

– WAN-IF – Interface between AHDs and wide area network (WAN).

– HRN-IF – Interface between WAN health devices and health record network (HRN).

The CDG are a product of the Personal Connected Health Alliance (PCHA), which is an international not-for-profit industry organization enabling end-to-end (E2E), plug-and-play connectivity of devices and services for personal health management and healthcare delivery.

Its mission is:

Generating greater awareness, availability and access to plug-and-play, consumer-friendly personal health technologies to empower individuals to better manage their health and wellness, anywhere at any time. For more information visit: www.pchalliance.org.

In the DGs, reference is made to specifications from: Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), ISO/IEEE, Bluetooth, ZigBee, Internet Engineering Task Force (IETF), World Wide Web Consortium (W3C), Organization for the Advancement of Structured Information Standards (OASIS) and Object Management Group (OMG).

0.1 Organization

The CDG is comprised of a series of specifications, which taken as a whole represent a yearly release. Table 0-1 shows the different specifications included in this release.

Table 0-1 – Design specifications

Recommendation	Area covered
ITU-T H.810	System Overview
ITU-T H.811	TAN/PAN/LAN
ITU-T H.812	WAN
ITU-T H.812.1	Observation upload
ITU-T H.812.2	Questionnaire
ITU-T H.812.3	Capability exchange
ITU-T H.812.4	Authenticated persistent session (APS)
ITU-T H.813	Health record network (HRN)

This specification is organized in the following manner:

Introduction and clauses 0 to 5: Introduction and terminology – These clauses provide useful background information to help understand the structure of the specifications.

Clause 6: System overview – This clause explains the overall end-to-end architecture and scope of the design guidelines.

0.2 Guideline releases and versioning

As guidelines evolve over time, different versions are created. Table 0-2 shows the mapping of guidelines releases to version revisions.

Table 0-2 – Guideline releases and corresponding version numbers

Continua design guidelines	Also known as	Major version	Minor version
1.0		1	0
2010	1.5	1	5
2010 + Errata		1	6
2011	2.0, Adrenaline	2	0
2011 + Errata		2	1
2012	Catalyst	3	0
2012 + Errata		3	1
2014	Endorphin	4	0
2014 + Errata		4	1
2015	Genome	5	0

Subsequent to the initial version the yearly release of the CDG includes maintenance updates and additional guidelines that cover new functionalities. Where applicable an Errata release may be published that implements all ratified bugs for the prior release.

0.3 What's new

This is the first version of this specification as a separate re-formatted document.

Compared to preceding versions of the Continua Design Guidelines, the following changes were made to the content of this specification:

Across the PAN-IF

– PAN-IF interface guidelines for LP wireless PAN (Bluetooth LE) for Weight Scales are included.

– The PAN-IF interface guidelines for PAN wired (USB) and PAN standard wireless (Bluetooth) for Sleep Apnoea Breathing Therapy Equipment (SABTE) are included.

Guidance on handling time adjustments in devices with limited memory was added.

Across the WAN-IF

– Uploading observations using RESTful HTTP method.

– Significant clarifications and edits for handling of sensor timestamps across the WAN-IF interface.

– The guidelines for creating a PCD-01 document were re-written for easier implementation.

– New guidelines for the exchange of questionnaires and questionnaire responses, consent management, and enforcement using the RESTful HTTP method.

– New guidelines for APS using message queuing telemetry transport (MQTT).

– New guidelines for capability exchange using HL7 HRF specification.

0.4 White papers

This clause highlights white papers that have been published to address areas not directly covered by the CDG.

These white papers can be found here: http://www.continuaalliance.org/connected-health-vision/white-papers, and they are also listed in the bibliography.

Where relevant, additional links may be found in the appropriate clause of the CDG.

0.4.1 Implementation guidelines for cellular modems embedded into medical devices

In order to aid members who wish to implement wireless connectivity directly into medical sensors by physically attaching a cellular module to the sensor, a white paper has been published to address device-specific recommendations.

Work has been carried out with leading operators, device vendors and cellular organizations like GSMA to provide an overview of mobile network-specific considerations that should be kept in mind when designing medical sensors with embedded modems, so that they are interoperable and optimized for use with cellular connectivity.

0.4.2 Recommendations for USB PHDC device driver interoperability

This paper defines a position on USB PHDC driver interoperability pertaining to the CDG. Potential problems with interoperability related to Windows USB PHDC device drivers are evaluated and recommendations that developers of PAN Managers for USB transport can implement are made. Based on the analysis of these problems, recommendations for a strategy is discussed and the handling of generic Windows drivers based on WinUSB and LibUSB are provided. This paper does not cover application level interoperability beyond the development of USB drivers.

0.5 Certification programme

A test and certification programme is designed and run by the Personal Connected Health Alliance to ensure that certified products conform to the standards and specifications defined in the design guidelines and its underlying standards. Devices featuring the Continua logo indicate that the device has met the Continua conformance requirements as well as basic interoperability requirements with other CDG-compliant devices.

Devices passing such programme may use the Continua defined logo to indicate their compatibility. Details are spelt out in clause 6.1.4.

Recommendation ITU-T H.810

Interoperability design guidelines for personal health systems

1 Scope

The Continua Design Guidelines (CDG) include guidelines for the TAN-IF, PAN-IF (wired, standard wireless and low-power wireless), local area network interface (LAN-IF) (sensor LAN), WAN-IF and HRN-IF.

The TAN-IF (near-field communication (NFC)) guidelines are defined for the following device specializations: pulse oximeter, blood pressure monitor, thermometer, weighing-scales, glucose meter, cardiovascular fitness, step counter, strength fitness, activity hub, adherence monitor, peak flow meter, fall sensor, motion sensor, enuresis sensor, contact closure sensor, switch sensor, dosage sensor, water sensor, smoke sensor, property exit sensor, temperature sensor, usage sensor, personal emergency response system (PERS) sensor, carbon monoxide (CO) sensor, gas sensor, heart-rate sensor, Basic 1-3 lead electrocardiograph (ECG) sensor, body composition analyser, international normalized ratio (INR) meter and sleep apnoea breathing therapy equipment (SABTE).

The PAN-IF guidelines for PAN wired (universal serial bus (USB)) and PAN standard wireless (Bluetooth) are defined for the following device specializations: pulse oximeter, blood pressure monitor, thermometer, weighing-scales, glucose meter, cardiovascular fitness, step counter, strength fitness, activity hub, adherence monitor, peak flow meter, fall sensor, motion sensor, enuresis sensor, contact closure sensor, switch sensor, dosage sensor, water sensor, smoke sensor, property exit sensor, temperature sensor, usage sensor, PERS sensor, CO sensor, gas sensor, heart-rate sensor, Basic 1-3 lead ECG sensor, body composition analyser, INR meter, SABTE, low power (LP) wireless: weight scale.

The PAN-IF guidelines for LP wireless PAN (Bluetooth low energy (LE)) are defined for the following: thermometer, heart-rate sensor, blood pressure monitor and glucose meter.

The sensor-LAN (ZigBee) interface guidelines are defined for the following device specializations: pulse oximeter, blood pressure monitor, thermometer, weighing-scales, glucose meter, cardiovascular fitness, step counter, strength fitness, activity hub, adherence monitor, peak flow meter, fall sensor, motion sensor, enuresis sensor, contact closure sensor, switch sensor, dosage sensor, water sensor, smoke sensor, property exit sensor, temperature sensor, usage sensor, PERS sensor, CO sensor, gas sensor, heart-rate sensor, Basic 1-3 lead ECG sensor, body composition analyser, INR meter and SABTE.

The WAN-IF guidelines are defined for 1) upload of device observations using simple object access protocol (SOAP) and RESTful HTTP; 2) exchange of questionnaires and questionnaire responses; 3) consent management and enforcement using SOAP and RESTful HTTP; 4) authenticated persistent session (APS) and 5) capability exchange using hData hRF.

The HRN-IF guidelines are defined for a health record interface towards (other) enterprise systems. In addition, the HRN-IF guidelines for consent management and enforcement are defined.

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.

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[ITU-T H.812] Recommendation ITU-T H.812 (2015), *Interoperability design guidelines for personal health systems: WAN interface: Common certified device class*.

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[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*.

