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D3.1

Definition of sensor components and communication strategy

Due date of deliverable:	M06 (30th June 2016)
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Lead Author:	Smartex
Lead partners:	Smartex, CERTH, Gruppo Sigla

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Change History

Ver.	Date	Status	Author (Beneficiary)	Description
0.1	22/04/16	draft	Smartex	Definition of report structure and partners' tasks
0.2	24/05/16	draft	Smartex	Integration of contribution from CERTH, SIGLA, SMARTEX and INSERM
0.3	08/06/16	draft	Smartex	Further integration of contributions and comments on top of draft0.2, plus introduction
0.4	17/06/16	draft	Smartex	Further integration of contributions, amendments and conclusions
1.0	20/06/16	final	Smartex	Final version for internal review
1.1	29/06/16	final	Smartex	Revision with small amendments integrating internal reviewers' comments
1.2	30/06/16	final	Smartex	Final revision

EXECUTIVE SUMMARY

On the basis of the outcomes of WP1 available at M06, i.e. deliverable D1.1 ("*Analysis of current practices*") and preliminary results of D1.2 ("*User requirements, use cases, UCD methodology and final protocols of evaluation studies*"), which have provided the consortium with user centred needs and systems requirements, the FrailSafe sensing components have been defined. The single elements composing the whole hardware architecture are:

- the wearable sensors (WWBS "Wearable WBan System"),
- a set of commercial devices with wireless connection to monitor strength, weight, blood pressure, arterial stiffness (dynamometers, scales, blood pressure monitor, Mobil-O-Graph),
- beacons, and
- mobile devices to be used:
  - as interactive platforms for data collection (questionnaires) and serious gaming, and
  - as sensor data gateways.

Starting from several possible technological options for each different sensor and hardware component, the devices described in the following pages have been selected, on the basis of the justifications explained hereinafter. These are the best selections the Consortium could achieve at this stage of development, but continuous cycles of investigations and analysis of results may lead in the future to modify some of the components if unexpected failure / limitations could be found in present choices or new hardware / firmware / software components are available during project development.

As anticipated in project DoA, a particular attention has been devoted to ensure maximum energy efficiency and to reduce energy consumption. For what concerns the mobile gateway, a special care is paid to reduce the battery drain caused by the power-hungry mobile/wifi radios commonly kept on continuously by frequent network requests. For what concerns more in general the energy saving, the adoption of a “cloud model”, architecture on which is based the system implemented by this project, should theoretically increase efficiency in the use of hardware, considering that hardware kept on-site by companies is often inefficient and underused.

WWBS central unit will be the hub of the inertial platforms that are spread on the wearable support: it will also elaborate some of the signals locally, transmitting only some processed data to the mobile device(s) and storing the raw ones for later (offline) analysis, unless raw data will be of need for real-time analysis and feedback. Data coming from the other sets of sensors (dynamometers, blood pressure holters and beacons) will use directly the mobile device(s) as gateway(s), while data from scales , due to the limited frequencies of collection of data, will be manually uploaded to the server.

A manufacturing plan will be designed and developed in future project activities ranking the different approaches that are essential for the whole concept like low energy power supply system, system behaviour in case of system failure, security aspects and performance issues, telecommunication aspects, ergonomics and usability: this deliverable shows the approach planned at this stage of architecture and technical development.

DOCUMENT INFORMATION

Contract Number:	H2020-PHC–690140	**Acronym:**	FRAILSAFE
Full title	Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions		
Project URL	http://frailsafe-project.eu/		
EU Project officer	Mr. Ramón Sanmartín Sola		

Deliverable number:	3.1	**Title:**	Definition of sensor components and communication strategy
Work package number:	3	**Title:**	Smart sensing, data acquisition and signal processing

Date of delivery	**Contractual**	**30/06/2016 (M06)**	**Actual**	30/06/2016
Status	Draft ☐		Final ☒	
Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public ☒	Consortium ☐		
Abstract (for dissemination)	This deliverable reports on the choices done in the selection of sensors for data collection and management. It uses results coming from the analyses of current practices (Task 1.1) and also preliminary results of the analyses of user requirements, user centred design (UCD) and use cases (Task 1.2). Sensors have been selected in a way to extend many standard measurements performed for frailty analysis and classification, but in a way that data can be collected and monitored outside hospital and without direct clinical control, in real life conditions, to evaluate new paradigms. To reach this goal some wireless solutions have been purchased or adapted to have long term monitoring (spot or continuous) of parameters from the heart (including blood pressure) and breathing, posture, walking and physical activities, strength, cognitive reaction or limitation, writing analysis and social inclusion.			
Keywords	frailty, frailty classification, wearable solutions, wireless communication, physiological monitoring, cognitive monitoring, older adults social inclusion, sarcopenia			

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TABLE OF CONTENTS

1. INTRODUCTION

This document reports the work the Consortium has performed in order to select the sensors useful to perform a long term monitoring of several parameters in older adults. As this monitoring activity foresees not only the collection of data coming from physiological signals and clinical and personal parameters (heart, respiration, posture and activity, weight) but also cognitive state of the end users, the word "sensor" must be accepted with a wider meaning, including also mobile devices.

Chapter 2 will discuss the parameters that the FrailSafe project will try to monitor in "natural" conditions (so outside hospitals) and in long term scenarios, when possible and reasonable. Sensors in this chapters are partly condensed in one innovative device (a set of garments for ECG, respiration, posture and activity monitoring and classification), otherwise are commercial devices for (wireless) blood pressure measurement, pulse wave, weight, indoor positioning.

Chapter 3 describes uses and technical specifications of mobile devices (smartphones and tablets) selected for their activity of sensor (GPS monitoring of outdoor activity), data collectors (from sensors described in Chapter 2 and for analysis of written test and social life) and as gateways.

Finally, a fourth Chapter has been included to introduce some aspects related to security and data protection issues.

2. SENSORS

The following parameters will be monitored with the final sensor sets within the FrailSafe project:

Parameter	Monitoring frequency (for FrailSafe project)
Weight	A few times within project timeframe
Arterial stiffness	A few times within project timeframe
Blood Pressure	Several times per day
Strength	Once a day (plus use during serious games)
Electrocardiogram (ECG)	Continuously, whenever possible, data analysis off line
Heart rate	Continuously, whenever possible, real time data analysis
Respiration signal	Continuously, whenever possible, data analysis off line
Respiration rate	Continuously, whenever possible, real time data analysis
Posture	Continuously, whenever possible, real time and offline data analysis
Activity classification	Continuously, whenever possible, real time and offline data analysis
User localisation at home	Continuously, whenever possible, real time and offline data analysis

The parameters showed in the table above were selected on the basis of present state-of-the-art definition and studies on frailty [1-14]. Selection was performed having as a criterion also the possibility to have those data monitored remotely at user's home, with the use of available technologies (in some cases adapted to this specific health condition), possibly with a limited need of interaction with specialized personnel, in order to have a data collection as genuine as possible. With the exception of the first four parameters, data will be collected using a wearable device which should enable long-term monitoring, depending on user's acceptability, monitoring protocols and technical needs (like battery charging, download of recorded data, etc.). The goal would be to have long, continuous recording, which can enable FrailSafe consortium to find new paradigms for frailty classification, monitoring and caring.

The first two parameters will be monitored in hospitals. These monitoring activities are limited in time (spot measurements). All the other parameters need to be monitored at home or outdoor, surely not in controlled environments. To collect all these data, FrailSafe will select some different solutions among the possible alternatives showed in the following pages.

2.1. WWBS

WWBS (Wearable WBan System) is a new wearable solution that takes its origin from an already developed product of Smartex, WWS (Wearable Wellness System)[1], with a further integration of some Inertial Measurement Units (IMUs) in order to have information of higher quality with regards to movement analysis. Together with data on movement, posture and physical activity it will record also data from the heart (a full ECG lead, similar to standard Einthoven DI lead) and respiration. Several academic papers have been published to show sensors and device reliability and comfort, together with system validation, also in clinical cases [15-23].

2.1.1. WWBS components

WWBS will be used for long term monitoring of several physiological parameters, together with data from some IMUs to be used to better classify and parameterise user's movements and physical activity.

Physiological parameters will be monitored using conductive fibres (produced by fibre producers on Smartex specifications) that will be knitted together with standard fibres to form integrated areas working as electrodes for ECG monitoring and as a piezoresistive sensor (i.e. a transducer that converts the stretch of the fabric due to thorax enlargement and restriction to an electrical signal) for respiration monitoring.

ECG raw signals will be analysed by the processor integrated in the electronic device and several parameters will be extracted: heart rate (**HR**), distance from consecutive QRS peak[2] points (**RR**), ECG quality signal. Raw data and processed parameter will be saved on an on-board micro-SD card, while processed parameters can be transmitted to gateway. From raw data also an analysis of Heart Rate Variability can be performed off-line.

