SensorART

A remote controlled Sensorized ARTificial heart enabling patients empowerment and new therapy approaches

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Publishable Summary

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Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Service)	
RE	Restricted to a group specified by the consortium (including the Commission Service)	
CO	Confidential, only for members of the consortium (including the Commission Service)	

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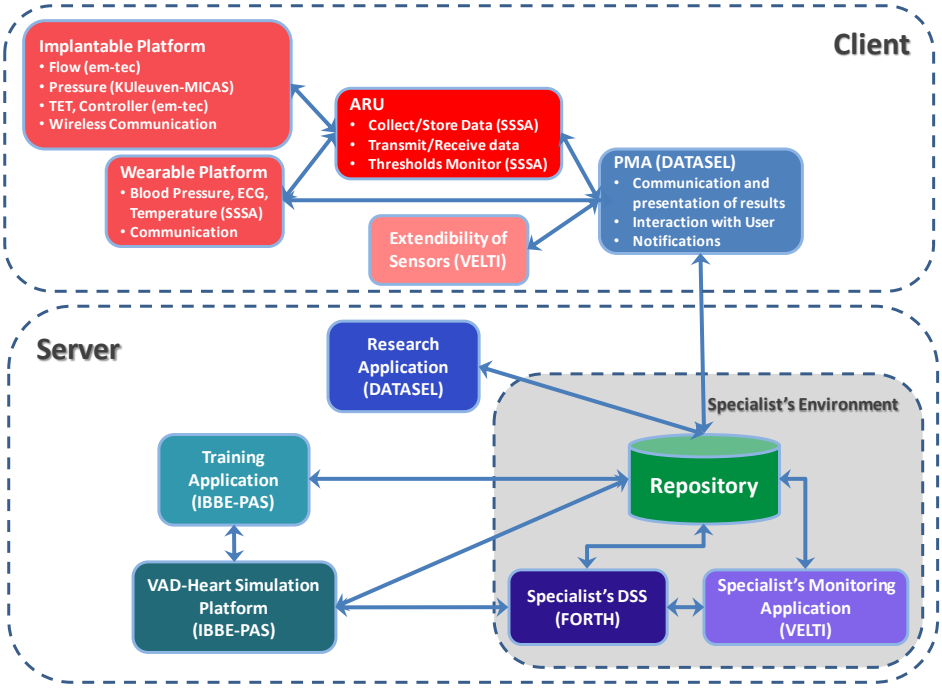
Publishable summary

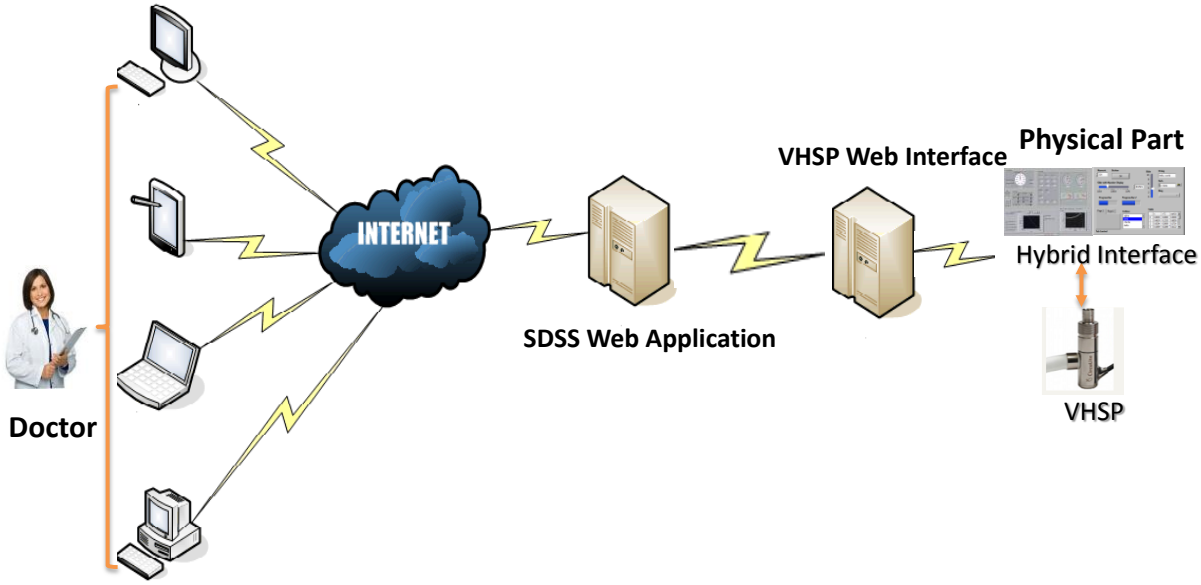
SensorART - A remote controlled Sensorized ARTificial heart enabling patient empowerment and new therapy approaches (Project Identifier: FP7-2009-ICT-248763; website: www.sensorart.eu) a large-scale integrated project, reached the third year of life. For the increasing of all the areas involved and for a more complete integration, this year has been the most challenging for the coordinator and for the whole consortium. In fact, the final definition of both the system architecture for the experimental, implantable platform dedicated to CircuLite pump as well as for the wearable platform, open, VAD-independent, with implementation of sensors and devices already certified for human use, has been finalized and agreed by the partners. As a consequence, some activities have been postponed – i.e. experimental testing of integrated sensors – not only due to the delay of getting sub-modules and/or different devices, but also for the ethical issues of reducing the number of animals utilized for experimental purposes and optimizing protocols for demonstration with almost definitive devices and/or platform.

