Project Title:	**Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions**
Contract No:	690140
Instrument:	Collaborative Project
Call identifier:	H2020-PHC-2014-2015
Topic:	PHC-21-2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention
Start of project:	1 January 2016
Duration:	36 months

D3.2

Preliminary WWBS prototype

Due date of deliverable:	M15 (31st March 2017)
Actual submission date:	17th May 2017
Version:	1.1
Date:	16th May, 2017
Lead Author:	Smartex
Lead partners:	Smartex

Horizon 2020
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Change History

Ver.	Date	Status	Author (Beneficiary)	Description
1.0	12/05/17	Final	Smartex	Final version for Consortium review
1.1	16/05/17	Final	Smartex	Final version after Consortium Review (UoP, CERTH, SIGLA)

Acronyms

AFE: Analog Front End

BR: Breath Rate

BT: BlueTooth™

DoF: Degree of Freedom

ECG: Electrocardiogram

HR: Heart Rate

IMU: Inertial Measurement Unit

PCB: Printed Circuit Board

RoHS: Restriction of Hazardous Substances Directive

EXECUTIVE SUMMARY

This deliverable summarises the principal aspects of the first version of the WWBS ("Wearable WBAN System"), developed within the FrailSafe project.

The system is composed by a sensorised garment, an electronic device and a software tool, for downloading the recorded data from the electronic device.

The sensorised garment is a shirt with short sleeves and a zip in the front to make don and doff easy even for people with limited agility. It has two fabric electrodes for ECG monitoring and a fabric piezorestistive sensors for respiration monitoring on the chest, and two small boxes on the sleeves where a 9-DoF IMU is placed (in each). On the chest there is also a pocket for the electronic device with a third, integrated 9-DoF IMU. All sensors are connected via cables to the device.

The electronic device collects data from the sensors placed in the shirt. A microprocessor elaborates several parameters and all (raw and processed) data are saved on a micro-SD. When needed, the same data (or part of them) can be transmitted via Bluetooth™ to a pc or an Android device for real time data analysis.

Within FrailSafe project, at the end of every monitoring cycle, end users selected by clinical partners must plug the electronic device to a PC via a USB cable, to allow the software tool to download the recorded data. Bluetooth streaming of data will be performed only in laboratorial conditions to develop and test real time algorithms.

The system is at present under the process of CE certification, a necessary step to let it be used by clinical partners. An updated version of this deliverable will be produced after CE certification is obtained in case of major changes to what hereinafter described.

This Deliverable was due at M15, but two orders of problems forced Smartex to deliver both report and prototypes with delay:

- Smartex standard PCB supplier produced the WWBS main boards with small defects that were not detectable either by standard electric tests or before components integration. The time spent before to understand the reason of the problems and then for the production of new PBC (with integrated components) generated a 40-day delay;
- In Amendment 1 to project contract the number of devices to be delivered at M15 passed from 1 to 8, involving tests in real conditions (so with older adults using them at home without the presence of technical/clinical personnel). This step requested the certification of also this intermediate prototype, at least for safety regulations (electrical safety and electromagnetic compatibility), otherwise Ethical Committee would have not accepted its use. WWBS is at present under certification and systems will be delivered only after certification is obtained.

This delay will not generate major implications anyway. For instance Group B will still use this device, with just a reduction of one time, i.e. 5 times instead of 6. Furthermore, as each clinical partner will have just two systems at this stage but 5 users per session, for 3 end users out of 5 there will be no difference in the planned protocol.

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. Jan Komarek		

Deliverable number:	3.2	**Title:**	Preliminary WWBS prototype
Work package number:	3	**Title:**	Smart sensing, data acquisition and signal processing

Date of delivery	**Contractual**	**31/03/2017 (M15)**	**Actual**	17/05/2017
Status	Draft ☐		Final ☒	
Nature	Report ☐	Demonstrator ☒	Other ☐	
Dissemination Level	Public ☐	Consortium ☒		
Abstract (for dissemination)	This deliverable describes the Wearable WBAN System (WWBS), a wearable system composed by sensorised garment, an electronic device and a software tool. It will allow to monitor older adults at home during standard day-time activities, collecting data from their heart, their respiration, their posture and their activity. Those data will be saved and them uploaded to cloud to let FrailSafe consortium to analyse them and develop algorithms and classifications in order to better understand frailty. The system will monitor one ECG lead, respiration and movement from 3 inertial platforms.			
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 results of the activities the Consortium has performed in order to develop a useful wearable system able to perform a long term monitoring of several parameters in older adults. This Wearable WBAN System (WWBS) is composed by a sensorised garment, an electronic device and a software tool.

Chapter 2 briefly summarises the sensors integrated in the WWBS and the monitored parameters.

Chapter 3 describes the sensorised garment and the "philosophy" of some solutions that have been taken in order to get the best compromise between user comfort and quality of collected data.

Chapter 4 describes the electronic device components and the principal testing performed.

In Chapter 5 the software tool for Windowsis introduced, detailing only the features that will be used for older adults' monitoring at their homes. Also the use of a limited version for android platform is briefly introduced.

Chapter 6 explains some of the decisions taken by the Consortium in order to optimise the end-user experience.

Finally a short Chapter 7 is dedicated to the EC certification process.

2. SENSORS

The following parameters will be monitored with the sensor placed on the WWBS:

Parameter
Electrocardiogram (ECG)
Heart rate
RR (distance in ms between 2 complexes[1])
RR Standard Deviation (SDNN)
Respiration signal
Respiration rate
Posture
Activity classification
Step counter

These data will be collected using the following sensors placed on the garment:

Sensor (Number)	Information and placement
Fabric electrodes (2)	Made of stainless steel, placed on the chest just below pectoral muscles, will be used ot monitor on ECG lead, parallel to Einthoven DI
Fabric piezorestive sensor (1)	Made of conductive carbon, placed on the chest in between the 2 fabric electrodes, will be used to monitor respiration due to extension of the thoracic cage
9 DoF IMU (3)	Inertial Platforms MPU9250 by "Invensense"[2], 2 placed in small boxes and located in the sleeves, 1 integrated in the electronic device

[1] https://en.wikipedia.org/wiki/QRS_complex
[2] https://www.invensense.com/products/motion-tracking/9-axis/mpu-9250/

3. SENSORISED GARMENT

This garment has been developed to collect many different types of information trying to reduce discomfort to a minimum. To make this shirt easily don and doff by people with potential limited mobility and skills, a frontal zip has been introduced, following the main negative comment received from interviews to potential end-users collected by clinical partners. Another important aspect to improve comfort is the use of natural material, i.e. cotton, to make the shirt breathable and cool, taking into account that two monitoring sites out of three are very hot in summer (Greece and Cyprus).

Another important aspect that had to be taken into account was the fact that these shirts would be used by different people during this clinical evaluation, so they need to be washed and disinfected before passing them from a user to another one, and that the user itself may desire to wash them (as they will need them for 5 days running or even longer - Group C will use the system for 2 months running). The shirt can be disconnected by the electronic device (which is not waterproof) and washed by hand or in a washing machine using a mild cycle (with a temperature inferior to 30°C), using oxygen-releasing additives (no bleach). All these restrictions in washing procedure will help the shirt to maintain a proper elasticity and will prevent degradation of performance (and so a good quality signal) of fabric electrodes and sensors.

The need to use these garments on different people with different sizes and on the opposite, the need to have fabric sensors placed in tight connection with the user's thorax, has brought the introduction of a strap with velcro (point 4 in Figure 2 and Figure 3). In this way the nurse can fix the strap with sensors adapting the vest to the end-user's thorax circumference at the moment of system delivery, and then the user can doff and don again the garment using the zip maintaining the adherence to his/her body.

As listed in the previous chapter, the garment integrates/embeds the following sensors/devices:

- 2 fabric electrodes (Point 2 in Figure 1) for ECG monitoring;
- 1 fabric piezoresistive sensor (Point 1 in Figure 1) for respiration monitoring;
- 1 electronic device (Point 6 in Figure 1) in a dedicated pocket on the chest for data collection (plus 1 IMU for monitoring of trunk movement)
- 2 IMUs (Point 3 in Figure 1) to monitor arms movements

IMUs are placed in pockets that guarantee their integral movement with the trunk and the arms. To reduce movement artifacts of the IMUs on the arms without creating hindrance of movement of the users or difficulties in fixing them (using for instance a similar solution to the one explained above for the trunk) sleeves have been prepared using fabric with a balanced elasticity.

The following pictures show all the above listed aspects.

