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New emerging biomedical technologies for home-care and telemedicine applications: the *Sensorwear* project

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1. Introduction

The *Grey Booming* phenomenon is one of the major issues indicated by the European Union as a problem to be analysed and faced by the Seventh Framework Programme (FP7). Statistics highlighted that elderly people (over 65 years old) should double in the next 40 years. The medical and health care to such an 'older' society means growing expenditures for the UE national health systems, which already amount to significant percentages of the Gross Domestic Product (GDP) in the different countries. The UE Healthcare Systems risk to collapse if strong countermeasures will not be undertaken. Agreeing with this assumption, the European Commission included among its priorities the stimuli to deeply remodel the national healthcare systems. France, United Kingdom, Holland, Austria, Italy and other countries drafted national programs in order to face this emerging problem. More in detail, cardiac and respiratory diseases have been identified as some of the most frequent causes of hospitalization; telemedicine and home-care have been therefore selected to face the negative evolution of these pathologies, both in clinical and economical terms, assuring domestic assistance for older people as well as disabled or chronic patients. The rationale of this choice is the opportunity of reducing the overall costs while maintaining high quality of care and providing an easy access to care from any place, at any time. Moreover the focus of healthcare consequently shifts from treatment to prevention and early diagnosis, thanks to the contribution of parallel wellness programs, too.

Increasing the impact of home-care solutions is a difficult challenge, since technological issues, such as biosignals monitoring, data communications and basic automated signal analysis coexist with the efforts to improve new technologies' acceptability by the patients, who need to interact with them for long time. Generally these users are not technologically skilled therefore textile sensors platforms represent an ideal way to develop the telemedicine approach.

Under these perspectives, the research and development of Wearable Health Systems (WHS) become even relevant. They are expected to play a significant role on the spreading of 'extra-hospital' cares, thus improving the national health policies effectiveness and the citizens' quality of life, too.

WHS are integrated systems on body-worn platforms, such as wrist-worn devices or biomedical clothes, offering pervasive solutions for continuous health status monitoring through non-invasive biomedical, biochemical and physical measurements (Lymberis & Gatzoulis, 2006). In other words, they provide not only a remote monitoring platform for prevention and early diagnosis, but also a valid contribution to disease management and support of elderly or people in need; in particular, they enable multi-parametric monitoring including body-kinematics, vital signs, biochemical as well as emotional and sensorial parameters in a defined social and environmental context.

The integration of electronics and clothing is an emerging field which aims to the development of multi-functional, wearable electro-textiles for applications together with body functions monitoring, actuation, communication, data transfer and individual environment control. Furthermore, the integration of advanced microsystems at the fibre core, in conjunction with user interfaces, power sources and embedded software, make R&D in this field extremely challenging. Moreover, current research is dealing with the development of stretchable conductive patterns and soft-touch substrates for component textile mounting and interconnection.

As a matter of fact, WHS cope with a variety of challenging topics, whose complexity increases with their integration: wireless communication, power supply and management, data processing, new algorithms for biosignal analysis, connection, sensors' cleaning and stability over time and external conditions, sensors positioning on the human body, user's interface, garment's elasticity and adherence to the skin and other minor themes.

Surely the first issue to be managed is the technological one - current state of the art has achieved a good level of maturity to be industrialized and brought to the market - but another key factor, that is still not mature enough, is the ergonomic or human factor in terms of device's usability, comfort and acceptance by the end user. According to the authors, *design for wearability* is necessary for the real and definitive acknowledgment of WHS in clinical applications, telemedicine and more (Andreoni, 2008). That's the reason why, besides the main objectives of developing healthcare wearable devices, meeting the aforementioned requirements for enhanced user-friendliness, affordability and unobtrusive monitoring in several clinical applications is becoming a growing topic of worldwide research about WHS.

In order to let WHS regularly break into the healthcare practice this and other issues should be solved, for example, from the commercial and industrial point of view, the consolidation of R&D results in different domains and their integration (David, 2007). The *Sensorwear* project tries to organically coordinate the emerging technologies in the field of wearable biomedical devices, conductive yarns or garments, embedded monitoring devices, automated alarm systems and ICT channels optimizations, in order to design a complete, automated service for home and clinical cardiac monitoring applications.

2. The international scenario of wearable telemonitoring systems

Wearable solutions for biophysical conditions monitoring can address many of the emerging issues previously described for a broad cross-section of user groups. Elderly care and disease management are just the immediate application, in addition to wellness and sport which represent significant segments that can benefit from continuous, remote and personal monitoring solutions.

