DELIVERABLE

D.5.8 – Contributions to standardization
Second year report

Project Acronym: UNCAP

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Revision:

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P	Public	**X**
C	Confidential, only for members of the consortium and the Commission Services	

1. Revision history and statement of originality

1.1. Revision history

Rev	Date	Author	Organization	Description
0.1	21/12/2016	Anne Wilson Martin Ford	GiStandards Ltd	First version of document
0.2	21/12/2016	Scott Cadzow	C3L	Contribution
0.9	22/12/2016	Irene Facchin	TRILOGIS	Quality Check
1.0	23/12/2016	Giuseppe Conti	TRILOGIS	Final review

1.2. Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

2. List of references

Number	Full Reference
[1]	OGC and ISO 19156:2011, Geographic information - Observations and measurements, Abstract Specifications, 10-004r3. Available online at: https://www.iso.org/obp/ui/#iso:std:iso:19156:ed-1:en
[2]	Empirica and WRC (2005): Various Studies on Policy Implications of Demographic Changes in National and Community Policies. Final Report. Available online at: http://www.rcc.gov.pt/SiteCollectionDocuments/ICT-ageing_vienna_handout08.pdf
[3]	Open mHealth. Available online at: http://www.openmhealth.org/
[4]	OGC 14-005r3, OGC® IndoorGML. Available online at: http://docs.opengeospatial.org/is/14-005r3/14-005r3.html
[5]	ISO 8601 on dates representation. Available online at: http://www.iso.org/iso/home/standards/iso8601.htm
[6]	Guidelines for Successful OGC Interface Standards, OGC document 00-014r1.
[7]	ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes. Available online at: http://www.iso.org/iso/catalogue_detail?csnumber=36786

3. Table of Acronyms

Acronym	Description
aaS	*as a service*
AHA	*Active and Healthy Ageing*
CE	*Conformité Européene (European Conformity)*
CEN	*Comité Européen de Normalisation*
CENELEC	*Comité Européen de Normalisation en Électronique et en Électrotechnique*
DOC	*Declaration of Conformity*
DWG	*Domain Working Group*
EP	*ETSI Project*
ETSI	*European Telecommunications Standards Institute*
IoT	*Internet of Things*
ISG	*Industry Specification Group*
LOINC	*Logical Observation Identifiers Names and Codes*
M2M	*Machine to Machine*
MDD	*Medical Devices Directive*
MeSH	*Medical Subject Headings*
O&M	*Observations and Measurements*
OGC	*Open Geospatial Consortium*
SAS	*Sensor Alert Service*
SOS	*Sensor Observation Service*
TC	*Technical Committee*
TC CYBER	*Technical Committee (TC) Cyber Security*
UMLS	*Unified Medical Language System*
UNCAP	*Ubiquitous iNteroperable Care for Ageing People*

4. Executive Abstract

The present document acts as a delta to the V1.0 of the deliverable published in December 2015 (*D.5.7 – Contributions to standardisation*). The previous document still applies; this version of the document presents new activity undertaken in 2016. It is important to note that the development of standards can take a very long time and is not under the sole control of the members of the UNCAP consortium. This particularly applies to standards work under the EU mandated organisations ETSI, CEN and CENELEC as well as within outher SDOs, such as OGC, where a work item may typically take 18 months to develop for publication (for simple reports) and in some cases take considerably longer.

UNCAP will create an ICT platform based on open standards, enabling monitoring, assisting, training and diagnosing health and psychological status of an ageing population. To ensure a successful uptake within this project, in line with Horizon 2020, this will be achieved by a robust and focussed Standardization plan.

The exploitation of UNCAP's results through the development of standards has been centred on key Technical Committees in CEN, Open Geospatial Consortium - OGC and ISO.

This report is the second of three deliverables on standardization activities and covers the second year of the project (Jan – Dec 2016). In particular, this report covers:

- A review of the requirements for use of European certification for CE Marking of medical devices (as in section 5) in light of future commercial exploitation of UNCAP and the role of elements of UNCAP as medical devices according to the definitions given in Directive 2007/47/EC.
- The submissions to Open Geospatial Consortium - OGC for standardization (as from section 6). It should be noted that the text included in the section 6, describing the standard AHA-ML as it is proposed to OGC, has been used for an official "OGC Discussion Paper" and now it has been proposed for the creation of a dedicated "standard working group" (SWG). The official motion by OGC for Approval of "AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile" as an OGC Discussion Paper has been passed in early 2016 during the 98th OGC Technical Committee Meeting of OGC and it is available from the OGC portal at http://www.ogcnetwork.net/node/1984. The full text of the paper is annexed to D.5.10. The on 7 December 2016, in the context of the 101st OGC Technical Committee Taichung, Taiwan the Health DWG of the OGC has recommends that the OGC Technical Committee approve an electronic vote on document [OGC 16-128] "AHA-ML (Active and Healthy Aging Mark-up Language) O&M Standards Working Group Charter" to form an OGC Standards Working Group.
- The standardisation activities carried on within ETSI.

An effective Standardization campaign showcasing successful technical activity will ensure maximum impact for the project. Software and hardware developers, including SME's, clinicians, researchers and other key stakeholders will be targeted in a variety of settings using a variety of methods, including conferences, journal articles and workshops. UNCAP aims to encourage the development of other technologies compatible with the UNCAP platform. Key actions include the development of relevant standards and the use of existing standards to support the innovative nature of the project.

This document provides a report on all standardization activities to date in the context of Task 5.6 “Standardization activities”.

5. Table of Content

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8. Terms and Definitions

For the purposes of this report, the definition of Asset Management is specified in the document BS ISO 55000:2014.

For the purposes of this report, the definitions specified in Clause 4 of the OWS Common Implementation Standard [OGC 06-121r3] shall apply.

9. European Certification (CE)

9.1. Overview for medical devices

NOTE: Version 1 of the present document considered CE marking in general and the text from V1 still applies.

A medical device is one that is classified as such and marked, in the EU, by an appropriate CE mark. In simple terms, a Medical Device (from Directive 2007/47/EC [i.2]) means: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but what may be assisted by such means.

Where an UNCAP partner declares that a device is classified as a medical device, the partner is required to make the necessary submissions in order to obtain the relevant marking. No activity in the standardisation domain has been undertaken in 2016 directly related to the conformance requirements related to CE marking.

Manufacturers play a crucial role in ensuring that products placed on the extended Single Market of the EEA are safe. They are responsible for checking that their products meet EU safety, health, and environmental protection requirements. It is the manufacturer's responsibility to carry out the conformity assessment, set up the technical file, and issue the EU declaration.

9.1.1. Compliance with harmonized standards

There is the option to use any international standard that has been harmonized to the medical device directives. If you comply with these harmonized standards you will conform with the relevant parts of the directive that are covered by these standards. This includes standards such as ISO 13485 covering quality management systems for medical device manufacturers and ISO 14971 covering risk management for medical devices and other process-specific standards, such as those covering sterilization.

There are also standards specific to individual types of medical devices. The use of these standards is not mandatory, however most manufacturers choose to use them.

9.2. Products that need CE marking

The following are examples of equipment that measure health information and require CE marking:

- **Pulse Oximeter,** to record oxygen concentration in the blood and the pulse rate;

Figure 1: Pulse Oximeter.

- **Electronic blood pressure monitor,** to record the level of the individual's blood pressure and allows the information to be uploaded remotely to a clinician;

Figure 2: Electronic blood pressure monitor.

- **Urine testing sticks,** to assist in the monitoring of patients with diabetes, primarily patients at risk of developing ketoacidosis, a complication of Type 1 diabetes;

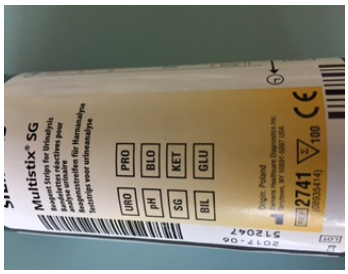

Figure 3: Urine testing sticks.

- **Blood glucose monitors,** to monitor glucose levels in those with Type 1 and Type 2 diabetes. Information can be stored in the device and uploaded to a clinician for analysis;

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Figure 4: Blood glucose monitors.

- **Spirometer,** to assess lung volume in patients with COPD (Chronic Obstructive Pulmonary Disease);

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Figure 5: Spirometer.

- **Peak flow meter,** to measure respiratory function, primarily in patients with asthma.

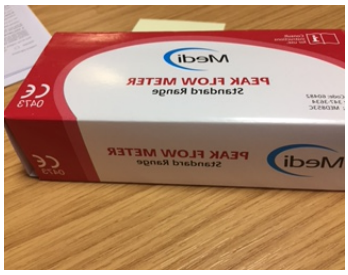

Figure 6: Peak flow meter.