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fitness equipment.
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[ISO/IEEE 11073-10472] ISO/IEEE 11073-10472:2012, *Health informatics – Personal health device communication – Part 10472: Device specialization – Medication Monitor*.
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3 Definitions

3.1 Terms defined elsewhere

The design guidelines uses the following terms defined elsewhere:

3.1.1 audit trail and node authentication (ATNA): Used in the context of the IHE IT infrastructure technical framework [IHE ITI-TF-1], audit trail and node authentication (ATNA) integration profile establishes security measures which, together with the security policy and procedures, provide patient information confidentiality, data integrity and user accountability.

3.1.2 relative time [ISO/IEEE 11073-20601]: This represents a number of ticks from some time reference point, but each device may have a different reference point. To convert to a *date & time*, one must know the duration of each counter tick and correlate some initial counter tick with a known reference point in *Universal Time*. Complementary to *Universal Time*.

3.2 Terms defined in this Recommendation

This Recommendation defines the following terms:

3.2.1 actor*:* Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities (adapted from [IHE PCD-TF-2]).

3.2.2 actuator: See actuator service component.

3.2.3 actuator information*:* The information accepted by an actuator service component for initiating external actions.

3.2.4 actuator service component: An actuator service component accepts control messages to initiate an external action. This includes, for example, displaying output on a screen, creating an audible notification, producing a tactile output, or controlling other systems (e.g., raising or lowering the heat in a home). This is represented in Continua as an actuator service component in a PAN device or LAN device.

3.2.5 aging independently (AI): One of the three vertical domains supported by Continua. It is complementary to disease management and health & fitness.

3.2.6 alarm: The external enunciation of either physiological conditions, equipment conditions, or other conditions that need attention. Alarm is complementary to alert and event.

3.2.7 alert: When an attempt should be made to notify somebody of a condition (e.g., an event), an alert is distributed within the system to actuator devices (either in the home or in a remote monitoring environment). Alert is complementary to alarm and event.

3.2.8 application hosting device (AHD): One of the Continua reference devices classes. An application hosting device is a central point of control in the Continua architecture. The application hosting device contains a number of client components that use the PAN, LAN and WAN interfaces to access one or more services on other devices to coordinate data collection, data analysis, data sharing and alerting.

3.2.9 AHD application: This is an application running on the application hosting device (AHD). The application may contain a number of client components (TAN, PAN, LAN, WAN) for purposes such as data collection, analysis and sharing.

3.2.10 batch communication: Collecting several documents or store and forward information together and transmitting them at the same time to increase the efficiency of bandwidth usage. Batch communication is complementary to transaction communication and streaming communication.

3.2.11 certified device class: Entity in the Continua E2E architecture for which a complete set of guidelines has been defined such that a device can be certified to comply with that set of guidelines via the Continua certification program.

3.2.12 client component: The Continua architecture uses a client/server (service) communication model across interfaces. A client component on one end interacts with a service component on the other end, via one of the defined interfaces (e.g., PAN, LAN, WAN or HRN interface).

3.2.13 clock: Refers to an entity that measures time.

3.2.14 clock synchronization: Refers to the process of updating a device's clock with other clocks in the environment.

3.2.15 command and response: An action or information is explicitly requested by another component in the environment. Commands and responses include the ability to get information, set configurations and execute actions. Command and response are complementary to notification.

3.2.16 comparable local time: Comparable local time refers to time (and date) that is specific to a physical device which can be compared and synchronized to Universal Time. The time zone and daylight savings time status for the physical device may not be known, but an offset to Universal Time can be obtained by querying the devices current time.

3.2.17 component: A component is an entity contained within a device as defined within the Continua architecture. In general, for any interface, there is a service component, with a well-defined set of functions on one side of the interface and one (or more) client components on the other side.

3.2.18 Continua LAN interface (LAN-IF): The Continua LAN interface connects one or more sensor/actuator client components to one or more sensor/actuator service components on a LAN.

3.2.19 Continua PAN interface (PAN-IF): The Continua PAN interface connects one sensor or actuator client component to an equivalent sensor (e.g., glucose meters, weighing scales, or heart rate monitors) or actuator (e.g., text output, alarms) service component over a personal area network.

3.2.20 Continua sensor-LAN interface: The Continua sensor-LAN interface is a particular sub-class of the Continua LAN interface. It connects one or more sensor/actuator service Components, which offer data/control at an application level, to one or more sensor/actuator client components on a sensor-LAN.

3.2.21 Continua sharing-LAN interface: The Continua sharing-LAN (also known as IP-LAN) interface is a particular sub-class of the Continua LAN interface. It connects one or more service components, which share data collected from possibly multiple measurement devices at an application level, to one or more client components on a sharing-LAN. In that sense, the sharing-LAN provides a common LAN representation regardless of where the underlying sensor or actuator lives.

3.2.22 Continua WAN interface (WAN-IF): The Continua WAN interface connects one or more remote monitoring client components to a remote monitoring service component (e.g., a PHR service hosted on a remote server) over a wide area network. For example, this could use IP or cellular network technology.

3.2.23 Continua HRN interface (HRN-IF): The interface between a disease management service (DMS) WAN device (WD) and an electronic health record (EHR) device.

3.2.24 continuous data collection: Continuous data collection takes samples at regular intervals. Continuous data collection is complementary to episodic data collection.

3.2.25 control: Control messages provide a mechanism to exchange commands and responses (e.g., get/set commands). These commands may be associated with physiology information or with equipment functionality.

3.2.26 counter*:* A counter is used to measure relative times (see the definition for relative time). Each counter tick is a very short length of time and may vary from counter to counter. It must be possible to query for the duration of each tick used by a counter.

3.2.27 counter synchronization: Refers to the process of synchronizing two or more counters within the environment. This is useful to ensure that the relative times from multiple devices can be correlated with one another.

3.2.28 cross-enterprise document media interchange (**XDM)**: The XDM protocol is published by the IHE. It provides a transport protocol for indirect communication of PHR documents transferred over the HRN interface.

3.2.29 cross-enterprise document reliable interchange (**XDR)**: The XDR protocol is published by the IHE. It provides a transport protocol for direct communication of health reports transferred over the HRN interface.

3.2.30 device: A device is a physical entity (box) and contains one or more components (functionality).

3.2.31 disease management: One of the three vertical domains supported by Continua. Disease management is complementary to health & fitness and aging independently.

3.2.32 document: A document holds summaries, reports, or histories for printing or sharing with other parties. A document is complementary to event and sensor information.

3.2.33 electronic health record (EHR): The electronic health record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter – as well as supporting other care-related activities directly or indirectly via the interface – including evidence-based decision support, quality management and outcomes reporting.

3.2.34 electronic medical record (EMR)*: EMRs* are computerized legal clinical records created in care delivery organizations (CDOs) such as hospitals and physician offices. An *Electronic Medical Record* is owned by the organization, practice or corporation that provided the health care – be it a clinic, a hospital or a doctor.

3.2.35 episodic data collection: Episodic data collection corresponds to an episode, usually at irregular intervals. The time between samples can vary widely from seconds to weeks or longer. Episodic data collection is complementary to continuous data collection.

3.2.36 event: The occurrence of a condition. An event is complementary to alert and alarm.

3.2.37 health device profile (HDP)*:* Bluetooth HDP is a standard profile defined by the Bluetooth SIG for health devices that use Bluetooth as an underlying transport standard. Bluetooth HDP may be used by Continua PAN devices.

3.2.38 health & fitness: One of the three vertical domains supported by Continua. Health & fitness is complementary to disease management and aging independently.

3.2.39 HRN receiver: A service component of the HRN interface that is the recipient of a health report. The health report is transferred via either XDR or XDM.

3.2.40 HRN sender: A client component of the HRN interface. An HRN sender transmits health reports to the HRN receiver via either XDR or XDM (or both).

3.2.41 IHE transaction: (definition adapted from [IHE PCD-TF-1]) An IHE transaction is a set of interactions between IHE actors that transfers required information through standards-based messages.

3.2.42 integrity: A part of system reliability that relates to information consistency and assuring that information will not be accidentally or maliciously altered or destroyed. Incorrect, corrupted data cannot be mistaken for being correct.