[1] http://smartex.it/index.php/en/products/wearable-wellness-system
[2] https://en.wikipedia.org/wiki/QRS_complex

The same will happen to **respiratory** raw signals: the change in electrical resistance of the piezoresistive sensor will be measured and a respiration rate will be calculated (**BR**) and delivered, if requested, to the gateway, while raw data will be saved.

Design of this unit is still under evaluation, as the vest developed for present product (WWS) is not thought for people with reduced mobility of arms. Comfortable solutions have been discussed and will be further studied together with clinical partners and end-users under task 1.2 as part of the User Centred Design (UCD) activity. Final solutions will be showed in D3.2.

Regarding **movement and posture analysis**, there will be the need to monitor position and movement of the trunk and of all limbs, upper and lower. In order to simplify the design of the garments, the quality of the recordings and the comfort of the user, the system will be split in two or more components, a vest/T-shirt that will monitor trunk and upper limbs and a pair of trousers or other solutions for lower limbs monitoring.

There are already some publications on the analysis of gait as a methodology for Frailty classification, where IMUs have been used, fixing them to lower limbs and lower back during very short sessions (5-meter walk or 15 seconds) in controlled environments. Some other standard tests for mobility assessment have been shown to be strong predictors of frailty: for instance the Timed Up and Go (TUG) test, developed at the end of the last century, can predict a descent into frailty, or the Five-times-sit-to-stand (FTSS) test, as assessment for fall risk. Reviewing the literature, anyway, some doubts are raised about TUG efficacy in prediction of fall and also in frailty classification, mainly due to the simplification related to use a single parameter (total time of test) as discriminating factor. For this reason, many publications have been produced on results of the same tests performed with the user wearing accelerometers or IMUs, called iTUG (instrumented) or ETUG (extended), with sensors usually placed at waist or chest, but also at shanks, thighs, lower back and sternum. Again, all measurements taken in these studies were very short and performed in laboratories, and the success in fall prediction was calculated comparing measurements with results from questionnaires collected in the months following the testing phase [24-36].

A different approach is offered with the possibility to monitor people at home for a full day with the sensor usually placed again on the trunk [24][37]: in this case the physical activity, in terms of time spent sitting vs. walking and number of changes of position (sitting/standing and vice versa) were the main indicators of presence (or absence) of the frailty condition.

Both approaches will be studied in order to collect as many data as possible at the beginning, and to select the best option(s) for the final evaluation phase. Other publications on gait reconstruction and analysis will be taken into account to develop and verify different sensors positions and number (some of them report the use of sensors to monitor patient suffering of other diseases, like Parkinson’s, dementia, etc.), and also monitoring of other fine movements that can be a clue for frailty onset [38-45]. Finally, many publications strongly suggest to extend the obtained results to as many users as possible, to reach stronger statistical evidence [29][34][36].

Inertial measurement units: several IMUs are available at present on the market, but only a few have on-board ability (i.e. microprocessors) to calculate quaternions[3] from raw data. This option is considered at present important in order to reduce the load of streamed data and so saving battery consumption; some devices have been listed and described in Annex I, Section 1. In any case some IMUs without microprocessor have been anyway selected and listed in Annex I, section 2 of this report and one of them will be integrated in the PCB of the WWBS in order to optimise cost and dimension of WWBS electronic device: at present tests have been performed on MPU9250 by "Invensense"[4].

Among those with chip on-board (and algorithms for quaternion calculation) the following three have been selected as solutions eligible for FrailSafe project:

- BNO055 by "Bosch Sensortec"[5]
- UM7-LT Orientation Sensor by " CH Robotics"[6]

[3] https://en.wikipedia.org/wiki/Quaternion
[4] https://www.invensense.com/products/motion-tracking/9-axis/mpu-9250/
[5] https://www.bosch-sensortec.com/bst/products/all_products/bno055

- FMT1030 by "Fairchild"[7]

The FrailSafe consortium is more oriented to the purchase of the CH Robotics or the Fairchild IMUs because, even if they are more expensive (130 USD/Euro vs. 40) they have a buffer for data too, which can reduce the risk of missing delivery of data. All solutions are wired, in agreement with the communication strategy below.

On the basis of the request of the PO (after the conclusion of the phone review organised to take a decision on a query for contract amendment) the purchase of a **commercial product** was requested in order to start the collection of data coming from a set of IMUs: this device will be used to provide CERTH with data useful for algorithm development in the project phases preceding WWBSs production and delivery. At the time of preparation of this report a final choice has not been taken, as selected producers are slow in providing FrailSafe consortium with details on technical specifications and prices. At present the following producers have been selected and contacted:

Company System	**Price**	**Access to data**	**Battery life** (operating / standby)
Xsens (MTw Development Kit Lite)[8]	▪ **550€ / Sensor** ▪ **+ 450€ / USB Dongle** Compatible with Windows and Linux.	▪ Communicates through proprietary USB dongle with Windows / Linux PC. ▪ C++ wrapper ▪ Matlab Wrapper	3.5h / 90h
STT Systems (STT-IWS)[9]	▪ **425€ / Sensor** ▪ **+ Cost of accessories (Straps,…)** Compatible with Windows or Android.	▪ Streams via standard Wi-Fi or Bluetooth.	*Pending reply*
APDM (Opal)[10]	▪ **4.000$ / System** Includes 2 sensors.	▪ Streams data to local PC via proprietary wireless protocol through a proprietary hub. ▪ They offer an SKD but haven't been able to ensure it is suitable and if it really offers access to the data we need in real time.	8h / 50h
X-IO (X-IMU)[11]	▪ **309$ / Sensor** ▪ **+ 5$ for Velcro strap**	▪ Streams via Bluetooth ▪ C++ API	*Pending reply*

Any of the above listed devices, independently from battery duration, have not been thought for long term monitoring sessions, but attempts will be done in order to collect also this type of information.

2.1.2. WWBS communication strategy

The best option for long term monitoring, in order to simplify charging operation to the subjects of this work (i.e. older adults) when at home, would be to have just a couple of devices (one per garment), and not to have 5-8 independent units. This would also simplify

[6] https://www.chrobotics.com/shop/um7-lt-orientation-sensor
[7] https://www.fairchildsemi.com/products/sensors/mems-motion-sensors/motion-tracking-module/FMT1030.html
[8] https://www.xsens.com/products/mtw-development-kit-lite/
[9] http://www.stt-systems.com/products/inertial-motion-capture/stt-iws/
[10] http://www.apdm.com/wearable-sensors/
[11] http://www.x-io.co.uk/category/open-source/x-imu-open-source/

data synchronisation. For this reason, the best communication strategy would be to centralise data from all IMUs placed on the limbs to a central unit using a cable communication, instead of wireless, so that all IMUs are powered by the central unit, and limiting the wireless communication to 2 to 3 channels only (limiting power consumption required by wireless transmission of large quantities of data). This strategy is desirable but susceptible to changes depending to feedback from the results of other (technical and clinical) partners' activities. WWBS will communicate wireless to the smartphone using Bluetooth technology protocol 2.1; due to the amount of data coming from IMUs, it is not possible to use the low energy version (4.0 aka BLE). Security of data will be based on Bluetooth encryption protocol.

2.1.3. WWBS ergonomics, usability and safety

Regarding the design of the garments, a compromise must be found among the following needs:

- length of monitoring time: the goal is to have monitoring periods as long as possible, but obviously this can generate conflicts with needs or simply be useless;
- comfort of the garments: users must find them nice, useful, easy to wear and accept the idea to wear them for long periods, in cold and hot weather, taking also into account their age and limitation in mobility;
- all sensors, for different reasons, must stay in tight contact with the body, so the garments cannot be loose: this functional requirement clashes with user comfort, mainly in long term monitoring;
- electronic devices must be detachable or water-proof, to allow garment washing;
- electronic components must be charged from time to time, so this operation must be easy to perform.

In the frame of task 1.2 Mood Boards have been prepared by Smartex and delivered to clinical partners in order to have a feedback from clinicians, carers and end users on materials, wearability, thermal comfort, user needs and habits, etc.

In any case all materials, both fabric and device case, will be checked for their use with human beings, using only materials certified for long-term contact to human skin. Specifically, all textile material will be Oeko-Tex[12] certified when possible, otherwise independent tests will be performed to prevent any risk.

2.2. Dynamometers

2.2.1. Reasons to prefer the use of dynamometers instead of the ErgoGlove for project purpose

According to FrailSafe GA (page 20 of Annex 1, Description of Task 3.2) *"[...] The wearable platform will be completed by a system for hand grip strength estimation. A careful investigation will be conducted on state of the art to choose the solution that can best fit project requirements. Digital dynamometer or more versatile solution (e.g., ErgoGlove by Hoggan) will be investigated to execute force evaluation and testing and measure overall hand grip strength. [...]*".