9.3. How to place a CE marking on a product

Once the conformity assessment requirements for CE marking has been satisfied, the CE marking must be attached to the product or its packaging. There are specific rules for using the CE marking for the product, as well as rules for the reproduction of the CE marking logo.

In general, the CE marking should be attached to the product itself; however, it can also be placed on the packaging, in manuals, and on other supporting literature. Rules covering the use of the CE marking vary depending on the specific European Union Directive that applies to the product and it is advisable to study the applicable guidance.

However, the following general provisions all apply:

- CE markings must only be affixed by the manufacturer or the authorized representative.
- The CE marking cannot be affixed to products that are not covered by the relevant European Directives.

- When attaching the CE marking, the manufacturer take full responsibility for the product's conformity with the requirements of the relevant directives.
- The manufacturer must only use the CE marking to show the product's conformity with the relevant directives.
- The manufacturer must not affix any marking or sign that may misconstrue the meaning or form of the CE marking to third parties.
- Other markings affixed to the product must not cover up the CE marking.
- Member states shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking itself. Member states shall also provide penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

The general principles of the CE marking are contained within Regulation (EC) No 765/2008, which sets the requirements for accreditation and market surveillance relating to the marketing of products.

For specific rules that may apply to your CE marking, read about the EC product directives.

9.4. Reproducing the CE marking logo

There are different factors that the manufacturer must conform to when reproducing the CE marking image on the product. Some will depend on the specifics of the Directive that covers the product itself. However, in most cases the following should apply:

- the CE marking must consist of the initials 'CE' in the standard, recognizable form;
- if the size of your marking is reduced or enlarged, the letters CE must be in proportion to the standard version;
- the CE marking must be at least 5 millimeters - unless a larger minimum dimension is specified in the relevant Directive;
- the CE marking must be affixed to the product or to its data plate - if this is not possible or not warranted because of the nature of the product, it must be affixed to the packaging and accompanying documents;
- the CE marking must be easily visible, readable and permanent.

Figure 7: Example of CE marking.

9.5. Keep documentation for CE marking

Once the CE marking has been placed on the product, the manufacturer must keep certain documentation. The Market Surveillance Authorities can ask for this information at any time to check that a CE marking has been legitimately affixed to a product.

The information the manufacturer must keep will vary depending on the specific directives relevant to the product. However, the manufacturer must keep general records of:

- how the product is manufactured;
- how the product conforms to the relevant national standards;
- the addresses of manufacture and storage places;
- the design and manufacture of the product;
- which New Approach Directives apply to the product and how they have been met;
- the European Community type-examination certificates - if applicable.

The manufacturer should keep the information in the form of a technical file, which can be supplied upon request by the enforcement authority.

9.6. The manufacturer's Declaration of Conformity

The Declaration of Conformity (DOC) is a document that may be required to accompany a product and in which the manufacturer, or his authorized representative within the European Economic Area, indicates that the product meets all the necessary requirements of the directives applicable to the specific product.

The DOC also contains:

- the name and address of the manufacturer;
- the information about the product, such as brand and serial number.

The DOC must be signed by an individual working for the manufacturer or an authorized representative, and the employee's function must also be indicated. Download a sample EU Declaration of Conformity.

9.7. CE marking enforcement

A number of bodies enforce CE marking legislation. Enforcement is important to prevent misuse of the CE marking and ensure product safety standards.

Enforcement - or **market surveillance** - is undertaken by nominated public authorities (Market Surveillance Authorities) in each member state. Each state has separate ways of enforcing the legislation once it has been implemented into national law.

Market Surveillance Authorities and processes will vary depending on which Directives are applicable to the product. The following bodies, amongst others, are responsible for CE marking enforcement in the UK:

- Trading Standards Services;
- the Health & Safety Executive;
- the Medicines and Healthcare product Regulatory Agency;
- the Vehicle Certification Agency;

- the National Measurement Office.

If an enforcement body finds that the product does not meet CE marking requirements, they may give the manufacturer an opportunity to ensure it is correctly CE marked. If the manufacturer fails to comply with this, he will have to take the product off the market. He may also be liable for the payment of a fine or to be imprisoned.

9.8. CE marking – Self Certification

The manufacturer needs to demonstrate that the medical device meets the requirements in the Medical Devices Directive (MDD) by carrying out a conformity assessment. The assessment route depends on the device:

- The manufacturer can place a CE mark on the product to show that the medical device has met the requirements when it has passed the conformity assessment.
- Register the device with the relevant competent authority if he hasn't already done so (MHRA in the UK).
- The manufacturer can place a CE mark on the product and place it on the market when he has done this.

10. Active and Healthy Ageing Mark-up Language (AHA-ML) an O&M profile

10.1. Overview

This section provides a proposal for a new O&M (Observations and Measurements) profile focused on Active and Healthy Ageing, called AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile - Discussion Paper. This section introduces the overall need for such a profile and it discusses the measures which have been identified.

10.2. AHA-ML an O&M profile

10.2.1. Introduction

Given the on-going demographic changes caused by an ageing population, alternative approaches should be evaluated in order to overcome inevitably high healthcare costs, in terms of: pressure on pensions systems, ageing of the workforce and health and social care needs increase. UNCAP responds to this challenge through the development of an open ICT infrastructure that leverages on location and sensor-based technologies to create radically new paradigms for service care delivery,

UNCAP is delivering a suite of innovative ready-to-be-marketed ICT products and services, based on consumer-grade technologies, designed to help elderly people with cognitive impairments live a more independent life. The solution that will be developed is composed of a cloud platform used to collect, store and analyse data coming from a number of different devices and sensors. Those sensors, most of which are wearable or portable, provide a large variety of measurements that have to be shared with the server in order to being processed.

From a technical standpoint this is being done through fostering of:

- **Openness**, through release of open specifications and open software components.
- **Scalability**, through use of cloud-centric approaches.
- **User friendliness**, ensuring compliance with all most common usability standards.
- **Privacy and security**, through attention to all related privacy and security aspects.
- **Interoperability and use of open standard**, through support for a range of open standards from the Geospatial Consortium (OGC) and beyond (e.g. HL7, Open mHealth [3]) for all its key services (e.g. position, sensors, building automation systems, clinical assessment, storage of clinical data etc.) allowing for future extensions in terms of hardware and software.

Starting from this outlook, UNCAP is proposing the definition of a new profile to extend the O&M conceptual model to directly report data related to the Active and Healthy Aging domain, thus called AHA-ML. The conceptual model may then be used to define an XML (or JSON) schema to be used for the exchange of observations related to this specific domain.

10.2.2. Why a specific O&M profile for active and healthy aging is needed

The need for an Active and Healthy Ageing domain-specific profile emerges from the requirement to integrate data and information across multiple systems and sensors. There is a large variety of data and concepts acquired from bio-sensing technologies which are in most cases in a proprietary format. Therefore, it is necessary to identify the concepts shared in different applications and aggregate the semantics of commonly used features under a single definition.

The added value, with respect to other available standards (e.g. Open mHealth [3]), is the integration of the geographic information and the possibility – leveraging on SensorML – of aggregating the information about the specific sensor used and the description of the measurement procedure.

10.2.3. The overall approach

As part of the UNCAP project emerged the need to standardize the flow of measurements acquired from a large variety of sensors (both bio-sensors and not).

During the first year of the UNCAP project, the Consortium has involved all technologies providers, those that are part of the consortium, in order to address and specifically identify the list of measures required by their technologies. To that list, other measures were added in order to consider the possibility for future integration of new technologies.

Another input was collected from the pilot sites – addressing nursing homes and home care scenarios – by leveraging on the use cases collected during the preparation phase, which involved clinical staff from 11 hospitals and nursing homes from different Counties. Clinicians and specialists described and highlighted a number of requirements to cover their specific needs. Those requirements were then translated into use cases and consequently in sensors to be adopted and relative measurements.

The Consortium has then identified for each entry a reference to some publicly available vocabularies in order to provide a well-defined description of the intended measure. Each vocabulary addresses different objectives. Some examples of those that have been selected as reference for this work:

- **Logical Observation Identifiers Names and Codes (LOINC)**, a publicly available database specialized on the identification of medical laboratory observations.
- **Medical Subject Headings (MeSH)**, a vocabulary that indexes biomedical scientific literature (books and articles).
- **Unified Medical Language System (UMLS)**, a collection of many biomedical vocabularies.

The resulting set of measurements is composed of 35 entries that have been reported in the following sections. Each measure will be also related and associated with the geographic position where it was collected.