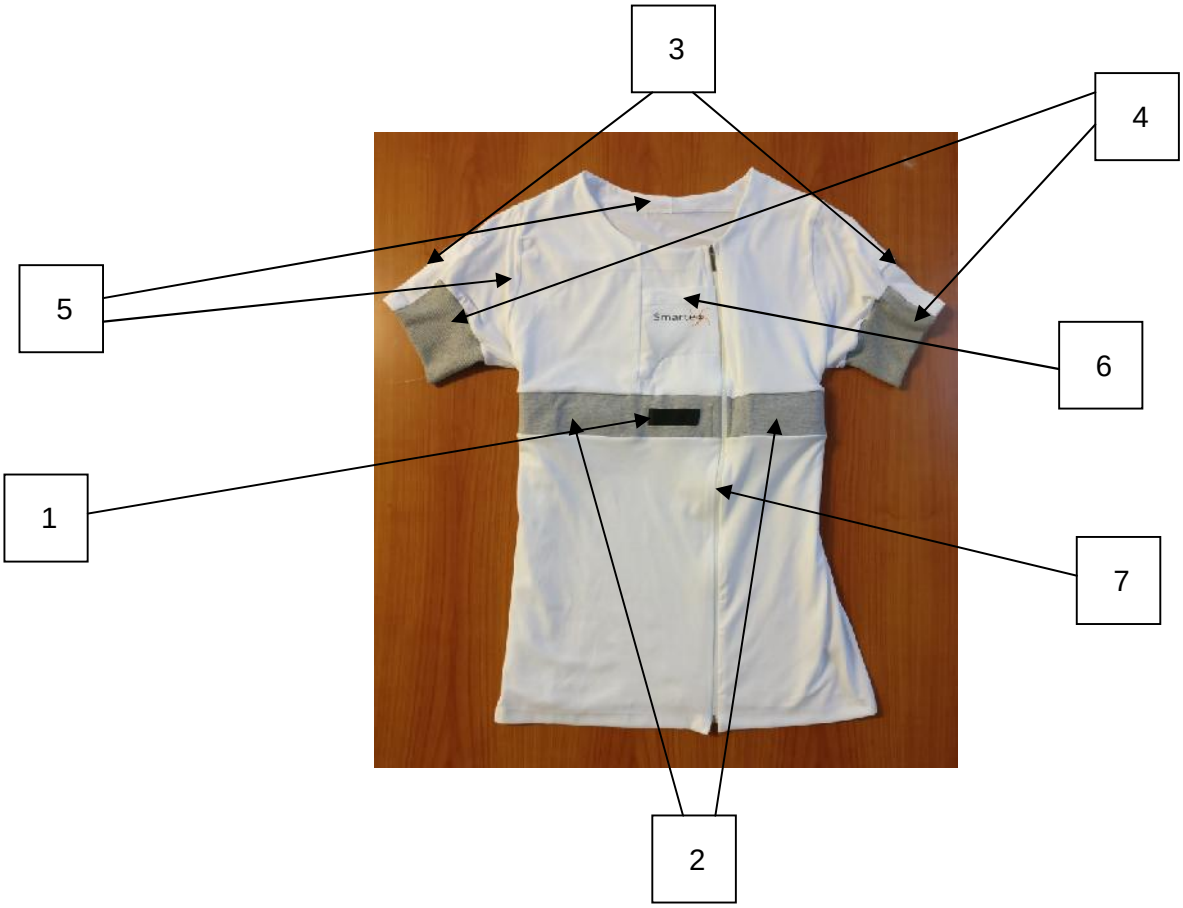


Figure 1. WWBS- sensorised garment: front view.

Legenda:

1. Fabric Piezoresistive sensor
2. Fabric Electrodes (in the inner side)
3. Pockets for IMUs
4. Elastic sleeves (to fix better IMUs to arms without reducing user's comfort)
5. Tubular solution for cable protection
6. Pocket for electronic device
7. Zip for easy don and doff

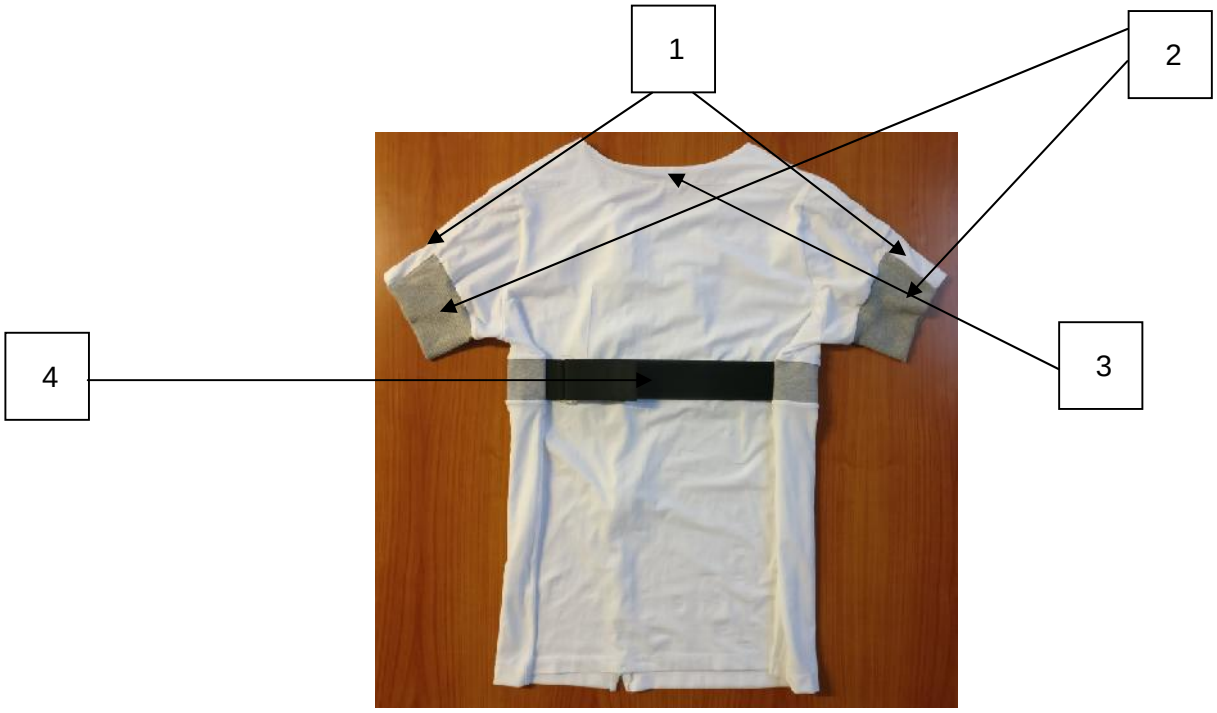


Figure 2. WWBS- sensorised garment: rear view.

Legenda:

1. Pockets for IMUs
2. Elastic sleeves (to fix better IMUs to arms without reducing user's comfort)
3. Tubular solution for cable protection
4. Strap solution to optimise the same garment to people with different sizes

Figure 3. WWBS-sensorised garment: fixing strap.

Fixing this strap at the beginning of the first day of monitoring will allow users to have the correct circumference of the sensorised sector and will allow user to zip/unzip the garment any time they desire without losing the correct tension.

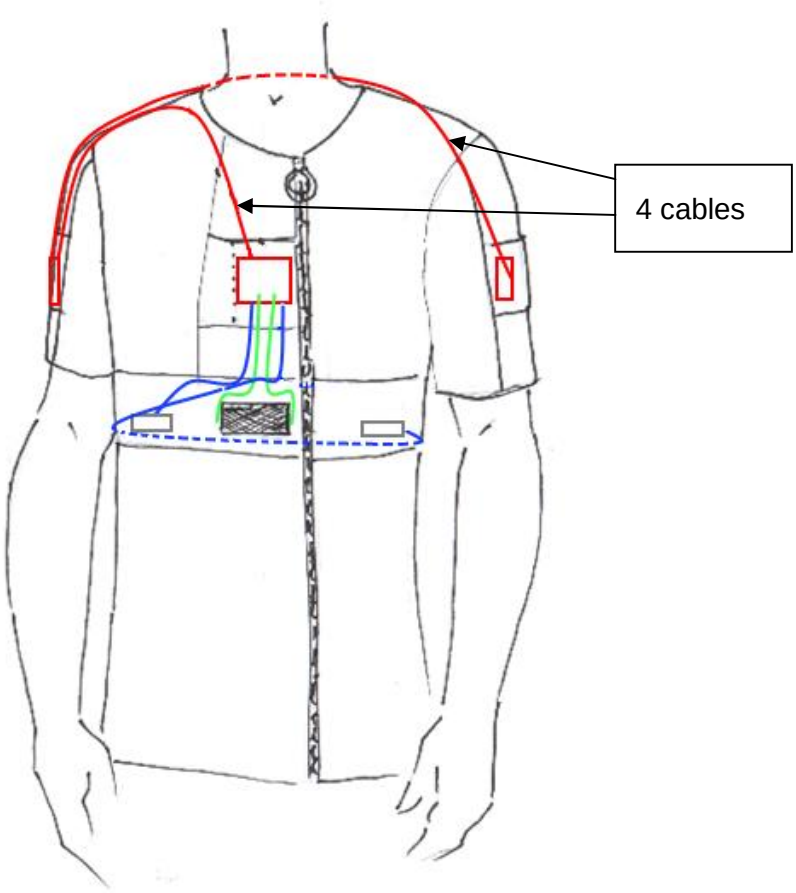


Figure 4. WWBS-sensorised garment: cabling.

Figure 5. WWBS-sensorised garment: pictures.