During the last years, different research projects all over the European Union were dedicated to the creation of telemonitoring systems based on wearable or standard sensors. MyHeart is one of the most important and complete among them. Notwithstanding the relevant efforts that have been made since 2000 by the granted projects of the Seventh Framework Program (FP7), researchers and industries are still trying to improve patients' condition monitoring at home using unobtrusive sensors built into everyday objects able to automatically report to clinicians¹ (Lymberys & De Rossi, 2004). These examples and other projects demonstrated both the importance of such applications and the technological problems related to the creation of such a systems.

On the other side, pilot studies were lead in order to evaluate the potential impact of home-care monitoring in terms of costs through a comparison with standard instrumentation. The EU Commission, in fact, has underlined the economical potentialities of such solutions, but also has pointed out doubts with the achievement of the potential results and the effective introduction of these technologies in the healthcare systems (COM 689, 2008).

All the predictive models, analysis and studies confirmed the importance of the wearable telemonitoring scenario, but many problems occur if one aims to the implementation of an industrial project and not only to a research prototype (Lymberis & Paradiso, 2008).

The Sensorwear project tries to avoid the segmentation of technologies and competences, concentrating a small, skilled group of people for the creation of a wearable, unobtrusive, low cost and fully automated solution whose usability, reliability and release of brief information are the most peculiar qualities.

The market analysis has shown there are no commercial solutions able to assure those requirements with a complete wearable system for daily clinical monitoring. It is not uncommon reading about prototypes or finding patents about wearable systems for health care and catching poor information coming from military applications context, not accessible by definition (Pantepopulous & Bourbakis, 2008). To date, the main companies involved in the development of wearable monitoring systems such as Body Media Inc., Sensatex Inc., Textronics Inc. and Vivometrics Inc., experience every day the need for more consistent and remote monitoring of individuals for a variety of purpose: from elderly care to chronic disease management and others. Their solutions are just beginning the transition from the development phase into commercialization, facing the barrier of the regulatory approval, which remains critical for many of the producers.

Just to give an example, a common electrocardiograph, the instrument allowing the execution of an electrocardiogram exam, costs about 600€ in the UE market and cannot be used with wearable sensors to provide unobtrusive measures. The paradigm of measures transparency requires solutions' refinement or improvement or the design of new integrated systems when noise, artefacts or ergonomic deficiencies enlarge.

The Sensorwear system points at achieving these crucial objectives.

¹ For more details, go to: <http://heartcycle.med.auth.gr> and <http://www.ehealthnews.eu> .

3. The Sensorwear project

The Sensorwear project focuses on design and development of a low-cost, industrial solution for smart home-monitoring and hospital applications. The objective is not to create a life-support system, but a reliable, cost effective solution able to monitor biosignals detecting specific conditions requested by clinicians and to transmit them consequently through a long-range communication channel.

The project is granted by the Regione Lombardia and it involves the Politecnico di Milano - INDACO Department -, three technological partners (STMicroelectronics, Microsystems and SXT-Sistemi per Telemedicina), one clothes manufacturer (MCS - Manifatture Cotoniere Settentrionali), a service provider company for the textile and clothing sector (Centro Tessile Cotoniero) and the Mater Domini Hospital in Castellanza (IT), the project's clinical partner. We will illustrate the main aspects related to the project's objectives, technical solutions, applications and expected results in the following paragraphs.

3.1 Objectives and overall architecture

The Sensorwear project aims at developing a complete home monitoring service able to collect a set of different biosignals in a transparent way during the spontaneous activity of the subjects: this paradigm is known as unobtrusive measure. An important part of the project is the creation of a Body Sensor Network (BSN) dedicated to the health state monitoring through record, process and transmission of the biosignals and some useful parameters obtained from them. BSN is mainly based on wearable sensors for the collection of biopotentials (like the electrocardiographic signals, the ECG) and integrated and miniaturized electronic solution based on Bluetooth® technology.

The detailed objectives of the project are (Fig. 1):

- Research, development and production of a System in Package (SIP) solution for monitoring, processing and transmission.
- Research, development and production of embedded sensors.
- Creation of fully featured t-shirts with integrated SIP devices to be tested and used both at home and in hospital.
- Development of software and algorithms for the processing and management of signals, data and alarm for the different applications.
- Development of software for remote data receiving and database integration.

