PROJECT DELIVERABLE REPORT

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Advanced personalised, multi-scale computer models preventing osteoarthritis

SC1-PM-17-2017 - Personalised computer models and in-silico systems for well-being

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Abbreviations

Short	Long
EC	European Commission
EU	European Union
WP	Work Package
KOA	Knee Osteo Arthritis
OA	Osteo Artritis
GRF	Ground Reaction Forces
DOF	Degree of Freedom
IMU	Inertial Measurement Unit
OVP	Overvoltage Protection

1 Executive Summary

This deliverable relates to the activity performed, during the reporting period, within OACTIVE WP 5: Behaviour Modelling and Environmental Biomarkers. In particular the report refers to Task 5.1, led by Smartex, focused on the development of the sensing wearable platform, foreseen by OACTIVE project for the acquisition of objective parameters correlated to the behavioural model.

The wearable platform has been conceived as a flexible and adaptable tool capable to provide motion data collected directly from the OA patients; these data will be used to develop and feed the behavioural model. OACTIVE, targets patient-specific OA prediction and interventions by using a combination of mechanistic computational models, simulations and big data analytics. Once constructed, these models will be used to simulate and predict optimal treatments, better diagnostics and improved patient outcomes, for this reason the sensing platform will be used to improve the robustness of the OACTIVE behavioral model, meanwhile the platform will be evaluated to assess the feasibility and reliability of its use for ambulatory monitoring to support remote customized intervention.

The system design is based on the outcomes of WP2, where user requirements have been identified (D2.1) and system specification has been defined (D2.3). The architecture of the OACTIVE system has been designed taking into consideration the functional requirements and considering that the clinical studies will concern the collection of data in 3 different countries (Spain, Greece and Cyprus) with patients who could develop OA, athletes and elderly subjects with developed OA; the studied subjects will have different sizes, gender, musculoskeletal characteristics and habits, then to create a solution compatible with the operational scenarios, a flexible and adaptable and modular architecture was defined.

The resulting sensing platform is based on a set of IMU sensors, to be applied mainly on the lower limbs and on sensing insoles for the evaluation of the GRF. The platform is based on a modular architecture to guarantee a flexible configuration adaptable to the operating scenarios. The system developed in the frame of WP5 is a tool for the acquisition of physical activity features that will be used to feed the behavioural model. The behavioural analysis and modelling, aim of the upcoming activity (T5.2), will be carried out following different approaches (e.g. Generalized Linear Models (GLMs), Bayesian Belief Networks (BBNs)). This will lead to the identification of relevant features and the association to each subject with a data dictionary. A personalized tuning of the modelling process will be possible, allowing for the evaluation of progress of each individual in terms of their physical activity, as result it will provide essential for the development of advanced machine learning frameworks in WP6.

2 Introduction

Osteoarthritis (OA) is a complex disease affecting mostly the weight-bearing joints of the lower limbs, such as the hip and in particular the knee in addition to the hands and spine. The whole joint is usually involved, affecting the musculoskeletal functionality, the general mobility and body movement in general. Although the usual population associated with OA disease is the elderly, athletes and younger individuals are also susceptible. A large percentage of knee injured athletes develop OA later in life, in their 40s or 50s, following successful operative repair of knee ligaments occurred when they were young. The development of the disease in such a relatively young age leads to a long period of living with the consequences of OA. Depending on the population, injuries, occupational activities, and obesity appear to be the most common causes of OA in young and athletic populations. Obesity and a history of traumatic knee injury and structural hip deformities are key risk factors for the early development of knee or hip OA, and can impact on the incidence among younger people.

OA is difficult to define, predict or treat, for this reason is important preventing or delaying the onset of the joint degeneration. Medical risk factors known to influence development of the disease include advanced age, gender, hormonal status, body weight or size, usually quantified using body mass index (BMI), family history of disease and also genetic causes. Other known risk factors for the onset and progression of OA include joint loading during occupational or physical activity and sports participation, muscle weakness, a past history of knee injury and joint operations (ACL injury and reconstruction, meniscal damage and partial meniscus removal) and depression. Although many of the above factors are fixed, other risk factors, behavioural correlated such as body weight, physical activity and occupation are modifiable. For many people occupational activities involving physically demanding jobs, such as manual handling of heavy loads or prolonged kneeling may be associated with the disease.

The OACTIVE approach is based on a multi-scale holistic analysis where patient-specific information from various levels, including molecular, cell, tissue and whole body, are integrated and combined with information from other sources such as, environmental, behavioural and social risk factors, to generate predictors for personalized interventions aiming at delaying the onset and/or slowing down the progression of OA.

Purpose of WP5 activity is the identification of behavioural features and social risk factors correlated to OA. Considering the lack of homogeneity of the population sample that is associated with this disease, a preliminary work was done to design and develop a sensing platform adaptable to different users profiles.

The platform is intended to be compatible with the OACTIVE data collection protocol, the idea is to set a system capable to collect data correlated to movements, in a controlled environment, to get contextualized information on the quality of movements and behavioural data over a diversified category of subjects. These pilot studies will provide inputs to the holistic analysis. The ambition is to design a sensing system that in a future optimization will be able to identify in a remote monitoring the main features correlated to the quality of movement, on the basis of the individual model, the platform will be used to follow the individual trend in a long term monitoring.

The platform will be able to collect behavioural features to feed the predicting algorithms based on the multi-scale models at the individual patient level, data will be correlated to the development and progression of the disease. The acquisition of objective and reliable data in ambulatory conditions, allows to assess the appropriate and tailored treatment at each stage. This has the potential to maximize the efficacy of treatment and to provide a tailored intervention. This could include to provide feedback based on the observed trend, and making informed decisions about the house environment (e.g., avoid stairs and steep terrain), occupation (e.g., avoid heavy manual work, kneeling), lifestyle (e.g., ensure adequate nutrition for joint health) and recreational activities (e.g., avoid certain sports whilst ensuring that adequate physical activity and mobility of joint is maintained). OACTIVE sensing platform may also provide inputs about the necessity of surgery and improve the rehabilitation efficiency on the base of tailored remote intervention.

3 Requirements and System Specifications Analysis

The activity carried out in the frame of WP5 is based on the analysis reported in the User Requirements D2.1 and in the System Specifications Report D 2.3.

Following the overview of the use cases defined in D2.1 and the specifications of the different components of the OACTIVE system, the design of the sensing tools has been based on a sub set of specifications addressing the clinical studies needs and compatible with the personalised intervention module.

The main components of the OACTIVE system are:

A. Multiscale Modelling

B. Biomarker Profiling

C. Environmental, behavioural and social risk factor profiling

D. Big data analytics and machine learning

E. Personalized interventions

As shown in Figure 1, the three components (A, B, C) inform the data fed into the Big data analytics and machine learning component (D) and the output from this deep learning process will be used to inform the personalized interventions (E) and the data validation.

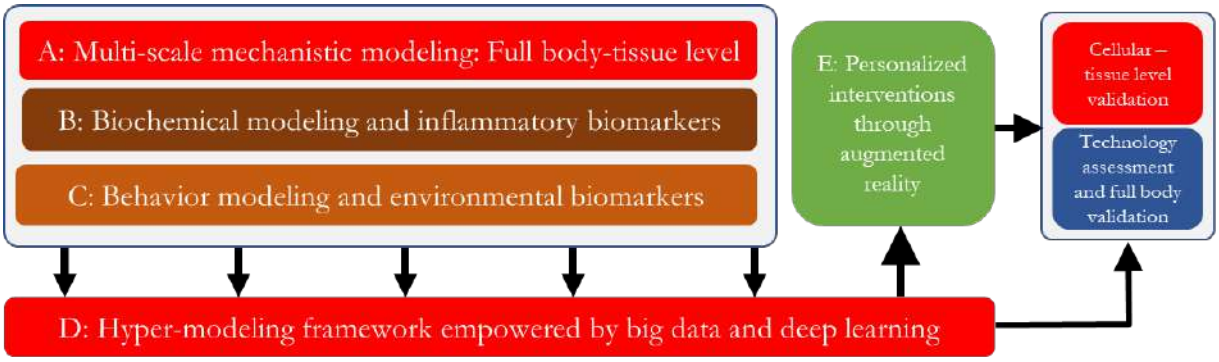

Figure 1: OACTIVE system pipeline with architectural overview of system component interdependencies

The system developed in the frame of WP5 is a tool for the acquisition of physical activity features that will be used to feed the behavioural model. The system is based on a modular architecture to guarantee a flexible configuration adaptable to the operating scenarios. A preliminary evaluation on available sensing solutions has been performed to investigate about their compatibility with the OACTIVE system specifications.

