Continua®
HEALTH ALLIANCE

Connecting people and technology for healthier living

# Continua Use Case Ballots 2009-2011

# Continua Use Case Ballots 2009-2011

## *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 2009-2011.

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.

## *2009 Use Cases*

# Aging Independently over IP WAN: Pro09-01

Document Control

| Version | Date | Ballot date | Status |
|---|---|---|---|
| **5** | 10 Sep 2009 | Sep 2009 | Final for ballot |

Project Abstract

| **Use case Title** | **Enable an IP standard for telecare data traffic between home and remote monitoring centre** |
|---|---|
| **Description** | Enable the an IP communications link for data (alarms, polling data, lifestyle monitoring events) and 2-way voice between the home and the telecare monitoring centre that provides interoperability between different in-home telecare equipments and remote monitoring centre solutions.<br>The solution must be scalable, capable of being deployed in environments with fibre to the premises (FTTP) and meet any regulatory requirements for resilience in emergency situations (such as loss of power to the home during a fire)<br><br>Special attention is needed for security and privacy since the link will be used for information that could be used to identify vulnerable individuals |
| **Scope** | This use case addresses the interoperability related issues of the WAN interface between home hub or equivalent personal communications device and monitoring centre.<br><br>Due to the complexity of some features, such as a live VOIP connection, the scope is broken down into packages which can be phased as follows:<br><br>Phase 1 – IP connectivity and message definition for alarms and control messaging over the WAN<br>Phase 2 – IP connectivity to include streaming for voice<br><br>Exclusions:<br><br>Developing a radio standard for in home AI devices to replace current regulated radio spectrum. It is anticipated that this will be the subject of a separate future Use Case.<br><br>The use case is dependent on related systems and service performance standards such as resilience and usability. This work falls outside the scope of |

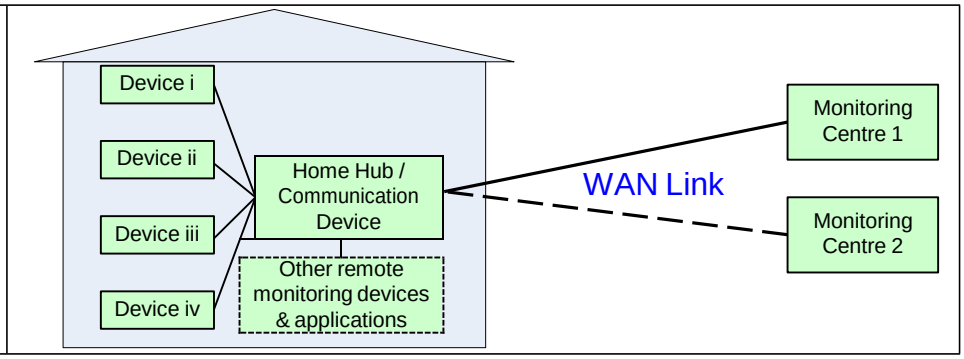
| | |
|---|---|
| | the Continua Use Case and it is assumed it will be progressed by the Telecare Services Association or other regional standards bodies as appropriate. (Corresponding existing examples are TSA service standards and EN50134 series product/system performance standards). |
| **Actors** | Consumer<br>Monitoring Service Operator<br>Monitoring service engineer / Installation Engineer<br>Care provider |
| **Minimal Guarantees** | In case of failure:<br>- High resilience is provided for alarms traffic<br>- No data loss is incurred (all types, or just alarm and certain medical data?)<br>- Continua implantation needs to enable voice services provided by a 3rd party to be maintained to accepted performance standards<br>Must be able to work simultaneously with a normal array of 'home' IP related services running over the same broadband connection (home automation, entertainment etc as well as other remote monitoring services, such as telehealth)<br><br>Installation expertise should be at the "plug and play" level in terms of IP WAN interface.<br><br>External dependency: Home Hub must be able to continue to pass alarms signals to a monitoring centre in the event of a power-failure in a premises<br><br>Must pass a unique ID for both the AHD and device passing the call to enable (1) caller/premises and (2) where applicable the device generating an alarm to be recognised. |
| **Success Guarantees** | Must address known issues including:<br>• Physical definition of IP<br>• Separation of streaming (voice & video) and data and signalling<br>• Plug and play security, Network address and routers/firewalls<br>• Firewall management<br>• VOIP issues many proprietary approaches few standards<br>• Data encryption and security - In hand elsewhere<br>• Dynamic IP address<br>• Quality of service/ Syn/Async connectivity/diversity<br>• Installation maintenance standard of engineers / level of engineering required must be minimised to be suitable for non specialist (i.e. not require advanced IT training).<br>• Payload data structure.<br><br>External dependencies<br>• Continued availability of comms link in the event of mains power supply interruption. Physical deployment battery backup and alternate communications means should be considered.<br>• Unregulated nature of network and impact on system architecture<br><br>Note – these points could be expanded to define minimum essential requirements for an acceptable IP standard(s) |

**Continua Health Alliance Use Case**

| | |
|---|---|
| **Trigger** | This event is triggered by:<br>- An application running on the Home Hub that initiates a process to send data to the remote Monitoring Centre.<br>- The remote Monitoring Centre application initiates a process to send a command to the Home Hub.<br>Either of these may or may not be in reaction to some external event. |
| **Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)** | Most Telecare data will need to be transferred to support a real-time critical alarm situations. Alarm situations normally initiate a voice call. In such alarm situations, link availability and reliability are major considerations (possibly requiring contingency solutions).<br><br>Some Telecare data may not be considered real-time critical (eg batched Activities of Daily Living data, reminder configuration information etc) which can be stored and forwarded later should a link not be available.<br><br>Increasingly, systems may also generate significant 'engineering' traffic polling sensors to confirm they are still active, acquiring battery charge states etc. Much of this will result in traffic over the WAN.<br><br>This project would seek to establish endorsed requirements for, and specification of, an open protocol for transport of both the above data categories over IP data links.<br><br>Generic Process<br><br>It is recognized that the bulk work that needs to be accomplished in these examples is independent of the telecare domain. Or in other words, the primary work being done is independent of the payload.<br><br>IEEE 11073 point of care device series of standards is likely to provide a god starting point for developing globally applicable data standards for the interface, building on standards currently set out in BS8521 and other widely used proprietary formats. .<br><br>In many cases, it is expected that the Home Hub will do minimal processing of the data from devices.<br>.<br>Even though the data payload is viewed generically like this it is still useful to characterize the data into 5 fundamental types:<br><br>Episodic – data for single asynchronous incident<br>Streaming – continuous stream of real time data<br>Document – arbitrary large collection of data<br>Control – communication that commands the receiver to alter its behaviour<br>Alarms – communication that carries a variable sense of urgency<br><br>By this categorization we can fragment the problem, as the mechanisms chosen to move the payload would have to match the underlying needs of each category.<br><br>For the chosen scope of this project, the data types would be mapped to communication means that have the needed corresponding QOS properties expected by each data type.<br><br>Further project discussions would encompass: |

| | |
|---|---|
| | Requisite security and privacy for the particular category<br>Information model conversion(s) if desired.<br>Data format (binary, XML, etc)<br><br>**Basic Flow**<br>1) Home Hub → Remote Monitoring Centre<br>Fundamentally the flow is to deliver data contained on the Home Hub to an arbitrary Monitoring Centre via a WAN interface. The precise steps to accomplish this would be determined as part of this work but would be probably consist be along the lines of:<br>Home Hub has data that it wants to communicate to a remote Monitoring Centre. This data probably comes from attached devices but could be other data as well. It may be a single data point or a collection of many data points.<br>The data is augmented. The specifics of this would have to be ironed out but it would probably entail augmenting the data with some additional data such as device ID, timestamp, User ID, or any other needed relevant data for this flow.<br>The data is prepared for transmission. Here the data could be converted (information model and/or format). Then the required security and privacy measures would be enacted (the required security may also be done by the transport utilized).<br>The data is sent.<br>An acknowledgement that the data was received successfully by the remote Monitoring Centre<br><br>2) Remote Monitoring Centre → Home Hub<br>Typically this flow is to deliver low volume traffic such as command data from a remote Monitoring Centre to the Home Hub via a WAN interface. The precise steps to accomplish this would be determined as part of this work but would be probably consist be along the lines of:<br>The remote Monitoring Centre has command data that it wants to communicate to a Home Hub. This command may be for use by the Home Hub or could be ultimately for use by a device attached to the Home Hub.<br>The data is augmented. The specifics of this would have to be ironed out but it would probably entail augmenting the data with some additional data such as remote Monitoring Centre ID, timestamp, target Home Hub ID, or any other needed relevant data for this flow.<br>The data is prepared for transmission. Here the data could be converted (information model and/or format). Then the required security and privacy measures would be enacted (the required security may also be done by the transport utilized).<br>The data is sent.<br>An acknowledgement back to the remote Monitoring Centre that the data was received successfully by the Home Hub. |
| **Failure Modes** | Cross refer to 'success guarantees.<br><br>Main failure modes:<br>- Unable to send message<br>- Unable to initiate parallel voice call<br>- Poor voice quality<br>- Unable to survive during power outage |

**Continua Health Alliance Use Case**

| | |
|---|---|
| **Diagram (optional)** |  |



## References:


1. BS 8521:2009 Specification for dual-tone multi-frequency (DTMF) signaling protocol for social alarm systems
2. BS 5839-6:2004 Fire Detection and Alarm Systems for Buildings: Code of Practice for the Design, Installation and Maintenance of Fire Detection and Fire Alarm Systems in Dwellings
3. Continua Health Alliance Interoperability Guidelines Version 1

# Technical Feasibility Review: Pro09-01

| Version | Date | Change Description |
|---|---|---|
| 3 | 18th Aug 2009 | **Final assessment for ballot with details of the use case elements** |

## Use Case Description

| | |
|---|---|
| Title | Telecare Communications IP WAN |

**Note:** The assessment of this use case has been sub-divided into 4 separate elements.

## Use Case Element 1

| | |
|---|---|
| Description | AI non-critical events and data upload on the WAN |
| Categorization | ☐ C1: Already done<br>☒ C2: Instantiation of existing interface (e.g. new sensor on the PAN)<br>☐ C3: Scope extension of architecture (e.g. LAN interface)<br>☐ C4: Vision setting is required<br>☐ C5: Defer (i.e., not feasible for V2) |
| Estimated timeline to complete the guidelines | ☒ Early 2010 (V1.5)<br>☐ Early 2011 (V2.0)<br>☐ Early 2012 |
| Dependencies & road blocks | • AI messages not yet defined (placeholder only) in V1.5 WAN guidelines, whilst less critical than for alarms it is still highly desirable to achieve near real-time to allow “snap-shot” type views of a person to be available in a timely manner..<br>• Plug and play implementation with demanding unreasonable levels of expertise, i.e. by non trained staff or end user.<br>• Security = Privacy, Authorization and Authentication<br>• Network address and routers/firewalls<br>• Quality of Service, diversity of communication paths<br>• Firewall management and Dynamic IP addressing issues |

## Use Case Element 2

| | |
|---|---|
| Description | AI critical alarms and control on the WAN |
| Categorization | ☐ C1: Already done<br>☒ C2: Instantiation of existing interface (e.g. new sensor on the PAN)<br>☐ C3: Scope extension of architecture (e.g. LAN interface)<br>☐ C4: Vision setting is required<br>☐ C5: Defer (i.e., not feasible for V2) |
| Targeted guideline release | ☐ Early 2010 (V1.5)<br>☒ Early 2011 (V2.0)<br>☐ Early 2012 |
| Dependencies & road blocks | • Alarms & Control messages not yet defined (placeholder only) in V1.5 WAN guidelines (payload structure). |

| | |
|---|---|
| | • Plug and play implementation with demanding unreasonable levels of expertise, i.e. by non trained staff or end user.<br>• Security = Privacy, Authorization and Authentication<br>• Network address and routers/firewalls<br>• Quality of Service, diversity of communication paths<br>• Firewall management and Dynamic IP addressing issues<br>• Effects of deferring use case element out of V2….. Likely to result in competitive/proprietary standards being developed outside of Continua |

## Use Case Element 3

| | |
|---|---|
| Description | AI Voice over IP communications on the WAN |
| Categorization | ☐ C1: Already done<br>☒ C2: Instantiation of existing interface (e.g. new sensor on the PAN)<br>☐ C3: Scope extension of architecture (e.g. LAN interface)<br>☐ C4: Vision setting is required<br>☐ C5: Defer (i.e., not feasible for V2) |
| Estimated timeline to complete the guidelines | ☐ Early 2010 (V1.5)<br>☐ Early 2011 (V2.0)<br>☒ Early 2012 |
| Dependencies & road blocks | • Dependency on AI critical alarms & control.<br>• VOIP, many proprietary approaches few stable standards.<br>• Quality of Service, diversity of communication paths<br>• Plug and play implementation with demanding unreasonable levels of expertise, i.e. by non trained staff or end user.<br>• Security = Privacy, Authorization and Authentication<br>• Network address and routers/firewalls and other causes of port blocking / packet throttling by commercial service providers. |

## Use Case Element 4

| | |
|---|---|
| Description | AI real time data streaming on the WAN |
| Categorization | ☐ C1: Already done<br>☐ C2: Instantiation of existing interface (e.g. new sensor on the PAN)<br>☐ C3: Scope extension of architecture (e.g. WAN or LAN interface)<br>☒ C4: Vision setting is required<br>☐ C5: Defer (i.e., not feasible for V2) |
| Estimated timeline to complete the guidelines | ☐ Early 2010 (V1.5)<br>☐ Early 2011 (V2.0)<br>☐ Early 2012<br>☒ > 2012 |
| Dependencies & road blocks | • Assumes applications such as video<br>• Dependency on AI critical alarms & control<br>• and issues raised in Voice over IP |

# Continua Patient-reported Outcomes Measures (PROM) Device-Server Interoperability: Pro10-04

| Use Case Title | **UC 2010 Project 10 04 Continua Patient-reported Outcomes Measures (PROM) Device-Server Interoperability** |
|---|---|
| Theme(s) | ☒ Disease management<br>☒ Health & Fitness<br>☒ Aging Independently |
| Relation with implemented previous use case(s) | **In response to draft reviewer recommendation**, the draft UC content was compared to aspect of medications monitoring standards (IEEE 11073-10472). A number of aspects, namely study protocol definition, content (terminology) standardization, aggregation and questionnaire server functions were not covered or not explicit from 10472. These aspects have been added here, with a supplement to the title to distinguish. Standards for medication adherence could also be exercised if the UC was prioritized for Continua development.<br><br>This use case concerns the creation of Continua interoperability standards to enable large-scale use of devices for recording patient-reported outcomes (for definition and significance to the personal health agenda, see abstract below). The focus of the use case is on the interoperability standards required to provide a generic framework for multiple types of PROMs (i.e. a framework that remains content or data payload-neutral) so that any PROM scenario can be served by the use case.<br><br>The use case cites external efforts to standardize the terminology for PROMs-like approaches that overlap, namely health-related quality of life (HRQL), Patient Reported Outcome (PRO) measures. In the UK, the Department of Health use the term 'PROMs' for before and after studies that typically include outcomes of operations. This use case, however, applies the term PROMs in its widest generic context.<br><br>Standardization, quantification, and longitudinal aggregation of patient outcome results (to evaluate if interventions have been efficacious or otherwise) are our core interest. Collaboration is sought with Continua companies interested in device standardization for the purpose of longitudinal outcomes analysis as part of multivariable analytics and stratified medicine approaches.<br><br>The devices supported by the use case should work alongside previous device specializations and provide for end-user simplicity to provide - as near as can be realized - 'plug-and-play' operation for PROMs data integration. Common co-applications will be medication adherence monitoring, pharmacovigilance applications, biochemical analyte recording, physiological and psychological variable monitoring. |
| Description and | **PROMs device definition:** Patient-reported outcome measures (PROMs) capture |

| | |
|---|---|
| Scope | patient's perceptions on their health and the impact that any treatments or adjustments to lifestyle have had on their quality of life. Such data can be provided by an individual about themselves, or by others on their behalf. Patient-centred outcomes monitoring, is increasingly needed to improve the cost effectiveness and quality of health services. PROMs may be deployed and collected as dedicated devices or as part of other devices.<br><br>There are two main use cases:<br><br>1. The definition, planning and scheduling of a questionnaire which the patient shall answer at pre-defined times or frequency. This use case includes deployment of the questionnaire to the subject.<br><br>2. The completion of the completed questionnaire for reporting and analysis.<br><br>**Demand for PROMs device global interoperability:** Across the world healthcare provider services are in a continual process of reform as they try to deliver the highest quality and best outcomes for patients – often with diminishing resources. While health service executive statements speak of 'improving quality of life', 'reducing inequalities', 'better patient experience' etc. the 'frontline' services are finding it difficult logistically to record routine data that can be readily aggregated to form an outcomes evidence base. Continua standards-based interoperability could powerfully contribute to the transformation of health services if it routinely supported PROMs devices.<br><br>**Multi-disciplinary and multi-professional PROMs stakeholders**: Patients' perception of service effectiveness in terms of quality of life, safety and experience is an increasing driver of change. However there are major practical difficulties in deploying appropriate questionnaires, ensuring that they are completed and collating the results. AS a result, such instruments are seldom used as part of routine home care.<br><br>Stakeholders in quality and outcomes monitoring include the patient, professionally qualified team members (clinical and allied professions), resource managers, outcomes researchers (including epidemiologists), health economists, health strategists, change management specialists, healthcare system designers and executive policy makers.<br><br>From analysis of their needs, the following requirements have emerged:<br>• to be quick, simple and understandable by all named stakeholders<br>• to be embed as a routine part of the care process and provide benefits to patients and clinicians<br>• to minimize the cost of deploying new questionnaires or changes in data collection protocols<br>• to be condition-independent and applicable across all healthcare domains<br>• be geographically-agnostic and work across all localities, institutions, and national borders (that might reasonably be encountered on the patient path).<br>• Support multi-language use. |

**PROMs device interoperability as a strategic part of improvement agendas:**
Quality & outcomes evidence is at the heart of the modernization and improvement agendas in many countries. In the UK for example, GPs are paid according to the Quality and Outcomes Framework (QOF). Lord Darzi's High Quality Care for All (2008) recommended that 'quality should be at the heart of everything we do'. To be improved, quality has to be measured, ideally by a standardised plug & play device that produces information in standard formats so that can be abstracted into longitudinal outcomes analysis systems. The 2008 Darzi review also introduced new methods to

1. access evidence about best practice
2. support clinicians to measure quality to provide evidence for improvement (we cannot improve what we do not measure)
3. require quality information to be published (i.e. by making it available to the public) and
4. reward the delivery of high quality care.

Continua standardization of PROMs device interoperability would support the creation of distributed collaborative systems with harmonised data security and information governance standards to aggregate intra-episodic (and hitherto disconnected) data across the individual patient's path in an ethically governed manner.

**Example usage scenario**

*John is discharged home from hospital after suffering from a myocardial infarction. He agrees to undertake a structured exercise program, which includes monitoring his weight, exercise level (pedometer) and a patient reported outcome (PRO) measure to monitor his perception of physical and mental symptoms, how much he can do and independence/autonomy. He records this every day using a simple touch-screen questionnaire device, which takes only a few seconds to complete. The instrument transmits the data to the health record system, where the results form part of his personal health record. John can check his recorded progress (as his memory for past health states is not good) and see how he is getting on by displaying a time-series of his past measures in graphical form. He can also compare how he is progressing in comparison with other patients who have had myocardial infarctions.*

*John finds the system quick and easy to use. It also provides reassurance to his wife Mary, who is naturally rather anxious about whether or not John will make a full recovery. She can also monitor John's progress and see how he is getting on in comparison with others who have had the same problem. His doctor can also review the data remotely and check that John is recovering as expected and if not can take remedial action. This means that John does not need to attend so many check-ups. The data is standardised to enable aggregation and audit. John and Mary find the PROMs data much easier to understand than other results such as his blood chemistry, to which he also has access.*

The PROMs data is standardised within the Continua ecosystem, enabling aggregated information on each patient's recovery to be used as part of regional

| | |
|---|---|
| | continuous quality improvement programs, where it becomes an important measure of effectiveness. |
| **Actors** | 1. Clinician<br>2. Questionnaire server<br>3. PROMs device<br>4. Subject (patient)<br>5. Results server |
| **Minimal Guarantees** | Clinician can see if patient fails to complete PROMs |
| **Success Guarantees** | On completion new PROMs results are available for analysis on server. |
| **Trigger** | Clinician instigates regime that requires subject to complete PROMs data. |
| **Steps of Basic Flow** | 1. Clinicians instigates regime on Questionnaire server<br>2. Questionnaire and protocol are downloaded from server onto PROMs device<br>3. Patient is identified and reminded to answer questionnaire<br>4. Patient answers questionnaire<br>5. Results are transmitted to server<br>6. (Optional) patient (or carer or clinician) looks at his/her previous results. |

## Marketing Feasibility Review: Pro10-04

| | |
|---|---|
| **Reviewer** | MWG |
| **Date** | June 30, 2010 |
| **Market Need** | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>~~May or may not be a clear market need from a Continua Mission and Vision perspective~~<br><br>X - Addresses significant market need from a Continua Mission and Vision Perspective<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | • No marketing impact for Continua<br>• ~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br>• ~~Significant marketing impact for Continua~~ |

| | |
|---|---|
| Additional Comments | Standardization of PROM input from tele-health patients will have a positive impact on promoting payment for outcome based health care. Since the value of RPM will be judged by outcome as well, PROM standardization will be in the best interest of Continua. |

## Technical Feasibility Review: Pro 10-04

| | |
|---|---|
| **Reviewer (2 reviewers)** | TWG |
| **Date** | 27 June 2010 |
| **Type of use case** | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |
| **Architectural Impact** | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| **Technology availability** | ~~Yes, technology to do this is abundantly available~~<br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |
| **Standard availability** | ~~No suitable SDO available~~<br>Suitable SDO available<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | ~~Less than 1 year~~<br>Between 1 and 2 years<br>~~Longer than 2 years~~ |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | For full use case fruition the needs would be:<br><br>1) PAN and LAN - A new 104xx specialization to be comprehensive enough to cover a wide range of devices<br>2) WAN - Defined bi-directional flow(s) across the WAN interface – V2 discussions are already planned to include this<br>3) HRN – some work may be needed to fully express the new data in the PHRM<br>4) E2E Security – In order to protect client privacy and data integrity/authenticity, it may be necessary to implement a full end-to-end security system that protects from spoofing and phishing. This is currently not in the scope of the E2E Security team's goals for the near term. |
| Additional Comments | 1) PAN and LAN - depending on the functionality extent attempted, this specialization would be the first to introduce device programmability flows which may cost additional time to work through completely<br>2) PAN and LAN – unsure there is a clear world-wide recognized set of protocols and/or content definitions.<br>3) WAN - V2 discussions are already planned to include this topic – should immediately join the conversations to ensure accommodation<br>4) This probably introduces some new or at least increased security concerns in ensuring the delivery and usage of the content delivered to the device and the subsequent recorded observations (this may require an end-to-end security/authenticity system which is currently not in place and not in scope for TWG E2E Sec task force)<br>5) A reduced function version of this device (static pre-defined questions/answers) may be currently possible based on the 10472<br>6) This does not address some of the other use case aspects such as operational questions of who/how data is pushed to the device and how data is ultimately distributed to all actors<br>7) This does not take into account the operational questions of how data is safely and accurately aggregated<br><br>Overall Assessment:<br><br>Medium to difficult, given the security implications |

## Test & Certification Feasibility Review: Pro10-04

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ☒ Least – Existing Test Procedures in the Test Tool will need to be modified.<br><br>Moderate – New Test Procedures will need to be added to the Test Tool.<br><br>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.<br><br>Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br><br>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<br><br>(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.<br><br>Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br><br>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.<br><br>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.<br><br>☐ 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 | TCWG (Raul Gonzalez) noticed that TWG's analysis showed that we may need to add the ability to send messages from the WAN Receiver to the WAN Sender in order to accomplish this. If true, the effort would be Medium. The changed items would be:<br>Test Tool architecture: Large<br>Estimated CESL/Test Tool development time: Moderate<br><br>Estimated CESL/Test Tool cost: Moderate<br><br>**Overall assessment criteria:**<br><br>**Easy** – Two or more "Least" items *and* no "Large" items. |

## Regulatory Feasibility Review: Pro10-04

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | FDA regulates software and hardware used to collect data in clinical trials. Any software / hardware incorporating this connectivity solution would be regulated by FDA.<br><br>At present, FDA does not actively regulate electronic health records, but they have stated they reserve the right to. If the information collected through this type of system is meant to supplement a given patients EHR, then it would be considered as an accessory to the EHR and come under the same level of FDA regulation. |
| Additional Comments | |