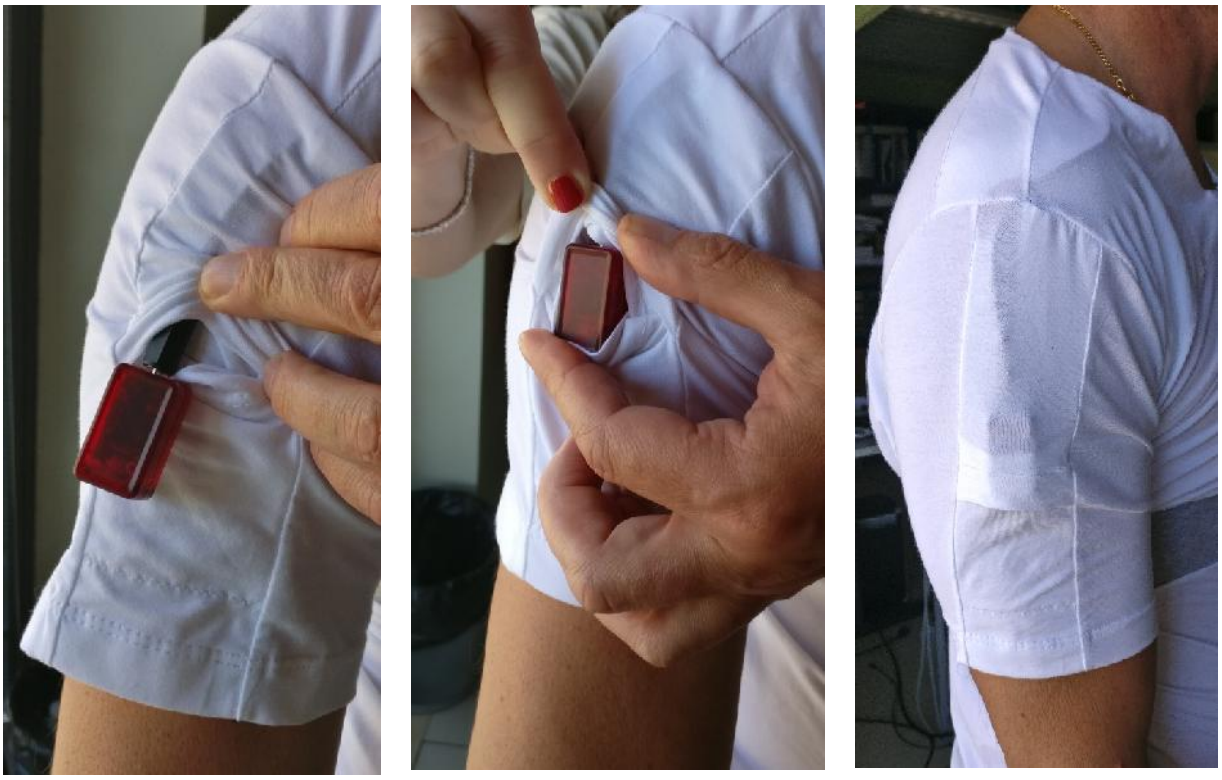


Figure 6. WWBS-sensorised garment: right external IMU.

The two external IMUs are connected to the central device via a 4-pin jack and are removable. They must be placed within their dedicated pockets on arms.

4. ELECTRONIC DEVICE

Within the framework of FrailSafe project it has been developed the electronic board to acquire signals from the garment. According to the requirements of the project the board embeds a 9-DOF IMU to gather information on posture and activity of the final user. The board will implement also the capability to record acquired data on an SD card.

The board has been developed dividing the design process for its main functional blocks, as it is possible to see from the logical structure of the project in the figure below.

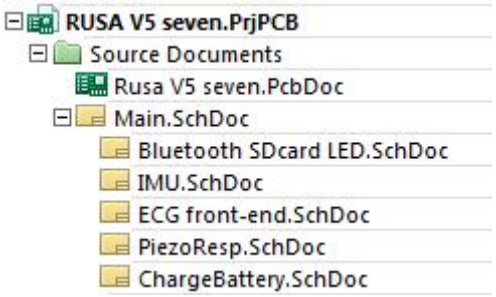


Figure 7. Project logical structure.

The schematic in the figure below shows the main sheet: it is possible to observe the main blocks of the board as well as the JTAG connector necessary to program the micro controller.

The Bluetooth module is the WT12, a standard Bluetooth 2.1 module produced by Bluegiga Technologies, while the onboard IMU is the 9250 by Invensense. These latter parts do not require particular hardware testing, for this reason they have not been included in the descriptions of components done in the following section.

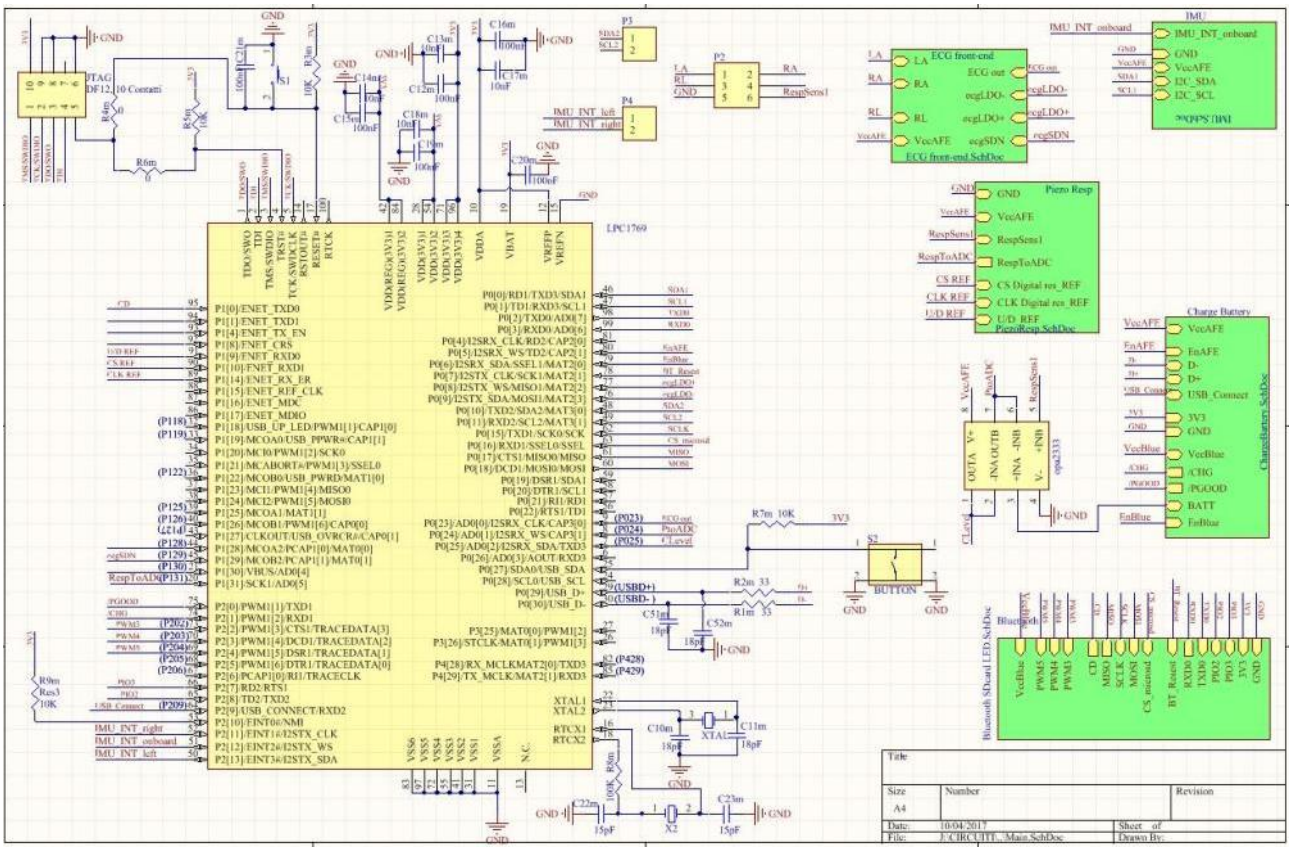


Figure 8. Main sheet of the project.

4.1 ECG analog front end.

The board is equipped with AD8232 chip that offers a fully integrated single-lead ECG front end. In particular it has been used to acquire the ECG lead signal from the two fabric electrodes placed on the chest of the user.

This component introduces an inherent **gain of 100**.

The conditioning of the signal is obtained filtering at low and higher frequency. At base band and very low frequency the signal is filtered by a double order High Pass (HP) filter with cut frequency at **fc = 0,34 Hz**.

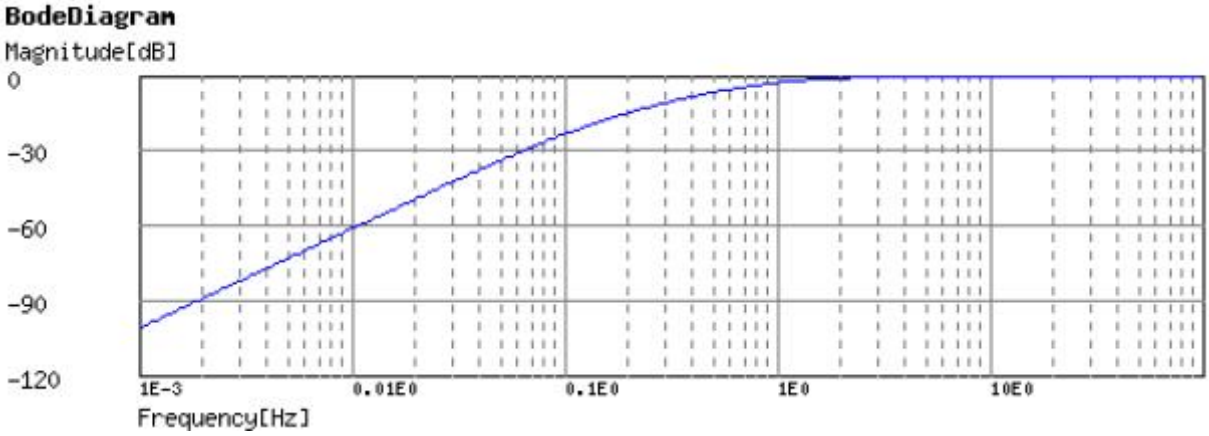


Figure 9. High Pass filter amplitude Bode diagram.

At higher frequency it has been implemented a second order, Low Pass (LP) Sallen Key filter with:

- fc =27,64Hz
- Q = 0,556
- ψ = 0.898
- Gain LP = 5

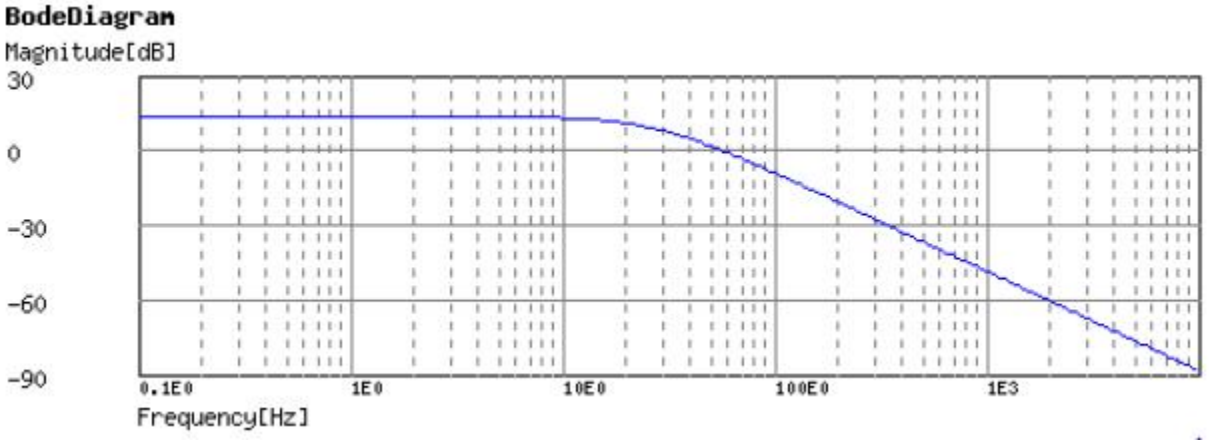


Figure 10. Low Pass filter amplitude Bode diagram.

