Continua®
HEALTH ALLIANCE

Connecting people and technology for healthier living

Continua Use Case Ballots 2012-2014

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Contents

Introduction

This document presents the Continua Use Case for external publication. These use cases were submitted for approval for development by member ballot in the years 2012-2014.

Continua's Interoperability Guidelines are developed to meet interoperability use cases which have been proposed by the membership and approved at ballot. The procedures for the development and support of use cases are set out in the Continua Use Case Lifecycle Process (section 4.3). Once approved at ballot, a use case would normally remain open to development of new Interoperability Guidelines for a period of 4 years, after which it becomes 'closed' unless there is a case put forward for an extension.

Once approved for development, a use case may be divided into one or more 'work items' which are the discrete increments of capability that are incorporated into the Interoperability Guidelines. In more complex cases, this means some Work Items may be completed and published as Guidelines while others remain in development.

This document provides details of all use cases that have been worked on by Continua and includes:

- **Closed, Not Approved** - Proposals for use cases that have been presented for ballot but not approved.
- **Open, In Development** - Use cases that have been approved and work to develop the supporting Interoperability Guidelines is underway. This includes Use Cases that have become time-expired but still have one or more Work Items already in development that have not yet time expired.
- **Open, Partially Complete** - Use cases for which some elements have been addressed in published Interoperability Guidelines while further aspects remain in development. This also includes Use Cases that have become time-expired but still have one or more Work Items already in development that have not yet time expired.
- **Open, In Service** - Use cases for which the Interoperability Guidelines have been published and are in use and no further development can be undertake. This includes use cases that may have been partially completed and then become time-expired for the remaining aspects of the requirements.
- **Closed, Time Expired** - Use cases that have been approved at ballot but are now closed as work to complete the interoperability Guidelines was not completed before the use case became time expired.

The use cases in this document are presented in date order and listed by the unique project identifier allocated by Continua for tracking the development.

As the nature and format for the use cases has evolved over the years the following notes will help in understanding the use cases presented in this document:

- These are interoperability use cases, and specify the requirements for interworking of different components. As such, they differ from typical end product use cases in that only essential details of the mode of use are provided. For example, the blood pressure monitoring device will specify the data to be transferred, and some aspects of usability, but does not further elaborate on the

actual end-use case for blood pressure monitoring (e.g. as part of a home monitoring regime for management of heart failure).

- The first round of development in 2006 started with a blank sheet of paper and the process was different from subsequent years. Proposals were developed into a series of 'archetypal use cases' which were ranked at ballot into relative priorities. The ballot for this round provided a priority ranking of the archetypal use cases and in some cases, development work further refined the requirements (e.g. specifying the initial range of device types that would be included in the first edition of the Design Guidelines)
- From 2007 onwards, use cases work from the established Continua end to end architecture and specify the additional interoperability requirements being requested.
- In 2012, Continua moved from an annual cycle for collecting new ideas to one that provided three opportunities each year.
- Some use cases are further supported by Feasibility Assessments. These are reviews provided by the various work groups to assist in the evaluation of the use case for the member ballot.

Ballot Status

ID	Name	Ballot Date	Result
Pro12-01	Sleep apnoea breathing therapy equipment	May 2012	Approved
Pro12-03	Continuous Glucose Monitoring (CGM)	September 2012	Approved
Pro12-04	Waveform	September 2012	Approved
Pro12-05	Streaming Video	September 2012	Approved
Pro13-01	Insulin Pump Command and Control	September 2013	Approved
Pro14-02	Portable Critical Care Device Monitoring	January 2015	Approved

2012 Use Cases

Sleep apnoea breathing therapy equipment: PRO12-01

Please read the 2012 call for use cases process description before submitting project abstracts:
2012 Process Overview

Document Control

Version	Date	Change Description
1	2012-02-05	Initial version.

Device Description

Title	Sleep apnoea breathing therapy equipment
Theme(s)	☒ Disease management ☐ Health & Fitness ☐ Aging Independently
Relation with implemented V1 use case(s)	The sleep apnoea breathing therapy equipment is similar to other IEEE device specialization (e.g. Respiration Rate Monitor) or Continua Use Cases (e.g. Pro11-02 Sleep Measuring Device and Pro11-03 Sleep Apnea Measuring Device). Like the Pro11-03 Sleep Apnea Measuring Device and Pro11-05 Remote Device Configuration this project reaches its full performance if the case related setting of the device is possible.

Description	Sleep apnoea breathing therapy equipment treats various kinds of sleep related diseases by positive airway pressure and measures the performance of the sleep therapy. The output and input of a sleep apnoea therapy device over its data interfaces should be separated into:
	
	- Equipment Data and Settings
	  ○ Device data (e.g. Device Type, Serial Number, SW-Version, …)
	  ○ Device state (e.g. Standby, Drying, Therapy, …)
	  ○ Maintenance data (e.g. Hours of Flow Generation, Hours of Filter Use…)
	  ○ Technical alerts (e.g. Empty Humidifier, …)
	- Patient Settings (e.g. Patient-ID, Patient User Interface Language, …)
	- Therapy Data and Settings
	  ○ Therapy mode (e.g. CPAP, Auto-CPAP, BiLevel, …)
	  ○ Therapy parameters (e.g. IPAP, EPAP, …)
	  ○ Compliance data (e.g. Hours of Patient Use, …)
	  ○ Continuous waveforms data (e.g. Flow over time, Pressure over time, …)
	  ○ Events data (e.g. Apnoeas, Hypopneas, …)
	  ○ Analysis data (statistics of therapy data, e.g. AHI, oAHI, cAHI, …)
	  ○ Therapy alerts (e.g. High Leakage, …)
	
	The data and settings are transferred from and to the device in a sleep laboratory, in a physician/ventilation service office or at patient's home.

Healthcare Professionals use some of these data to monitor the performance of the sleep apnoea therapy and to update the current setting of the device in order to improve the performance of the therapy according to the patient needs. Furthermore Healthcare Service Providers use some of these data for maintenance of the device and / or charging the public health insurance or the patient directly for providing this therapy service. And patients use some of these data to get a better insight in the performance of their therapy and for their own motivation (e.g. sleep diary).

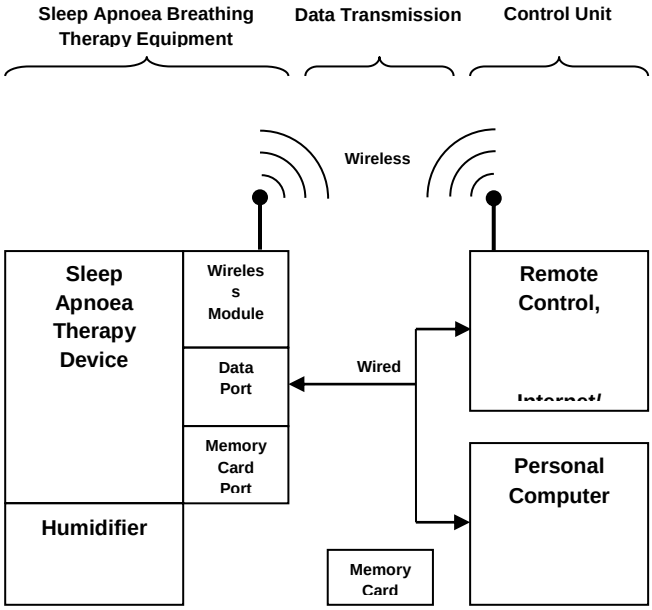
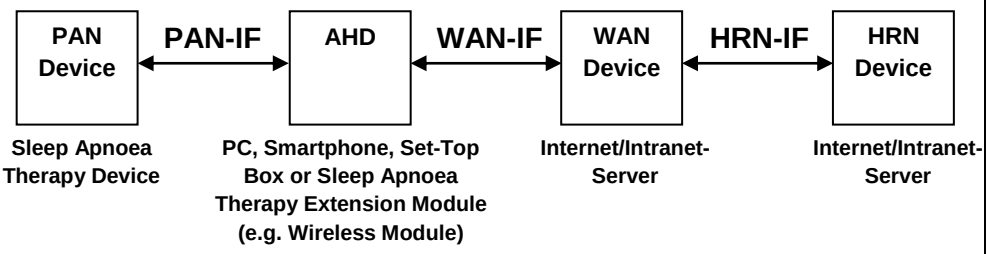


Figure 1: Data interfaces of sleep apnoea breathing therapy equipment as described in ISO/IEC 80601-2-70, chapter BB.2 Model data interface.

According to these following requirements exists:

1. A sleep apnoea therapy device **shall** be able to deliver its information about the sleep apnoea therapy provided to an AHD (e.g. PC, Smartphone) using the PAN-IF.
2. A sleep apnoea therapy device **shall** be able to deliver its information about the sleep apnoea therapy provided to a WAN Device (e.g. Intranet-Server) using the WAN-IF.
3. A sleep apnoea therapy device **can** be able to deliver its information about the sleep apnoea therapy provided to a HRN Device (e.g. Internet-Server) using the HRN-IF.
4. A sleep apnoea therapy device **should** be able to receive new settings from an AHD (e.g. PC, Smartphone) using the PAN-IF.
5. A sleep apnoea therapy device **shall** be able to receive new settings from a WAN Device (e.g. Intranet-Server) using the WAN-IF.
6. A sleep apnoea therapy device **can** be able to receive new settings from an HRN Device (e.g. Internet-Server) using the HRN-IF.

