H.810 Interoperability design guidelines for personal connected health systems

Version 2016

August 4, 2016

Table of Contents

Figures

Tables

0 Introduction

The Continua Design Guidelines (CDG) defines a framework of underlying standards and criteria required to ensure the interoperability of components[1] used for applications monitoring personal health and wellness. It also contains design guidelines 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:

- Personal Health Devices (PHD) Interface – Interface between a Personal Health Device (PHD) and Personal Health Gateway (PHG).
- Services Interface – Interface between Personal Health Gateway (PHG) and Health & Fitness Services.
- Healthcare Information System (HIS) Interface – Interface between Health & Fitness Service and Healthcare Information System.
- .

Figure 0-1 high-lights the abovementioned interfaces in the Continua end-to-end (E2E) reference architecture.

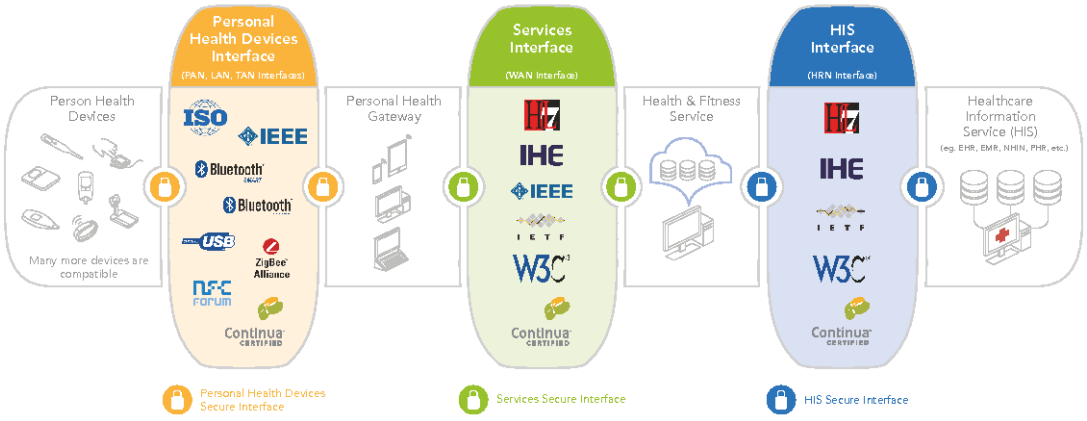

Figure 0-1- Continua E2E reference architecture

The CDG are a product of the Personal Connected Health Alliance which is an international not-for-profit industry organization enabling end-to-end, plug-and-play connectivity of devices and services for personal health management and healthcare delivery. Its mission is " to facilitate the development and adoption of personal health solutions that foster independence and empower people to better manage their health and wellness from anywhere, at any time. Making health and wellness a convenient part of daily life through personal connected health technologies." For more information visit: www.pchalliance.org.

In the design guidelines, references are made to specifications from Health Level 7 (HL7), and from Integrating the Healthcare Enterprise (IHE), ISO/IEEE, Bluetooth, ZigBee, Internet Engineering

[1] There are two types of components, a client component (e.g. observation sender) and service component (e.g. observation receiver). A device may implement one or more Continua certified client componets, however it may also implement components not certified by Continua.

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 guidelines documents which taken as a whole represent a yearly release. Table 0-1 shows the different guidelines documents included in this release.

Table 0-1 – Design Guidelines Documents

Document Name	Also known as
H.810	System Overview
H.811	Personal Health Devices (PHD) Interface
H.812	Services Interface
H.812.1	Observation Upload Capability
H.812.2	Questionnaire Capability
H.812.3	Capability Exchange Capability
H.812.4	Authenticated Persistent Session Capability
H.813	Healthcare Information System (HIS) Interface

This guidelines document is organized in the following manner:

Introduction and Clauses 0-4: Introduction and terminology – These clauses provide useful background information to help understand the structure of the design guidelines documents.
Clause 5: 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
2015 + Errata		5	1

Continua design guidelines	Also known as	Major version	Minor version
2016	Iris	6	0
2016 + Errata		6	1

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 which implements all ratified bugs for the prior release.

0.3 What's New

Compared to preceeding versions of the Continua Design Guidelines the following changes were made to the content of this guidelines document:

Across the PHD-IF the following new capabilities have been introduced:

- Design guidelines for Continuous Glucose Monitor and Pulse Oximeter using Bluetooth LE as transport technology.
- Design guidelines for Continuous Glucose Monitor and Insulin Pump Monitor PHD 11073-20601 device specializations.
- All CDG documents being updated with new architecture concepts and terminologies.

Across the HIS interface design guidelines for the DIRECT capability have been introduced. DIRECT provides a simple and secure standard based method for sending health information to the known and trusted participants over the internet using HIS-IF.

0.4 White papers

This clause highlights white papers that have been published to facilitate understanding of these design guidelines and 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 Fundamentals of Data Exchange

The purpose of this white paper is to provide a basic description of the data that is being exchanged between sensors, gateways, and end services and the value-add Continua provides beyond the referenced standards to make implementations truly interoperable.

0.4.2 Introduction to the Continua Design Guidelines

The purpose of this white paper is to provide a high level overview of the Continua Design Guidelines, an introduction to each of the standards and specifications that were chosen by its members to be part of the design guidelines, and the rationale behind their selection.

0.4.3 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.

0.4.4 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 are made that developers of Personal Health Gateway (PHG) using USB transport can implement. 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 capability implemented by products conform to the standards and specifications defined in the design guidelines and its underlying standards. Devices featuring the Continua logo indicate that a component implemented by a 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 spelled out in Clause 5.1.4.

1 Scope

This version of CDG include guidelines for the Personal Health Devices (PHD)-IF, Services-IF and HIS-IF.

PHD-IF further consists of design guidelines on the use of a transport technology i.e. NFC, USB, Bluetooth, Bluetooth LE and ZigBee for a specific certified capability. An overview of the capabilities defined under each of these transport technologies is given below.

Table 1-1- Capability classes defined across PHD-IF

Capability	Transport				
	USB	Bluetooth	Bluetooth LE	NFC	ZigBee
pulse oximeter	Yes	Yes	Yes	Yes	Yes
blood pressure monitor	Yes	Yes	Yes	Yes	Yes
thermometer	Yes	Yes	Yes	Yes	Yes
weighing-scales	Yes	Yes	Yes	Yes	Yes
glucose meter	Yes	Yes	Yes	Yes	Yes
cardiovascular fitness	Yes	Yes		Yes	Yes
step counter	Yes	Yes		Yes	Yes
strength fitness	Yes	Yes		Yes	Yes
activity hub	Yes	Yes		Yes	Yes
adherence monitor	Yes	Yes		Yes	Yes
peak flow meter	Yes	Yes		Yes	Yes
fall sensor	Yes	Yes		Yes	Yes
motion sensor	Yes	Yes		Yes	Yes
enuresis sensor	Yes	Yes		Yes	Yes
contact closure sensor	Yes	Yes		Yes	Yes
switch sensor	Yes	Yes		Yes	Yes
dosage sensor	Yes	Yes		Yes	Yes
water sensor	Yes	Yes		Yes	Yes
smoke sensor	Yes	Yes		Yes	Yes
property exit sensor	Yes	Yes		Yes	Yes
temperature sensor	Yes	Yes		Yes	Yes
usage sensor	Yes	Yes		Yes	Yes
PERS sensor	Yes	Yes		Yes	Yes
CO sensor	Yes	Yes		Yes	Yes
gas sensor	Yes	Yes		Yes	Yes
heart-rate sensor	Yes	Yes	Yes	Yes	Yes
basic 1-3 lead ECG sensor	Yes	Yes		Yes	Yes
body composition analyser	Yes	Yes		Yes	Yes
INR meter	Yes	Yes		Yes	Yes
sleep apnea breathing therapy equipment (SABTE)	Yes	Yes		Yes	Yes
continous glucose monitor	Yes	Yes	Yes	Yes	Yes
insulin pump monitor	Yes	Yes		Yes	Yes

Services-IF guidelines are defined for the following capability classes using different transports such as SOAP, RESTful HTTP and MQTT.