As per the O&M standard [1], an observation is "an act associated with a discrete time instant or period through which a number, term or other symbol is assigned to a phenomenon. The phenomenon is a property of an identifiable object, which is the feature of interest of the observation. The observation uses a procedure, which is often an instrument or sensor but may be a process chain, human observer, an algorithm, a computation or simulator. The key idea is that the observation result is an estimate of

the value of some property of the feature of interest, and the other observation properties provide context or metadata to support evaluation, interpretation and use of the result."

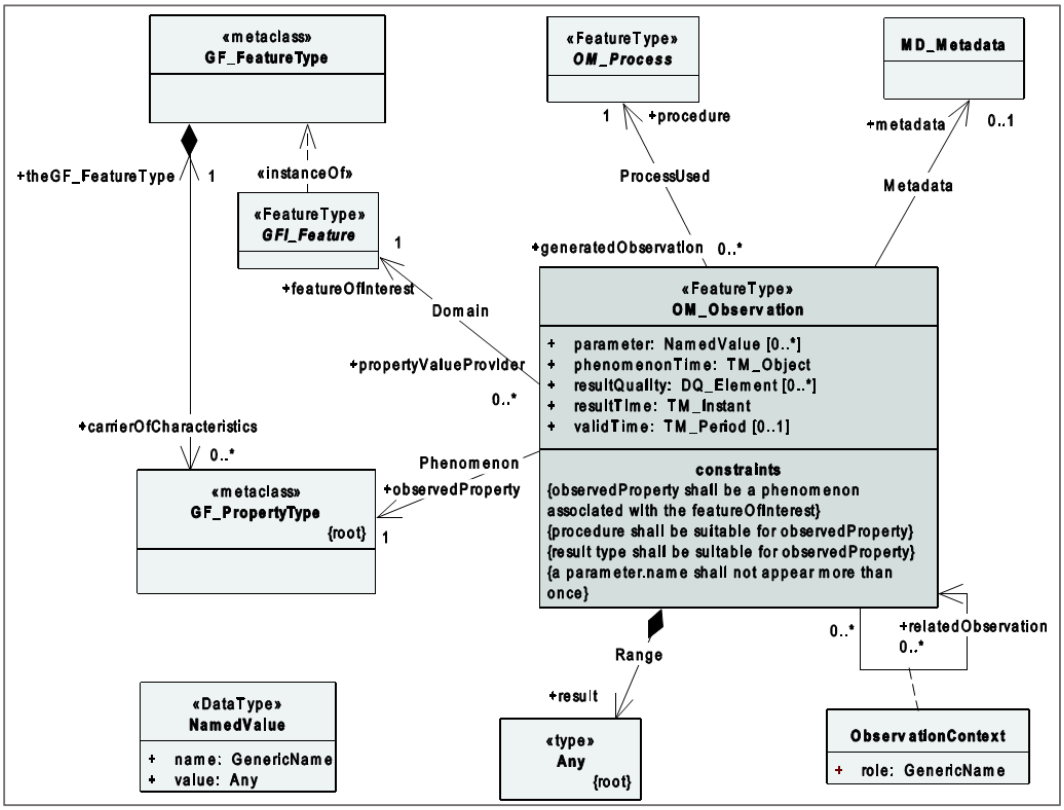

Figure 8: The basic Observation type.

The attributes associated with an observation are:

- **phenomenonTime**: describes the time that the result applies to the property of the feature-of-interest. This is often the time of interaction by a sampling procedure or observation procedure with a real-world feature. In our case, it may refer to the time a blood sample was collected from the patient.
- **resultTime**: describes the time when the result became available, typically when the procedure associated with the observation was completed. For some observations, this is identical to the phenomenonTime. Following the previous example, it reports the time at which the blood sample was analysed and the value of glucose was extracted.
- **validTime**: describes the time period during which the result is intended to be used. This is an optional attribute and since we have not yet envisioned an example in which this may be useful it will be probably not be provided.
- **parameter**: shall describe an arbitrary event-specific parameter. This might be an environmental parameter, an instrument setting or input, or an event-specific sampling parameter that is not tightly bound to either the feature-of-interest or to the observation procedure. In this specific scenario this attribute can be used to define the location where body temperature is measured (e.g. mouth).
- **resultQuality**: describes the quality of the result. This instance-specific description complements the description of the observation procedure, which provides information concerning the quality of all observations using this procedure.

In the following Figure 9 are also depicted the possible interactions with other components/standards of OGC for the scenario envisioned:

- **Sensor Observation Service (SOS)** to manage and retrieve data and metadata from the registered devices by relaying on the O&M standard.
- **Sensor Alert Service (SAS)** to be used upon the detection of anomalies to send alerts to a specific user (e.g. a clinician or next of kin).
- **Sensor Alert Service (SAS)** to provide asynchronous notification of sensor events.
- **SensorML** to describe the sensor and the measurement process.

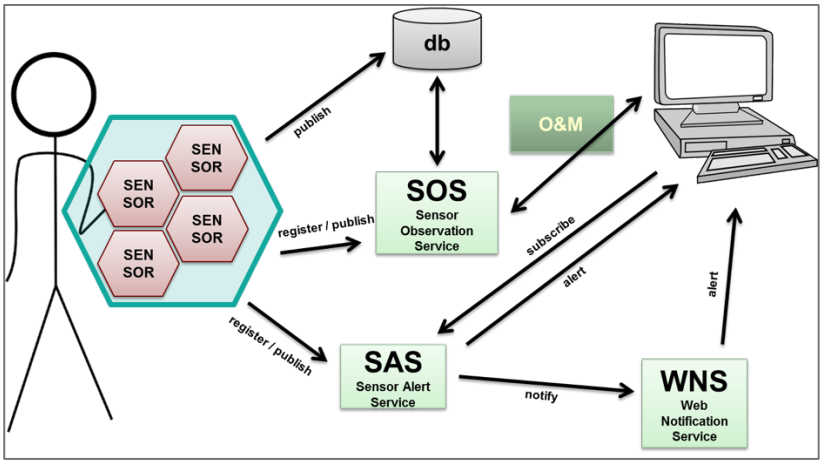

Figure 9: Possible integration with other OGC standards.

10.2.4. The measurements

This section reports the measures identified as relevant to comprehensively represent the psychophysical condition of an elderly person. In general terms, the Consortium focused on those measurements required by the sensors/devices that will be integrated in the UNCAP platform while considering also further measurements which could be relevant in general terms. The following list is therefore non exhaustive and many other may be added in the future.

Table 1: measurements proposed within the O&M profile.

Measurement	Vocabulary reference	Unit of Measure	Sensor
Affinity This relates to the emotional state related to a degree of affinity detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Amount Extent of permanence in bed	none	hours/day	many sensors can produce such information including, but not limited to:

It represents the time spent in bed (or, more generally, at rest) during a 24hrs interval.			accelerometers, smart sensing floor, pressure sensors, solutions based on the use of video cameras and in general any device able to detect the position of the user
Amount of physical exercise Represents the time-spent by the user doing physical exercise (i.e. not at rest).	none	hours/day	any sensor capable of monitoring the physical exercise (e.g. accelerometers, pedometers, indoor location based technology)
Attention This relates to the emotional state related to a degree of attention detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Basal metabolic rate Represents the amount of energy (in calories) necessary to maintain the body functioning in normal healthy conditions (e.g. blood circulation, breathing, cell growth, etc.) when at rest.	none	kcal/day	usually basal metabolic rate is calculated manually, through the following formulas: for men: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(years) + 5$ for women: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(years) - 161$ More precise measurements may be achieved through use of direct or indirect calorimetry in a laboratory environment.
Blood glucose Levels of glucose found in the blood. Optimum	UMLS C0005802	mmol/L (millimol/litre)	glucometers

testing times are when fasting and post prandial.		and mg/dl (normal range 70-110mg/dl)	
Blood Oxygen Saturation Represents the percentage of haemoglobin saturated with oxygen at the time of the measurement.	UMLS C0523807	Percentage time series (normal 95%-100%, low <90%, emergency <80%)	Pulse oximeter
Blood pressure It is the pressure exerted by circulating blood upon the walls of blood vessels. It is defined as diastolic and systolic pressure of the blood. It is a compound measure that should report both values.	UMLS C1271104	mm Hg (low <90/60), normal from 90/60 to 140/80, high >140/90)	blood pressure meter (sphygmomanometer)
Body fat percentage Body fat is the amount of fat in the body, compared to everything else.	UMLS C0518026	percentage	A smart scale is the simplest (yet less accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.
Body height Represents the distance from the bottom of the feet to the top of the head.	UMLS C0005890	Cm	self- reported
Body mass index Body Mass Index (BMI) is a measure of body fat based on height and weight that applies to adult men and women.	UMLS C0578022	kg/m^2	smart scale or self-reported
Body temperature Body temperature is a measurement of the body's ability to generate and expel heat. This varies depending on the location where the measurement is taken (e.g. mouth, axilla, etc.). The location should be taken into consideration and added as a parameter.	UMLS C0005903	°C (normal 36.5–37.5 °C)	thermometer