During proposal writing and later on during the GA production, both clinical and technological partners thought that the use of the ErgoGlove[13] produced by Hoggan would provide data of

[12] https://www.oeko-tex.com/en/business/business_home/business_home.xhtml
[13] http://www.hogganhealth.net/ergoglove.php

great benefit for project success, as it is the only device that can generate a pattern of data enabling single finger monitoring. So the consortium was fascinated by the fact that a very refined analysis could be included into frailty description, something really beyond the state of the art. This aspect convinced the whole consortium to put aside a large budget for their purchase.

At the kick-off meeting we understood that this type of information was really important and innovative, but not so important for clinicians as the long term monitoring of strength evolution: ErgoGlove devices must be calibrated every time they are switched on, and they provide relative values of strength, on the base of the calibration performed. This information is very useful to understand the way finger are separately used during hand grip or in monitoring finger use during different hand activities, but absolute strength values cannot be obtained, so comparison between values recorded in two different sessions is not possible.

For this reason, the consortium took the decision to look for dynamometers, that can provide the study with absolute values, and Smartex was asked to look for devices available on the market. This decision of the consortium was subject of a phone review with PO and reviewers and it was accepted.

2.2.2. Selection of Dynamometers

There are many clinical dynamometers off-the shelf, but, as one of the main options was the possibility to upload automatically the monitored data and to make the device interact with tablets to allow their use in serious games, the search was immediately reduced to a few ones able to communicate their results wirelessly.
As it can be seen in Annex II, which contains technical specifications, there are just a few that use Wi-Fi or Bluetooth protocols, and most of them are not open, i.e. data can be visualised and saved only in proprietary devices (JTECH) or through extra modules, that make their price not competitive and/or create an unnecessary further step of complexity (Biopac and Biometrics). Furthermore, the impossibility to have full access to data would make their use in the interaction with PC and tablets during gaming impossible.
So Smartex requested medical and technical partners to take a decision between only two devices, the Neulog Hand Dynamometer[14] and the Hoggan MicroFet HandGrip[15]. Their price is similar (below € 500 for a device covering project requirements) and also accuracy, they differ in range but they are both within clinical interest. The consortium finally decided for the Hoggan product for the following three reasons:

1. it transmits data using Bluetooth;
2. compared to the Neulog product, its design is more focused on use in the health care professional environment, while the other is more academics oriented;
3. it switches off automatically if not used (a nice feature to save battery).

[14] https://neulog.com/Downloads/NeuLog_User_Guide_Ver_6_11b.pdf
[15] http://www.hogganhealth.net/grip.php

Figure 1: Hoggan MicroFet HandGrip.[16]

All these issues are really important aspects to be taken into account for a device that must be robust and used at home by final users alone and not in a protected environment (like a laboratory).

2.3. Scales

Weight loss is one of the main Frailty criteria. The assessment of Body weight, Body Mass Index (BMI) and Body Fat is important in the follow up of elderly subjects for frailty. The FORA scale[17] measures body weight, BMI, body fat and stores measurement results with the corresponding personal profile number in the scale memory. Results in memory can be transmitted to the personal computer by either cable or wireless connection to smartphones. This allows to transmit and review the measurement data on a computer for up to 135 sets of measurement results.

2.4. Blood Pressure monitoring device

It has been recognized for more than 50 years that Self Blood Pressure Monitoring (SBPM) readings at home are lower than those recorded by a doctor. The discrepancy between pressures recorded at home and in the clinic, which has been confirmed repeatedly, is primarily a result of the white-coat effect, and is present regardless of either patients or their relatives measure the blood pressure.
European Society of Hypertension (ESH) is strongly advocating a regimen of measuring blood pressure 3 times in the morning and 3 in the evening for a period of 5 consecutive days.
With FORA's advanced blood pressure monitoring technology and different modes (auscultatory, average) both patients and doctors can obtain triplicate readings with the ease of pressing one button. The FORA application also allows the Bluetooth-enabled FORA devices to transmit the results instantly to iOS and Android devices and expand health management capabilities.
The monitor has also the capability to detect irregular heart rhythm (IRB technology).
There are several wireless scales and blood pressure monitoring devices on the market; FORA products were selected for the following reasons:

- FORA blood pressure measuring devices[18] and weight scales are clinically validated.

[16] Picture courtesy of Hoggan Health Industries
[17] http://www.foracare.com/weightscale-W310.html
[18] http://www.foracare.ch/Meter-P30plus.html

- FORACARE company provides customers with an SDK which allows FrailSafe system to develop its own mobile application and transfer data from the devices directly to FrailSafe portal.
- The BP device has only 3 big buttons, so it is easy to be used by old people.
- Storage conditions:-20°C to 60°C (-4°F to 140°F), relative humidity below 95%
- BP devices could be used also in auscultatory mode.

Last but not least, FORA made a very good commercial offer for the purchase of 24 blood pressure measuring devices and 6 weight scales: total value of the offer (including freight via courier) was € 240.

2.5. Pulse waves monitoring device

Age is the main clinical determinant of large artery stiffness. Central arteries stiffen progressively with age, whereas peripheral muscular arteries change little with age. A number of clinical studies have analyzed the effects of age on aortic stiffness. Increase of central artery stiffness with age is responsible for earlier wave reflections and changes in pressure wave contours. The stiffening of aorta and other central arteries is a potential risk factor for increased cardiovascular morbidity and mortality. Arterial stiffening with aging is accompanied by an elevation in systolic blood pressure (SBP) and pulse pressure (PP). Although arterial stiffening with age is a common situation, it has now been confirmed that older subjects with increased arterial stiffness and elevated PP have higher cardiovascular morbidity and mortality. Increase in aortic stiffness with age occurs gradually and continuously, similarly for men and women. Although large artery stiffness increases with age independently of the presence of cardiovascular risk factors or other associated conditions, the extent of this increase may depend on several environmental or genetic factors.

Mobil-O-Graph Agedio B900[19] measures the vascular age non-invasively with a simple method using a blood pressure cuff fitted on the upper arm, with a method that is clinically validated. The measurement duration is about 5 minutes.

This product has been selected by FrailSafe consortium as it is the unique connected device on the market that estimates the arterial stiffness (Pulse Wave Velocity) and the central Blood Pressure without tonometer probe and because the manufacturer claimed to be ready to adapt the settings of the device to project requirements, like automatic trigger of measurements. Furthermore, a discount superior to 50% of initial price has been obtained.

2.6. Indoor monitoring sensors

Within FrailSafe, indoor monitoring of the older persons will be carried out using Bluetooth beacons. Bluetooth beacons are small-sized devices which continuously emit a radio signal with a unique ID, using the Bluetooth Low Energy (BLE, 4.0) communication protocol. Once a BLE-compatible device, such as a smartphone or tablet, enters the proximity of a beacon, it can read its unique ID, as well as use the beacon signal strength in order to approximately deduce the distance between the device and the beacon. If several beacons are placed in an area, a smartphone or tablet device moving in that area can receive notifications from each beacon whenever it enters its proximity. Furthermore, if the coordinates of each beacon in this area are known, the distance measurements from the device to all beacons can be combined in order to estimate the coordinates of the device in this area. Applications of beacons include guiding and advertising systems in supermarkets, airports and similar facilities, informing people about their current position and providing directions. Examples of beacons can be seen in Figure 2.

[19] http://www.iem.de/en/products/mobil-o-graph.html

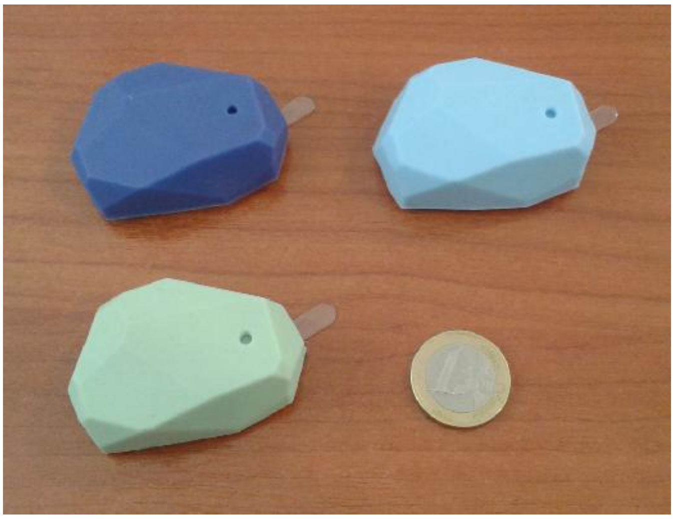

Figure 2: A few representative beacons, from Estimote™.

