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SmartVista: Smart Autonomous Multi Modal Sensors for Vital Signs Monitoring

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1 Abstract

Cardiovascular diseases (CVD) remain the leading cause of mortality and a major cause of morbidity in Europe. Every year there are more than 6 million new cases of CVD in the EU and more than 11 million in Europe as a whole. With almost 49 million people living with the disease in the EU, the cost to the EU economies is €210 billion a year. There is a growing demand for a reliable cardiac monitoring system to catch the intermittent abnormalities and detect critical cardiac behaviours which, in extreme cases, can lead to sudden death. The objective of the Smart Autonomous Multi Modal Sensors for Vital Signs Monitoring (SmartVista) project is to develop and demonstrate a next generation, cost-effective, smart multimodal sensing platform to reduce incidences of sudden death caused by CVD, and will contribute to the EU vision of an Internet of Things for healthcare. The key innovation in SmartVista is to integrate 1D/2D nanomaterials based sensors to monitor the heart, thermoelectric energy harvesters to extract energy from the body to power the system and printable battery systems to store this energy. Together these will result in a self-powered device that will autonomously monitor the electrocardiograph, respiratory flow, oxygen flow and temperature of the patient. This information will then be transmitted wirelessly for online health processing. This real-time self-powered monitoring of a patient's health is currently not available. Thus, the technology that will be developed in SmartVista will position us at the forefront of digital health and wearable biosensor technology for wireless monitoring in hospitals and of remote patients, both of which are necessary in this era of an aging population.

2 Introduction

The SmartVista project aims to develop a smart multi-modal sensing platform for health vital signs monitoring using 1D/2D nanomaterials based sensors, on-chip thermal energy harvester, novel printable battery system and wireless platform enabled by 3D heterogeneous integration of these subsystems (see Fig. 1). The SmartVista sensors will reduce the risk of sudden deaths from cardiovascular disease, by enhancing detection and diagnosis performance. An electrocardiograph (ECG) is normally used to monitor abnormal heart rhythm, but sleep apnea could also lead to heart disease and stroke.

Today's hospital-based monitoring systems are bulky and expensive, whereas wearable ECGs or respiratory monitors suffer from inaccuracies and short battery life. The SmartVista program will develop a flexible platform by integrating nanomaterials based sensors with ultra-high sensitivity to monitor ECG, respiratory flow, oxygen flow, the chemical analysis of human sweat composition and temperature powered by body heat energy conversion strategy through high efficiency thermoelectric generator to prolong the life of the printed battery. Additionally, the Roll-to-Roll manufacturing process of these patches will be developed to demonstrate the future scalability of this technology.

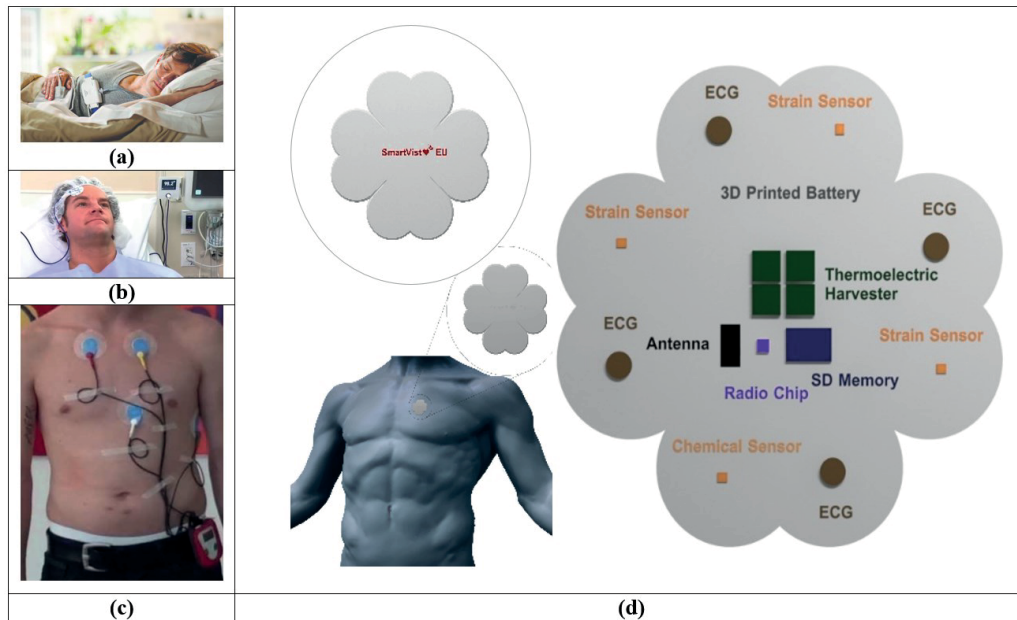


Fig. 1: Market leading sleep apnea monitor, (a) Alice NightOne, Philips, (b) Temperature skin sensor from 3M, (c) State-of-art holter ECG monitor, MT-101, Schiller, (d) SmartVista platform replacing all above sensors (a-c). 3D illustration of SmartVista system for multi-modal sensing of vital signs for continuous health monitoring showing sensors, micro-thermoelectric generators, printable thin film battery, analog circuit and wireless transmitter.