The sensing platform is based on a set of IMU sensors, to be applied mainly on the lower limbs and on sensing insoles for the evaluation of the GRF.

Considering that the clinical studies will concern the collection of data in 3 different countries (Spain, Greece and Cyprus) with patients who could develop OA, athletes and the elderly OA patients, as reported in Table 1; the studied subjects will have different sizes, gender, musculoskeletal characteristics and habits, then to create a solution compatible with the operational scenarios, a flexible and adaptable and modular architecture was defined according to the Technical Requirements for the design and development of OACTIVE wearable sensors, reported in

Description of task (workflow, plan of experiments/actions)	This work relates to Task 5.1 and Task 5.2 and includes the following steps: Selection of possible hardware platforms Preliminary tests to evaluate the functionality of the platforms Preliminary tests on signals integration Evaluation of best suitable solution Design and implementation of the system User Behavioral Analysis Technical support for acquisition and data analysis Optimization of system functionalities on the base features that will be identified as relevant for the behavioural model.
2. Technical Specification (standards, requirements etc) of any technologies to be used in the task	The system should offer a modular approach: 1 module for upper body 1 module for lower limbs 1 module for feet IMUs placement should cover: trunk, pelvis, leg (thigh), leg (calf or tibia), feet for a total of 8 IMUs. The system should offer standard wireless communication with a remote host (PC). Bluetooth protocol can offer a good compromise between power consumption, communication efficiency and compliance with multiple platforms (windows, android). IMUs should guarantee 9 degree of freedom (DOF) The system should assure comfort to the user in term of wearability, usability, unobtrusive-ness
3. Software to be used (software requirements and any standards)	ELECTRONIC Board CAD, Development SW for embedded systems (IAR), C# or other for user interface
4. Hardware to be used (Computer hardware requirements and any standards)	IMUs, Bluetooth modules, Micro Controllers, active and passive electronic components for PCB development. Laboratory instrumentation for HW test and

	debug of prototypes
5. Inputs needed from other partners/tasks	CERTH: Shoe specs for system integration

Table *2* (from D2.3) and following the specifications reported in Table 3.

Acquisition Centre	**HULAFE - Spain**	**ANIMUS - Greece**	**NIC - Cyprus**
Targeted patients	Healthy ones in high risk of developing OA	Post-traumatic evaluation of athletes	Elderly people
Population size	More than 100 patients	More than 90 patients	More than 130 patients
Targeted patients	Healthy ones in high risk of developing OA	Post-traumatic evaluation of athletes	Elderly people

Table 1 OACTIVE Studies

1. Description of task (workflow, plan of experiments/actions)	This work relates to Task 5.1 and Task 5.2 and includes the following steps: Selection of possible hardware platforms Preliminary tests to evaluate the functionality of the platforms Preliminary tests on signals integration Evaluation of best suitable solution Design and implementation of the system User Behavioral Analysis Technical support for acquisition and data analysis Optimization of system functionalities on the base features that will be identified as relevant for the behavioural model.
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Table 2. Technical Requirements of OACTIVE wearable sensors

Requirements	Implications
The system has to fit subjects with different sizes	Different sizes has to be implemented (S.M.L)
The system has to fit male and female	Different gender models wherever needs will be designed
The system has to be don on and off easily	Design solution to easily don on and off will be taken into account
The system has to be used by an high number of subjects (> 100)	Elastic bands or leggings will be washable and can be disinfected
The system has to be user friendly for the operator	Local GUI or APP to easily manage the data acquisition
The system has not to impede the natural behaviour of the subject (motion freedom)	Wireless solutions
The system focus mainly on knee OA (KOA)	The IMUs placement will cover: trunk, pelvis, leg (thigh), leg (calf or tibia), feet
The system has to be flexible, number of IMU and positioning can be customized	Modularity
The system has to provide data to build the	Data will be available in a standard data format

behavioural model	(csv, edf, txt…)
The system has to be compatible with the OACTIVE data management plan	Data will be anonymised.
The system has to reduce the risk of data loss	Local back up solution will be implemented

Table 3. New set of Wearable Sensing Specifications for the design of the platform

According to the outcomes of WP2, and following the decisions taken during the plenary meetings, the main characteristics of the IMUs wearable platform has been defined:

- The platform has to be composed by 8 IMUs necessary to cover the lower limbs (legs, feet), pelvis and chest.
- The communication with remote host should be wireless. Standard Bluetooth protocol has been chosen due to the high data rate of the entire platform.
- Sampling frequency of each electronic must be high enough to guarantee a correct reconstruction of movement (100 Hz suggested)
- The system must follow a modular approach. Depending on the needs, it would be possible to use only a sub set of the wearable platform.
- Due to the number of measurements, the wearable system should guarantee user friendly use and easiness in don and doff the sensors for a faster setup.
- Desktop application to manage the platform (devices pairing, streaming, recording)

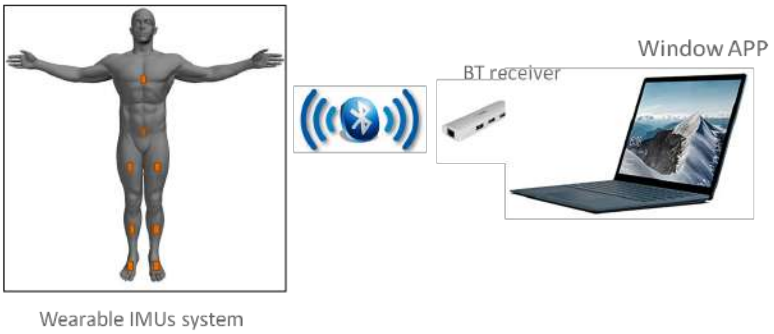


Figure 2: Main blocks of the OACTIVE Wearable IMUs platform

4 OACTIVE Wearable Sensors

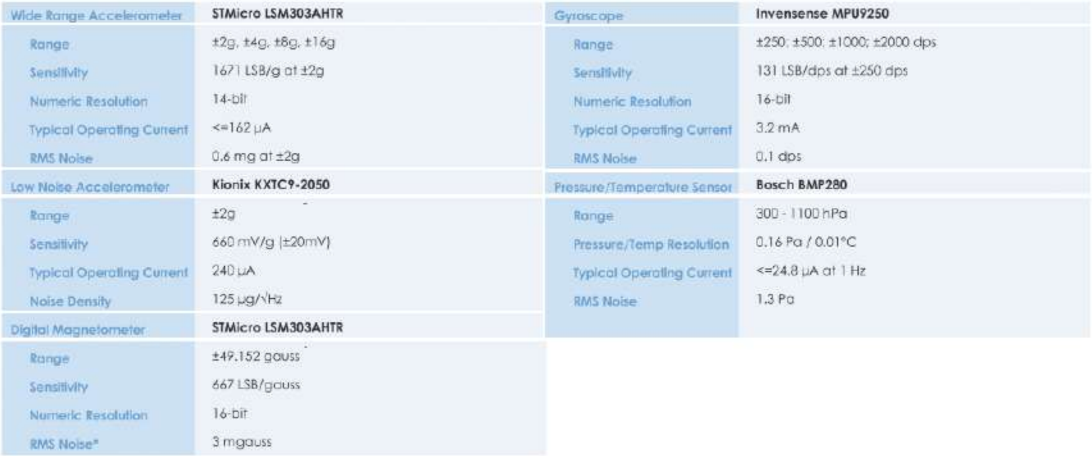
4.1 IMUs system

4.1.1 Commercial hardware platforms

A preliminary overview of the performances of IMUs systems available off the shelf has been performed. Among the available systems, two main candidates have been considered, removing from the list other products that have been evaluated as not reliable on the base of the experience reported by the clinical partners. The first one was the **Shimmer3** platform.

