SensorART

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

Grant Agreement number: 248763

Project acronym: SensorART

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

Funding scheme: Large-scale integrating project (IP), FP7-ICT-2009.5.1: Personal Health Systems Heart Failure

Project website address: www.sensorart.eu

D1.4
Publishable Summary

Due date of deliverable: 30/04/2012

Actual submission date: 15/05/2012

Start date of project: 01/03/2010 Duration: 48 months

Organisation name of lead contractor for this deliverable: CNR

Deliverable author: M. GIOVANNA TRIVELLA
Deliverable contributors: ALL

Version: Final

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
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)	

Table of Contents

1 Publishable summary

SensorART - A remote controlled Sensorized ARTificial heart enabling patient empowerment and new therapy approaches (Project Identifier: FP7-2009-ICT-248763) a large-scale integrated project, reached the second year: main changes have been requested after the review in may 2011 by the reviewers comments. As consequence, immediate actions have been communicated to the Consortium from July 2011 and immediately started. From the plenary meeting in October 6-7, the consortium changed in some way by the exit of Bangor University and the planned insertion of em-tec as new industrial partner. The Project Coordinator and the Scientific Technical Manager, after a visit to em-tec in Finning (Germany) together with the partner CircuLite, decided to propose their inclusion as partner, by considering their expertise and competence in all the control modules of Synergy pump: this plan received a preliminary approval by the Project Officer and it has been accepted by the entire consortium as promising acquisition. These major modifications required a DoW amendment, a budget reallocation and a shift of work activities among partners.

In order to achieve the main objective of Sensorized VADs, as strongly recommended by the Commission, the workplan has been focused on a smaller number of sensors feasible for implementation, by considering that the demonstration of a sensorized VAD is what can make the project unique and can bring the most important innovation.

Furthermore, because TET (transcutaneous energy transfer) represents a key element of the project research as well as a crucial point with high degree impact, the consortium, in order to define the entire architecture of the Sensorized VAD (electronic components and implantable parts), has recognized that em-tec, as industrial alternative, can speed up the work and give a demonstrator for testing as soon as possible. For these working activities em-tec has been accepted on board from December 1.st, 2011.

On the other side of wearable platform, the contact immediately taken during summer with other EU projects (HeartCycle and BraveHealth) did not succeed: the PC prospected a validation of HeartCycle wearable sensors in VAD patients, but the temporal shift between the two projects (two years) has been the reason of a negative answer from its coordinator. From BraveHealth's coordinator a cooperation has been foreseen, but up to now not concrete action has followed.

Other sensorized jackets, already validated in heart failure subjects during rehabilitation protocols seem promising for application in VAD implanted patients. Parallel validation of wearable contractility sensor and lung water measurements by ultrasound comet detection are ongoing activities.

A System Architecture technical team has been organized in order to define the system architecture, the telemetry characteristics, and to work on risk assessment and failure analysis by accelerating the validation procedure of the entire system: the anticipation of experimental activities along the time of different subcomponent production will facilitate the test pathways and help to find contingency solutions.

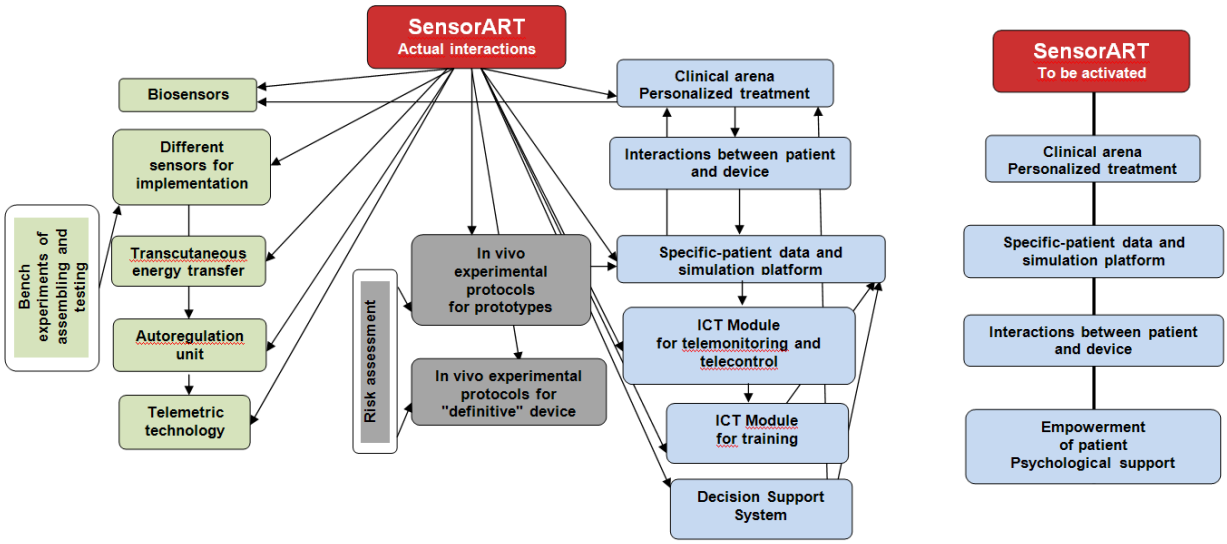
Moreover, a SensorART junior team, working on weekly basis, able to induce and actively maintain collaboration among the different activities has been a successful choice.
The junior team represents the "trait d'union" among the different partners and disciplines of the project and a concrete, real working arm, helping the PC to understand and to overcome ongoing problems. In fact, an IP-ICT coordinator must face multiple commitments, among which the most difficult is the translation of different field languages instead of organizing the translational research, which is, on the other side, the most attractive challenge!