# Personal Health Monitoring Report (PHMR) Enhancements: Pro10-05A

| Use Case Title | Pro10-05A Personal Health Monitoring Report (PHMR) Enhancements |
|---|---|
| Theme(s) | ~~Health and Fitness~~<br><br>x Chronic Disease management<br><br>~~Aging Independently~~<br><br>~~Other – specify:~~ |
| Relation with implemented V1 use case(s) | This is an enhancement of the PHMR report for the HRN (previously XHR) interface. |
| Description | <overview of the use case focusing on the aspects that require interoperability><br><br>This project further defines the HRN interface guidelines by defining sub-specializations of the HL7 v3 PHMR report to enable simple prioritization of messages in order to support ranking on HRN receiver device workflow manager.<br><br>These enhancements address concerns raised by clinicians about the impact of<br><br>- Provide mechanisms for managing and prioritizing potentially large volumes of 'wellnesss' data.<br>- Manage clinical liability by controlling the flow of data into clinical records<br><br>The outcome of this use case is likely to involve an update to the Continua Interoperability Guidelines with a testable message set for the HRN interface. This part is similar to the current scope of Continua certification. |
| Scope | The scope covers the HRN PHMR message format |

| | |
|---|---|
| Actors | <actors and their roles in this use case><br><br>**Remote Monitoring Nurse** (RM Nurse) – Responsible for monitoring the patient using a Continua-compliant WAN device (remote monitoring management system).<br>**Clinician** – Responsible for the care of a patient with a long term condition, referred patient to remote monitoring programme. E..g. General Practitioner / Primary Care Physician<br><br>**Patient** – Participating in a remote monitoring programme and uses a PHR |

| | |
|---|---|
| Minimal Guarantees | <end state of the world if the use case is not completed successfully><br><br>Messages contain a text reference to priorities |

| | |
|---|---|
| Success Guarantees | <actor interests that are satisfied upon successful completion of use case><br><br>General<br><br>Messages are flagged with one of at least 3 grades in order to support ranking on HRN receiver device workflow manager:<br><br>**'For Action'** – a report sent from the WAN Device to the HRN at the instigation of the sender requesting action by the recipient. Typically the contents would be defined by the sender at the time the report is initiated including:<br><br>the type of readings to be sent,<br><br>the time period to be covered .<br><br>the ability to select some or all of the results in the time period e.g. send only readings outside threshold, or exclude known anomalies<br><br>The thresholds set for the patient at the time of the aletrt<br><br>Optional: an indicator to identify readings outside threshold parameters<br><br>Optional: A second threshold that triggers notification to the referring clinician<br><br>Text notes detailing the reason for the referral.<br><br>**'For Information'** – a report sent from the WAN Device to the HRN at the instigation of the sender to update the recipient. The contents would be the same as the 'for action' note.<br><br>**'Routine'** – a report generated on a pre-agreed schedule. The contents may be automatically generated by the sending machine<br><br>**Remote monitoring nurse**<br><br>The WAN device supports the ability to define multiple recipients for a message, with only one recipient able to be flagged 'for action'.<br><br>**Clinician**<br><br>The HRN device is able to present messages in priority order based on the flag in the HRN message header. |

| | |
|---|---|
| Trigger | <the event that initiates the use case><br><br>The RM Nurse decides that there is a need to send information to a referring clinician. |
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor perspectives, if applicable) | <numbered steps of the use case><br><br>Routine messages:<br><br>Step 1. RM Nurse configures report generation tool in WAN device to automatically generate 'Routine PHMR'<br><br>Step 2. Optional: RM Nurse reviews PHMR before sending<br><br>Step 3. Receiving Clinician views PHMR in in-coming workflow.<br><br>Step 4Receiving clinician opens PHMR, reviews results, flags those to be entered in the record.<br><br>Step 5 Optional: Receiving clinician is able to record a comment on the PHMR in the record.<br><br>**Action and Information messages:**<br><br>Step 1. RM Nurse uses the report configuration tool to generates an ad-hoc report, selecting the time range to be covered, the readings to be included and adding a text note detailing the reasons for generating the report<br><br>Step 2. RM Nurse defines the distribution of the report including 'action' and 'information' recipients<br><br>Step 3. Receiving Clinician views PHMR in in-coming workflow.<br><br>Step 4 Receiving clinician opens PHMR, reviews results, flags those to be entered in the record.<br><br>Step 5. Optional: Receiving clinician is able to record a comment on the PHMR in the record. |

| | |
|---|---|
| Failure Modes | <identify scenarios that would cause a success scenario (or flow) to fail><br><br><optionally, identify steps or workarounds to handle the potential failure><br><br>Messages sent to multiple 'action' recipients where responsibility for completing an action would be ambiguous. |
| Diagram (optional) | |

## Marketing Feasibility Review: Pro 10-05A

| | |
|---|---|
| Reviewer | MWG |
| Date | June 30, 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>~~May or may not be a clear market need from a Continua Mission and Vision perspective~~<br><br>X - Addresses significant market need from a Continua Mission and Vision Perspective<br><br>-Mission<br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | X - No marketing impact for Continua<br><br>~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br>~~Significant marketing impact for Continua~~ |
| Additional Comments | Defining HRN message priority mechanisms will enhance the relevance of data input from tele-health applications for clinicians and therefore is good for Continua. |

## Technical Feasibility Review: Pro10-05A

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 06/28/2010 |
| Type of use case | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ~~Yes, technology to do this is abundantly available~~<br><br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |
| Standard availability | ~~No suitable SDO available~~<br>~~Suitable SDO available~~<br>Standard completed<br>~~Standard used in the market~~ |
| Estimated development time | Less than 1 year<br>Between 1 and 2 years<br>Longer than 2 years |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | Define the constraints in the implementation guideline.<br><br>e.g. One of solutions could be the XDS metadata that the document recipient can see and query the flag<br><br>There are several options (probably a combination of - typeCode and eventCodeList) |
| Additional Comments | The receiver must understand the meaning of these priority codes to take an action. In HRN we don't mandate the receiver to do anything until we actually certify the HRN receivers. |

## Test & Certification Feasibility Review: Pro10-05A

| | |
|---|---|
| Reviewer | ~~TC~~WG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ☒ ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br><br>Moderate – New Test Procedures will need to be added to the Test Tool.<br><br>~~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.~~<br><br>Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br><br>~~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<br><br>(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.<br><br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish~~<br><br>~~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.<br><br>~~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.~~<br><br>~~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 | TCWG (Raul Gonzalez) pointed out that if we need to change the current HRN tool to receive multiple messages at the same time, this moves to a Medium effort because the Test Tool Development Time and Estimated CESL and Test Tool Cost would move to Moderate. We do not believe this will be required, but wanted to note.<br><br>Note also that TCWG's analysis assumes that the certification approach will not need to change (i.e., focus will be on the interface and only HRN Senders will be certified). I believe in past discussions, we decided that changes in approach to certification (ex. adding HRN Sender certification) do not come through as use cases, but instead come through as requests to TCWG.<br><br>**Overall assessment criteria:**<br><br>**Easy** – Two or more "Least" items *and* no "Large" items. |

## Regulatory Feasibility Review: Pro10-05A

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | Products described in this use case scenario will likely be regulated as a medical device by FDA. The level of regulation is unknown based upon the information given.<br>The described application is providing some attributes of an MDDS (Medical Device Data System) as described in FDA's draft guidance document. However, there are attributes of the use case scenario that could push it beyond MDDS (e.g. if the notices are considered alarms or the primary means for the healthcare professional to render a medical decision). If this is the case, then MDDS is not valid; worst case scenario is that FDA considers unclassified which defaults to Class III. |

| | |
|---|---|
| Additional Comments | |

# HRN Interface Implementation Requirements: Pro10-05B

| Use Case Title | Pro10-05B HRN Interface Implementation Requirements |
|---|---|
| Theme(s) | ☐ ~~Health and Fitness~~<br>x ☐ Chronic Disease management<br>☐ ~~Aging Independently~~<br>☐ ~~Other – specify:~~ |
| Relation with implemented V1 use case(s) | This is an enhancement of the PHMR report for the HRN (previously XHR) interface. |
| Description | <overview of the use case focusing on the aspects that require interoperability><br><br>This project further defines the HRN interface guidelines by defining implementation requirements for the PHMR that specify requirements for both WAN and HRN Device application behaviors in order to address clinical governance concerns<br><br>These enhancements address concerns raised by clinicians about the impact of<br>- Provide mechanisms for managing and prioritizing potentially large volumes of 'wellnesss' data.<br>- Manage clinical liability by controlling the flow of data into clinical records<br>- Ensuring clinicians retain control of data quality for information held in their record systems<br><br>The outcome of this use case is likely to involve additional guidance to vendors on the requirements for implementation of the HRN interface. As a minimum it is intended that this guidance should be issued as part of the interoperability guidelines. While adherence to the implementation guidelines could be demonstrated by product testing, this would extend the scope of testing beyond the ability to demonstrate interoperability and involve witness testing that applications met the interface implementation specification. It would be for Continua membership to decide whether this additional scope was justified. |
| Scope | The scope covers the implementation requirements related to the HRN message sender and HRN receiver |
| Actors | <actors and their roles in this use case><br>**Remote Monitoring Nurse** (RM Nurse) – Responsible for monitoring the patient using a Continua-compliant WAN device (remote monitoring management system).<br><br>**Clinician** – Responsible for the care of a patient with a long term condition, referred patient to remote monitoring programme. E..g. General Practitioner / Primary Care Physician<br><br>**Patient** – Participating in a remote monitoring programme and uses a PHR |
| Minimal Guarantees | <end state of the world if the use case is not completed successfully><br><br>Messages contain a text reference to priorities |

| | |
|---|---|
| Success Guarantees | <actor interests that are satisfied upon successful completion of use case><br>General<br><br>Messages are flagged with one of at least 3 priority grades in order to support ranking on HRN receiver device workflow manager (covered by use case PRO10-05B.<br><br>**Remote monitoring nurse**<br><br>The WAN device supports:<br>• The ability to vary the frequency of messages for routine messages,<br>• The ability to define multiple recipients for a message, with only one recipient able to be flagged 'for action'.<br>• The ability to vary the content of messages including the period of coverage and the range of results presented<br><br>**Clinician**<br><br>The clinician retains control over what is placed in the clinical record (receiving HRN Device):<br>• Systems that receive PHMR's MUST compel users to review data before importing and or storing in the patient's record and<br>• MUST allow users to determine whether to accept all, none or some data items<br><br>**Patient (for PHR implementations)**<br><br>The patient is provided with equivalent controls to the clinician. |
| Trigger | <the event that initiates the use case><br>The RM Nurse decides that there is a need to send information to a referring clinician. |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | <numbered steps of the use case><br>Routine messages:<br><br>Step 1. RM Nurse configures report generation tool in WAN device to automatically generate 'Routine PHMR'<br><br>Step 2. Optional: RM Nurse reviews PHMR before sending<br><br>Step 3. Receiving Clinician views PHMR in in-coming workflow.<br><br>Step 4Receiving clinician opens PHMR, reviews results, flags those to be entered in the record.<br><br>Step 5 Optional: Receiving clinician is able to record a comment on the PHMR in the record. |

| | |
|---|---|
| | **Action and Information messages:**<br><br>Step 1. RM Nurse uses the report configuration tool to generates an ad-hoc report, selecting the time range to be covered, the readings to be included and adding a text note detailing the reasons for generating the report<br><br>Step 2. RM Nurse defines the distribution of the report including 'action' and 'information' recipients<br><br>Step 3. Receiving Clinician views PHMR in in-coming workflow.<br><br>Step 4 Receiving clinician opens PHMR, reviews results and flags those to be entered in the record.<br><br>Step 5. Optional: Receiving clinician is able to record a comment on the PHMR in the record. |
| Failure Modes | <identify scenarios that would cause a success scenario (or flow) to fail><br><optionally, identify steps or workarounds to handle the potential failure><br><br>Messages sent to multiple 'action' recipients where responsibility for completing an action would be ambiguous.<br>RM nurse unable to filter results resulting in known erroneous data being sent.<br>Readings appear in clinical record before clinician has reviewed and accepted, leading to liability for action on as yet unread information.<br>Clinician unable to retain control of data quality by selecting which readings are placed in the core clinical record. |
| Diagram (optional) | |

## Marketing Feasibility Review: Pro10-05B

| | |
|---|---|
| Reviewer | MWG |
| Date | June 30, 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>~~May or may not be a clear market need from a Continua Mission and Vision perspective~~<br><br>X - Addresses significant market need from a Continua Mission and Vision Perspective<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal |
| | health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | X - No marketing impact for Continua<br><br>~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br><br>~~Significant marketing impact for Continua~~ |
| Additional Comments | Defining HRN message management mechanisms will enhance the relevance of data input from tele-health applications for clinicians and therefore is good for Continua. |

## Technical Feasibility Review: Pro10-05B

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 06/28/2010 |
| Type of use case | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | Yes, technology to do this is abundantly available<br>~~Technology exist, but is not yet used in the market~~<br>~~No, this is currently not possible~~ |

| | |
|---|---|
| Standard availability | ~~No suitable SDO available~~<br>Suitable SDO available<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | Less than 1 year<br>~~Between 1 and 2 years~~<br>~~Longer than 2 years~~ |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | 1. New guidelines for the HRN receiver for managing and prioritizing + controlling the flow of data – guidelines will be about the HRN Receiver behavior instead of the interface.<br><br>2. process of certifying HRN receiver?<br><br>3. data quality, frequency–needs guidelines around the PHMR document. The metadata may not be available beyond the HRN receiver.<br><br>- The multiple recipients, period and range may be already covered in PHMR – may need specific guidelines. |
| Additional Comments | We will need to establish guidelines for he HRN receiver on the system requirements level. This is a new area – until now we focused on the interface between devices, not on the device design itself. |

## Test & Certification Feasibility Review: Pro10-5B

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | Least – Existing Test Procedures in the Test Tool will need to be modified.<br><br>~~Moderate – New Test Procedures will need to be added to the Test Tool.~~<br>~~Large – Use case covers a new area, and a new Test Tool will~~ |
| Technology Availability (CESL and Test Tool impact) | Least – Technology to implement the use case exists in open source or current CESL code.<br><br>~~Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise~~<br><br>~~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<br><br>(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.<br><br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br><br>~~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<br><br>~~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.~~<br><br>~~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 | TCWG's proposal is that we verify that these Design Guidelines are met via product conformance statements in the Certification Application. This is what we have done in the past for features that are beyond the scope of a Test Tool to test. Because of this, certification effort is minimal and involves only changing documentation.<br><br>Note also that TCWG's analysis assumes that the certification approach will not need to change (i.e., focus will be on the interface and only HRN Senders will be certified). I believe in past discussions, we decided that changes in approach to certification (ex. adding HRN Sender certification) do not come through as use cases, but instead come through as requests to TCWG.<br><br>**Overall assessment criteria:**<br><br>**Easy** – Two or more "Least" items and no "Large" items. |

## Regulatory Feasibility Review: Pro10-05B

| | |
|---|---|
| Reviewer | RWG |
| Date | 30 July 2010 |
| Regulatory Impact Assessment | Products described in this use case scenario could be regulated as a medical device by FDA. The level of regulation is unknown based upon the information given.<br><br>The described application is providing some attributes of an MDDS (Medical Device Data System) as described in FDA's draft guidance document. However, there are attributes of the use case scenario that could push it beyond MDDS (e.g. if the notices are considered alarms or the primary means for the healthcare professional to render a medical decision). If this is the case, then MDDS is not valid; worst case scenario is that FDA considers unclassified which defaults to Class III. |
| Additional Comments | |

# HRN Clinician Response Message (CReM): Pro10-06

| Use Case Title | Pro10-06 HRN Clinician Response Message (CReM) |
|---|---|
| Theme(s) | ~~Health and Fitness~~<br><br>Chronic Disease management<br><br>~~Aging Independently~~<br><br>~~Other – specify:~~ |
| Relation with implemented V1 use case(s) | This is an extension of the functionality of the HRN (previously XHR) interface provided to meet the 2006 / V1 Use case A009 "Asynchronous Patient - Medical Provider Interaction" |
| Description | This project would establish a capability for an HRN Device user to respond to a PHMR.<br><br>Building on the proposed extension to the Personal Health Monitoring Report (PHMR) where messages can be flagged 'For Action' 'For Information' or 'Routine', this response message could be used with any PHMR. This would give the user the most flexibility to be able to respond as they saw fit, so for example, they may want to comment on a "For Information Only" PHMR, or if they noticed that the threshold levels in a "Routine" PHMR needed to be changed then they could point this out using the CReM.<br><br>It is proposed that the scope of this message is constrained as follows:<br><br>a. The message can only be raised in response to a PHMR. It would not be possible, at this stage, for the CRM to be initiated as an ad-hoc message to the WAN device, although that capability may be possible in future iterations<br>b. To restrict the complexity of the interactions and therefore the feasibility of delivering a message, the use case would assumes a simple, one-to-one relationship between WAN and HRN devices.<br>c. Due to potential issues with information becoming out of date and therefore incomplete, it would not be possible for the HRN device to use this message to refer the PHMR onwards to another HRN device, or to respond 'cc' to others. |

| | |
|---|---|
| Scope | The scope covers the HRN response message format and implementation requirements related to the HRN message sender and HRN receiver |
| Actors | <actors and their roles in this use case><br><br>**Remote Monitoring Nurse** (RM Nurse) – Responsible for monitoring the patient using a Continua-compliant WAN device (remote monitoring management system).<br><br>**Clinician** – E..g. General Practitioner / Primary Care Physician. A user of an HRN Device who is responsible for the care of a patient with a long term condition, has referred patient to a remote monitoring programme.<br><br>**Patient** – Participating in a remote monitoring programme. |
| Minimal Guarantees | <end state of the world if the use case is not completed successfully><br><br>Current situation continues where clinician's responses are transmitted by other means and transcribed into remote monitoring record. |
| Success Guarantees | <actor interests that are satisfied upon successful completion of use case><br><br>Clinician is able to respond to issues raised in a PHMR<br><br>Clinician is able to communicate structured information which may include information on symptoms, diagnoses, remote monitoring parameters (thresholds, frequency) and medications<br><br>Clinician is able to hand back care to RM Nurse with instructions for onward referral to a third party.<br><br>Clinician is able to copy CReM message to third party recipients of the original PHMR. |
| Trigger | <the event that initiates the use case><br><br>Clinician receives a PHMR. The event will normally be triggered by a PMHR flagged as 'for action' but may also be raised in response to review of other forms of PHMR |

| | |
|---|---|
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor perspectives, if applicable) | <numbered steps of the use case><br><br>Step 1. Clinician reviews PHMR and decides to generate a CReM reply<br><br>Step 2. Clinician configures reply which can include:<br><br>- Information on diagnoses,<br>- Changes to monitoring regime<br>- Changes to medications<br>- Text instructions including advice for onward referrals.<br><br>Step 3 Receiving RM Nurse views CReM in in-coming workflow.<br><br>Step 4 Receiving RM Nurse opens CReM, reviews information and completes follow-up actions as directed<br><br>Step 5 Optional: Receiving RM Nurse is able to record a comment on the CReM in the monitoring record. |
| Failure Modes | <identify scenarios that would cause a success scenario (or flow) to fail><br><br><optionally, identify steps or workarounds to handle the potential failure><br><br>CReM is limited to a simple 'reply to sender' to avoid issues with replicating data than may have been superceded by new information I the Remote Monitoring Records (WAN Device).<br><br>CReM not flagged as an incoming message requiring review and action by RM Nurse.<br><br>CReM receipt not recorded in sending system leaving clinician uncertain about reply. |
| Diagram<br>(optional) | <insert diagram> |

## Marketing Feasibility Review: Pro10-06

| | |
|---|---|
| Reviewer | MWG |
| Date | June 30, 2010 |

| | |
|---|---|
| Market Need | No significant market need from a Continua Mission and Vision perspective<br><br>May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>X - Addresses significant market need from a Continua Mission and Vision Perspective<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | X - No marketing impact for Continua<br><br>Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)<br><br>Significant marketing impact for Continua |
| Additional Comments | Defining PHMR response message mechanisms will enhance the ability to respond to data input from tele-health applications for clinicians and therefore is good for Continua. |

## Technical Feasibility Review: Pro10-06

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 06/28/2010 |
| Type of use case | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |

| | |
|---|---|
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ~~Yes, technology to do this is abundantly available~~<br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |
| Standard availability | ~~No suitable SDO available~~<br>Suitable SDO available<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | Less than 1 year<br>~~Between 1 and 2 years~~<br>~~Longer than 2 years~~ |
| Steps needed for completion<br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | - Select standards for transport + payload of the inbound interface<br>- Define guidelines for the new inbound interface<br>- Associate the outbound and inbound messages so they can be related<br>- address related security guidelines |
| Additional Comments | I don't see need for changes in the PHM Report standard - but possibly in the transport and need for inbound HRN capability.<br>Currently, there is no inbound capability for the HRN interface – so hospital by default can't control the message frequency. They can always control it on the HRN side because you are document source. So this would require an inbound extension of HRN<br>Note: There is contradiction – this project seems to be advocating 1-1 between Sender and receiver – the previous project 1005B proposed 1 sender to -many receivers |

## Test & Certification Feasibility Review: Pro10-06

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br>Moderate – New Test Procedures will need to be added to the Test Tool.<br>~~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.~~<br>Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>~~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<br><br>(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.<br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br>~~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<br>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.<br>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 | **Overall assessment criteria:**<br><br>**Easy** – Two or more “Least” items *and* no “Large” items. |

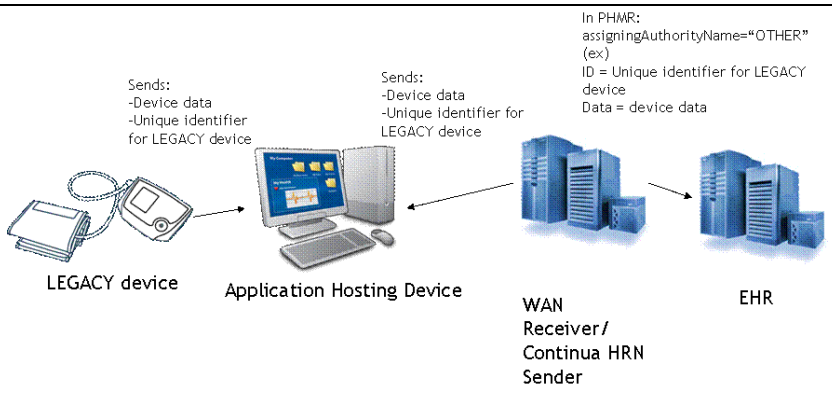
## Regulatory Feasibility Review: Pro10-06

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | No likely regulatory impact based upon the changes noted in the document.<br><br>However, the Products described in this use case scenario could be regulated as a medical device by FDA. The level of regulation is unknown based upon the information given.<br><br>The described application is providing some attributes of an MDDS (Medical Device Data System) as described in FDA's draft guidance document. However, there are attributes of the use case scenario that could push it beyond MDDS (e.g. if the notices are considered alarms or the primary means for the healthcare professional to render a medical decision). If this is the case, then MDDS is not valid; worst case scenario is that FDA considers unclassified which defaults to Class III. |
| Additional Comments | |

# PMHR Extension for Legacy Data Association: Pro10-07

| Use Case Title | Pro10-07 PHMR Extension for Legacy Device Data Association |
|---|---|
| Theme(s) | ~~Health and Fitness~~<br><br>Chronic Disease management<br><br>~~Aging Independently~~<br><br>~~Other – specify:~~ |
| Relation with implemented V1 use case(s) | This is an extension of the HRN interface to accommodate legacy device and vital sign measurements along with the Continua device information and measurements. |
| Description | Earlier use cases such as remote patient monitoring using the xHR interface to convey medical device and vital sign measurements assumed that Continua devices were providing the input. However, remote patient monitoring commonly employs a combination of Continua and legacy devices to capture patient vital signs. It is important to extend the existing xHR interface to also support associating legacy device data with legacy device information in order to assure widespread adoption of the xHR (HL7 PHMR) standard.<br><br>Principally, a suitable alternative to the EUI-64 device ID should be provided for legacy devices. The device ID links vital sign measurements to the capturing device and supports medical coding of additional device attributes, however degraded for legacy devices. Examples of legacy devices include weight scales, thermometers and certain types of at-home diagnostic tests.<br><br>The goal of this use case is to incorporate all available patient vital signs measurements and associated device information as part of the xHR interface in order to maximize the potential for remote patient monitoring. The optional inclusion of legacy device information will encourage early adoption of the standard interfaces as the legacy devices get phased out over time.<br><br>**Responses to San Diego F2F concerns** |

| | |
|---|---|
| | Below are comments on the issues brought up during the San Diego F2F.<br><br>*From UCWG: "It is unclear what the main barrier is. The abstract mentions unique device ID but HNR team confirmed PHMR supports legacy data types."*<br><br>Response: While PHMR may support legacy data types, there is no way to associate the device that sent the legacy data with the data that was sent. This piece is critical for clinicians to make effective decisions. This has been clarified in text above.<br><br>*From UCWG: The proposal to assign a new unique devices ID to legacy data may make it look like this data has a Continua provenance. This should be discussed with the RWG to make sure that the implications are reflected in the range of use cases being discussed with the FDA.*<br><br>Response: The proposal would make it clear that the data is not coming from a Continua device. In the current architecture, a Continua device is denoted by setting assigningAuthorityName to EUI-64. For a legacy device, this assigningAuthorityName would be set to something different, such as "OTHER" or "Legacy." This would make it clear that the data did not come from a Continua Certified device. |
| Scope | HRN Senders – The modified PHMR report would be adopted by HRN Senders. No changes are needed to other devices in the ecosystem. However, it does imply that non-Continua PAN Agents could have their data reported in the HRN. Some changes may be necessary to WAN to ensure the data passes through. |
| Actors | This use case would involve users using either legacy or Continua Certified devices to send data through the PAN and WAN to a HRN Sender. |
| Minimal Guarantees | If this use case is not in place, a clinician will be unable to determine which device provided the data they are using unless that data came from a Continua Certified device. We believe this may actually undermine the adoption of HRN because it will only be useful to a small set of devices initially. We would rather allow legacy device information to be associated with its data now to grow the market for Continua HRN Senders as the market for Continua Certified PAN |

| | |
|---|---|
| | devices grows. |
| Success Guarantees | If this use case is in place, then clinicians can associate all data sent with the device that sent it, regardless of whether that device was Continua Certified or not. |
| Trigger | This use case is triggered by a legacy device sending data through the HRN. |
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor perspectives, if applicable) | 1. User connects a legacy personal healthcare device to an application hosting device.<br>2. User takes a measurement, and data is sent to the application hosting device and from there to a WAN Receiver/HRN Sender.<br>3. When data is sent from the WAN Receiver/HRN Sender to the Electronic Health Record, it includes information that associates the legacy personal healthcare device with the data taken from the device. |
| Failure Modes | This flow could fail if a piece of the solution was not in place (ex. no AHD, no WAN Receiver).<br><br>[Note: I'm not sure that some of these fields are applicable to this use case. The majority of the useful data is in the Description.] |
| Diagram<br><br>(optional) |  |

## Marketing Feasibility Review: Pro10-07

| | |
|---|---|
| Reviewer | MWG |
| Date | June 30, 2010 |
| Market Need | No significant market need from a Continua Mission and Vision perspective |

| | |
|---|---|
| | X - May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | X - No marketing impact for Continua<br><br>~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br><br>~~Significant marketing impact for Continua~~ |
| Additional Comments | The benefit of this Use Case is that it will allow many legacy systems to be integrated by the HL7 PHMR standard at the xHR level of the Continua architecture. The negative from a marketing standpoint is that allowing legacy devices to integrate at the xHR level may weaken the need to create Continua certified devices. |

☒

## Technical Feasibility Review: Pro10-07

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 27 June 2010 |
| Type of use case | ~~Address new end-user need~~<br>~~Consider new technology for existing use case~~<br>Consider new technology for sub-segment of existing use case |

| | |
|---|---|
| Architectural Impact | No Architectural Impact<br>e.g. add new measurement device<br>~~Architectural Change/ Extension needed~~<br>~~e.g. introduce unforeseen interface or API~~ |
| Technology availability | Yes, technology to do this is abundantly available<br>~~Technology exist, but is not yet used in the market~~<br>~~No, this is currently not possible~~ |
| Standard availability | ~~No suitable SDO available~~<br>~~Suitable SDO available~~<br>~~Standard completed~~<br>Standard used in the market |
| Estimated development time | Less than 1 year<br>~~Between 1 and 2 years~~<br>~~Longer than 2 years~~ |
| Steps needed for completion<br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | This is probably simply a modification to existing Continua guidelines/interfaces. |
| Additional Comments | This might be teased apart into two items.<br>1) Assignment of suitable EUI-64 for categorization<br>2) Guideline / Interface alteration to allow the non-compliant device identification to recorded and passed as part of the device information<br>3) Similar discussion / work is definitely needed in the WAN interface. As the WAN interface typically uses a generic algorithm to encode 20601 information, it might actually be best to discuss also in the IEEE-PHD. |