The Shimmer3 Consensys IMU Development Kit provides a solution in body worn applications. It is available in customizable configuration from 1 to 15 Shimmer3 IMUs with integrated 9 DoF (plus altimeter) inertial sensing via accelerometer, gyroscope and magnetometer, each with selectable range. Shimmer is designed for wearable and remote sensing applications. The development kit includes the Consensys Base hardware and a multi sensor management system. The base allows users to easily configure and capture data from up to 15 Shimmers simultaneously and provides ability to: charge Shimmers, data download through MicroSD Card access, program Shimmers and configure. The simultaneous management of multiple sensors is achieved by the software Consenys, developed by Shimmer, in its Pro version.

Figure 4: Shimmer Consensys base (left) , Shimmer3 wireless unit IMU (right)



Wide Range Accelerometer	STMicro LSM303AHTR
Range	±2g, ±4g, ±8g, ±16g
Sensitivity	1671 LSB/g at ±2g
Numeric Resolution	14-bit
Typical Operating Current	<=162 µA
RMS Noise	0.6 mg at ±2g
Low Noise Accelerometer	**Kionix KXTC9-2050**
Range	±2g
Sensitivity	660 mV/g (±20mV)
Typical Operating Current	240 µA
Noise Density	125 µg/√Hz
Digital Magnetometer	**STMicro LSM303AHTR**
Range	±49.152 gauss
Sensitivity	667 LSB/gauss
Numeric Resolution	16-bit
RMS Noise*	3 mgauss

Gyroscope	Invensense MPU9250
Range	±250; ±500; ±1000; ±2000 dps
Sensitivity	131 LSB/dps at ±250 dps
Numeric Resolution	16-bit
Typical Operating Current	3.2 mA
RMS Noise	0.1 dps
Pressure/Temperature Sensor	**Bosch BMP280**
Range	300 - 1100 hPa
Pressure/Temp Resolution	0.16 Pa / 0.01°C
Typical Operating Current	<=24.8 µA at 1 Hz
RMS Noise	1.3 Pa

Figure 3: Shimmer3 sensors specifications

The Shimmer3 Wireless Sensor Unit contains accelerometers, a gyroscope and a magnetometer to enable a complete 9 DoF solution.

Despite the claimed functionalities, this solution has been considered too expensive, as it required to buy a minimal closed configuration (base+ sensors+ software) to test the performance of the sensors.

The second product was MetaMotionR, a complete development and production platform by MBIENTLAB Inc for wearable and connected device applications. The board, based on the nRF52 SOC from Nordic built around a ARM® Cortex™ M4F CPU and Bluetooth Low Energy, features ultra-low power performances providing energy efficient communication and central processing. The device provides real-time and continuous monitoring of motion and environmental sensor data. On-board sensors include a triple-axis gyroscope, accelerometer, and magnetometer, as well as a barometric sensor, a temperature sensor and a luminosity sensor. An on board sensor fusion algorithm combines the measurements from 3-axis gyroscope, 3-axis geomagnetic sensor and a 3-axis accelerometer, to provide a robust absolute orientation vector in form of Quaternion or Euler angles. The board comes in a very small rectangular form factor and is powered by a 100 mAh lithium-ion 3,7 V battery.

Figure 5: MetaMotionR board(left) and MetaHub device (right)

The development kit is completed by MetaHub. The MetaHub is a Linux based development environment with Bluetooth, WiFi, computer power, and the ability to connect multiple Sensors at once. The MTH comes with pre-loaded Operative System (OS) to get- send commands to MetaSensors, graph sensor data, setup automatic downloads and more.

Gyroscope	Range:	± 125, ± 250, ± 500, ± 1000, ± 2000°/s
	Resolution:	16 bit
	Sample Rate:	0.001Hz – 100Hz stream – 800Hz log
Accelerometer	Range:	± 2, ± 4, ± 8, ± 16 g
	Resolution:	16bit
	Sample Rate:	0.001Hz – 100Hz stream – 800Hz log
Magnetometer	Range:	±1300µT (x,y-axis), ±2500µT (z-axis)
	Resolution:	0.3µT
	Sample Rate:	0.001Hz – 25Hz

Sensor Fusion	
Outputs:	Quaternion, Rotation Matrix, Euler Angles (Robust Heading / Yaw, Pitch, Roll), Linear Acceleration, Earth Acceleration (Gravity)
Update rate:	100Hz
Accuracy:	<1° RMS

Figure 6: MetaMotionR sensors specification

According to nominal specification (Figure 3), the MBIENTLAB development kit seemed to match OACTIVE requirements. It has been considered as an option for development of OACTIVE wearable IMUs system. After some testing, it shown some limitation, in particular at high sampling frequency (100 Hz) or if more than 3 units were connected to the same Bluetooth dongle, continuous streaming and connection issues has been encountered with consequent loss of data.

Due to the observed technical problems, to the incompatibility of the available commercial solutions with OACTIVE specifications, to the impossibility to integrate other commercial systems like the Xsense system (described in D7.1), it has been decided to develop a new system.

4.1.2 Hardware development, case

Within the framework of Oactive project it has been implemented the electronic board necessary to develop the wearable platform for behavioral modeling of the OA patient. 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 transmit data via Bluetooth protocol and will implement also the capability to record the acquired data on an internal 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 *7*

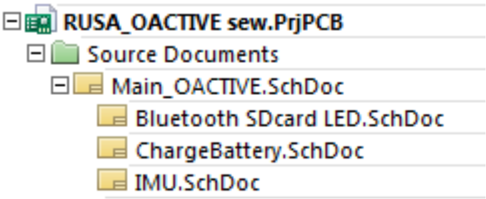
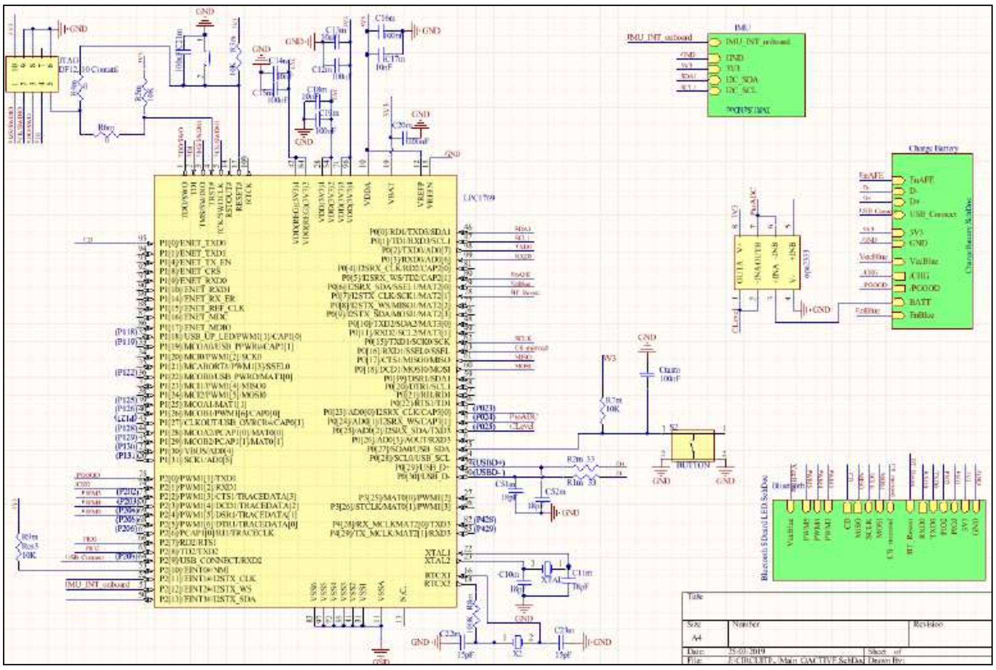

RUSA_OACTIVE sew.PrjPCB
Source Documents
Main_OACTIVE.SchDoc
Bluetooth SDcard LED.SchDoc
ChargeBattery.SchDoc
IMU.SchDoc

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, IMU, power management, Bluetooth and SD card driver.