	 **Figure 2: Use Case Sleep apnoea breathing therapy equipment applied to Continua Health Alliance Reference Topology.**
Connectivity	☒ Wired ☒ Wireless
Device Type	☒ Actuator Device ☒ Measurement Device ☐ Display Device ☐ Other Device
Additional remarks	Telehealth solutions for sleep apnoea breathing therapy equipment as described in this use case are commercially available. These are proprietary solutions and only accessible for devices within the framework of the equipment manufacturer.
Request to Expedite	Yes. This use case could be proceeded by the shortened cycle because it is similar to other IEEE device specializations (e.g. Respiration Rate Monitor) or Continua Use Cases (e.g. Pro11-02 Sleep Measuring Device and Pro11-03 Sleep Apnea Measuring Device). Only a different nomenclature is needed.
Peer Review	*<Details of UCWG members who have undertaken a peer review of the completed use case>* Name: Peer review assessment: Satisfactory / Requires Revision Date completed:

Exchanged Data

Full details of exchanged data are not required for the member ballot. Details have been provided with the draft use case and will be subject to review during the technical development stage .

Feasibility Assessment TWG

Use case:	PRO12-01 Sleep apnoea breathing therapy equipment
Reviewer (2 reviewers)	TWG
Date	03/12/2012
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☐ No Architectural Impact e.g. add new measurement device ☒ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☒ Yes, technology to do this is abundantly available ☐ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☒ Suitable SDO available ☐ Standard completed ☐ Standard used in the market
Estimated development time	☐ Less than 1 year ☐ Between 1 and 2 years ☒ Longer than 2 years
Steps needed for completion - New technology? - Standards development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	The technology for this use case is already in the market; however devices currently use proprietary protocols. No standards are currently available. The device will be able to use existing Continua transports and to follow 11073-20601 as base standard, after defining proper extensions with respect to alarming and command & control functionality. . Significant extensions of the WAN and HRN protocols are required to support the setting of the therapy equipment from WAN and HRN devices. Today, the WAN and HRN interface support uploading and reporting functionality only. No changes are anticipated.
Additional Comments	If only data reporting is implemented then the overall assessment easy. If command and control for device settings is required then

	overall assessment is medium. However this is one of several devices waiting on command and control. It is assumed that PAN and LAN can be both used. Some language should be changed (fatal device error) Equipment settings are currently not in scope for IEEE Details of some of the continuous waveforms will require review in IEEE Events will require review in IEEE in order that real time reporting is supported in addition to later reporting Use case contains many data types that may require some consolidation. Also, a use case document is not a technical requirements document. Therefore it is suggested to remove the detailed technical requirements from the document (e.g. the set of required data types), and rather describe the basic steps and user needs regarding for employing sleep apnea breathing therapy equipment.

Feasibility Assessment TCWG

Use case:	Pro12-01 Sleep Apnoea Breathing Therapy Equipment
Reviewer	TCWG
Date	2012-04-02
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☒ Moderate – New Test Procedures will need to be added to the Test Tool. ☐ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☐ Least – Technology to implement the use case exists in open source or current CESL code. ☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise ☐ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time (Assumes a moderate workload implementing 5-6 other use cases at the same time)	☐ Least – Less than nine months for both CESL and the Test Tool to finish. ☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☐ Large – Greater than fifteen months for both CESL and the Test Tool to finish.
Estimated CESL and Test Tool Cost	☐ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☒ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☐ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.
Additional Comments	This UC will be implemented by creating a new IEEE 11073 device specialization. Therefore, CESL and Test Tool already have the baseline support for IEEE 11073-20601 and it is necessary to extend their functionality to a new device specialization only. According UC description, the Sleep Apnoea equipment (agent) sends observed value to manager, and the manager may also configure the agent. The remote agent configuration

	is not performed in current device specs, and therefore it is not supported in CESL and it is not tested in Test Tool. This is a new functionality that may increase considerably the CESL and Test Tool implementation complexity. Work to be done for CESL: - Create example agent implementation for the new device spec - Modify CESL GUI Manager to support and present observations from the new device spec - Modify CESL WAN Bridge to include observations from the new device spec into PCD-01 document. Work to be done for Test Tool: - Integrate new CESL pieces into Test Tool - Create PAN-LAN Agent and Manager Test Cases for the new device specialization - Create WAN Sender and Receiver Test Cases for the new device specialization - Modify the existing HRN Test Cases to check in PHMR document the elements related with new device specialization.
Overall assessment	**Medium** – – No more than one “Large” item

Continuous Glucose Monitor: PRO12-03

Document Control

Version	Date	Change Description
0.1	May 8, 2012	Original Draft

Device Description

Title	**Continuous Glucose Monitor**
Theme(s)	☒ Disease management ☐ Health & Fitness ☐ Aging Independently
Relation with implemented V1 use case(s)	The use cases of a standardized communication to a Continuous Glucose Monitor (CGM) show some similarities to the existing Blood Glucose Meter (BGM) use cases from 2006. However, there are also significant differences, as pointed out in the remainder of the use cases described below, e.g., CGM measurements are typically periodic (instead of episodic), a CGM sensor measures glucose from body fluids and may also require calibration to blood-based glucose measurements. A CGM device may allow user and manufacturer specific settings such as the periodic measurement rate. Note that use case Pro11-14 "Bi-directional exchange of glucose data between devices for the purpose of instant calibration and comparison of glucose results from alternate sources" was approved in 2011, but has not proceeded through further development. It is proposed that the work on use case Pro11-14 be absorbed into this new CGM device use case, as the bi-directional exchange of glucose data between devices is required by the current CGM device technologies for calibration purposes as mentioned above and is intended for Pro11-14.
Description	A CGM device allows a patient to monitor their glucose level at a periodic rate as optionally set through the communications interface by the device manufacturer. This "continuous" glucose monitoring improves therapy control as opposed to the single, episodic finger stick measurements of a blood glucose meter (BGM). Frequent measurements provided by a CGM give a patient greater insight as to the fluctuations in blood glucose levels throughout the day, and in turn, can reduce the risk of developing diabetic complications. A CGM device is typically composed of three components: the sensor, the transmitter, and the receiver. With current technology, the sensor consists of a small metallic

filament that is inserted into the fatty layer below the skin where it measures the glucose level from the interstitial fluid. Typically, there is a mechanical means (e.g., an adhesive patch) used to keep the sensor in place. A sensor typically needs to be replaced periodically; a separate transmitter connected to the sensor is used to wirelessly transmit the measurements to the receiver. This receiver is often a separate handheld device that can display trend graphs and other statistics along with the current measurement. Insulin pumps, and other personal electronic devices (PED), can also serve as the receiver of the CGM measurements.

There are three key communication modes that require a standard for interoperability of the CGM device.

1) **Communication supporting calibration.** As CGM devices typically measure glucose from a body fluid containing glucose, they need to be calibrated against a blood-based glucose measurement. As such, the transmitter needs to communicate with the BGM to receive this calibration measurement. Data transfer for the purpose of calibration may be realized between the BGM and the CGM transmitter directly, or may be mediated through the CGM receiver (see Figure 1 below).

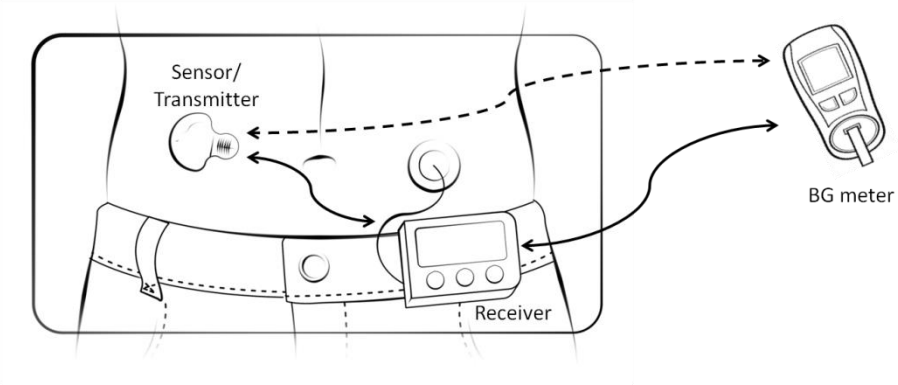


Figure 1: CGM Calibration

As depicted here, the calibration may be conducted directly between the BG meter and the CGM Sensor/Transmitter (dashed line) or mediated through the CGM receiver (solid line).

2) **Communication supporting CGM data transmission between the transmitter and the receiver.** As a CGM may be transmitting data to either a designated CGM receiver, an insulin pump or other personal electronic device, an interoperable standard of communication would better support the variety of devices that could be used. Depicted in Figure 2 as an insulin pump, the receiver could also be a mobile phone, a stand-alone CGM receiver, a BG meter, or another personal electronic device.

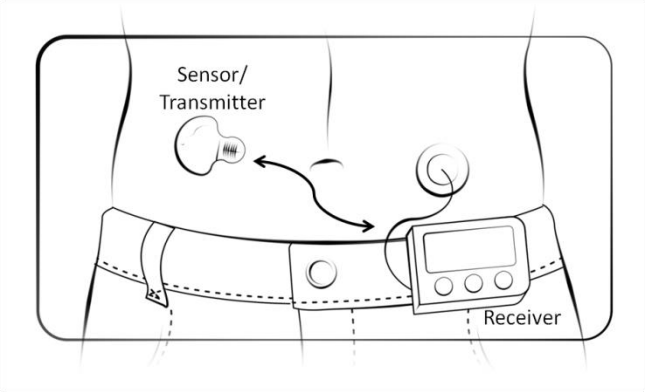
<table>
<tr><td></td><td>


Figure 2: Sensor Data Transmission

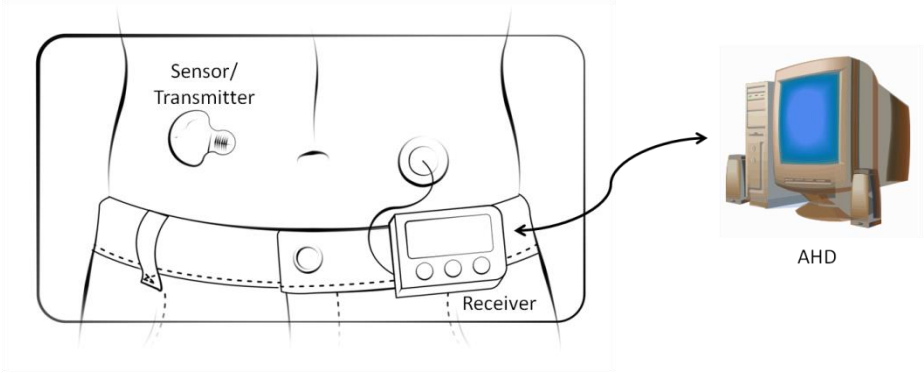
3) Communication between the receiver and a collector device. The CGM device, or its receiver, may periodically send the measurement results to the patient's Application Hosting Device (AHD) upon availability or the exchange may take place after a CGM session (hours or days). Furthermore, the patient's AHD may request results of a dedicated time period. This functionality, in addition to the store and forward scenario, requires timestamps for each measurement result. The AHD as referenced here could be a PC, mobile phone, or other device.