For the implantable platform, we are in the process of developing sensors to be inhoused into the micro Synergy pump of CircuLite together with the ongoing work for on a Transcutaneous Energy Transfer (TET) in order to exclude the use of cables. This field of activity requires: 1. high level of knowledge of regulations and requirements, 2. rigorous methodology in all the phases, 3. bench testing to verify reproducible measurements, 4. risk assessment during the design, assembling and test steps, 5. evaluation of possible interferences and their correction, 6. energy consumption calculation and verification. Previously, the single sensor must be accurately tested for cable sealing, connectors stability together with biocompatibility of materials. Many laboratory steps have been overcome: the electronic control of the pump needs to be integrated for the whole system and connected to the external autoregulation unit within the experimental scenario. Solid work has been performed in this year and the consortium is now prepared for a bench demonstration of the system.

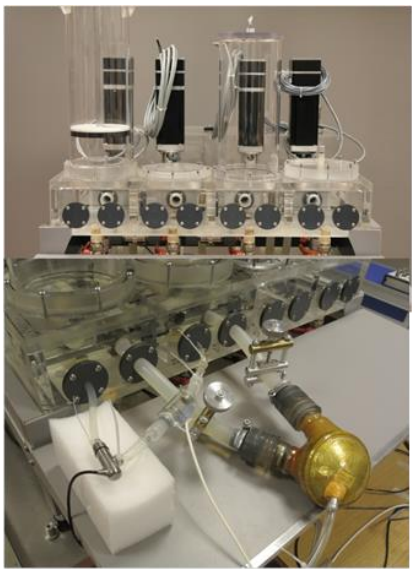


SDSS in the SensorART Platform

For the wearable platform, an already certified device usable in human being for monitoring heart failure patients (MagIc t-shirt) has been acquired. This device has been inserted within a defined system for continuous and/or intermittent measurements to be remotely sent throughout the autoregulation unit or directly to the Patient Monitor Application (PMA) and after to the Specialist Monitor Application (SMA). Preliminary usability tests have been performed in collaboration with European RobotERA project on a group of elderly people.
The Specialist Decision Support System (SDSS, see figure in the previous page) has been implemented and validated with the available data given by the clinical partners; the different tools are structured and tested with the available data. In summary, the list of the tools is: Association Rules Tool, Statistics Tool, Treatment Support Tool, Monitoring Tool, Weaning Tool, Pump Speed Selection and Suction Detection Tool. The structure and the features of SDSS have been partially described in some published papers and presented within international conferences. The integration of SDSS and simulator has been accomplished (see scheme below, VHSP: VAD–Heart Simulation Platform).