Table 1-2-Capability classes defined across Services IF

Capability	Transport		
	SOAP	RESTful HTTP	MQTT
Observation upload	Yes	Yes	
Questionnaires and questionnaires responses		Yes	
Consent Management and enforcement	Yes	Yes	
Authenticated persistent session			Yes
Capability exchange		Yes	

HIS-IF guidelines are defined for the following capability classes using different transports such as IHE XDR, IHE XDM and DIRECT.

Table 1-3- Capability classes defined across HIS IF

Capability	Transport		
	IHE XDR	IHE XDM	DIRECT
Personal Health Monitoring Report (PHMR) sharing	Yes	Yes	Yes
Consent Management and enforcement	Yes		

2 References

All normative references for Continua design guidelines can be found in section Normative References.

3 Definitions

All formal definitions used in the design guidelines can be found in section Formal Definitions.

4 Conventions

4.1 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.

4.1.1 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.

4.1.2 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 4.1.1 are in **bold** font when used in the requirement sense.

4.1.3 Design guidelines format

This clause details the format of a DG, see an example in Table 4-1.

Table 4-1 – Design guideline example

Name	Description	Comments
PHD-IF-USB-Personal-Healthcare-v1.0	Continua USB service and client components **shall** implement the USB Personal Healthcare Device Class v1.0 plus the Feb. 15, 2008 errata, subject to the requirements listed below.	

The design guideline table heading categories are as follows:

- **Name** – A unique label for the design guideline
- **Description** – Text that describes the design guideline
- **Comments** – Supplementary information about a design guideline such as a justification for it, dependencies, etc.

5 System overview

5.1 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 document, "Continua architecture" and " Continua E2E architecture" are used interchangeably.

5.1.1 Devices, components, application and interfaces

The Continua architecture distinguishes devices (physical entities) from components (logical entities) and applications (a software program). This distinction is general and not specific for Continua reference capability classes, Continua certified capability classes, or Continua logo-ed capability classes that are defined later in this document (See Clause 5.1.4). Devices may host zero or more applications. An application may have one or more capabilities. A capability may then implement client and (or) service components depending on the use case.
The above is depicted by Figure 5-1.

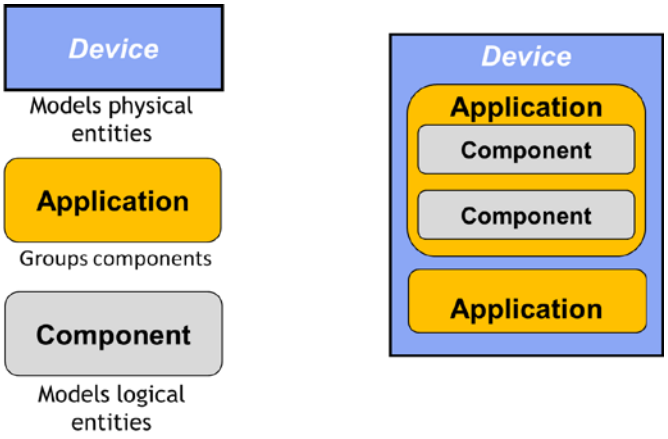

Figure 5-1 – Device, component and application

Components implement and require the implementation of a number of interfaces as shown in Figure 5-2.

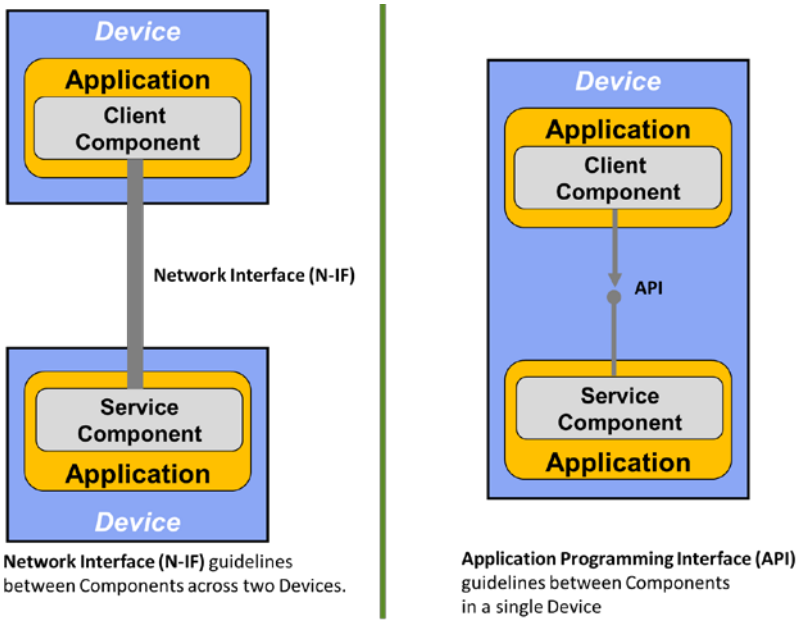

Figure 5-2 – Interfaces between components

The CDG make the distinction between network interface (N-IF) guidelines and application programming interface (API) guidelines. A component implementing an API is depicted by Figure 5-3.

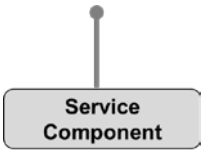

Figure 5-3 – Component implements API

A component requiring the implementation of an API is depicted by Figure 5-4.

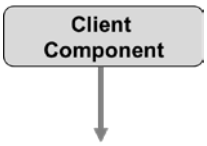

Figure 5-4 – Component requires implementation of API

A component implementing a network interface specification is shown by Figure 5-5.

Figure 5-5 – Component implements network interface

A component requiring an implementation of a network interface is displayed by Figure 5-6:

Figure 5-6 – Component requires implementation of network interface

The main difference between an API and N-IF is that an API is an interface between components within a single device and N-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.

Figure 5-7: below shows the current focus of Continua design guidelines. For Continua the current focus is on the interoperability between two devices i.e. network interface guidelines. In future versions of Continua there might be a need for a common middleware, which would provide interfaces to different applications running on the same device, hence the API guidelines might fall under the scope of Continua.

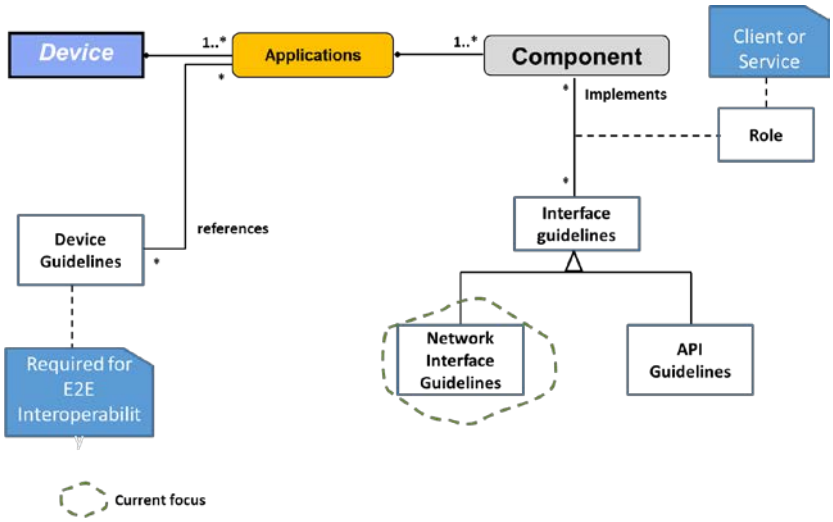

Figure 5-7- Current focus of Continua design guidelines

5.1.2 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 network interfaces.