# Test & Certification Feasibility Review: Pro10-07

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ☒ Least – Existing Test Procedures in the Test Tool will need to be modified.<br><br>☐ ~~Moderate – New Test Procedures will need to be added to the Test Tool.~~<br><br>☐ ~~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.~~<br><br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br><br>☐ ~~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<br>(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.<br><br>☐ ~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br><br>☐ ~~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.<br><br>☐ ~~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.~~<br><br>☐ ~~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 | Overall assessment criteria:<br><br>**Easy** – Two or more “Least” items and no “Large” items. |

## Regulatory Feasibility Review: Pro10-07

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | The device / system that incorporates this Continua solution will likely be regulated by FDA as a medical device. The level of regulation is unknown at present.<br><br>I recommend against using "Continua" as an identifier for legacy devices. However, I further recommend that any ID provided to a legacy device communicates to the end user that the device is a legacy device so that the user of the data is aware that the device may not have the particular capabilities associated with a non-legacy device. Perhaps simply indicating "Legacy1", "Legacy2",…"LegacyX" to indicate which devices connected to a given network are legacy devices. If the user setting up the system is allowed to input a descriptor to associate with each legacy device ID, then the resultant information would have more meaning and use. |
| Additional Comments | |

# Tap and Go: Pro10-08

| Use Case Title | "Tap and Go" or "Tap 'n Go" devices, both disposable and reusable. This use case was formerly known as "Touch and go" |
|---|---|
| Theme(s) | Disease management<br><br>Health & Fitness<br><br>Aging Independently<br><br>The use case applies to all Continua segments |
| Device type | Measurement |
| Exchanged data | Conforming to IEEE Personal Health Devices and additional Continua Guidelines. For example, IEEE 11073-10472-2010. |
| Connectivity | Wireless |
| Relation with implemented previous use case(s) | "Tap and Go" applies to many previous device specializations, including adherence monitors, activity monitors, blood glucose monitors, blood pressure monitors, thermometers, etc.<br><br>"Tap and Go" enables new use cases, for example, disposable diagnostic and report cards and sensors, some of which will build on current Continua Guidelines.<br><br>Extended functionality is enabled for existing use cases, for example blood glucose spot monitoring/screening prior to continuous monitoring.<br><br>For some implementations of certified devices, for example the CPX-186 Converter, adoption of "Tap and Go" will result in a simplification of devices for Adherence Monitoring. |
| Applicable interfaces | "Tap and Go" is relevant to communication from devices (Pan-if) |
| Standards availability | Near Field Communication (www.nfc-forum.org).<br><br>This non-profit organization of over 140 leaders in Mobile Communications and Consumer Electronics and Payment Providers (eg Visa, Amex, and Mastercard), is dedicated to promotion of |

| | |
|---|---|
| | interoperable solutions using NFC technology for mobile consumers.<br><br>The NFC forum recently established a working group to integrate Personal Health Devices conforming to IEEE 11073 family of standards and respecting Continua Guidelines.<br><br>NFC mobile phones are widely used in Japan. In 2010 there is limited availability in Europe and USA with broad availability planned for 2011. Other devices on the market such as PCs also support NFC interface. |
| Benefits and rationale | "Tap and Go" is intended to provide the following benefits:<br><br>- Intuitive ease-of-use. Simply touch a Continua device to a manager to communicate data. No learning required.<br><br>- Small form factors, even credit card size devices or smaller. Devices may fit in a wallet or purse, enabling maximum mobility and discrete usage in public places.<br><br>- Very low power (0-3mA on transmit) to enable long device lifetime independent of battery renewal. Typically several months life for active tag devices in use with standard coin cell batteries and up to 2 years shelf life after configuration. In the case of passive tag implementations, useful life is not battery dependent (no battery).<br><br>- Low cost (sub-1$ potential for key module), facilitating disposable and reusable device types that retail for <20$.<br><br>- Intuitive privacy. Device and reader must be in close proximity (tapped) to communicate rather than relying on longer distance wireless solutions and pairing protocols on user level.<br><br>- Personal Use. "Tap and Go" devices are intended for personal use and NOT for sharing.<br><br>- Low data volumes and communication frequency. Data volumes are low as is frequency of communications. Typically a user of a (disposable) Adherence Monitor may check medication events once every two days over a 30 day period, whereas a diabetes patient may transfer data once weekly or even once every two months during a regular visit to a doctor.<br><br>- Seamless communication with standard mobile devices. Typically a |

| | |
|---|---|
| | user may use a mobile phone to view and communicate data. |
| Example scenarios | Example usage scenario: Chris<br><br>Chris is 47 years old with mild hypertension and a BMI of 30. His company doctor has identified that Chris has a heightened risk of serious illness and has prescribed medication to be taken daily. Chris is also advised to record his blood pressure and weight weekly on Sunday morning.<br><br>Like many chronic patients on daily medication, Chris has difficulty remembering whether he has taken his dose. With the Continua system, Chris is able to tap his medication package and see on his mobile phone when the last dose was taken and when the next dose is due. His medication prescription is renewed every 30 days and the old packaging made available to his pharmacist with a complete record of his adherence.<br><br>Every week he taps his blood pressure meter and weight scale and sends the reading via his mobile phone to his physician, along with the record of medication adherence read from his medication package. He is also able to send information about other symptoms. Chris finds the “tap and go” system easy to use.<br><br>The received data is analysed every Monday by the company medical service and exceptions are highlighted. Depending on the data, the company doctor may call Chris for discussion or schedule an appointment.<br><br>To screen the risk for diabetes, Chris has been given a set of disposable blood screening cards. Should a visual signal (red led) be displayed he is advised to contact his physician for more detailed testing. |

| | |
|---|---|
| | The company like the approach because it may prevent a serious and costly medical event. They are extending the system to other employees with a heightened risk, for example, diabetics, pregnant women, and those with respiratory conditions. There are few extra costs incurred – the system runs on the company-issued mobile phone without installation or service charges and uses standard Continua devices and embedded sensors.<br><br>Chris likes the system too. He can check his adherence himself and finds the routine of reporting his vital signs weekly motivates him to reduce weight, take more exercise (he is thinking of buying a Continua pedometer himself), and is reassured that his data is reviewed regularly without having to visit the doctor. The "tap and go" system is easy to use and requires no instruction or technical steps.<br><br>Example usage scenario: John<br><br>John is a 52 year old male. John disease state has advanced more than Chris'. John was diagnosed with type 2 diabetes about 1 year ago. As an obese person he deals with hypertension and uses oral medication to keep both his blood pressure and blood glucose level under control. He uses a tap 'n go medication pack to record compliance.<br><br>John uses a tap 'n go enabled blood glucose meter checking his glucose levels 2-5 times per week. Once a week he swipes the blood glucose meter to download his 2-5 bG results into a diabetes management system which is linked via the internet to his primary care physician for tracking and therapy adjustment.<br><br>John is especially happy about the ease of use – no cable to attach, no buttons to press to transfer the readings. The manufacturer of the blood glucose meter sees a benefit in the low cost, low power, small footprint and low complexity implementation of the technology. |
| Security aspects | In the first review TWG asked for the user scenario to be expanded to reflect security issues and implications for other elements in the architecture.<br><br>Physical security. No special requirements are made for the Continua system. John has small children and keeps his medicines locked in a |

| | |
|---|---|
| | cabinet while at home, while Chris lives alone and keeps his in his bathroom. John keeps his vital sign monitors in his closet to prevent the children playing with them.<br><br>Authentication. The medical centre is prepared for occasional "false" readings – it is always possible that a device is used incorrectly or by a wrong person. A succession of unlikely readings will cause an telephone intervention to ask for an explanation, maybe offering to provide more training in correct usage of the meters.<br><br>Data security in the device. No special precautions are required. The devices conform to Continua standards so no patient identification is kept in the device. The devices are uniquely identified by Device IDs which may be known by the medical centre.<br><br>Privacy while tapping. The client must touch two devices – the personal health device and the reader/mobile phone to transfer data. This is private behavior which requires a deliberate and conscious decision by the client to transfer data. Accidental tapping could conceivably occur eg in a crowded train, when a fellow passenger happens to have a mobile phone loaded with exactly the same application as Chris or John. In this case someone may receive a copy of data from an unknown person and without any context. The data on the monitor is not lost.<br><br>WAN level security should conform to Continua Guidelines.<br><br>Future extensions. NFC (for example) technology is used for highly secure applications such as payments and personal identification, as well as low or no security cases. In high security cases a specific application layer may be built on top of the NFC stack depending on future use cases. It is NOT the intention to add this level of complexity into Continua "Tap and Go" devices now as it will make the system more difficult to use and could restrict the ability of John or Chris to share their data as they choose and easily. |

| | |
|---|---|
| Regulatory aspects | "Tap and Go" devices are designed for ease-of-use and simplicity.<br><br>There is always an assumption that recorded data is interpreted by a professional prior to any medically significant intervention. The professional must be aware that:<br><br>- the data may come from someone other than the patient. (Not authentic)<br>- the data may not be accurate (The device is not used correctly or is not accurate)<br>- the data may have been modified prior to transmission to AHD or WAN level.<br><br>"Tap and Go" devices are NOT expected to require additional regulation. |
| Restrictions | Devices using the "Tap and Go" interface will be Continua compatible with data packets conforming to IEEE 11073 specifications and appropriate Continua Guidelines. |

## Marketing Feasibility Review: Pro10-08

| | |
|---|---|
| Reviewer | MWG |
| Date | July 07. 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>X - May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br>We believe through the efforts of a collaborative industry |
| Marketing Impact | No marketing impact for Continua<br><br>X - Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)<br><br>Significant marketing impact for Continua |
| Additional Comments | The Tap and Go physical action is humanly intuitive to transfer data which makes it interesting and different from other transport protocols. There also seems to be a strong market demand for NFC enabled cell phones in the Japan and EU market but not in the US. However, this adds another PAN transport with similar benefits to the Continua ecosystem which could possibly dilute interoperability as devices have yet another transport to incorporate. Also, there are significant security issues that will need to be addressed by TWG due to no secure pairing mechanism and simply relying on close proximity of devices to initiate a data transfer. Another concern is that the NFC Forum is just now beginning its certification process and work on an IEEE 11073 version of the specification. |

## Technical Feasibility Review: Pro10-08

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 23/06/10 |
| Type of use case | ~~Address new end-user need~~<br>Consider new technology for existing use case<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | No Architectural Impact<br>e.g. add new measurement device<br>~~Architectural Change/ Extension needed~~<br>~~e.g. introduce unforeseen interface or API~~ |

| | |
|---|---|
| Technology availability | ~~Yes, technology to do this is abundantly available~~<br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |
| Standard availability | ~~No suitable SDO available~~<br>Suitable SDO available<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | ~~Less than 1 year~~<br>Between 1 and 2 years<br>~~Longer than 2 years~~ |
| Steps needed for completion<br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | **Transport:** The use case suggests to add NFC as a new communications transport (for Continua) to the list of supported transports for the PAN-IF. However NFC devices can incorporate and communicate over Bluetooth and Wireless transport after the initial connection over NFC. These additional transports may not be Continua certified – can a device that supports this behavior be certified?<br><br>**SDO:** The NFC Forum (www.nfc-forum.org ) has established a working group addressing conformance to IEEE 11073. The underlying Layer-2 protocol supports two modes (connectionless and connection-oriented) and is based on IEEE802.2 and ISO/IEC 18092. So while the NFC Forum is not a standards body there are standards in place. There are multiple possible standards, for example RFID, and Continua must satisfy itself that the one adopted by the NFC Forum is the most appropriate one. |
| Additional Comments | **Too far too soon?** – this is a use case proposition and as such perhaps goes too far by tying itself to specific technology/solution. Should this be rejected and a new submission requested that focuses on the problem statement rather than the solution?<br><br>From the current use case description, the real need that is |

| | |
|---|---|
| | addressed by the use case is not obvious. It should be motivated why 'tapping' is a real need. The document states that the suggested solution provides "Intuitive ease-of-use" and "No learning required", which is targeted by the current PAN interfaces (wired, wireless standard, wireless low-power) as well.<br><br>**Market penetration** is expected to be 15-20% of phones by 2012 at the premium (smart phone) end of the global market; no geographic figures were available. This will impact adoption at the low end / developing countries where the low device cost would be expect to be most appealing.<br><br>Different market areas (Japan, Europe, Americas) have different maturity levels and adoption of NFC devices (mobile phones, passive devices) within different markets (travel, micro payments etc.) This presents Continua with a good entry point for this use case and an opportunity to influence standards in this emerging technology. However the markets may also be fragmented with no clear leader able to help establish and drive standards – defacto or 'real'.<br><br>**Market Use** – widely used in Japan with a closed standard. Starting to be used elsewhere with a more 'open' standard – e.g. France.<br><br>**Data Integrity** – NFC has no pairing as such therefore there is a risk that a device could send data to an incorrect AHD. The question is what happens to the data that was on the device? Has this now been lost? Does this stop NFC devices from being used as medical devices?<br>**Data Transfer -** if used as medical devices then connection orientated mode be mandated to ensure successful data transfer to the AHD from the device. This will not prevent unexpected data transfer events to unknown AHDs.<br><br>**New Standards/Guidelines -** May need to build new standards for these device types and liaise with other industry groups (e.g. NFC Forum) which may introduce significant delays. 18 months +<br><br>**Overall Assessment: Difficult –** The technology exists in varying states of maturity and adoption in various markets and geographies. Creating Continua guidelines, interface standards and liaising with other industry bodies is expected to push development time to at least two years. |

## Test & Certification Feasibility Review: Pro10-08

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br><br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br><br>☐ 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.<br><br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br><br>☐ 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<br>(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.<br><br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br><br>☐ 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.<br><br>☒ 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.<br><br>☐ 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 | Note: This analysis assumes that IEEE 11073 PHD data can be used over this transport. If not, the assessment is “difficult” as the architectural impact and technology availability would be “large.” |

☐

# Regulatory Feasibility Review: Pro10-08

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | No regulatory registration issues (provided the above assumptions are correct). This is principally a design option that a manufacturer can decide to employ or not. The finished device manufacturer will need to support and justify any regulatory registration decisions that incorporate this design feature. The use cases presented indicate a range of device classifications that FDA regulates. |
| Additional Comments | |

# Application Portability Across Mobile Platforms: Pro10-10

| Use Case Title | Pro10-10 Application portability across mobile platforms |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | No relation with V1 |
| Description | Defining a mechanism that will allow Healthcare applications to target different AHD platforms and support Continua certified and legacy sensors prevalent in the ecosystem today |
| Scope | Affects E2E but is focused exclusively at the transport/application layer level |
| Actors | Fred, a mid fifties overweight middle management employee with high blood pressure.<br><br>Fred's employer who wants him to maintain fitness<br><br>Fred's physician who directs Fred on a course of exercise and diet<br><br>Fred's insurance company manager<br><br>Fred's mobile phone …. lifeline to the internet. |
| Minimal Guarantees | Fred has to do a lot of testing and digging in newsgroups. At least he identifies a combination of mobile phone and application that can run the services as he and the other actors need it. |
| Success Guarantees | Efficient coaching, feedback, optimal insurance rates for Fred, an overall healthy Fred. Fred's device landscape interacts perfectly, even through updates and replacements of his mobile phones and phone applications. |
| Trigger | Fred's employer wants him to report fitness data. Fred's insurance company informs Fred of change in rate criteria and as a |

| | |
|---|---|
| | consequence asks him to report data to their portal. Fred fears to lose his job and to pay increased insurance rates. |
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor perspectives, if applicable) | **Basic situation, Trigger**<br><br>Fred is an active middle management person in his mid fifties who has had some challenges with his weight and blood pressure. He is slightly active and desires to help himself attain a higher level of fitness while reducing his reliance upon medication.<br><br>He has visited his family doctor and has been told that exercise and diet will help him attain this goal and Fred has searched the internet and has found a variety of diet and exercise platforms that require him to adhere to and report against a concise plan of diet and exercise.<br><br>His company healthcare coverage requires yearly check ups for his job status and Fred has been told he is not at the fitness and health level required by his policy. His company respects the challenges Fred is under regarding his weight and have offered financial support as long as Fred can reliably report his progress.<br><br>**Fred's first solution for monitoring and reporting**<br><br>The training package that works best for Fred is a web based platform that analyzes his current status through a fitness questionnaire and requires that Fred attend a class at a local gym for direct evaluation. Fred's company will pay for the eval but has no policy for devices so Fred is shopping for the best deal for the results he needs. The gym he attend sells a variety of sport packages that offer an even more varied assortment of health options<br><br>Fred wants to track and trend his caloric intake, calorie consumption through activity, blood pressure at regular intervals as suggested by his physician and his weight morning and night. The least expensive product that suits his needs is a wrist mounted display that gathers his personal activity based data from remote sensors. He hands in monthly written fitness reports to his employer. He is happy to use this package and goes on his merry way.<br><br>**Secondary need from the insurer: add more devices and online monitoring** |

| | |
|---|---|
| | A few months later his insurance company wants him to relay his activity directly to them to maintain his current coverage. They give him a logon to their health management portal to enter his data online.<br><br>Fred tries to get create a habit of recording his data each day. He forgets regularly and is in jeopardy of having to pay substantially more for his insurance coverage. He searches for an automated solution. The insurance company wishes to avoid connectivity problems. The insurance portal therefore is using Continua interfaces and it will only accept data if it comes out of Fred's mobile phone via a Continua certified application. Fred therefore searches and finds such an application for his mobile phone, which will take the existing sensor data directly, store it and forward the correlated results to any web site Fred needs. Fred buys the application and goes about the collection process and finds a BP cuff that he likes and a weight scale that he likes that all have existing and certified communication strategies. He puts everything together and successfully reads out the data from these products to his new Continua certified mobile phone application. From there the data goes directly on to the insurance portal. Fred is amazed and successfully transmits data regularly from now on..<br><br>**Changing phone platforms**<br><br>Fred has also been told that his company phone plan will change to a phone from companyB and they will not pay for his companyA phone any longer. Fred really wants to continue to use his simple inexpensive reliable portable application solution for years to come. Fortunately the application is also available for the new phone. Fred is happy that application providers can all use an interoperable system that allows his current products to continue to do their job now and in the future. His investments pay back in better quality of life and also bring in financial bonuses. And, again, both Fred and his insurance are happy that there are “Continua certified applications”, which interact seamlessly and without fuss with the insurance portal. |
| Failure Modes | Fred, out there alone, tries out many applications, He does not find one application that successfully transmits his data to the server. He therefore has to read the values from the device displays and enter them into the insurer’s health management portal manually |

| | |
|---|---|
| Diagram (optional) | <insert diagram> |

Marketing Feasibility Review: Pro10-10

| | |
|---|---|
| Reviewer | MWG |
| Date | July 07, 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>X - May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | ~~No marketing impact for Continua~~<br>~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br>X - Significant marketing impact for Continua |
| Additional Comments | The concept of an API that lets your port across AHD platforms is very interesting. However, not sure if this would mean a different API per Operating system (i.e. Linux, Android, Windows CE, Apple iPhone, etc.) There is concern from a Marketing perspective that this API sets a dangerous precedence. Up until this point in time, Continua has spent a good deal of its effort making sure Continua Certified devices communicate with each other well by rigorously defining guidelines and certification processes for transport between devices. This type of API would now negate that focus and allow NON-compliant transport protocols into the Continua system at the AHD level. This API will erode the necessity for device manufacturers to create Continua Certified agents. Historically, Continua has picked transport protocols with a broad base of vendor support and a robust certification process to insure that Continua is building on top of a stable transport protocol. With this API, that vetting will not be necessary. |

# Technical Feasibility Review: Pro10-10

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | June 25, 2010 |
| Type of use case | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | Yes, technology to do this is abundantly available<br>~~Technology exist, but is not yet used in the market~~<br>~~No, this is currently not possible~~ |
| Standard availability | No suitable SDO available (for operating system API)<br>Suitable SDO available (for web API)<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | ~~Less than 1 year~~<br>~~Between 1 and 2 years~~<br>Longer than 2 years |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | The interoperability promise of portable applications is a totally different one than what Continua has worked on so far (interoperability between different devices). Therefore it is key to thoroughly analyse the marketing and logoing implications of pursuing application portability.<br><br>A well known example of application portability across mobile platforms is Java. This environment is supported on a large number of mobile devices, which shows that it is possible to enable application portability. Unfortunately over the past years Java has lost ground to the execution environments of individual mobile device vendors (e.g. iPhone apps, Blackberry apps, Symbian apps, Windows mobile apps, Android apps, etc).<br><br>Nokia is using Qt to enable cross platform application portability, this is different from Java (where the application binaries can be used on different platforms); with Qt the source code can be compiled to target different platforms.<br><br>There doesn't appear to be a standardization organization which defines operating system APIs for mobile platforms, every execution environment defines the APIs themselves. Java does this in the most open way through the Java Community Process.<br><br>In the ideal situation the actual application would not need to know anything about the underlying transports which carry the data. Specifying a rich enough API which truly abstracts the workings and features of the various underlying transports is no easy task.<br><br>Another approach would be to do it via web browser/web apps instead of an API in the operating environment. Most of modern mobile software environments include a web browser, and web apps can run in all of them. So, a standard web API could run on every platform (if it is supported by the particular web browser on that platform), and it would be very easy to create Continua based web |

| | |
|---|---|
| | applications that could potentially run in all platforms (not only mobile environment). There are already some standardization efforts that could be taken into account on this line, all taking place in the World Wide Web Consortium (W3C):<br><br>• W3C Mobile Web Initiative (http://www.w3.org/mobile)<br>• W3C WebApps working group (http://www.w3.org/2008/webapps/)<br>• W3C Device APIs and Policy Working Group (http://www.w3.org/2009/dap/)<br>One of possible paths to achieve a mobile interoperability and portability environment for mobile apps would be:<br><br>1) Define a standard API to access and manage Continua defined objects (measures, interfaces, etc.) based on JavaScript language.<br><br>2) Propose this API to W3C DAP working group as one of available APIs for web development.<br><br>3) Create a reference implementation of this API, based on an OpenSource environment<br><br>4) Browser developers would be encouraged to add support for this API.<br><br>Notice that there are more challenges in application portability than just the APIs. Mobile devices vary greatly in terms of screen size/resolution, input methods and processing capabilities. This means that even when it is possible to transfer an application from one mobile device to another it does not mean that the application will have a high quality user experience on every device.<br><br>An important topic for further discussion relates to the testing/certification of an API. This will require a different way of testing compared to the current interoperability testing. The complexity will depend heavily on the chosen approach, e.g. would we need test apps for every type of mobile platform? |
| Additional Comments | Possibly schedule a roadmap with intermediate meaningful steps along the path to enabling full application portability.<br><br>Clarify if the path of web browser API is an option for this use case (e.g. can we assume the availability of a web browser on an AHD). |

## Test & Certification Feasibility Review: Pro10-10

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 22nd, 2010 |
| Test Tool Architecture Impact | ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br>~~Moderate – New Test Procedures will need to be added to the Test Tool.~~<br>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.~~<br>~~Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise~~<br>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<br><br>(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.~~<br>Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>~~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.~~<br>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.<br>~~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 | It was difficult to tell what this UC referred to from the description.<br>**Overall Assessment Criteria: Difficult** – two or more "large' items |

## Regulatory Feasibility Review: Pro10-10

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | Provided that the claims associated to the Continua devices described in this scenario remain as fitness claims, then the FDA regulation will be minimum to none. If the claims are for improved outcomes for the users cholesterol, blood pressure, etc. then the devices are likely to be regulated by FDA. |
| Additional Comments | |