Figure 3: CGM receiver to collector communication
</td></tr>
<tr><td>Connectivity</td><td>☒ Wired
☒ Wireless</td></tr>
<tr><td>Device Type</td><td>☐ Actuator Device
☒ Measurement Device
☒ Display Device
☐ Other Device</td></tr>
<tr><td>Additional</td><td>The underlying standards development process has already begun, as development of a communication standard for CGM devices has been undertaken by the IEEE Personal</td></tr>
</table>

remarks	Health Device Working Group (IEEE P11073-10425). The Medical Devices Working Group of the Bluetooth Special Interest Group (SIG) is likewise developing a standard profile for CGM data communication over Bluetooth Low Energy, which will be compatible with IEEE P11073-10425. The standard being developed by the Bluetooth SIG will cover all communication involving the sensor/transmitter (modes 1 and 2) as this will require Continua Low Power Wireless PAN transport (via BLE). Communication between a receiver device and an AHD would be covered by IEEE P11073-10425 over any Continua PAN transport (USB, Bluetooth) as well as by the Bluetooth SIG standard for when low power wireless communication is being used.
Request to Expedite	Yes, we are requesting an expedited development process for the CGM device due to pressures to quickly deliver CGM products to the market with a standards-based communications interface. Existing commercial products already support the described data communication with proprietary low power RF communication protocols.

Exchanged Data

See Data Clusters document for examples.

Data Type	Format	Unit	Comment	Priority	Direction	Transmission
<name of the data element>	<format: eg. xxx.xx for float, string(255), xxx for integer>	<units of measure, if applicable>		<M = mandatory, O = optional>	<O = outbound from device, I = inbound to device>	<E = episodic, C = continuous>
Session Start Time	xxx	YYYY-MM-DD hh:mm:ss		M	O	E
Measurement Time (in CGM sequence)	xxx	minutes	Relative in time to session start	M	O	C
Measurement Period	xxx	minutes	(Result communication interval)	M	I	E
Glucose Concentration	xxx	mg/dL	Measurements made by CGM	M	O	C
CGM Sample type and Location	enum		Enumerated list of options	O	O	E

Data Type	Format	Unit	Comment	Priority	Direction	Transmission
Calibration Measurement (from BGM)	xxx	mg/dL	Received from BGM	O	I	E
Calibration Time	YYYY-MM-DD hh:mm:ss		Accompanies each calibration value	O	I	E
Calibration Sample Type and Location	enum		Enumerated list of options	O	I	E
Next Calibration Time	xxx	minutes	Relative time in minutes, informs user of next necessary calibration	O	O	E
Device and Sensor Status	bit-code		Separate bits provide status information	O	I	E

Feasibility Assessment TWG

Use case:	Pro12-03 Continuous Glucose Monitor
Reviewer (1 reviewer)	Krishna Shingala
Date	July 14, 2012
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☒ No Architectural Impact e.g. add new measurement device ☐ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☒ Yes, technology to do this is abundantly available ☐ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☒ Suitable SDO available ☐ Standard completed ☐ Standard used in the market
Estimated development time	☒ Less than 1 year ☐ Between 1 and 2 years ☐ Longer than 2 years
Steps needed for completion - New technology? - Standards development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	IEEE PHD working group has initiated work on Continuous Glucose Monitoring Device Specialization. Bluetooth Medical Devices Working Group has initiated work on creating necessary profiles and services. The standard aims at data compatibility with the PHD standard.
Additional Comments	The BLE Standard may be adopted earlier than the PHD one. However, the groups will work closely to ensure data compatibility.
Overall assessment	**Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year.

Feasibility Assessment TCWG

Use case:	Pro12-03 CGM (Continuous Glucose Monitoring)
Reviewer	TCWG
Date	7/2/2012
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☒ Moderate – New Test Procedures will need to be added to the Test Tool. ☐ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☐ Least – Technology to implement the use case exists in open source or current CESL code. ☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise ☐ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time	☐ Least – Less than nine months for both CESL and the Test Tool to finish. ☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☐ Large – Greater than fifteen months for both CESL and the Test Tool to finish.
Estimated CESL and Test Tool Cost	☐ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☒ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☐ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.
Additional Comments	Reviewer 1 Nothing exotic in terms of development (tools already support BTLE and 11073) but likely a significant amount of work (possibly some complexity). The use-case introduces many new devices and some devices would have dual roles (be both an Agent and a Manager so would need to be tested separately). For the CGM Receiver, certification at Bluetooth for both BTLE and HDP (or USB) would be required.

	Do we have to support simultaneous transmission of multiple transports (BTLE and IEEE 11073)? This could be a significant variable on further increasing complexity (to high medium). The CGM IEEE spec is only now starting. **Reviewer 2** Architecture Impact: This UC will use interfaces already available in Test Tool (PAN-LAN and BTLE). However, at this moment the Test Tool does not use two or more interfaces simultaneously. It shall be necessary to modify the Test Tool to be able to send and receive across two different interfaces at the same time. Technology Availability: It shall be necessary to extend CESL support for new IEEE CGM device specialization and also for new BTLE profile (it may require additional effort if CGM Transmitter must receive calibration values from BG Meter). Development Time/Cost: The development would require: • Test Cases for IEEE CGM: Manager side (PC/AHD) and Agent Side (CGM Receiver) • Test Cases for BTLE CGM: Agent side (CGM Transmitter) and Manager Side (CGM Receiver and PC/AHD) • Test Cases for BTLE BG Calibration: Agent side (CGM Transmitter) and Manager side (BG Meter for Calibration). This development would be similar to develop 1 IEEE Dev Spec for CGM + 1 BTLE Profile for CGM + 0.75 BTLE Profile for BG Calibration. Reviewer 3 This project is already a PAR in IEEE. It really consists of two separate interfaces; a BTLE and normal 20601 PAN interface. For CESL the fundamentals for both of these interfaces are already present so no new technology will need to be developed. However, BTLE can be very different for each specialization so unlike new 20601 device specializations which are scalable, developing example BTLE applications requires quite a bit of additional work. There will be some trickiness simulating the chain as a single application (BTLE to receiver which is not a manager that then sends 20601 PAN data to manager). This would be a medium level development.
Overall assessment	**Easy** – Two or more “Least” items *and* no “Large” items

Regulatory Impact Assessment

Use case:	Pro12-03 CGM (Continuous Glucose Monitoring)
Reviewer	RWG
Date	20 Jul 2012
Regulatory Impact Assessment	The implementation of design to comply with the standard may include additional regulatory burden.
Additional Comments	Healthcare regulations related to legally placing a CGM product on the market are typically more extensive than required for episodic BGM systems. For example, in the USA a CGM product must gain market approval through the premarket approval (PMA) process; this is a more expensive (time and dollars) registration approval process than the 510(k) (premarket notification) process. There are also significant levels of oversight for marketing of a PMA product compared to a 510(k) product. Currently, FDA is not clear on how they intend to regulate products that incorporate design attributes that are clearly specific for a medical purpose; in this case, standardized communication with CGM products. FDA will decide, case-by-case, whether a device containing such a standardized communication interface will be considered an accessory to the CGM device or not. An accessory device adopts the same regulatory burden as the 'parent' device. This could mean that devices incorporating such a standard may be regulated under a PMA in the USA. Similar discussions on how this particular scenario will be regulated are underway in nearly every country.