For the CDG, the focus is on device interoperability. This implies a focus on network interface 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 network interfaces. 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.

5.1.3 Reference capability classes and system topology

Devices are physical entities that can host a number of applications, where application is program that implements a specific funcationality and implemenents one or more (client and/or service) components. The Continua E2E architecture distinguishes different reference capability classes based on the component classes hosted on that device.

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

- **Personal Health Device:** This is a reference capability class that implements at least one Personal Health Device (PHD)-IF service components. Real word examples of PHD-IF service components are pulse oximeter, blood pressure monitor, thermometer or weighing-scales capabilities classes, where the physical transport media could be BLE, ZigBee, Bluetooth, USB and NFC.
- **Personal Health Gateway:** This is a reference capability classs that implements at least one PHD-IF client component or Services-IF client component. Example of a PHD-IF client component is an app (e.g. running on smart phone) that collects observations (e.g. vital signs measurements) from PHD-IF service components.
- **Health & Fitness Service:** This is a reference capability class that implements at least one Services-IF service component or HIS-IF client component. Example of Services-IF service component is a remote server that collects observations (e.g. vital signs measurements from PHD devices or questionnaire responses) from Services-IF client component.
- **Healthcare Information System:** This is a reference capability class that implements at least one HIS-IF service component. Example of HIS-IF service component is General Physician EMR that is able to receive personal health monitoring (PHM) document from HIS-IF client component.

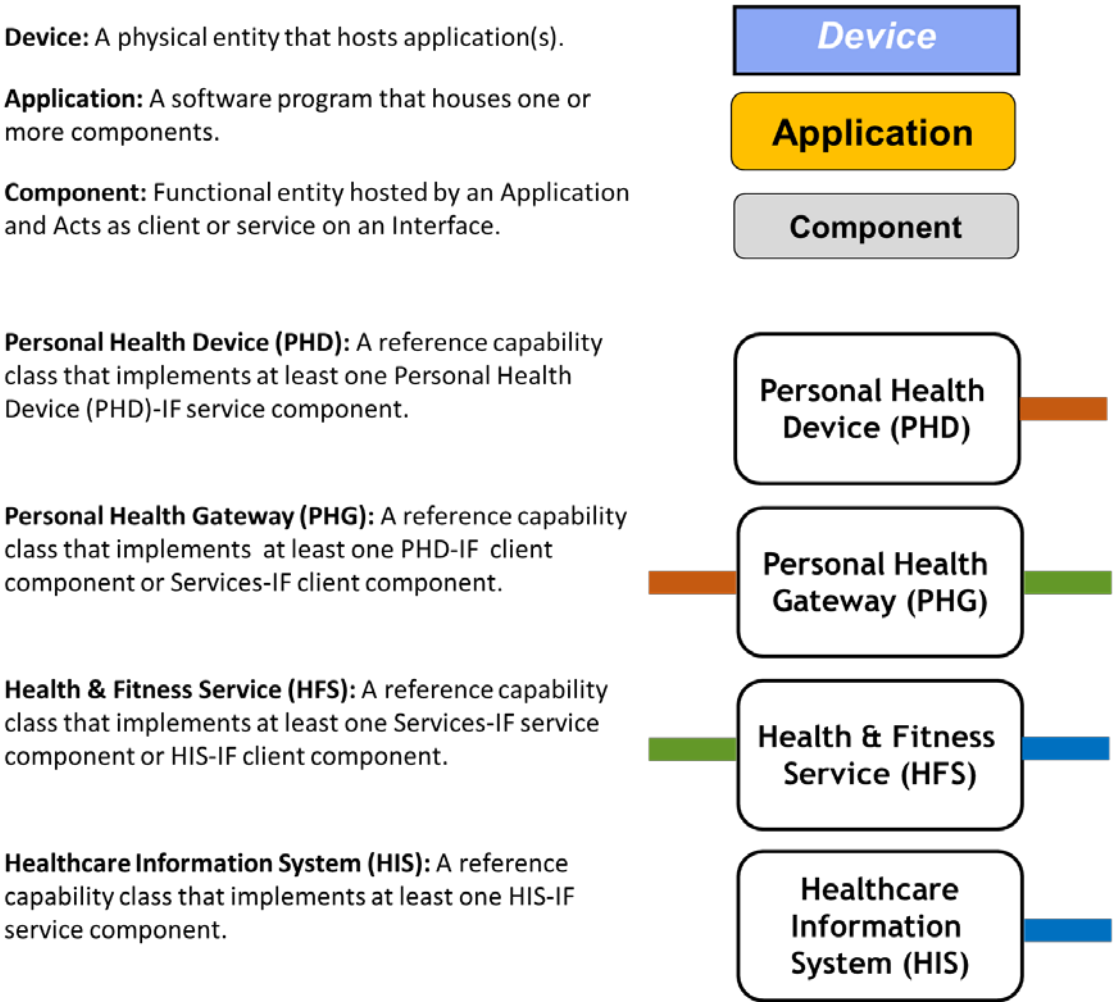

Figure 5-8 – Definitions and graphical notation

The distinction between the different interfaces is based on architectural dimensions (e.g. who-stakeholders, where-geography, and what-functaions & features). The highest level (the basis for the reference device classes) has the following dimensions:

- Personal Health Devices Interface. This is the interface used by personal health devices (e.g. blood pressure meter, pulse oximeter, thermmometer) in order to report observations (measurements) taken by these devices to a personal health gateway (e.g. health & fitness app on smartphone or tablet or dedicated hub) usually in the home but not necessarily. The key stakeholder here is the user (e.g. a user suffering from a chronic condition (COPD, diabetes)).
- Services Interface. This is the interface used by personal health gateway (e.g. health & fitness app on smartphone or tablet or dedicated hub) in order to forward collected observations (or measurements) from personal health devices to a remote health & fitness service provider. An example of the remote health & fitness service is a telehealth service provided by a home health agency (HHA). Health & fitness service could be hosted in the cloud. Some of the key stakeholders here are skilled nurse, remote coach for diet or fitness.
- Healthcare Information System Interface. This is the interface used by health & fitness service in order to report and share patient data with a healthcare information system (HIS). Examples of HIS are EMR, PHRs, EHRs, laboratory information system (LIS) etc. One of the key stakeolders for HIS are the care providers such as General Physician.

The topology constraints for the Continua ecosystem are defined using the reference capability classes described above. These reference capability classes provide an abstract model for real-world devices and are the basis for further specialization. Personal Health Device could be futher specialized on the type of transport media being used such as NFC, Bluetooth, ZigBee and USB. The Continua reference topology imposes a number of constraints on how reference capability classes are physically connected. See Figure 5-9.

Figure 5-9 – Reference topology

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

- Personal health device “can serve” * 0 or more personal health gateways at a time.
- A personal health gateway “can use” 0 or more personal health devices at a time.
- Health and Fitness Services “can serve” 0 or more personal health gateways at a time.

- Health and Fitness Service “can use”) 0 or more Healthcare Information Systems at a time.
- Healthcare Information System “can serve” 0 or more Health and Fitness Services at a time.