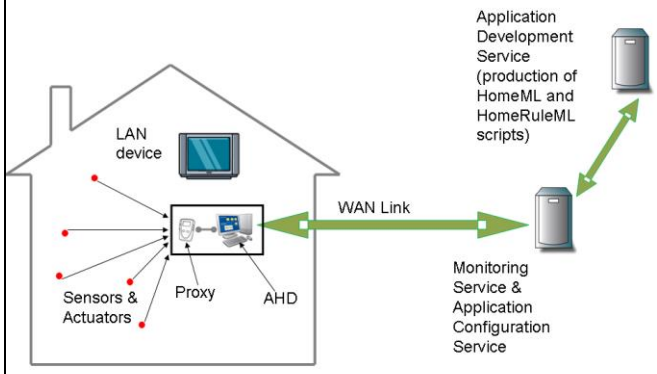
# Use of Modeling Languages within the Smart Homes: Pro10-15

| Use Case Title | Use of modeling languages within Smart Homes |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | This project relates to the V1 use case for AI, HF and DM, since it potentially incorporates the use of PAN, LAN and WAN interfaces. Sensors and actuators can be supported by Proxy LAN devices or connect directly to the AHD. |
| Description | This Use Case is applicable to high-level interaction of devices and sensor-based systems in a home setting. The interaction is based on the information collected from sensors and devices present in the ambient environment of the home. The assumption for this use case is that there are multiple general purpose sensors present at home, and the overall system has to be configured in such a way that a person without special knowledge can be able to a certain degree modify / adjust system behavior without risk of making it dysfunctional.<br><br>A home is an environment where there is a low variability in terms of concepts (that is types of rooms, equipment used, actions performed), although there may be a significant variability in sensing devices. Many sensors may be able to provide information about what is happening in the home environment, but in many cases there is no direct connection between the device reading and the information it provides.<br><br>One way to solve this is to create a set of knowledge rich concepts for the home, define relations between them and bind them to the outputs of devices, sensors or systems. Based on this high level rules and relations may be easily added, customized and reused, specifically in two ways:<br><br>1. Ad-hoc creation or customization: The information, relations |

| | |
|---|---|
| | and rules need to be added by a responsible person or a caregiver using simple and high-level descriptions.<br>2. Reuse in common cases: The acquisition and update of information, relations and rules in instances of change in the environment from existing database of relations and rules thus eliminating the need to manually modify or input relations or rules. |
| Scope | The overall system includes several levels.<br><br>1. On the lowest level are general purpose sensor devices. We assume that these sensor devices are able to provide self-configuration up to the level of providing information of what kind of data they are able to provide. For example, a sensor node with a reed switch connected should be able to provide information that it is a reed switch and explain the basic meaning of its output values. As far as the platform is concerned, UPnP and OSGi or equivalent technologies which are certified by Continua since these are mature and widely used in the smart home area.<br>2. On the next level, there is a system which binds specific sensors to specific objects in the house, for example, connects a particular reed switch with a grocery cupboard.<br>3. There is a system which uses the above output to reason about events happening in the environment.<br>4. There is a system which enables certain type of actuation to be performed onto environment or person<br>5. There is a tool which allows a person without skills in the computer systems to create / program certain responses to be enforced using actuators described under point 4, in case certain events are detected by a system described under point 3<br><br>This use case is addressing the points 2,3,4 and 5.<br><br>For limited set of scenarios, the above can be implemented using simple markup languages and existing datasets created using them and deployed within smart home environments. There exists an example of such datasets and community-developed rules based on HomeML (HML) and HomeRuleML (HRML). |
| Actors | Elderly staying alone at home<br><br>Care-givers, doctors |

| | |
|---|---|
| | Relatives |
| Minimal Guarantees | Depending on the condition of the person who is a target of the smart home care system, and of the environment type, different minimum guarantees may be configured.<br><br>If the basic safety of an elderly staying at home can be always ensured even in the absence/failure of any sensor system, then the minimal guarantee is that the system should understand its limitations and no erroneous actuator actions are enforced.<br><br>If there exist certain critical conditions which need to be monitored, then, in the event of failure of failure of certain sensors or systems, caregiver should be informed about the situation.<br><br>There are chances of spoiled devices or battery running out of wireless devices within the home. An infrastructure that is resilient to such situations will be highly desirable. |
| Success Guarantees | The sensors present in the environment has to be able to communicate with higher level systems and to correctly identify themselves<br><br>The sensors present at home has to be properly assigned to objects<br><br>There should be a description of how complex events of interest are observed<br><br>Tool for rules modification has to be able to express rules complex enough and able to check rule consistency and correctness.<br><br>The actuation has to be safe or reminders have to be properly configured so that they are delivered to the correct person on time |
| Trigger | Use of any of the smart devices at home, such as fridge (with RFID tags, reed-switch), TV, food items with RFID-tag.<br><br>Changes in the ambient environment, such as high temperature near the stove, light switched-on, etc. |
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor | Here, we consider the following scenario happening in a smart home system:<br><br>*Mr. Lim, an elderly person suffering from mild dementia, stays at home with his family, all of whom are generally not* |

| | |
|---|---|
| perspectives, if applicable) | *present at the home during the daytime. For health reasons, Mr Lim is required to limit his sugar intake. Therefore there is a limit on certain types of food and drinks he is allowed to take. Nevertheless, since he may forget about this limit, reminders need to be established.*<br><br>*Mr. Lim's dietician creates a rule which requires a warning to be sent to Mr. Lim if he tries to consume food in excess of the sugar level limit. Mr. Lim's son scans the bar codes on drinks and marks them with passive RFID tags. After that, if Mr. Lim tries to take apple juice for the third time during the day, he is prompted to avoid doing this, through an appropriate reminder. On the other hand, when Mr. Lim tries to consume tomato juice or his grandchild tries to take out the apple juice from the fridge, no reminder is delivered.*<br><br>Scenario possible implementation:<br><br>The example system uses the HomeML and HomeRuleML XML based rules and descriptions of a smart home, along with objects and sensors that are present in the home.<br><br>Environment configuration step: Sensors assigned to household objects and identification is configured by caregiver or a relative using simple descriptions. Important objects/sensors: Mr. Lim (RFID tag), fridge (RFID reader), fridge door (reed switch), juice containers (RFID tags). The RFID readers are Continua devices. These devices are connected to a Continua AHD device via Proxy devices, or in some cases directly to the AHD device. WAN connectivity between the AHD device and services running remotely allow the monitoring of a number of statistical and intervention functions as necessary.<br><br>High level rule introduction step: Custom rules created by a doctor (the dietician): reminders of daily sugar intake<br><br>General environment information reused: HomeML contains information that food is stored in the fridge and in the cupboards in the kitchen<br><br>Sensors detect simple events and transmit information about them to complex event detection system.<br><br>Important events derived: HomeML contains description of simple |

| | |
|---|---|
| | events (Mr. Lim is present at the kitchen, fridge is open, RFID of juice container changes location) and description of how more complex events of taking out the drinks are derived from simple events.<br><br>Actuation: Reminder is sent to a patient in the case of critical event<br><br>General object information reused: Sugar content of certain foods and drinks, using scanned bar codes and content database.<br><br>Rules reused: If there are no separate rules for each type of drink, or for different locations at which drinks are stored, then the single rule is reused. |
| Failure Modes | Sensor and actuator failures:<br><br>Some of the sensors or actuators can fail or may need battery replacement. There can be network failures. The sensor, actuator and network failures can be detected by UPnP type of protocols. In this case system should be able to detect the failure / fact of missing sensor and actuator, and check if minimal guarantees can be provided.<br><br>Event detection failures:<br><br>Event not detected based on input provided |
| Diagram<br><br>(optional) |  |

## Marketing Feasibility Review: Pro10-15

| | |
|---|---|
| Reviewer | MWG |
| Date | July 07, 2010 |
| Market Need | X - No significant market need from a Continua Mission and Vision perspective<br><br>~~May or may not be a clear market need from a Continua Mission and Vision perspective~~<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | ~~No marketing impact for Continua~~<br><br>X - Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)<br><br>~~Significant marketing impact for Continua~~ |
| Additional Comments | This use case gets into standardizing applications and the general consensus was that this is not something Continua should address at this time. |

## Technical Feasibility Review: Pro10-15

| | |
|---|---|
| Use case: | Pro10-15 Use of modeling languages within Smart Homes |
| Reviewer (2 reviewers) | TWG |
| Date | June 22, 2010 |

| | |
|---|---|
| Type of use case | Address new end-user need<br>~~Consider new technology for existing use case~~<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | Yes, technology to do this is abundantly available<br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |
| Standard availability | No suitable SDO available<br>~~Suitable SDO available~~<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | ~~Less than 1 year~~<br>~~Between 1 and 2 years~~<br>Longer than 2 years |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | This use cases describes a potential solution to more easily analyse and process the data that is gathered in the personal telehealth ecosystem, particularly in the home. This is not part of the traditional scope of Continua, where the focus is on communication interoperability and not on how to use that data (which doesn't mean that it is not a valuable topic!).<br><br>This use case discusses a "rules engine" running on the Continua WAN device and a modeling language to define sets of "rules". These two combined form a way to create applications that process incoming data based on the defined rules and execute certain actions. The goal is to make it easier to make such applications and make it possible for non-technical people to configure the applications.<br><br>The possible solutions described in the use case refer to HomeML and HomeRuleML, both were first introduced in 2007 in a paper at the 5th International Conference on Smart homes and health Telematics, Nara, Japan. It is unclear if this has been used in industry since and if there are potential standards developing organizations available which could take ownership of turning this into a true standard.<br><br>At this point it is not fully clear what the role of Continua would be in bringing this further, e.g. what sort of guidelines would Continua create for this, how can it be tested/certified and what would get a Continua logo. |

| | |
|---|---|
| Additional Comments | If possible add more detail about the adoption in industry of modeling languages such as HomeML.<br><br>Indicate if possible what the role of Continua could be in bringing this further in terms of type of guidelines, certification and logging. |

☐

☒

☐

## Test & Certification Feasibility Review: Pro10-15

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 23rd, 2010 |
| Test Tool Architecture Impact | ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br>Moderate – New Test Procedures will need to be added to the Test Tool.<br>~~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.~~<br>Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>~~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.<br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br>~~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.~~<br>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.<br>~~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 | It is unclear at this time how this will be technically implemented. However, if the scope is just to add some HML or HRML meta-data to the interface, then the effort is as defined above. If this involves creating a new meta-WAN or meta-HRN interface, then the effort would be larger.<br><br>**Overall assessment criteria:**<br><br>**Medium** – All items not Red or Green |

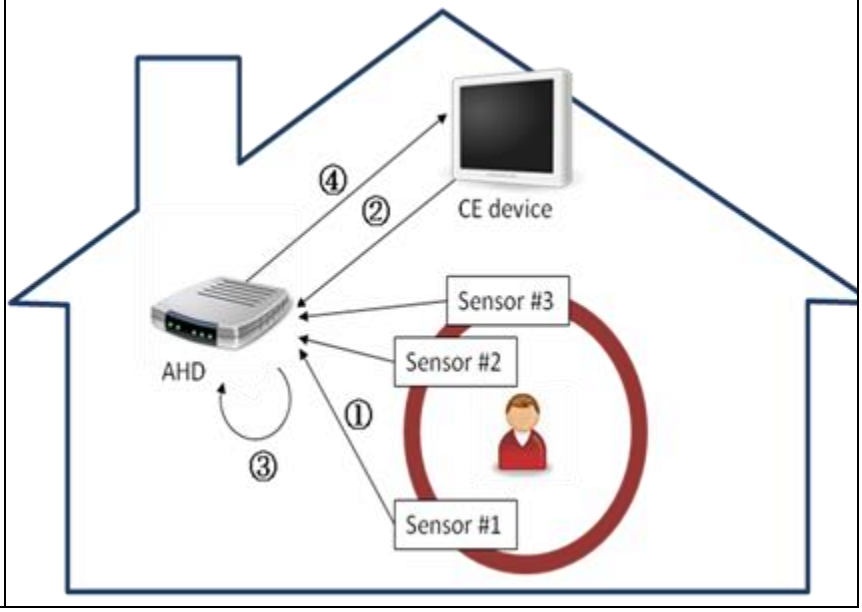
## Regulatory Feasibility Review: Pro10-15

| | |
|---|---|
| Reviewer | RWG |
| Date | 23 July 2010 |
| Regulatory Impact Assessment | Provided that none of the sensors involved are a medical device or used in such a manner to meet the definition of a medical device, then there is no FDA regulatory impact for this scenario. |
| | There are variations of the scenario which, collectively, could meet the definition of a medical device per US Food Drug and Cosmetic Act §201(h). In part this states:<br><br>> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . .<br><br>If the use of the system is considered part of the mitigation or treatment of the given disease state, then the system could be considered a medical device. If installed for a given individual per or with significant physician direction, then this would be considered a custom device. If the system is sold as a kit or all parts in a given configuration meant to support a specific disease condition (e.g. Kit A is designed specifically for use with dementia patients), then the kit would be considered a medical device. |
| Additional Comments | |

# AHD to CE Device Communication: Pro10-16

| Use Case Title | AHD to CE Device Communication |
|---|---|
| Theme(s) | ☒ New Features for existing interfaces (e.g. increased security)<br>☐ New Transports for existing interfaces (e.g. PAN high-power radio. See note 4 below)<br>☐ New Interfaces (i.e. LAN interface support) |
| Relation with implemented V1 use case(s) | The current use case can be built upon the key architectural interface for (IP)LAN/PAN/(IP)WAN interfaces by which data can be exchanged between Healthcare Devices and AHDs and between AHDs. The objective for this specific use case is to make an enhancement to the current interface to enable data exchange between AHDs and CE devices. |
| Applicable Interfaces | Personal Area Network Interface (PAN-IF)<br>Local Area Network Interface (LAN-IF)<br>Wide Area Network Interface (WAN-IF)<br>~~xHeath Record Network Interface (xHRN-IF)~~ |
| Rationale for Feature | The main objective of this use case is to enable an interface where Continua data can be rendered at the consumer electronics devices in the home network. The CE devices would be able to interact with the continua ecosystem particularly interfaces with the AHD device. The interface between the AHD and CE devices can be enabled using LAN, PAN or IP WAN interfaces. There are millions of IP enabled consumer electronics devices in the market and the focus of this use case is to enable these devices to interface with the Continua AHD devices and support the following features:<br>- A consumer electronic device such as DTV can render health information that are stored in an AHD<br>- Support of health and fitness games: The AHD devices can communicate with the CE entertainment devices to realize different fitness gaming scenarios.<br>- Upload of fitness data gathered from non-continua devices to an AHD |

| | |
|---|---|
| Requirements | The primary requirement for this use case is to enable data communication between healthcare Devices and AHDs or between AHDs that are separated by some distance. For example, the devices can be located in different rooms in the home. The use case is expected to support the following features:<br><br>• Enable the exchange of Healthcare Device data in the home network.<br>• Enable the "proxying" of Healthcare Device data, connected via Continua PAN Interfaces, to/from PAN/LAN/IP WAN<br>• Enable the sharing Healthcare Device data (i.e. multiple users of the same Healthcare Device data) via an PAN/LAN/IP WAN<br><br>The PAN/LAN/ IPWAN are the currently existing interfaces in Continua. The IP-LAN interface is also an existing use case in Continua. The existing IP LAN use case is proposed to share data among devices that include sensor to AHD and AHD to AHD. The current use case can be built upon the architectural interface of IP LAN in which case the realization of IP LAN interface is a pre-requisite to realize this use case.<br><br>The AHD to CE Device communication use case will enable an interface such that AHDs are able to share data with CE devices. This new use case project would provide recommendations for the following features/functions:<br><br>• Discovery of AHD devices and services in the home network. This would include advertisement of AHD device description and services provided by the AHD so that the services can be accessed by the CE devices.<br>• Rendering of health data from AHD to CE devices. This can work either in pull or push mode scenarios. The services running in the AHD will enable a CE device to access the data from the AHD device or data can be pushed to the CE devices.<br>• Any changes to data in the AHD will be notified to the CE device based on the subscription/notification mechanism.<br>• The project would define protocol to be used between the AHD and the CE devices to exchange data<br>• The project would not recommend any new data format rather use existing data format defined by Continua and IEEE 10073<br><br>The requirements for the feature described above can be realized using UPnP/DLNA specifications. |

| | |
|---|---|
| Sample Scenarios | 1. AHD collects data<br>2. CE device access the AHD<br>3. Rendering data encapsulation for CE devices<br>4. Data is rendered to the CE device<br>  |

## Marketing Feasibility Review: Pro10-16

| | |
|---|---|
| Reviewer | MWG |
| Date | July 07, 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>X - May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal health systems that empower people and organizations to better manage their health and wellness |
| | -Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | ~~No marketing impact for Continua~~<br><br>X - Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)<br><br>~~Significant marketing impact for Continua~~ |
| Additional Comments | Interesting gaming consoles to AHD application. Will be interesting use case. Not sure if there is much need outside gaming console application. Some concern about competition with ZigBee in the LAN which will cause some marketing impact |

## Technical Feasibility Review: Pro10-16

Please note that the use case presented for ballot has been updated to clarify some of the points raised in the Technical Feasibility Assessment. The following technical assessment has not been refreshed to reflect these comments.

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 29 June 2010 |
| Type of use case | ~~Address new end-user need~~<br>Consider new technology for existing use case<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | ~~No Architectural Impact~~<br>~~e.g. add new measurement device~~<br>Architectural Change/ Extension needed e.g. introduce unforeseen interface or API |
| Technology availability | ~~Yes, technology to do this is abundantly available~~<br>Technology exist, but is not yet used in the market<br>~~No, this is currently not possible~~ |

| | |
|---|---|
| Standard availability | ~~No suitable SDO available~~<br>Suitable SDO available<br>~~Standard completed~~<br>~~Standard used in the market~~ |
| Estimated development time | ~~Less than 1 year~~<br>Between 1 and 2 years<br>~~Longer than 2 years~~ |

| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | **New Technology?** The concept for this use case is to allow Consumer Electronics devices within the home to act as interfaces for Continua data. It would seem to fit into the vision of Continua, as the TV is the most heavily used interface in the home, and represents a parallel to current PC and cellphone-based interfaces, and very well aligned with the personal telehealth space. It appears that the proposal is too implementation-specific, since there are multiple Continua interfaces that could support this connectivity.<br><br>**Standards Development?** Given the Continua interfaces currently specified and that IEEE11073 is already in place, it would seem that new standards development is not necessary. There may be some tweaks that are required to improve device or service discovery for a particular interface. CE manufacturers may wish to develop standardized approach to render 11073 data, but that is not necessary for success of this use case.<br><br>**New Continua Interfaces?** Without getting too implementation-specific, it would seem that CE devices that interact with the Continua ecosystem could do so via at least the AHD (via LAN and PAN I/F) or IP WAN. Again, this is a matter for the TWG to consider.<br><br>This project adds additional feature to the IP LAN interface. The IP LAN IF is yet-to-be worked out as there was not enough interest/sponsors for v2, so this effort needs to be completed.<br><br>**Modification to Continua Interfaces?** The use case as described concentrates on the interface between the AHD and the CE device. It is possible that some or all the interfaces already approved have the ability to support this new use case, but it is also likely that there could be changes to those interfaces – a number of issues could include service and device discovery and advertisement, resolution of push and pull, etc. There is also a security component that would need to be considered for this data exchange protocol.<br>**Other Items?** The use case suggests that UPnP and DLNA specifications could help realize the desired functionality. However, there is no liaison relationship at this time between Continua and either UPnP, DLNA, or CEA. One would need to be created. It is also unknown whether these groups have a health care group or focus. Thus, there may also be the need to establish health care specific rules within one of those groups to address privacy and other security issues. |
|---|---|

| | |
|---|---|
| Additional Comments | **General -** The use case as described includes implementation specifics – it would be better that the use case focused on the problem (interacting with the Continua system from within the home by CE devices like TV sets) and allow the TWG to address "how" to do this. While there appear multiple Continua interfaces to which this could apply, selection of the IP-WAN interface that is to be added based on an already approved use case. Will require the completion of the progress for that already approved UC.<br><br>**Market value** – There are more and more connected TV sets and other CE devices. The Consumer Electronics Association (CEA) has published a number of market reports over the last year or so showing broad support from consumers for "connected" TVs, and there are more TVs that have some form of connectivity including Ethernet, Wi-Fi, ZigBee, or Bluetooth included. Through one of these interfaces it may be possible to cause to be rendered "widgets" on the display that could be useful for health care application developers in the Continua ecosystem.<br><br>**New Standards/Guidelines -** May need to build new standards for these device types and liaise with other industry groups (e.g. DLNA, UPnP, Bluetooth, ZigBee, Wi-Fi) which may introduce significant delays.<br><br>**Overall Assessment: Medium -** The technology exists in varying states of maturity and adoption in various markets and geographies. Creating Continua guidelines, interface standards and liaising with other industry should take no more than one to two years. |

## Test & Certification Feasibility Review: Pro10-16

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 23rd, 2010 |
| Test Tool Architecture Impact | ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br>~~Moderate – New Test Procedures will need to be added to the Test Tool~~.<br>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.~~<br>~~Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise~~<br>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.~~<br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br>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.~~<br>~~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.~~<br>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 | Effort on this use case is large because the IP-LAN would need to be developed. In addition, the addition of communication code between an AHD and a CE would need to be developed.<br><br>→ I wonder if we could take this use case through DLNA to see if they would support it. I know I took a similar use case through DLNA about four years back (TCWG).<br><br>**Overall Assessment Criteria:**<br>**Difficult –** Two or more "Large" Items. |

## Regulatory Feasibility Review: Pro10-16

| | |
|---|---|
| Reviewer | RWG |
| Date | 30 Jul 2010 |
| Regulatory Impact Assessment | The specific addition to the use case does not have any additional regulatory burden.<br><br>However, the devices mentioned in the use case examples could be regulated to a degree depending upon the claims and objective intent made apparent by the device manufacturer and the type of health information involved. |
| Additional Comments | |

# Wearable Mobile Nurse Call: Pro10-17

| Use Case Title | Pro10-17 Wearable Mobile Nurse Call |
|---|---|
| Theme(s) | ~~Health and Fitness~~<br>Chronic Disease management<br>Aging Independently<br>~~Other – specify:~~ |
| Relation with implemented V1 use case(s) | An extension of V1 use cases where an AHD is a wearable device capable of interoperable and secure voice communication |
| Description | This use case describes a battery powered AHD with a WiFi IP interface capable of 2 way VOIP over a range of 45 feet in an American construction home with VPN level security. The AHD device should be wearable for up to a week after a hospital operation with a couple of hours of talk time without recharge. The device should also enable interoperable communication with glucometer. |
| Scope | A specific set of interoperability requirements for a wearable AHD nurse call device |
| Actors | Fred, an uninsured diabetic who visits the ER frequently.<br>Wilma, an insured diabetic who has just had a surgical operation. |
| Minimal Guarantees | Fred and Wilma will be more likely to talk to their care taker because they know their care taker will respond within a short period of time after they push the button on their AHD and they have been encouraged to do this through experience. |
| Success Guarantees | Fred and Wilma use their glucometers and take care of themselves so that subsequent conversations with a caretaker towards the end of the week following their hospital visit can be positive. |
| Trigger | Fred's care takers want Fred to control his diabetes and talk to a care taker whenever he has questions to minimize his ER visits. Wilma's care takers want her to monitor her glucose levels more closely and talk to a care taker if she has any strange symptoms in order to reduce her chances of rehospitalization. |

| | |
|---|---|
| Steps of Basic Flow<br><br>(Include flow descriptions from multiple actor perspectives, if applicable) | **Current situation1, Trigger**<br><br>Fred has recently been laid off due to his job being sent overseas. The stress of his declining job situation and a related divorce caused him to develop Type II diabetes. As a result of the legal battle surrounding his divorce, he had to sell his home and move back in with his mother. He is uninsured and now drinks heavily. His mother lives off of a social security pension and is very concerned about her son. Every once and a while, Fred drinks too much and passes out with a high fever. His mother takes him to the emergency room where he is treated for hyperglycemia and released. The hospital Fred visits assigns a social worker to him and gives him a mobile phone and glucometer. Fred talks to his social worker on occasion but eventually loses the phone and doesn't use the glucometer.<br><br>**Wearable AHD Call, Trigger**<br><br>After a few months, the hospital system begins giving diabetics who frequent the ER with hyperglycemia a wireless amulet with a glucometer which can communicate with it. Fred receives one of these amulets on one of his emergency room visits with a glucometer and begins wearing it. He goes to a nearby McDonalds to talk with his social worker who can also see whether he has been monitoring his glucose levels and recharges the device once a week with the USB charger he has from his old mobile phone. Although he still drinks, he binges less because he doesn't want to explain why he didn't take a reading for the last two days. His mother still takes him to the emergency room on occasion, but when he arrives, his amulet contains a history of glucometer readings that enable ER staff to quickly determine his situation.<br><br>**Current situation2, Trigger**<br><br>Wilma has just been discharged from the hospital following a colonectomy. After a few days at home, she starts feeling nauseated and her stomach is slightly distended. She doesn't want to call the hospital to be put on hold while she waits to talk to someone she doesn't know about something which may not be a problem. A couple of days later she wakes up in the middle of the night vomiting and looks pregnant. Her husband rushes her to the emergency room. |

| | |
|---|---|
| | **Wearable AHD Call, Trigger**<br><br>Wilma has just been discharged from the hospital following a colonectomy. Upon leaving the hospital, she receives an AHD amulet which enables her to talk to her nurse through her home wireless network. Her husband connects the amulet to their existing access point by pushing a button(WPS PBC) on it and the WiFi access point at the same time. After a green LED lights up on the device, she pushes the talk button and a few seconds later she recognizes the voice of her hospital nurse. After a few days at home, she starts feeling nauseated and her stomach is slightly distended. She pushes the button and after a few minutes of conversation with the nurse her husband takes her back to the hospital where she is checked in and treated the same day. |
| **Failure Modes** | Because the hospital has not worked out an agreement with local businesses providing WiFi, Fred's amulet cant be preconfigured to work and local enterprise staff don't help him.<br><br>Wilma's husband doesn't know how to connect with WiFi they have at home because it was installed by a professional with their cable service. |
| **Diagram** | <insert diagram> |

## Marketing Feasibility Review: Pro10-17

| | |
|---|---|
| Reviewer | MWG |
| Date | July 07, 2010 |
| Market Need | ~~No significant market need from a Continua Mission and Vision perspective~~<br><br>X - May or may not be a clear market need from a Continua Mission and Vision perspective<br><br>~~Addresses significant market need from a Continua Mission and Vision Perspective~~<br><br>-Mission<br><br>Our mission is to establish an ecosystem of ***interoperable*** personal |
| | health systems that empower people and organizations to better manage their health and wellness<br><br>-Vision<br><br>We believe through the efforts of a collaborative industry organization, Continua can enable an ***interoperable*** personal health ecosystem where diverse products and services can combine into new solutions with significant health benefits for people worldwide. |
| Marketing Impact | X No marketing impact for Continua<br><br>~~Adds some marketing complexity for Continua (e.g. to 'plug and play' logo certification)~~<br><br>~~Significant marketing impact for Continua~~ |
| Additional Comments | VOIP for AHDs enhances Ecosystem for Continua |

## Technical Feasibility Review: Pro-10-17

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 27/06/2010 |
| Type of use case | ~~Address new end-user need~~<br>Consider new technology for existing use case<br>~~Consider new technology for sub-segment of existing use case~~ |
| Architectural Impact | No Architectural Impact<br>e.g. add new measurement device<br>~~Architectural Change/ Extension needed~~<br>~~e.g. introduce unforeseen interface or API~~ |
| Technology availability | Yes, technology to do this is abundantly available<br>~~Technology exist, but is not yet used in the market~~<br>~~No, this is currently not possible~~ |

| | |
|---|---|
| Standard availability | ~~No suitable SDO available~~<br>~~Suitable SDO available~~<br>~~Standard completed~~<br>Standard used in the market |
| Estimated development time | ~~Less than 1 year~~<br>Between 1 and 2 years<br>~~Longer than 2 years~~ |

| | |
|---|---|
| Steps needed for completion<br><br>• New technology?<br>• Standards development?<br>• New Continua interfaces?<br>• Modification to Continua interfaces?<br>• Other changes? | The use case describes the use of the WAN interface for vital signs upload as well as for VoIP communication. These functionalities are captured by the V1.5 WAN-IF related use case and the Telecare/PERS use case scheduled for V2.0, respectively.<br><br>GL completion may depend on extensions to the V1.5 WAN interface currently in progress to support voice/streaming, and alarm communication. A requirement added by this use case is a strict requirement on wearability (small form factor) of the AHD in combination with a requirement on energy consumption. At this point it is unclear whether these requirements are already covered or will be covered by the defined guidelines and selected standards according to the above mentioned WAN-IF related use cases for V1.5 and V2.0. A thorough gap analysis would be required to answer these questions.<br><br>Furthermore, the use case proposes WiFi as a possible solution for the physical interface of the AHD used to establish a WAN-IF connection. This is not consistent with the current guidelines approach for the WAN-IF, which is to describe everything on top of IP but to abstract away of the physical transport below the IP layer. The need for breaking this concept should be carefully analyzed and based on good reasoning.<br><br>Another requirement described by the use case is the easy connection setup with existing WiFi infrastructure (at home, at McDonalds), which essentially is a requirement for a retrofit scenario. The degree on how the interoperability experience can be shaped via the creation of guidelines is limited for a retrofit scenario. Again it should be noted that guidelines on the connection setup of a WiFi based WAN-IF connection are applying to the sub-IP layer, which is outside the scope of the current WAN-IF concept.<br><br>Also, the compliance to common Continua security requirements in retrofit scenarios could be difficult to achieve. |
| Additional Comments | |