Waveform: PRO12-04

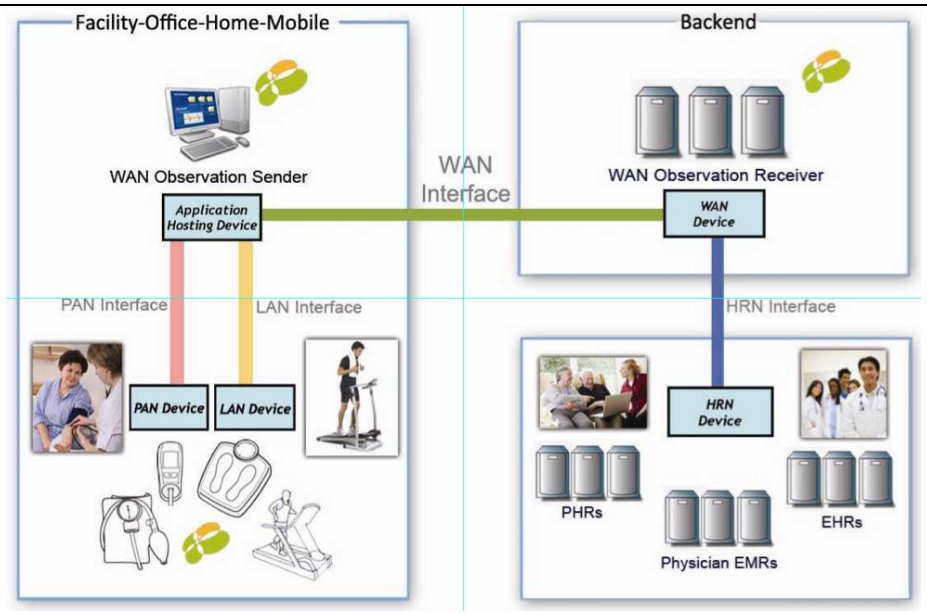
Document Control

Version	Date	Change Description
0.3	25 April 2012	Final for ballot. Revised Key Requirements based on feedback from Continua membership

Project Description

Title	Provide longitudinal, continuous, and non-invasive assessment of biometric data in most efficient fashion via wireless network.
Theme(s)	☒ Health and Fitness ☒ Chronic Disease management ☒ Aging Independently ☐ Other – specify:
Relation with implemented V1 use case(s)	This project is related to but separate from the Embedded Area Network Use Case.
Description	Maximizing efficiency of the PAN and WAN interfaces is key to providing the longest, least intrusive, and most continuous study interval between device recharging.
Scope	WAN Interface

Problem statement, and/ or Benefit(s) provided to end user	Clinical researchers need mechanisms to help provide longitudinal, continuous, and non-invasive assessment of biometric data for long-term ambulatory monitoring. Typical applications include monitoring ECG, inertial body sensors, photoplethysmographic signals, post-operative respiratory complications, ankle joint angle to assess Ankle-Foot Orthoses efficacy, and enable timely response to agitation events in dementia patients minimizing patient stress and risk for injury. Long-term cellular connectivity greatly expands the opportunity for such assessments.
Actors	ECG patch, wearable photoplethysmogram (PPG) sensor, inertial Body Sensor Network, medical device dongle, ankle-foot-orthoses, and accelerometer-based devices with wireless PAN/LAN and/or WAN connectivity.
Minimal Guarantees	Ability for aforementioned device to transmit biometric data over the wireless WAN interface.
Success Guarantees	Provide clinicians longitudinal and continuous data stream in non-invasive fashion for a period of at least 24 hour to allow them to assess biometric data on par with that collected in a wired environment.
Trigger	Clinician determines that non-invasive longitudinal and continuous assessment of a patient is necessary for proper care and treatment.
Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)	1) Clinician evaluates patient and determines that remote, continuous, and long-term monitoring of key parametric data is essential for the observation, treatment, and care. 2) Clinician secures appropriate Continua compliant device to perform the monitoring. 3) Clinician creates the necessary accounts on the data monitoring network. 4) Clinician activates the device to operate on the cellular network that provides sufficient coverage area for where the patient lives and works. 5) Clinician provides patient basic instruction on when and how to charge the device. 6) Patient goes about daily business or as otherwise instructed by the clinician. 7) Clinician collects and assesses biometric data for the duration of the study. 8) Patient returns monitoring device to clinician.
Failure Modes	Patient travels out of coverage area, fails to charge the device as instructed, or fails to keep the sensor properly affixed. Monitoring system will notify clinician when communications to the monitoring device is lost.

Diagram (mandatory)	
Request to Expedite	NO, not an expedited development process requiring parallel development in TWG.

Key Requirements

No	Keyword	Requirement Description	Acceptance criteria	Comments
1	Data Rate	Data rate shall be sufficient to recreate a 120 hz 12 bit waveform in near real time.	Interface shall support a minimum data rate of 9600 bps.	
2	Batch Transmission	Device shall be able to store waveforms for later transmission.	Waveform shall be accurately reproduced following XX second loss of radio signal.	Storage of waveforms essential for optimal use of network resources and device power.

No	Keyword	Requirement Description	Acceptance criteria	Comments
3	Interface Selection	Interface shall have a policy to dynamically select between available interfaces based on connectivity cost and performance.	Demonstrate connectivity in preferred order (e.g. wired, wifi, cellular).	
4	Maintain IP Connectivity	Interface shall seek the best WAN interface to provide seamless IP connectivity under mobility constraints.	Demonstrate IP connectivity over wired, wifi, and cellular.	Seamless does not imply maintaining IP when switching between wired, wifi, or cellular.
5	Security	Interface shall ensure data stream can only be accessed by authorized user.		See Security.
6	Data Integrity	Interface shall employ end-to-end integrity protection / checking.		See Security.
7	Interoperable	Interface shall interoperate with the new WAN receiver.	Data will be successfully exchanged between WAN sender and WAN receiver	

Feasibility Assessment TWG

Use case:	Pro12-04 Waveform
Reviewer (2 reviewers)	TWG
Date	11-JUL-2012
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☒ No Architectural Impact e.g. add new measurement device ☐ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☒ Yes, technology to do this is abundantly available ☐ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☐ Suitable SDO available ☐ Standard completed ☒ Standard used in the market
Estimated development time	☒ Less than 1 year ☐ Between 1 and 2 years ☐ Longer than 2 years

Steps needed for completion - New technology? - Standards development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	In 2011 IHE PCD has developed the Waveform Content Message which is a Content Profile which will extend existing IHE PCD profiles to provide a method for passing near real-time waveform data using HL7 V2 observation messages. This content profile is fully aligned with the existing Continua WAN interface and can therefore be easily added in Continua. On the PAN/LAN/TAN interface IEEE 11073 already supports transmitting near real time waveform data and this data can be wrapped into the IHE PCD Waveform Content Message.
Additional Comments	The IHE PCD Waveform Content Message spec can be found here: http://www.ihe.net/Technical_Framework/upload/IHE_PCD_Suppl_Waveform_Content_Message_WCM_TI_2011-07-01.pdf The latest "Trial Implementation" (TI) version of WCM is dated 2012-05-20, is being reviewed by the IHE staff, and no further voting is required. Relative to the 2011-07-01 version cited above, it includes several optimizations to reduce the amount of meta-data that is sent regarding filters and other waveform attributes.
Overall assessment	**Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year

Feasibility Assessment TCWG

Use case:	Pro12-04 Waveform
Reviewer	TCWG
Date	7/2/2012
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☒ Moderate – New Test Procedures will need to be added to the Test Tool. ☐ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☐ Least – Technology to implement the use case exists in open source or current CESL code. ☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise ☐ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time	☐ Least – Less than nine months for both CESL and the Test Tool to finish. ☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☐ Large – Greater than fifteen months for both CESL and the Test Tool to finish. (Assumes a moderate workload implementing 5-6 other use cases at the same time)
Estimated CESL and Test Tool Cost	☐ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☒ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☐ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.
Additional Comments	Reviewer 1 Agree on the problem statement and need and should be doable as Waveform is already apart of PAN via 11073 (via RTSAs) though I've never seen it implemented.

	Reviewer 2 Architecture Impact: This UC will use interfaces already available in Test Tool (PAN-LAN and WAN). My major concern is security requirements because it seems that this UC is based in EAN. Security for EAN will be different than SAML2.0 token and therefore it will be necessary to include in Test Tool support for EAN security. Technology Availability: It shall be necessary to include support for EAN security. It is necessary that security selected in EAN Use Case can be implemented with open source libraries. Development Time/Cost: I am assuming that Waveform transmission will be based on existing methods in PAN-LAN (i.e. RTSA) and WAN (PCD-01 matrix). The complexity may be located in security requirements and also in handover requirements (if they finally are included in Guidelines). If this UC is implemented in Test Tool jointly with EAN UC, the development effort may be reduced if both UC select the same security requirements. Reviewer 3 In theory the infrastructure for waveform data is present but so far never been used (RTSA on the PAN side) and there is facilities for transmitting waveform data over the WAN in PCD-01 (even less tested or used). There could be potential issues with the inefficient HTTP bridge to go from CESL C++ to Java WAN sender with this data load requirement. The use case also throws a lot of devilish details about authorization which may create surprises. This would be a medium effort as a first guess.
Overall assessment	**Medium** – No more than one “Large” item.

Regulatory Impact Assessment

Use case:	Pro12-04 Waveform
Reviewer	RWG
Date	20 Jul 2012
Regulatory Impact Assessment	There may be additional regulatory burden imposed upon the device manufacturer who includes design characteristics for compliance to this standard in their devices.
Additional Comments	Regulatory The intended use of a given technology is significant in determining the level of regulation imposed. The use case in question can be used in two general manners: 1) support of clinical trials to capture data related to the trial, and 2) support of therapy or diagnostic decisions for individual patients. Both uses have regulatory oversight by most Federal healthcare authorities. As example, FDA is not currently clear on how they intend to regulate products that incorporate design attributes that are clearly specific for a medical purpose; in this case, standardized communication with medical products. FDA will decide, case-by-case, whether a device containing such a standardized communication interface will be considered an accessory to the medical device or not. An accessory device adopts the same regulatory burden as the 'parent' device. Similar discussions on how this particular scenario will be regulated are underway in nearly every country.