3.2.43 interoperability: The ability of client components in a device to communicate and share data with service components in an unambiguous and predictable manner to exchange data accurately, effectively and consistently; and to understand and use the information that is exchanged. Continua has created and selected requirements to incorporate into these design guidelines to ensure that Continua certified devices embody the principal of interoperability.

3.2.44 interface: An interface is an information interchange point between two components.

3.2.45 LAN device: A LAN device is a device that embeds a service component that acts on a LAN interface.

3.2.46 LAN interface: See Continua LAN interface.

3.2.47 local time: Local time refers to a time (and date) that is specific to a geographic location. The time zone for that location may or may not be known. If it is known, converting to Universal Time is straightforward.

3.2.48 measurement*:* A measurement is a measurable observation that is received from a device.

3.2.49 non-certified interface: This represents any interface whose service and client components will not be certified by Continua. In some cases, these are proprietary interfaces that are unlikely to become certified at any time in the future. In other cases, it may represent an interface that has not been addressed by Continua yet, but could be in the future.

3.2.50 notification: Information is sent to one or more components in the environment via regular packets in a data stream, or via some non-deterministic mode such as publishing events and measurements to subscribers. Notification is complementary to command and response.

3.2.51 observation*:* An observation is an observable datum from the physical world.

3.2.52 PAN device: A PAN device is a device that houses a service component that exposes the PAN interface.

3.2.53 PAN interface: See the Continua PAN interface clause of this Recommendation.

3.2.54 PCD-01*:* It is the IHE patient care device transaction 01, which is a transaction used to communicate patient care device (PCD) data.

3.2.55 persistent session: A component in the conceptual model of an AHD that is administratively created. A persistent session stores and forwards observations to a WAN device. Observations enter a persistent session for forwarding when the observation meets a set of criteria defined in admission rules associated with the particular persistent session.

3.2.56 personal healthcare monitoring report (PHMR): An XML document conforming to "HL7 Implementation Guide for Personal Healthcare Monitoring Report (PHMR) International Realm Based on HL7 CDA Release 2.0" The personal healthcare monitoring report is a document that carries personal health monitoring data. The data transmitted from sender is either in the form of a summary or in the form of raw data. The summarization may be a result of analysis by an authentic disease management service provider. The data has multiple characteristics including: representation of measurements captured by devices; representation of notes, summary and other types of narrative information that may be added by care givers or by the user themselves; and representation of graphs that may be added by intermediary devices that represent user health trends.

3.2.57 personal health record (PHR): The personal health record (PHR) is an electronic, universally available, lifelong resource of health information needed by individuals to make health decisions. Individuals own and manage the information in the PHR, which comes from healthcare providers and the individual. The PHR is maintained in a secure and private environment, with the individual determining rights of access. The PHR is separate from and does not replace the legal record of any provider.

3.2.58 privacy: An aspect of system security (preventing undesired system use) that deals with providing access to the parties to which the information belongs and to parties that have explicitly been allowed access to certain information (also known as confidentiality).

3.2.59 quality of service (QoS): Quality of service is the collection of properties that define characteristics of an interface connection. This set of these properties includes aspects of the communication link such as reliability, latency, bandwidth, etc.

3.2.60 reference device class: The basis of the guidelines framework includes a number of reference device classes where topology constraints are explicitly noted.

3.2.61 sensor: See sensor service component.

3.2.62 sensor information: The information provided by a sensor service component.

3.2.63 sensor service component: A sensor service component allows access to digital representations of external conditions and events. This includes measurements of temperature, motion or electrical conditions.

3.2.64 service component: Service is a specific type used in the Continua architecture for any component that provides a service to a client component.

3.2.65 simplicity: Simplicity is the property, condition, or quality of being simple or un-combined. It often denotes beauty, purity or clarity. Simple things are usually easier to explain and understand than complicated ones.

3.2.66 store and forward: This is a technique that is often used by a device when the connection to a partner may be intermittent. The sender stores the data and transmits all stored data to its partner at a later moment in time (e.g., when connection is available again). The most typical use of store and forward is with episodic data; however, this technically can also be used with continuous data.

3.2.67 streaming communication: A continuous, uninterrupted flow of data (e.g., measurements and/or events) from one component to another. Typically this data is sent in near real-time and contains data sampled at regular intervals. Multiple samples may be placed in a single communication packet to utilize the network bandwidth efficiently. Streaming communication is complementary to transaction communication and batch communication.

3.2.68 time code: When relative time data is communicated, a time code is added to the data to indicate the relative time at which the data was collected, transmitted, or received.

3.2.69 time mark: The term time mark is used in instances where either a time code or timestamp can be used.

3.2.70 timestamp: When comparable local time or Universal Time data is communicated, a timestamp is added to indicate the time at which the data was collected, transmitted or received.

3.2.71 transaction communication: A communication method where one component exchanges acknowledged notifications or command and responses with another component to ensure reliability. Transaction communication is complementary to streaming communication and batch communication.

3.2.72 Universal Time: This represents time (and date) with respect to some well-known reference point (e.g., UTC). Once synchronized, all devices that support Universal Time report the same time within the limits of clock drift error. Universal Time is complementary to relative time.

3.2.73 WAN application: This is an application running on the WAN device (WD). The application may contain a number of WAN service components and/or HRN client components for purposes such as data collection, analysis and sharing.

3.2.74 WAN device (WD): A WD is defined by the Continua end-to-end (E2E), reference architecture as a WAN observation receiver Device, an HRN sender device, or both.

3.2.75 WAN interface: See the Continua WAN interface clause within this Recommendation.

3.2.76 WAN observation receiver device: A Continua certified device class. This device class implements the WAN interface component that sinks device observations.

3.2.77 WAN observation sender device: A Continua certified device class. This device class implements the WAN interface component that sources device observations.

4 Abbreviations and acronyms

The design guidelines uses the following abbreviations and acronyms:

AA	HL7 Acknowledgement Accepted
AHD	Application Hosting Device
AI	Ageing Independently
API	Application Programming Interface

APS	Authenticated Persistent Session
ASTM	American Society for Testing and Materials
ATNA	Audit Trail and Node Authentication
BMI	Body Mass Index
CCCC	Continua Certified Capability Classes
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDG	Continua Design Guidelines
CE	Compute Engine (*deprecated*)
CMS	Cryptographic Message Syntax
CO	Carbon monoxide
CRC	Cyclic Redundancy Check
DEC	Device Enterprise Communications
DG	Design Guideline
DMO	Disease Management Organization
DOC	Device Observation Consumer
DOR	Device Observation Reporter
E2E	End-to-end
ebXML	electronic business using extensible Markup Language
ECC	Error Correcting Code
ECG	Electrocardiograph
EDI	Electronic Data Interchange
EHR	Electronic Health Record
EMR	Electronic Medical Record
EUI	Extended Unique Identifier
FCS	Frame Check Sequence
FTP	File Transfer Protocol
GUID	Globally Unique Identifier
HC	Health Care
HDP	Health Device Profile
HF	Health and Fitness
HIE	Healthcare Information Exchange
HIPAA	Health Insurance Portability and Accountability Act
HTTP	Hypertext Transfer Protocol
HR	Health Report
HRF	hData Record Format

HRN	Health Record Network
HRN-IF	Health Record Network Interface
HTTPS	Hypertext Transfer Protocol over Secure Socket Layer
IF	Interface
IIHI	Individually identifiable health information
INR	International Normalized Ratio
ITI	IT Infrastructure
N-IF	Network Interface
IP	Internet Protocol
L2CAP	Logic Link Control and Adaptation Protocol
LAN	Local Area Network
LAN-IF	Local Area Network Interface
LE	Low Energy
LP	Low Power
MAC	Media Access Control
MCAP	Multi-Channel Adaptation Protocol
MDEP	MCAP Data End Point
MDS	Medical Device System
MITM	Man In The Middle
MQTT	Message Queuing Telemetry Transport
MSH	Message Header
MTOM	Message Transmission Optimization Mechanism
NHIN	Nationwide Health Information Network
NFC	Near-field communication
OSI	Open Systems Interconnection
OUI	Organizationally Unique Identifier
PAN	Personal Area Network
PAN-IF	Personal Area Network Interface
PC	Personal Computer
PCC	Patient Care Coordination
PCD	Patient Care Device
PCD-01	IHE Patient Care Device Transaction 01
PERS	Personal Emergency Response System
PHDC	Personal Healthcare Device Class
PHM	Personal Healthcare Monitoring
PHMR	Personal Healthcare Monitoring Report
PHR	Personal Health Record