5.1.4 Reference, certified and logo-ed capability classes

Reference capability classes form the (abstract) basis for the guidelines framework. Based on the reference capability classes, a large number of specializations are possible. These include certified capability classes and logo-ed capability 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 capability classes). However, there is a requirement for further specialization of these classes. An example is the certification of a PHD weighing-scales capability instead of just a personal health device. The architecture does not define the certified capability classes but does impose the constraint that the certified capability classes are a specialization (possibly indirect) of at least one reference capability class. Vendors can create a product that satisfies the associated guidelines for more than one certified capability class. These products (e.g. a personal health gateway that supports to collect observations from a range of PHD

capabilities (e.g. pulse oximeter, weighing-scales) can receive multiple CDG-compliant certificates. Product literature should clearly denote the certified capability classes supported by that product.

The need or desire to add logos to physical devices or applications is recognized as it signifies interoperability. Adding logos only makes sense if a device or application implements a continua capability class and it is certified (certified capability classes). Usually a certified capability class match logo-ed certified capability class however not always. For example, authenticated persistent session 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 capability classes in this version of design guidelines,the logo-ed capability classes match the certified capability classes. In addition to the Continua logo for implementing a certified capability, a device or application may use logo from other base standard bodies for example, Bluetooth, USB or ZigBee. A device or application shall list the capabilities for which it has obtained the certification.

5.1.5 Other views of the architecture

Continua has defined its own architural concepts in order to describe views of its members about personal health ecoystem. The concepts have been defined taking into account different stakeholders such as users of the system, operators of the system and providers of the system. Hower different views of the Continua reference architecture and capabilities defined within this architecture are possible. Figure 5-10 below depicts key concepts pertaining to systems and their architectures as a context for understanding the practice of architecture description. For more background information consult ISO/IEC IEEE42010 document.

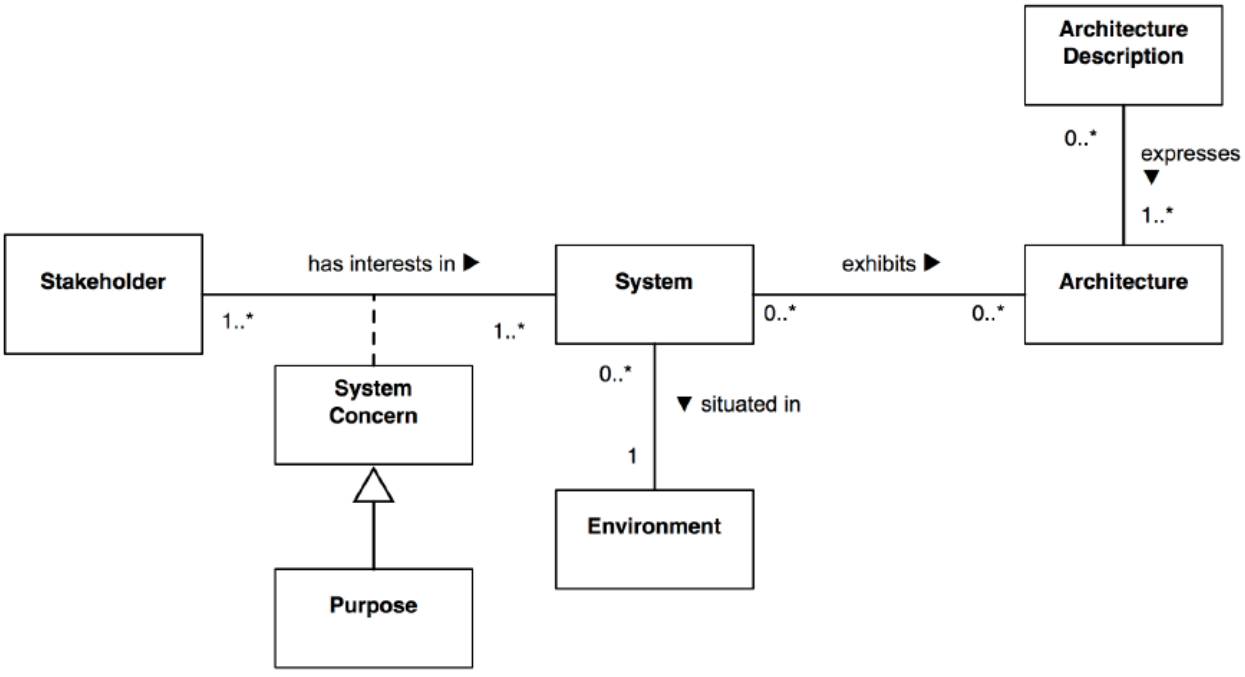

Figure 5-10- Context of architecture description [ISOIECIEEE42010 {ED1.0}]

Figure 5-11 below describes the conceptual model for an architecture description. It is used to describe an architecture for a system of interest. For more background information consult ISO/IEC IEEE42010 document.

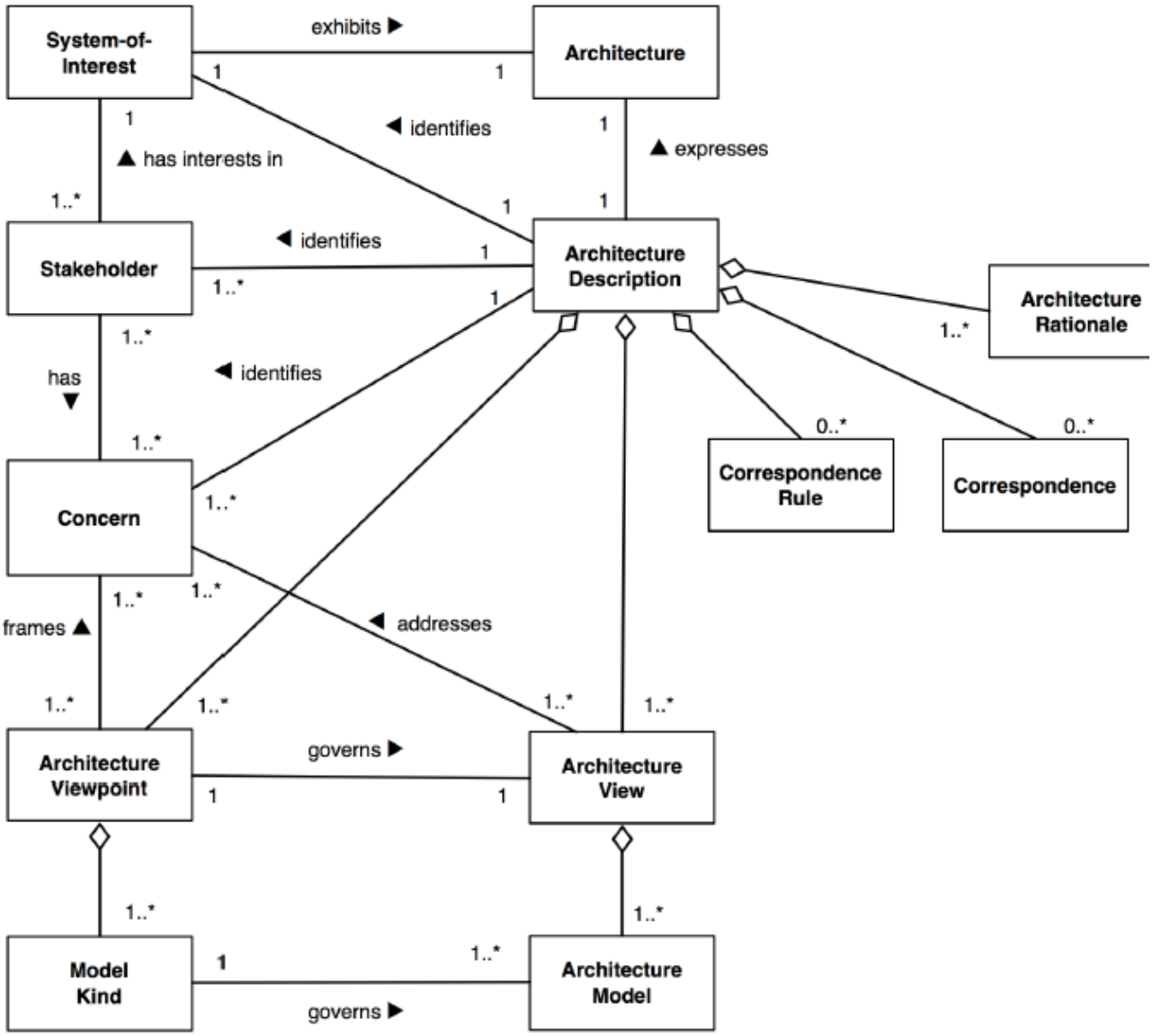

Figure 5-11- Conceptual model of an architecture description

For example, Continua reference architecture and concepts can be easily translated and represented using concepts and views defined by IHE (Integrating Healthcare Enterprise). IHE has the following concepts:

- Integration profile: It solves a specific integration problems and is a representation of a real-world capability that is supported by a set of actors that interact through transactions. It avoids having two different mechanisms to do the same thing.
- Actor: It is an information systems or component of information system that produce, manageor act on categories of information required by operational activities in the enterprise. They are assigned to profiles when they have a role to fill.
- Transaction: It is an interaction between actors that communicate the required information through standard-based message. It should complete a specific task and should usually select a single standard for one single task.

5.1.5.1.1 In the following we show how to represent continua PHD-IF capabilities using IHE concepts and terminologies.PHD-IF: Communicate PCHA Data Transaction

5.1.5.1.1.1 Scope

This transactions is used to transfer measurement data from Personal Health Device (PHD) Sensor Data Source Actors to an appropriate consumer in a standardized manner. This transaction allows a single Sensor Data Consumer Actor to process data from any compliant sensor device (blood pressure cuffs, glucometers, coagulation meters, sleep apnea breathing therapy equipment, etc.)

This transaction is typically the only point at which a human is involved. Once the measurement data is received by the Sensor Data Consumer, the process of delivering the data to its final destination in its final form at a Content Consumer is automated [IHE RPM Profile].

5.1.5.1.1.2 Actor Roles

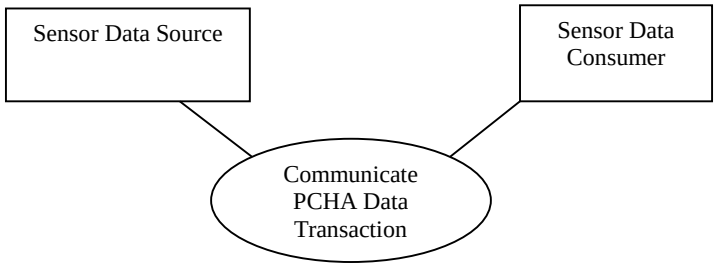

Figure 5-12- Use Case Diagram

Table 5-1- Actor Roles

Actor:	Sensor Data Source
Role:	This actor is responsible for taking the measurement on the patient, packaging it into a standardized form and sending it to a consumer in a standardized manner.
Actor:	Sensor Data Consumer
Role:	This actor receives measurement data from one or more Sensor Data Source actors (sensor devices)

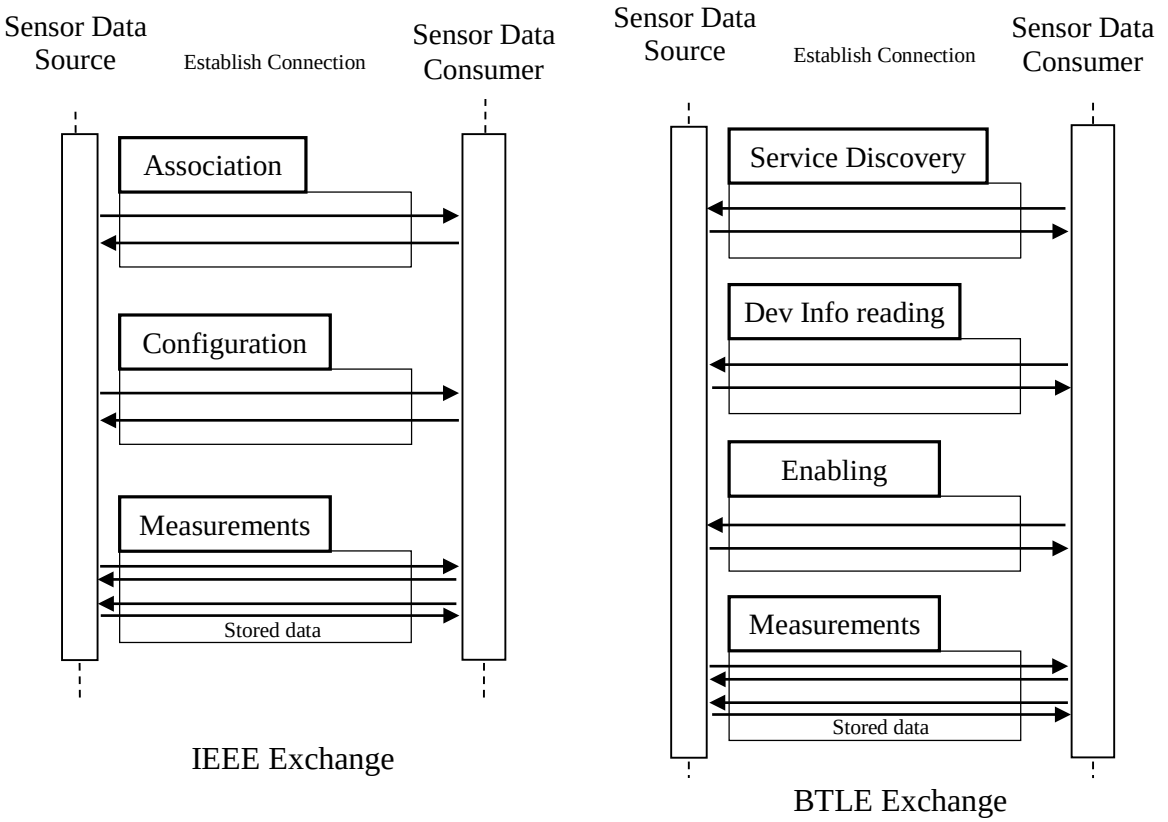

Figure 5-13- PHD-IF Communicate PCHA Data Transaction

The above Figure 5-13 illustrates the sequence of events that take place in the two different implementations of the PCHA transaction. In both cases there is series of exchanges that allow the Sensor Data Consumer to either receive or request measurement data from the Sensor Data Source. It should be noted that the Sensor Data Consumer only requests data from the Sensor Data Source if the Sensor Data Source indicates that it has permanently stored data.

5.1.6 Compatibility

5.1.6.1 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 5-14.

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 5-14.