Body weight Measurement of the body mass weight.	UMLS C0005910	Kg (normal values depend on many factors such as age, gender and height)	smart scale or self-reported
Bone density It represents the amount of mineral matter per square centimetre in bones.	UMLS C0005938	g/cm^2	Smart scale. More accurate techniques are available but requires specialist referral for radiography examination.
Calories burned Amount of calories burned.	LOINC 41981-2	Kcal	it can be inferred from the type, duration and intensity of the physical activity
Electroencephalography (EEG) It is used to record electrical activity of the brain. A number (the number depends on the device) of – generally non-invasive – sensors is applied on the scalp to measure voltage variations generated by neurons' activity.	UMLS C0234550	voltage [V] time series. It is a time series of multiple measures depending on the number of electrodes applied.	EEG device
Engagement This relates to the emotional state related to a degree of engagement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Excitement This relates to the emotional state related to a degree of excitement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Fatigue This relates to the emotional and physical state related to a degree of fatigue detected by the	none	float between 0 and 1	portable EEG

system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.			
Focus This relates to the emotional and physical state related to a degree of focus detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Galvanic Skin Response Galvanic Skin Response is the variation in electricity conductance when external or internal stimuli occur to the user. It can be clearly related with sweat.	UMLS C0016989 - MESH D005712	mS (Siemens)	galvanic skin response meter
Heart rate It is the number of contractions of the heart in a specific time span (the reference time is generally a minute). The degree of activity can affect the outcome and in laboratory conditions an exercise tolerance test (ETT) can be carried out.	UMLS C0018810	bpm (beats per minute) and can be a single measurement or a time series (at rest the following conditions are commonly acknowledged: Tachycardia >100 and Bradycardia <60)	chest strap or pulse oximeter
Interest This relates to the emotional and physical state related to a degree of interest detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG

Location Describes the position of the user/device when the measurement was collected. It should be considered as a parameter associated to any measure.	ISO 19141:2008 (moving features).	lat/lon	any sensor capable of recovering the geographic positions from different technologies (GPS, Wi-Fi, Bluetooth, etc.)
Mini mental state examination score (MMSE) The mini-mental state examination is a test used to evaluate cognitive impairments of a person. It is generally used to address dementia and assess the progression severity of the illness.	UMLS C1532985	integer between 0 and 30 (normal >25, moderate impairment 18-24,significant impairment <18)	the score id defined upon the completion of a questionnaire
Falling condition Reports the event a user has fallen.	UMLS C0085639	boolean	wearable accelerometers, smart sensing floor, smart video based surveillance, location based system, caregiver reports
Relaxation This relates to the emotional and physical state related to a degree of relaxation detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Respiratory rate The number of times an individual breathes within a given time, the lungs (respiration) usually per minute.	MESH D056152	bpm time series	specialized chest strap
Sleep duration Time spent sleeping in bed per day. The time spent awake at bed should not be taken into consideration.	UMLS C0424574	minutes	self-reported or using applications extracting information from accelerometers, EEG and more
Sleep quality Quality of the sleep detected using different sensors. It should be	SNOMED CT 248254009	float from 0 to 1	self-reported or using external sensors such as EEG monitors, accelerometers, bracelets, etc.

related with the duration of the sleep.			
Step count Number of steps taken during a specific time span (generally a day).	LOINC 55423-8	integer	pedometer or similar devices based on the use of data collected from accelerometers and GPS receivers
Stress levels This relates to the emotional and physical state related to a degree of stress detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Surprise This relates to the emotional and physical state related to a degree of surprise detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.	none	float between 0 and 1	portable EEG
Time spent alone Amount of time spent alone per day.	none	minutes	self-reported or acquired from smart location technologies
Total body water Amount of water content in the body.	UMLS C0429632	percentage	A smart scale is the simplest (yet least accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.

10.2.5. Possible example of use

10.2.5.1. Scenario 1

Giulia, a 71 years old woman, was diagnosed with chronic cardiac disease. The treatment plan consists of periodic sampling of blood to determine optimum drugs levels and ECG monitoring. Each result has to be shared with her family doctor and her cardiologist.

Moreover, her family doctor suggested she periodically participate in Nordic walking sessions that the local gym is organizing. Giulia agrees to follow the suggestion and brings with her a smartphone which, connected to a chest strap, measures the heart rate continuously during the session. The information is complemented with the

geographic information collected from the GPS module integrated in the smartphone. Giulia shares each session with her family doctor and instructor allowing them to monitor her progress and adapt her treatment plan accordingly.

10.2.5.2. Scenario 2

Luca is a university researcher who is studying the evolution of an ageing population across Europe. He is trying to correlate the costs in the different health care systems with the lifestyle and health problems in each country. Out of the many parameters he is interested in, there are:

- Physical activity
- Weight
- Sleep quality and duration

Through his university he is able to connect to an exposed service from which he can gather those parameters in an anonymised and aggregated manner. Data are collected from a vast number of users across Europe and are shared with Le in real time.

10.2.6. Conclusions and recommendations

This section presents the proposal for the definition of an O&M profile specifically designed to address Active and Healthy Aging scenarios and it explains the details of the envisioned profile. For each measure a definition is given together with a few examples of devices that are able to collect such measure. This profile is required to address specific scenarios that are otherwise not covered by other standards.

In early 2016, the current O&M profile was submitted to the Health DWG (Domain Working Group) of the Open Geospatial Consortium (OGC) which later resoluted on a recommendation to the Technical Committee of OGC for the creation of a dedicated Standard Working Group (SWG). The recommendation has been officially brought forward during the last OGC Technical Committee meetings in Taichung, Taiwan in December 2017. The TC has decided to put the creation of the SWG to electronic voting. The voting procedure will be started in early 2017.

11. Standardisation activity in privacy, security and eHealth domains at ETSI

As noted in *D.5.7 - Contributions to standardization*, the participation in ETSI (see http://www.etsi.org) in each of 2015 and 2016 has been to develop standards that address the broad interoperability requirements for privacy, security and eHealth across each of the domains of syntax, semantics and interconnectivity. The overall introduction to the domain of ETSI's work from D.5.7 still applies.

It is reinforced that UNCAP has no status in ETSI (or indeed in CEN/CENELEC) as UNCAP is not a legal body in its own right. In order to take work from UNCAP (or any other project in a similar state) to ETSI it has to be introduced by an ETSI member. For UNCAP, this role has been taken by partner C3L. When standards are published, they are necessarily anonymous with respect to the contributors (although the rapporteur and supporting members is known and visible on the ETSI work programme management tool). This means that whilst contributions may be made by C3L on behalf of UNCAP and in response to requirements coming from UNCAP, this is not made public in the final ETSI publication.

There is one exception in the Industry Specification Groups (ISG) where a Group Specification may indicate in an annex the names and affiliations (including acknowledging funding sources such as UNCAP) of the contributors. Where C3L is involved in the development of GSs, this acknowledgement has been given, similarly where UNCAP has lent specific input, e.g. in the eHEALTH work item, this has been explicitly referenced and acknowledged.

11.1. EP eHEALTH

As noted in *D.5.7 - Contributions to standardization,* a first work item was raised in early 2015 and has been in development across the meeting calendar of the group. As also noted in the 2015 report, the overall meeting attendance of EP eHEALTH has been somewhat disappointing and due to changes in circumstances a few meetings have had to be moved to later dates with an overall review expected in early 2016 with the ETSI Board. This review was held and the group was re-enabled. For this to continue, C3L has given titular support to the chair of the group (he now formally represents C3L in dealings with ETSI and acts for C3L as chair of ETSI EP eHEALTH). This formally means that C3L (in supporting UNCAP) also is named as the rapporteur of all the active work items in this group and its chair.

Development of the work items has been slower than ideal. In part this has been caused by the fact that meetings of ETSI bodies require that 4 actively contributing members take part in each meeting and can be recorded as contributing to the development of the work. This has not always been achieved (note that UNCAP only have one consortium member active in ETSI). A formal acceptance of the ETSI "Stable draft" status was achieved in November 2016. This will now be fed into work across other groups including CYBER (see 11.2), and oneM2M/smartM2M (see 11.5). The security issues of determining proof of integrity of large distributed and mutable structures are being developed to identify solutions in parallel in each of LI (see 11.3) and NVF (see 11.4).