PIN	Personal Identification Number
POTS	Plain Old Telephone Service
QoS	Quality of Service
RBAC	Role Based Access Control
RHIO	Regional Health Information Organization
RPM	Remote Patient Monitoring
SDP	Service Discovery Protocol
SDU	Service Data Unit
SDWG	Structured Documents Workgroup
SOAP	Simple Object Access Protocol
SpO2	Percentage of Oxygen Saturation in blood
SSL	Secure Socket Layer
SSP	Secure Simple Pairing
TAN	Touch Area Network
TCP	Transmission Control Protocol
TCWG	Test and Certification Working Group
TLS	Transport Level Security
TWG	Technical Working Group
UCUM	Unified Code for Units of Measure
UDP	User Datagram Protocol
USB	Universal Serial Bus
UTC	Coordinated Universal Time
v1	Version 1
WAN	Wide Area Network
WAN-IF	Wide Area Network Interface
WD	WAN Device
XDM	cross-enterprise Document Media interchange
XDR	cross-enterprise Document Reliable interchange
XDS	cross-enterprise Document Sharing
XDS.b	cross-enterprise Document Sharing-b
XML	extensible Markup Language

5 Conventions

5.1 Guideline terminology and conventions

This clause defines the format and terminology for the Design Guidelines (DGs) where the term *Continua* is used to designate functionality and architectural elements defined in the DGs, or devices that are implemented according to it.

5.1.1 Guideline compliance classifiers

The details of each guideline will carry a compliance classifier from the following set (adapted from [b-IETF RFC 2119]):

– **Shall** – This term designates the minimum set of requirements that ensure interoperability and/or robust operation between components. All components and interfaces are expected to comply with these requirements when expressed in unconditional form. A conditional requirement expressed in the form, "If X, then Y "shall" be implemented", means that the requirement "Y" must be met when the conditional aspect "X" applies to a given implementation.

– **Should** – This term designates strongly recommended items. Under most circumstances, implementations include "should" requirements; however, it is recognized that there may exist valid reasons in particular circumstances where it is preferable not to implement a "should" requirement. These conditions must be carefully understood and weighed up given that this may reduce the interoperability of that product.

– **May** – The use of this term highlights to product implementers features that "may" exist in the marketplace. All products must be prepared to interoperate with implementations that have and have not implemented the requirement. If optional features are included in a product, they must comply with the requirement to ensure interoperability with other implementations.

5.1.2 Guideline font usage conventions

The following font usage conventions are used within the CDG to provide additional clarity:

Requirement terms are in **bold** font. The terms described in clause 5.1.1 are in **bold** font when used in the requirement sense.

5.1.3 Design guidelines format

This clause details the format of a DG, see an example in Table 5-1.

Table 5-1 – Design guideline example

Name	Description	Comments
Wired_PAN_USB_ Personal_ Healthcare_v1.0	Continua PAN wired USB service and client components **shall** implement the USB Personal Healthcare Device Class v1.0 plus the 15 Feb. 2008 errata, subject to the requirements listed below.	

The design guideline table heading categories are as follows:

– **Name** – A unique label for the guideline

– **Description** – Text that describes the design guideline

– **Comments** – Supplementary information about a design guideline such as a justification for it, dependencies, etc.

6 System overview

6.1 E2E system architecture

This clause defines the end-to-end (E2E) architecture for the Continua ecosystem. The Continua architecture is used for several purposes:

– definition of common concepts

– definition of topology constraints for the Continua ecosystem

– serve as a basis for the guidelines framework by providing a basic structure, providing rules for refinement and extension of this structure, and the association of guidelines with elements in this structure.

NOTE – In this Recommendation, "Continua architecture" and " Continua E2E architecture" are used interchangeably.

6.1.1 Devices, components, application and interfaces

The Continua architecture distinguishes devices (physical entities) from components (logical entities) and applications (logical entities). This distinction is general and not specific for Continua reference device classes, Continua certified device classes, or Continua logo-ed device classes that are defined later in this Recommendation (see clause 6.1.4). Devices may host zero or more applications which may then group zero or more components. The above is depicted by Figure 6-1.

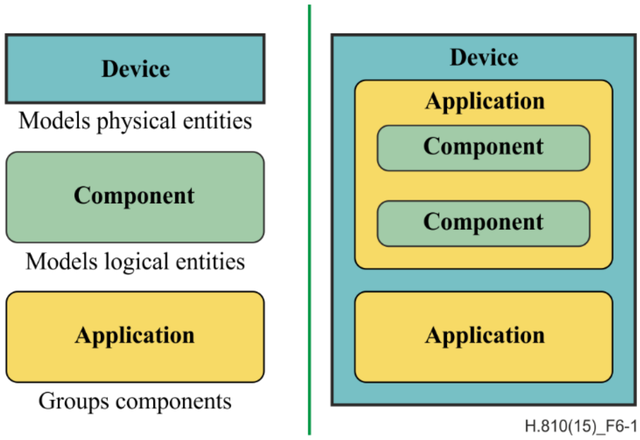

Figure 6-1 – Device, component and application

Components implement and require the implementation of a number of interfaces as shown in Figure 6-2.

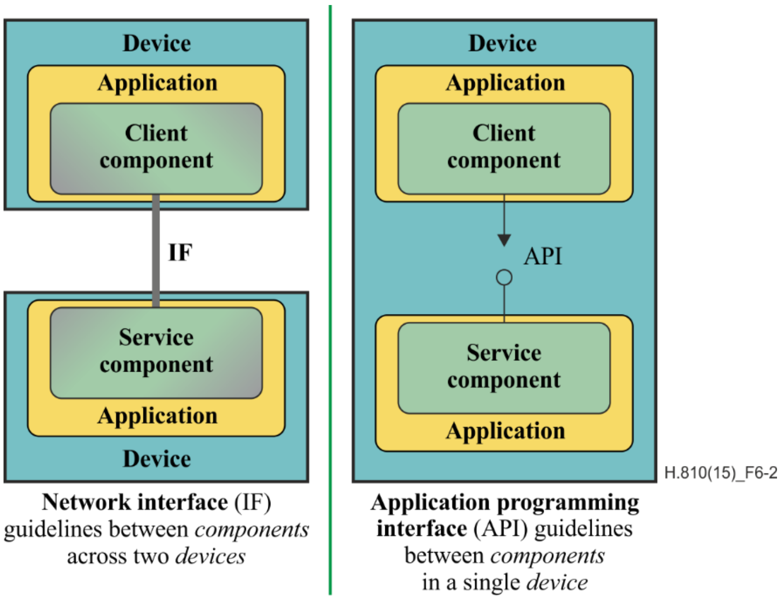

Figure 6-2 – Interfaces between components

The CDG makes the distinction between network interface (N-IF) guidelines and application programming interface (API) guidelines. A component implementing an API is depicted by Figure 6-3.

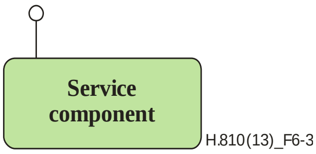

Figure 6-3 – Component implements API

A component requiring the implementation of an API shown in Figure 6-4.

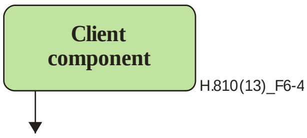

Figure 6-4 – Component requires the implementation of an API

A component implementing a network interface specification is shown by Figure 6-5: a service component with left-top to right-bottom shading.

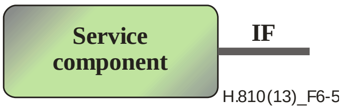

Figure 6-5 – Component implements N-IF

A component requiring the implementation of an N-IF is shown in Figure 6-6: A client component with right-top to left-bottom shading.

Figure 6-6 – Component requires implementation of of an N-IF

The main difference between an application programming interface (API) and network interface (N-IF) is that an API is an interface between components within a single device and an IF is the interface between components on multiple devices.