In order to fulfil those items, the fundamental point of the product industrialisation, which is a peculiarity of the Sensorwear project, is continuously kept into consideration. In this way, the final solution is expected to be compliant with the specifications for medical devices of class IIa. Garments' testing, which is an ongoing concern, is an unavoidable step in order to ensure biocompatibility.

The architecture of the system is essentially composed by four main systems:

1. t-shirt with embedded electrodes for the collection of bio-potentials
2. preconditioning and acquisition system
3. processing and transmission device
4. remote data management software.

The second and third systems compose a body gateway able to directly control a mobile phone without requiring the user interaction. Actually, the possibility to act in a fully automated way is another significant feature of the Sensorwear device.

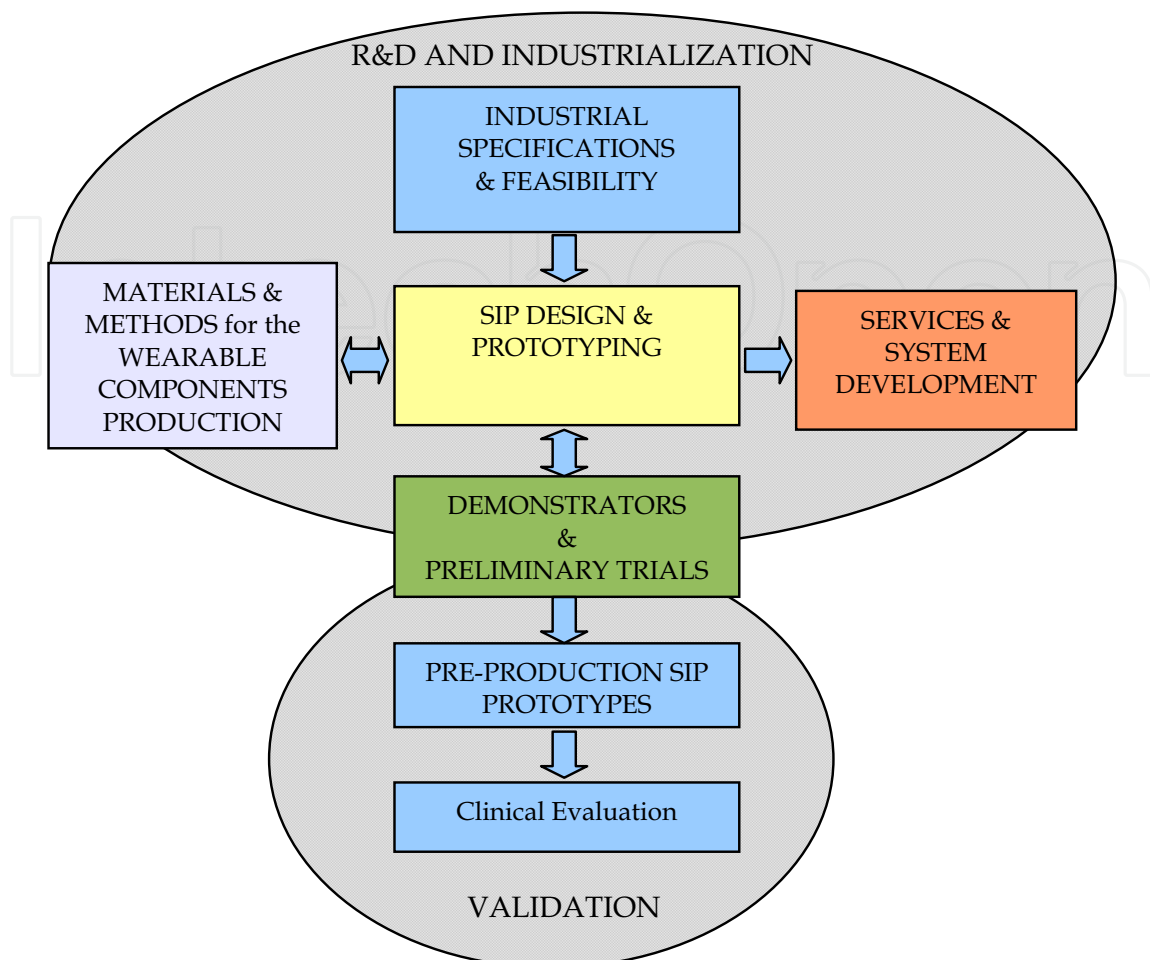


Fig. 1. Sensorwear main activities: different tasks and their relationships.