Considering the gain of the AD8232, the total nominal gain of the front end is **G tot = 500.**

In order to achieve a higher rejection of artifacts and noise, it has been introduced, via software, a digital filter with the following features:

- Filter type: Low Pass
- Filter model: Butterworth
- Filter order: 16
- Sampling Frequency: 250 Hz
- Cut Frequency: 25.000000 Hz

Testing of the ECG Analog Front End (AFE) has been done using as input on the electrodes different sinusoidal waves with same amplitude but different frequency.

Amplitude pp [mV]	Frequence [Hz]
3,1	0,1
3,1	0,5
3,1	1
3,1	5
3,1	7,5
3,1	10
3,1	27,5
3,1	100
3,1	250

From the figure is possible to observe the effect of the filters, both at very low and high frequencies as well of the effect of the 16th order SW filter.

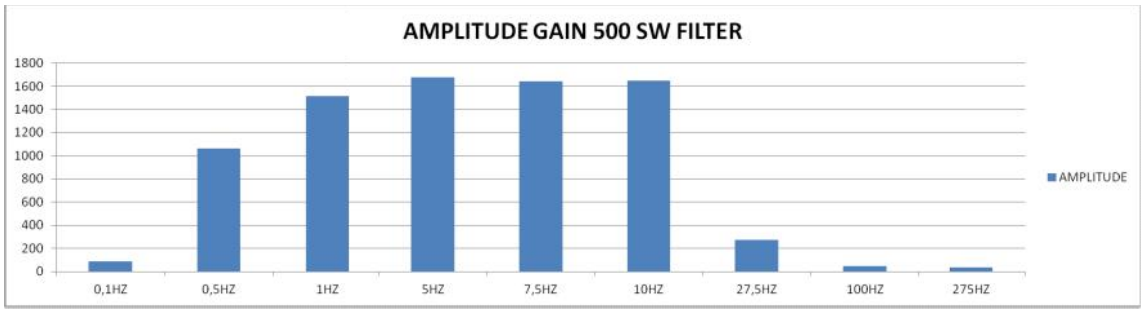


Figure 11. Filter effect.

Testing also highlighted a real gain on EKG signal equal to Greal = 430 in the band of interest.

This attenuation is due to, besides the natural distance from ideality, the combined effect of HP an LP filtering that reduces the range of frequency for flat band (see Bode diagram above)

4.2. Breath (PiezoResp) analog front end.

The circuit has been designed to power with constant current the piezoresistive sensor used to monitor the user's respiration activity. This current is obtained with a specific configuration of a LM334 integrated circuit. The circuit could provide current up to 10 mA without suffering any damage. For the purpose of the project the current has been set to **Isens = 10 uA.**

The acquisition chain introduces an amplification **Gresp = 4.**

4.3. Battery charger.

Based on Texas Instruments chip bq24074, the circuit has been designed to power a lithium polymer battery with capacity between 600 and 1000 mAh a. This component has been chosen in order to introduce additional safety measures beyond the ones already implemented on the battery pack.

Following some of the technical specification of the battery charger developed:

- **Fast charge current: I_{chg}= 330 mA**
  Current set for the constant current phase of the charging process.
- **Max input current: $I_{in\text{-}max}$= 800 mA**
- **Adjustable termination threshold: 20 mA**
  End of charge current threshold, charge is considered completed when the current entering the battery achieve this threshold
- **Dynamic Charge Timer: 5h**
  Safety timer, charge will be suspended after this time.
- **Thermal control:** operation limit between 0 - 50 Celsius
  Using an 10 Kohm NTC thermistor charge is suspended if temperature of the battery pack goes outside 0 - 50 Celsius limits.
  The thermistor should be placed close to battery pack.
  In the actual configuration this control is foreseen but not implemented.

Figure 12 shows a charge cycle of the battery. According to the specification it is possible to see the first phase at constant current, (Ichg =330 mA). The current then decreases 20 mA, once achieved this value the charge is considered complete and supply current goes to zero.

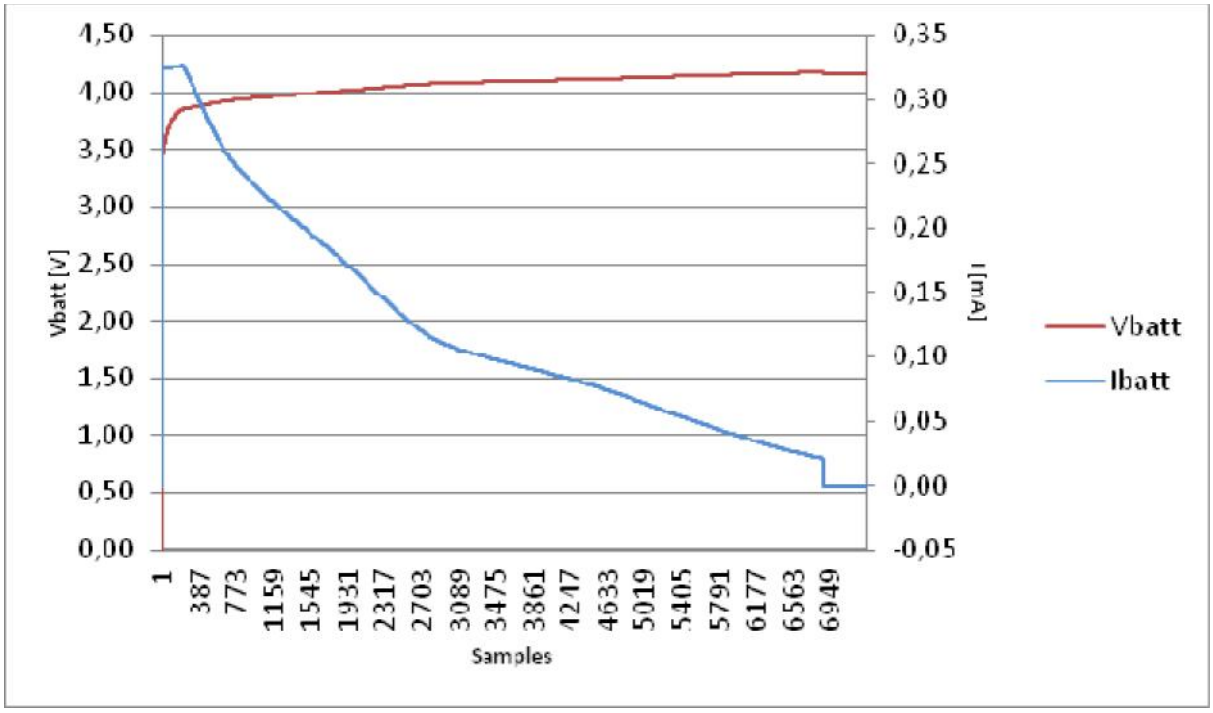


Figure 12. Battery Charge Cycle.

The circuit has a protection against overvoltage (OVP), if the input voltage goes over 10,5 V the charge is interrupted until the input voltage drops again under the threshold (see Figure 13).

When in OVP condition, the electronic board is directly supplied by the battery.

The board is equipped with a micro USB connector type AB. This allows to use for charging both a PC or a wall adapter connected to domestic main.

Max voltage accepted is 10,5 V while max input current is 1,5 A.

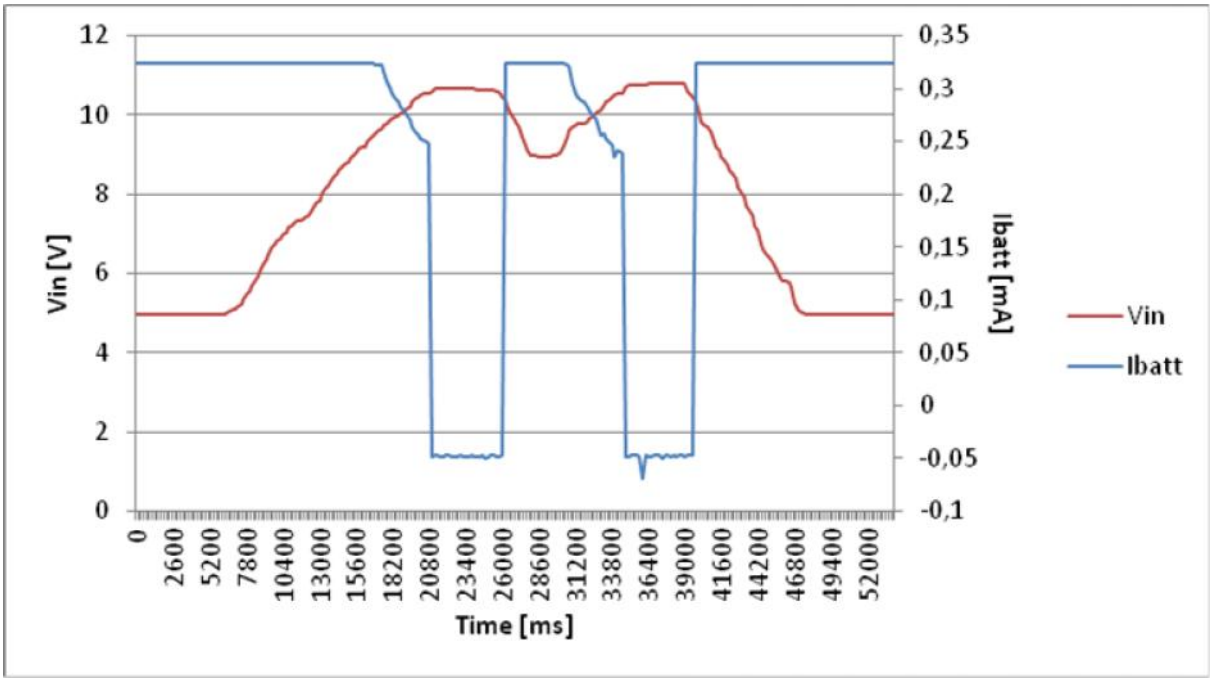


Figure 13. Over Voltage.