The junior team is constituted by young, active and competent people circulating among different research units, aimed at coordinating and exploiting the possibilities and the skills of young researchers involved in the project. Its constant interaction permitted to establish a fruitful exchange of ideas and activities among the groups of Rome, Warsaw and Leuven, and created the link to Milano group.

ESAO (European Society for Artificial Organs) conference in Porto, October 8-12, was a chance to present the common activities during the Conference sessions and especially during the Young ESAO Initiative. It has been very important for our research project to hear that the future lines of research in Europe and in USA in the field of VADs (Ventricular Assist Devices), presented at the Porto Conference, confirm that SensorART project is exactly on the track: in fact TET and telemedicine are considered the main challenges for the next years!

In order to provide more information on biomarkers for BioMEMS development by the medical expertise, the CNR focus group on molecular biology interacts directly with UCBL on the basis of significant data derived by previous and ongoing studies carried out in Leuven (KULeuven-CS) and in Milano (HONIG-CNR). Dissemination papers have been already published and others are ready to be submitted. Because a specific attention is paid in addressing basic and translational research toward marker detection of heart recovery by considering the strategy to recovery one of the most ambitious goal of SensorART project, an innovative area of investigation in VAD patients has been recently defined, by a protocol submitted to the HONIG Ethical Committee.

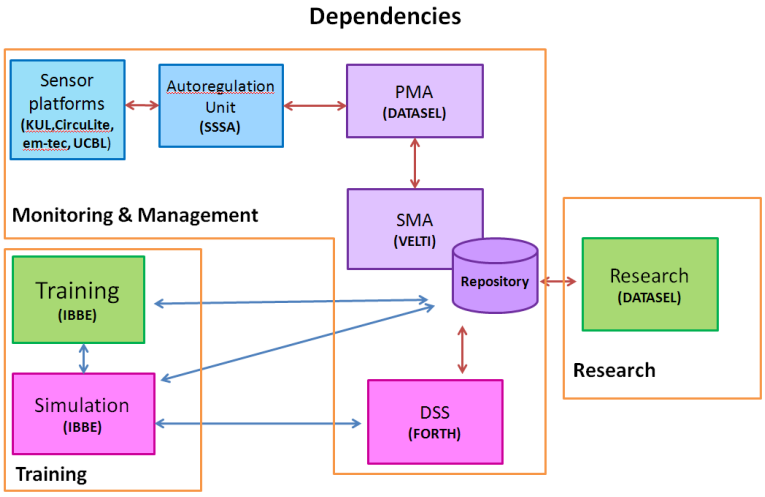
The results of the work done in the second year can be represented in the followings by the scheme of the modules initially defined in the project proposal, that became actively interconnected (actual interactions: modules on the left). On the right the modules that require to be activated in the near future are shown.



As previously underlined, the interdisciplinarity of the Consortium obliged to a constructive translation and cultural exchange of different languages. Furthermore, the working hypotheses of the experimental team helped to define a right methodology as well as the protocols for the scientific dossier, by maintaining always the awareness on risk assessment for each step and/or element of the SensorART platform. The clinical team strongly indicated needs to technical partners while industrial partners always remembered concrete and realistic plans.

On TET, general requirements have been evaluated. Many actors are currently active in the wireless powering competitive arena, and some of them are coming to the market with commercial solutions. However, at present, none of these systems is suitable for the SensorArt platform. Nevertheless, a constant monitoring of new developments, both in the research field and in the market, is a priority for the consortium. Inductive coupling is at this moment considered the most reliable way of transferring energy trough the skin. The design of a TET for a VAD system is a fine compromise between high power transfer and patient safety. In fact, the system should comply with the norms that regulate the exposure of the human body to the electromagnetic radiation. Another critical point is the coil alignment. TET systems are quite sensitive to misalignment: mechanisms to compensate this effect are under investigation.