The signals identified for the specific purpose of the telecardiology application are:

- Three ECG leads
- Body movement
- Respiratory frequency
- Cardiac output monitoring.

The ECG signal is the most important one allowing the device to detect useful parameters like Heart Rate (HR), arrhythmias and their classification, ST line anomalies. ECG is a primary source of indications about health condition, so it receives, at least at early stages, greater attention.

The body movement is recorded through a three-axial accelerometer, whose properly processed signals allow determining the number of steps and the body position with respect to the earth gravity.

Furthermore, it is possible to detect the changing of the cardiac output during the day and also the respiratory movements through impedance cardiography measure (ICG).

3.2 Technological key-point and main issues

The main objectives of this project deal with the creation of an industrial, compact, easy to use, automated solution designed with a special attention to elderly people. These

demanding requirements are addressed by the different skills of the partners on yarns and textile solutions, electronic design and production, data collection and databases.

WEARABLE SENSORS

The t-shirts were designed in order to facilitate the integration of sensors during the industrialization and to assure the best sensors' positioning for ECG and ICG signals quality. The design of garments is a crucial point in the field of unobtrusive measures, in fact as previous research projects and studies have evidenced, it needs configurations able to reduce the effects of movements, without impacting the comfort. The testing phase for the t-shirt, their sensors and sensors' position has started with the ECG signal check, following a specific protocol. First of all the signals are recorded with the first prototype and standard electrode in the Einthoven's configuration, afterwards the device has to collect signals through the t-shirt. The last scheduled test requires to connect the prototype to standard electrodes but placed in the same positions of the wearable ones. Each recording is done 3 minutes at rest and 3 minutes into action.

ERGONOMIC and MECHANICAL ASPECTS

As far as the design of the t-shirts and the adherence of sensors affect the quality of the ECG and ICG signals, the enclosure of the device and its connection to the sensors pathways strongly impact on both the usability and the industrial sustainability. Our analysis of the production process and its related constraints evidenced the necessity to conceive custom boxes in order to create a real comfortable solution without renouncing to an appealing product. The enclosure will also include the visual signalling with yellow and green leds, compliant to the specifications for Holter medical devices (Fig. 2).

Moreover the custom case can be inserted in a docking station, directly sewed to the t-shirt and including the sensors connectors.

At this purpose, a custom solution is not a cost-effective one, while the use of the docking station as mating support can allow the choice of stable, reliable although simple and cheaper connectors.

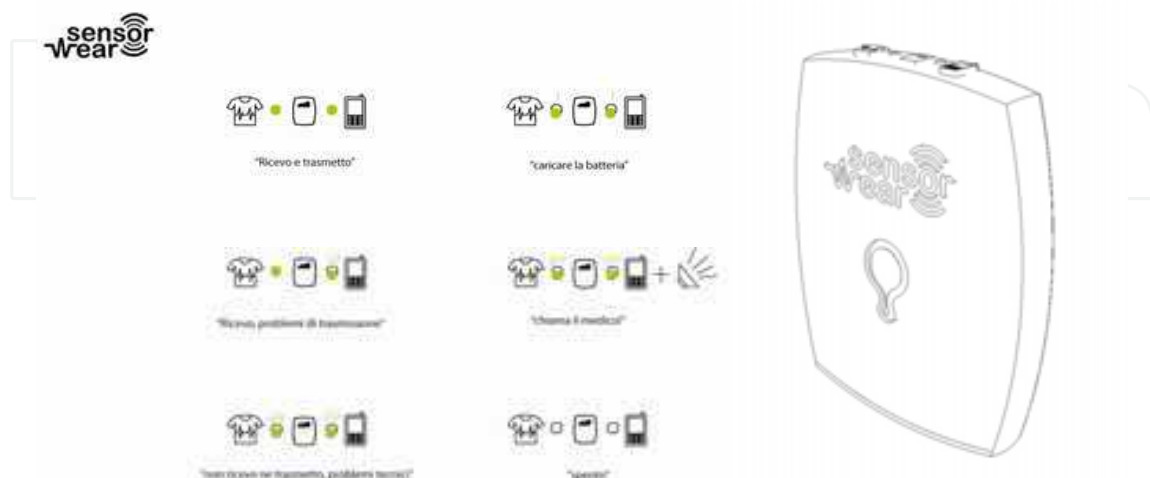


Fig. 2. The ergonomic study for the user interface and the device shape as regards wearability issues.