Streaming Video: PRO12-05

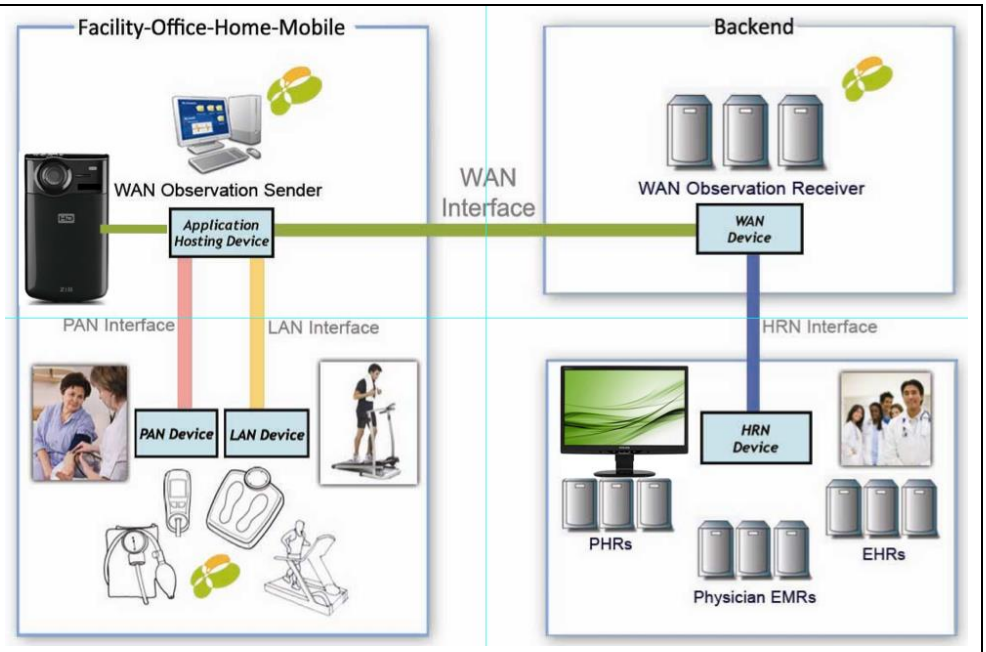
Document Control

Version	Date	Change Description
0.3	25 April 2012	Final for ballot. Revised Key Requirements based on feedback from Continua membership

Project Description

Title	Enable efficient streaming of two-way video over wireless network.
Theme(s)	☒ Health and Fitness ☒ Chronic Disease management ☒ Aging Independently ☐ Other – specify:
Relation with implemented V1 use case(s)	This project is related to but separate from the Embedded Area Network Use Case.
Description	To ensure interoperability of various video camera, networks, and hospitals, devices must utilize common compression and encryption schemes. In addition, they must negotiate use of network resources in real-time to deliver the best combination of resolution and frame rate to properly serve the end-users.
Scope	WAN Interface
Problem statement, and/ or Benefit(s) provided to end user	Video is becoming a more common tool used as a force multiplier in telemedicine, extending the reach of doctors to serve a larger geographical region, or to make a more broad range of disciplines available to a disaster site on an as-needed basis.
Actors	Video cameras with wireless broadband WAN connectivity Video monitors with wireless broadband WAN connectivity Cellular mobile network to provide broadband communication

	Gateways & routers capable of securely transcoding encrypted video
Minimal Guarantees	The ability for video camera to transmit and video monitor to display video with resolution and/or frame rate and latency sufficient for doctor to visually assess medical condition with sufficient confidence to direct necessary medical intervention to a field personnel.
Success Guarantees	Provide doctors of a variety of disciplines with virtual presence at disaster site to correctly direct field medic.
Trigger	A natural disaster (for instance) that requires more emergency on-site medical support than can be provided by local authorities. Life threatening injury that happens in a remote region. General medical assessment at remote location when/where not feasible/practical to reach by conventional means.
Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)	Emergency medical personnel receive request for assistance through traditional mechanisms (e.g. 911, Emergency Disaster Response). Doctor on duty discovers or determines not feasible or practical to respond via conventional methods (e.g. life flight, ambulance) Continua compliant video cameras and monitors air-dropped or brought to emergency site by local authorities. Field personnel initiate video call to supporting hospital Supporting hospital accepts incoming video call and provides qualified personnel to administer medical support. Field personnel aim camera at subject and follow instructions from the supporting hospital.
Failure Modes	In the event that the emergency services must be provided at a site outside network coverage sufficient for streaming video, voice instruction can be provided. In the event of no coverage, then conventional treatments would be used.

Diagram (mandatory)	
Request to Expedite	NO, not an expedited development process requiring parallel development in TWG.

Key Requirements

No	Keyword	Requirement Description	Acceptance criteria	Comments
1	Mobile Resolution	Video signal to mobile device shall use standardized horizontal and vertical resolutions.	Interface shall maintain a minimum of QCIF (176x144)	
2	Clinic Monitor Resolution	Video signal to typical monitor shall use standardized horizontal and vertical resolutions	Interface shall maintain a minimum of DCIF (528x324)	Do we push for 720P or leave that to market forces?
2	Bit Rate	Interface shall determine appropriate bit rate for application based on available WAN performance.	Video stream shall be evaluated across WAN with minimal, nominal, and optimal performance.	
3	Frame Rate	Video shall be presented at a frame rate that creates a moving image sufficient to allow a tending physician to properly assess the patient condition.	Interface shall support a minimum of 14 frames per second.	
4	Latency	Latency of the video shall be minimized to support real-time conversation.	Latency shall be less than 0.33 seconds.	
5	Codec	Video frame sample size shall be reduced to make efficient use of network, memory, and power resources.		MPEG1, MPEG4, H.263, and H.264 are popular codecs that should be considered.
6	Security	Video shall be transmitted in secure manner to ensure patient privacy.	Interface shall ensure video stream can only be accessed by authorized users.	Secure Scalable Streaming my be considered.

No	Keyword	Requirement Description	Acceptance criteria	Comments
7	Adaptive	Interface shall scale up or down performance based on parameters such as network conditions and remaining battery life.	Video shall remain meaningful when transmitted on 3 pre-determined levels of network performance.	
8	Data Integrity	Interface shall employ end-to-end integrity protection / checking.		See Security.
9	Interoperable	Interface shall interoperate with the new WAN receiver.	Data will be successfully exchanged between WAN sender and WAN receiver	
10	Interface Selection	Interface shall have a policy to dynamically select between available interfaces based on connectivity cost and performance.	Demonstrate network connectivity over interfaces supported by device.	
11	Maintain IP Connectivity	Interface shall seek the best WAN interface (wired, wifi, cellular) to provide seamless IP connectivity under mobility constraints.	Demonstrate IP connectivity over wired, wifi, and cellular.	Seamless does not imply maintaining IP when switching between wired, wifi, or cellular.

Feasibility Assessment TWG

Use case:	PRO12-05_Streaming_Video
Reviewer (2 reviewers)	TWG
Date	14-JUL-2012
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☒ No Architectural Impact e.g. add new measurement device ☐ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☒ Yes, technology to do this is abundantly available ☐ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☒ Suitable SDO available ☐ Standard completed ☒ Standard used in the market
Estimated development time	☒ Less than 1 year ☐ Between 1 and 2 years ☐ Longer than 2 years

Steps needed for completion - New technology? - Standards development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	- The current standards used on the WAN-IF are not suitable for video streaming - New standard would be required for encoding the streaming video (e.g. H.264, MPEG-4, MJPEG, MPEG, etc.) - New standard for the exchange of video streaming (e.g. RTSP http://tools.ietf.org/html/rfc2326) - New standards for providing confidentiality, integrity, and authenticity (e.g. DTLS http://tools.ietf.org/html/rfc4347)
Additional Comments	- From the description of the use case it is not clear whether this use case only targets the WAN-IF or also HRN-IF. Please clarify this - The figure also shows the HRN-IF, is this the case? Please clarify this. - The actors mentions about cellular mobile network, gateways and routers, Continua e2e architecture doesn't have any such actors, please clarify this. This would imply change into the architecture.
Overall assessment	**Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year

Feasibility Assessment TCWG

Use case:	Pro12-05 Streaming Video
Reviewer	TWG
Date	7/2/2012
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☐ Moderate – New Test Procedures will need to be added to the Test Tool. ☒ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☐ Least – Technology to implement the use case exists in open source or current CESL code. ☐ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise ☒ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time (Assumes a moderate workload implementing 5-6 other use cases at the same time)	☐ Least – Less than nine months for both CESL and the Test Tool to finish. ☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☒ Large – Greater than fifteen months for both CESL and the Test Tool to finish.
Estimated CESL and Test Tool Cost	☐ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☐ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☒ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.
Additional Comments	Reviewer 1 Nice use-case though it seems that it may be a large task to build streaming video infrastructure within CESL and the Test Tool (specifically the Interface Requirement: Demonstrate network connectivity over interfaces supported

	by device - need a dynamic policy to select the interfaces). Reviewer 2 Architecture Impact: Although the UC will use the WAN interface, it will be based in a totally different payload. Technology Availability: Currently, WAN interface sends PCD-01 messages as payload only. It is not possible to re-use or extend functionality already included in Test Tool. The UC will require to implement the support for Streaming Video. Development Time/Cost: I am assuming that Streaming Video transmission will be based on a similar WebService infrastructure than PCD-01 message transmission. The Test Cases implementation effort will depend on level of testing (for instance, do we want to test Video codecs? The QoS?). I am assuming a medium level of testing. Reviewer 3 This infrastructure is 100% absent in CESL; it sounds more to me like DLNA. This project would be a major undertaking and would introduce a completely new facet (like BTLE) with streaming video format knowledge to CESL. Was DLNA looked at?
Overall assessment	**Difficult** – Two or more “Large” items.

Regulatory Impact Assessment

Use case:	PRO12-05_Streaming_Video
Reviewer	RWG
Date	20 Jul 2012
Regulatory Impact Assessment	There may be additional regulatory burden on the device manufacturer who implements design characteristics supporting compliance to this use case standard in their device.
Additional Comments	Regulatory The intended use of a given technology is significant in determining the level of regulation imposed. The use case in question implies that the communication standard would support remote diagnosis and therapy decisions. Most, if not all, healthcare authorities regulate this intended use. For example, FDA regulates telemedicine / telepresence devices. The level of regulation depends upon the intended use, which is in part determined by how reliant a care giver is on the information being received by the device. The other aspect to consider in this particular case is what claims are being made by the entity employing the standard in their device. FDA is not currently clear on how they intend to regulate products that incorporate design attributes that are clearly specific for a medical purpose; in this case, standardized communication with medical products. FDA will decide, case-by-case, whether a device containing such a standardized communication interface will be considered an accessory to the medical device or not. An accessory device adopts the same regulatory burden as the 'parent' device. Similar discussions on how this particular scenario will be regulated are underway in nearly every country.