11.2. TC CYBER

As noted in *D.5.7 - Contributions to standardization,* the work in TC CYBER addresses all aspects of security in ICT, thus it acts as a horizontal point of reference where detail

or explicit specialisation is not required. For UNCAP, work has been raised in a number of areas that are key to the long-term success of eHEALTH solutions based on UNCAP, thus addressing identity management and privacy verification. This is further supported by complimentary work in the areas of protection requirements for Critical Infrastructure (see definition below for its relevance to UNCAP and eHealth in general), and for examination of methods to achieve crypto-agility for long term protection of data from threats arising from Quantum Computing specifically and advances in attack capability over the lifetime of data. Data lifetimes in eHealth may be in the order of 10s of decades whereas cryptographic algorithms are considered "safe" for periods that rarely exceed 20 years.

To this end, C3L as UNCAP partner authored the first ETSI report on Quantum Computing Impact on security of ICT systems (now published as ETSI EG 203 310 in June 2016). The rationale for this in UNCAP is that it establishes the requirement for providing crypto-agility in any ICT based system. The work contained in EG 203 310 has been expanded in further work where UNCAP has been acknowledged (to date) as a supporter in ETSI's ISG QSC and their report number 4. In this case the eHealth domain has been used as a case study in determining the risk for deployment of quantum safe cryptography. This latter work is anticipated to be published very late in 2016 or early in 2017. The work in this domain (Quantum Cryptography) will then move into TC CYBER as a formal sub working group.

The other main achievement in 2016 for CYBER has been publication of ETSI TR 103 303, "Protection measures for ICT in the context of Critical Infrastructure". For UNCAP, the main aim here is to develop a longer term work programme that acknowledges the role of ICT in critical infrastructure and this includes eHealth as a major component. What this work has done is to lay the foundation for a new strategic topic in ETSI CYBER of Critical Infrastructure Protection (CIP), the work programme for which was endorsed in September 2016 with the acceptance of the first new work item in this domain (see Figure 10).

The key elements of the standardisation programme identified in D.5.7 are continuing. Thus work on identity management, identity protection, and on attribute based encryption within the framework of attribute based access control.

2016-11-09 **Work Programme** Version 2.3.3

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Details of 'DTS/CYBER-0024' Work Item

Work Item Reference	Type	STF	Technical Body in Charge	Standard Not Ready For Download
DTS/CYBER-0024	TS		CYBER	
Current Status (Click to View Full Schedule)	**Latest Version**	**Cover Date**	**Standstill**	**Creation Date**
TB adoption of WI (2016-09-23)				2016-09-13
Rapporteur	**Technical Officer**		**Harmonized Standard**	
Scott Cadzow	Sonia Compans		No	

Title	CYBER Critical Infrastrucure Metrics for Identification of CI
Scope and Field of Application	To prepare an ETSI TS that defines the metrics against the ICT elements to establish a system as critical infrastructure (CI). To address the following points from TR 103 303: -- Are the impacts of a successful attack on the CI understood? -- Have those impacts been used to properly categorize the CI? -- Have any dependencies relating to the CI been captured and analysed? -- Have any interdependencies relating to the CI been captured and subjected to further analysis? -- Can the owner of the CI and its location be quickly ascertained? -- How frequently will the categorization of this CI need to be reviewed? The TS will specify the metrics to address the above points in close co-operation with the CI authorities of both EU Member States and other jurisdictions (also needs to take account of trans-national CI facilities). The TS will be part 1 of a multi-part TS to be defined in due course but with the following structure: Part 1 – CI identification Part 2 – CI reporting and registration Part 3 – measures for CI integrity base point calculation Part 4 – measures for access control to protect CI
Supporting Organizations	VODAFONE Group Plc, Cadzow Communications, CESG, P3 communications GmbH, Attorney-General's Department, Yaana Limited

Keywords	Projects	Clusters	Frequencies	Mandates	Directives
CONFIDENTIALITY Critical Infrastructure SECURITY Security by default					

Official Journal	
Remarks	2016-09-23 COMPANS TB adoption of WI CYBER, see contribution CYBER(16)008016r2 2016-09-23 COMPANS WI proposed to TB CYBER, see contribution CYBER(16)008016r2 2016-09-22 CADZOW WI proposed to TB CYBER, see contribution CYBER(16)008016r1 2016-09-13 CADZOW WI proposed to TB CYBER, see contribution CYBER(16)008016

Figure 10: ETSI TC CYBER Work Programme.

One of the intentions for UNCAP's involvement in this new work item is to promote the CIP measures necessary to sustain a healthy living environment by defining metrics that establish health monitoring equipment of the types connected to the UNCAP box as CI elements and thus subject to the protections offered through CIP.

Work continues on the identity management and identity protection work items. Again these are key to overall protection of equipment in the domains represented in UNCAP. The approach being taken is to define a structured role or capability based identification model. This is based on the thought experiment of two parties in a crowded room needing to make a secure connection where they do not know each other in advance. They also do not actually know if they are in the room together. Thus, the parties have to find each other amongst a pool of adversaries all of whom has the opportunity to intercept the discovery protocol and to attempt a masquerade attack.

The approaches to protection being studied is addressed across 3 phases:

- **Step 1: certified class association:**

  This step requires that devices declare what they are (as opposed to who they are). In work to date we have strongly recommended an extended taxonomy (so a class like taxonomy with attributes of inheritance and with both attributes (data elements) and functions). Classically (i.e. in philosophy), the purpose of an ontology is to structure knowledge to answer questions such as:

  - What can be said to exist?
  - What is a thing?
  - Into what categories, if any, can we sort existing things?
  - What are the meanings of being?
  - What are the various modes of being of entities?

  In a modern/future world such as that represented in the use-cases of UNCAP, each device seeks a controller - in other words we have a "headless" device where the relevant drivers are in the controller. This is much like a network or PC connected printer where the driver and controls are external to the printer. The PC can search the network for a printer. Thus, it searches not for a specific named printer, but for an entity of type printer. Once found, it then establishes a relationship with it by naming it.

- **Step 2: Refinement of the obligation of trust protocol:**

  The obligation of trust protocol extends non-repudiation by defining the boundaries of the trust relationship that is mutually enforceable between 2 parties (and defines to what extent a 3rd party can be involved). The general assumption we are starting from is that the relying parties have no direct relationship but may share one or more 3rd parties (at several removes in some instances).

  In the privacy protection domain, taking account that privacy has to be reversible (for good citizen reasons), this means that ultimately all parties have to sign off to abide by their preferences prior to really exchanging data. The problem in IoT is that negotiation of trust (any negotiation) is expensive in time and processing which is particularly harming for low power devices.

  One avenue that may be worth exploring is adding in aspects of a recommender network, in particular collaborative filtering (working with other parties to determine the trust level), and to a lesser extent some aspects of content filtering (although content filtering actually exposes data that may be private and may lean too close to unauthorised content inspection).

- **Step 3: Normative standardisation:**

  This is the step that will occur in most depth after the meeting of TC CYBER in Sorrento and will be seen by making certain parts of the draft TSs normative and testable.

11.3. TC LI

There is no direct work for UNCAP being done in the LI group, whose remit is to ensure that law enforcement is able, with appropriate authorisation, to view data held in, or transmitted through, ICT systems. There is a challenge raised by M2M and IoT that encompasses the domain of UNCAP that needs to be made visible to this group and to

ensure that each side of the divide (law enforcement on one side and the M2M/IoT community on the other).

There is an increasing concern of IoT devices (these are at the core of UNCAP) being used in cyber-attacks and the role of law enforcement in denying access to such capability in IoT devices is becoming increasingly critical. There is a genuine concern that malicious actions against IoT devices could have Critical Infrastructure impacts. The need to keep abreast of this activity is a key element in addressing the security requirements in UNCAP and the privacy protection needs of those who use UNCAP.

11.4. ISG NFV

As noted in *D.5.7 - Contributions to standardization,* there is a need to keep abreast of the NFV group in order to address the management of virtualised functions across networks. This is an extension of the middleware model of UNCAP and is the model of choice of almost all network providers for future evolution and is also the model of choice that is redefining the "cloud" and many of the aaS technologies (where aaS is an acronym of "as a service" and this could be "Network function aaS", "Storage aaS", "Processing aaS", and so on). Activity started in response in this group addresses definition of the use cases, actors and stakeholders in deploying such virtualised networks.

11.5. smartM2M and oneM2M

smartM2M is the ETSI face of the global partnership project oneM2M whose scope includes the IoT and M2M aspects of eHealth. As was indicated in D.5.7, the primary role for UNCAP here was to assist in the development of a scripting language for privacy protection policy exchange. This is now being extended to address (alongside the work in CYBER) security protection of M2M/IoT objects.