## Test & Certification Feasibility Review: Pro10-17

| | |
|---|---|
| Reviewer | TCWG |
| Date | June 23rd, 2010 |
| Test Tool Architecture Impact | ~~Least – Existing Test Procedures in the Test Tool will need to be modified.~~<br>Moderate – New Test Procedures will need to be added to the Test Tool.<br>~~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.~~<br>~~Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise~~<br>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<br><br>(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.~~<br>~~Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.~~<br>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.~~<br>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.<br><br>~~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 | Based on the UC description, this appeared to be a request for adding VOIP to the WAN. Scores above reflect that understanding. |

## Regulatory Feasibility Review: Pro10-17

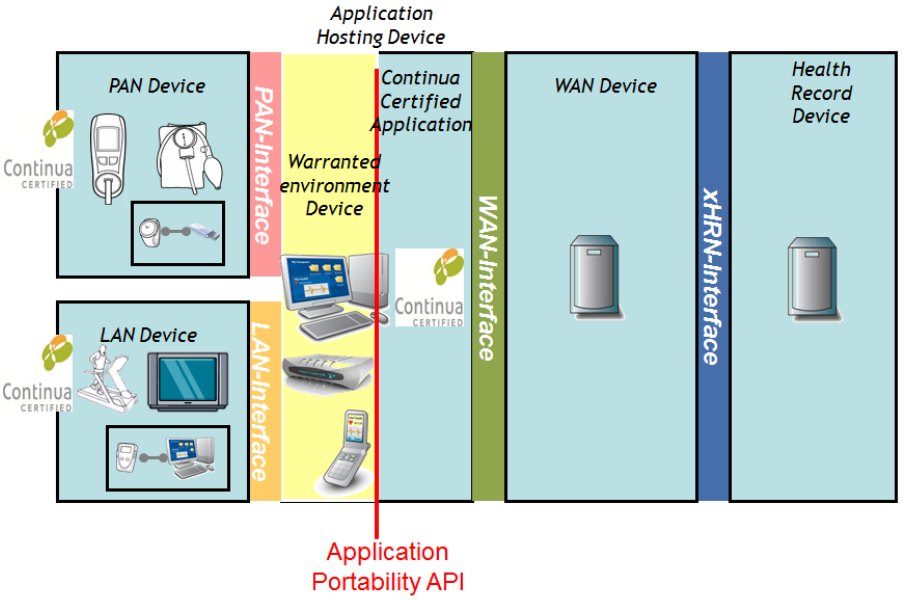
| | |
|---|---|
| Reviewer | RWG |
| Date | 30 Jul 2010 |
| Regulatory Impact Assessment | The device as described in the scenario will be regulated by FDA as a Class II device. Should the device interface with a Class III device (e.g. continuous glucose monitor), then the described device will also become Class III. |
| Additional Comments | |

# 2011 Use Cases

## Application Portability: Pro10-10 (revised and resubmitted)

| Use Case Title | UC 2010 Project Pro10-10 Application portability across mobile platforms |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently |
| Relation with implemented previous use case(s) | Adapts PAN and LAN interface<br>Aligns with PRO11-09 Mobile Web Health API. There is some commonality of requirements between the proposals Pro10-10 and Pro11-09. |
| Description | Current situation:<br>- Several mobile Operating Systems, with different HDP implementations<br>- Several mobile hardware manufacturers, using these multiple OS implementations<br>- Several walled garden ecosystems, like market places governed by handset manufacturers, telecommunications operators, etc.<br><br>The Continua Health Alliance certification process is focused on certifying the complete stack:<br>- hardware<br>- transport layer<br>- communication and data manager<br>- end user application<br><br>Based on market expectations, where the move is towards 'write once, run anywhere', developers would like to create end user health and wellness applications, that could run on any mobile device without modification, and those applications would be capable of exploiting the benefits of hardware interoperability enabled by Continua PAN and WAN interfaces. However, at present, if the same application is moved from one hardware platform or OS to another additional coding is required. The additional coding is needed to interface with the specific platform or OS used in the new platform and this increases costs, complexity and can be a major barrier to widespread pervasiveness of Applications<br>This use case seeks to define an application portability interface (API) that enables a Continua certified application to run on several platforms or OS's with minimal additional cost.<br>There is demand from the developers to have a standard that avoids the need to re-certify for each hardware and OS platform. The aspiration is for a fully converged world. An acceptable interim state is to define the application API such that any instantiation of the Continua device stack is consistent across different underlying transports.<br>The existing mobile applications market is growing fast with an estimated 5000+ health related apps alone available today. It is also attracting many developers and software vendors in the new fields of mobile applications. Business models for mobile |

| | |
|---|---|
| | applications in the health and wellness market will benefit from a Continua certification process that supports certification of software for mobile devices independent of hardware and OS platform.<br>Technically, it is possible to develop an API to manage the IEEE data format according to Continua guidelines. Developers could then use this to build applications. However, while it is technically feasible to be Continua compliant the current situation means that it can be a costly and difficult process to manage: developers need to certify their software on each individual target hardware / OS platform and on each separate transport layer it would use. That is a huge market barrier which limits growth because of the additional effort for software developers.<br>This requirement is not bounded by current medical device regulations. It is accepted that FDA/EU MDD requirements may not at present support this sort of capability, but such restrictions would not apply in fitness and wellness applications. |
| Scope | Continua certification of an AHD framework layer which sits over the development framework that the end user applications are built on<br>In this situation, developers could build applications using Continua defined warranted environments that support certified development frameworks, so their applications would be also "Continua compliant" applications. |
| Actors | - Developers would have a Continua defined warranted environment that offers the components for building applications for Health and Wellness.<br>- The behavior of the warranted environment components may be defined by an API that is compliant with Continua guidelines, on how it manages IEEE data format.<br>- The API defines how the application takes IEEE data from the manager within the device (whatever device is used), how it manages errors and exceptions (connectivity problems for example) and how it manages data security.<br>- The warranted environment is hardware and OS independent. The development framework is defined by its relationship with the API, not the technology underneath, so it is up to developers to implement it on the technology they would prefer. Each implementation could be certified, in terms of API compliance. |
| Minimal Guarantees | A phased introduction of application portability<br>Phase 1: Definition of Continua application portability interface for specific operating systems. Certification by Continua of applications to use this interface. The combination of a Continua certified application and a device certified to meet warranted environment criteria would establish a fully compliant Continua AHD supporting the PAN or LAN interface capability.<br>Where a cell phone was used as the AHD, the phone itself would be certified by an external industry body and would not require specific Continua certification or be required to carry the Continua logo.<br>The choice of operating systems to be supported should be aligned to the selection of candidates for MCESL. It is proposed that the priorities for this are defined in the requirements phase.<br>Phase 2: Definition of a common application portability interface that can be used across multiple operating systems. |
| Success Guarantees | In this situation, developers could build applications using Continua defined warranted environments to achieve a complete interface capability, so their applications would be also "Continua compliant" applications.<br>The intention is for application portability. The device must be able to operate autonomously (without web connectivity). The point here is that to enable an API there must be some standard expectations of the interface with the AHD device to enable control of the PAN interface communications. |

| | |
|---|---|
| | As results of this use case, Continua would provide (the definition of) a warranted environment comprising:<br>- An API that defines how Continua compliant applications shall connect to the mobile platforms.<br>- a development framework that implements the API<br>- A testing tool to certify that the development framework is Continua compliant.<br>- a testing tool, to certify that applications are compliant to the API<br>- An open reference implementation of a mobile application using this API. |
| Trigger | End user loads a Continua certified application onto their own device |
| Failure Modes | |
| Diagram (optional) |  |

7.

## Technical Feasibility Review: Pro 10-10

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | August 3 2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☒ No suitable SDO available<br>☐ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☐ Between 1 and 2 years<br>☒ Longer than 2 years |

| | |
|---|---|
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | The following steps need to be completed in the technical phase:<br>- Specify the "warranted AHD environment" and select which platforms to focus on initially (Android, iOS, Symbian, BlackBerry, Windows Phone, …)<br>- Determine which features of the underlying transports (PAN/LAN/TAN) need to be supported by the API (e.g. device discovery, network setup/pairing, IEEE 11073-20601 methods)<br>- Determine if a local health data cache is required in the AHD environment (will the API directly talk to the sensors or talk to a local health data cache)<br>- Define the API functions/requirements<br>- Select the appropriate standards body to standardize this API<br>Develop the certification process for how to test and certify applications that make use of the API and how to certify the warranted AHD environment (could be done by outside parties) |
| Additional Comments | **Overall assessment criteria: Difficult** – Any of the following apply:<br>- Standard availability: "No suitable SDO available", or<br>- Technology availability: "Technology exist, but is not yet used in the market"<br>- Technology availability: "No, this is currently not possible"<br>- Estimated time to development "Longer than 2 years" |

## Test & Certification Feasibility Review: Pro10-10

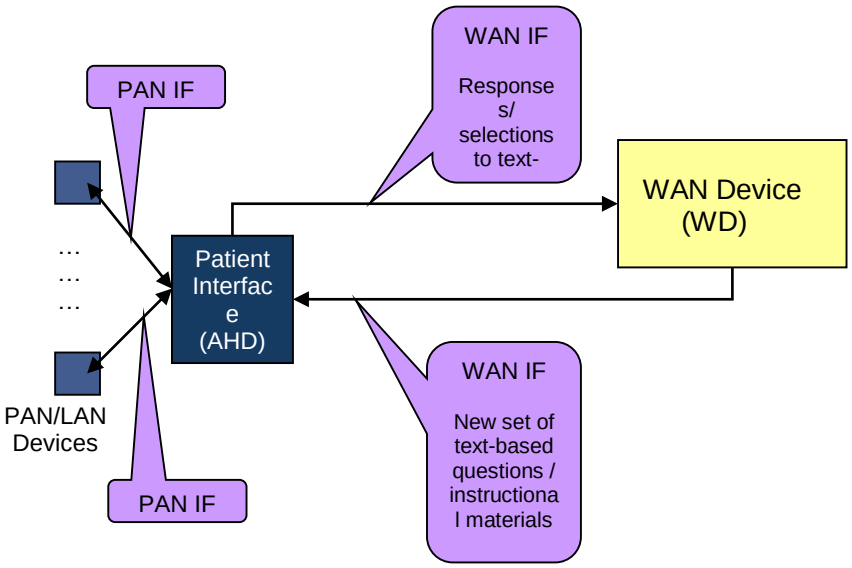
| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☐ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☒ Large – Use case covers a new area, and a new Test 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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<br>(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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☒ 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.<br>☐ 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.<br>☒ 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 | **Editorial Comment: The use case document has been revised after this assessment was completed.**<br>Raul (AT4 Wireless) on CESL - A reference framework for a mobile phone platform must be developed. The effort and complexity will depend on the selected mobile platform and number of platforms selected (Android, iPhone, MeeGo, etc). This estimation is for one platform, for instance, Android.<br>Raul on Test Tool - Currently, Continua Certification Program is focus on interfaces. This UC request to focus on API verification, this will cause a change in testing approach and a completely new test tool needs to be developed for this UC. It seems that WC3 is producing some testing tools that may be used in certification program; this might reduce the Test Tool development efforts.<br>Besides, a specific certification program must be put in place for this UC because it is focus in API certification (software and platform) instead of current certification program that is focus in Interfaces certification. The approach needs to be discussed deeply in TCWG and MWG in order to have a clear idea about the testing scope and the logo usage in this kind of software and mobile platform.<br>Brian (LNI) - It's not clear to me what is meant by 'API'. Some more concrete examples would help illustrate what is trying to be conveyed here.<br>Michael (TOM) - This is really more of a Continua Reference System which differs slightly as we'd really be certifying the design based on a specific application of an AHD. As long as all other AHDs were equal (implemented the design) they could be certified by Continua as end product AHDs without further certification testing (see new Type O program where the listing cost has been cut significantly for relabeled devices). Suggest that this could be a CESL Project or would the TF prefer a separate project?<br><br>Note that the Test Tool can/will utilize CESL for testing end devices, if necessary.<br>**Overall assessment criteria: Difficult** – Two or more "Large" items. |

# Text Based Questionnaires: Pro11-01

| Use Case Title | Pro11-01 Transmitting text-based questions and related answer responses/selections, or text-based instructional material, in a tele-monitoring system via WAN-IF |
|---|---|
| Theme(s) | ☐ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | New use case |
| Description | The current Continua WAN standard is incomplete and will be the subject of attention over the next year. The current WAN standard focuses solely on security/authentication and protocols for transmission by the AHD of vital sign readings from PAN and LAN devices to the WAN Device (WD). Key missing protocol are: 1) the transmission to the AHD of text questions to be asked to the patient, possibly with options for the answers, or instructional text to be presented to the patient, 2) transmission to the WD of the actual text questions asked to the patient and the related answer responses/selections provided by the patient. |
| Scope | Permit the easy integration of different 3rd party Application Hosting Devices (AHD) into any WAN Device (WD) platform with support of text-based questionnaires. |
| Assumptions | The AHD is the initiator and the WD is the responder (Push to WD). AHD initiates connection to the WD either due to some patient action (for example, clicking a button on the AHD), or by some pre-programmed auto connection (time based or some other alarm).<br>Due to the following issues, it is not recommended for the WD to initiate connection to the AHD:<br>1. Security – AHD can easily "block" all inbound packets, thereby making the system more secure.<br>2. AHD with POTS modem – In order to support AHD's with POTS modem, it is not possible for WD to initiate connection to the AHD.<br>However, technically the WD could initiate connection to the AHD and this could be implemented as an option if the above issues are not a concern.<br>In addition to the Chronic Disease Management and Aging Independently, this use case could also apply to Health and Fitness especially due to its capability to handle educational material. |
| Actors | **Patient** – operating the AHD and peripherals, answering the text-based questions by selecting the appropriate responses, reviewing text-based instructional materials.<br>**Clinician** – tele-monitoring the patient, selecting the set of text-based questions and text-based instructional material to have sent to the patient, reviewing the responses/selections to understand if a clinical visit is required.<br>**AHD** – collecting the text-based questions and text-based instructional material from the WD, presenting the questions and instructional material to the patient, and delivering the answers to previously responded questions to the WD.<br>**WD** – providing the text-based questions and text-based instructional material to the AHD, and storing the patient's responses/selections to any previously answered |

| | |
|---|---|
| | questions. |
| Minimal Guarantees | If the use case fails for any reason, the AHD shall be unable to deliver to the patient text-based questionnaires and text-based instructional material to the patient, or provide answers to text-based questions to the WD. As a result, delivery of care will be limited to vital sign gathering only. Efficient and effective care via the tele-monitoring system will not be possible, since 1) subjective symptoms can't be accessed, 2) providing therapy changes, care hints or text based directions for the patients won't be feasible, 3) providing text-based educational material for the patient won't be possible.<br>The minimal guarantee operationally, is that the AHD must persist any previously provided text-based questionnaires and instructional materials, as well as any responses/selections to these questionnaires, until such time as the AHD successfully connects to the WD. The AHD is assumed to re-attempt connection to the WD at some pre-defined interval or at the request of the patient. |
| Success Guarantees | **Patient** – receives care appropriate text-based questionnaires and instructional material that augments the patient's experience with the tele-monitoring system. This helps increase compliance and empowers the patient, which in turn improves outcomes and quality of life.<br>**Clinician** – receives responses to care appropriate, subjective, text-based questionnaires thereby improving the clinician's understanding of the patient's health condition. Knows that the patient is receiving care appropriate instruction. This helps the clinician better select the course of care for the patient, and increases clinician confidence in the tele-monitoring system achieving the desired outcome.<br>**AHD** – allows the AHD to more easily interface to arbitrary WD systems, receive text-based questions and instructional material and deliver selected responses, and presents the questions and instructional material to the patient.<br>**WD** – allows easier support of 3rd party AHD for text-based questionnaires and instructional materials.<br>The operational success guarantee is that the AHD, upon successfully connecting to the WD and receiving a new set of text based questionnaires and instructional material, must deliver that text-based material to the Patient via its user interface. It must also deliver any answer responses/selections that result to the WD. |
| Trigger | The possible triggers are 1) the Patient starts the tele-monitoring session by themselves, or 2) a reminder indicator of some sort triggers the Patient to start the session. |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | Pre-conditions:<br>1) The AHD and related PAN and LAN devices for tele-monitoring, are delivered to the patient's home, setup, physically connected and configured to connect to the WD.<br>2) The AHD must be able to interpret the text-based questionnaires, including the choices for possible answers, and text-based instructional materials, embedded in the payload transmitted by the WD and present such to the Patient on the AHD user interface.<br>3) The AHD must be able to collect the answer responses/selections to the text-based questionnaires, and format these into a payload for delivery to the WD.<br>4) The WD must be able to format text-based questionnaires and instructional material payloads for delivery to the AHD and receive answer payloads from the AHD and process.<br>Basic flow:<br>1) The AHD connects to the WD and requests if there are any available text-based |

| | |
|---|---|
| | questionnaires or instructional materials.<br>2) The WD identifies the AHD and sends any new text-based questionnaire and/or text-based instructional material to the AHD for use with the Patient, or an empty response.<br>3) The AHD acknowledges receipt of the download to the WD and WD notes the success.<br>4) The AHD connects to the WD and uploads any available answer responses/selections made by the patient to the text-based questionnaires.<br>5) The WD identifies the AHD and processes the uploaded answer selections. The WD then acknowledges receipt of the upload to the AHD and AHD notes the success.<br>Post conditions:<br>1) The AHD at the patient's home is provided with a new text-based questionnaire and/or instructional materials.<br>2) The WD receives and processes the responses/selections of the latest text-based questionnaire answered by the patient. |
| Failure Modes | 1) Interruption of communication. Not an issue as re-try will happen again later and all information is persisted. |
| Diagram (optional) |  |

**Key Requirements – Chart listed below**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 1 | AHD Request Questionnaire | The AHD must query/request if there is a new text-based questionnaire or instructional material for the patient using the service provided by the WD. The AHD must use the QBP-Q11 message of the HL7 2.x standard (query by parameter) to request the survey for the patient identified in the QBP message. | None. | The interrogative model of the HL7 2.x standard is used where the AHD (Client) initiates a query (Request for Questionnaire) to the WD (server) which is the owner of the data. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **2** | WD Send Questionnaire | The WD must create an XML assembly (payload) using some standard schema (XSD) for the new text-based questionnaire or instructional materials to be sent to the AHD. This XML assembly must be embedded in the OBX segment (OBX.5) of an RSP-K11 message from the HL7 2.x standard.<br><br>See provided example in the Attachments section below. | Proper identification and authentication of the AHD is required. | The WD responds to the query by returning the questionnaire.<br>Text based questions are often presented to patients as part of an AHD daily interaction. These questions may be presented in various manners and at various times to gather feedback from the patient.<br>In order to gather the best possible responses and provide the patient feedback, it is our experience that such questions generally take the form of a decision graph. Depending on the answer selected or input by the patient, it is generally required to have a follow-on question, or series of questions for any given question.<br>In this manner, text based questions result in a nested series of questions and answers much like if-then-else software constructs, and these can be succinctly expressed using an XML hierarchy. Note that it is not desirable to standardize the fields in the XML payload as it allows vendors a wider degree of freedom in the design/type of questionnaires or instructions. |
| **3** | AHD Acknowledge | The AHD must send an acknowledgment using the ACK message from the HL7 2.x standard in response to the RSP-K11 after having successfully received and persisted the new text-based questionnaire or instructional materials. | None. | The AHD ACKs the receipt. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **4** | AHD presents to patient | The AHD parses the XML containing the questions (bases on standard schema) and presents the questions and educational material to the patient and collect responses from the patient | Questionnaire available to the AHD | |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **5** | AHD Send Answers | The AHD must map the actual questions answers and related responses/selections into an XML assembly (payload) using some standard schema (XSD).<br>This XML assembly must be embedded in the OBX segment (OBX.5) of an ORU-[R01/R30] message from the HL7 2.x standard.<br>See provided example in the Attachments section below.<br>The AHD must consume the service provided by the WD to upload the ORU-[R01/R30] message containing the assembly with actual questions answered and the responses/selections provided by the patient. | Answers available. | The observation model of the HL7 2.x standard is used where the AHD (Client) sends a dataset (Answers to Questionnaire) to the WD (server) which is the owner of the data.<br>The responses may take the form of the actual question or simply the question identifier along with manually entered numeric values, selection of an answer from a range of choices, or simply a binary yes or no. In some cases the questions have no responses and are just information or instruction to the patient with the only choice being readiness to continue. These answer responses/selections can be succinctly expressed using an XML hierarchy.<br>Note that it is not desirable to standardize the fields in the XML payload as it allows vendors a wider degree of freedom in the design/type of questionnaires or instructions. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **6** | WD Acknowledge | The WD must send an acknowledgment using the ACK message from the HL7 2.x standard in response to the ORU-[R01/R30] message received from the AHD.<br><br>The acknowledgment must indicate whether the message was successfully processed or there was an error during processing of the message.<br><br>The AHD must re-transmit the message unless it has received an ACK from the WD. | Proper identification and authentication of the AHD is required. | The WD ACKs the receipt. |
| **7** | **Communication Protocol** | The AHD and the WD will communicate using SOAP based Web Services similar to what is outlined in Continua 2010 guidelines for the vitals transmission from AHD to WD. | | |
| **8** | Security | WS-I BSP1.1 (an extension of WS-I 1.0) Web Service security standard will be used, as recommended by the Continua 2010 guidelines. This standard uses WSS4J for implementing Username/Password token authentication with password digest (Apache WSS4J provides a java implementation of WS-I BSP 1.1 standard) | | |

## Technical Feasibility Review: Pro 11-01

| | |
|---|---|
| Reviewer ( 2 reviewers) | Martin Rosner, Chis Johnson |
| Date | 17 June 2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | - Assess which SDO is most suitable and define the standard in that SDO<br>- New Continua IF for bi-directional use of the WAN-IF<br>- Modification/addition to current WAN-IF<br>Security considerations / threat analysis |
| Additional Comments | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>- Very well written UC<br>- Consider combining efforts with 2010 PROMs UC<br>- Why not also address the health and fitness domain?<br>- AHD presenting the material to Patient is missing from Actors, Success Guarantees, and Key Requirements sections<br>- Consider Push model as well (not only Pull from AHD); what triggers the AHD to Pull?<br>- Decision graph is but only one criteria for the data model; consider other criteria as well<br>- Why XML? Are there any other (higher level) standards?<br>- Threat assessment and safeguards for DoS attacks should be considered.<br>- Should build on 11073-10472<br><br>**Overall assessment criteria: Medium** – Consider new technology for existing use case or all items not red or green |

## Test & Certification Feasibility Review: Pro 11-01

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☒ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - There are open source tools like APACHE that can be used to implement the transport connection for this UC. The degree of complexity for this implementation may depend on the flexibility to create the XML files including the questionnaire. This is a rough estimation.<br>This Test Case will request to include in Test Tool verification for new kind of transaction in WAN Interface (transport and message syntax/semantic verification). Besides, it should be necessary to verify the protocol state machine (Questionnaire request, Questionnaire send, Questionnaire ACK, Answers send, etc).<br>Brian (LNI) - This item appears to be adding more types of messaging to the WAN. It is difficult to judge the complexity these additions will introduce since we are not really clear with the current WAN.<br>Michael (TOM) - The same test tool could be used, but with enhancement but the level of effort could be Large if requirements scope spreads into PAN (i.e., such as the Manager controlling the Agent).<br>**Overall assessment criteria: Medium** – All items not Red or Green |

# Sleep Monitor Device: Pro 11-02

| Use Case Title | Pro11-02 Sleep Monitor Device |
|---|---|
| Theme(s) | ☒ Disease management<br>☒ Health & Fitness<br>☒ Aging Independently |
| Relation with implemented V1 use case(s) | No. |
| Description | A sleep measuring device is a device with measures the sleep wake of a patient. The output measurement is a hypnogram is showing the different stages of sleep and awake.<br>A new device specialization similar to the Cardiovascular Fitness and Activity Monitor is required. The requirement is to deliver this sleep data measurement to health repositories using the xHR, PAN, LAN and WAN interfaces. These repositories use Health Level Seven (HL7) version 3 Clinical Document Architecture (CDA) in accordance with the Personal Health Monitoring Report (PHMR) specification. |
| Connectivity | ☒ Wired<br>☒ Wireless |
| Device Type | ☐ Actuator Device<br>☒ Measurement Device<br>☒ Display Device<br>☐ Other Device |
| Additional Remarks | Additional information:<br>http://members.continuaalliance.org/apps/org/workgroup/ucwg/download.php/7855/Pro11%2002%20S0273_SleepMinder.csv |

**Exchanged Data Data Clusters document**

| Data Type | Format | Unit | Comment | Priority | Direction | Transmission |
|---|---|---|---|---|---|---|
| Sleep/Wake | Binary per 30 second epoch | na | | M | O | E |
| Sleep Stage | Int{1,2,3,4) | na | | M | O | E |
| Sleep Efficiency | 1-100% | na | | O | O | E |
| Sleep Duration | hh:mm | s | | O | O | E |
| Sleep Onset | hh:mm | | | | | |
| Sleep Latency (time to sleep) | hh:mm | s | | O | O | E |
| Final Awaking | hh:mm | s | | O | O | E |
| Breathing Rate | Float (2.1) | breaths per minutes | | O | O | C |

## Technical Feasibility Review: Pro 11-02

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 07/08/11 |
| Type of use case | ☐ Address new end-user need<br>☐ Consider new technology for existing use case<br>☒ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☒ No Architectural Impact<br>e.g. add new measurement device<br>☐ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | This use case appears to request a new IEEE 11073 Device Specialization. This reviewer was not able to find any existing or in-process device specializations on the IEEE web site that matched the described behavior of the use case.<br>The underlying sensor technology that takes the physiological measurements is not described in this use case, but only the data transport mechanisms are relevant for Continua certification.<br>Given that this use case fits into the existing Continua architecture, contingent upon the 11073 device specialization specification and the Rosetta Translation / Containment rules for rendering in PCD-01, this use case does not require any new or (substantially) modified interfaces. |
| Additional Comments | As to "Technology Availability," this reviewer is not aware of the stage of development of the underlying sensor hardware, and it appears that no 11073 device specialization wok has commenced.<br>**Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