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. The MPU-9250 is a 9-axis MotionTracking device that combines a 3-axis gyroscope, 3-axis accelerometer, 3-axis magnetometer and a Digital Motion Processor™ (DMP). For precision tracking of both fast and slow motions, the parts feature a user-programmable gyroscope full-scale range of ±250, ±500, ±1000, and ±2000°/sec (dps), a user-programmable accelerometer full-scale range of ±2*g*, ±4*g*, ±8*g*, and ±16*g*, and a magnetometer full-scale range of ±4800 μ T. Communication with all registers of the device is performed using either I2C at 400kHz or SPI at 1 MHz. For the purpose of the project the IMU has been set at ±2000°/sec (dps) and ±2g with a sampling frequency of 100 Hz.

An evaluation board has been used to test the preliminary functionalities of the device. The power is guaranteed by a 1000 mAh Li-Po battery. The charging circuitry is based on Texas Instruments chip bq24074, chosen in order to introduce additional safety measures beyond the ones already implemented on the battery pack.

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

- **Fast charge current: Ichg= 330 mA**
  Current set for the constant current phase of the charging process.
- **Max input current: Iin-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.

Figure 8 shows a charge cycle of the battery acquired in a former test on the battery charger. It is possible to see the first phase at constant current, (Ichg =330 mA); the current then decreases to 20 mA, once achieved this value the charge is considered complete and the supply current goes to zero.

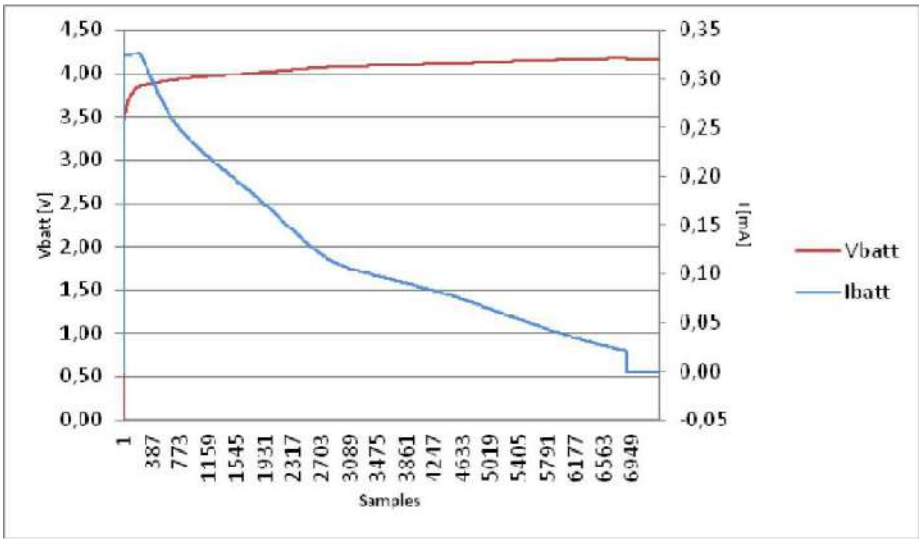


Figure 8: Battery charge cycle

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

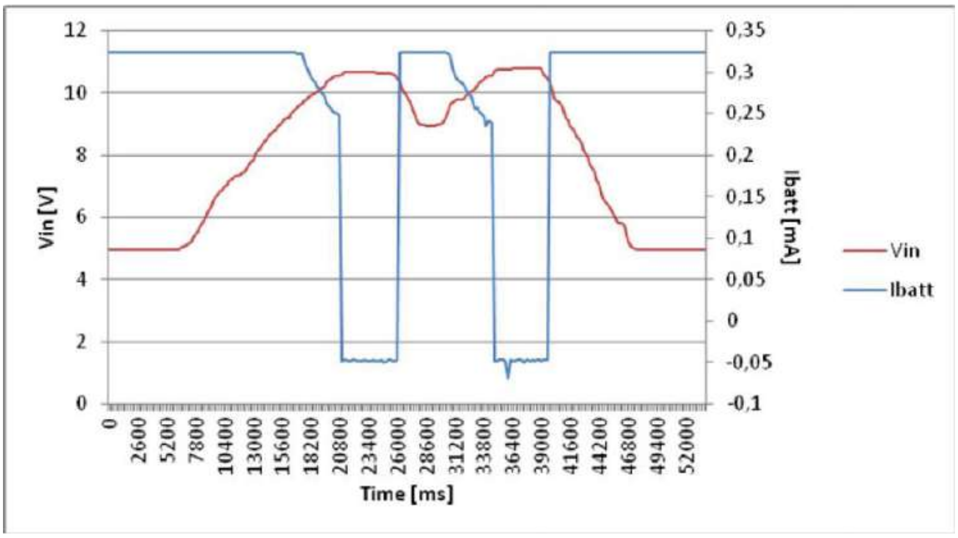


Figure 9: Over Voltage protection

The following figures show the final design of the board. 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.

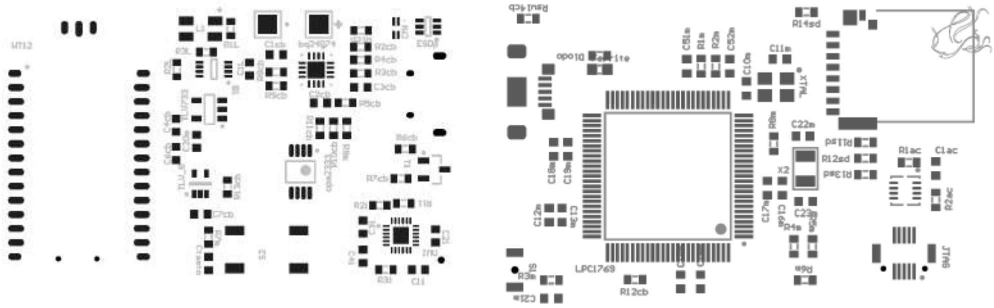


Figure 11: Drowning of the final board TOP layer (left) BOTTOM layer (right)

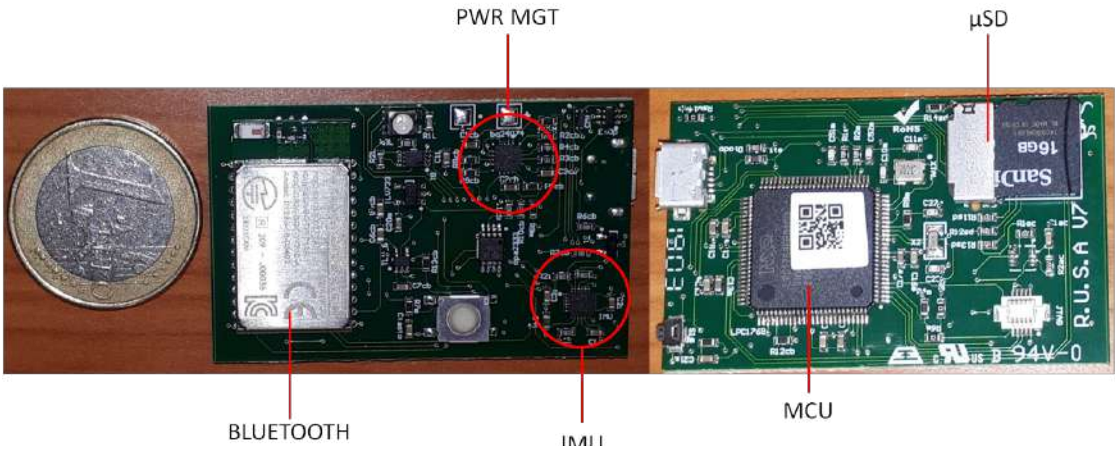


Figure 10: OACTIVE IMU board

TOP layer includes: Bluetooth module, battery charger, IMU, status led, control button.

On the bottom layer are placed, microcontroller and micro SD holder, micro USB connector, reset button, JTAG connector.
Also the package of the devices has been considered.
The case has been designed considering different materials and different prototyping technologies.
Following some sketches from the design, and the prototype assembled.