2013 Use Cases

Insulin Pump Command and Control: PRO13-01

Document Control – Use Case

Version	Date	Change Description
6	28 Aug 2013	Final for ballot. Comments from regulatory review incorporated

Project Description

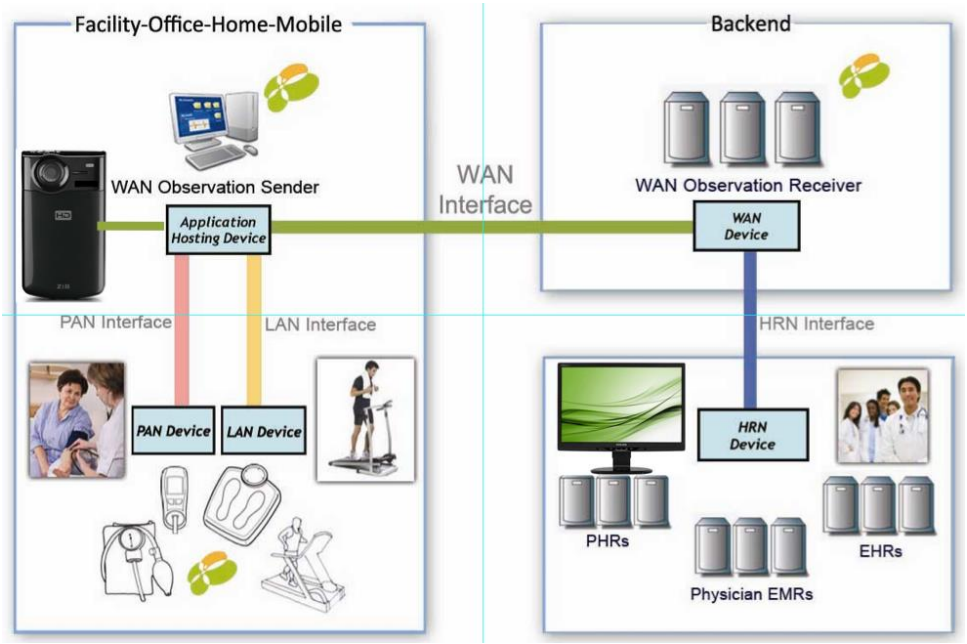
Title	Insulin Pump Command and Control
Theme(s)	☐ Health and Fitness ☒ Chronic Disease management ☐ Aging Independently ☐ Other – specify:
Relation with implemented V1 use case(s)	This use case is an extension of the original *Insulin Pump Monitor Device* Use Case (UC 24, 2008). The original use case focused on monitoring the insulin pump device – this use case considers the requirements relating to controlling the device settings and actions.
Description	An insulin pump provides a means for continual delivery of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII). By adjusting the insulin level during the day to match the individual's biological rhythms and to compensate for food intake, insulin pumps can help to stabilize blood glucose levels. This stability in glucose levels – glycemic control – reduces the frequency of diabetic complications. Given the need to maintain stable glucose levels over time, there is great value in the review and analysis of insulin delivery and other associated events recorded by the insulin pump. Work is already underway to create interoperable standards for the **monitoring** of the insulin pump (the aforementioned Use Case, and its associated Work Items). This Use Case extends the need for interoperability to the insulin pump **controls**, notably:

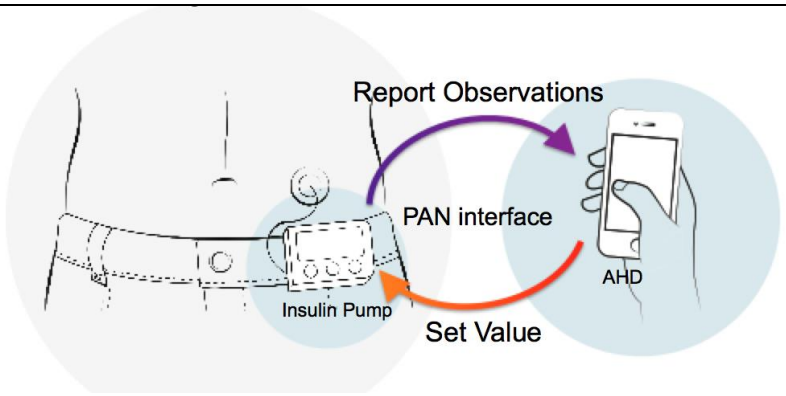
	- programming a *24-hour insulin basal profile setting* - setting the active profile and activating the profile. - setting a specific basal rate for a temporary period of time and activating the temporary rate (as controlled by the user under certain circumstances). - stopping or cancelling a temporary basal rate - setting a *bolus* delivery and activating the bolus (commonly used to match the intake of a meal) - stopping or cancelling a bolus delivery - programming *insulin-to-carbohydrate ratio profiles* and/or the insulin sensitivity/*correction factor* Interoperable control over the insulin pump should enhance the development of novel disease management software (predominantly developed for mobile devices). Interoperability would be of particular value for the ongoing development of artificial pancreas technology. This technology would allow for ongoing control over insulin delivery based on measured glucose changes from a continuous glucose monitor (thereby in essence, substituting for the endocrine functionality of the pancreas). Interoperability among insulin pumps would enable accelerated innovation in the domain of artificial pancreas technology.
Scope	The scope of this use case includes the control of the insulin pump through connected compute engines, notably mobile devices, and laptops.
Problem statement, and/ or Benefit(s) provided to end user	Insulin pump devices are predominantly controlled manually or via proprietary communication protocols. This limits the tools made available to insulin pump users. Interoperability would enable effective development of diabetes management software. It would also accelerate innovation of artificial pancreas technology, which is seen as the future of effective diabetes therapy as indicated by the recent publication and release of the Final Guidance for Industry and the Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems [1] and through initiatives funded by JDRF and the American Diabetes Association.
Actors	**Clinician** – a clinician – or perhaps a designated technician supporting the clinician – would likely be involved in initiating the connections between the insulin pump and an AHD that is used to control the pump.

[1] Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259305.pdf

	Insulin Pump User – the insulin pump users may run the programs on an AHD that would allow them to control the insulin pump (deliver boluses, temporary basal rates, or adjust the 24-hour profile or carbohydrate profile). **Family Caregiver** – in certain situations, a family caregiver may take the place of the insulin pump user in controlling the device (e.g. a parent caring for a child, or a family member providing support for an elderly relative). * Note: Authentication of the users (e.g., end user, support, or healthcare professional) of the device is also critical. The approach to accomplish authentication and the strength of authentication should be driven by the manufacturers intended use and risk assessment of the various use cases.
Minimal Guarantees	If the use case fails, all changes in settings on the device must be controlled manually by the patient (or in some scenarios, the clinician, or family caregiver) and the device should return to a safe state. In some cases, that might be a continuation of delivery an in other cases this would be to stop deliver. In either case, the user should be able to interface directly with the pump to halt delivery, and manual control over settings, as well as bolus and temporary rate delivery, is currently a standard operational mode for insulin pump devices. The minimal guarantee operationally is that the insulin pump must persist with the programmed insulin delivery as the therapy should not be halted if there is a broken communication connection or similar issue. Upon re-establishing connection, an AHD could resume control of the device.
Success Guarantees	An effective interoperable standard will result in either a patient, family caregiver, or clinician being able to connect to establish connectivity with the pump and relay all the necessary commands and configuration settings. These would include: • The upload of new 24-hour insulin profiles (either new profiles that could be used by the patient, or overwriting a profile already stored on the device). • Activation of a profile (essentially switching from one profile to another). After activation, the selected profile would now dictate the hour-by-hour changes of insulin delivery rates. • Setting of a temporary bolus rate (certain situations allow the user to set a temporary rate different from the bolus rate – such temporary rates would usually be set for a few minutes up to a few hours) • Commanding the delivery of a bolus insulin dose. • Setting other device parameters including the carbohydrate-to-insulin ratio profiles as well as the correction factor (also known as 'insulin sensitivity).

Trigger	The trigger would be initiated by the user of the insulin pump through the operation of the AHD. As has been noted, the program could also be operated by a clinician or family caregiver. In the case of artificial pancreas technology, the application itself may send these commands directly, as its mode of operation is to make automated adjustments of insulin delivery based on control algorithms.
Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)	***User control*** Precondition: John, an insulin pump user begins use with a Continua-enabled insulin pump that works with a diabetes management application run on a smartphone. Step 1: With the smartphone application, John programs a new 24-hour insulin profile, and uploads it to the insulin pump. Expected result: The insulin pump's basal rate profile is updated. Step 2: With another command, he activates this profile, and the insulin pump now begins to use it as the hour-by-hour basal insulin levels for delivery. Expected result: A new active profile is set. Step 3: At 2pm, John programs a temporary basal rate into his device to compensate for the exercise he will have during an afternoon soccer game. Expected result: The temporary basal rate command is received by the insulin pump, and insulin delivery is adjusted. Step 4: At 6pm, John programs a bolus to account for the carbohydrates he is consuming for his dinner. Expected result: The bolus command is received by the insulin pump, and the appropriate bolus is delivered. ***Clinician control*** During a follow-up visit, John takes his insulin pump to the clinic and connects it to an AHD to download historical information. John's physician reviews the recorded data from John's insulin pump and continuous glucose monitor. She decides that John's basal insulin profile and carbohydrate profile should be adjusted. She educates John on the modifications to his profiles and uses an application to set his new insulin pump profiles. ***Artificial Pancreas***

	An artificial pancreas application on John's smartphone receives data from his continuous glucose monitor. This data provides the application with information to compute an amount of insulin to be delivered to maintain glucose control. Every 3 minutes, the application commands a "micro-bolus" to stabilize John's blood glucose level. The micro-bolus command is sent to the insulin pump and in response the insulin amount is properly delivered.
Failure Modes	If there is a wireless connection failure between the AHD and the insulin pump, commands would not be able to be sent to the insulin pump to control delivery. In such a case, the application on the AHD should clearly indicate that commands are not being received. To ensure such incidents are identified, the application should clearly indicate whether a command has been received and acted upon. In case of a continual interruption in the wireless connectivity, the user can be alerted to take manual control of the insulin pump to ensure the proper insulin amounts are still being delivered. As well, as an insulin pump would be programmed with a 24-hour profile, this basal insulin would continue to be delivered to the patient in the absence of the AHD control.
Diagram (mandatory)	As with the prior use case for the insulin pump, this command and control use case still resides in the Continua E2E architecture as a PAN Device. 