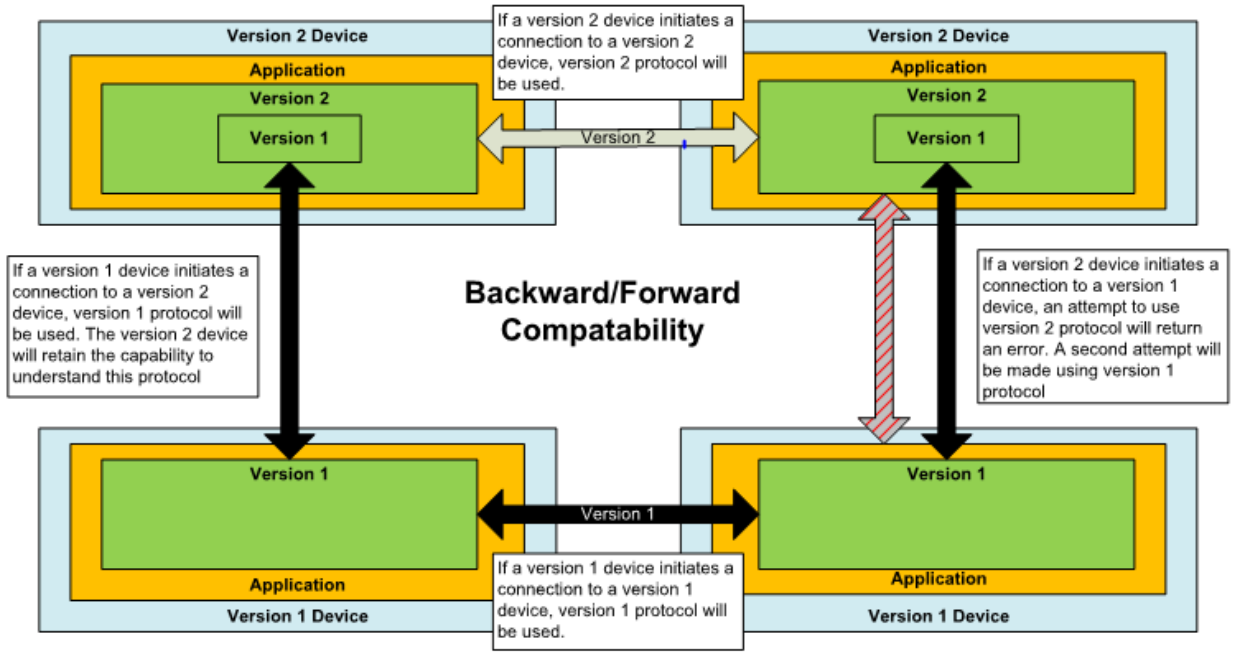

Figure 5-14 – Backward compatibility and Forward compatibility

5.1.6.2 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 network interface specifications. These principles address the proper definition of a network interface 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.
A network interface 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

Network interface specifications will evolve over time. For extensibility and compatibility, multiple versions of a network interface specification are considered. This provides guidance on how the network interface 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 network interface 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.

5.1.7 Quality of service strategy

5.1.7.1 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 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.

5.1.7.2 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 5-2 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 5.1.7.5. Best results would be achieved if all transport technologies could operate in the lower right corner of Table 5-2 (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 5-2 – Reliability and latency

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

5.1.7.3 Reliability vector

The reliability terms ***good***, ***better***, ***best*** from Table 5-2 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.

5.1.7.4 Latency vector

The terms Very High, High, Medium, and Low from Table 5-2 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.

5.1.7.5 Reliability.Latency pairs

The following text provides further details on the six bins identified in Table 5-2.

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

1. **good.low:** This bin provides 'good' reliability with low end-to-end transport latency. Some additional characteristics are:
   – '**Good**' relative reliability needs
   – the sampled analogue data can easily be grouped together
   – overall end-to-end latency = ~100ms (relative to transport).
2. **good.medium:** This bin provides 'good' reliability with medium end-to-end transport latency. Some additional characteristics are:
   – '**Good**' relative reliability needs
   – the sampled analogue data can easily be grouped together
   – overall end-to-end latency = ~1s (relative to transport).
3. **better.medium:** This bin provides 'better' reliability with medium end-to-end transport latency. Some additional characteristics are:
   – '**Better**' relative reliability needs
   – a measured parameter (blood pressure, SpO2 (blood oxygen saturation), heart rate, etc.)
   – overall end-to-end latency = ~1s (relative to transport).
4. **best.medium:** This bin provides 'best' reliability with medium end-to-end transport latency. Some additional characteristics are:
   – '**Best**' relative reliability needs
   – also known as get/set device parameters; also know as events and/or notifications; also known as request/response
   – control/status of both physiological and equipment functionality
   – overall end-to-end latency = ~1s (relative to transport).
5. **best.high:** This bin provides 'best' reliability with high end-to-end transport latency. Some additional characteristics are:
   – '**Best**' relative reliability needs
   – both physiological driven alarms and equipment issued alarms
   – overall end-to-end latency = ~10s (relative to transport).
6. **best.veryhigh:** This bin provides 'best' reliability with very high end-to-end transport latency. Some additional characteristics are:
   – '**Best**' relative reliability needs
   – print, transfer or exchange of summaries, reports or histories
   – overall end-to-end latency = ~100s (relative to transport).

5.1.8 E2E security

Security is essential in dealing with medical information that is very sensitive in nature. The design guidelines have been developed so that it supports the development of secure systems.
Security, for its own sake, may be excessive, making it unnecessarily expensive or 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 5-3 lists the confidentiality, integrity and availability requirements considered in the design guidelines. Advanced security and privacy requirements such as identity management, 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. Identity management enables the management of user identities across the Continua E2E architecture, hence associating health information with the right individuals. 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 5-3 – An overview of security technologies used in the design guidelines

Standard bodies	Security standard	Security requirements	Interface
IETF	TLS v1.0 [IETF RFC 2246]	Confidentiality, integrity and authentication	HIS-IF
IHE, IETF	IHE XDM (S/MIME) [IHE ITI TF-1 XDM]	Confidentiality, integrity and authentication	HIS-IF
IHE, OASIS	[IHE ITI TF-1 XUA], [IHE TFSXUA++]	Entity authentication	HIS-IF
IHE, HL7	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	HIS-IF
HL7	IG for HL7 CDA R2 Consent Directive [HL7 CDA IG]	Consent management	Services-IF, HIS-IF
IHE, W3C, IETF	XML Encryption Specification [W3C XMLENC] IHE Document Encryption (DEN) Profile [IHE ITI DEN]	Consent enforcement	Services-IF
IHE, IETF	IHE Document Encryption (DEN) Profile [IHE ITI DEN]	Consent enforcement	HIS-IF
IHE, W3C	IHE Document Digital Signature (DSG) [IHE ITI TFS DSG]	Non-repudiation of origin	HIS-IF
IHE	IHE ATNA [IETF RFC 3881]	Auditing	Services-IF, HIS-IF
OASIS, IETF	WS-I BSP (TLS v1.0) [OASIS WS-I BSP], TLS v1.1 [IETF RFC 4346]	Confidentiality, integrity and service authentication	Services-IF
IETF, OASIS	WS-I BSP (WS-Security + SAML 2.0) [OASIS WS-I BSP], OAuth 2.0 [IETF RFC 6749]	Entity authentication	HIS-IF
Bluetooth SIG Inc., Zigbee Alliance	ZigBee security [ZigBee HCP], Bluetooth security [Bluetooth HDPv1.1]	Confidentiality, integrity and authentication	PHD-IF

5.1.9 Overview of standards used across PHD-IF

Table 5-4 provides an overview of standards used across PHD-IF, along with the purpose of using a specific standard.