Figure 13: Sketches of the OACTIVE IMU module

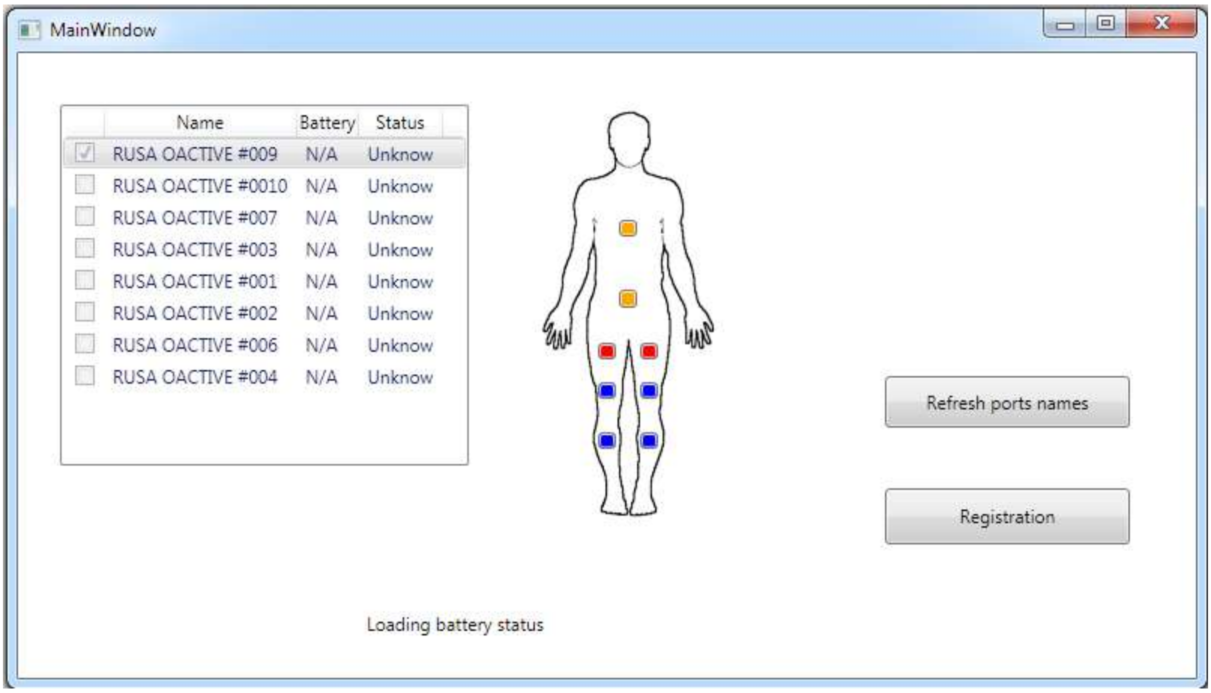
Figure 12: Case of OACTIVE IMU module

Shape and dimension has been optimized for the device handling and to guarantee comfort when the electronics is worn with the textile band. The user interface is controlled by one button (activation, synchronization, pairing) while the management of the overall system is guaranteed by the windows application described in the next section.

4.1.3 Windows application

The OActive APP records data from multiple Bluetooth devices that gather data on motion and the position in the space of the person wearing them.

The application, developed in CSharp language with Windows Presentation Foundation (WPF), runs on Windows computer. The Oactive IMU platform is characterized by the presence of multiple devices recording simultaneously, for this reason the software consists of a multithreading system with a thread for each device from which data is recorded. Each electronic has its own serial port with which the connection and streaming of data is established. The interface is managed by the SewLib library, through the COM ports used to manage the devices. A special function has been developed to know the name of the port (COM1, COM2, COM3 etc.) starting from the MAC address of every device. In this way, given the MAC Address it is possible to obtain the name of the port of each paired device. This function must be performed every time the devices are paired to proper setup the system.



	Name	Battery	Status
☑	RUSA OACTIVE #009	N/A	Unknow
☐	RUSA OACTIVE #0010	N/A	Unknow
☐	RUSA OACTIVE #007	N/A	Unknow
☐	RUSA OACTIVE #003	N/A	Unknow
☐	RUSA OACTIVE #001	N/A	Unknow
☐	RUSA OACTIVE #002	N/A	Unknow
☐	RUSA OACTIVE #006	N/A	Unknow
☐	RUSA OACTIVE #004	N/A	Unknow

Loading battery status

Figure 14: APP interface for manage IMUs sensors

Before starting the APP, the device has to be paired from the Windows control panel. In the OActive.exe.config configuration file it is necessary to enter the names of the device that will be used (eg "RUSA OACTIVE # 005"). The device names must be entered as values of the fields Device1, Device2, Device3, Device4, Device5, Device6, Device7, Device8. Each number corresponds to a position of the device on the body. Completed this setup phase, it is possible to start the application. Clicking on "Refresh ports names" update the communication port of the devices paired (this must be done every time the pairing is performed). At this point, the program requires the device to return the battery level. If this operation is successful, it means that the device is ready for use. It is possible at this step to select the device for the measurement session. Clicking on the button corresponding to the position of the device on the body a pop up show graphs of the quaternion transmitted by the selected sensor. The files containing the recorded data are then saved in a subfolder in csv format.

4.1.4 Garment, textile accessories

OACTIVE project aims at the implementation of a sensing platform able to acquire information on the movement functionality. There are several aspects that have been considered in the design of the platforms, first of all the functionality of the sensors, the sensing capability is based on the use of inertial platforms, that have to be located in a precise area of the patient body, all the sensors are wireless connected with a reading portable computer. The system has to guarantee that the IMU position on the patient body will not change during the use. In summary the first requirement concerns the functionality of the system in term of sensing capability, that is related to the fitting of the whole set of the sensors on the body, moreover the project foresees a data acquisition campaign on subjects with different anthropometrics characteristics, leading to the requirements on the easiness of use during the experiment and on the adaptability of the platform to the different body sizes.

The design study has also considered comfort and wearability as essential requirements of the system. OA patients may present movement impairments, then they cannot easily perform tasks like wearing or putting off a garment or adjust the position of the sensors on the body, for this reason the design was based on the concept that the system components have to be easily put on and off and maintained. Another aspect that has been taken into account is the thermal comfort, if the system has to be worn in a domestic environment for a long period; the basic fabric components of the garment have to be light and transpiring, at the same time a part of the garment structure has to be strong enough to allow a good fit of the sensors on the body, in the right location.

The first step of this process was a preliminary discussion, internal to the consortium, to collect some feedbacks both from technical and clinical partners in order to share a common vision of the wearable system and a design solution capable to fit with the data campaign routine.

The results obtained have been considered as the guideline for the development of the system.

The work was organized according the following tasks:

1. Wearability study	2. Sensors functionality study	3. Integration study	4. Prototype study
Materials selection			
Model and pattern of the prototype			
Cutting of the fabric components of the prototype			
Manufacturing			
Testing: Laboratory evaluation, Usability test			
Changes of the model according users feedback			

Two models have been implemented, a leggings model for the long-term use on the same subject, and a band model with different sizes to be used during the data acquisition campaign on different subjects and on different body areas.