	
Request to Expedite	Yes, we hope this can be expedited. As the work on the initial insulin pump use case is close to completion, this expansion of the use case will follow directly thereafter.

Key Requirements

No	Keyword	Requirement Description	Acceptance criteria	Comments
01	Basal profile setting	Programming a *24-hour basal profile setting*		
02	Active basal profile	Setting an active basal profile		
03	Active basal profile	Activating a basal profile		
04	Basal rate set	Stopping or cancelling an active basal profile		
05	Basal rate set	Setting a temporary basal rate		
06	Basal rate set	Stopping or cancelling a temporary basal rate		
07	Bolus delivery	Setting a bolus delivery		

No	Keyword	Requirement Description	Acceptance criteria	Comments
08	Bolus delivery	Stop or cancel a bolus delivery		
09	Insulin to carbohydrate ratios	Programming the insulin to carbohydrate ratios		
10	Insulin sensitivity / correction factor	Programming the insulin sensitivity / correction factor		

Feasibility Assessment TWG

Use case:	PRO13-01 Insulin Pump Command and Control
Reviewer (4 reviewers)	TWG
Date	2013-07-22 – 2013-08-05
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☐ No Architectural Impact e.g. add new measurement device ☒ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☐ Yes, technology to do this is abundantly available ☒ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☒ Suitable SDO available ☐ Standard completed ☐ Standard used in the market
Estimated development time	☐ Less than 1 year ☒ Between 1 and 2 years ☐ Longer than 2 years

Steps needed for completion - New technology? - Standards development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	- This use case can be supported as a new IEEE 11073 device specialization. However this would require a planned architectural extension of the 11073-20601 base protocol to support command and control. - This extension would need to cover security requirements, such as the usage authorization scheme, beyond what's currently supported in 11073 – for example what class of users is allowed to change the basal rate. A proper security risk analysis should be done. - Strong authentication of the end user of the device is also critical. It is possible that a household will have multiple insulin pumps. The authentication of the end user of the insulin pump shall be able to detect situations in which the AHD is connected to the wrong

	PAN/LAN/LP-PAN server, and should (shall?) also be able to detect when the user of the physical device has changed. Ideally authentication is based on some level of biometric identification that is strongly coupled to the profiles/insulin monitoring device. - At an end-to-end level this use case could be used to allow command & control of devices connected to an AHD from a WAN device. At least, this should be possible using this and other device specializations that support CandC via an AHD.
Additional Comments	The CandC mechanisms needed should be aligned across device specializations needing them and not be restricted to just this device type. I guess it must be made clear that Insulin Pump -CandC is a device class that extends an Insulin Pump monitor device in order to do control in a meaningful way. Are there additional (technical) safety requirements involved that must be met for such device? There are risks related to using it that must be handled / controlled. The need to ensure patient safety may result in significant regulatory requirements. The regulatory advantages that Continua certification would bring to a component developer should be considered. The use case seeks to foster the development of an interoperable ecosystem. Interoperability may need to be considered not only from a technical point of view but from a regulatory point of view. Even though it is not explicitly stated in the use case, the ability to provide remote control over the insulin pump beyond the AHD is a natural extension and should be discussed.
Overall TWG assessment	**Difficult** – Any of the following apply: • ~~Standard availability: "No suitable SDO available", or~~ • Technology availability: "Technology exist, but is not yet used in the market" • ~~Technology availability: "No, this is currently not possible"~~ • ~~Estimated time to development "Longer than 2 years"~~

Feasibility Assessment TCWG

Use case:	Pro13-01 Insulin Pump Command and Control
Reviewer	TCWG
Date	2013-08-27
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☒ Moderate – New Test Procedures will need to be added to the Test Tool. ☐ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☐ Least – Technology to implement the use case exists in open source or current CESL code. ☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise. ☐ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time (Assumes a moderate workload implementing 5-6 other use cases at the same time)	☐ Least – Less than nine months for both CESL and the Test Tool to finish. ☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☐ Large – Greater than fifteen months for both CESL and the Test Tool to finish.
Estimated CESL and Test Tool Cost	☐ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☒ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☐ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.
Additional Comments	**Extensions Needed** [Reviewer 1] This use case appears to require extension of the

	existing IEEE 11073-20601 base protocol to support command/control. Will need to have Test Tool extensions to cover specifications defined in the IEEE 11073-10xxx device specialization. [Reviewer 2] The effort is definitely possible given our current testing methodology and strategies. This effort is really just adding more functionality from the direction of the Manager to the Agent. There will likely be new -20601 protocol commands and features that enable Command and Control, so an update to our tools would be required for this as well (so not just an update to the device specialization). Within the test tool, there will be new command and control settings and device configurations that enable devices to be tested for configuring the Agent. The test tool will need to be able to configure an agent device under test then test that it behaves properly (so many more testing scenarios). **Security** [Reviewer 1] The command and control use case presents additional user/patient risk as unexpected programing causes patient harm/death. Consequently, we expect additional security and authentication control. Due to the enhanced risk, the certification program must address interoperability testing well. [Reviewer 2] As security will be more of a concern, Continua may feel the need to ensure the level of security needed above what is available via transport technologies. This may also be brought into -20601 but this remains to be discussed/vetted within that group. **CESL** Work to be done for CESL: - Modify CESL GUI manager to send insulin pump controls (programming pump, control pump). - Extension of example agent implementation to support allowing manager to control insulin pump agent and to accept new/updated device settings. - Need to update and add new actions (functionality) to the existing CESL library to execute new actions. - Need to account for security requirements. If from the transport level, then we can leverage existing transport security protocols. However, if this use case introduces a new security mechanism

	(not yet implemented in CESL), level of work may be exponentially more. **Test Tool** Work to be done for Test Tool - Integrate CESL extensions (relate to Command and Control) into Test Tool - Create PAN-LAN-TAN agent and manager test cases for the insulin pump device specialization. - Create WAN Sender & Receiver Test Cases for the new use case. *Note: Current test tool do not yet send PCD-01 messages over the WAN-IF. Test Tool currently in development only tests messages over the PAN-LAN interface. WAN-IF test cases are not yet available. So, if we add this C&C use case, we (TCWG) should also reconsider developing the WAN-IF test cases for Insulin Pump.* - Need to account for security requirements. If from the transport level, then we can leverage existing transport security protocols. However, if this use case introduces a new security mechanism (not yet implemented in Test Tool, or covered by transport level testing), level of work may be exponentially more.
Overall TCWG assessment	**Medium** – No more than one "Large" item.

Regulatory Impact Assessment

Use case:	Pro13-01 Insulin Pump Command and Control
Reviewer	RWG
Date	12 Aug 2013
Regulatory Impact Assessment	Implementation of the feature will need to consider not only technical feasibility of the particular intended use, but also the regulatory possibilities in the intended marketing regions The need to ensure patient safety may result in regulatory considerations (e.g., new risks or risk mitigations); most regulatory authorities for insulin pumps consider the device to be of relatively high risk. The classification of these devices is unlikely to change, regardless the standards or special controls that might be developed. Manufacturers continue to be responsible for verification and validation of their particular design and risk mitigation strategies, regardless the standard complied with. The regulatory advantages that Continua certification is designed to accomplish, while not yet realized, should aid in clarifying design characteristics a component developer should consider and that regulatory authorities should find acceptable to supplant some verification and validation activities. The minimal guarantee should be a default to a safe state. In some cases, that might be a continuation of delivery, but there could be a case where the interrupted command is “stop delivery”. The user should be able to interface directly with the pump to halt delivery. Authentication is needed, but the approach to accomplish authentication and the strength of authentication should be driven by the manufacturers intended use and risk assessment of the various use cases. Currently in the EU Command and Control of devices is not allowed via internet
Additional Comments	

2014 Use Cases

Portable Critical Care Device Monitoring (Battery Status and Location): PRO14-02

Document Control – Use Case

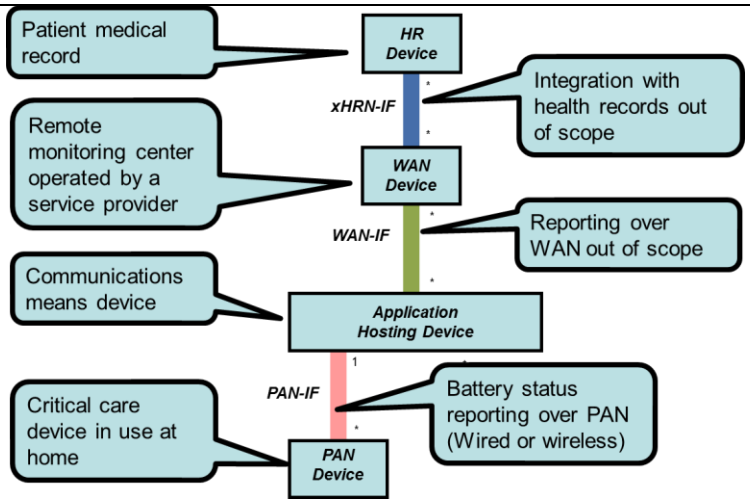
Version	Date	Change Description
3	20 Oct 2014	Final for ballot. Updated to reflect feedback from TWG