At the end of November a technical meeting among clinical and ICT partners was held in the stimulating environment of IBBE-PAS in Warsaw. The clinical partners started to concretely check the potentiality of hybrid platform and simulation modeling not only in terms of training tool, but also in terms of innovative evaluation of a therapeutic approach for different patients.



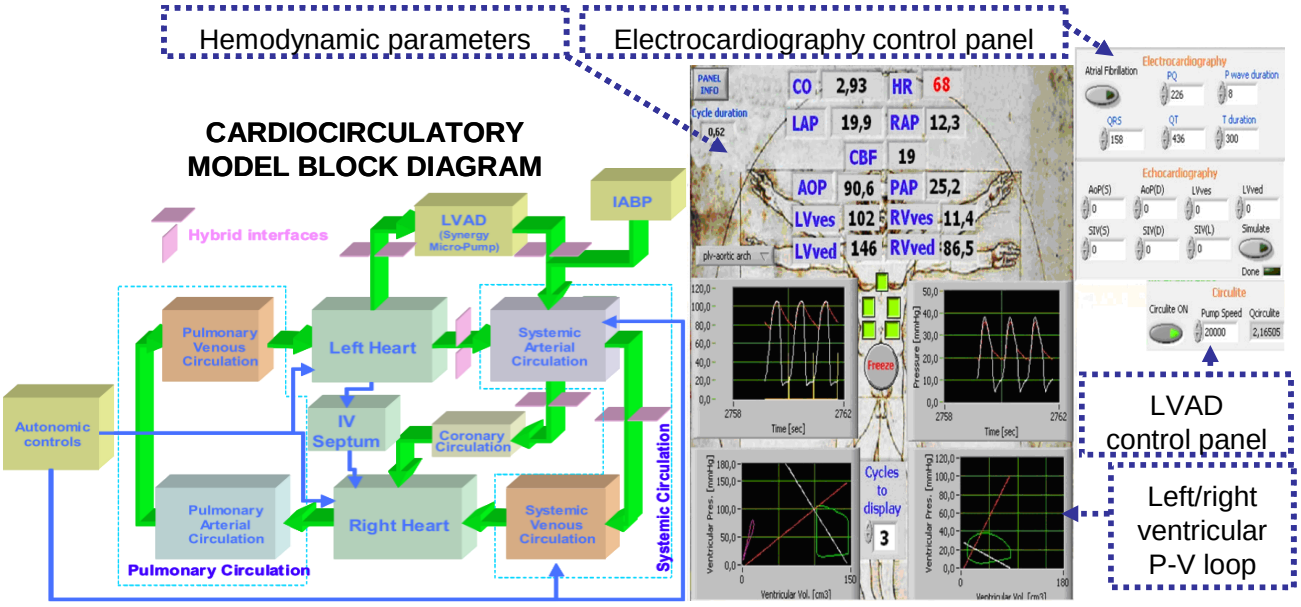
The above scheme identifies how each system will be used and what are the dependencies and interactions (PMA Patient Monitor, SMA Specialist Monitor application). Up to date, the work derived by CNR-ROMA/KULeuven-CS/IBBE-PAS on signal acquisition and simulation, obtained by both hybrid and numerical models, has activated: the analysis of patient data at KULeuven-CS; the evaluation of real patient data before the VAD implantation at HONIG; the acquisition and analysis of data from left ventricular assist devices implanted on animals (sheep).

Data mentioned above are used to characterize the hemodynamic condition of each patient in terms of: peripheral arterial resistance, arterial compliance, arterial pulmonary resistance, heart rate and cardiac output. Left and right ventricular volumes and septum

dimensions were evaluated using echocardiography data. Data are also used for the development and the validation of the cardiovascular simulator able to provide a reliable representation of the pathological condition of each patient. Moreover, the simulator will permit, in a circular way, to predict the effects of the pump implantation on patient hemodynamics and of pump performance at different speeds.

The Specialist's Decision Support System (DSS in the dependencies scheme) has been designed and implemented (first prototype) by FORTH, as a Web-based application allowing the specialists to get the most informative decisions based on three types of knowledge: existing/established knowledge, user specific knowledge, data driven knowledge. The SDSS effectively assesses and exploits real patient data (from the Specialist's Monitoring Application), as well as simulated patient data (from the VAD-Heart Simulation Platform).

In the followings the hybrid model and an example of the print screen of the cardiovascular simulator are reported.



The framework of training activities has been also defined, with the simulator at the center, to maintain the active interaction among clinical partners and ICT experts.

The experimental phases to validate subcomponents and subsystems of SensorART platform have been anticipated; the testing of interactions between recipient and device and the signal acquisitions guarantee a better and deeper procedure of risk analysis and contingency overcoming.