2.6.1. Operations

According to the description of Task 2.3 in the DoA, a part of the lifestyle information of older people will be acquired through physical activity monitoring with tracking systems. In this respect, an indoor localization system using beacons will be developed, in order to monitor the people's movements and habits within their homes. In particular, beacons will be placed in places within the home which are important to be monitored, such as the bedroom and the bathroom. The older person will carry a smartphone running the localization application: an alternative could have been to wear a wearable BLE-compatible device, such as a smartwatch, but will not be implemented due to cost limitations (FrailSafe consortium might consider the opportunity to purchase a few ones to test this option, anyway). As the person moves in the home, the application will regularly log the ID of the nearest beacon, as well as the distances from all beacons. The data collected can be used to extract two types of information:

- Room-level position: this is the information about which room the person is in at any time.
- Exact position: this is the information about the absolute coordinates of the person in the whole area. The coordinates regard only the position of the person in a fixed coordinate system, disregarding the direction of the person (e.g. it cannot detect if the person is in vertical or horizontal position).

Further processing of these kinds of data can reveal activity-related information, such as which rooms the person spends the most time in, how much time he/she spends in each room, frequent patterns of movements, etc.

Independently from person locationing, beacons can also provide information on room temperature, that will be uploaded to server.

With regard to the operational characteristics of beacon technology, they closely resemble RFID (Radio-frequency identification[20]) technology, where tags can be placed at various positions or on various objects and their unique IDs can be read by an approaching RFID reader. The most prominent characteristic of RFID tags is that they can be completely passive, i.e. requiring no internal energy source, acquiring the energy needed for the transmission of the ID from the RF field of the approaching reader. However, beacons were preferred over RFID for the following reasons:

- Passive RFID tags usually operate on very small distances from the reader, some centimetres, up to one or two meters. However, within a home, larger distances need

[20] https://en.wikipedia.org/wiki/Radio-frequency_identification

also to be considered. In order to achieve communication over larger distances, active RFID tags need to be used, i.e. ones containing a battery. Bluetooth beacons also contain a battery and can operate adequately in a range up to 20m, thus covering the needs for indoor monitoring, while their signal can reach even larger distances, up to 70m.

- Using RFID technology requires a dedicated device for reading the IDs of the RFID tags, i.e. the RFID reader. Such equipment would need to be bought and carried by the older person while moving inside the home. Beacons have the advantage that they can be detected by common devices, such as smartphones and tablets, as well as by wearable devices, such as smartwatches, which may also be used for other purposes within the context of FrailSafe.

2.6.2. Telecommunication aspects

The beacons that will be used in FrailSafe communicate using the Bluetooth Low Energy protocol (BLE)[21], also known as Bluetooth Smart. BLE uses the same frequency range as the classic Bluetooth protocol, i.e. the 2.400 GHz - 2.4835 GHz ISM band. However, BLE uses fewer channels, each having the double bandwidth compared to classic Bluetooth. The data are transmitted using Gaussian frequency shift modulation, achieving a 1Mbit/sec bit rate, with a maximum transmit power of 10mW. In order to avoid collisions and interferences with other devices operating in the same band, BLE uses random frequency hopping.

BLE-compatible devices utilize the Generic Attribute Profile (GATT), which is a hierarchical data structure encapsulating the necessary information to be transferred, such as measurement values, times and service IDs. BLE communication is performed in a client-server model, where the client, e.g. a smartphone, sends GATT requests to the server, e.g. a temperature sensor, which in turn sends responses back to the client.

2.6.3. Performance issues

The operational range of the beacons can reach up to 70m. However, the accuracy of the measurement, i.e. the confidence regarding the signal strength power, used for the estimation of distance, is decreased as the handheld device moves away from the beacon. However, the environments in which the beacon-based localization will be deployed are patient's houses, where the distances between the handheld devices and the beacons do not exceed a few meters. In such small distances, the distance measurement is rather accurate, especially for the needs of FrailSafe.

However, the signal of a beacon is usually subject to noise by interferences with the environment, leading to fluctuating measurements of distance, even if the handheld device does not move relative to the beacon. This makes proper positioning of the beacons necessary. Beacons are by design very unlikely to interfere with other beacons, cell phones or with the other Bluetooth devices of the FrailSafe vest. Even if they interfere, the interference does not last, due to the frequency hopping feature of the Bluetooth protocol, so this will not cause significant errors in the measurements. However, beacons highly interfere with metals and water, and they can interfere with microwaves. In order to achieve as accurate measurements as possible, metallic objects or water between the beacons and the person carrying the smartphone should be kept as few as possible, e.g. if the patient's bed has any metallic frames under the mattress, it would be best not to put the beacon under the bed, but rather on the wall. Beacons should also be placed away from microwave ovens, if possible, although this is not so strict, since it is not expected that the ovens are active for a long time each day.

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[21] Specification of the Bluetooth system, Covered Core package version 4.2, Dec 02, 2014, https://www.bluetooth.org/DocMan/handlers/DownloadDoc.ashx?doc_id=286439&_ga=1.3481266.381487544.1463385000

2.6.4. Ergonomics and usability

An important factor that guided the selection of beacon technology for indoor localization is their easy installation in the target areas. One just needs to place a beacon in a place that needs to be monitored, e.g. stick it on a wall or put it under the bed. The fact that no further equipment, such as cables, etc., needs to be installed makes them easy to be installed in a person's home and uninstalled when the monitoring period is over. Furthermore, the fact that no configuration of the beacons or the application is needed at the time of installation (apart from a possible recording of the coordinates of each beacon, if the exact person location is needed) is important, since the installation will be performed by clinical personnel with limited technical knowledge.

In order for a person to be localized within a beacon-equipped environment, the person needs to carry a BLE-compatible device, running an operating system capable of reading the beacon IDs. Smartphones, tablets and smartwatches are such devices. However, the device should be easy to carry without distracting the moving person from performing everyday activities. This makes smartwatches the best option, while excluding tablets. Smartphones can also be used, if they are placed e.g. in a pocket, so that they do not cause any distraction. Within the FrailSafe project, smartphones will be used for communicating with the beacons. Using smartphones as beacon detectors has the advantage of not requiring extra equipment. Moreover, smartphone can be reused for other purposes of the project, such as step monitoring.

The Estimote™ beacons[22] have been selected for use in the FrailSafe project. They have been selected primarily for the following reasons, mostly regarding their usability for application developers:

- They are compatible with the Apple iBeacon™ protocol, which is the most commonly used beacon communication protocol. They also support the Google Eddystone™ beacon data format, as well as custom formats. These characteristics make them easier to be combined with various platforms and architectures.
- They can be detected by both iOS and Android devices.
- They are accompanied by an easy-to-use software development kit (SDK).
- They have been largely used and tested by the community and there is a lot of information and examples available, regarding their operation.
- Their price is relatively low, with development beacons costing about €18 each and sticker versions costing about €9 each.

2.6.5. Low energy power supply system

Bluetooth beacons operate using the Bluetooth Low Energy (BLE) protocol (also known as Bluetooth Smart), which has been designed to provide similar communication range with classic Bluetooth, with considerably reduced power consumption. Classic Bluetooth and BLE are designed for different applications. Classic Bluetooth is used for transferring large amounts of data, which is an energy consuming procedure. On the other hand, BLE is designed for applications transferring small amounts of data, such as health and fitness monitoring or the Internet of Things, which allows operating with much lower amounts of energy.

The Estimote™ beacons that will be used within FrailSafe operate using a 1000 mAh CR2477 coin battery, which can last for about 3 years, in medium range requirements. The battery life can be extended if the broadcasting signal power is reduced through the beacon settings, which of course has a decreasing impact in the beacon's range.

[22] http://estimote.com

2.6.6. System behaviour in case of system failure

Within the context of beacon-based indoor localization, system failure may be caused by:

- a beacon not transmitting, e.g. due to malfunction or battery drain,
- a beacon being moved from its expected position.

In both cases, the localization system will continue to function, but the measurements will most probably be erroneous. In order to reduce the amount of error, malfunction detection and mitigation strategies need to be adopted, as described in the following.

Beacon malfunction: A beacon that ceases to be detected due to beacon malfunction can be confused with a beacon not detected due to it being very far away from the detector. Room-level beacon localization is based on sensing the beacon that is closer to the handheld device and reporting that the person is in the room associated with this beacon. If the nearest beacon to the handheld device stops transmitting, the device will consider the next closest beacon, reporting the wrong room. In order to avoid this behaviour, a minimum amount of transmitting power can be considered for each beacon, below which the beacon is not considered close to the device in any case. In this way, when the closest beacon to the device stops functioning, the device simply will not report that the person is in that room or in any of the other rooms. In applications of exact localization, the person coordinates are computed using well-known measurement fusion techniques, such as Kalman filters or Bayes filters. Such techniques have the property of providing more accurate results if more sensors, hereby beacons, are used for the measurements. Thus, in case of beacon failure, the coordinate measurement will be based on fewer beacons, and will be less accurate. However, due to the existence of other beacons in the area, the measurements will still be able to roughly capture the coordinates of the person.