For these design guidelines, the focus is on the interoperability between devices. Interoperability is enabled via the characteristic behaviour of devices found in a communications system. There are fundamental characteristics that manifest as part of the interface specifications that define the configuration and formats to facilitate interoperability. These specifications are the contracts between devices that ensure that a dialogue can occur.

6.1.2 Design guideline types

Interface guidelines are implemented by zero or more components and a component may implement zero or more interface guidelines. Interface guidelines can be created for APIs as well as N-IFs.

For the CDG, the focus is on device interoperability. This implies a focus on N-IF guidelines. In future versions of the CDG, there may be a need for common middleware that gives a unified view for services and clients on the different service N-IFss. The API guidelines will then fall under the CDG scope as well.

Interface guidelines enable interoperability across a single interface. Device guidelines are specified to enable E2E interoperability (interoperability across interfaces) and interaction with the environment.

This version of the CDG contains both interface guidelines, as well as device guidelines.

6.1.3 Reference device classes and system topology

Devices are physical entities that can host a number of components. The Continua E2E architecture distinguishes different reference device classes based on the component classes hosted on that device.

Reference device classes are used to define topology constraints for the Continua ecosystem and form the basis of a guidelines framework. Topology constraints are defined for the Continua ecosystem as some topologies are not viable.

The current Continua E2E architecture distinguishes the following reference device classes:

– **TAN device:** This is a device that deploys at least one TAN-IF service component. TAN-IF service components are TAN-IF sensor service components, TAN-IF storage service components, TAN-IF actuator service components, etc.

– **PAN device:** This is a device that deploys at least one PAN-IF service component. PAN-IF service components are PAN-IF sensor service components, PAN-IF storage service components, PAN-IF actuator service components, etc.

– **LAN device:** This is a device that deploys at least one LAN-IF service component. Additionally, these service components can be instances of one of the subclasses of LAN-IF service components.

– **Application hosting device (AHD):** This is a device that deploys at least one PAN-IF client component, LAN-IF client component, TAN-IF client component, or WAN-IF client component.

– **WAN device (WD):** This is a device that deploys at least one WAN-IF service component or at least one HRN-IF client component.

– **HRN device:** This is a device that deploys one or more HRN-IF service components.

– Figure 6-7 shows the above definitions and the associated graphical representation.

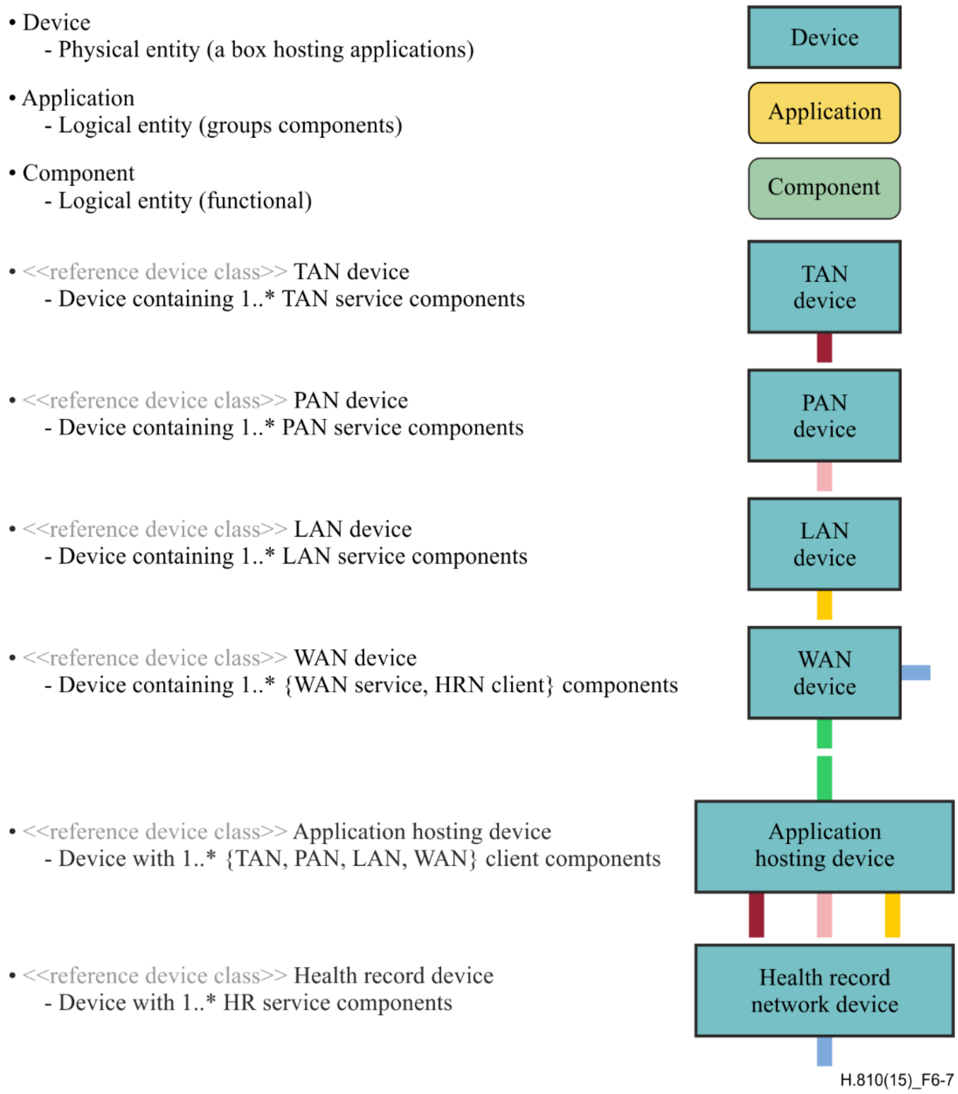

Figure 6-7 – Definitions and graphical notation

The classification of devices, according to the criteria listed above, is not exclusive. As an example, a device is able to be a LAN device and an AHD. It can contain a number of client components (application hosting) and one or more LAN-IF service components (LAN device).

The distinction between the different interfaces is based on architectural dimensions. The highest level (the basis for the reference device classes) has the following dimensions:

– Information exchange in close proximity (TAN). The interface provides ad-hoc communication with proximity-based pairing when a TAN device is brought close to the AHD.

Information exchange around a person (PAN). The architecture is not restrictive in the range around a person that is covered by the network. In practice, this will depend on the range of the cable or radio in a certain environment given certain power requirements. No infrastructure is required for the PAN (adhoc network).

– Information exchange at a location (LAN). The network is able to cover an entire location (building/campus). The LAN may rely on a network infrastructure in order to get the required coverage.

– Information exchange across the globe (WAN). This interface is typically the interface from the home/office/mobile towards the back end of a personal telehealth service provider.

– Reporting to enterprise systems (health record network). This interface enables reporting to for example the hospital and other personal telehealth service providers.

This architectural dimension is illustrated by Figure 6-8.

Figure 6-9 shows the reference device classes with a number of real-world examples.