Project Description

Title	Portable Critical Care Device Monitoring (Battery Status and Location)
Theme(s)	☐ Health and Fitness ☐ Chronic Disease management ☐ Aging Independently ☒ Other – specify: Emergency Preparedness (Battery Status/Location)
Relation with implemented V1 use case(s)	Creates battery status reporting as a separate stand-alone device type. Will be able to reference protocol descriptions established in 11073-10201 section 7.5.9 Battery object. Full use case also involves capability covered in Pro11-13 Location Services
Description	Establishing a battery status and reporting PAN device. The homecare devices available today are allowing more and more critical care device dependent patients to live and function at home. This greatly reduces their healthcare cost and provides a better environment for the patient as well. However at the same time this achievement can become an issue during a disaster that disrupts power to these devices. During these types of disasters patients are leaving their location and going directly to hospitals to get the power that their devices need. As a result this problem has created interference with the hospitals ability to quickly provide assistance to the injured due to being overwhelmed by the critical care homecare patients needing power for their devices. The infrastructure is also placed at risk due to the additional power use that has not been anticipated by the Hospital. To eliminate the need for patients to leave their locations during an adverse event affecting power at the location of the patient, the

	development and distribution of a new critical care tracking device is being considered. The new device being discussed is called a "Communication Means Device (CMD)" is an Application Hosting Device that connects to a critical homecare device using the PAN interface (Wired - USB or Low-power wireless - BLE). The critical care device will report power status and location.
Scope	The scope of this project is to establish an a new device specialization for the reporting of the following information: • Current device power status (eternal, battery), • Battery charge status (%) • Estimated time remaining (hours, if provided). Device location can be reported in accordance with standards developed to meet Pro11-13. The following aspects of this use case are out of scope: • Transmission of information from the AHD to the WAN Device over the WAN interface. It is not intended to certify the WAN interface for critical care device status reporting. The standard should be consistent with other device data reports that could be carried over a Continua certified WAN interface. • The logic for operation of the application on the AHD (the CMD). • Reporting of location where this information is generated by the AHD (referred to as the CMD in this use case).
Problem statement, and/ or Benefit(s) provided to end user	By gaining access to the systems that have already been established by industry to track the elderly, children, Alzheimer's patients, etc. support services during an adverse event can be contacted and directed to aid the patient at the patient's last known location.
Actors	Homecare Patient: Patient dependent on a critical care device used in a homecare application. The critical care device (PAN Device) would have the communication means device (AHD) connected to it through a USB connection. Optional extension – wireless using BLE. Medical device manufacturer: Provides the critical care medical device to the patient for homecare use. This device will have a USB port and will communicate to the communication means device using the substandard protocol developed in the project. Industry Personal tracking service provider: Provides the Communication Means device that uses the substandard protocol developed to communicate with the critical care device via a USB port.
Minimal	The minimal guarantee should be a default to a safe state.

Guarantees	Where there is a communication failure with the PAN Device, that event should be recorded by the AHD ('CMD') and available for reporting over the WAN interface (WAN out of scope of this use case). Out of scope for interoperability guidelines: AHD should retain the last known reading before communications failure.
Success Guarantees	An effective interoperable standard will result in reporting of battery status of the PAN Device ('critical care device')
Trigger	Regular reporting of power and battery status from the PAN device to the AHD triggered by a request from the AHD. The rules for this are out of scope, but the reporting frequency could be changed once triggered by notification of some type of weather related event or an infrastructure failure where there is a possibility of the loss of power. Automatic transmission of a change of status by the PAN device when a. There is a loss of power to the PAN device. b. At pre-determined levels of battery charge
Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)	Precondition: George is fully dependent on a portable homecare ventilator. This ventilator is equipped with a main battery for normal portable use and an internal backup battery for hot swapping the main battery or for emergency use in the event of main battery failure. George has also equipped this ventilator via the USB port with a communication device that has been supplied by a patient tracking service provider. Through the use of a common communication driver the communication device is able to receive information from the ventilator providing the power status (AC or Battery) and the current charge status of the main battery and backup battery as defined by the definitions provided in IEEE 11073-10201 section 7.5.9. Step 1: An extreme weather event has occurred affecting the power for a five mile radius around Georges home. Step 2: The tracking service provider receives communication information from George's ventilator that provides location; the ventilator has switched to battery power and has 6 hours remaining of estimated run time. Step 3: The tracking service provider confirms that there has been an event that has affected the power in George's location. Step 4: The tracking service provider begins the notification process established by George or his caregiver. This notification process may direct the tracking service provider to first contact a family member that has agreed to provide support for George when needed in this type of case. If they are unable then the instructions will provide a second level

	to go to and so on until George has received the help needed.
Failure Modes	During the event the communication means device fails to function or communicate out. Mitigation: Patient tracking service provider confirms an event has occurred and acts on the last reported position and battery status provided before loss of communication.
Diagram (mandatory)	
Request to Expedite	State whether you have requested an expedited development process requiring parallel development in TWG: ~~Yes or~~ No*. If answering *Yes*, please provide rational.

Key Requirements

No	Keyword	Requirement Description	Acceptance criteria	Comments
01	Power status	Current device power status (external power or battery power)		External power will report 'yes' if any form of external power source is used – including mains electricity or local stand-by generator.
02	Battery Charge	Battery charge status as % of full capacity		
03	Battery time	Estimated time remaining (if provided) in hours of operation remaining		
04	Location			Only reported if captured by the Critical Care Monitoring Device
05	Device UID	Device unique ID		
06	Time stamp	Time of reading		Requirement will be subject to Continua guidelines to be developed on time stamps.

Feasibility Assessment TWG

Use case:	Pro14-02 Portable Critical Care Device Monitoring (Battery Status and Location)
Reviewer (2 reviewers)	TWG
Date	2014-11-12
Type of use case	☒ Address new end-user need ☐ Consider new technology for existing use case ☐ Consider new technology for sub-segment of existing use case
Architectural Impact	☒ No Architectural Impact e.g. add new measurement device ☐ Architectural Change/ Extension needed e.g. introduce unforeseen interface or API
Technology availability	☒ Yes, technology to do this is abundantly available ☐ Technology exist, but is not yet used in the market ☐ No, this is currently not possible
Standard availability	☐ No suitable SDO available ☒ Suitable SDO available ☐ Standard completed ☐ Standard used in the market
Estimated development time	☒ Less than 1 year ☐ Between 1 and 2 years ☐ Longer than 2 years
Steps needed for completion - New technology? - Standards	Reporting on battery/power status is considered a useful

development? - New Continua interfaces? - Modification to Continua interfaces? - Other changes?	interoperable feature for life-critical equipment – on the sensor interfaces - mainly PAN/LAN. The TAN interface seems less suitable to be used for this UC. Supporting this would imply: • a new IEEE 11073-104xx specialization to be developed by the IEEE PHD WG • and the development of a new profile / service in the Bluetooth Med WG.
Additional Comments	Reporting the data from this new sensor device over the existing WAN interface / services should be kept in mind.
Overall assessment	**Easy**. – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year

Feasibility Assessment TCWG

Use case:	Pro14-02 Battery Status and Location Reporting
Reviewer	TCWG
Date	Dec 11, 2014
Test Tool Architecture Impact	☐ Least – Existing Test Procedures in the Test Tool will need to be modified. ☒ Moderate – New Test Procedures will need to be added to the Test Tool. ☐ Large – Use case covers a new area, and a new Test Tool will need to be created to address the needs of the area.
Technology Availability (CESL and Test Tool impact)	☒ Least – Technology to implement the use case exists in open source or current CESL code. ☐ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise ☐ Large – Technology to implement the use case will need to be written, and no contractors exist with this expertise.
Estimated CESL and Test Tool Development Time **(Assumes a moderate workload implementing 5-6 other use cases at the same time)**	☒ Least – Less than nine months for both CESL and the Test Tool to finish. ☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish. ☐ Large – Greater than fifteen months for both CESL and the Test Tool to finish.
Estimated CESL and Test Tool Cost	☒ Least – Cost is less than $20,000 total (for CESL and Test Tool) to do. ☐ Moderate – Cost would allow TCWG to keep within a $300,000 total budget for Test Tool and $200,000 total for CESL, assuming 5-6 other similar sized projects. ☐ Large – Cost would put TCWG beyond a $300,000 total budget for Test Tool and $200,000 total for CESL assuming 5-6 other moderate sized projects.

Additional Comments	Use case states CMD is connected to the critical homecare device over all transports. It seems like the immediate intent is for USB-based solutions. Introduction of each transport will increase the scope of test tool (more test cases) and CESL development (minimal – add attribute and use). Estimated level of work is assumed "Least" because we assume that this UC does not introduce a major change to the architecture. The group assumed that it is acceptable to use existing 20601 objects to report position and current MDS power status and battery level attributes for reporting. Similar for BLE.
Overall assessment criteria	**Easy** – Two or more "Least" items *and* no "Large" items.

Regulatory Impact Assessment

Use case:	Pro14-02 Battery Status and Location Reporting
Reviewer	RWG
Date	29-DEC-2014
Regulatory Impact Assessment	The feature itself is not a regulated medical device. However, the feature is designed to be incorporated into any number of regulated medical devices. The manufacturer incorporating the function will need to assess whether the feature addition is sufficient cause to require new approval of the entire device. In most cases, the feature by itself will not cause a need for a new filing unless the feature is relied upon mostly or solely to mitigate patient or user risk. Each finished device must be assessed by the manufacturer for each jurisdiction they wish to sell the device in.
Additional Comments	