Beacon being moved: Erroneous results can also be computed if a beacon is accidentally moved from its expected position. In this case, exact localization will be mostly affected, since each beacon is assigned to specific coordinates within the area. The computation of coordinates is distance-based, merging the handheld device’s distances from fixed beacon points. If a beacon is displaced, the computed coordinates will be wrong. On the other hand, room-level localization may not be affected. If the beacon is moved within the limits of the same room, the interference of the room walls may prohibit it from being confused with other beacons. The same holds in cases where the beacon displacement is small relative to its distance to the nearest beacon.

Both cases need to be handled in order to avoid wrong measurements. Regular checks about the beacon transmission and position, performed by visiting personnel or the older persons themselves, could prove beneficial. Such failures may also be detected by examining the recorded data, either automatically or manually, for any sudden changes in behaviour exhibited by the older person.

2.6.7. Security and data protection

The BLE protocol supports several mechanisms to ensure the security of the communication between devices and the privacy of the data being transferred[23]. Pairing between two devices is established before any data exchange is performed. During the pairing procedure, the involved parties exchange identity information to set up a secure channel and get the encryption keys needed for the future data exchange. In Bluetooth LE, the pair of private and public keys is generated by the host of the Bluetooth functionality, e.g. the smartphone, instead of the Bluetooth controller itself. This facilitates the upgrade of the key generation algorithms without the need to modify the controller. BLE uses AES-CCM encryption, which is performed by the Bluetooth controller. The low energy features of BLE also support transferring data over an unencrypted channel. In this case, data signing is used to ensure

[23] https://www.bluetooth.com/~/media/files/specification/bluetooth-low-energy-security.ashx?la=en

authentication. As a further mechanism to provide data privacy, BLE supports frequent modification of the address of a Bluetooth device, in order to reduce the ability to track a device over a large period of time. Using the above mechanisms, the BLE protocol provides protection against man-in-the-middle attacks, passive eavesdropping and identity tracking.

From an application point of view, the data transferred between a beacon and the smart mobile device contain only information relevant to the indoor localization. The information exchanged between the beacons and the held device is:

- the unique IDs of the beacons, and
- the distances of the beacons to the held device.

The information logged by the held device is:

- the information sent by the beacons,
- the position of the device (either room-level or exact), computed using the information from the sensors, and
- the time that this position has been recorded.

3. MOBILE DEVICES

Mobile devices, such as smartphones and tablets, have penetrated our everyday life with a constantly increasing rate over the past decade. The latter, combined with the latest advances of their sensing and networking capabilities (e.g. high-accuracy IMUs, 4G/5G wireless technology), reaching connectivity rates capable of constantly transmitting huge amounts of data, render mobile devices the perfect candidates for collecting personalized information. Mobile devices will be exploited to their fullest potential within FrailSafe, as they will act as the central node of data acquisition, directly as a sensorial component, and indirectly as a user feedback and input terminal, as well as a gateway to transmit data collected by other nearby sensor hardware (e.g. Beacons, WWBS etc.). Specifically, mobile devices will participate multimodally in FrailSafe's communication scheme in the following contexts:

- As a purely sensorial component, by using the integrated sensors (e.g. accelerometers, gyroscopes, pedometer, GPS etc.) to track the end user's location and create mobility profiles and assess the user's activity.
- As an input device, playing FrailSafe games, , filling questionnaires to determine the user's cognitive state and provide self-evaluation tests, requesting feedback from the user about their experience with FrailSafe products.
- As a logging component, where the device will record and track various statistics from the user's game experience, as well as meaningful quantitative metrics such as reaction times, completion times etc.
- As a communication gateway, where the mobile device will be responsible for gathering all the fused data from all peripheral sensor components (WWBS, Beacons etc.), fuse it and transmit it to a remote Database for offline analysis as well as provide online analysis feedback.
- for processing certain measurements in real time and triggering alarms.

Below the mobile devices' each communicational role is further detailed in order to extract the minimum capabilities needed for a device to satisfy FrailSafe's sensor and communicational requirements.

3.1. Mobile devices as sensor components

Modern smartphones and tablets come with a great variety of sensor hardware integrated within them, along with the networking hardware capable of transmitting their data in real-time. Indicatively, a typical high-end mobile phone or tablet includes the following sensors:

- 3-axis rotational/linear accelerometers
- Pedometer
- 3-axis gyroscopes
- Magnetometers
- GPS
- Pressure sensor
- Thermometer
- Ambient light sensor

FrailSafe will take advantage of most of the aforementioned sensors in both the indoor and outdoor setup to better estimate required information obtained by other components and also track other multi-parametric environmental conditions for offline analysis. In the indoor setup, the data obtained from the device's IMU will be used synergistically with the data from the Beacon cluster and fused to refine the user's absolute position in the area, as well as augment this information with his orientation, current speed and acceleration. This multi-dimensional data contributes to the tracking of the user's complete 6 degrees-of-freedom (6-DOF) inertial state, which is analyzed in real-time to provide feedback and adjustments to the

AR Serious Games, as well as communicated to the Offline Analysis Server to extract mobility and activity patterns and profiles.

In the outdoor setup, all data acquisition is done solely by the mobile device (smartphone). Since the user won't be in a monitored environment, meaning the absence of the Beacon cluster used to determine his/her position, the device's GPS and networking components will be used to acquire a location estimation. For this purpose, the FrailSafe GPS Tracker will be developed, that will unobtrusively monitor the user's location by combining, in a low-energy consumption scheme, the following sources:

- Network data: Location is provided with low accuracy from the network (cell towers)
- GPS: Location is provided with high accuracy along with extra information from satellite fixes
- WiFi: Location is obtained through the closest WiFi network (low-accuracy)

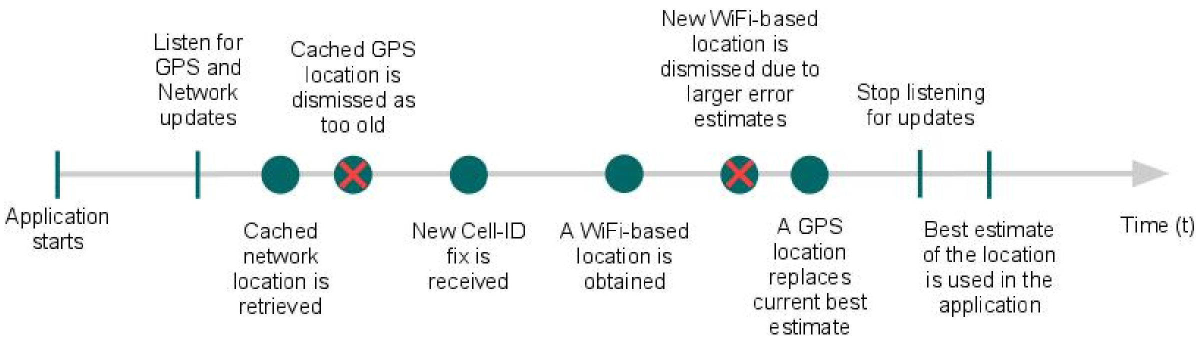

Figure 3: Location-acquisition strategy based on the Android developer guidelines[24].

As shown in Figure 3, the implemented application will take advantage of all the available location providers to acquire a location in frequent intervals, which will be used along with the embedded sensor data in accordance with the scheme described in the indoor scenario. Outdoor location providers also offer, whenever possible, the following data:

- Satellite count
- Location accuracy
- Elevation
- Speed

These will serve as additional information, also communicated to the Offline Analysis Server, where they will be used to better estimate activity metrics, such as distance travelled, calories burnt and activity classification (Walking, running, driving etc.).

3.2. Mobile devices as input devices

Within FrailSafe, smartphones and tablets will also be the main source of direct user input, allowing the user to undergo self-evaluation tests and complete provided questionnaires without restricting him to an indoor environment. This way, it is possible to control user's cognitive state in both the indoor and outdoor setups. The user will be asked to provide feedback on his/her AR Serious Games sessions, and asked to answer questionnaires to assess their behavioral and cognitive state.

Furthermore, tablets will also be used by nurses to fill in the clinical assessment questionnaires during their visits at participant's home.