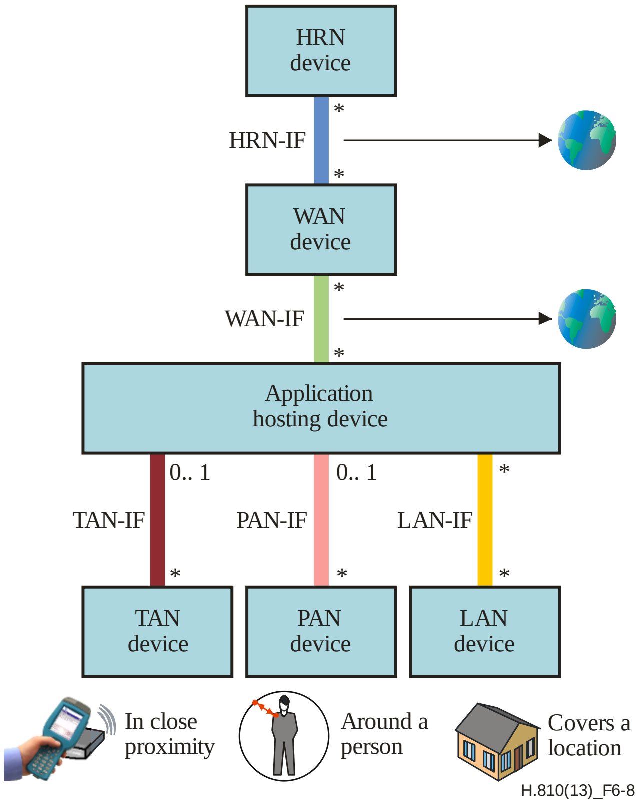

Figure 6-8 – Architectural dimension basis for reference device classes

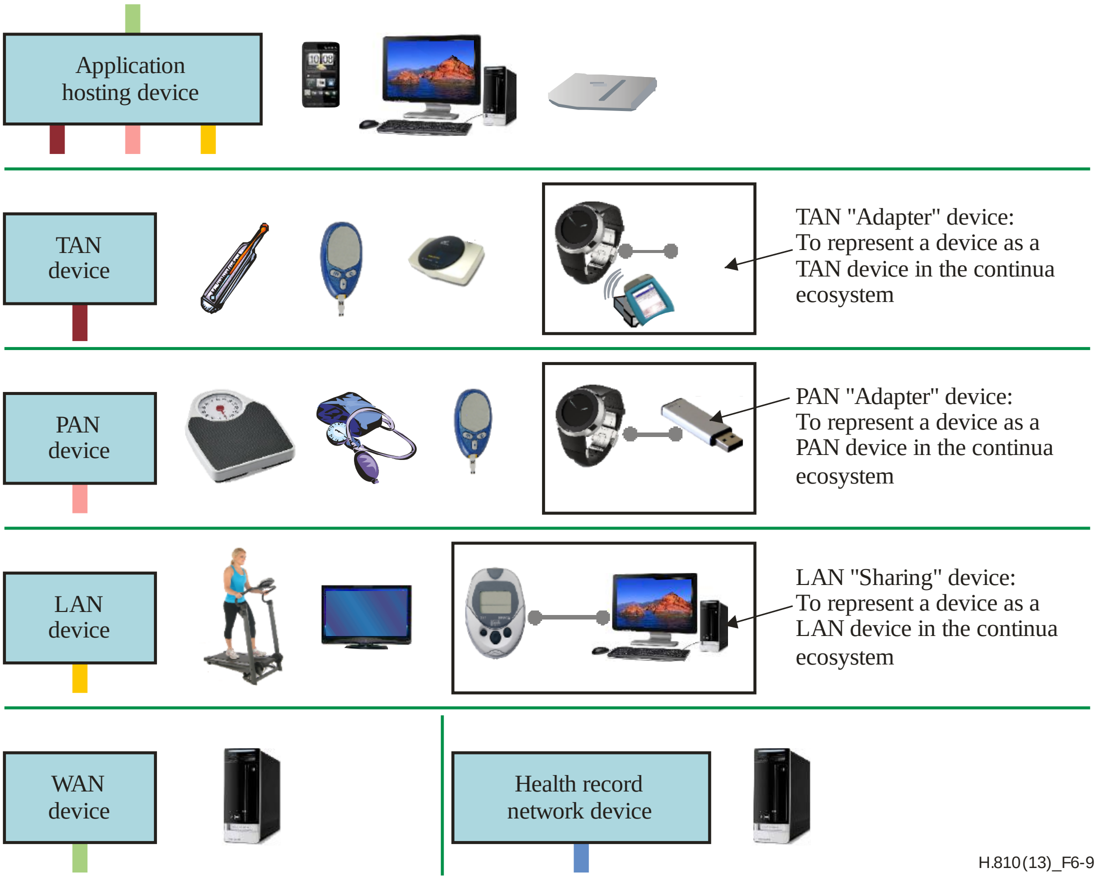

Figure 6-9 – Reference device classes and real-world examples

The topology constraints for the Continua ecosystem are defined using the reference device classes described above. These reference device classes provide an abstract model for real-world devices and are the basis for further specialization.

The PAN interface is specialized further based on the following dimension: wired – wireless. The wireless PAN interface is specialized further based on the following dimension: standard wireless – LP wireless. The result is the guidelines for a wired PAN interface (USB) and wireless PAN interface (Bluetooth) and for a LP wireless PAN interface (Bluetooth LE).

The LAN interface is specialized further based on the following dimension: sensor– sharing. Sensors act as a sensing unit device on the interface. Sharing devices act as a single device offering measurements collected from possibly multiple measurement devices (notion of aggregation). The result is guidelines for a sensor-LAN interface (ZigBee). Guidelines for a sharing-LAN interface are out of the scope of this version of the guidelines.

The Continua reference topology imposes a number of constraints on how reference device classes are physically connected. See Figure 6-10.

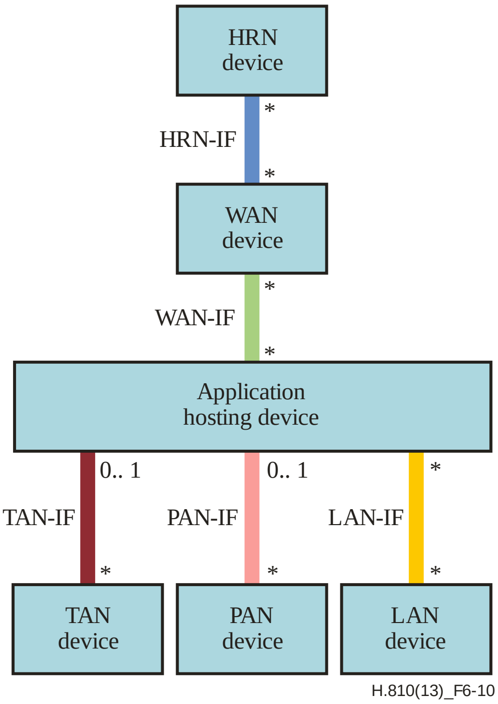

Figure 6-10 – Reference topology

This reference topology gives the following rules for the topology of the Continua ecosystem:

– TAN device "can serve" 0 or 1 AHDs at a time

– PAN device "can serve" 0 or 1 AHDs at a time

– LAN device "can serve" 0 or more AHDs at a time

– An AHD "can use" 0 or more {TAN,PAN,LAN,WAN} devices at a time

– WAN device "can serve" 0 or more AHDs at a time

– WAN device "can use" 0 or more HRN devices at a time

– HRN device "can serve" 0 or more WAN devices at a time.

6.1.4 Reference, certified and logo-ed device classes

Reference device classes form the (abstract) basis for the guidelines framework. Based on the reference device classes, a large number of specializations are possible. These include certified device classes and logo-ed device classes.

It is desirable to define a number of certifiable guidelines. Certification only makes sense for entities that are part of the Continua E2E architecture (reference device classes). However, there is a requirement for further specialization of these classes. An example is the certification of a PAN standard wireless weighing-scales device instead of just a PAN device. The architecture does not define the certified device classes but does impose the constraint that the certified device classes are a specialization (possibly indirect) of at least one reference device class. Vendors can create a product that satisfies the associated guidelines for more than one certified device class. These products (e.g., multifunction devices and AHDs that support a range of Continua PAN devices) can receive multiple CDG-compliant certificates. Product literature should denote the certified device classes supported by that component.

The certification programme described in clause 0.5 allows that combinations of devices meet the requirements of one or more certified device classes. In this case, the combination of devices is conceptually seen as one logical device (composite device) that consists of multiple physical devices, see Figure 6-11.