ELECTRONICS

As regards the electronic point of view the final objective is a scaled solution composed by a SIP for the analogue preconditioning and digital processing and a Bluetooth transmission system with a Dial-Up Network (DUN) profile. The latter specification faces the problem of long-range data transmission within the application model addressed to people who are not used or skilled to work with a PC, but usually are equipped with a generic mobile phone. The only constraint included in this scenario is the need of a Bluetooth connection, but nowadays we know it is easy to find it also in low-end mobile phones.

For what concerns the electronic design, the two main topics are the miniaturization of the circuitry and the reduction of power consumption in order to reach at least 5 days of continuous working with small, commercial batteries. Our technological partners already designed and developed products or prototypes able to collect the proposed signals through wearable sensors in a reliable way, but they need to be improved since all the solutions are not optimized in terms of power consumption and scalability. The design of a SIP solution requires the refinement of previous solutions and the research of new components that can be integrated with it. The choice of new elements is one of the strategies taken to achieve a low-power design, even if it implies to test again the performance of the system in terms of signal quality, signal-to-noise ratio, drifts and all the parameters influencing the compliance with the medical specifications. The final design, the list of components and the features of the system as output of the whole project will be released after the completion of the ICG tests. To date, the logical structure of the prototype in use is described in Fig. 3.

Signals are real-time recorded and processed in order to extract parameters relevant for the clinicians who will receive them through the remote server. Dialling, connection and authentication procedures are directly controlled by the wearable unit, thus excluding any user intervention. The processing output is directly stored in the remote database. The use of a new generation of 32-bit microcontroller unit (MCU) allows the management of the entire process, optimizing the power consumption at the same time.

Different strategies of power management are investigated for each working condition.

In fact there are two different situations:

- the normal one, when only brief parameters are transmitted, once in every minute;
- the “alarm” condition, during which also the raw signals are transmitted.

This latter configuration allows a prompt analysis of the ECG by the clinicians, who can decide to reject the alarm or to activate countermeasures.

This fully automated model of service is based on the possibility to identify different critical conditions from the biosignals applying the rules provided by the clinicians and embedded in the CPU. After the trigger of a possible critical situation has launched, the DUN Bluetooth profile tries to directly connect itself to the remote server and to transmit the raw signals, beginning from the past last minute, until the remote operator will decide to stop the “alarm condition”. Its management implies the possibility to use also GPRS data transmission, because the 3G network coverage is still not ensured in all the neighbouring areas. As a consequence, we are also exploring data compression algorithms for raw signals transmission in case of poor mobile network coverage.