11.6. Summary of ETSI activity

There is close interaction between all of the activities at ETSI. As previously stated, the root is the work in EP eHEALTH on use cases and this is extended through the work in each of the increasingly specialised bodies as it comes closer to a set of standards that are normative (as opposed to establishing boundaries and requirements for detail work). The effort in developing standards is not inconsiderable and requires attendance at both face-to-face and online meetings at a frequency of at least one meeting per week. To date (mid-November 2016) this has required 95 days in whole or in part to attending meetings and a further 90 or so days in development of input to these meetings (to the year end the expected days required in support of standards effort will be approximately 190 days).

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Contents

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OGC® O&M AHA profile (Active and Healthy Ageing profile) Discussion Paper

i. Abstract

This document provides a proposal for a new O&M (Observations and Measurements) profile focused on Active and Healthy Ageing, called AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile - Discussion Paper). This document introduces the overall need for such a profile and it discusses the measures which have been identified.

ii. Keywords

The following are keywords to be used by search engines and document catalogues.

ogc, o&m, profile, aha-ml, health

iii. Preface

Increasingly fast aging population is set to challenge health and care systems. Healthcare costs are set to increase with the future change in demographics that will cause healthcare cost to skyrocket with aging population. In some areas of the world, such as in most European countries, healthcare is the single most expensive budget cost in EU countries (often beyond 60% of total budget).

By 2060, age distribution in EU27 will change dramatically [2], with average age increasing from 40.4 to 47.9 and average life expectancy increasing from 76.7 o 84.6 (the largest increase planned in the most recent member states). By 2060, life expectancy at 65 will increase by 5 years (22.4 years for man and 25.6 for women) and the number of persons aged 80+ will triplicate from 23.7 to 62.4 mill. (EU27) bringing to a doubling of the "old-age dependency" factor.

In general terms, the effect of this aging trend will be amplified by a growth in population in EU27 countries that will expand until 2035, when it will reach 520.7 mill., to decrease to 505 mill. by 2060 (Eurostat). As a result of such demographics trend, public health expenditure in EU27 is set to grow from 7.2% of GDP in 2010 to 8.5% in 2060, making current healthcare system inappropriate and unsustainable. This situation is clearly calling for new care & assistance paradigms.

This paper shows the first results of the project UNCAP "Ubiquitous iNteroperable Care for Ageing People" (www.uncap.eu), funded by the Horizon 2020 programme of the European Commission. UNCAP is a pilot-centric innovation action driven by several high-tech SMEs that, with support from few research centres, aims to deliver a suite of innovative ready-to-be-marketed ICT products and services, based on consumer-grade

technologies, designed to help elderly people with cognitive impairments live a more independent life, based on use of open standards. To facilitate exchange of comprehensive data regarding psychophysical conditions, UNCAP has identified a set of comprehensive measurements which have been grouped within a convenient O&M profile.

iv. Contributors contact points

All questions regarding this document should be directed to the editor or the contributors:

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v. Revision history

Date	Release	Editor	Primary clauses modified	Description
2015-10-15	1	Leonardo Plotegher		First draft
2016-02-18	1.1	Fabio Roncato		Minor revision to include the comments made by Kym Watson and other members of the Health DWG
2016-02-18	1.2	Fabio Roncato		Minor change

1 Introduction

Given the ongoing demographic changes caused by ageing population, alternative approaches should be evaluated in order to overcome inevitably high healthcare costs, in terms of: pressure on pensions systems, ageing of the workforce and health and social care needs increase. UNCAP responds to this challenge through the development of an open ICT infrastructure that leverages on location and sensor-based technologies to create radically new paradigms for service care delivery,

UNCAP is delivering a suite of innovative ready-to-be-marketed ICT products and services, based on consumer-grade technologies, designed to help elderly people with cognitive impairments live a more independent life. The project, which started on January 2015, will last 3 years and it involves 23 partners from 9 countries. The solution that will be developed is composed of a cloud platform used to collect, store and analyze data coming from a number of different devices and sensors. Those sensors, most of which are wearable or portable, provide a large variety of measurements that have to be shared with the server in order to being processed.

The overall goal of the project is to:

- Improve **effectiveness** of the **health care processes** through more effective **evaluation processes** during the hospital-hospice recovery.
- Enhance home care treatment and prevention, in order to **delay cognitive impairment** of elderly and possibly **postpone the necessity of recovery** at hospitals or hospices.
- Support more **independent living** and improve **quality of life** and **dignity** of **cognitively impaired aging users** by helping them be more independent and for longer time.

From a technical standpoint this is being done through fostering of:

- **Openness**, through release of open specifications and open software components.
- **Scalability,** through use of cloud-centric approaches.
- **User friendliness**, ensuring compliance with all most common usability standards.
- **Privacy and security**, through attention to all related privacy and security aspects.
- **Interoperability and use of open standard,** through support for a range of open standards from the Geospatial Consortium (OGC) and beyond (e.g. HL7, Open mHealth [3]) for all its key services (e.g. position, sensors, building automation systems, clinical assessment, storage of clinical data etc.) allowing for future extensions in terms of hardware and software.

Starting from this outlook, UNCAP is proposing the definition of a new profile to extend the O&M conceptual model to directly report data related to the Active and Healthy Aging domain, thus called AHA-ML. The conceptual model may then be used to define

an XML (or JSON) schema to be used for the exchange of observations related to this specific domain.

2 References

[1] OGC and ISO 19156:2011, Geographic information - Observations and measurements, Abstract Specifications, 10-004r3

[2] Empirica and WRC (2005): Various Studies on Policy Implications of Demographic Changes in National and Community Policies. Final Report

[3] Open mHealth. Available online at: http://www.openmhealth.org/

[4] UNCAP Project Deliverable "D1.1 - Use cases description, system requirements and PIA/TRVA", http://www.uncap.eu/downloads

3 Conventions

3.1 Abbreviated terms

AHA	Active and Healty Ageing
BMI	Body Mass Index
ECG	Electrocardiography
EEG	Electroencephalogram
JSON	JavaScript Object Notation
LOINC	Logical Observation Identifiers Names and Codes
MMSE	Mini mental state examination score
MeSH	Medical Subject Headings
O&M	Observations and Measurements
SNOMED CT	SNOMED Clinical Terms
UMLS	Unified Medical Language System
XML	Extensible Markup Language

4 Why a specific O&M profile for active and healthy aging is needed

The need for an Active and Healthy Ageing domain-specific profile emerges from the requirement to integrate data and information across multiple systems and sensors. There is a large variety of data and concepts acquired from bio-sensing technologies which are in most cases in a proprietary format. Therefore it is necessary to identify the concepts shared in different applications and aggregate the semantics of commonly used features under a single definition.

The added value, with respect to other available standards (e.g. Open mHealth [3]), is the integration of the geographic information and the possibility – leveraging on SensorML – of aggregating the information about the specific sensor used and the description of the measurement procedure.

5 The overall approach

As part of the UNCAP project emerged the need to standardize the flow of measurements acquired from a large variety of sensors (both bio-sensors and not).

During the first year of the UNCAP project we have involved all technologies providers, those that are part of the consortium, in order to address and specifically identify the list of measures required by their technologies. To that list other measures were added in order to consider the possibility for future integration of new technologies.

Another input was collected from the pilot sites – addressing nursing homes and home care scenarios – by leveraging on the use cases collected during the preparation phase which involved clinical staff from 11 hospitals and nursing home from 6 different European Nations (http://www.uncap.eu/scenarios/). Clinicians and specialists described and highlighted a number of requirements to cover their specific needs. Those requirements were then translated into use cases and consequently in sensors to be adopted and relative measurements. An example of what we intend as possible use cases is visible in section 7.

We have then identified for each entry a reference to some publicly available vocabularies in order to provide a well-defined description of the intended measure. Each vocabulary addresses different objectives. Some examples of those that have been selected as reference for this work:

- Logical Observation Identifiers Names and Codes (LOINC) is a publicly available database specialized on the identification of medical laboratory observations (https://loinc.org/).
- Medical Subject Headings (MeSH) is a vocabulary that indexes biomedical scientific literature like books and articles (https://www.nlm.nih.gov/mesh/).
- Unified Medical Language System (UMLS) is a collection of many biomedical vocabularies (https://www.nlm.nih.gov/research/umls/).

The resulting set of measurements is composed of 35 entries that are reported in the following sections. Each measure will be also related and associated with the geographic position where it was collected.

As per the O&M standard [1], an observation is "*an act associated with a discrete time instant or period through which a number, term or other symbol is assigned to a phenomenon. The phenomenon is a property of an identifiable object, which is the feature of interest of the observation. The observation uses a procedure, which is often an instrument or sensor but may be a process chain, human observer, an algorithm, a computation or simulator. The key idea is that the observation result is an estimate of the*

value of some property of the feature of interest, and the other observation properties provide context or metadata to support evaluation, interpretation and use of the result."