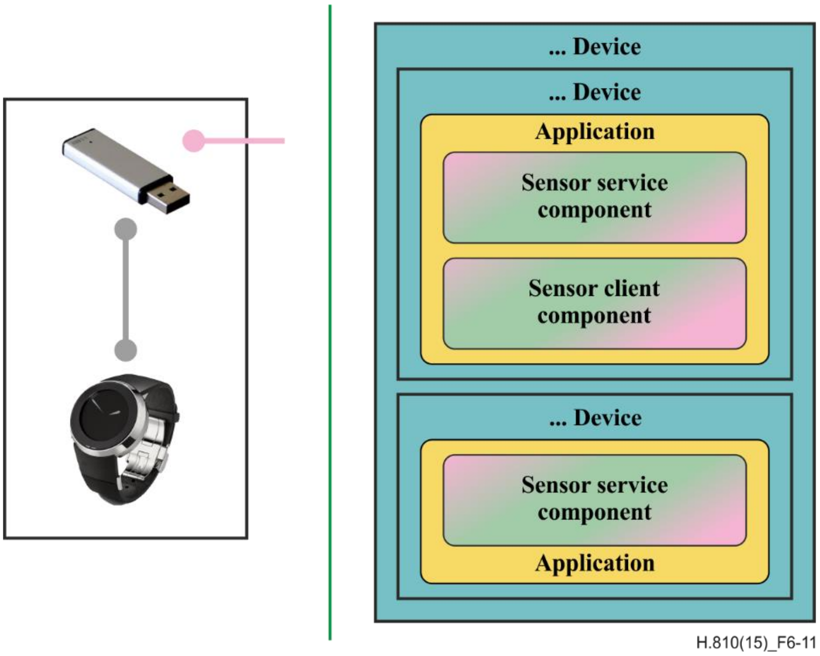

Figure 6-11 – Example composite device

The need or desire to add logos to devices is recognized. Adding logos only makes sense for entities that are certified (certified device classes). However, there is further specialization of these classes. The "logo-ing" scheme selected for this version of the CDG does require further specialization of the certified device classes. For example, an APS certified device class will be an un-logo-ed certified device class as it is an infrastructure component and does not deliver full out of the box interoperability between the two certified devices. For the rest of the certified device classes,, the logo-ed device classes match the certified device classes. All certified PAN devices are allowed to use the CDG certification logo in addition to the one from e.g., USB or Bluetooth. All certified sensor-LAN devices may use the CDG certification logo in addition to the ZigBee logo. All TAN devices may use the CDG certification logo in addition to the NFC logo. All certified AHDs are allowed to use the CDG certification logo in addition to the USB, Bluetooth or ZigBee logo and shall list the device classes that were certified.

6.1.5 Compatibility

6.1.5.1 Definitions

Extensibility

This is the ability to extend a system (design-time) with new capabilities and applications over time with minimal effort (sometimes confused with forward compatibility).

Backward compatibility

This is the ability of a system to interoperate (run-time) with other systems that were designed for earlier versions of that system. See Figure 6-12.

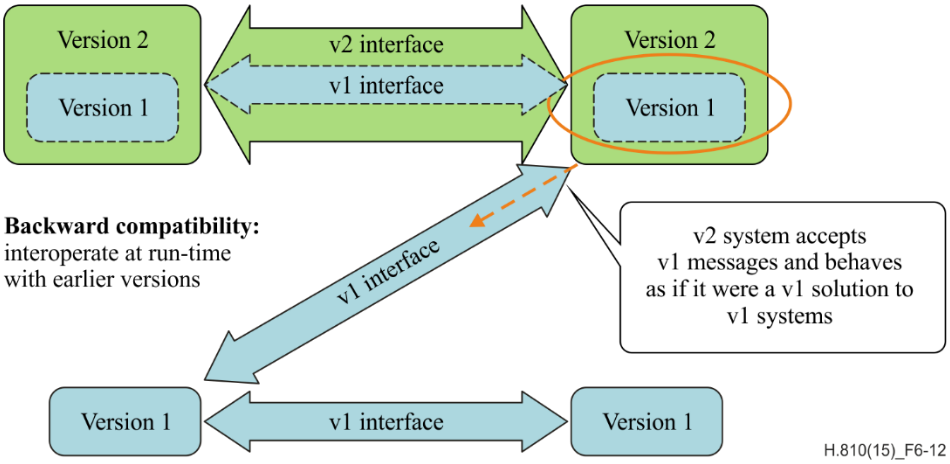

Figure 6-12 – Backward compatibility

Forward compatibility (robustness, future-proofness):

This is the ability of a system to accept input (run-time) from other systems that were designed for later versions of that system. See Figure 6-13.

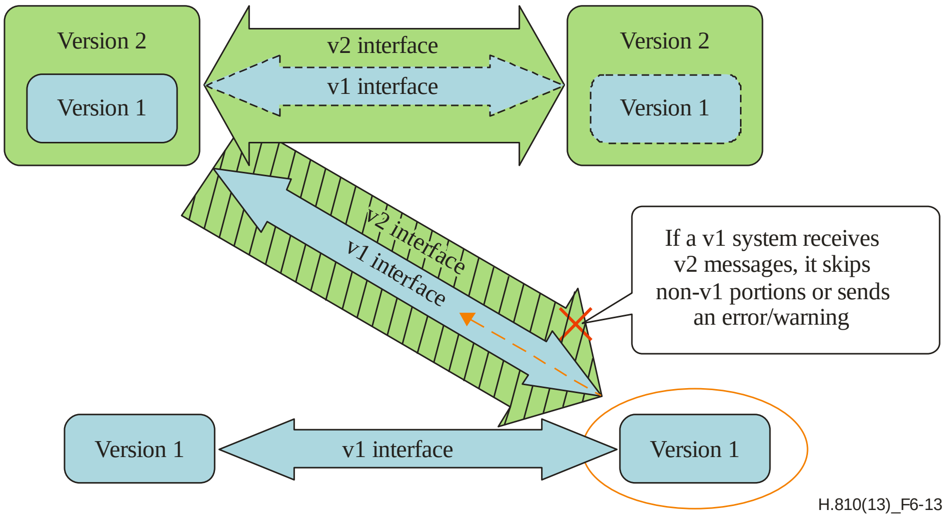

Figure 6-13 – Forward compatibility (robustness, future-proofness)

6.1.5.2 Philosophy

The Continua E2E architecture should have the flexibility to incorporate reasonable future changes. On the other hand, devices need to maintain interoperability (as much as possible) when guidelines evolve over time. Additionally, devices based on different versions also need to interoperate. This clause provides a logical analysis of the principles to be taken into account in the definition of N-IF specifications. These principles address the proper definition of an N-IF specification, as well as the constraints on the evolution of these specifications. The aim is that two devices based on different versions of the guidelines are compatible and together they provide the functionality expected from the oldest version of the guidelines involved.

An N-IF specification consists of:

– interoperable protocol

– semantics of command and messages

– common data format and data specializations

– commands and exchange protocol

- consistent communication framework
- transport / network protocol
- network
- N-IF specifications will evolve over time. For extensibility and compatibility, multiple versions of an N-IF specification are considered. This provides guidance on how the N-IF specifications were allowed to evolve.
- To address the concerns with respect to extensibility and compatibility, the following are guidelines for the definition and evolution of N-IF specifications:
- A component should have well-specified behaviour for all possible input. (Only) Unknown portions of messages / commands are ignored. A component should not crash on any input (forward compatible). When (part of) a message is not understood a warning should be returned.
- Messages / commands are extended in later versions. Semantics of the extended messages / commands should include the semantics of the original message (extensibility).
- Semantics of messages / commands should not change in later versions (backward compatible).
- Messages / commands are not removed in later versions (backward compatible)
- The consistent communication framework is only replaced by a backward compatible framework in later versions (backward compatible).
- The transport / network protocol are only replaced by a backward compatible protocol in later versions (backward compatible).
- The network is only replaced by a backward compatible network in later versions (e.g., USB 1.0 by USB 2.0) (backward compatible).

NOTE - The guidelines listed above allow for vendor-specific extensions (first bullet). The last five bullets targeting backward compatibility are probably not realistic to maintain indefinitely. However, messages, commands, consistent communication framework, transport / network protocol and network are supported by components for at least two versions after they were marked as deprecated.

6.1.6 Quality of service strategy

6.1.6.1 General overview

The ability to transfer quality of service (QoS) information from component to component is an important requirement on the Continua architecture. This clause defines the CDG approach to enable the transfer of QoS information between components.

Quality of service (QoS) is a very broad area with numerous attributes. A representative list of QoS attributes is:

1. reliability
2. latency
3. bandwidth
4. forward and reverse channel set up / tear down times
5. monetary cost
6. energy cost (often useful in wireless communications).

There are certainly others. All attributes are not equally applicable to all applications or to all transport technologies.

In the area of healthcare communications, reliability and latency are considered the most important attributes that need to be managed effectively and thus are addressed in the design guidelines. It is envisioned that other QoS attributes are addressed as the Continua ecosystem grows, expands and develops new uses.

6.1.6.2 Reliability and latency

At the extreme, there is a trade-off between the application reliability and latency attributes when deciding which of these two attributes is more important to a particular piece of data.