## Test & Certification Feasibility Review: Pro 11-02

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☒ 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.<br>☐ 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 | Raul (AT4 Wireless) - This UC should require to modify the CESL manager to support a new device specialization and create a reference agent<br>This is a ballpark estimation because the UC description does not provide enough information about how is going to be implemented the UC. I understand that the UC covers the PAN/LAN interface, WAN Interface and HRN interface and it will follow a similar data capture approach than current existing device specializations (i.e. the data will be transfer through PAN/LAN interface following an IEEE 11073 protocol, through WAN Interface using a PCD-01 message and through HRN Interface using a PHMR document).<br>Brian (LNI) - Here is my general comment regarding most of the specializations. The forgotten aspect is the development of the standard itself (in my opinion it is the weak link). This work is done 100% by volunteers 90% of whom still have 100% day-job responsibilities in addition to their volunteer work. That means progress is slow and inconsistent and the development always has to take a back seat to the day-job responsibilities. Specializations are often finalized with much less review and scrutiny then the developing committees would like. On the other hand, once the new standard is developed, most of the tools are in place to create the |

| | |
|---|---|
| | actual implementations and tests. So in theory, it seems these should sit on the low category of the three levels provided. The long term costs will be the weaknesses of the standards for interoperability and use case failures that are not discovered until devices are in the market.<br>Michael (TOM) - Seems straight-forward as a new device specialization (but new test procedures will be needed although quite similar to existing for a device specialization).<br>**Overall assessment criteria: Medium** – All items not Red or Green |

# Sleep Apnea Monitor: Pro 11-03

| Use Case Title | Pro11-03 Sleep Apnea Monitor |
|---|---|
| Theme(s) | ☒ Disease management<br>☒ Health & Fitness<br>☒ Aging Independently |
| Relation with implemented V1 use case(s) | No.<br>Might be used in conjunction with a CPAP machine. |
| Description | A sleep apnea measuring device is a device with measures the AHI (and other indices) of a patient. The Apnea-Hypopnea Index (AHI) is expressed as the number of apneas and hypopneas per hour of sleep.<br>A new device specialization similar to the Cardiovascular Fitness and Activity Monitor is required. The requirement is to deliver AHI measurements to health repositories using the xHR, PAN, LAN and WAN interfaces. These repositories use Health Level Seven (HL7) version 3 Clinical Document Architecture (CDA) in accordance with the Personal Health Monitoring Report (PHMR) specification. |
| Connectivity | ☒ Wired<br>☒ Wireless |
| Device Type | ☐ Actuator Device<br>☒ Measurement Device<br>☒ Display Device<br>☐ Other Device |
| Additional Remarks | |

**Exchanged Data Data Clusters document**

| Data Type | Format | Unit | Comment | Priority | Direction | Transmission |
|---|---|---|---|---|---|---|
| AHI Index | Integer range | Na | Events/hours | M | O | C |
| RDI Index | Integer range | Na | Events/hours | M | O | C |
| Apnea Index | Integer range | Na | Events/hours | M | O | C |
| Hypnoa Index | Integer range | Na | Events/hours | M | O | C |
| Configuration of device | | | | M | I | E |

## Technical Feasibility Review: Pro11-03

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 7/5/2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☒ No Architectural Impact<br>e.g. add new measurement device<br>☐ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | There will have to be another device specialization done for 11073/20601. This could take up to a year or more to implement. There is no need for a new continua interface, as this device should would similar to the rest of the device specializations and does not require any special control functions. |
| Additional Comments | This would appear to be ***easy***, except for the fact that the device specialization is not yet done. The time to implement the ability the Apnea monitor will depend on the approach of the IEEE PHD group in pursuing the Apnea monitor specialization, and the ability to obtain an author to implement the specialization.<br>**Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

## Test & Certification Feasibility Review: Pro11-03

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☒ 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.<br>☐ 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 | Raul (AT4 Wireless) - This UC should require to modify the CESL manager to support a new device specialization and create a reference agent.<br>Same comment as UC Pro 11-02. If both UC are going to be implemented, the test tool cost can be reduced because it is expected that both use case share similar verification content.<br>Brian (LNI) – Need CESL to support new device specialization. Same comment as for Pro11-02.<br>Michael (TOM) - Seems straight-forward as a new device specialization (but new test procedures will be needed although quite similar to existing device specialization).<br><br>**Overall assessment criteria: Medium** – All items not Red or Green |

# Body Composition Analyzer: Pro11-04

| Use Case Title | Pro11-04 Body composition analyzer |
|---|---|
| Theme(s) | ☒ Disease management<br>☒ Health & Fitness<br>☐ Aging Independently |
| Relation with implemented V1 use case(s) | Body composition analyzer is a new device specialization for the PAN interface |
| Description | A body composition analyzer (BCA) is a device that analyzes the constituents of the human body. BCA devices may use a variety of techniques for measuring body composition. One typical method is body impedance analysis that measures the impedance with pairs of probes applied at the feet and/or hands and calculates the body composition from these impedances. (IEEE 11073-10420 is not only for BCA devices using body impedance analysis. BCA devices which use other methods could be also supported by IEEE 11073-10420 standard.)<br>The measurement data set transmitted by a body composition analyzer contains:<br>body fat,<br>body height,<br>body weight,<br>The measurement data set may be expanded and contain:<br>body mass index(BMI),<br>fat free mass(FFM),<br>soft lean mass(SLM), and<br>body water.<br>The timestamp of the measurement data and the personal information of user are also transmitted with the measurement data set.<br>The BCA device can measure body composition of the user in stand-alone mode without any manager device associated. |
| Connectivity | ☒ Wired<br>☒ Wireless |
| Device Type | ☐ Actuator Device<br>☒ Measurement Device<br>☐ Display Device<br>☐ Other Device |
| Minimal Guarantees | If this use case is not in place, a clinician will be unable to determine which device provided the data they are using unless that data came from a Continua Certified device. We believe this may actually undermine the adoption of HRN because it will only be useful to a small set of devices initially. We would rather allow legacy device information to be associated with its data now to grow the market for Continua HRN Senders as the market for Continua Certified PAN devices grows. |
| Additional remarks | The communication protocol between a BCA device and a manager device has been set out in the IEEE 11073-10420 device |

| | |
|---|---|
| | specialization standard.<br>(Current status of 11073-10420 : IEEE publishing completed) |

**Exchanged Data: Data Clusters document**

| Data Type | Format | Unit | Comment | Priority | Direction | Transmission |
|---|---|---|---|---|---|---|
| Body fat | xxx.xx | percent (or kilogram, or pound) | | M | O | E |
| Body height | xxx.xx | centimeter or inches | | M | O | E |
| Body weight | xxx.xx | kilogram (or pound) | | M | O | E |
| Body mass index | xxx.xx | kg/m^2 | | O | O | E |
| Fat free mass | xxx.xx | kilogram or pound | | O | O | E |
| Soft lean mass | xxx.xx | kilogram or pound | | O | O | E |
| Body water | xxx.xx | kilogram or pound or percent | | O | O | E |

## Technical Feasibility Review: Pro11-04

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 7/5/2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☒ No Architectural Impact<br>e.g. add new measurement device<br>☐ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available***<br>☐ Suitable SDO available<br>☒ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **The current IEEE implementation of the BCA (11073-10420) does not support setting the height from the manager, only the front panel of the device. This will need to be adjusted either in 20601 (to allow the setting of these parameters), or in 10420 (resubmission) to allow for setting the height.<br>Please clarify if it is acceptable to split this use case in 2 work items<br>1. BCA as defined in 11073-10420<br>2. Extended BCA with setting the height from the manager<br><br>The use case currently only provides for the height metric to be in CM. The 11073-10420 does provide for height in inches when one uses the extended configuration of the weight scale. |
| Additional Comments | **Editorial Comment: The use case document has been revised since the text in this assessment was written. In April 2011The Board of Directors approved the start of work within TWG to progress this use case at risk. Inclusion in Continua's Interoperability Guidelines is still subject to success in this Promoter member ballot.**<br>This would appear to be ***easy***, except for the fact that the device specialization is not yet done. The time to implement the ability to be able to set the height and weight from the manager side- will depend on the approach and in obtaining an author to the modification to 10420 within the IEEE.<br>**Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

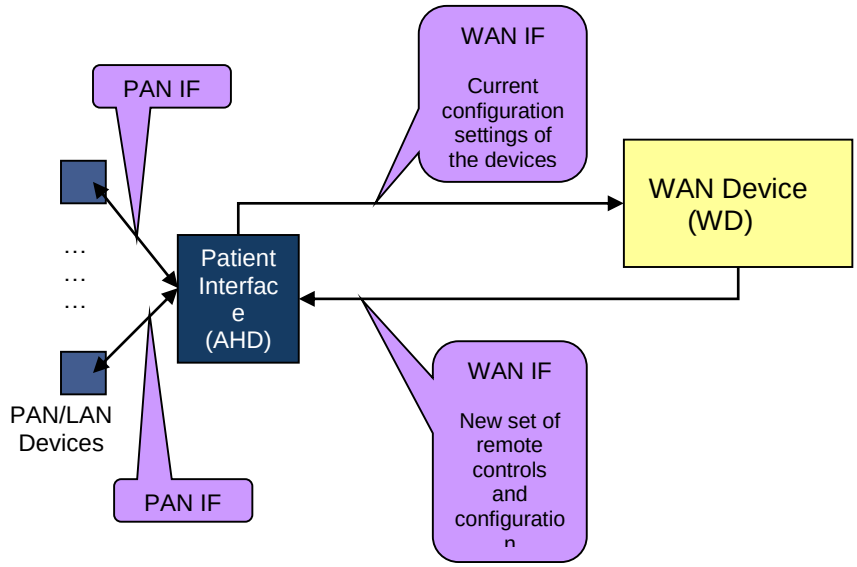
## Test & Certification Feasibility Review: Pro11-04

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☒ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☐ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☐ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - This UC should require to modify the CESL manager to support a new device specialization and create a reference agent, however, this UC is pretty similar to current Weighing Scale Device specialization so the effort should be smaller than the Sleep UC<br>The UC description is focused in PAN/LAN interface only, I suppose that it will request to upload the Body Composition Analyzer through WAN and HRN interfaces. The test tool cost estimation is provided assuming that it will request to test PAN/LAN, WAN and HRN interfaces. If finally, the UC covers PAN/LAN interface the estimation cost should be lower.<br>Brian (LNI) - Need CESL to support new device specialization. Same comment as for Pro11-02.<br>Michael (TOM) - Seems straight-forward as a new device specialization (but new test procedures will be needed although quite similar to existing for a device specialization). Not sure why only shown for Wireless (shouldn't it include USB as well)? Note that TWG has identified Height as possibly needed which would require a modification to the device spec.<br>**Overall assessment criteria: Easy** – Two or more “Least” items *and* no “Large” items. |

# Remote Device Control: Pro11-05

| | |
|---|---|
| Use Case Title | Pro 11-05 Configuration of patient device in a tele monitoring system via WAN-IF |
| Theme(s) | ☐ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use cases | New use case |
| Description | The current Continua WAN standard is incomplete and will be the subject of attention over the next year. The current WAN standard focuses solely on security/authentication and protocols for transmission by the AHD of vital sign readings from PAN and LAN devices to the WAN Device (WD). Key missing protocol is the transmission of AHD and medical device peripheral settings to the AHD, for remote control or configuration of the devices. |
| Scope | Permit the easy integration of different 3rd party Application Hosting Devices (AHD) into any WAN Device (WD) platform with support for control or configuration of devices. |
| Assumptions | The AHD is the initiator and the WD is the responder. |
| Actors | **Logistics** – deliver an appropriate AHD device and related medical device peripherals as ordered by the Clinician. Receive and refurbish devices being returned by the Patient.<br>**Service Technician** – Manages the AHD and medical device peripherals remotely by sending remote controls or changing configuration for one or more AHDs in the tele-medical system. Optionally provides service for unpacking and setting up the AHD and medical device peripherals in the Patient's home.<br>**Patient** – unpacking and setting up the AHD and medical device peripherals (unless performed by a Service Technician), then operating the AHD and peripherals, controlling user settings such as language options, volume and display brightness.<br>**Clinician** – tele-monitoring the patient, selecting the assigned medical device peripherals, and the set of text-based questions and text-based instructional material to have sent to the patient, reviewing the responses/selections to understand if a clinical visit is required.<br>**AHD** – sending the current device configuration (which includes standard configuration such as connection parameters, time zone etc. and optionally custom configuration) information to the WD, and collecting device control and configuration information from the WD, and using it to adjust the operational characteristics of the AHD or medical peripherals.<br>**WD** – receiving configuration information from the AHD and storing it in the system, then providing the device control and configuration information to the AHD. |
| Minimal Guarantees | If the use case fails for any reason, all changes to default settings for the AHD and peripherals must be done by the patient themselves or logistics and / or service technicians prior to delivery at the patient's home, or after setup. The delivery process is more complex and carries the additional risks of mixing up patient specific pre-configured devices. Worst case patient may be confronted with complex configuration issues or with wrongly configured devices. Globally operating service providers / manufacturers may in the worst case need to handle country specific variants of the same devices, and effective |

| | |
|---|---|
| | inventory management cross borders would be more difficult.<br>The minimal guarantee operationally, is that the AHD must persist and utilize any previously provided or default control or configuration settings, until such time as the AHD successfully connects to the WD. The AHD is assumed to re-attempt connection to the WD at some pre-defined interval or at the request of the patient. |
| Success Guarantees | **Logistics** – is assured that device control and configuration can be performed remotely whenever necessary and that only the type of devices delivered needs to be controlled.<br>**Service Technician** – is assured that the regardless of the devices being setup and operated, the control and configuration of the devices is greatly simplified due to remote control and configuration from the tele-medical system.<br>**Patient** – receives a simpler and more reliable setup and configuration of their devices that augments the patient's experience with the tele-monitoring system. This helps increase overall satisfaction the tele-monitoring system provider.<br>**Clinician** – is assured that the patient setup is correct and can be adjusted if required which increases clinician confidence in the tele-monitoring system.<br>**AHD** – allows the AHD to more easily interface to arbitrary WD systems and receive remote control and configuration information.<br>**WD** – allows easier support of 3rd party AHD for remote control and configuration.<br>The operational success guarantee is that the AHD, upon successfully connecting to the WD, delivers the current AHD configuration information to the WD, and receiving a new set of remote control and configuration information from the WD, must execute these controls as well as persist and utilize these new configuration settings. |
| Trigger | The possible triggers are 1) the Service Technician or Patient initiates the download of remote control and configuration upon initial setup, or whenever desired, via the user interface on the AHD or 2) the AHD connects to the WD automatically upon initial setup, and then afterwards on some pre-defined interval, exchanging remote control and configuration information routinely, and propagating any changes desired by the Service Technician or tele-medical system provider. |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | *Pre-conditions*:<br>1) The AHD and related PAN and LAN devices for tele-monitoring, are delivered to the patient's home, setup, physically connected and configured by default to connect to the WD.<br>2) The AHD must be able to interpret the remote control and configuration information, embedded in the payload transmitted by the WD, and execute the desired commands and persist and utilize the desired configurations.<br>3) The AHD must be able to format its current configuration information into a payload for delivery to the WD.<br>4) The WD must be able to format remote control and configuration payloads for delivery to the AHD and receive current configuration payloads from the AHD and process.<br>*Basic flow*:<br>1) The AHD connects to the WD and uploads the current configuration information, which includes standard configuration such as connection parameters, time zone etc. and optionally custom configuration.<br>2) The WD identifies the AHD and processes the uploaded configuration information. The WD then acknowledges receipt of the upload to the AHD and AHD notes the success.<br>3) The AHD connects to the WD and requests if there are any available remote controls or configuration settings.<br>4) The WD identifies the AHD and sends any available remote control or configuration information to the AHD which includes standard configuration such as connection parameters, time zone etc. and optionally custom configuration, or an empty response. |

| | |
|---|---|
| | 5) The AHD acknowledges receipt of the download to the WD and WD notes the success.<br>*Post conditions*:<br>1) The AHD at the patient's home executes the remote controls and persists and utilizes any new configurations provided.<br>2) If some of the configuration information provided is for the medical device peripherals connected to the AHD, then this configuration information should be communicated to the medical device peripheral upon its next connection via the PAN interface (assuming this is supported in the PAN or LAN protocol). |
| Failure Modes | 1) Interruption of communication. In the event of interruption of communication upon the initial connect an error message should be provided to prompt the Patient or Service Technician to try again. In the event of interruption of communication on a routine basis, then the AHD should simply retry at some predefined interval until communication is successful. |
| Diagram (optional) |  |

**Key Requirements – Chart Listed Below**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **1** | AHD Send Configuration | The AHD must map the actual configuration into an XML assembly (payload) using some standard schema (XSD). This XML assembly must be embedded in the OBX segment (OBX.5) of an ORU-[R01/R30] message from the HL7 2.x standard. The AHD must consume the service provided by the WD to upload the ORU-[R01/R30] message containing the assembly with the current configuration information for the AHD. | None. | The observation model of the HL7 2.x standard is used where the AHD (Client) sends a dataset (Config Information) to the WD (server) which is the owner of the data. The remote control and configuration information may take the form of some standard command, such as “update firmware” or a standard configuration setting, such as date/time setting, connection settings, allowed medical devices or localization settings. These can be succinctly expressed using standard XML hierarchy. Note that it is desirable to allow customized fields in the XML payload along with the standardized fields, as it allows vendors a wider degree of freedom in the design/type of remote commands and configuration properties. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **2** | WD Acknowledge | The WD must send an acknowledgment using the ACK message from the HL7 2.x standard in response to the ORU-[R01/R30] message received from the AHD.<br><br>The acknowledgment must indicate whether the message was successfully processed or there was an error during processing of the message.<br><br>The AHD must re-transmit the message unless it has received an ACK from the WD. | Proper identification and authentication of the AHD is required. | The WD ACKs the receipt. |
| **3** | AHD Request Configuration | The AHD must query/request if there are any new remote controls or any new configuration information using the service provided by the WD. The AHD must use the QBP-Q11 message of the HL7 2.x standard (query by parameter) to request the information for the AHD identified in the QBP message. | None. | The interrogative model of the HL7 2.x standard is used where the AHD (Client) initiates a query (Request for Config information) to the WD (server) which is the owner of the data. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **4** | WD Send Configuration | The WD must create an XML assembly (payload) using some standard schema (XSD) for the new remote controls or new configuration information to be sent to the AHD. This XML assembly must be embedded in the OBX segment (OBX.5) of an RSP-K11 message from the HL7 2.x standard. | Proper identification and authentication of the AHD is required. | The WD responds to the query by returning the remote control commands and configuration information for the device.<br><br>The remote control and configuration information may take the form of a command, such as “update firmware” or a configuration setting, such as date/time setting, connection settings, allowed medical devices or localization settings. These can be succinctly expressed using an XML hierarchy.<br><br>Note that it is not desirable to standardize the fields in the XML payload as it allows vendors a wider degree of freedom in the design/type of remote commands and configuration properties. |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| **5** | AHD Acknowledge | The AHD must send an acknowledgment using the ACK message from the HL7 2.x standard in response to the RSP-K11 after having successfully received and persisted the new remote controls and configuration information.<br><br>Since processing of the remote controls commands may take time there is no defined way to acknowledge in the HL7 exchange that a particular remote control has been executed, so the results of execution should be logged in configuration information and delivered in a later connection. | None. | The AHD ACKs the receipt. |
| **6** | Communication Protocol | The AHD and the WD will communicate using SOAP based Web Services similar to what is outlined in Continua 2010 guidelines for the vitals transmission from AHD to WD. | | |
| **7** | Security | WS-I BSP1.1 (an extension of WS-I 1.0) Web Service security standard will be used, as recommended by the Continua 2010 guidelines. This standard uses WSS4J for implementing Username/Password token authentication with password digest (Apache WSS4J provides a java implementation of WS-I BSP 1.1 standard) | | |

## Technical Feasibility Review: Pro11-05

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | June 29 2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☒ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Good use case, very thorough!<br>One item concerns me, the comment on page 4: *"Note that it is not desirable to standardize the fields in the XML payload as it allows vendors a wider degree of freedom in the design/type of remote commands and configuration properties."*<br>Does this mean that the intent is to agree on the HL7 message to send remote device control data but not on the data content of the message? That does not really create interoperability then. If the message content is not standardized then the AHD vendor and WAN device vendor still need to work together to agree on the message content before meaningful remote device control can be done.<br>I would suggest to include two tracks in this use case:<br>1. Standardizing a way to send a remote device control message from the WAN device to the AHD<br>2. Agree on the message structure/content to create true interoperability. This will not be an easy task as it means that agreement needs to be reached on the exact parameters that can be controlled both for the AHD and for the connected PAN/LAN devices. However without this second step the value of the first step is limited.<br><br>One topic that I didn't see any attention for in the use case is security. As settings of the device can be modified you want to make sure that only the right person/system is able to make those modifications. This will certainly also be required by FDA. Please add your thoughts on these security items. |
| Additional Comments | **Overall assessment criteria:** |

| | |
|---|---|
| | **Medium** – Consider new technology for existing use case *or* all items not Red or Green<br>**Difficult** – Any of the following apply:<br>• Standard availability: "No suitable SDO available", or<br>• Technology availability: "Technology exist, but is not yet used in the market"<br>• Technology availability: "No, this is currently not possible"<br>• Estimated time to development "Longer than 2 years" |

## Test & Certification Feasibility Review: Pro11-05

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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<br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☒ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) – There are open source tools like APACHE that can be used to implement the transport connection for this UC. The degree of complexity for this implementation may depend on the parameters to be configured. This is a rough estimation.<br>This Test Case will request to include in Test Tool verification for new kind of transaction in WAN Interface (transport and message syntax/semantic verification). Besides, it should be necessary to verify the protocol state machine (Send Configuration ACK, etc). Additionally, if new configuration sent by WAN Receiver requires to configure a PAN/LAN agent, it should be necessary to verify with test too other IEEE 11073 messages.<br>Brian (LNI) - More WAN complexity that may spill over into another gray area: 20601 control of PAN/LAN devices. What is an AHD's configuration? Can this be well standardized?<br>Michael (TOM) - The same test tool could be used, but with enhancement but the level of effort could be Large if requirements scope spreads into PAN though this isn't identified as a current requirement within the UC (i.e., such as the Manager controlling the Agent).<br><br>**Overall assessment criteria: Medium** – All items not Red or Green |

# Legacy Data: Pro11-06

| Use Case Title | Pro11-06: Legacy Data |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☐ Chronic Disease management<br>☐ Aging Independently<br>☒ Other – specify: Legacy Sensor Data |
| Relation with implemented V1 use case(s) | Originally part of the Pro10-10 Application Portability Use case, the requirement to support Non-Continua certified device data was removed and became this Use Case. |
| Description | The Continua Architecture specifies the use of the IEEE 11073 application layer protocol for sensor data flowing from the PAN/LAN layer to the WAN layer, however this is not the only sensor data transport / protocol that is available in the personal health, wellness and fitness markets. The ability to receive alternative formats of sensor data and pass that data through the Continua architecture will help increase market adoption by broadening the range of devices able to participate in the eco-system. One obvious method to achieve this goal is to add a software adaptation layer as data is accepted from Non-Continua certified devices to allow the rest of the architecture to be used in normal fashion, with data correctly marked as to source of origin.<br>The network connectivity of the legacy sensors to the AHD is not at issue in this use case. No changes to the Design Guidelines for the Continua PAN or LAN interfaces are proposed. |
| Scope | AHD adaption of Non-Continua data to WAN sender PCD-01 format. |
| Actors | (1) Non-Continua (Legacy) sensor devices.<br>(2) Legacy-data capable AHD. |
| Minimal Guarantees | (1) Device readings are sent over WAN in a PCD-01 format with suitable transport security (existing clinical grade or proposed consumer grade).<br>(2) Legacy device readings can be certified as they appear at the Continua WAN Sender I/F. |
| Success Guarantees | (1) Ability to support additional data sensor types.<br>(2) Ability to certify an end-to-end Continua solution including legacy sensors. NOTE: This is likely to map into a "Phase 2" work item. |
| Trigger | Growing number of personal fitness and wellness devices that can not currently pass data through Continua AHD to WAN/HRN/PHR services |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | (1) A Non-Continua sensor device takes readings<br>(2) It sends readings to the a legacy sensor data receiver on an AHD<br>(3) An adaption layer in the AHD translates the data to PCD-01 format<br>(4) The AHD sends the data via the WAN-IF Sender function |
| Failure Modes | Data is incorrectly tagged or secured, or unreadable by WAN receiver or HRN/PHR. PCD-01 data is incomplete with respect to the corresponding device specialization containment rules. |

| | |
|---|---|
| Diagram (optional) | <insert diagram> |

**Key Requirements**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 1 | Identify Sensors of Interest | A quick market survey of wellness and fitness market segment sensor devices, to select those for consideration. | Select a small number of device families with a significant market share. | |
| 2 | Identify data payload encodings | Identify the sensor data payload encoding formats used, and evaluate them for compatibility with the IEEE 11073-10101 Domain Information Model. | Preference for (1) standardized, or (2) formally specified and published data formats and DIM compatibility. | |
| 3 | Create a Legacy Framework | Devise a general framework for vendors to bring their legacy devices into the Continua Architecture by means of well defined elements in an AHD implementation, e.g., a translation table. | Provide text for the Design Guidelines that will enable vendors to create legacy data modules for their own sensor devices. | Having a general framework will encourage legacy sensor vendors to bring their work into Continua. |
| 4 | Create Legacy Data Implementation | Devise at least one example legacy data importation method and the accompanying data format translation tables. | Validate the correct sensor observation translation and transmission via the WAN I/F Sender. | Having one concrete example is a always helpful. |
| 5 | Device Class and Assertions | Determine what Continua Device Class should be created for legacy sensors, and what assertions can be made for sensor data integrity, authenticity and origin identification. | Clear tagging of legacy data as to legacy origin, and the level of data integrity and source device identification. | "It is what it is." |
| 6 | End-to-end Certification | Determine if it is possible to apply end-to-end data integrity and source origin authenticity on a par with Continua certified devices. | | This is a "Phase 2" deliverable, likely targeted as a different release cycle of the Design Guidelines. |