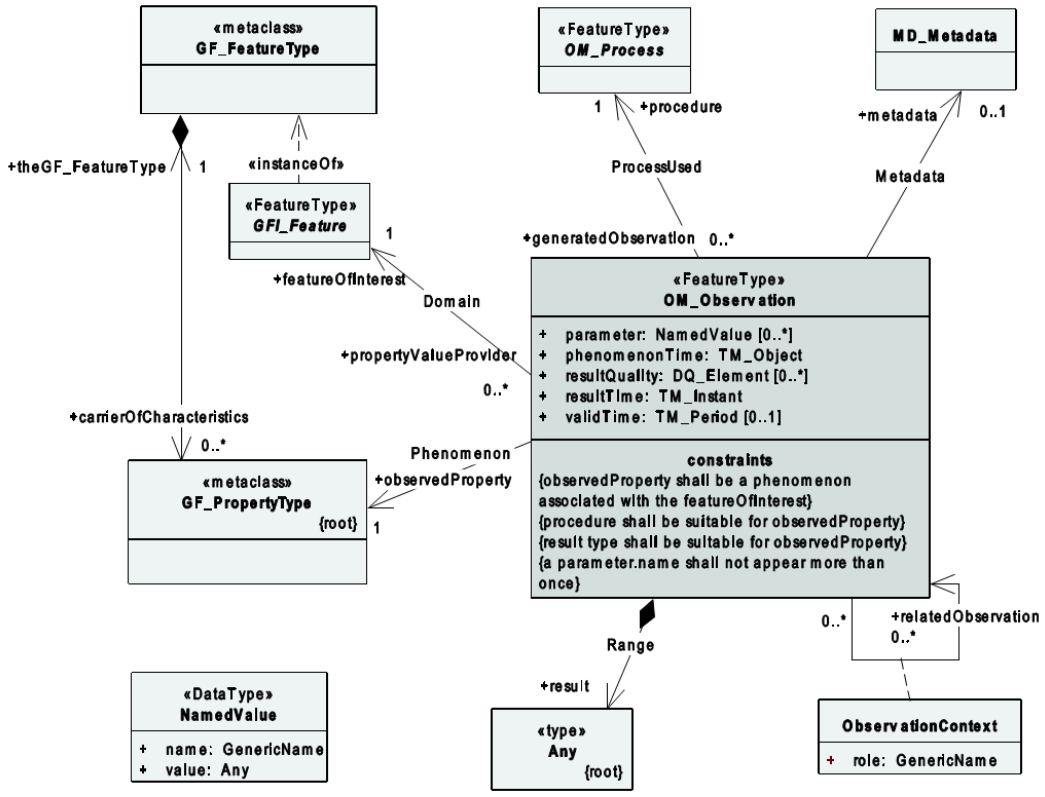

Figure 1: The basic Observation type

The attributes associated with an observation are:

- phenomenonTime: *describes the time that the result applies to the property of the feature-of-interest. This is often the time of interaction by a sampling procedure or observation procedure with a real-world feature*. In our case it may refer to the time a blood sample was collected from the patient.
- resultTime: *describes the time when the result became available, typically when the procedure associated with the observation was completed. For some observations, this is identical to the phenomenonTime*. Following the previous example it reports the time at which the blood sample was analyzed and the value of glucose was extracted.
- validTime: *describes the time period during which the result is intended to be used*. This is an optional attribute. Medical observations often have a period of validity after which the doctor says that a new observation or measurement is needed. This identifies the time after which the measurement should be repeated. A simple example could be the blood pressure or blood glucose levels.
- parameter: *shall describe an arbitrary event-specific parameter. This might be an environmental parameter, an instrument setting or input, or an event-specific*

sampling parameter that is not tightly bound to either the feature-of-interest or to the observation procedure. In this specific scenario this attribute can be used to define the location where body temperature is measured (e.g. mouth).

- resultQuality: *describes the quality of the result. This instance-specific description provides information about the quality of the measurement. This value is strongly related with the sensor adopted and the procedure followed during the acquisition*.

The procedure used during the observation will be described following the SensorML approach. New procedures that adopt different scales for the values or that use different technologies for the acquisition process produce obviously results that are different. Those variations should be taken into consideration and made available together with the observed value. Our proposal is to include this information in the description of the sensor according to SensorML. Taking as an example a simple blood test there is a variability that depends on the laboratory conducting the exam (variability that depends on various reason, the most important of which is the instrumentation used). For this reason also the ranges of some measurements (ranges in terms of "normal value") have not yet been defined. Ranges are correlated with the procedure implemented during acquisition and the type of technologies that will be used.

In the following figure are also depicted the possible interactions with other components/standards of OGC for the scenario envisioned:

- Sensor Observation Service (SOS) to manage and retrieve data and metadata from the registered devices by relaying on the O&M standard.
- Sensor Alert Service (SAS) to be used upon the detection of anomalies to send alerts to a specific user (e.g. a clinician or next of kin).
- Sensor Alert Service (SAS) to provide asynchronous notification of sensor events.
- SensorML to describe the sensor and the measurement process.

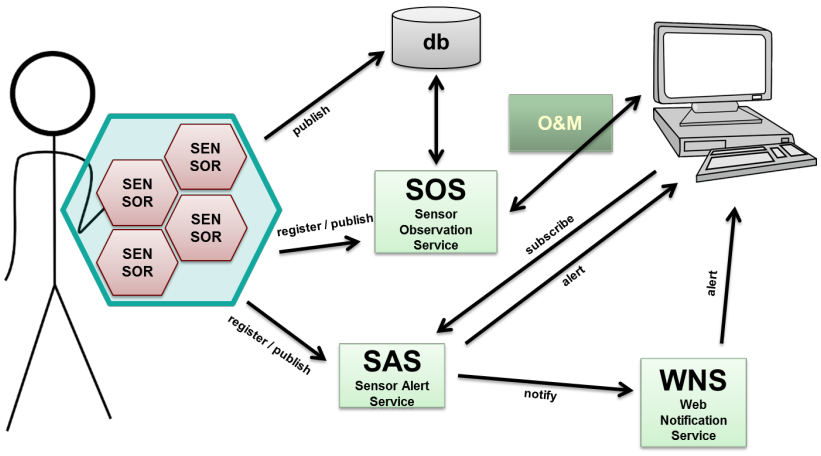

Figure 2: Possible integration with other OGC standards

The observation uses a procedure, which is often an instrument or sensor but may be a human observation in some cases. The observation could be the estimate value of some

property observed by a human. Observation properties provide context to support evaluation, interpretation and use of the result

6 The measurements

This section reports the measures identified as relevant to comprehensively represent the psychophysical condition of an elderly person. In general terms, we focused on those measurements required by the sensors/devices that will be integrated in the UNCAP platform while considering also further measurements which could be relevant in general terms. The following list is therefore non exhaustive and many other may be added in the future.

6.1 Affinity

This relates to the emotional state related to a degree of affinity detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.2 Average time in bed

It represents the numbers of hours that are spent at rest in general (at bed or sleeping in chairs) in an interval of 24hrs with a reference one day, measured in hours.

Vocabulary reference: none

Unit of measure: hours/day.

Sensor: many sensors can produce such information including, but not limited to: accelerometers, smart sensing floor, pressure sensors, solutions based on the use of video cameras and in general any device able to detect the position of the user.

6.3 Amount of physical exercise

Represents the time-spent by the user doing physical exercise (i.e. not at rest).

Vocabulary reference: none.

Unit of measure: hours/day.

Sensor: any sensor capable of monitoring the physical exercise (e.g. accelerometers, pedometers, indoor location based technology).

6.4 Attention

This relates to the emotional state related to a degree of attention detected by the system in the performing of a given task (e.g. a cognitive game). There is no specific normative data that could fit this value. This is evaluated during a specific task (e.g. a cognitive game) by the EEG or other devices able to acquire and extract such information. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.5 Basal metabolic rate

Represents the amount of energy (in calories) necessary to maintain the body functioning in normal healthy conditions (e.g. blood circulation, breathing, cell growth, etc.) when at rest.

Vocabulary reference: LOINC 50042-1

Unit of measure: kcal/day.

Sensor: usually basal metabolic rate is calculated manually, through the following formulas:

- for men: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(years) + 5$
- for women: $BMR = 10 * weight\ (kg) + 6.25 * height(cm) - 5 * age(years) - 161$

More precise measurements may be achieved through use of direct or indirect calorimetry in a laboratory environment.

6.6 Blood glucose

Levels of glucose found in the blood. It should be related with the time (e.g. on waking) and relation with meal.

Vocabulary reference: UMLS C0005802

Unit of measure: mmol/L (millimole/liter) or mg/dl

Sensor: glucometers.

6.7 Blood Oxygen Saturation

Represents the percentage of hemoglobin saturated with oxygen at the time of the measurement.