1. There are times when ***low*** latency is more important than reliability. It is acceptable to drop "some" data as a trade-off to getting the data quickly. For example, when sending real-time waveform data, it is more important to get the data sent quickly versus an absolute guarantee that all data has been delivered.
2. There are times when the ***best*** reliability is more important than timeliness. For instance, sometimes it is required that all data is transmitted correctly and it is acceptable to wait for data to be retransmitted (delayed) to achieve this correctness guarantee.

Table 6-1 maps the data transfers involved in CDG use cases across latency and reliability vectors. The boxes with icons denote the latency and reliability combinations that are, or could be utilized by CDG use cases. For more detail on the meaning and use of the reliability/latency pairs in these boxes, see Clause 6.1.6.5. Best results would be achieved if all transport technologies could operate in the lower right corner of Table 6-1 (i.e., best reliability and low latency, such as a processor bus with an error correcting code (ECC). However, typical inter-device transport technologies cannot achieve this.

Table 6-1 – Reliability and latency

Reliability.latency bin {typical use graphic}		**Relative reliability**		
		Good	**Better**	**Best**
Latency (overall E2E)	Very high			best.veryhigh
	High			best.high
	Medium	good.medium	better.medium	best.medium
	Low	good.low		

6.1.6.3 Reliability vector

The reliability terms ***good***, ***better***, ***best*** from Table 6-1 are not absolute definitions, but rather 'relative' definitions based upon the transport technology of interest. In other words, ***best*** reliability ≥ ***better*** reliability ≥ ***good*** reliability with respect to the statistical likelihood of transmitting the data successfully. While there are no absolute definitions, notice that:

1. The ***good*** application reliability requirement corresponds to the "no guarantees" data path or the "lossy" data path options of any given transport technology (i.e., the least stringent reliability characteristics option).
2. The ***best*** application reliability requirement corresponds to a given transport technology's most reliable data transfer mechanism. This is typically an acknowledged transport data transfer service that is explicitly aware of the successfully transferred data.

The following is a casual definition (by way of example) for the use of these three healthcare application reliability modes. Consider a viewable waveform, a blood pressure measurement and a "life threatening" alarm.

1. For the viewable waveform, it is acceptable for 'some' data to be lost in transmission. The waveform information is continuously flowing and the loss of 'some' data in the waveform display does not cause any degradation in the clinician's ability to interpret the waveform. This maps to ***good*** reliability.

2. A "life threatening" alarm is an asynchronous and significant event. Every moment counts in response to this alarm. The highest reliability and the most robust data path are typically used for these events. This maps to ***best*** reliability.

3. For a blood pressure measurement, the measurement is an infrequent, but repeatable, event. If a single measurement was lost in transmission, while not desirable by any means, it would typically not have a dramatic impact on the person. This maps to ***better*** reliability.

Thus, from the overall application point of view, ***best*** reliability ≥ ***better*** reliability ≥ ***good*** reliability.

6.1.6.4 Latency vector

The terms very high, high, medium and low from Table 6-1 are also relative definitions based upon the transport technology of interest. In the context of personal healthcare, very high latency typically refers to a maximum of 100 seconds, high latency typically refers to a maximum of 10 seconds, medium latency typically refers to a maximum of 1 second and low latency typically refers to a maximum of 100 milliseconds. However, these latencies are transport-dependent and the actual values may change based on the transport.

6.1.6.5 Reliability.Latency pairs

The following text provides further details on the six bins identified in Table 6-1.

NOTE - In the current version of the design guidelines, only the good.medium and best.medium bins are utilized. Future versions of the design guidelines could use additional bins.

1. **good.low:** This bin provides 'good' reliability with low E2E transport latency. Some additional characteristics are:
   - '**good'** relative reliability needs
   - the sampled analogue data can easily be grouped together
   - overall E2E latency = ~100 ms (relative to transport).

2. **good.medium:** This bin provides 'good' reliability with medium E2E transport latency. Some additional characteristics are:
   - '**good'** relative reliability needs
   - the sampled analogue data can easily be grouped together
   - overall E2E latency = ~1 s (relative to transport).

3. **better.medium:** This bin provides 'better' reliability with medium E2E transport latency. Some additional characteristics are:
   - '**better**' relative reliability needs
   - a measured parameter (blood pressure, percentage of oxygen saturation in blood (SpO2), heart rate, etc.).
   - overall E2E latency = ~1 s (relative to transport).

4. **best.medium:** This bin provides 'best' reliability with medium E2E transport latency. Some additional characteristics are:
   - '**best**' relative reliability needs
   - also known as get/set device parameters; also known as events and/or notifications; also known as request/response
   - control/status of both physiological and equipment functionality
   - overall E2E latency = ~1 s (relative to transport).

5. **best.high:** This bin provides 'best' reliability with high E2E transport latency. Some additional characteristics are:

– '**best**' relative reliability needs
– both physiological driven alarms and equipment issued alarms
– overall E2E latency = ~10 s (relative to transport).

6. **best.veryhigh:** This bin provides 'best' reliability with very high E2E transport latency. Some additional characteristics are:
   – '**best**' relative reliability needs
   – print, transfer, or exchange of summaries, reports or histories
   – overall E2E latency = ~100 s (relative to transport).

6.1.7 E2E security

Security is essential in dealing with medical information that is very sensitive in nature. This specification has been developed so that it supports the development of secure systems.

Security, for its own sake, may be excessive, making it unnecessarily expensive, or it may be insufficient, creating unacceptable risk. Furthermore, security requirements are not static and tend to become more stringent over time. Therefore, security must be considered holistically.

Table 6-2 lists the confidentiality, integrity and availability requirements considered in the design guidelines. Advanced security and privacy requirements, such as identity management (including authentication), non-repudiation of origin and consent management are included. Confidentiality signifies that data is accessible only to those who have the right to know. Integrity is the assurance that data has not been tampered with or modified in any way to undermine its authenticity. Availability denotes having timely access to information, whence access rights are verified. Identity management enables the management of user identities across the Continua E2E architecture, hence associating health information with the right individuals. Authentication is part of identity management, whereby the identity credentials and associated rights of a user, service or entity are validated. Non-repudiation of origin is provided through the use of digital signatures and guarantees that the sender of information cannot later deny (or repudiate) having sent the information. Consent management enables patients to provide and manage their consent preferences, which serves as a basis for governing access to and usage of their individual identifiable health information.

Table 6-2 – An overview of security technologies used in the design guidelines

Security standard	Security requirements	Interface
TLS v1.0 [IETF RFC 2246]	Confidentiality, integrity and authentication	HRN-IF
IHE XDM (S/MIME) [IHE ITI TF-1 XDM]	Confidentiality, integrity and authentication	HRN-IF
[IHE ITI TF-1 XUA], [IHE TFSXUA++]	Entity authentication	HRN-IF
IHE ITI-44 : Patient Identity Feed HL7 V3, IHE ITI-45: PIXV3 Query transaction, IHE ITI-47: Patient Demographics Query HL7 V3 transaction [IHE ITF PIX PDQ]	Identity management	HRN-IF
IG for HL7 CDA R2 Consent Directive [HL7 CDA IG]	Consent management	WAN-IF, HRN-IF
XML Encryption Specification [W3C XMLENC] IHE Document Encryption (DEN) Profile [IHE ITI DEN]	Consent enforcement	WAN-IF
IHE Document Encryption (DEN) Profile [IHE ITI DEN]	Consent enforcement	HRN-IF
IHE Document Digital Signature (DSG) [IHE ITI TFS DSG]	Non-repudiation of origin	HRN-IF
IHE ATNA [IETF RFC 3881]	Auditing	WAN-IF, HRN-IF
WS-I BSP (TLS v1.0) [OASIS WS-I BSP], TLS v1.1 [IETF RFC 4346]	Confidentiality, integrity and service authentication	WAN-IF
WS-I BSP (WS-Security + SAML 2.0) [OASIS WS-I BSP], OAuth 2.0 [IETF RFC 6749]	Entity authentication	WAN-IF
ZigBee security [ZigBee HCP]	Confidentiality, integrity and authentication	LAN-IF
Bluetooth security [Bluetooth HDPv1.1]	Confidentiality, integrity and authentication	PAN-IF

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