4.3.1. Power consumption test.

To satisfy the requirement of the project in term of monitoring session duration, it is necessary to size correctly the capacity of the battery that will power the circuit. To do this it is fundamental to know the power consumption of the electronic in all of its mode of operation. Figure 14 shows current absorption of the RUSA in different working phases.

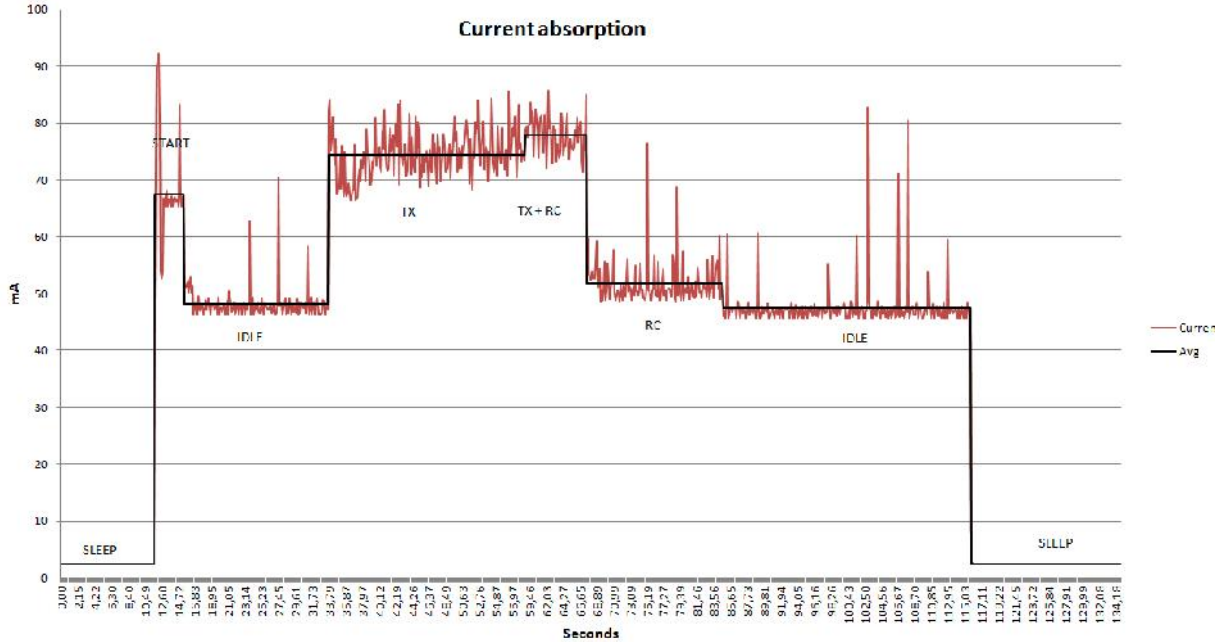


Figure 14. Current absorption of the electronic device in different working phases (see Legenda below).

The table below reports average measured values and the respective mode in which the measure has been taken.

Sleep	2,34 mA
Start-up	66,7 mA
Idle	48,2 mA
Streaming (TX)	74,4 mA
Streaming + Recording (TX-RC)	77,8 mA
Recording	51,7 mA

It is possible to see that if the electronic is transmitting data and at the same time it is recording data on the SD card the power consumption does not exceed the 80 mA, this means that in theory, with a battery of 1000 mAh, it could be possible to achieve more than 12 hours of operation.

4.4. Board assembly.

Following figures show the final design of the board, placament of components and its routing. All the components used are compliant to RoHS directive (*Restriction of Hazardous Substances Directive*) that restricts the use of six hazardous materials (e.g. Lead, Mercury, Cadmium, Hexavalent chromium) in the manufacture of various types of electronic and electrical equipment.

TOP layer includes: Bluetooth module, battery charger, ECG front end, IMU, JTAG connector, status led, reset button and control button.

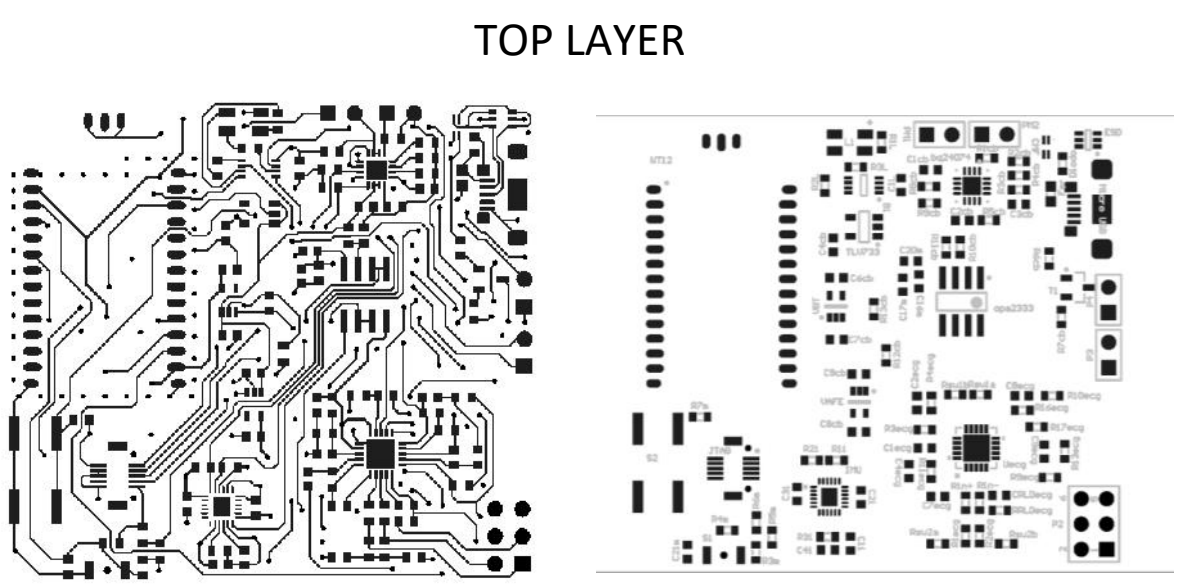


Figure 15. TOP layer routing and components placement.

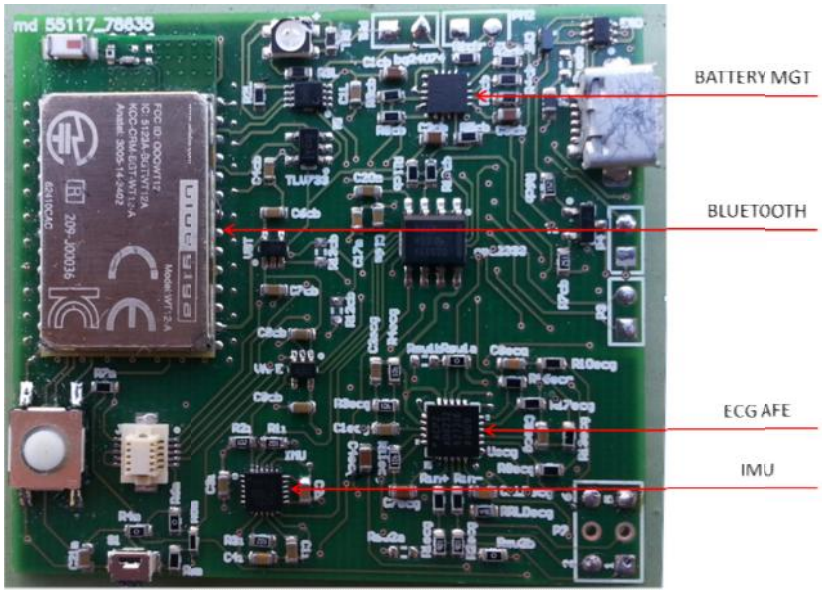


Figure 16. TOP layer.

On Bottom layer are placed, breath analog front end, microcontroller and micro SD holder.