[24] https://developer.android.com/guide/topics/location/strategies.html

3.3. Mobile devices as logging components

Mobile devices will also track and log various activity statistics, mainly related to the user's AR Game sessions. Although the implemented modules will be part of Task T5.2 "Games framework development" as described in page 30 of Annex 1, Description of Task 5.2 *"[...] Log system: While users go through games, it is not only scores that need to be recorded. When therapists need to check the users' performance they usually require more complete data. The log system will take care of recording this data while playing in real time, so it will be ready to be uploaded to the user database after each session. [...]*", it needs to be described here, as a communication component, since it contributes to the overall transmitted information. During each Game session, the device will log various statistics and quantitative metrics including, but not limited to:

- Completion percentages: The number of game objectives completed, as well as their completion rate.
- Completion times: The speed required to complete a specific task in a game session.
- Reaction times: The time required to react to an event in a game session.
- Various game-dependent metrics: Specific task-related metrics (e.g. trajectory variance in a simple line-following game).

These metrics will be communicated to the Offline Analysis Servers and used to offer clinicians a more complete view of the user's progress and state in the respective games, as well as offer an insight in the user's physiological and motor state.

3.4. Mobile devices as communication gateways

As described in the FrailSafe DoA, mobile devices will also act as communication/processing gateways for the peripheral and wearable sensors, operating as a fusing component by combining the data acquired by the WWBS and other sensor components (e.g. Beacon cluster), and communicating them to the Offline Analysis Server and the VPM through a home gateway in case of an indoor setup, and directly through the network in case of an outdoor setup. This requires the mobile device to support all modern communication protocols (Wi-Fi, Bluetooth, 4G etc.) in order to satisfy the required connectivity needs. Since the volume of the transmitted information is not negligible, as it consists of multiple sensor streams, a power-efficient and data-efficient scheme will be employed, especially in the case of the outdoor scenario, so as to not exceed common mobile data usages. For this purpose, the sensing and transmission intervals will be spaced out when being outdoors, restricting information transmission to once a day, when a Wi-Fi connection is not available.

According to the process of continuous refinement of the solution designed through the system described in this document, the mobile gateway will be chosen on the basis of the evaluation of the efficiency and the performance needed to guarantee a high enough quality of the service. The first device to be tried will be the smartphone, and in case it will result to be insufficient, the tablet will act as a gateway. In the hypothesis that neither will the tablet do, showing insufficient performances, a compliant solution will be tested, probably using a mini-pc, eventually based on Android as well.

The device that will be chosen as the gateway will be the one that will perform the online data analysis as well. This device will analyze the collected data and potentially identify emergency situations for the older people. A special effort will be made to assess the balance of the older person and identify loss of balance, tendency to fall, and loss of orientation (indoors and outdoors). Additionally medical indicators will be examined such as increased heart-rate. In case of such an emergency situation, an alarm will be triggered notifying the older person, but also the clinicians through the VPM.

A particular attention has been devoted to ensure maximum energy efficiency and to reduce energy consumption. Under this point of view, for what concerns the mobile gateway, a special care is paid to reduce the battery drain caused by the power-hungry mobile/wifi radios commonly continuously on due to frequent network requests. The implementation of the Android applications, part of the works of this project, will have a special focus on reaching this objective. Several strategies will be adopted for limiting the number, the frequency and the duration of the network accesses[25]. First of all, it will be avoided, whenever possible, to implement processes and services performing constant requests. Other measures will be taken into account, when possible, for minimizing in general the usage of the network: as reducing the amount of data sent or received (compressing data and using succinct data protocols), as caching static resources, as optimizing pre-fetch caching size, as pre-fetching data and as any other implementation strategy/technique for reducing the number of active connections.

For what concerns the energy saving, more in general, the adoption of a "cloud model" architecture on which is based the system implemented by the project should theoretically increase efficiency.

The main advantage proposed on the energy efficiency topic by a cloud architecture is meant to overcome the issues caused by the use of infrastructural hardware kept on-site by companies, i.e. it is often inefficient and underused. The cloud strategy to face these problems is based on the fact that putting these resources in a central location offers the possibility for the consortium to buy on-demand the needed computing power and time of processing unit in bulk, reducing the overall necessity for more computers.

A second advantage, strictly related to the mobile ecosystem and to the details of its design, comes from the opportunity to offload computation intensive tasks from mobile devices to cloud servers to save energy on mobile devices.

3.5. Minimum Specifications

Although the FrailSafe architecture has been designed in a way to employ the usage of mobile devices, having considered the capabilities of a typical modern smartphone or tablet, there is still a need to define the minimum requirements of such a device. Based on the communication requirements described above, the minimum and recommended specifications needed for a mobile device to operate within FrailSafe can be seen in the table below.

Requirement	Minimum	Recommended
Networking	GSM/CDMA	GSM/CDMA/HSPA/LTE
Communication	Bluetooth v4.x, WiFi, GPS	Bluetooth v4.2, WiFi 802.11 a/b/g/n/ac, GPS, NFC
OS	Android 4.4+ (KitKat)	Android 6.0 (Marshmallow)
Sensors	Accelerometer, Gyroscope, Compass	Rotational/Linear Accelerometer, Gyroscope, Compass, Magnetometer, Barometer, Proximity, Thermometer, Light

[25] https://developer.android.com/training/monitoring-device-state/index.html

4. INTRODUCTION TO SECURITY AND DATA PROTECTION ISSUES

This paragraph aims at introducing the security, safety and data protection issues that will be deeply considered and faced in Task T3.4 and accurately described in D3.2 and D3.3.

Nowadays, healthcare applications make extensive use of wireless sensor networks (WSN), monitoring the patients by using wireless medical sensor networks (WMSNs). However, since the physiological data of an individual belongs to the category of the highest sensitive personal information, data integrity and security in transmission are mandatory requirements of healthcare applications.

As highlighted in the project proposal, also in WP3, the WBAN (Wireless Body Area Network) and the associated information infrastructure will be designed considering safety and data protection issues of paramount importance to be compliant with protective legislation such as the EU Data Protection Directive, 95/46/EC EU Directive (DPD) and with the new Regulation EU 2016/679 (in force since 24 May 2016), the General Data Protection Regulation (GDPR) [47].

4.1. Main security and data protection requirements

The generic, but most important security requirements of a network and information system can be summarized as follows [48]:

- **Availability**: data must be accessible and services must be operational, despite possible disruptive events (i.e., power supply cuts, natural disasters, accidents or attacks);
- **Authentication**: is the confirmation of an asserted identity of entities or users, including also the possibility for anonymity;
- **Integrity**: is the confirmation that data which has been sent, received, or stored are complete and unchanged. This is particularly important where data accuracy is critical, such as medical data;
- **Confidentiality**: is the protection of communications or stored data against interception and reading by unauthorised persons. It is particularly needed for the transmission of sensitive data and is one of the requirements to address data protection of users of communication networks.

4.2. Preliminary security and data protection requirements in WBAN

As it is known, the main difference between wired and wireless networks is the vulnerability at the physical layer; this means that the wireless data transmitted in the wireless network is easily captured or eavesdropped by passive or active attackers.

It is clear that the strict security needs of healthcare applications characterized by a WBAN is a big challenge, since safety and privacy of medical data have to be guaranteed all the way from the sensor nodes to the back-end services. Then, the exchange of users' medical data leads to privacy and security concerns requiring security services, especially important when many users, clinical teams and/or health institutions need to interact with each other.

In order to guarantee security services such as privacy, confidentiality, availability, authentication, etc., strict and scalable security mechanisms are required by the different legal directives on data protection, safety and privacy mentioned in Paragraph above.

Consequently, a security framework based on the WBANs 802.15.6 standard [49], produced by the IEEE 802 Working group for standardisation, that is a communication standard optimized for low-power in-body/on-body nodes to serve a variety of medical and non-medical applications[26] will be considered.

[26] The standard defines a Medium Access Control (MAC) layer supporting several Physical (PHY) layers.

Wireless Body Area Network (WBAN) is the most common type of network within a health monitoring system, responsible for collecting measurements from sensors with low-power radios using short range communication through unreliable links and it is clear that the weak point of such a network is the **Data communication security** that must be hardly faced. At this level, security issues that must be addressed are hereafter synthetically listed and described:

- **Data integrity** in order to ensure that no data changes have been done by any adversary before reaching the storage. Literature suggests that one of the mechanisms to achieve data integrity is to use a message authentication code, employed at the sender and receiver sides to verify that the data is not modified by an adversary [50];
- **Data authentication** should guarantee that the data is sent by a trusted sender [50]. Data authentication can be achieved using a Message Authentication Code (MAC) that is generally computed from the shared secret key;
- **Data freshness** in order to guarantee that all received data is fresh. This means that all data frames are in correct order, and not replicated for disruption purposes. There are two types of data freshness guarantees, both needed in WBANs; weak and strong freshness. The weak one guarantees just the ordering of frames, not tackling possible delays, while the latter makes guarantees on both order and delay. Weak freshness in WBANs is required by low-cycle body sensors, such as blood pressure, while strong freshness is required during synchronising measurements with higher duty cycle, for instance in ECG [51];
- **Data confidentiality,** in order to protect the data from a disclosure, the system requires data confidentiality. Particularly, during communication, there is a possibility of overhearing and eavesdropping the sensitive information by the adversary. Generally, encrypting the data with secret key and sharing the secret key through a secure channel is one of the ways to acquire confidentiality;
- **Availability** to enable patient data to always be available to the physician, for example. In case of loss of availability of one node in the system, redundancy that enforces switching operation from a disabled node to an available node can be used, remember to use forward and backward secrecy [50].