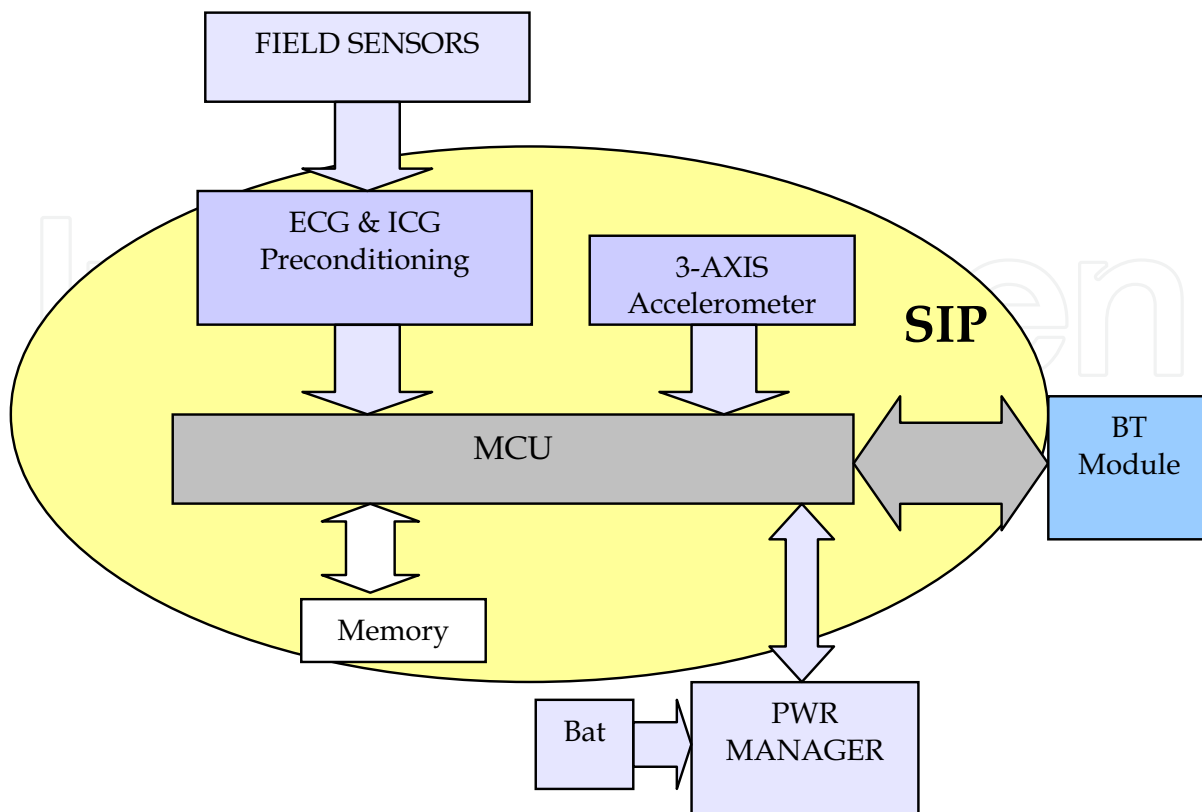


Fig. 3. The electronic device, the SIP components are evidenced.

SERVER and WEB-SERVICE

The hospital security model generally denies the possibility to directly connect a remote device to a local server, physically and logically placed inside the hospital, according to both the Italian and other countries regulation. On the same purpose, it is worth noting that it is not mandatory placing the main data collector inside the hospital network, in fact through a secure web-service application the operators can access data while being in the hospital, or more precisely, in a control room where the physiological parameters and alarms can be constantly observed by them. The use of different servers in order to cover the involved area in a better way and to create a local node to distribute the collision management overhead in case of multiple alarm conditions is thus made possible. The problem of priority management could not be faced at the mobile phone level because a typical mobile service provider can grant dedicated server resources only with business contracts. The mobile phone is just a transparent modem connected to the server. The policy in case of a coincidence of alarms is a matter of debate, but speaking from the informatics point of view, as soon as the connection mobile-server is established through the standard port, the link should be automatically turned on a specific port, in order to set free the common resource for the next alarm.

4. Preliminary results and conclusions

During one year and half of work the consortium faced the problems related to the industrialisation and certification of the product. Since some partners were already involved in such area of the market, preliminary operations like market survey or patent analysis were almost ready at the early stage of the project. This way it was possible to promptly release the main specifications for the system, although the industrialisation process is still a work in progress. In fact the targeted customers population, predominantly composed by not-or-less technology skilled people, requires a detailed analysis on specific components responsible for the usability and allowing a user-friendly system’s management and handling.

As anticipated, we are currently addressing the testing phase on the t-shirts in terms of biocompatibility and clinical performances.

Regarding the hardware, we are testing the low-scaled device. The SIP will be the final result of the project because the design and production of a SIP system is an expensive and complex process, requiring a lot of efforts in order to reduce the risk of a major fault. For this reason we are carrying out specific tests collecting data on performances and trying to understand potential criticism before starting the first production.

	Current status	Industrialisation problems	Compliance with specifications [%]
T-shirt	Prototyping and validating 2 nd release	Sensors embedding and connectors	70%
Hardware	SIP desing	Integration in the T-shirts	100%
Firmware	Testing and consolidation	Refine power management	80%
Algorithms	Testing	None	100%
System software	Developing	-	-

Table 1. Current project checkout list.

During the last months, the firmware has been tested on the same devices (MCU and Bluetooth module) in terms of power consumption and transmission throughput. Based on current measures, we forecast it will be possible to ensure a 5-days working time with a commercial Lithium-Ion or Lithium-Polymer battery with less than 500mAh of capacity with the transmission protocol already working.

Although there are still some critical aspects highlighted in Table 1, several problems related to the creation of a commercial unobtrusive and fully automated wearable monitoring solution have been solved. Moreover a great boost to the project has come from the introduction of a System in Package solution, the heart of the electronic device, which could probably have a deep impact also in next products and projects.

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