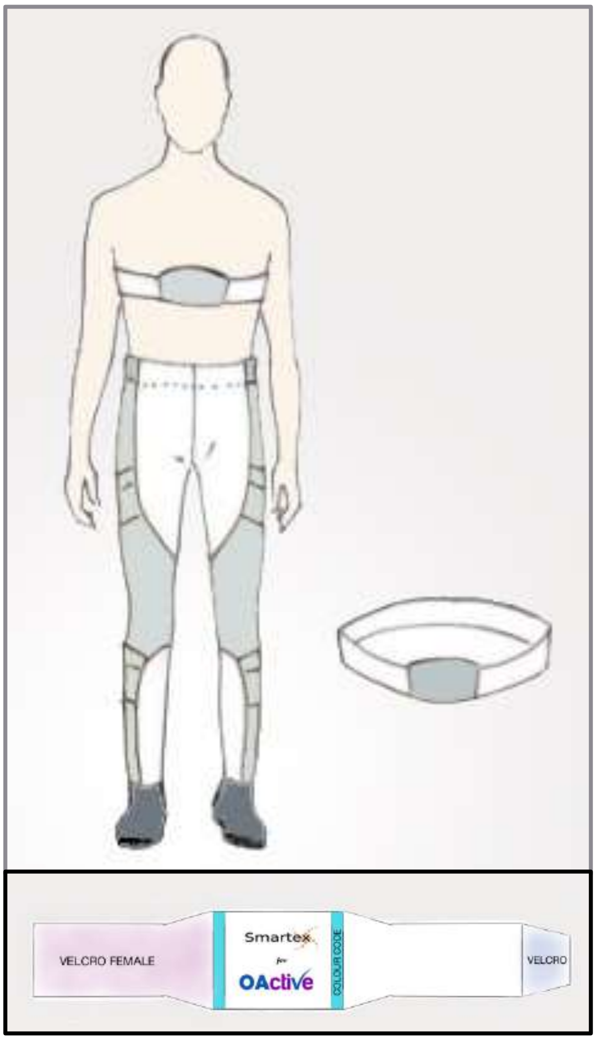


Figure 15: Textile models, suit and eleastic

The leggings are conceived with two different fabrics, with different weights, to guarantee a reliable fitting of the sensors on the body. In the figure the grey areas correspond to the more elastic and heavier material. On the band the grey area correspond to the sensor holding pocket. To facilitate the use of band with different length, a code colour has been designed for the identification of the length of the band, according a Small, Medium and Large Size. The band is conceived with three different areas, the central area for the sensing with a reduced stretch capability, the lateral regions are realized with elastic material, for the fitting there is an elastic female VELCRO area and for the closure a male VELCRO insert.

4.2 Smart Shoe

Since the initial stages of the project, it was decided by the consortium partners that the possibility of developing a lower cost version of the Wi-Shoe as well the possibility to adapt cost effective available existing sensors for the intended tasks should be investigated. The most expensive components in Wi-Shoe are the force sensors and for this reason, during this subtask focus was put on examining the possibility of using cheaper sensors for measuring force. A cheaper solution could be the use of flexible pressure sensors, such as Flexiforce sensors by Tekscan. Load cells and Flexiforce sensors were combined in the same insole (a working prototype of Wi-Shoe has been used (borrowed from Cyric)), in order to be able to directly compare their measurements. Four Flexiforce sensors were placed in selected positions (two different configurations) directly under the load cells. The figures below present the testing prototypes. Since there is no ECM capable of measuring simultaneously 19 load cells and 4 Flexiforce sensors, 2 ECMs were used on the same foot: One ECM v1 for the load cells and one ECM v2 (preliminary prototype) for the Flexiforce sensors. Since it was not possible to fit 2 ECM units in the same sole and since the Flexiforce cables also needed to be driven outside the shoe, the Podartis Teradiab shoe was used for the trails, instead of the Podartis Activity shoe. The Teradiab shoe is the one used also for the preliminary tests and it is an easy to use post-operation shoe. The figure below presents the prototype.

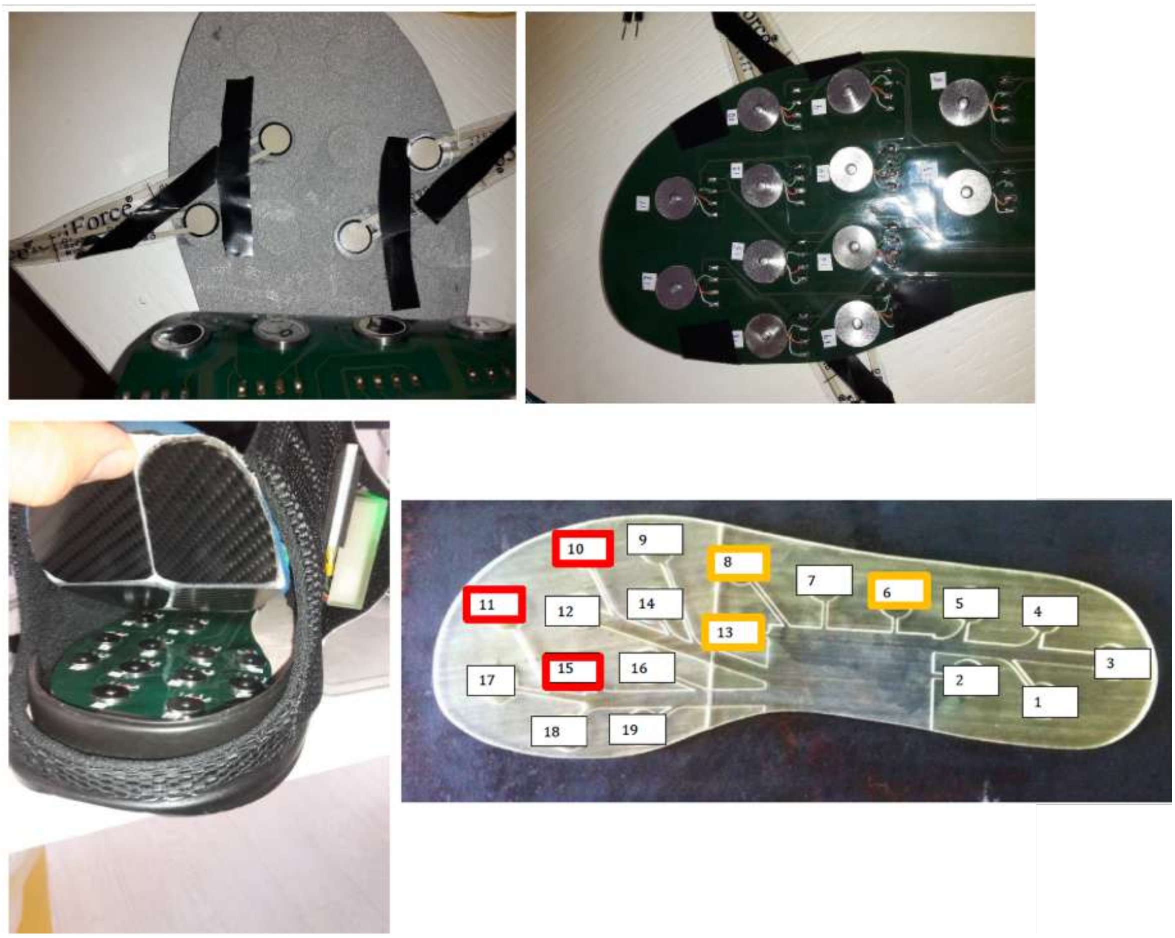


Figure 16 The setup used to test load cells and Flexiforce sensors simultaneously.

The initial configuration was with the **Flexiforce sensors in positions 10, 14, 15, 19**. This configuration covers two positions where very low force are generally detected and two positions where higher forces are usually detected. The following figure presents a snapshot of a single step (right foot) during this experiment and the contribution of each sensor to the total forces measured. Separate graphs are provided for load cells and Flexiforce sensors, in order to be able to compare the results.