Data confidentiality and integrity are the other issues that must be addressed in the WBAN in order to be compliant with **Data storage security**. *Dependability* is one of the most critical properties, even if in the literature it has been given limited attention; it ensures quick retrieval of patient data, even in case of individual node failure and malicious modifications.

In order to guarantee the above mentioned security and data protection requirements, the Task T3.4 WBAN communication, protocol and integration will be faced taking into consideration the three levels of security defined by the IEEE 802.15.6 standard [52]:

1. **Level 0**, *unsecured communication*: this is the lowest security level where data is transmitted in unsecured frames. There is no mechanism for data authentication and integrity, confidentiality and privacy protection, and replay defence;
2. **Level 1**, *authentication only*: this is the medium security level where data is transmitted in secured authentication but is not encrypted. The confidentially and privacy is not supported by this mode;
3. **Level 2**, *authentication and encryption*: this is the highest security level where data is transmitted in secured authentication and encryption frames providing solutions to all of the problems not covered by the level 0 and level 1. The required security level is selected during the association process, i.e., when a node is joining the network. For unicast communication, a pre-shared Master Key (MK) or a new key (established via unauthenticated association) is activated. Then a Pairwise Temporal Key (PTK) is established, which is used once per session. For multicast communication, a Group Temporal Key (GTK) is shared with the corresponding multicast group.

5. CONCLUSIONS

The following parameters will be monitored within the FrailSafe project using the following sensor sets:

Parameter	Sensor/device
Weight	FORA scale
Pulse waves	Mobil-O-Graph
Blood Pressure	FORA blood pressure monitor
Strength	Hoggan dynamometer
Electrocardiogram (ECG)	Wearable WBan System (WWBS)
Heart rate	
Respiration signal	
Respiration rate	
Posture	
Activity classification	
Reconstruction of fine movements (in full or in part)	
User localisation at home	Estimote^{TM} iBeacon

Scales, Mobil-O-Graph, blood pressure monitor and dynamometers have been or will be soon purchased to be used from the first round of end user monitoring. The iBeacon devices have also been purchased, but they will not been used in the first round because a dedicated software will be developed within the first months of the project in order to monitor user's position at home, so a first version will not be tested before the second monitoring round.

As the WWBS will be developed during the first two years of the project and 15 systems will be finally delivered only at M24, and on the base of a request of PO after a telco review, some sets of commercial inertial platforms have been selected as useful tools to start collecting data from users during the first rounds, to let the consortium develop dedicated algorithms and improve overall knowledge on short- and long-term monitoring in not controlled conditions (if possible). The decision on which set will be purchased has not been taken at the time of this report delivery.

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ANNEX I - TECHNICAL SPECIFICATIONS OF MAIN COMMERCIAL IMUS

I.1. IMUs with embedded algorithm

I.1.1. Wireless

X-IMU by "x-io Technologies"

Web site: http://www.x-io.co.uk/products/x-imu/

On-board sensors

- Triple axis 16-bit gyroscope – Selectable range up to ±2000 °/s
- Triple axis 12-bit accelerometer – Selectable range up to ±8 g
- Triple axis 12-bit magnetometer – Selectable range up to ±8.1 G
- 12-bit battery voltage level
- Factory calibrated
- Temperature compensated (gyroscope only)
- Selectable data rates up to 512 Hz

On-board algorithms

- IMU and AHRS algorithms provide real-time measurement of orientation relative to the Earth
- Internal states updated at 512 Hz
- Algorithm 'initialise' and 'tare' commands can be sent in real-time
- Complete sensor calibration algorithms for user maintenance

Connectivity

- USB
- Bluetooth – Class 1, 100m range, SPP
- Micro SD card – Supports FAT16/32 and SDHC

Comments: It is equipped with Bluetooth module and microSD card to record data. The maximum data rate is selectable up to 512Hz for quaternion data. API available in some languages. Cost: x-IMU with Housing and Battery – £309.00

IMU brick by "Tinkerforge GmbH"

Web site: https://www.tinkerforge.com/en/shop/bricks/imu-brick.html

Features

- Full fledged IMU/AHRS with 9 degrees of freedom (3-axis each: accelerometer, compass, gyroscope)
- No accumulating errors, no gimbal lock!
- Factory calibrated, automatic continuous self-calibration during operation
- Calculates quaternions, linear acceleration, gravity vector as well as independant heading, roll and pitch angles
- Directly readable by USB, extendable by two Bricklet ports

Connectivity: WiFi

Technical Specifications

Property	Value
Acceleration, Magnetic, Angular Velocity Resolution	14bit, 16bit, 16bit
Heading, Roll, Pitch Resolution	0.01° steps
Quaternion Resolution	16bit
Sampling Rate	100Hz
Dimensions (W x D x H)	40 x 40 x 19mm (1.57 x 1.57 x 0.75")
Weight	12g

Comments: It is equipped with WiFi module. The maximum data rate is selectable up to 100 Hz for quaternion data. API available in several languages. Cost: IMU 9 DoF plus Master brick plus WiFi brick = € 150

I.1.2. Wired

FMT1030 by Fairchild/Xsens:

Web site: https://www.fairchildsemi.com/products/sensors/mems-motion-sensors/motion-tracking-module/FMT1030.html

Features:

- Complete module providing many user-configurable outputs
- Incorporates Fairchild's highly accurate Inertial Measurement Unit FIS1100
- Provides Euler angles (roll, pitch, and yaw) rotation matrix (DCM) and quaternions), orientation and velocity increments Δq and Δv) and sensors data (acceleration, rate of turn, magnetic field).
- Roll/Pitch Accuracy (Dynamic): 3.0 deg
- Heading Accuracy: 3.0 deg
- Minimal requirements on host processor
- No knowledge of inertial sensors signal processing required for best performance
- Industry-leading signal processing pipeline (AttitudeEngineTM) with vibration-rejection
- Short time to market with turn-key solution
- Drivers and examples on ARM® mbedTM
- Low Power (45 mW at 3.0 V)
- PLCC28-compatible PCB (12.1 x 12.1 x 2.6 mm)

Comments : It is equipped with I2C, SPI and UART communication protocol. The maximum data rate is up to 100 Hz for quaternion data. Cost: €137

BNO055 by "Bosch Sensortec"

Web site: https://www.bosch-sensortec.com/bst/products/all_products/bno055

The BNO055 can output the following sensor data:

- Absolute Orientation (Euler Vector, 100Hz).Three axis orientation data based on a 360° sphere

- Absolute Orientation (Quaterion, 100Hz).Four point quaternion output for more accurate data manipulation
- Angular Velocity Vector (100Hz). Three axis of 'rotation speed' in rad/s
- Acceleration Vector (100Hz). Three axis of acceleration (gravity + linear motion) in m/s^2
- Magnetic Field Strength Vector (20Hz). Three axis of magnetic field sensing in micro Tesla (uT)
- Linear Acceleration Vector (100Hz). Three axis of linear acceleration data (acceleration minus gravity) in m/s^2
- Gravity Vector (100Hz). Three axis of gravitational acceleration (minus any movement) in m/s^2
- Temperature (1Hz). Ambient temperature in degrees celsius

Comments : It is equipped with I2C and UART communication protocol. The maximum data rate is fixed at 100 Hz for quaternion data. Cost : € 40

<u>**UM7-LT Orientation Sensor by " CH Robotics"**</u>

Web site: https://www.chrobotics.com/shop/um7-lt-orientation-sensor

Sensors and processing

- Excellent gyro bias stability over temperature
- Adjustable low-pass filter and EKF settings provide customizable performance for various applications
- States and sensor data synchronized to GPS position and velocity using optional external GPS module
- Allows for alignment calibration and third-order bias and scale factor temperature compensation for accelerometers, gyros, and magnetometer
- Magnetometer soft and hard-iron calibration can be performed through the CHR serial interface software