BOTTOM LAYER

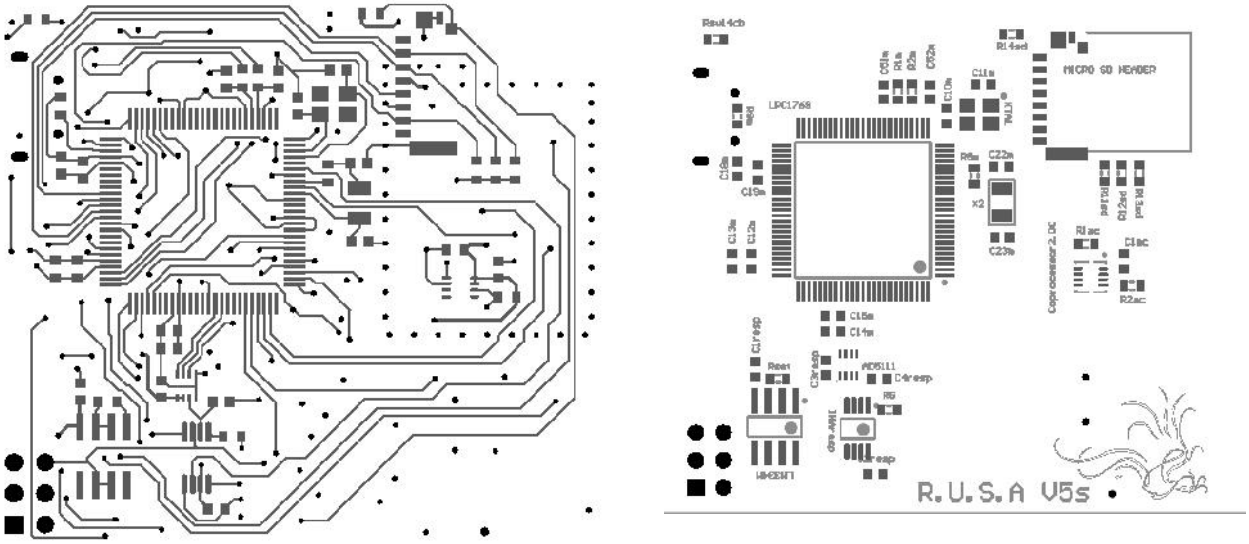


Figure 17. BOTTOM layer routing and components placement.

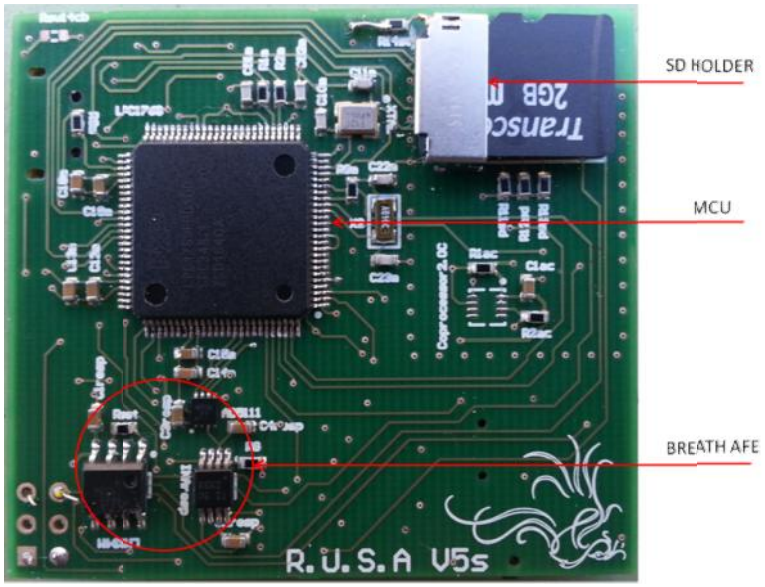


Figure 18. BOTTOM layer.

4.5. Device case.

The case for the board has been realized in polyamide powder by laser sintering process. The material used, PA2200 BALANCE 1.0 of EOS GmbH Electro Optical Systems, is bio compatible according to EN ISO 10993 and USP/level VI/121°C, and approved for food contact in compliance with EU Plastic Directive 2002/72/EC (exception: high alcoholic foodstuff).

Following some drawings of the design.

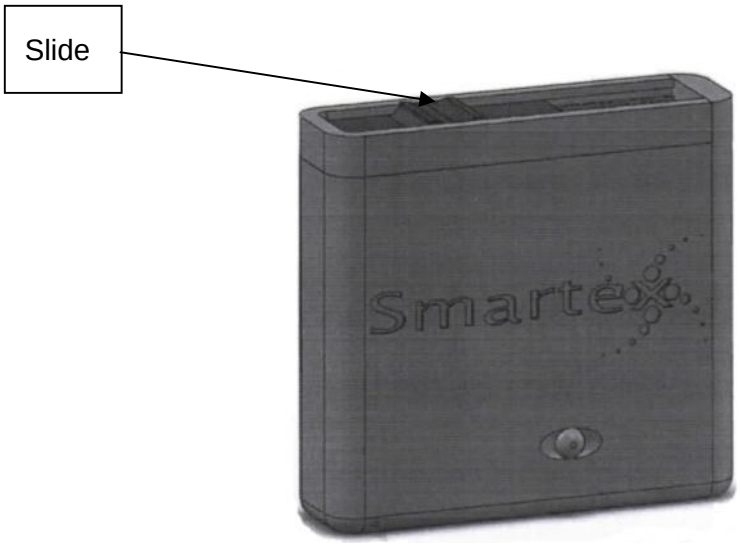
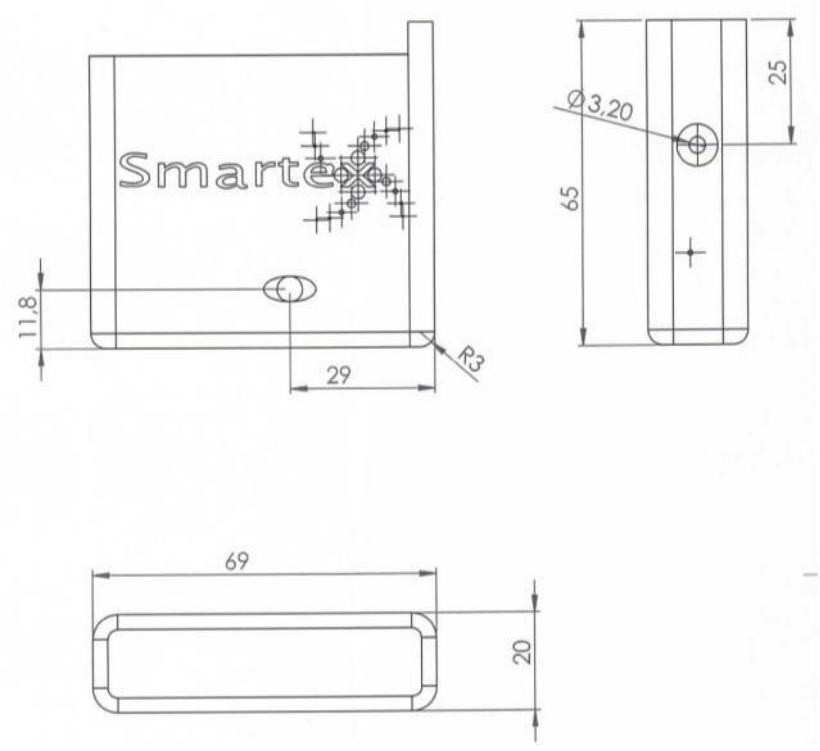


Figure 19. Case.



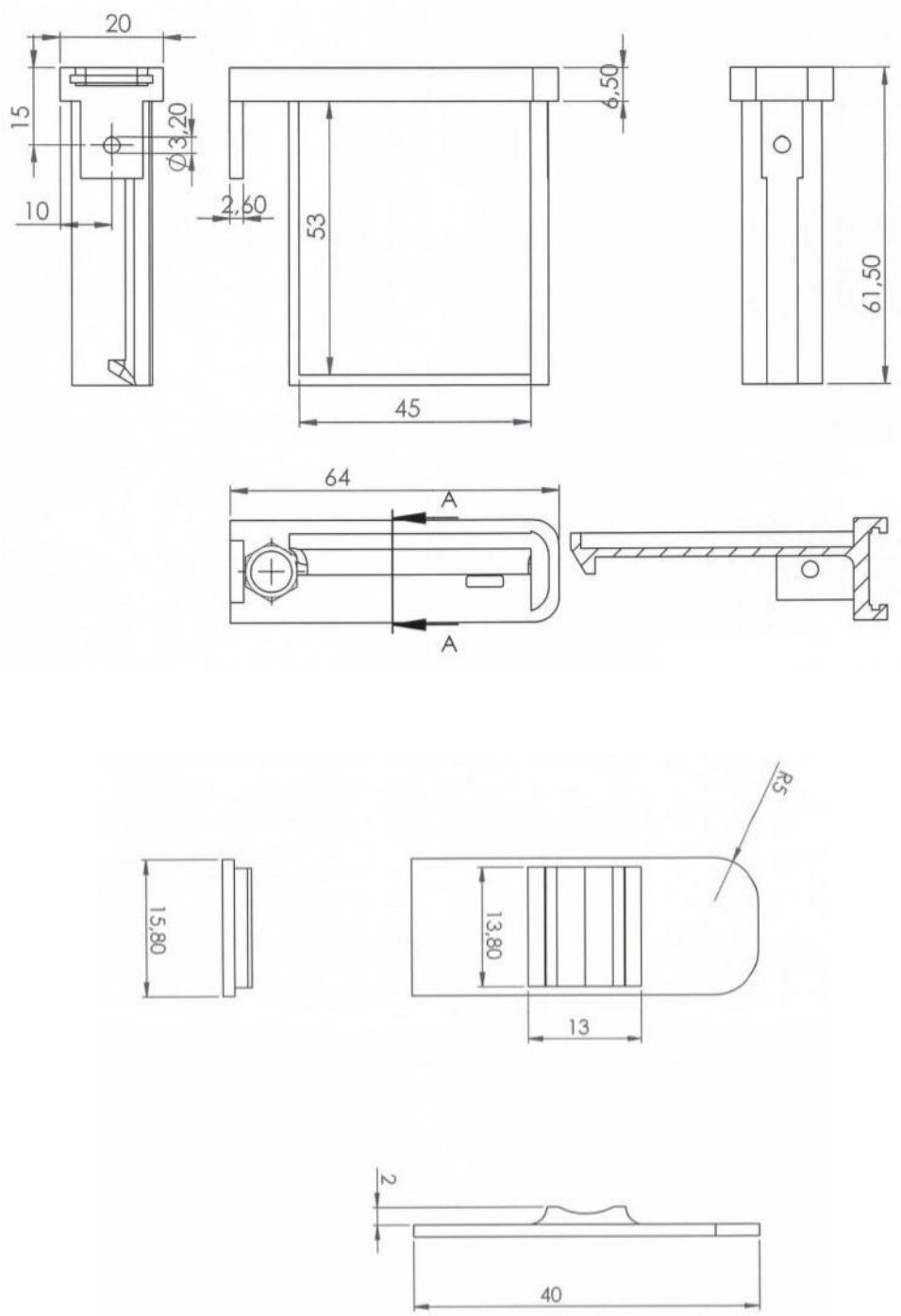


Figure 20. Drawing of the case.