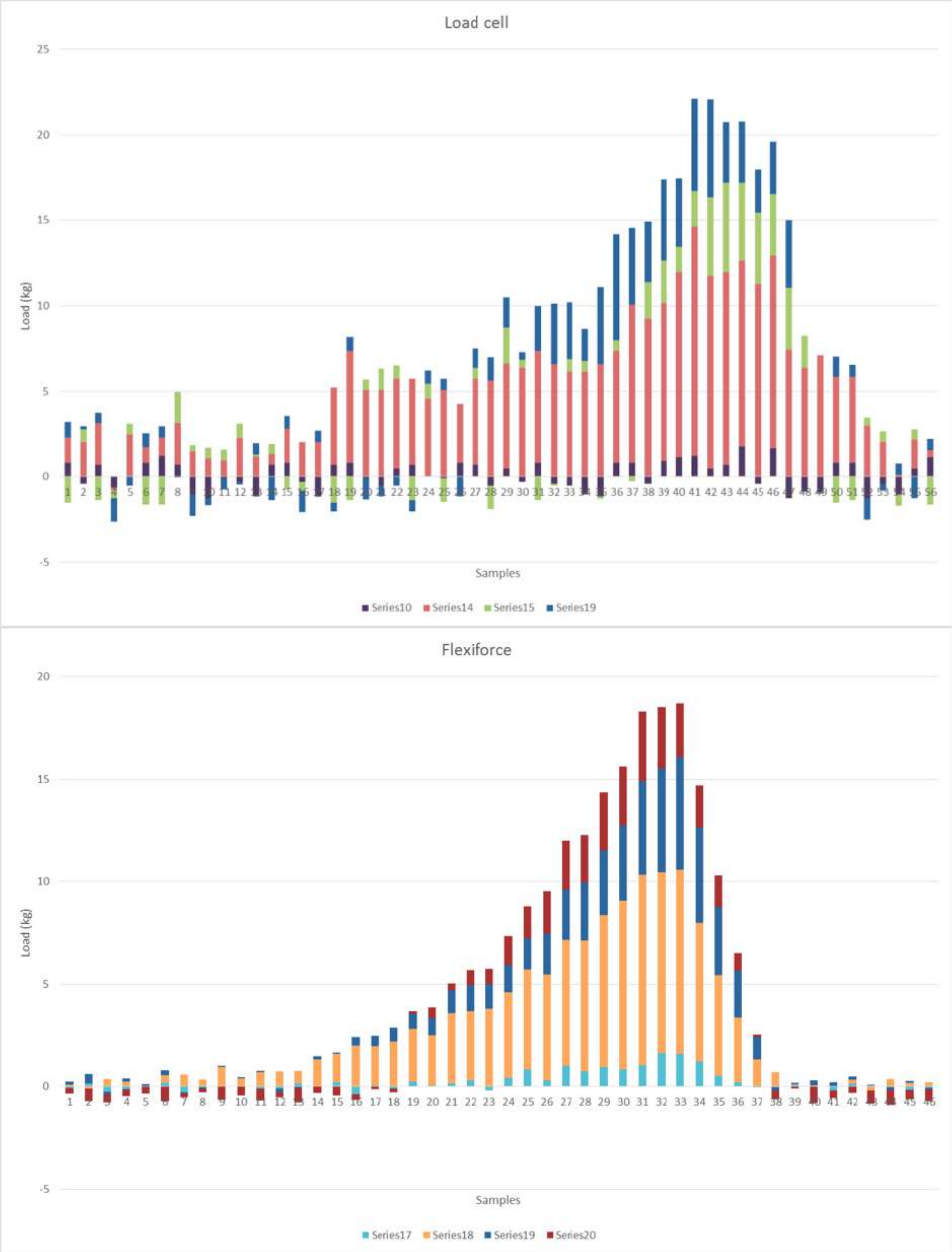


Figure 16: The graph on the top presents the forces measured by each of the 4 selected load cells during a single step. The graph below presents the forces measured by the 4 Flexiforce sensors in the same positions. Sensor order is the same in the two diagrams, so: Series 10, 14, 15 and 19 in the first diagram correspond to Series 17, 18, 19, 20 in the second one.

The results were quite encouraging. In fact, the general behaviour of the forces is the same in both cases, even though lower forces are measured by the Flexiforce sensors. The following figure presents several steps together from the same trial. Similar behaviour is observed.

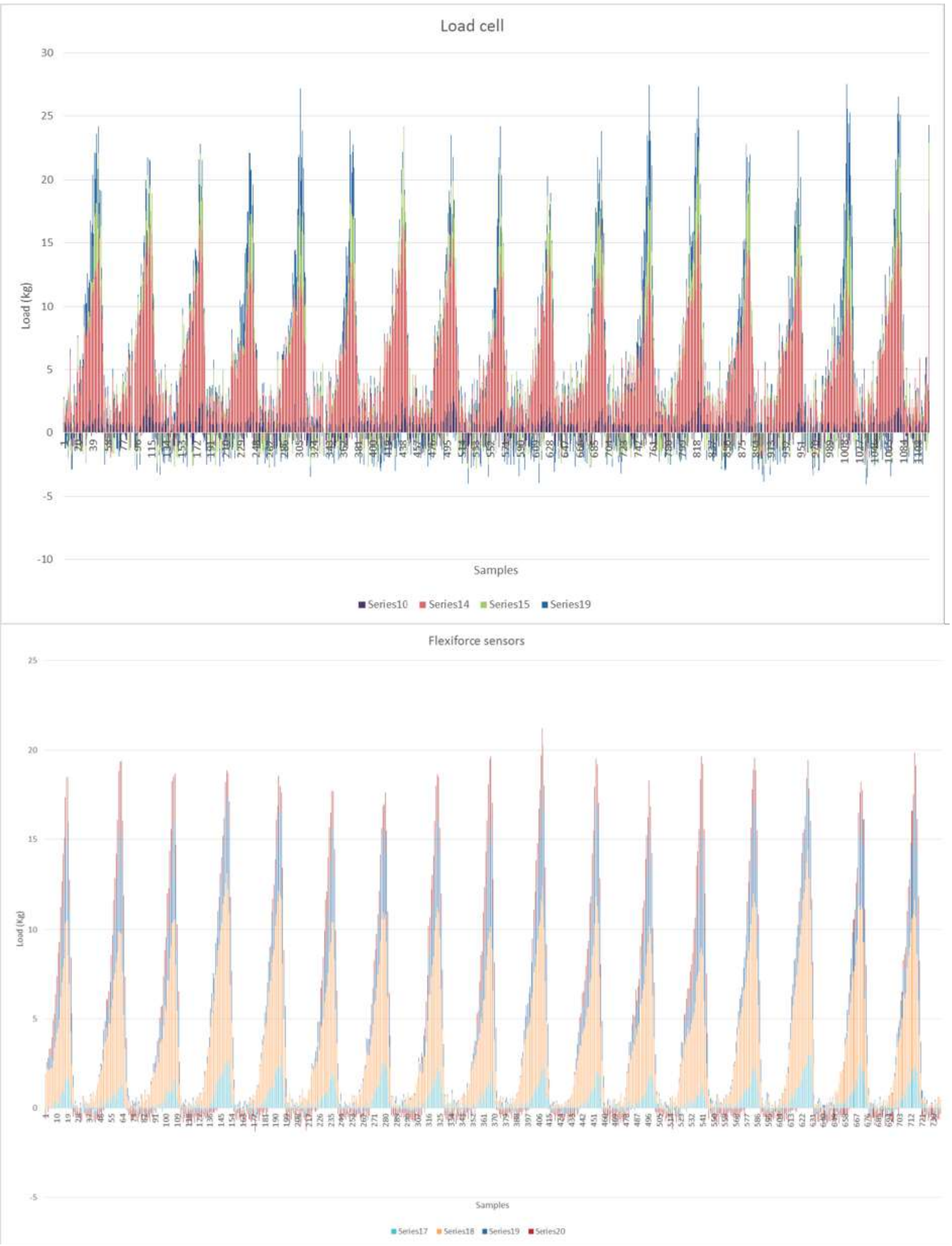


Figure 17: Load cells vs. Flexiforce sensors comparison in the same positions

According our results the use of Flexiforce sensors (or similar sensors) is a cost effective alternative solution to the load cells used in the Wi-Shoe system. This will allow reducing the final system cost.

5 Towards Behavioural Model

The data collected will form a personalized dictionary for each subject, containing information about the specific behavioural patterns of the corresponding individual. These dictionaries can then be combined in a dataset, ready to be used in a data analytics framework, resulting in the construction of behavioural models.

One key aspect of the data modelling process is the selection and/or extraction of relevant attributes (features) from the multisensory data collected, that will help identify certain behavioural patterns which may influence the progression or the onset of the disease in the subjects tested. Another key component of the analysis is the identification and detection of possible associations between the various sets of variables and attributes that will be extracted, and the subsequent quantification of the existing associations in a comprehensive and interpretable framework. Thus, the fundamental requirements for the data analysis framework lead us to models that feature the following capabilities:

1. The fusion of data derived from different sources. The multisensory data comprising the whole body of the dataset come from different devices, with different modalities, therefore a fusion-capable model is required for their appropriate handling.
2. The ability to perform feature selection (implicit and/or explicit) and feature extraction, as well as the potential to identify statistical relationships between the various sets of identified features. One of the most crucial components of the modelling process is, as has been stated above, the identification of relevant attributes that play a crucial role in the behavioural patterns of each subject, and the subsequent codification of their possible statistical relationships.
3. Model interpretability. This is an essential requirement, since the output of the models is going to be heavily used by human experts in an attempt to better understand the behavioural patterns that are associated with osteoarthritis.