Vocabulary reference: UMLS C0523807

Unit of measure: Percentage time series (normal 95%-100%, low <90%, emergency <80%).

Sensor: Pulse oximeter.

6.8 Blood pressure

It is the pressure exerted by circulating blood upon the walls of blood vessels. It is defined as diastolic and systolic pressure of the blood. It is a compound measure that should report both values.

Vocabulary reference: UMLS C1271104

Unit of measure: mm Hg (low <90/60), normal from 90/60 to 140/80, high >140/90).

Sensor: blood pressure meter (sphygmomanometer).

6.9 Body fat percentage

Body fat is the amount of fat in the body, compared to everything else.

Vocabulary reference: UMLS C0518026

Unit of measure: percentage.

Sensor: a smart scale is the simplest (yet less accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.

6.10 Body height

Represents the distance from the bottom of the feet to the top of the head.

Vocabulary reference: UMLS C0005890

Unit of measure: cm.

Sensor: Statometer or self- reported.

6.11 Body mass index

Body Mass Index (BMI) is a measure of body fat based on height and weight that applies to adult men and women.

Vocabulary reference: UMLS C0578022

Unit of measure: kg/m^2.

Sensor: smart scale or self- reported.

6.12 Body temperature

Body temperature is a measure of the body's ability to generate and get rid of heat. It varies on the basis of the location where the measurement is taken (e.g. mouth, armpit, etc.). The location should be taken into consideration and added as a parameter.

Vocabulary reference: UMLS C0005903

Unit of measure: °C (normal 36.5–37.5 °C)

Sensor: thermometer.

6.13 Body weight

Measurement of the body mass weight.

Vocabulary reference: UMLS C0005910

Unit of measure: Kg (normal values depend on many factors such as age, gender and height).

Sensor: smart scale or self- reported.

6.14 Bone density

It represents the amount of mineral matter per square centimeter in bones.

Vocabulary reference: UMLS C0005938

Unit of measure: g/cm^2.

Sensor: smart scale. More accurate techniques are available but require a specialist and a laboratory environment.

6.15 Calories burned

Amount of calories burned during a specific physical activity.

Vocabulary reference: LOINC 41981-2

Unit of measure: kcal.

Sensor: it can be inferred from the type, duration and intensity of the physical activity.

6.16 Electroencephalography (EEG)

It is used to record electrical activity of the brain. A number (the number depends on the device) of – generally noninvasive – sensors is applied on the scalp to measure voltage variations generated by neurons' activity.

Vocabulary reference: UMLS C0234550

Unit of measure: voltage [V] time series. It is a time series of multiple measures depending on the number of electrodes applied.

Sensor: EEG device.

6.17 Engagement

This relates to the emotional state related to a degree of engagement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.18 Excitement

This relates to the emotional state related to a degree of excitement detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.19 Fatigue

This relates to the emotional and physical state related to a degree of fatigue detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.20 Focus

This relates to the emotional and physical state related to a degree of focus detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.21 Galvanic Skin Response

Galvanic Skin Response is the variation in electricity conductance when external or internal stimuli occur to the user. It can be clearly related with sweat.

Vocabulary reference: UMLS C0016989 - MESH D005712

Unit of measure: mS (Siemens).

Sensor: galvanic skin response meter.

6.22 Heart rate

It is the number of contractions of the heart in a time span (the reference time is generally a minute). Should be considered in relation with the activity carried during the measurement (at rest, walking, etc.).

Vocabulary reference: UMLS C0018810

Unit of measure: bpm (beats per minute) and can be a single measurement or a time series (at rest the following conditions are commonly acknowledged: Tachycardia >100 and Bradycardia <60).

Sensor: chest strap or pulse oximeter.

6.23 Interest

This relates to the emotional and physical state related to a degree of interest detected by the system in the performing of a given task (e.g. a cognitive game). There is not a specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.24 Location

Describes the position of the user/device when the measurement was collected. It should be considered as a parameter associated to any measure. It will be usually an indoor location but this can not be true for some cases.

Vocabulary reference: ISO 19141:2008 (moving features).

Unit of measure: lat/lon and floor number.

Sensor: any sensor capable of recovering the geographic positions from different technologies (GPS, Wi-Fi, Bluetooth, etc.).

6.25 Mini mental state examination score (MMSE)

The mini-mental state examination is a test used to evaluate cognitive impairments of a person. It is generally used to address dementia and assess the progression severity of the illness.

Vocabulary reference: UMLS C1532985

Unit of measure: integer between 0 and 30 (normal >25, moderate impairment 18-24, heavy impairment <18).

Sensor: the score id defined upon the completion of a questionnaire.

6.26 Falling condition

Reports the event a user has fallen.

Vocabulary reference: UMLS C0085639

Unit of measure: boolean.

Sensor: wearable accelerometers, smart sensing floor, smart video based surveillance, location based system, caregiver reports, …

6.27 Relaxation

This relates to the emotional and physical state related to a degree of relaxation detected by the system in the performance of a given task (e.g. a cognitive game). There is no

specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.28 Respiratory rate

The number of times an organism breathes with the lungs (respiration) per unit time, usually per minute.

Vocabulary reference: MESH D056152

Unit of measure: bpm time series.

Sensor: specialized chest strap

6.29 Sleep duration

Time spent sleeping in bed per day. The time spent awake in bed should not be taken into consideration. Sleep duration has been identified as a risk factor for cardiometabolic disease and mortality.

Vocabulary reference: UMLS C0424574

Unit of measure: minutes.

Sensor: self-reported or using applications extracting information from accelerometers, EEG and more.

6.30 Sleep quality

Quality of the sleep detected using different sensors. It should be related with the duration of the sleep.

Vocabulary reference: SNOMED CT 248254009

Unit of measure: float from 0 to 1.

Sensor: self-reported or using external sensors such as EEG monitors, accelerometers, bracelets, etc.

6.31 Step count

Number of steps taken during a time span (generally a day).

Vocabulary reference: LOINC 55423-8

Unit of measure: integer/time.

Sensor: pedometer or similar devices based on the use of data collected from accelerometers and GPS receivers.

6.32 Stress levels

This relates to the emotional and physical state related to a degree of stress detected by the system in the performing of a given task (e.g. a cognitive game). There is no specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.33 Surprise

This relates to the emotional and physical state related to a degree of surprise detected by the system in the performing of a given task (e.g. a cognitive game). There is no specific normative data that could fit this value. The condition during the measurements has been taken have to be explicitly defined.

Vocabulary reference: none.

Unit of measure: float between 0 and 1.

Sensor: portable EEG during a specific activity (e.g a cognitive game).

6.34 Time spent alone

Amount of time spent alone per day.

Vocabulary reference: none.

Unit of measure: minutes/day.

Sensor: self-reported or acquired from smart location technologies.

6.35 Total body water

Amount of water content in the body.

Vocabulary reference: UMLS C0429632

Unit of measure: percentage.

Sensor: a smart scale is the simplest (yet less accurate) sensor that can be used. More accurate techniques are available but require a specialist and a laboratory environment.

7 Possible examples of use

7.1 Scenario 1

Giulia, a 71 years old woman, was diagnosed a chronic cardiac disease. The treatment plan consists of periodical sampling of blood to determine drugs levels and ECG monitoring. Each analysis has to be shared with her family doctor and her cardiologist.

Moreover, her family doctor suggested her to periodically participate in nordic walking sessions that the local gym is organizing. Giulia agrees to follow the suggestion and brings with her a smartphone which, connected to a chest strap, measures the heart rate continuously during the session. The information is complemented with the geographic information collected from the GPS module integrated in the smartphone. Giulia shares each session with her family doctor and instructor in order for them to monitor her progresses and react accordingly to adapt the treatment.

7.2 Scenario 2

Luca is a university researcher who is studying the evolution of aging population across Europe. He is trying to correlate the costs in the different health care systems with the lifestyle and health problems in each country. Out of the many parameters he is interested into, there are:

- Physical activity
- Weight
- Sleep quality and duration

Through his university he is able to connect to an exposed service from which he can gather those parameters in an **anonymized** and aggregated manner. Data are collected from a vast number of users all across Europe and are shared with Luca in real time. All the data gathered are provided to Luca in way that will protect the people (elderly) privacy.

8 Conclusions and recommendations

This paper presents the proposal for the definition of an O&M profile specifically designed to address Active and Healthy Aging scenarios and it explains the details of the envisioned profile. For each measure a definition is given together with a few examples of devices that are able to collect such measure. This profile is required to address specific scenarios that are otherwise not covered by other standards.

The current O&M profile will be submitted to the Health DWG for further actions.

The technical platform of UNCAP (www.uncap.eu) will ensure full implementation of the profile hereby proposed.