The slide on the top covers alternatively the USB port or the connector for the garment: this has been introduced to make impossible that by mistake a user already wearing the garment and connected to the device could also connect the device to a charger.

5. SOFTWARE

Clinical partners will receive a software program, developed for Windows platforms, that will enable them to download data saved on the micro-SD to a PC. This software has many other features bur they won't be used for the goals of this project. A very simplified version of the same software, developed to run on android devices, will be given to clinician, to let them make a quick test of the quality of signals when delivering the WWBS to end-users.

5.1. Windows Software.

Once the WWBS has been collected by the nurse and taken back to their office, the electronic device must be connected to a PC using a (micro) USB cable and the "SmartScope" software launched.

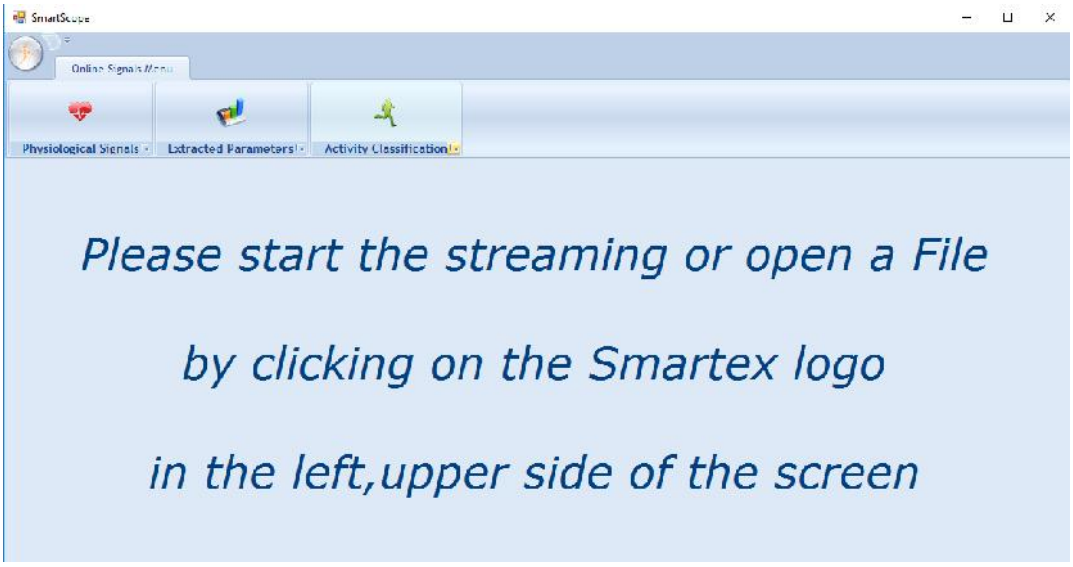


Figure 21. SmartScope.

By clicking on Smartex logo on the top left several options become available (see Figure 22).

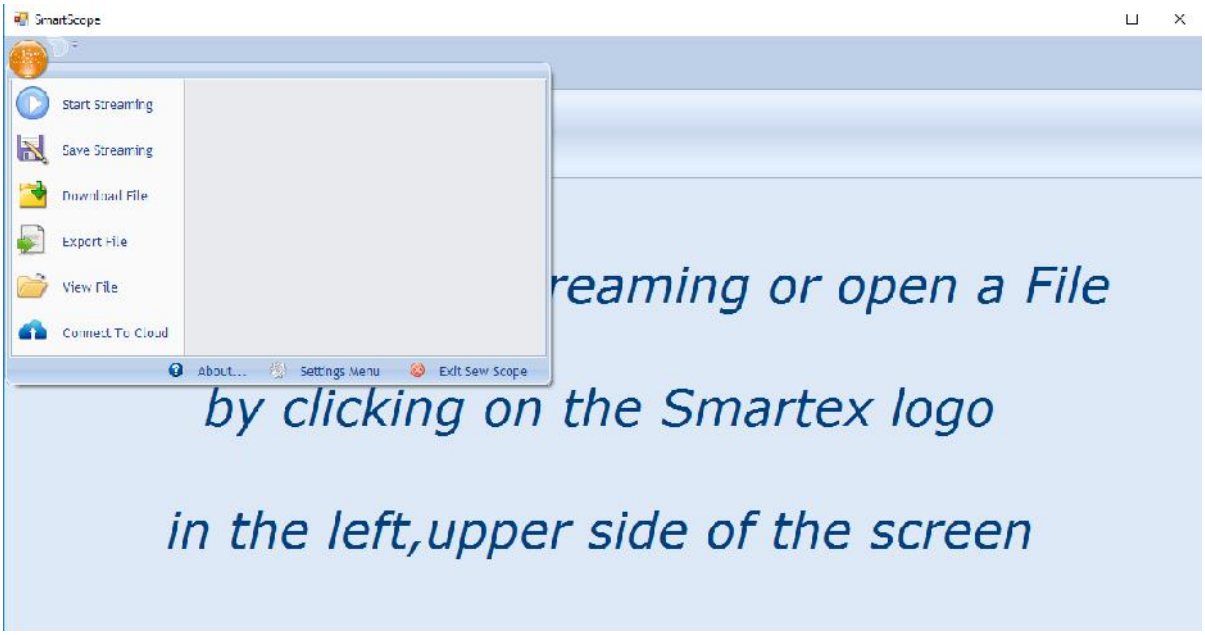


Figure 22. SmartScope menu.

Click on the "Download File" button. The following window will open.

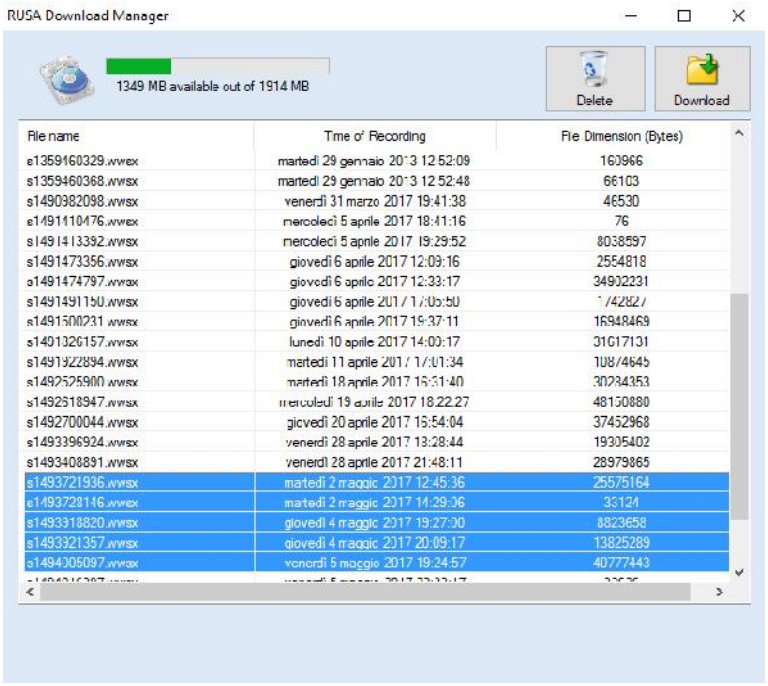


Figure 23. Download Manager.

All recorded files available on the micro-SD will be listed. The one(s) of interest can be downloaded by selecting them and clicking on the "Download" button. A new "Save as..." window will ask for file name(s) and directory.

File format is a proprietary one (.wwsx) that has been optimised to compress data as much as possible, so that files upload can be faster. In any case this file can be quickly converted by the SmartScope software in (heavier) standard formats, i.e .csv (Comma Separated Values) and .edf (European Data Format), to enable their use in open applications produced by third parties.

On the top left of the window above, there is an indication of the usage of the space on the micro-SD. If the free space is small, old files can be selected and deleted.

5.2. Android App.

This app is a very simplified version for android device of the software introduced above, and its use within this project is limited to provide a way to test if the shirt has been worn correctly and quality of data from heart and respiration is good, as both signals are heavily based on how the garment is donned.

This is the procedure to follow:

Once the electronic device and the android device have been paired, the "SmartViewer" app can be launched, then the button "Start" touched and the device of interest selected (it will come as "RUSA 5...." followed by several digits).

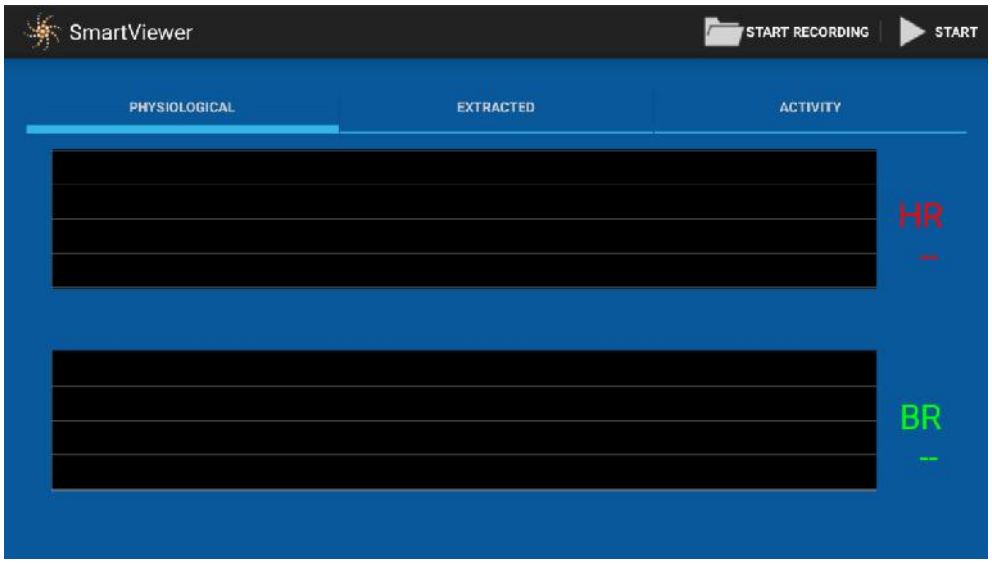


Figure 24. SmartViewer.