Given the above requirements, there are two main approaches that are going to be followed in the modelling process, namely Generalized Linear Models (GLMs) and Bayesian Belief Networks (BBNs).

Generalized Linear Models:

Generalized linear models provide a simple yet powerful framework for various data analysis techniques. They are suitable for data fusion and feature selection via methods such as elastic-net regularization and group-lasso regularization, and their linearity ensures the interpretability of the results.

Bayesian Belief Networks:

Bayesian belief networks are probabilistic models that are excellent at encoding statistical associations and dependencies among various sets of variables. Their outputs, being probabilistic in nature, are heavily used by human experts in order to mine knowledge for the better understanding of the underlying processes that govern the corresponding field of application.

The behavioural analysis based on the above two modelling frameworks will prove useful for the following tasks:

1. The identification of relevant features and their corresponding statistical associations will prove essential for the development of advanced machine learning frameworks in WP6.
2. Since each subject will be associated with a data dictionary, a personalized tuning of the modelling process will be possible, allowing for the evaluation of progress of each individual in terms of their physical activity.

6 Potential use for personalised interventions tools

The aim of a gait retraining system is to reduce the Knee Adduction Moment (KAM) or other related indicators in order to improve patients' comfort and delay the progression of OA by adapting the gait habits of the users. Biofeedback assisted rehabilitation and intervention technologies have the potential to modify clinically relevant biomechanics. To perform this type of intervention one must obtain the kinematics and kinetics of user using either indoor or outdoor solutions. The indoor approach has proven to be reliable and accurate, since we can use state-of-the-art measurement equipment. However, this method can be expensive, time consuming and cumbersome, especially for the patient and demands many sessions of training in a laboratory. Hence, the outdoor solution has the potential to provide a more flexible alternative to the indoor solution for the gait intervention framework. Acquisition of the kinematics and kinetics for the analysis in an outdoor environment requires wearable solutions, such as IMUs and ground reaction smart shoes.

Figure presents a schematic diagram of the mobile gait retraining solution. Eight IMUs will be attached to the body segments (foot L/R, shank L/R, thigh L/R, pelvis and torso) in order to collect information on motion of the patient. GRF shoes will be used to record the reaction forces between the ground and feet. AR glasses will be utilized to provide visual feedback to the user. Vibrotactile feedback could be also included in order to alert the user to correct his/her behaviour. The information would be transmitted to a station through wi-fi which will process the various information and provide real-time, personalized feedback. The visual feedback may target gait characteristics such as stride width, foot progression angle, trunk sway, etc., by providing differential cues through the feedback devices.

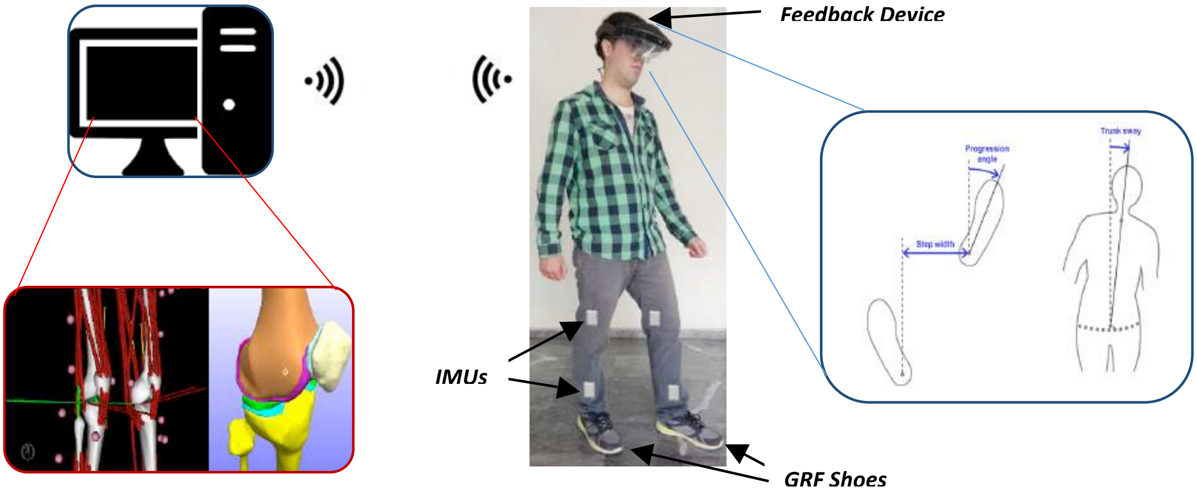


Figure 18: Mobile gait retraining solution that will collect and provide wireless, real-time and personalized intervention through AR and other feedback devices.

One of the technical challenges of this framework is the real-time reconstruction of kinematics (IK) from IMU measurements. More specifically, the IMUs can measure the linear and angular acceleration. IK requires position level information, thus the acceleration must be integrated twice, provided appropriate initial conditions. Unfortunately, different measurement errors can amplify and propagate resulting in inaccurate estimation of the position variables. In addition, movement artefacts due to changes in the attachment positions of the sensors can induce errors it is thus important to validate this approach against the immobile solution.

The system that will be used by the station will be similar to the one developed for the immobile solution. The main difference will regard the IK module, for which a different approach will be adopted to solve the IK problem using IMUs information. Furthermore, the feedback devices that will be used by the mobile solutions will differ than the indoor solution, thus the differential cues that will be provided to the patient have to be adapted to the specific device used in each context (e.g., screen projection, AR glasses, vibrotactile, etc.).

However, the development of such a solution presents difficulties regarding mainly the feasibility and the practicality of use. IMUs used in this setup are developed in prior work during WP5, in which the goal is primarily to acquire data related to behaviour information and they were not intended for kinematic and dynamic analysis. Moreover, the user is required to wear additional hardware devices compared to the immobile solution, thus making it inconvenient for the user. These reasons, along with the technical challenges of this framework described above, lower the priority of its development as the potential of the mobile solution is yet to be explored.

7 Conclusions

OACTIVE, targets patient-specific OA prediction and interventions by using a combination of mechanistic computational models, simulations and big data analytics. Once constructed, these models will be used to simulate and predict optimal treatments, better diagnostics and improved patient care. This document presents the activity conducted within the WP5 finalized to the construction of the behavioural model of the OA patient. The aim of WP5 is, indeed, the identification of higher-level physical, mental/emotional, and social states-correlates parameters and information that can be used to provide personalized diagnosis and recommendations for patient-specific treatments. The generation of the behavioural model requires the interpretation of data gathered directly from the patient by the means of a wearable platform. This deliverable presents the results of the activities (task 5.1) devoted to the development of the OACTIVE wearable system. The design is based on the outcomes of WP2 where user requirements and technical specification has been defined. The wearable system is composed by two main sub-systems: an IMUs wearable system for data on patient's motion and sensorized shoes or insoles designed to evaluate the GRF. Considering that the clinical studies will concern the collection of data in 3 different countries (Spain, Greece and Cyprus) with subjects that range from potential patients, athletes and elderly OA patients; the studied subjects will have different sizes, gender, musculoskeletal characteristics and habits, then to create a solution compatible with the operational scenarios, a flexible, adaptable and modular architecture was defined. The IMUs wearable system, managed by a Windows application, offers the opportunity to connect up to 8 modules placed on lower limbs, pelvis and torso of the patient. Each module, equipped with a 9 DOF inertial platform provides raw data and quaternion. The system will collect quantitative data directly from the patient; these data will be used to feed the behavioural model. Data will be analyzed following different approaches to identify relevant features and associate to each subject a data dictionary. As result, a personalized tuning of the modelling process will be possible, allowing the evaluation of progress of each individual in terms of physical activity. This will be essential for the development of advanced machine learning frameworks in WP6. The platform has been designed aiming at a future potential application for the personalised interventions tools (WP7). It is important to remark that the wearable platform is intended primarily to acquire data related to behavioural information and it is not intended for kinematic and dynamic analysis aiming at a future exploitation for remote care applications.