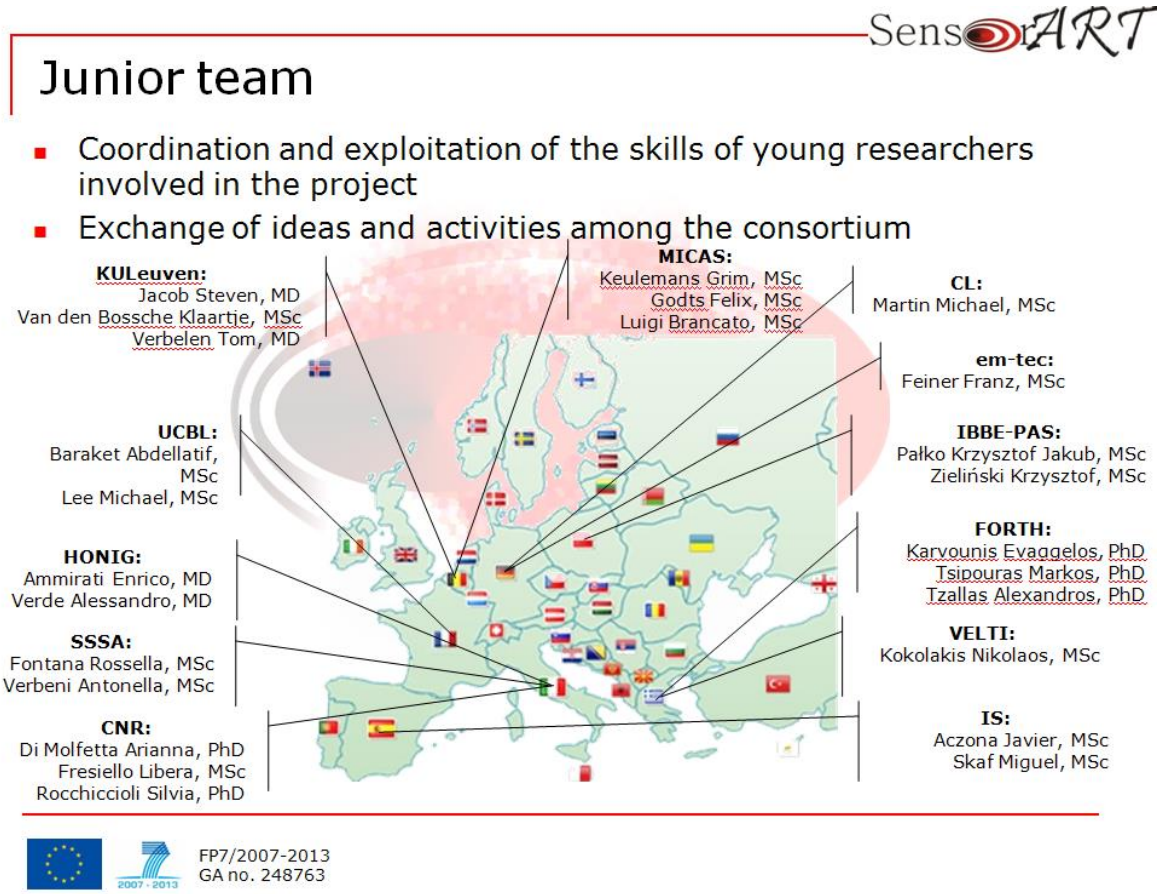
Schematic representation of the SDSS-VHSP Connection