Standards Body	Specific Standard	Functionality / Purpose of using this standard	Which of the ISO/OSI 7 Layers?
ISO/IEEE	11073-20601 11073-104xx	Application level services, protocol, data semantics and formats for PHD devices	Layer 5 to 7: Session .. Application
Bluetooth SIG	Core Specification	Wireless transport connection (in 2 flavors – BR/EDR and LE)	Layer 1 to 4: Transport .. Network
	Health Device Profile (HDP)	Shim between Bluetooth and 11073	Layer 4: transport
	Gatt Profiles and Services	Application level services, protocol, data semantics and formats for medical and sport & fitness devices	Layer 5 to 7: Session .. Application
	PHD Transcoding Whitepaper	Maps LE observations to 11073 observations	Layer 7 / application
ZigBee	Zigbee Specification	Wireless transport link	Layer 1 to 4: Transport .. Network
	Health Care Profile (HCP)	Shim between Zigbee and 11073	Layer 4: transport
USB	USB 2.0 (or later backward compatible versions)	Wired Transport connection	Layer 1 to 4: Transport .. Network
	USB Device Class Definition for Personal Healthcare Devices (PHDC)	Shim between USB and 11073	Layer 4: transport
NFC Forum	NFC Logical Link Control Protocol (LLCP) Technical Specification, Version 1.1	Touch transport	Layer 1 to 4: Transport .. Network
	NFC Data Exchange Format (NDEF)Technical Specification, Version 1.0	Data layer protocol	Layer 4: transport
	Personal Health Device Communication (PHDC)	Shim between NFC and 11073	Layer 4: transport

6 Normative References

The following table contains the normatives references that have been used in the design guidelines in order to define different capability classes across different interfaces in Continua end-to-end

architecture. All design guidelines and other references are subject to revision; users of the design guidelines are therefore encouraged to investigate the possibility of applying the most recent edition of the design guidelines and other references listed below.

[ANSI/HL7 CDA]	ANSI/Health Level Seven (2005-04), *HL7 Clinical Document Architecture, Release 2.0*. http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition2010.zip
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[Bluetooth CTS]	Bluetooth SIG, *Current Time Service, Version 1.1*. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=241871
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[Bluetooth GLS]	Bluetooth SIG, *Glucose Service, Version 1.0*. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=248026
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[Bluetooth HRP]	Bluetooth SIG, Heart Rate Profile, Version 1.0. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=239865
[Bluetooth HRS]	Bluetooth SIG, *Heart Rate Service, Version 1.0*. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=239866
[Bluetooth HTP]	Bluetooth SIG, *Health Thermometer Profile, Version 1.0*. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=238687
[Bluetooth HTS]	Bluetooth SIG, *Health Thermometer Service, Version 1.0*. https://www.bluetooth.org/docman/handlers/downloaddoc.ashx?doc_id=238688
[Bluetooth MCAP]	Bluetooth SIG, *Multi-Channel Adaptation Protocol, Version 1.0*. https://www.bluetooth.org/DocMan/handlers/DownloadDoc.ashx?doc_id=119995
[Bluetooth PHDT v1.4]	Bluetooth SIG, *Personal Health Devices Transcoding White Paper, v1.4* https://www.bluetooth.org/DocMan/handlers/DownloadDoc.ashx?doc_id=272346
[Bluetooth PHDT]	Bluetooth SIG, *Personal Health Devices Transcoding White Paper, v1.5*. https://www.bluetooth.org/DocMan/handlers/DownloadDoc.ashx?doc_id=272346
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[H.813]	Personal Connected Health Alliance (2015), *Health Record Network Interface Design Guidelines.*
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[IHE ITI-TF-2]	Integrating the Healthcare Enterprise (2009-08), *IHE IT Infrastructure Technical Framework, Volume 2 (ITI TF-2), Revision 6.0 (in particular its Appendix V, Web Services for IHE Transactions)* http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol2x_FT_2009-08-10.pdf
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[IHE PCD-TF-1]	Integrating the Healthcare Enterprise (2006-08), *IHE Patient Care Device Technical Framework, Volume 1: Integration Profiles (Revision 1.1).* http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_rev1.pdf.
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[IHE TFS DSG]	IHE IT Infrastructure (ITI), *Technical Framework Supplement: Document Digital Signature 2009-2010.Trial Implementation Supplement*. http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Digital_Signature-2009-08-10.pdf
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[ISO/IEEE 11073-10421]	ISO/IEEE 11073-10421:2012, *Health informatics – Personal health device communication – Device specialization Peak expiratory flow monitor (peak flow)*. http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=61056
[ISO/IEEE 11073-10441]	ISO/IEEE 11073-10441:2015, *Health informatics – Personal health device communication – Device specialization – Cardiovascular fitness and activity monitor*. http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=64868
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[ZigBee Spec]	Zigbee Alliance (2008-01), *ZigBee Specification* http://www.zigbee.org/Specifications/ZigBee/Overview.aspx

6.1 Equivalent IEEE and ISO specifications

ISO adopts certain IEEE specifications under the "ISO/IEEE Partner Standards Development Organization Cooperation Agreement". The table below shows ISO equivalents of IEEE 11073 personal health device specifications referenced by the Continua Design Guidelines. Typically ISO versions are published one or more years after the IEEE version.

Table 6-1 – ISO Equivalents specifications for IEEE 11073 personal health device specifications

Description	IEEE 11073 standard	reference	ISO equivalent	reference
10101 Nomenclature	-	-	ISO/IEEE 11073-10101:2004	[b ISO/IEEE 11073-10101]
20601 Protocol (v1)	IEEE 11073-20601-2008	[IEEE 11073-20601-2008]	ISO/IEEE 11073-20601:2010	[ISO/IEEE 11073-20601-2010]
20601 Protocol Amendment (v2)	IEEE 11073-20601a-2010	[IEEE 11073-20601A-2010]	ISO/IEEE 11073-20601:2010/Amd 1:2015	[ISO/IEEE 11073-20601-2015A]
20601 Protocol (v3)	IEEE 11073-20601-2014	[IEEE 11073-20601-2014]	-	-
10404 Pulse oximeter	IEEE 11073-10404-2008	[IEEE 11073-10404]	ISO/IEEE 11073-10404:2010	[ISO/IEEE 11073-10404]
10406 Basic Electrocardiograph (ECG) (1 to 3-lead ECG)	IEEE 11073-10406-2011	[IEEE 11073-10406]	ISO/IEEE 11073-10406:2012	[ISO/IEEE 11073-10406]
10407 Blood Pressure Monitor	IEEE 11073-10407-2008	[IEEE 11073-10407]	ISO/IEEE 11073-10407:2010	[ISO/IEEE 11073-10407]
10408 Thermometer	IEEE 11073-10408-2008	[IEEE 11073-10408]	ISO/IEEE 11073-10408:2010	[ISO/IEEE 11073-10408]
10415 Weighing scale	IEEE 11073-	[IEEE 11073-	ISO/IEEE 11073-	[ISO/IEEE 11073-

	10415-2008	10415]	10415:2010	10415]
10417 Glucometer	IEEE 11073-10417-2011	[IEEE 11073-10417]	ISO/IEEE 11073-10417:2014	[ISO/IEEE 11073-10417]
10418 INR monitor	IEEE 11073-10418-2011	[IEEE 11073-10418]	ISO/IEEE 11073-10418:2014	[ISO/IEEE 11073-10418]
10419 Insulin Pump	IEEE 11073-10419-2015	[IEEE 11073-10419]	-	-
10420 Body composition analyzer	IEEE 11073-10420-2010	[IEEE 11073-10420]	ISO/IEEE 11073-10420:2012	[ISO/IEEE 11073-10420]
10421 Peak flow monitor	IEEE 11073-10421-2010	[IEEE 11073-10421]	ISO/IEEE 11073-10421:2012	[ISO/IEEE 11073-10421]
10424 Sleep Apnea Breathing Therapy Equipment	IEEE 11073-10424-2014	[IEEE 11073-10424]	-	-
10425 Continuous Glucose Monitor	IEEE 11073-10425-2015	[IEEE 11073-10425]	-	-
10441 Cardiovascular Fitness and Activity monitor	IEEE 11073-10441-2013	[IEEE 11073-10441]	ISO/IEEE 11073-10441:2015	[ISO/IEEE 11073-10441]
10442 Strength fitness equipment	IEEE 11073-10442-2008	[IEEE 11073-10442]	ISO/IEEE 11073-10442:2015	[ISO/IEEE 11073-10442]
10471 Independent living activity hub	IEEE 11073-10471-2008	[IEEE 11073-10471]	ISO/IEEE 11073-10471:2010	[ISO/IEEE 11073-10471]
10472 Medication Monitor	IEEE 11073-10472-2010	[IEEE 11073-10472]	ISO/IEEE 11073-10472:2012	[ISO/IEEE 11073-10472]

7 Formal Definitions

7.1 Terms defined elsewhere

The design guidelines uses the following terms defined elsewhere:

Term	Definition
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.
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*.