## Technical Feasibility Review: Pro11-06

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | July 8, 2011 |
| Type of use case | ☒ Address new end-user need<br>☒ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☒ No suitable SDO available<br>☐ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>The description of this use case does not match well with what is commonly expected from a use case description. Actually, it is missing a description of steps or actions between a user and a system which leads the user towards something useful. Rather the description addresses aspects of the solution space, containing several technical proposals, which should not be part of the use case description.<br>The following concerns and issues are raised under the assumption that the intent of this use case is to support legacy data upload from the AHD over the WAN interface (with 'legacy data' being data from non-Continua certified measurement devices):<br>Why is the PAN-IF in scope for this use case? The intent is to include legacy 'data' at the AHD, not to enable a connection to legacy 'sensors' via certified interfaces.<br>Why is it considered helpful to "include alternative transport protocols" for the PAN-IF? The Continua PAN-IF is fully defined in the Continua Guidelines and already includes several transport options (PAN-IF sub-classes: wired, wireless, and low power wireless). Additional transports would negatively impact interoperability and are out of scope also with respect to the use case submission guidance as defined by the Continua Board of Directors.<br>Legacy data is received by the AHD via proprietary, non-certified interfaces and then converted to a format proper for transmission over the WAN interface. Hence, the focus should be on the WAN interface. The questions to be answered are the following: Is the WAN interface as defined in the latest Guidelines version enabling the transmission of 'legacy' data? If not, is it feasible to define a WAN-IF extension for properly indicating the origin of the data (from |

| | |
|---|---|
| | a Continua certified device versus from a legacy device).<br>Given the above discussion, the Basic Flow is suggested to rather be the following:<br>(1) A Non-Continual sensor device takes readings<br>(2) It sends readings via a proprietary interface to a receiver on an AHD<br>(3) Adaption layer in the AHD translated the data to PCD-01 format<br>(4) AHD sends it on to the Continua-Compliant WAN-IF receiver<br><br>The crucial aspect is that the legacy data needs to be able to be mapped onto the WAN-IF data format. If that mapping is not possible, the WAN-IF cannot be used for uploading the data.<br>**TOM Review:** Fully agree with concerns noted above and need to note however that Continua has an existing certification, the Cypak Converter, that converts the data from a non-Continua device into 11073 data. Although this is one member's legacy devices that are converted via PAN IF, I guess the difference perhaps is that Continua would supply the mapping tables, published within the DG, so that other Continua members could convert the targeted legacy devices accordingly when creating an AHD.<br>This would require that the adaptation layer itself be certified by Continua on an AHD device (as a Certified Device Class of its own – something like an AHD with 'Non-Continua Converted Data').<br>If this is feasible for Continua, for certification I can see where the AHD with 'Non-Continua Converted Data' device is sent to a Continua test lab along with the targeted legacy or proprietary agent-like devices whose data will be converted. Continua would need to know which non-Continua devices were used in order to verify the data prior to it being converted. The list of these devices along with the AHD with 'Non-Continua Converted Data' device would be certified. |
| Additional Comments | The use case needs clarification.<br>**Overall assessment criteria: Medium** – Consider new technology for existing use case *or* all items not Red or Green |

## Test & Certification Feasibility Review: Pro11-06

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - For this UC assessment, I am assuming that CESL will only need to include a lookup table to translate the identifiers to PCD-01 message.<br>I am assuming that Test Tool will verify only the PCD-01 message sent by AHD through the WAN Interface.<br>Michael (TOM) - Fully agree with concerns noted by Lars Schmitt and need to note however that Continua has an existing certification, the Cypak Converter, that converts the data from a non-Continua device into 11073 data. Although this is one member's legacy devices that are converted via PAN IF, I guess the difference perhaps is that Continua would supply the mapping tables, published within the DG, so that other Continua members could convert the targeted legacy devices accordingly when creating an AHD.<br>This would require that the adaptation layer itself be certified by Continua on an AHD device (as a Certified Device Class of its own – something like an AHD with 'Non-Continua Converted Data').<br>If this is feasible for Continua, for certification I can see where the AHD with 'Non-Continua Converted Data' device is sent to a Continua test lab along with the targeted legacy or proprietary |

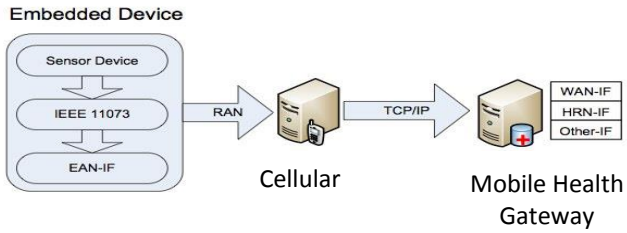
| | |
|---|---|
| | agent-like devices whose data will be converted. Continua would need to know which non-Continua devices were used in order to verify the data prior to it being converted. The list of these devices along with the AHD with 'Non-Continua Converted Data' device would be certified.<br>**Overall assessment criteria: Easy** – Two or more "Least" items *and* no "Large" items. |

# Embedded Area Network: Pro11-07

| Use Case Title | Pro11-07 Embedded Area Network |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | New interface for embedded sensors |
| Description | Embedded Area Network (EAN) is a concept for where a cellular module is embedded in the medical sensor to communicate to the remote service via wireless networks.<br>This Use Case is directed at a specific type of Embedded Medical Sensor (EMS) that is unable to implement the Continua AHD concept or WAN observation sender due to limited capabilities (specifically tier 1 as defined below) not just for processing capability reasons but also for strong user identification and security reasons which are not feasible on a small (physical) and low power unit<br>In an effort to categorise the type of embedded sensor that is initially intended to be covered by this Use Case a three tier model is proposed as follows:<br><u>Tier 1</u><br>Cannot run Continua Stack as defined in Guidelines V1.5<br>Designed to support periodic and not high duty cycle continuous data<br>• Low cost<br>• Small size<br>• Low processing power and memory<br>• Small battery (coin cell)<br><br>Tier 2 (may not run Continua Stack as defined in Guidelines V1.5)<br>• Low to medium cost<br>• Medium to larger size (up to the size of a regular feature phone module)<br>• Low to medium processing power and memory<br>• Medium to larger battery<br><br>Tier 3 (can run Continua Stack as defined in Guidelines V1.5)<br>• Medium to higher cost<br>• Larger size (up to the size of a regular phone)<br>• Higher processing power and memory<br>• Large battery (e.g. rechargeable Lithium-ion 1000mA or larger)<br><br>There are also design considerations for scalable use in mobile network architectures that are requested to be taken in to account when considering the technical solution for this Use Case, the specific considerations are being agreed by the GSMA embedded health project and are around:<br>• Scalability<br>• Data Rate |

| | |
|---|---|
| | • Signaling<br>• Identity management<br>• Power management<br>Due to the limitations of a Tier 1 device data translation consideration should be given to the use of IEEE 11073 data semantics / transport protocols and HL7 for their suitability over wireless communication protocols.<br>The GSMA embedded health project envisions that the Wireless Network could be used to provide support for the Continua stack in the form of a wireless network-based gateway. This would eliminate the need for the Tier 1 EMS to support the Continua stack resulting in a reduction in the cost and size of the EMS while increasing its battery life.<br>Consideration should also be given to how strong user identity will be managed when the EMS is unable to provide the usual functions of an AHD (keyboard/display/ability to enter username/password etc) and how existing functionality of the mobile network being used to transfer the data can be re-used to enable an alternative but similarly strong level of security.<br>Consideration should be given to alternative methods of identification when the device has limited input capability, such as NFC type fob or SIM/UICC<br>This is a new market opportunity that has seen new devices in this category appear recently, the desire is to standardize the method of connecting through mobile networks to enable an interoperable back end with a plug and play front end and avoid a fragmented and proprietary vertical market. |
| Scope | • Embedded cellular modem in medical device/sensor (Tier 1 as defined above)<br>• Mobile network connectivity<br>• Network based gateway to perform some functions<br>• Cellular device transmit power and battery consumption<br>• Communication protocols designed for wireless transmission<br>• Streamlined communication for scalable implementation |
| Actors | • Embedded Medical Sensor (EMS) – medical sensor with a physically attached cellular module used for communications<br>• Cellular Mobile Network to provide communication<br>• Mobile network Infrastructure to provide functionality not possible on EMS |
| Minimal Guarantees | The ability for embedded, machine to machine devices to deliver observations to PHR/EHR solutions in a standardized and interoperable fashion is a requirement for the mobile operators and should be done this way to ensure scalability |
| Success Guarantees | The ability to embed cellular in to medical devices seamlessly with guaranteed compatibility and interoperability |
| Trigger | The growth of M2M and the ability to deliver and out of the box experience for consumers, which provides a seamless and easy experience for connecting devices, by being pre-provisioned and ready to go from the point of delivery or issue, is an increasingly attractive offer that can simplify the overall experience for both provider and patient.<br>Advanced security mechanisms can be utilized to enable secure access to healthcare records on enabled devices directly by health care providers and can put users in control of the access to their health data<br>Also for those that do not have a mobile device currently or do not want to use the one they have for specific health applications embedded solutions provide the ability to keep medical activities separate from normal mobile use |
| Steps of Basic Flow (Include | The embedded devices may not be able to support the traditional Continua architecture of having device -> pan-if -> AHD -> wan-if -> PHR/HRN for several reasons outlined above.<br>Assuming a basic level of capability as outlined above in the three tier model and defining a new |

| | |
|---|---|
| flow descriptions from multiple actor perspectives, if applicable) | interface for how these operate and still implement the features of E2E healthcare delivery should ensure that embedded health is secure and scalable.<br>Step by Step<br>Use Case 1<br>Angus is diagnosed with a chronic disease (diabetes) and is provided with a dedicated sensor that he has to use to monitor himself so that the clinician can review accurate data with him. He does not own a PC or have broadband in his house and owns a PAYG feature phone that he cannot use with the sensor and does not want to either for personal reasons as well as the restrictive tariff he is on<br>In this instance the dedicated sensor he is provided with has embedded connectivity in the form of a cellular modem (M2M module) which is provided on prescription to include the costs of the sensor and all traffic generated by taking readings and the web service where they are stored<br>At the point of prescription the clinic registers the MSISDN of the sensor to Angus on the Health IT system that the clinic uses, this then creates a secure element on the device that is under the direct control of the clinic to store Angus's patient information, they ask Angus to enter a 4 digit PIN which he must use each time he takes a reading to verify it is him using the sensor, along with the secure element of the UICC this creates a two –factor authentication of the user for the device ensuring a secure system. It also ensures that all readings from the sensor go directly to his personal medical diary online under his account.<br>Angus takes the sensor home and the following day takes a reading which involves the following steps:<br>Power up the sensor which asks for a 4 digit PIN which he enters<br>[a customer call centre function will need to be provided for forgotten, resetting PINs OR Angus must take the device back to the clinic]<br>Once the PIN is verified Angus takes a reading which is sent to the HIT system with no further interaction required<br>[verification of upload displayed back to device?]<br><br>Use Case 2<br>Nigel decides that he wants his elderly father Graham to start monitoring his blood pressure as his last visit to the GP showed a tendency to low blood pressure and he wants to keep track of this in case it gets worse, he doesn't want his father to end up in a chronic condition with no warning as he lives over 100 miles away, he also doesn't want to move his family to be closer unless absolutely essential and Graham refuses to move out of his house<br>Nigel goes to the Blue mobile phone store as he recalls an advert about how they could sell you a service to monitor health conditions; once he gets there he speaks to a consultant at the store about his requirements.<br>The consultant asks a few questions about what equipment Graham has already which is simply a fixed line telephone and Digital broadcast TV, also Graham has an aversion to mobile phones but Nigel suspects that is simply because he doesn't know how to use them but won't admit it, he also tells the consultant that he wants a simple as possible out of the box solution with no bills or setup required by his dad Graham.<br>The consultant suggests a remote monitoring solution that; while it is not considered as emergency care, will provide a daily graph of blood pressure and other signs with minimal complication. Nigel signs up for the service and the device is provisioned in the store for Graham, there is no PIN as the expectation is that only Graham will use the sensor and if he lends it to a friend once it will not cause an alarm.<br>That weekend Nigel drives over to visit graham and shows him how to put the cuff on correctly and then to press the Start button – and that's it he tells him, no more buttons, no setup and most importantly no bills to worry about as the whole service is paid for as a subscription that |

| | |
|---|---|
| | Nigel pays directly to Blue Mobile.<br>Grahams GP is also given access to the web service that stores the records created by the Blue Mobile health service which he uses to monitor and track Grahams progress alongside his own observations |
| Failure Modes | Implications on the security model, can embedded modules provide the equivalent level of security to the current guidelines to enable delivery of clinical data |
| Diagram (optional) |  |

**Key Requirements**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 1 | Embedded cellular module | Hardware attached cellular module | that provides all communication capability | GSM or CDMA |
| 2 | Cellular communications | Uses 3GPP or 3GPP2 defined communication protocols | Uses standard communication protocols | |
| 3 | Power consumption | Runs from coin cell battery or small capacity rechargeable battery (>300mAh) | Can provide service from small capacity battery | Assumes Tier 1 Device |
| 4 | User identification | Must be able to uniquely identify user to EHR | Two factor authentication of user shall be possible | May be difficult for Tier 1 device |
| 5 | Data Bandwidth usage | To fit with design constraints around scalability the bandwidth between EMS and network should be as lightweight as possible | Size of communication protocol between EMS and network | Should consider, state, signaling and data payload |
| 6 | WAN/HRN | Continua Compliant WAN/HRN sender from Mobile networks | Observation shall be sent as Continua compliant WAN/HRN | |

## Technical Feasibility Review: Pro11-07

| | |
|---|---|
| Use case: | Pro 11-07 Embedded Area Network |
| Reviewer (2 reviewers) | TWG |
| Date | 4-7-2011 |
| Type of use case | ☐ Address new end-user need<br>☐ Consider new technology for existing use case<br>☒ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☒ No suitable SDO available<br>☐ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Key question is how this will fit in the Continua Architecture?<br>Defining different WAN interfaces might be quick, but is not in line with the Continua mission and vision.<br>It is worthwhile to explore whether it is possible to define a single service contract for the WAN that with different bindings (that determine the transport, encoding and security approach) is able to accommodate the needs of the different use cases.<br>This would result into something like:<br>service contract + binding = network interface definition<br>An instance of such an interface definition would be an end point.<br>The concept of service contracts and bindings do not exist in the current architecture and should be carefully examined. |
| Additional Comments | Embedding this properly in the Continua architecture is difficult, but definitely worthwhile.<br>**Overall assessment criteria: Medium** – Consider new technology for existing use case *or* all items not Red or Green |

## Test & Certification Feasibility Review: Pro11-07

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br><br>☐ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☒ 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.<br>☒ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☒ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - This UC is also related with Pro11-10. If both UC are approved, several parts may be reused and total effort for both UC implementations may be reduced (for CESL and Test Tool).<br>Michael (TOM) - Unsure if this can be done using our existing test tool as the requirement is to test a cellular module connection between an Agent and a remote service over cellular. This is specific to mobile cellular devices so would need to test both an AHD and WAN device within a certification.<br>**Overall assessment criteria: Medium** – All items not Red or Green |

## Store and Forward: Pro 11-08

| Use Case Title | Pro11-08 : Store & Forward |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | None |
| Description | Using Cellular communications can introduce losses in connectivity due to coverage issues, battery going flat, cell congestion etc – while individual applications can implement a store and forward ability at the application layer this leads to a fragmented and inconsistent approach. This Use Case is raised to assess the potential for a standardized approach to reliable delivery for health applications using cellular communications, for example by leveraging the Mobile Network or converging with the measurement device gateway to act as a gateway in the network in case of lost connectivity |
| Scope | All cellular communications based AHD devices sending over WAN |
| Actors | |
| Minimal Guarantees | Readings are always delivered only once and are idempotent |
| Success Guarantees | No loss or duplication of data |
| Trigger | Cellular communications cannot guarantee 100% connectivity for a number of reasons, methods to counteract this are varied and fragmented currently, the proposal is to standardize the approach |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | Cellular based AHD connects to store and forward which in turn provides a reliable delivery service to HRN/PHR |
| Failure Modes | data is lost in transit or corrupted, duplicated |
| Diagram (optional) | |

## Technical Feasibility Review: Pro11-08

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 4-7-2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☒ No suitable SDO available<br>☐ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☒ Less than 1 year<br>☐ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | Reach consensus on framework for adding behavior guidelines.<br>Extend the Continua guidelines with behavior guidelines. |
| Additional Comments | This relates very much with the measurement device gateway behavior activity.<br>Is the objective to?<br>• Standardize the approach to address connectivity interruptions<br>• More general to specify behavior guidelines for an AHD that enable more predictable system integration<br>o behavior must be delivered even in the context of connectivity interruptions<br>1st would impact the ability to differentiate for AHD vendors.<br>2nd would be align with the objective of the measurement device gateway behavior guidelines.<br>**Michael (TOM):** Agree with comments above and that this UC could be an issue and standardizing to one approach would be ideal (great for Continua assuming this is a big issue) but suggest more clarification or examples of where this is a significant issue be provided.<br><br>If a significant issue, suggest that this be a new mandatory feature of Continua WAN Senders/Receivers and HRN Senders implemented within a cellular network via the DG rather than a use-case. Note that today we currently don't have any WAN devices certified so making this mandatory sooner is suggested. |

| | |
|---|---|
| | Certification of this feature should be quite feasible.<br><br>Please clarify how big of an issue this is within in each domains (i.e., Health and Fitness, Chronic Disease Management and Aging Independently)?<br><br>Is not having this requirement preventing adoption of Continua WAN/HRN within cellular?<br>**Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

## Test & Certification Feasibility Review: Pro11-08

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | Raul (AT4 Wireless) - For this UC assessment, I am assuming that the UC will be implemented based on current WAN Interface and adding several behavior Design Guidelines specifying how the AHD will implement the resend policy.<br>Brian (LNI) - I may be a little confused here or not understand the point but as I understand it this feature already exists in the reliable messaging capabilities (optional for sender) in the WAN.<br>Michael (TOM) - How big of an issue is this in each domains (i.e., Health and Fitness, Chronic Disease Management and Aging Independently)? Is not having this requirement preventing adoption of Continua WAN/HRN within cellular? Agree that this could be an issue and standardizing to one approach would be ideal (great for Continua assuming this is a big issue) but suggest more clarification or examples of where this is a large issue be provided.<br>If a significant issue, suggest that this be a new mandatory feature of Continua WAN Senders/Receivers and HRN Senders implemented within a cellular network via the DG rather than a use-case. Note that today we currently don't have any WAN devices certified so making this required sooner is suggested.<br>Certification of this feature should be quite feasible.<br>**Overall assessment criteria: Easy** – Two or more "Least" items *and* no "Large" items. |

# Mobile Web Health API: Pro11-09

| Use Case Title | Pro11-09 Mobile Web API |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | This New API to connect continua certified devices to the mobile handset browser can be used with any certified device so should be compatible with all Continua device specialisations |
| Description | Mobile phone browsers can be used to connect to a PHR using http or https and then collect observations from connected sensors natively via the browser without the need for an installed application, negating the need for application development for multiple handset OS environments.<br>Also means users do not have to know which app to install or indeed need to install anything on their device in order for it to work |
| Scope | Certified Devices, Mobile Handset Browser, API developed in W3C based on requirements generated from this Use Case |
| Actors | Continua device will create an observation and send via PAN-IF to the mobile device which will then connect the PAN-IF receiver to the browser and therefore PHR, investigation required for how AHD function takes place, and where |
| Minimal Guarantees | It will remain a requirement to develop applications for each handset OS to provide mHealth services using Continua certified devices |
| Success Guarantees | Adoption in handset browsers and ability to seamlessly connect any certified device, Guaranteed connectivity for any certified device directly to the PHR using the phone browser as a proxy/gateway |
| Trigger | Mobile internet use will outstrip desktop use within 5 years with a significant portion of people not having access to a computer, additionally the development environment for devices is complex and fragmented, not having to build an application each time will simplify ability to connect more sensors.<br>Increasingly devices are web enabled providing a simpler way to connect devices as the browser can provide a direct connection |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | User will connect medical device to mobile device using PAN-IF steps<br>User will launch browser and connect to PHR/PHA<br>a) User will perform an action on the PHR/PHA to request a reading from attached device OR<br>Medical device will establish connection to PHR/PHA and automatically upload observation<br>**Editorial Comment: PHA is a Personal Health Application.** |
| Failure Modes | Lack of adoption in handset OS browsers<br>Dropped connectivity<br>Empty battery/loss of power |
| Diagram | <insert diagram> |

## Technical Feasibility Review: Pro11-09

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 08-07-11 |
| Type of use case | ☐ Address new end-user need<br>☐ Consider new technology for existing use case<br>☒ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☒ Less than 1 year<br>☐ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>No new interface is needed, although should be considered how to handle the WAN Sender Device from Mobile Browser. The work should consider how the AHD would handle to authenticate and write information right into WAN Receiver Device, or implement the usual UC where WAN-IF and PAN-IF is implemented as part of AHD. Next step is to submit a proposal for a scripting API written in ECMAScript to W3C Devices API and Policy WG.<br>Work together with W3C to promote the API<br>Why is it a 'minimal guarantee' that it will remain a requirement to develop apps specific to the handset OS? I thought this is exactly what is intended to be avoided. Please clarify.<br>Does the success fully depend on adoption of the API by handset browsers? If there is no alternative via e.g. vendor specific applications, then there seems to be a considerable risk involved. |
| Additional Comments | Verify the impact of the utilization of extend configuration of IEEE device specializations in this scenario. Specify that the proposed UC is a read only scenario. Tentatively consider WebSocket for implementation (http://tools.ietf.org/html/draft-ietf-hybi-thewebsocketprotocol-09)<br>The term PHA is not defined.<br>The 'Actors' section does not list the actors, but rather describes a flow of steps of use. Also the sentence seems to be incomplete. Please clarify.<br>**Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

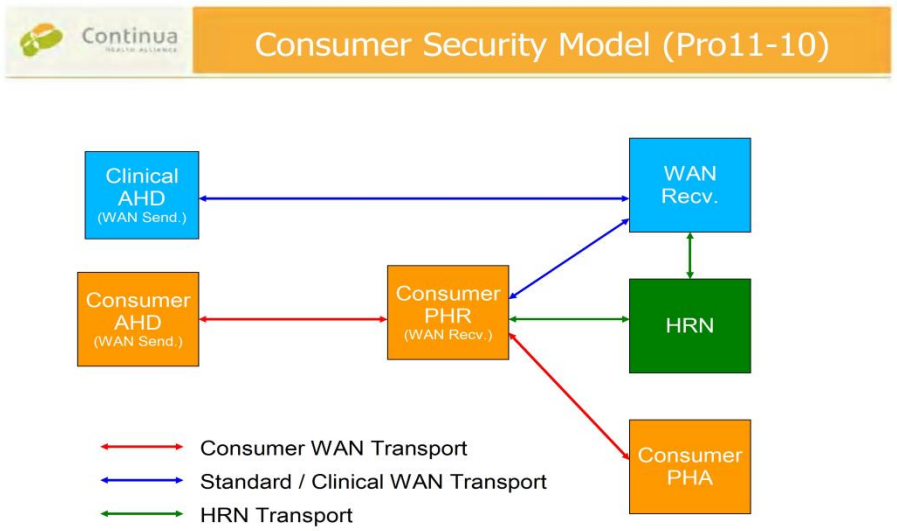
## Test & Certification Feasibility Review: Pro11-09

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☐ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☒ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☒ 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.<br>☐ 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.<br>☒ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - I believe that this Use Case is similar to Pro10-10 (Application portability), so my use case assessment is the same.<br>Brian (LNI) - How does this differ from Pro10-10? Is it time for DLNA and TCP in the Continua transport protocols?<br>Michael (TOM) - Likely more security measures will be needed and they will need to be tested. Development either via CESL or other project would be needed though I'm not sure what would keep companies from doing this already. Continua has already created the PAN to WAN bridge via Java so this could be leveraged. So, if I understand this, my phone's browser would automatically connect and send any PAN info it has collected to a WAN Receiver (WD) or HRN Receiver. Sounds similar to Pro10-10. Continua has developed the PAN to WAN bridge already (for DG v1.5) so this code could be used.<br>Would I need to be connected to a PAN agent at the moment I open the browser? Assuming yes but wonder if Manager's PM-Store could be used also (see other UC Pro11-8 mobile store and forward). Question also how the configuration of the WD be achieved? Could it be as simple as an opt-in to allow receipt of any data via my phone (and it could figure out what it was)? Continua could also develop this as a Reference Design, similar to Pro10-10.<br>**Overall assessment criteria: Difficult** – Two or more "Large" items. |

# Consumer Security Model: Pro 11-10

| Use Case Title | Pro 11-10 Wellness & Fitness Identity and Security Model |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☐ Chronic Disease management<br>☐ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | New security and identity management model and new web services transport model for non-clinical data flows for consumer wellness and fitness devices and applications. |
| Relation with proposed (2011) use case(s) | Pro11-07 Embedded Area Network and Pro11-09 Web API have requirements that potentially overlap with this use case. The desired outcome is for a single security model and web services transport model to be identified that can meet the requirements of all of these proposed use cases. |
| Description | The Wellness and Fitness (unregulated) market segment has requirements for user experience, data flow and data access rights management that are distinct from the Health Care / Clinical (regulated) markets.<br>The 2010 and 2011 Continua Design Guidelines specify an application transport suite (SOAP and WS-*) on the WAN I/F that is familiar to enterprise application developers for use on enterprise platforms. In the Health Care sector, the most likely enterprise adopters are hospitals and other large organizations. There is a broader market of established consumer platforms and application developers that may be tapped if an application transport framework familiar to them were also available, for example, the RESTful style Web API and OAUTH V2 user authorization. This would expand Continua brand penetration into small-to-medium sized companies and consumer-focused use cases such as Wellness and Fitness, increasing the rate of adoption and the visibility of the Continua Alliance.<br>Without a compelling eco-system of end-user applications connected with Continua solutions, it is difficult for consumer-focused developers to demonstrate the return-on-investment for utilizing Continua certified products - it is just a technology. The development of such an eco-system of engaging end-user applications is beyond the scope of Continua, but supporting a platform for these application developers would benefit Continua, developers and consumers. Such a platform allows the consumer-focused application developer to focus on engaging the end-user in their own health utilizing games, gamification techniques, social networks and data visualization. Engaging groups of end-users is non-trivial and has significant risk for the application developer, so a platform that removes technology barriers and provides a broader market of end-users with standards-based access to sensors is a positive move.<br>The requirements for the Wellness and Fitness Use Case are as follows:<br>• All hardware is either owned by the end-user or exists “in-the-cloud” as a service, and the user's hardware is priced for a mass consumer market.<br>• Data acquisition may be by a combination of Continua Certified (regulated) and unregulated sensors, devices and software.<br>• Users will have a direct client/subscriber relationship with a PHR provider, and can effectively manage data access rights via back-end management interfaces, such as web access or specialized value-add applications.<br>◦ User identity mapping is not required.<br>◦ Simple, user authentication based on pre-enrolled end-user identity is |

| | |
|---|---|
| | sufficient.<br>◦ Cloud-based identity management services, of the end-user's choosing, may optionally be employed.<br>- Simple data confidentiality and data integrity, such as provided in consumer grade e-commerce systems, is sufficient.<br>- At the application layer, the users' data flows directly from the user's Application Hosting Device (AHD) to the PHR, although at the transport and network layers store and forward services may be employed, and continuous network connectivity is not required.<br>- Distributed Consent Management, in the form of documents that travel with the data, is not required.<br>- The PHR will likely fill the role of the Continua WAN I/F Receiver.<br>- The PHR will likely use a CDA-based domain information model, and the PCD-01 data payload format. |
| Scope | (1) New security model. (2) New web services API model. |
| Actors | (1) A Continua AHD, with the security and identity model described herein, sends observations via its WAN I/F Sender to the WAN I/F Receiver of a PHR. The end-user maintains an identity management and data access control management relationship with the PHR.<br>(2) Third-party, value-add Personal Health Applications (PHA) access the end-user's data at the PHR using authorization delegated by the end user. The PHR may be the ultimate Identity Manager, or it may further delegate that role to a cloud-based Identity Manager of the end-user's choosing. |
| Minimal Guarantees | Devices and applications are able to connect to a PHR using the new security model to (1) deliver observations to the PHR, and (2) query data from the PHR. NOTE: It's anticipated that this use case will spawn three Work Items. The Work Items may be targeted for different release cycles of the Design Guidelines. |
| Success Guarantees | Adoption in consumer wellness and fitness devices and applications. |
| Trigger | The security model of the 2010 and 2011 Continua WAN-IF application transport suite poses two challenges to the swift adoption of Continua Design Guidelines in consumer (non-regulated) Wellness and Fitness market segments: (1) availability of numerous consumer-grade AHDs and (2) availability of a large selection of consumer-centric applications that engage users in their own health care by utilizing the Continua architecture.<br>To increase the adoption of Continua Design Guidelines there is a need to attract developers to add Continua protocols to consumer-grade platforms with a framework that is familiar to them and addresses the requirements of transporting sensitive health care data. |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | - The end-user activates his/her AHD device or AHD software on a mobile device.<br>- The end-user authenticates with his/her selected PHR(s) via the AHD, using consumer-grade methods, such as RESTful Web API and OAUTH V2 authorization services.<br>- The user's AHD connects observations for associated sensors and devices, e.g., over the existing PAN I/F, and sends them to the PHR.<br>- The PHR receives the observations and stores them in a datastore under the identity of the end-user and applying the end-user's previously |

| | |
|---|---|
| | configured data access control policy.<br>The end-user may access his/her data at the PHR via one or more PHAs that utilize the same consumer-grade WAN I/F as described herein, to check on progress toward goals, interact with family members and other health coaches, etc. |
| Failure Modes | Lack of adoption in consumer devices and applications. |
| Diagram |  |