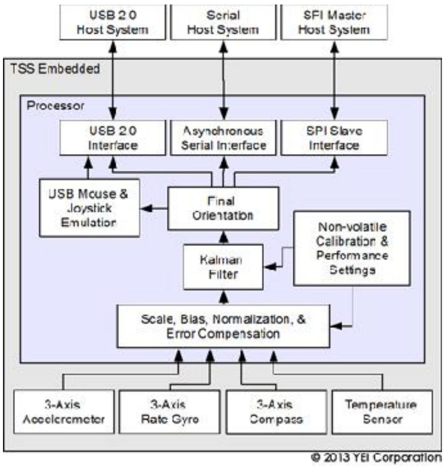
Communication

- Output data:
    - Attitude and heading (Euler angles)
    - Attitude quaternion
    - magnetometer, accelerometer, gyro data
    - GPS altitude, position, velocity (with optional external GPS)
- 3.3 V TTL serial interface (UART) with baud rates up to 921,600 bps can stream data or provide updates on request
    - Note: the main UART pins, TX, and RX, are 5V-tolerant and can be directly connected to 5 V systems that are guaranteed to read 3.3 V as high
- Transmits data using human-readable NMEA strings (up to 100 Hz broadcast), binary packets for higher efficiency (up to 255 Hz broadcast), or a combination of both
- Flexible communication architecture allows UM7 to transmit any combination of data at individually adjustable rates
- Connects to the CHR Serial Interface software to allow for real-time plotting of sensor data, logging, device configuration, and magnetometer calibration
- SPI interface available through expansion connector

Comments: It is equipped with SPI and UART communication protocol. The maximum data rate is fixed at 255 Hz for quaternion data. Cost: € 130

I.1.3. Wired, Bluetooth or Datalogger

<u>**YEI 3-Space SensorTM Embedded**</u>



Web site: https://www.yostlabs.com/yost-labs-3-space-sensors-low-latency-inertial-motion-capture-suits-and-sensors

General description

Part number	TSS-EM
Dimensions	23mm x 23mm x 2.2mm (0.9 x 0.9 x 0.086 in.)
Weight	1.3 grams (0.0458 oz)
Supply voltage	+3.3v ~ +6.0v
Power consumption	45mA @ 5v
Communication interfaces	USB 2.0, SPI, Asynchronous Serial
Filter update rate	up to 250Hz with Kalman AHRS(higher with oversampling) up to 850Hz with QCOMP AHRS(higher with oversampling) up to 1350Hz in IMU mode
Orientation output	absolute & relative quaternion, Euler angles, axis angle, rotation matrix, two vector
Other output	raw sensor data, normalized sensor data, calibrated sensor data, temperature
SPI clock rate	6 MHz max
Serial baud rate	1,200~921,600 selectable, default: 115,200
Shock survivability	5000g
Temperature range	-40C ~ 85C (-40F ~ 185F)

Sensor

Orientation range	360º about all axes
Orientation accuracy	±1º for dynamic conditions & all orientations

Orientation resolution	<0.08º
Orientation repeatability	0.085º for all orientations
Accelerometer scale	±2g / ±4g / ±8g selectable for standard models ±6g / ±12g / ±24g selectable for HH models(coming soon) ±100g / ±200g / ±400g selectable for H3 models(coming soon)
Accelerometer resolution	14 bit, 12 bit(HH), 12 bit(H3)
Accelerometer noise density	99µg/√Hz, 650µg/√Hz(HH), 15mg/√Hz(H3)
Accelerometer sensitivity	0.00024g/digit-0.00096g/digit 0.003g/digit-0.012/digit(HH) 0.049g/digit-0.195g/digit(H3)
Accelerometer temperature sensitivity	±0.008%/°C, ±0.01%/°C(HH, H3)
Gyro scale	±250/±500/±1000/±2000 º/sec selectable
Gyro resolution	16 bit
Gyro noise density	0.009º/sec/√Hz
Gyro bias stability @ 25°C	2.5º/hr average for all axes
Gyro sensitivity	0.00833º/sec/digit for ±250º/sec 0.06667º/sec/digit for ±2000º/sec
Gyro non-linearity	0.2% full-scale
Gyro temperature sensitivity	±0.03%/°C
Compass scale	±0.88 Ga to ±8.1 Ga selectable (±1.3 Ga default)
Compass resolution	12 bit
Compass sensitivity	0.73 mGa/digit
Compass non-linearity	0.1% full-scale

Comments: It is equipped with SPI and UART communication protocol. The maximum data rate is up to 250 Hz for quaternion data. There is a also a Bluetooth or datalogger version of this device. Costs: wired US$ 130, Bluetooth US$ 305, datalogger US$ 255.

I.2. IMUs without embedded algorithm

This is a short list of IMU without algorithm on board, these devices provide all 9 signals from the sensors without any fusion:

- MPU-9250 by Invensense (I2C communication protocol)
  - https://www.invensense.com/products/motion-tracking/9-axis/mpu-9250/
  - cost € 10
- 9 DoF Razor IMU by Sparkfun (I2C communication protocol)
  - https://www.sparkfun.com/products/10736
  - cost € 75

- 9-DOF IMU by Adafruit (I2C communication protocol)
    - https://www.adafruit.com/product/1714
    - cost € 20
- MinIMU-9 v5 by Polulu (I2C communication protocol)
    - https://www.pololu.com/product/2738
    - cost € 16

ANNEX II - TECHNICAL SPECIFICATIONS OF MAIN WIRELESS DYNAMOMETERS

<u>JTECH medical Tracker Freedom® Grip Gauge.</u>

It is sold at US$ 1.000. It communicates wirelessly, but only to a proprietary console, so collected data cannot either be used for real-time gaming or saved into FrailSafe database.

Commander Echo Grip Gauge		Commander ECHO Console (required but sold separately)	
Part Number:	CM306	Part Number:	CM300
Number of Repetitions per Test:	1-8	Number of Stored Tests:	20
Load Cell Capacity:	200 lb (90.72 kg)	**Weight:**	0.46 lbs (0.21 kg)
Units of Measure:	lb, kg, N	**Length:**	4.66 in (11.83 cm)
Weight:	0.92 lbs (0.42 kg)	**Width:**	2.61 in (6.63 cm)
Length:	8.15 in (20.70 cm)	**Depth:**	0.96 in (2.44 cm)
Width:	1.62 in (4.11 cm)	**Battery Type:**	Rechargeable Lithium-polymer
Depth:	4.01 in (10.19 cm)	**Battery Life:**	Approximately 24 hours of continual use
Battery Type:	Rechargeable Lithium-polymer		
Battery Life:	Approximately 15 hours of continual use		

<u>BIOPAC TSD121C</u>

Also this device can be connected only to a dedicated module, as it does not communicate with third parties' devices. Furthermore, the dedicated device needs the central Biopac module to work, so the full system is closed and very expensive.

Technical specification:

Isometric Range	0-100 Kg
Nominal Output	13.2 µV/kg (normalized to 1 V excitation)
Linearity	< ±0.03% of rated output
Nonrepeatability	< ±0.02% of rated output
Creep after 30 minutes	< 0.05% of rated output
Hysteresis	< ±0.02% of rated output (compression only or tension only)
Sensitivity	2.2 grams rms (5 V excitation, DC-10 Hz)
Weight	315 g
Dimensions	185 mm (long) x 42 mm (wide) x 30 mm (thick)

Cable Length	3 m
Interface	DA100C
TEL100C compatibility	SS25

Biometrics Hand Dynamometer

Again, it needs a proprietary dongle to work and no SDK is provided.

Dimensions	Standard Jamar configuration, calibrated and designed to work in compression only
Mass	630g
Accuracy	Better than 1% Rated Load
Rated Load	0 to 90Kg, or 0 to 200lb
Cable	Direct connection to DataLOG, DataLINK and K800 using cable type no. H2000

Hoggan MicroFet HandGrip

Technical specification:

The HandGRIP allows for the following tests	Maximum Grip, 5 Position Grip, Rapid Exchange Grip, Hand Fatigue Grip
Selectable units of measure	pounds (lbs.), Newtons (N), or kilogram-force (kgf)
Low and high threshold settings	Low – 0.8 lb. to 200 lbs. in 0.1 lb. increments and High – 3 lbs. to 200 lbs. in 0.1 lb. increments
Measurement accuracy	within 1%
Bluetooth enabled for wireless use	with either clinical or data collection research software

Auto shutoff to conserve battery life	Yes

Neulog Hand Dynamometer

It communicates via WiFi if equipped with a dedicated module and its design is more oriented to R&D applications than clinical ones, but accuracy, precision and range is similar to the Hoggan product. As it can be seen from the picture below, a system is composed by a handle connected to a module by a wire that needs a WiFi module and a battery. On the documents available from their web site it is claimed that data can be transmitted to all types of devices (pc, ios, android) that must be connect via WiFi direct (so there is no need for an external WiFi router) and visualised in a web browser, but SDK are available for data management personalisation. In a later attempt to get more information on this point, they finally replied that their product cannot be connected to any android device.

	Newtons	Pounds	Kilograms
Range and operation modes	0 to 500 N	0 to 112 lb.	0 to 50 kg
ADC resolution	16 bit		
Resolution	0.1 N	0.02 lb.	0.01 kg
Max sample rate (S/sec)	100	100	100