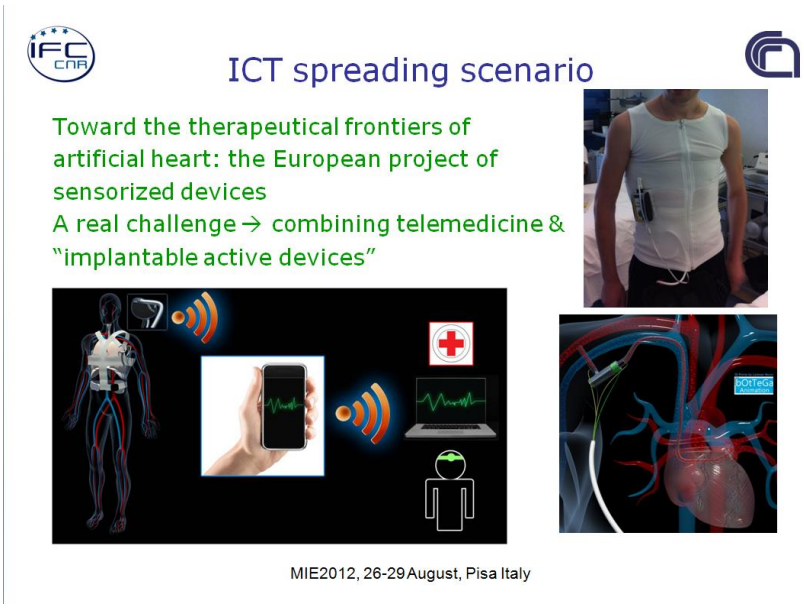


Moreover, within the framework of WP10, a single point of access is developed, allowing the specialist to access the SMA, SDSS and CKE modules via a single web interface, namely the Specialist's Environment, eliminating the need of multiple platforms, user authorization and authentication procedures, simplifying the overall process and enhancing specialists' experience. Moreover, by the numerical simulator of the cardiovascular system some clinical data have been used to reproduce haemodynamic condition not only after VAD implantation, but also before implantation, by taking into consideration a possible, predictive value.
The hybrid simulator of the cardiovascular system has been utilized to construct speed/flow curves with Synergy micropump and set for remote training course. A second, simplified hybrid simulator is ready to be transferred to a clinical arena for training purposes and for dissemination to different stakeholders.

Hybrid Simulator with Synergy micropump of CircuLite

The extensive dissemination made up to now gave great visibility of SensorART project. The active work of the Junior Team (see figure below for composition) was one of the way of a better interconnection among the partners. Furthermore, an increase of interdisciplinary understanding due to the continuous cooperation has been fruitful instrument for "European" versatile researcher training and education.





SensorART has indicated the way and it could be considered a pioneer example of concrete, integrated perspectives, by putting together the overregulated area of implantable devices and

Information Communication Technologies (see slide of project presentation at MIE 2012: Medical Informatics Europe conference).

Within the framework of the European Society for Artificial Organs, SensorART and in particular in the working group HEART Support, project gained more and more consideration during these years, due to the fact that TET and telemedicine application are confirmed to be the most relevant lines for future research in the VAD field.

Relative to the specific achievements on biosensors, it is important to underline that the project activity has pursued the detection of biomolecules of clinical relevance. In fact, due to the importance of specific cytokines as triggers of peculiar systemic inflammatory pathways for the prognosis at the time of LVAD implantation in patients, the evaluation of levels of IL-10 in the early phase of LVAD support is becoming a potential tool to identify end-stage heart failure patients prone to adverse outcomes and to guide early clinical decisions after LVAD implantation. In this context, the research activity has been focused on the realization of a biosensor characterized by label-free detection using gold microelectrodes developed by soft lithography, replica molding, microcontact printing, and wet etching on flexible polyimide (PI) substrates. Gold microelectrodes have also been developed on silicon by silicon technology with both developed biosensors on PI and silicon being chemical bonded and encapsulated by a polydimethylsiloxane (PDMS) microfluidic device. For the gold microelectrodes developed on PI, a Ag/AgCl reference electrode was integrated onto the designated reference electrode by silver electro-deposition. The developed biosensor is selectively sensitive to the detection of human IL-10 at very low levels of the IL-10 protein (1 pg/mL in phosphate buffered saline) using electrochemical impedance spectroscopy (EIS) [1]. Recent in vivo measurements of the SensorART BioMEMs prototype were made on PI with human IL-10 from LVAD patient samples. This has successfully shown that the designed, developed and fabricated SensorART BioMEMs prototypes can be applied to measure LVAD patient plasma samples and be comparable with ELISA tests. These biosensors were manufactured at reduced costs, preparation time (where no label or multiple wash were required), and reduced analysis time when compared to ELISA.

Finally, it is worth pointing out another important achievement in this period, even if it is not on the SensorART basis, was the CE mark obtained by our partner CircuLite for their Synergy micropump.

[1] A. Baraket, M. Lee, N. Zine, M. Sigaud, N. Yaakoubi, M. G. Trivella, M. Zabala, J. Bausells, N. Jaffrezic-Renault, A. Errachid *Sensors and Actuators B*, http://dx.doi.org/10.1016/j.snb.2013.02.088 (2013).