**Key Requirements**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| | | Consumer Security Model Work Item | | |
| 1 | Threat Model | Create a revised threat model for the security properties of this use case as it relates to the WAN-IF | Security threats address all known attack vectors | Base this work on the existing WAN-IF threat model |
| 2 | Security Requirements | Create a set of security requirements or properties that address all the risks identified in the threat model for the intended consumer market segment | Security requirements address all identified risks | |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 3 | Security Services | Identify security services, protocols, profiles, etc, that meet the Security Requirements, and that meet developer community and Market Acceptance criteria | Security Services meet Security and Market Requirements | There is a large body of commercial web services deployment that uses simple security services, such as IETF standard TLS, that should be considered. |
| 4 | User Identity Services | Identify user identity / user authentication services that meet both the Security and Market Acceptance Requirements. | User identity service need only support a direct account relationship with a single PHR provider (or a set of such relationships). | Consider existing federated identity services, as used in e-commerce solutions today, as well as standalone solutions. |
| 5 | Data Access Authorization Services | Identify data access control, user authorization delegation services that meet both the Security Requirements and Market Acceptance requirements. | Data access control needs to support the user's expectation for data consent policy enforcement, and scale to multi-vendor eco-systems. | The IETF standards track OAuth V2 protocol is one candidate for consideration. |
| | | Consumer Web Transport Work Item | | |
| 6 | Reliable Data Delivery | Identify reliable data delivery services that are compatible with the data transport and security services that have been chosen, and that also meet Market Acceptance criteria. | Reliable data delivery is guaranteed at the application layer or the transport layer. | |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 7 | Web Services API | Identify a web services API that meets the requirements of security, reliable data delivery and independent software developer acceptance criteria, as defined for the consumer market segment. | Ease of use, ease of adoption, and emergence of a vibrant value-add software developer eco-system will be the ultimate indicators of success. | The WS* web services API, as specified in the current guidelines, meets the technical requirements, but does not meet the consumer market acceptance requirements. |
| 8 | Continua Device Class | Determine if devices, software and systems using the technology described in this use case will have a separate Continua Device Class, for certification purposes, and how the data collected and stored using these consumer-grade mechanisms can be differentiated from clinical-grade data, when the PHR data is exported into an HRN. | User interoperability promises must be clear to understand and straightforward to test. Exported data, repurposed for clinical usages, must be appropriately tagged. | |
| | | Consumer Data Query Work Item | | |
| 9 | Data Query Services | Identify a standard mechanism and schema for data query (data flow from the PHR to the PHA) that is compatible with the other system components chosen to support this use case. | Ease of use, ease of adoption, and emergence of a vibrant value-add software developer eco-system will be the ultimate indicators of success. | While support for bi-directional data flows has been in the Continua requirements for a long time, development of guidelines to support that feature has lagged. |

## Technical Feasibility Review: Pro11-10

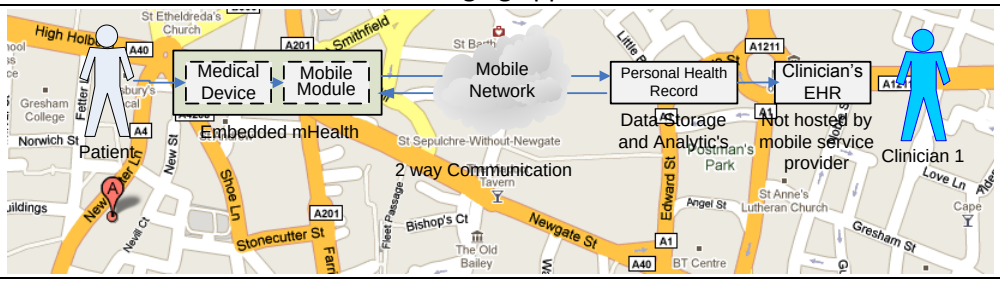
| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | 17 June 2011 |
| Type of use case | ☐ Address new end-user need<br>☐ Consider new technology for existing use case<br>☒ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☐ No Architectural Impact<br>e.g. add new measurement device<br>☒ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☐ Suitable SDO available<br>☒ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | - Threat assessment for consumer grade applications needs development and agreement<br>- Need agreement on what is 'new' as proposed by this UC; some parts of the UC seem to be already achieved by current version of the GLs<br>- Assessment of the standard proposed by the UC needs to be done; requirements and standards selection must reveal which standards are suitable to foster adoption by developers of health and wellness devices and services<br>- Implications of REST vs. Soap on the Continua architecture need to be considered<br>- This UC introduces a new IF as it requires querying data from the WAN Receiver<br>- New GLs will now need to be clearly marked for use in consumer vs. professional grade implementations. |
| Additional Comments | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>- See comments in the attached UC below.<br>- Health and wellness: important market to tap into and this UC can help with that. Technical challenges are of medium grade if we stick to the process.<br>- Though this UC introduces a new IF but worthwhile.<br><br>**Overall assessment criteria: Medium** – Consider new technology for existing use case *or* all items not Red or Green |

## Test & Certification Feasibility Review: Pro11-10

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☐ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☒ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - A new security model must be implemented and specific test cases to verify it have to be developed. Since this UC relaxes the security requirements, I suppose that APACHE or other open source tools should support the selected security model.<br>Brian (LNI) - I think this appears to be a valid concern as the current SAML security model complicates the WAN quite a bit and will likely hinder implementation. In some cases it's just not worth it and fitness seems to be a good case.<br>Michael (TOM) - Interesting UC which appears to be proposing a new classification of certification (lesser requirements for non-regulated devices). This may be suitable for other Proposed UCs within mobile devices. I believe that this would also help drive WAN certifications. I question if our current security model is too heavy even for PCs as we have no certifications to date. New test requirements within at least the test tool would be necessary for RESTful Web API and OAUTH V2 services (specs).<br>**Overall assessment criteria: Easy** – Two or more "Least" items *and* no "Large" items. |

## Location Services: Pro11-13

| Use Case Title | Pro 11-13 Location Services |
|---|---|
| Theme(s) | ☒ Health and Fitness<br>☒ Chronic Disease management<br>☒ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | Location services for Medical Sensors that can be used with existing interfaces PAN/WAN |
| Description | The need to use location data in a consistent, easy to use manner across a number of Use Cases based on knowing the location of the patient, for example to raise an alarm when a vulnerable person goes beyond some pre-defined boundary, which in turn allows for an event trigger such as an alarm raised to a carer. Parameters to be passed may include:<br>• Latitude<br>• Longitude<br>• Altitude<br>• Heading<br>• Speed<br>• Information about range/uncertainty of the determined location<br><br>There are many implementations of location data in use in devices currently:<br>• manual entry<br>• cell tower triangulation<br>• GLONASS<br>• Galileo<br><br>the proposition of this use case is to assess the value to standardize the method via IEEE – 11073 to provide a consistent method that developers can utilize |
| Scope | Any Use Case that requires Location Based Data to function |
| Actors | Medical device requiring location either embedded with GPS or using another method as described above or using a Mobile device over PAN-IF to request data |
| Minimal Guarantees | Time stamped accurate Location data is available with location accuracy (5, 10, 50 meters for example) |
| Success Guarantees | Location is accurate to within defined tolerance |
| Trigger | Desire to assess the validity of standardizing GPS information for medical observations/readings, making location a consistent feature across new use cases. Should GPS data be embedded in a reading to provide application layer with a permanent record of location a time of reading, or provided as a GPS trail that can be used with any application based on accurate time stamping |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if | An application to monitor location of a vulnerable patient to ensure they do not get lost by wandering outside a pre-determined and agreed area (by the care provider with the patient/guardian) can poll the GPS device periodically, with time set by a number of values such as battery life available, time of day, preset by service type for example, to receive an 11073 data structure that can be used to determine if the device is outside (or still inside) a preset geographical area. If an exception is |

| | |
|---|---|
| applicable) | determined by the application a predetermined event trigger can take place, the nature of this trigger is irrelevant to the GPS device whose sole purpose is to provide a reliable and accurate location fix when requested |
| Failure Modes | No location is determined or provided, a consistent lack of location data should be raised as a fault condition to the managing application |
| Diagram |  |

## Technical Feasibility Review: Pro11-13

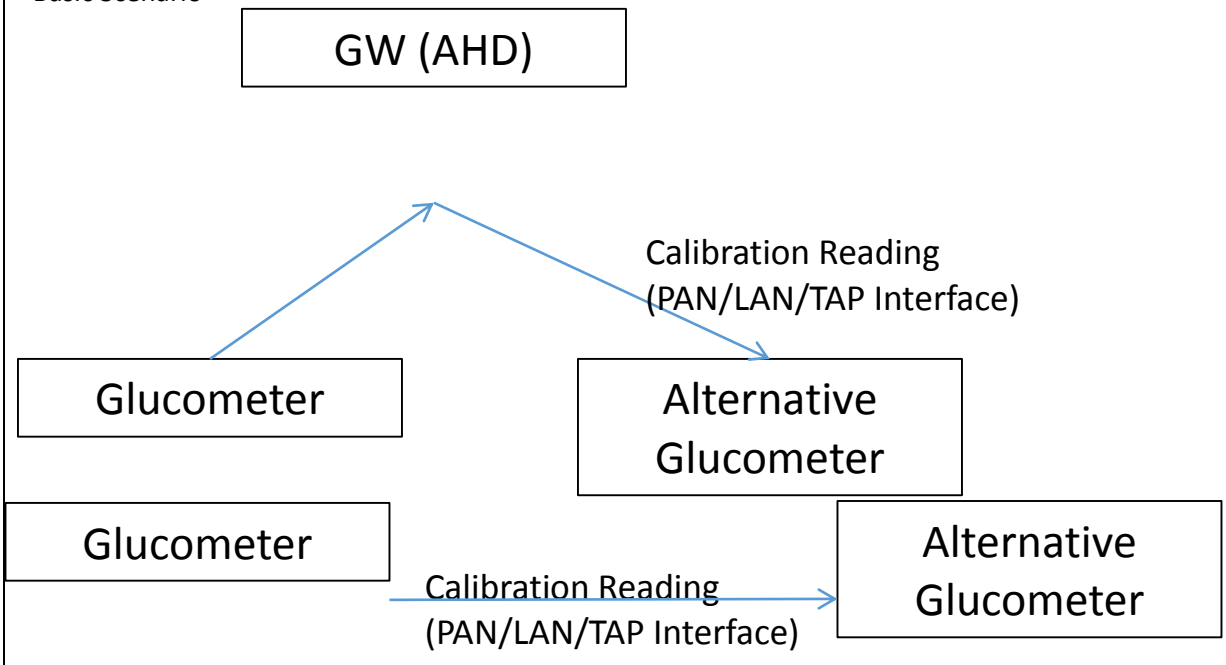
| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | June 29 2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☒ No Architectural Impact<br>e.g. add new measurement device<br>☐ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☒ Less than 1 year<br>☐ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>The underlying need of the use case is to exchange information about a location of an object<br>• Latitude<br>• Longitude<br>• Altitude<br>• Heading<br>• Speed<br>• Information about range/uncertainty of the determined location<br>Please include the full list of parameters in the use case.<br>GPS is just one technology to determine these parameters (others include manual entry, cell tower triangulation, GLONASS, Galileo, etc), therefore I propose to rename/refocus this use case on the user need (exchanging location information) and indicate GPS is just one of the examples for collecting this information<br>Exchanging location information has been done for a long time, existing standards include:<br>• NMEA 2000 (http://en.wikipedia.org/wiki/NMEA_2000)<br>• Geolocation API (http://dev.w3.org/geo/api/spec-source.html)<br>• And probably more<br>For the standards selection phase it will be important to learn from and align with these existing standards in the market.<br>Privacy is an important topic when sharing location information. The IETF is working on standards to define how to specify who can see a user's location with what level of granularity. Please make sure to include privacy considerations also in this use case. |
| Additional Comments | **Overall assessment criteria: Easy** – No architectural impact *and* Suitable SDO available *and* estimated time to development less than 1 year |

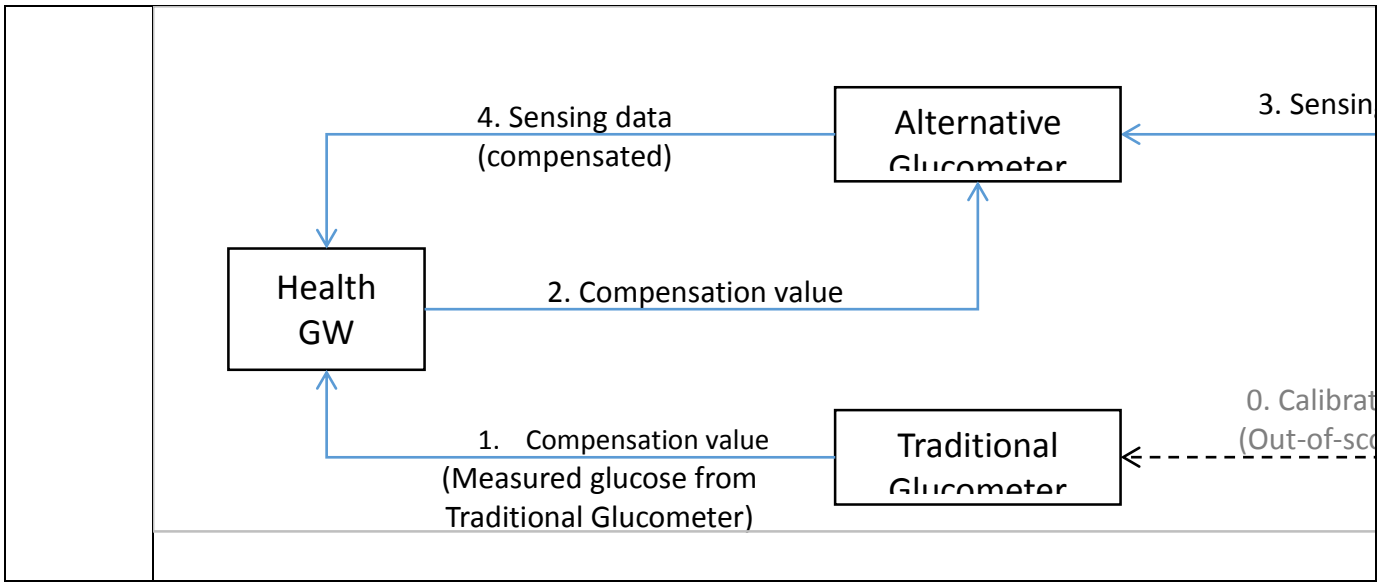
## Test & Certification Feasibility Review: Pro11-13

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☒ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☐ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☐ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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<br>(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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | **Editorial Comment: The use case document has been revised since the text in this assessment was written.**<br>Raul (AT4 Wireless) - For this UC assessment, I am assuming that this UC will need to specify a new IEEE device specialization. Maybe, IEEE Cardio device specialization could be used for this UC, in that case the CESL implementation should require a smaller effort.<br>Michael (TOM) - This UC enables a GPS data feature that will send accurate location data of a patient with a time-stamp. As it is proposed to be a feature within 11073 but can be applied to all device spec's that need location data.<br>Assuming that updates to 20601a and the device specs would be needed to standardize the use of location data. A bit confused by the steps noted below as it notes 'An application to monitor location…'. I don't believe this would be in-scope.<br>**Overall assessment criteria: Easy** – Two or more "Least" items *and* no "Large" items. |

# Device Calibration for Alternative Glucose Meter: Pro11-14

| Use Case Title | Pro 11-14 Device Calibration for Alternative Glucose Meter |
|---|---|
| Theme(s) | ☐ Health and Fitness<br>☒ Chronic Disease management<br>☐ Aging Independently<br>☐ Other – specify: |
| Relation with implemented V1 use case(s) | This use case indicates the interface between Sensor and GW (AHD). The use case can be realized using PAN and LAN interface. Additionally, The Tap and Go device interface (Pro10-08) use case can be a base scenario for the realization of this use case as well. |
| Description | Chronic diabetic patients generally check their glucose 7~8 times per day to monitor their glucose using a blood-based invasive glucose meter. This process is intrusive and could impose pain on the patients. For this reason, many patients may want to use Alternative Glucose meters that can provide a better user experience as compared to the traditional Invasive type. But, the accuracy of the alternative Glucose meters are lower as compared to the traditional Invasive type. This is due to the fact that the alternative types measure glucose from 'Intercellular fluid (Interstitial fluid) and not directly from the blood and accordingly the measured results could be different from actual glucose value due to patients' skin condition (e.g. thickness, humidity, etc.). Therefore the alternative Glucose meters need periodic calibration to compensate for the measured glucose value. Generally, the glucose value from the traditional Invasive Glucose meter is used as a compensation value for the alternative Glucose meter.<br>User scenario<br>- Tom is a chronic diabetic. So he is asked to check his glucose level 7 times everyday<br>- He bought an alternative Glucose meter to use outside his home as conveniently as possible<br>- When he wakes up in the morning, he measures his glucose with the traditional Invasive Glucose meter just once to obtain the compensation value.<br>- Then the measured value is transferred to the alternative Glucose meter from the traditional Invasive Glucose meter. The measured value will be used as a compensation data for the alternative Glucose meter<br>- After that Tom uses the alternative Glucose meter outside his home.<br>- The measured value from the alternative Glucose meter is compensated with the value form the traditional Invasive Glucose meter.<br><br>Note: Other invasive types of Alternative glucose monitors which use interstitial fluid, such as Continuous Glucose Monitors (CGMs) on the market today, require the same calibration method as described in the user scenario above. Thus, such invasive Alternative glucose monitors should be included in this use case. |
| Scope | Home network scenario |
| Actors | - Traditional Invasive Glucose meter: Measures patient's glucose, and sends the measured value to the Health GW or to the Non-invasive Glucose meter.<br><br>- Health GW (AHD): Collects the measured value from the Invasive Glucose meter and decides whether the collected value is to be used as the compensation data of the Non-invasive Glucose meter. The compensation data will be sent to the Non-invasive Glucose |

| | |
|---|---|
| | meter for device calibration<br><br>- Alternative Glucose meter: Compensates for the measured value with the compensation data from the Health GW (AHD). |
| Minimal Guarantees | <end state of the world if the use case is not completed successfully. These should correspond to acceptance criteria below> |
| Success Guarantees | The user or the AHD receives correct glucose reading using the alternative method which can be as good as traditional invasive Glucose meter reading. |
| Trigger | When a patient wants to calibrate their own alternative glucose meter, a patient initiates an application on the glucose meter or Health GW |
| Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable) | Please refer to diagram below<br>0. The traditional Invasive Glucose meter has measured the glucose value from a patient.<br>1. The traditional Invasive Glucose meter sends the measured value to the Health GW. This step can be done automatically after step 0.<br>2. The AHD decides whether the measured value is to be used for compensation. If the AHD decides that the measured value is to be used for compensation, the AHD sends the compensation data to the alternative Glucose meter<br>3. The alternative Glucose meter measures the patient's glucose and compensates for measure value with compensation data from the Health GW<br>4. The alternative Glucose meter shows the compensated value to the user or sends it to the AHD |
| Failure Modes | The step of reading glucose using invasive method followed by invasive method needs to be performed again in case of reading fails to provide correct glucose reading. |
| Diagram | <Basic Scenario><br>  <br><br><Enhanced Scenario with Health GW (AHD)> |




**Key Requirements**

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 1 | AHD (Health GW) receives data from traditional invasive Glucose meter | AHD interfaces with traditional invasive Glucose meter using Continua Standard interfaces | AHD provides interface (LAN/PAN/Tap and Go) to communicate with traditional invasive Glucose meter | Interface requirements on AHD |
| 2 | AHD (Health GW) interface with alternative Glucose meter | AHD interface allows AHD to write data on the alternative Glucose meter | AHD provides Continua Standard interface (LAN/PAN/Touch and Go) to communicate with alternative Glucose meter. | Interface requirements on AHD |
| 3 | Alternative Glucose meter interface | Alternative Glucose meter provides interface to retrieve data from the AHD (Health GW) | Alternative Glucose meter provides LAN/PAN/Touch and Go interface | Interface requirements on Alternative Glucose meter |

| No | Keyword | Requirement Description | Acceptance criteria | Comments |
|---|---|---|---|---|
| 4 | Alternative Glucose meter interface with traditional invasive Glucose meter | Alternative Glucose meter retrieves data directly from the traditional invasive Glucose meter | Alternative Glucose meter can read data from the traditional invasive Glucose meter through a commonly used interface between the two | Interface and interaction requirements on the alternative Glucose meter |
| 5 | AHD (Health GW) decides on compensation | The Health GW decides whether the measured value from the traditional invasive Glucose meter is to be used for compensation on the traditional invasive Glucose meter and sends the compensation data to the alternative Glucose meter | AHD sends compensation data to the alternative Glucose meter. | AHD can read traditional invasive Glucose meter's reading and decides whether compensation is required |
| 6 | Alternative Glucose meter compensation | The alternative Glucose meter compensates for the measured value with the compensation data from the Health GW or traditional Invasive Glucose meter | Alternative Glucose meter provides correct Glucose meter reading | Correctness can be determined by comparing invasive and alternative reading |

## Technical Feasibility Review: Pro11-14

| | |
|---|---|
| Reviewer (2 reviewers) | TWG |
| Date | July, 8 2011 |
| Type of use case | ☒ Address new end-user need<br>☐ Consider new technology for existing use case<br>☐ Consider new technology for sub-segment of existing use case |
| Architectural Impact | ☒ No Architectural Impact<br>e.g. add new measurement device<br>☐ Architectural Change/ Extension needed<br>e.g. introduce unforeseen interface or API |
| Technology availability | ☒ Yes, technology to do this is abundantly available<br>☐ Technology exist, but is not yet used in the market<br>☐ No, this is currently not possible |
| Standard availability | ☐ No suitable SDO available<br>☒ Suitable SDO available<br>☐ Standard completed<br>☐ Standard used in the market |
| Estimated development time | ☐ Less than 1 year<br>☒ Between 1 and 2 years<br>☐ Longer than 2 years |
| Steps needed for completion<br>- New technology?<br>- Standards development?<br>- New Continua interfaces?<br>- Modification to Continua interfaces?<br>- Other changes? | Generalizing on the specifics of this use case, it describes a method for one sensor device to communicate to another sensor device via a shared AHD. In the specific scenario of this use case, the data sharing is for the purpose of calibration / correlation / correction of readings taken by an non-invasive, less accurate sensor, with more accurate readings taken (presumably within a small time window) by an invasive sensor. The example scenario is for blood glucose readings.<br>The Continua architecture encompasses bi-directional communication between sensors and the gateway (AHD). Most of the work to date has been on uni-directional flow of sensor readings from sensor to gateway to back-end storage. The notion of inter-sensor communication, facilitated by the gateway (AHD) is somewhat new (or so this reviewer believes) but does not present architectural issues. It may require revision to specific design guidelines for the PAN or LAN interfaces.<br>It appears, upon initial review, that no new standards work would be required to take this use case forward. However, mechanisms of existing standards that have not previously been included in Continua certified device classes may be required. |
| Additional Comments | Should this work go forward, the revised design guidelines ought to address the generic issue of inter-sensor communication, in addition to the specifics of calibrating non-invasive sensors by means of contemporary invasive sensor readings.<br>This reviewer is not aware of whether the sensor technology described in this use case is currently available or deployed in the market, outside the scope of Continua.<br>**Feedback from TWG call**: please remove the term “non-invasive” from this use case as many types of glucometers can benefit from device calibration, so no need to restrict it to non-invasive glucometers only.<br>**Overall assessment criteria: Medium** – Consider new technology for existing use case *or* all items not Red or Green |

## Test & Certification Feasibility Review: Pro11-14

| | |
|---|---|
| Reviewer | TCWG |
| Date | 12 July 2011 |
| Test Tool Architecture Impact | ☒ Least – Existing Test Procedures in the Test Tool will need to be modified.<br>☐ Moderate – New Test Procedures will need to be added to the Test Tool.<br>☐ 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.<br>☒ Moderate – Some technology to implement the use case will need to be written. Contractors exist with this expertise<br>☐ 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.<br>☐ Moderate – Nine to fifteen months for both CESL and the Test Tool to finish.<br>☐ 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.<br>☐ 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.<br>☐ 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 | Raul (AT4 Wireless) - It should be necessary to add to PAN/LAN interface the calibration messages from AHD to Non-Invasive GM (I suppose that it would be a new kind of SET action or something similar in IEEE 11073).<br>Michael (TOM) - This would be an update to the GL Device Spec but there would be additional testing approach as there would be 2 agent devices that would need to be tested to verify an Agent certification (Non-invasive to Invasive Glucometer) and 3 devices for a Manager certification (not including interoperability testing).<br>**Overall assessment criteria: Easy** – Two or more "Least" items *and* no "Large" items. |