7.2 Terms defined in these design guidelines

The design guidelines define the following terms:

Term	Definition
Actor	Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities[2]
Actuator	See *Actuator Service Component*
Actuator Information	The information accepted by an *Actuator Service Component* for initiating external actions
Actuator Service Component	An *Actuator Service* 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 *Personal Health Device (PHD).*
Aging Independently	One of the three vertical domains supported by Continua. Complementary to *Disease Management* and *Health & Fitness*
Alarm	The external enunciation of either physiological conditions, equipment conditions, or other conditions that need attention. Complementary to *Alert* and *Event*
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). Complementary to *Alarm* and *Event*
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. Complementary to *Transaction Communication* and *Streaming Communication*
Certified Capability Class	Entity in the Continua 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 program.
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., PHD, Services,, *or HIS Interface*)
Clock	Refers to an entity that measures *Time*
Clock Synchronization	Refers to the process of updating a *Device's Clock* with other *Clocks* in the environment
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. Complementary to *Notification*
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
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

Term	Definition
Continua Personal Health Devices Interface (PHD-IF)	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 Component using transport media such as USB, BLE, Bluetooth, ZigBee or NFC. Examples of a sensor Service Component is glucose meters, weighing scales, heart rate monitors.
Continua Services Interface	The *Continua Services is an interface* between Personal Health Gateway (e.g. smart phone, tablet and dedicate hub) and Health & Fitness Service (e.g. disease management service, ageing independently service and wellness service). The Health & Fitness Service could be hosted in the cloud. IP based connectivity is assumed between Personal Health Gateway and Health & Fitness Service and Continua focuses on defining the behavior of the OSI Layers above IP.
Continua Healthcare Information System Interface (HIS-IF)	*HIS* is an interface between Health & Fitness Service (e.g. disease management service, ageing independently service, and wellness service) and Healthcare Information System (e.g. EMR, EHR, pharmacy information system).
Continuous	*Continuous* data collection takes samples at regular intervals. Complementary to *Episodic*
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
Counter	A *Counter* is used to measure *Relative Times* (see Relative Time definition below). 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*
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
Device	A *Device* is a physical entity (box) and contains one or more functional *components* and capabilities.
Disease Management	One of the three vertical domains supported by Continua. Complementary to *Health & Fitness* and *Aging Independently*
Document	A *Document* holds summaries, reports, or histories for printing or sharing with other parties. Complementary to *Event* and *Sensor Information*
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 interface - including evidence-based decision support, quality management, and outcomes reporting
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 St. Elsewhere, County-Municipal, or Dr. Smith
Episodic	*Episodic* data collection corresponds to an episode, usually at irregular intervals. The time between samples can vary widely from seconds to weeks or longer. Complementary to *Continuous*
Event	*The occurrence of a condition.* Complementary to *Alert* and *Alarm*
Health Device Profile (HDP)	Bluetooth Health Device Profile 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 PHDs.
Health & Fitness	One of the three vertical domains supported by Continua. Complementary to *Disease Management* and *Aging Independently*

Term	Definition
Health & Fitness Service	A Health & Fitness Service is remote monitoring service (e.g. disease management, ageing indepently and fitness service), hosted on a remote server (in cloud), that may implement at least one Continua defined capabilities in order to talk to Personal Health Gateway and/or Healthcare Information System (HIS).
Health & Fitness Service Application	This is an application running on the *Health & Fitness Service*. The application may implement a number of *Health & Fitness Service Components* AND/OR *HIS Client Components* for the purposes such as data collection, analysis and sharing.
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
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 capabilities embody the principal of interoperability
Interface	An *Interface* is an information interchange point between two *Components*
Local Time	*Local Time* refers to 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
Measurement	A measurement is a measurable observation that is received from a device
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
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. Complementary to *Command and Response*
Observation	An observation is an observable datum from the physical world
Personal Health Gateway (PHG)	One of the Continua Reference Capability classes. A *Personal Health Gateway* is a central point of control in the Continua architecture. The *Personal Health Gateway* contains a number of *Client Components* that *use Personal Health Devices and Services Interfaces* to access one or more *Services* on other *Devices* to coordinate data collection, data analysis, data sharing, and alerting.
PHG Application	This is an application- a piece of software/program that is running on the PHG. The application implements a specific capability and implements one or more (client and/or service) components for the purposes of data collection, analysis and sharing.
Personal Health Device (PHD)	A *Personal Health Device* is a Device that houses a *PHD Interface* Service Component that exposes *PHD Interface*. Examples of a *Personal Health Device* is glucose meter or blood pressure monitor.
Personal Health Devices Interface (PHD-IF)	See the *Continua PHD Interface* clause of this document
PCD-01	IHE Patient Care Device Transaction 01: Communicate PCD Data
Persistent Session	A component in the conceptual model of an PHG that is administratively created. The persistent session stores and forwards observations to a Health & Fitness Service . 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

Term	Definition
Personal Healthcare Monitoring Report *(PHMR, PHM Report, PHM Document)*	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
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
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)
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.
Reference Capability Class	The basis of the guidelines framework include a number of *Reference Capability Classes where topology constraints are explicitly noted*
Sensor	See *Sensor Service Component*
Sensor Information	The information provided by the *Sensor Service Component*
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
Service Component	*Service* is a specific type used in the Continua architecture for any *Component* that provides a *Service* to a *Client Component*
Services Interface	See the *Continua Services Interface* clause within this document
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
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
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. Complementary to *Transaction Communication* and *Batch Communication*
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
Time Mark	The term *Time Mark* is used in instances where either a *Time Code* or *Timestamp* can be used

Term	Definition
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
IHE Transaction	An IHE Transaction is a set of interactions between IHE actors that transfers required information through standards-based messages[3]
Transaction Communication	A communication method where one *Component* exchanges acknowledged *Notifications* or *Command and Responses* with another *Component* to ensure reliability. Complementary to *Streaming Communication* and *Batch Communication*
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. Complementary to *Relative Time*
XDM	The *Cross-Enterprise Document Media Interchange* protocol is published by the IHE. It provides a transport protocol for indirect communication of (e.g. PHR, EHR, EMR)documents transferred over the HIS interface
XDR	The *Cross-Enterprise Document Reliable Interchange* protocol is published by the IHE. It provides a transport protocol for direct communication of (e.g. PHR, EHR, EMR) documents transferred over the HIS interface

[3] http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_rev1.pdf 2.4

8 Abbreviations and Acronyms

The design guidelines uses the following abbreviations and acronyms:

AA	HL7 Acknowledgement Accepted
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
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDG	Continua Design Guidelines
CE	Compute Engine (*deprecated*)
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
HFS	Health and Fitness Service
HIE	Healthcare Information Exchange
HIPAA	Health Insurance Portability and Accountability Act
HTTP	Hypertext Transfer Protocol
HR	Health Report
HRF	hData Record Format
HIS-IF	Healthcare Information System 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
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
PHD-IF	Personal Health Device 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
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
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
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

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