The first screen shot ("Physiological") is at present the only one of interest. On the top the ECG signal is showed, together with the Heart Rate (HR), on the bottom the respiration and the Breathing Rate (BR).

Figure 25. SmartViewer: Physiological signals.

If the ECG signal is not good, two options can be tested to improve it:

1. Doff the shirt and spill some water on the fabric electrodes until they become dark grey; and
2. After wearing the shirt again, try to improve the tension of the strap to have the electrodes in tight adherence with the skin.

Ask the user to make some deep breaths, then to breath normally. If the respiration signal is not good, try to work again on the tension of the strap: the curve should be smooth but reactive to the change in respiration rhythm.

6. USER INTERACTION WITH THE WWBS AND USER MANUAL

To help end-users use FrailSafe WWBS easily and with no mistakes, two parallel approaches have been adopted:

- maximum simplification of the user interaction with the garment and the electronic device (and no use at all of the software tool); and
- presentation of daily routines in an extremely short user manual: a one-page document, provided to end user as a plastic coated fiche, so that it can be taken at home without any risk to damage, spot or wet it.

The following actions have been implemented to reach the goals listed above:

- The garment must be don and doff every day, and every time the end user desire to stop monitoring, because he/she desires a shower, a moment of relax or just because he/she is fed up and needs privacy. To let the user don and doff the garment easily a zip has been placed in the front of the shirt. As already explained in Chapter 3, to assure that anyway these garments (that have been design to have enough flexibility to cover several sizes) perfectly fits different people, the strap in the back has been introduced: in this way when the nurse visits the end user to provide him/her with the FrailSafe monitoring set, the garment can be fixed in order to obtain a good-quality signal (using the app showed in the chapter before) and the user does not need to worry about it.
- The garment has just one connector (8 pin) that can be plugged with the female part placed on the electronic device in one and just one way.

Figure 26. LEMO connector.

- The electronic device must be unplugged from the vest and plugged to its charger just once a day to charge it for the next-day session.
- If the user desires to wash the garment, this is possible: the only important thing is to unplug the electronic device, as it is not waterproof. Also the external IMUs are removable, but they have been protected against unplanned washing. Instruction for a correct washing has been listed on the back side of the one-page User Instruction Manual (see below).
- Data will be saved on the electronic device and the end user does not need to interact with them in any way: no downloading, no check, no use of any software tool. Data will be stored for the 5-day monitoring session on the incorporated micro-SD and then downloaded and uploaded to the server by the nurse.
- On the electronic device there is just one button that performs different activities but just two have been foreseen for the FrailSafe users: start/stop recording. How to perform these simple tasks have been clearly explained in the leaflet with instructions

and, in case user is not sure they have been performed correctly, tasks can be repeated.

- The user will have a very short user manual (one page), protected by a plastic film, in his/her mother language, as it is shown in Annex I.

Obviously, a full User Manual has been produced as part of the documentation required for EC certification (see next Chapter).

6.1. Real-time scenario.

End-users selected by clinical partners will be monitored only off-line, using the protocol described above (and in other deliverables in a more detailed way). But there is also an activity that will be performed in laboratory only to develop and tests real-time analysis of data coming from the sensors selected by the Consortium and described in Deliverable D3.1.

WWBS has a BT chip that allows real-time data streaming to PCs and mobile devices. Within FrailSafe, WWBS will transmit a selection of data to an android mobile phone so that algorithms developed to monitor movement parameters can be tested. Several tests will be performed in future months to improve algorithm performance in Frailty detection and classification, and also to optimise data selection and transmission, in order to reduce battery consumption of both devices and increase length of monitoring sessions.

7. WWBS CERTIFICATION

To be used and accepted by Clinical Ethical Committee, WWBS must be at least certified as a safe device, which means that must respects Standard Regulations with regards to electrical safety and electromagnetic compatibility. For these reason a full system (garment plus electronic device plus software tool) is at present under certification. As soon as this EC marking will be obtained, and according to Amendment 1 to this project contract, 8 systems will be distributed to clinical and technical partners.

The following Standards and technical Specifications, conforming to EC Harmonised Regulations will be followed to obtain EC marking:

- EN 60601-1-2
- EN 301489-1
- EN 301489-3[3]
- EN 60601-1
- ETSI EN 300328
- EN 62479 / EN 62311

Together with the testing part, the certification has required also the production of a User Manual, a Manufacturing Report and a Risk Analysis Report, and documents certifying the quality of all (textile and electronic) components needed for system production and their compatibility with human use and contact with human skin have been collected from component producers.

[3] This standard is not present in the Harmonised Regulation list at the time of this certification.

8. CONCLUSIONS

This document reports the results of the activities the Consortium has performed in order to develop a useful wearable system able to perform a long term monitoring of several parameters in older adults. This Deliverable is composed also of n. 8 prototypes.

This Wearable WBAN System (WWBS) is composed by a sensorised garment, an electronic device and two software tools.

This Deliverable was due at M15, but two orders of problems forced Smartex to deliver both report and prototypes with delay:

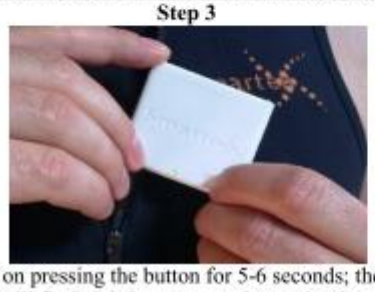
- Smartex standard PCB supplier produced the WWBS main boards with small defects that were not detectable either by standard electric tests or before components integration. The time spent before to understand the reason of the problems and then for the production of new PBC (with integrated components) generated a 40-day delay;
- In Amendment 1 to project contract the number of devices to be delivered at M15 passed from 1 to 8, involving tests in real conditions (so with older adults using them at home without the presence of technical/clinical personnel). This step requested the certification of also this intermediate prototype, at least for safety regulations (electrical safety and electromagnetic compatibility), otherwise Ethical Committee would have not accepted its use. WWBS is at present under certification and systems will be delivered only after certification is obtained.

This delay will not generate major implications anyway. For instance Group B will still use this device, with just a reduction of one time, i.e. 5 times instead of 6. Furthermore, as each clinical partner will have just two systems at this stage but 5 users per session, for 3 end users out of 5 there will be no difference in the planned protocol.

9. ANNEX I

USER INSTRUCTIONS

When you start recording

Step 1	Step 2
	
Moisten thoroughly the electrodes with tap water	Wear the shirt and plug the connector to the device
Step 3	**Step 4**
	
Keep on pressing the button for 5-6 seconds; the LED will flash 4-5 times green, then red; release immediately the button	Place the device inside the pocket on your chest

When you stop recording

Step 5

Keep on pressing the button for 4-5 seconds; when the LED will flash green release immediately the button. Now you can unplug the device and plug it to the charger and doff the garment.

IMPORTANT

- If you are not sure Step 3 or 5 has gone correctly, try again, until you feel sure the flashing is correct (RED = recording, GREEN = stop recording).
- Use the zip to don/doff the vest, DO NOT TOUCH THE VELCRO STRAP!
- REMOVE THE DEVICE BEFORE WASHING THE GARMENT!!!
- Call xxx if you need advice!

Maintenance and Care

Electronic device

Like any electronic device, SEW should be treated with care. In order to use it at its best please follow the suggestion below.

- Store your device in a dry and cool environment. Do not store it in a dump place.
- Keep your device clean. Use a dry and soft towel, do not use soap or water or organic solvents.
- Do not leave your device exposed to direct sunlight for prolonged periods.
- Do not expose to high temperature (> 50°C)
- The device includes a Bluetooth module, so its use must be avoided in those cases where the use of such communication is forbidden.
- Be careful to electrostatic discharges: the high sensitivity standard of the product make it very sensitive to discharge that could enter the device through the USB port.

Garment

The sensorised shirt is realised using natural and synthetic yarns and must be treated as an underwear.

- Washing must be done by hand or washing machine using a mild cycle (max temperature 30°C).
- The garment must be washed with a delicate soap (e.g. shampoo) **without using softeners.**
- Wash it separately.
- Do not bleach.
- Do not put the shirt in a drier.
- Do not iron.
- Do not pull cables coming out of the vest.
- Do not unplug the connector from the device pulling the cables.
- Be sure that the garment has been worn correctly, with the electrodes on the chest and in touch with the skin.
- The garment must be in tight contact with the body without any crease.

Safety rules

The WWBS system has been developed to work under standard environmental conditions and not in a water environment. It is useful to remind that:

- it is not allowed to wear it in swimming pool, in the see or anywhere else under water;
- the device is not waterproof, so please avoid to use it under rain;
- the system was tested to work:
  - with a temperature range between -5 and + 40°C;
  - up to 2.000 meters of altitude;
- the device must be removed from the garment before washing;
- **the connector on the garment must not be plugged in electric plugs or put in contact with exposed cables or in any other place different from the device plug (as shown in this User Manual);**
- **do not use other chargers different from the one provided with the WWBS**.