3 Objectives of SmartVista

Each year cardiovascular disease (CVD) causes 3.9 million deaths in Europe and over 1.8 million deaths in the European Union (EU) [1]. CVD accounts for 45% of all deaths in Europe and 37% of all deaths in the EU. These are alarming statistics and in most cases the cause is of ventricular arrhythmias, including ventricular tachycardia (VT) or ventricular fibrillation (VF) [1]. Ventricular arrhythmia is an abnormal electrocardiograph (ECG) rhythm and is responsible for 75%–85% of sudden deaths in persons with heart problems unless treated within seconds [1]. Most arrhythmias are caused by coronary heart disease, hypertension, or cardiomyopathy, and if not accurately diagnosed nor treated, immediate death occurs [2].

The implantable cardioverter-defibrillator has been considered as the best protection against sudden death from ventricular arrhythmias in high-risk individuals. However, most sudden deaths occur in individuals who do not have high-risk profiles. Long-term ECG

monitoring is the standard criterion for the diagnosis of ventricular arrhythmia. The standard method of 12-lead ECGs are obtained and analysed to detect any changes in the characteristics of the ECG signal. By extracting information about intervals, amplitudes, and waveform morphologies of the different heart signal (such as P-QRS-T waves,) the onset of the ventricular arrhythmia can be detected.

Over the last decade, many wearable ECG systems have been proposed and are even available on the market. Virtually all of them use some form of electrodes as a sensor that must make electrical contact with the patient's skin surface. This necessitates the use of sticky pads, pastes or gel. While this method works for stationary patients, it suffers from several problems. First, the material used to construct the electrode or the paste could cause skin irritation and discomfort, especially if the subject is performing rigorous physical exercise and may be sweating. Another problem is that, during motion, the electrodes may become loose, breaking electrical contact and causing high noise spikes in the data. Paste/gel-free resistive or capacitive contact ECG sensors have been developed. Many of them still suffer from similar noise levels to "wet" electrodes, and the contact can still cause irritation problems as well as being more sensitive to motion.

Numerous ECG sensors are already available on the market; however, such sensors are bulky and suffer from inaccuracies, large power consumption and short battery lifetime. Moreover, the majority of them are based only on ECG monitoring whereas multi-sensor functionality is desirable to holistically monitor several vital signals that can be essential for meaningful home health care, sporting activity and remote patient-doctor communication. This is even more crucial for aging population where the ability to survey and monitor several vital signals helps to reduce the risk factors early on, continuous assessment for disease prevention and maintaining optimum lifelong health quality.

Reliable vital signal sensors should satisfy several constraints such as wearability, portability, size, weight, longevity, ergonomics, monitoring time and most importantly autonomy and power consumption. Only after meeting these design parameters can such sensors be successfully used for continuous health monitoring in daily life. There is a tremendous necessity to develop a personalized smart multi-modal vital signs monitoring device that is seamlessly integrated with the skin with multi-fold increased sensor accuracy and powered by a battery backup and with a very low form factor. To address the aforementioned problems, we propose for the first time an electronic smart system with multiple sensors to monitor ECG, respiratory flow, oxygen flow, and temperature. The smart system will be compact and unobtrusive while consuming ultra-low power. To ensure autonomy of the smart system, we will customize the design with low complexity analog front-end circuitry and integrate energy a harvesting module with a self-powered mechanism for a printable battery to prolong battery life. This is a first worldwide attempt to provide a flexible multi-modal ultra-low power bio-signal monitoring device.

As a short-term objective, we will target the integration of novel sensors based on nanomaterials (such as 1D and 2D nanomaterials) on a flexible substrate together with analog processing, radio RF transmitter, and battery. Such a target will allow us to investigate the reliability and power consumption of the smart system while enabling multi-functional capability with novel sensors. As a mid-term objective, we will target the integration of a novel printable battery and energy harvesting module on flexible substrate together with sensors, an analog front-end unit and radio RF transmitter, which will ensure the ultra-low power consumption and increased autonomy of the multi-functional smart

sensor. The main objective of SmartVista is to develop a smart compact multi-sensory ECG system with several weeks of power autonomy while providing reliable measurements and continuous bio-signals monitoring.

4 Technologies to be developed in SmartVista

4.1 Micro-Thermoelectric Generator for Converting Body Heat into Electricity

A thermoelectric (TE) device can transform both thermal energy to electricity using the “Seebeck effect” and conversely enable cooling or heating using the “Peltier effect.” Microscale TE devices have tremendous advantages over macroscopic devices. The apparent advantage is the smaller size, which allows integration into smaller systems. Due to the use of small structures, the integration density increases and thereby, large number of thermocouples in the device leading to high power outputs especially for small temperature differences [3]. The present state of the art on the micro thermoelectric generator (μ TEG) is mainly fabricated using complementary metal – oxide semiconductor (CMOS) and micro-electromechanical systems (MEMS) compatible techniques [4].

Body wearable sensors and electronics are getting immense attention with the growth in IoT and TEGs are of interest in making these self-powered wearable devices by making them entirely rely on body heat, which can be harvested. Studies focused on body temperature measurements have revealed that the body parts with highest temperatures are namely the forehead, back of the neck and the chest. All these body parts are capable of creating a temperature gradient of 2-10 K depending upon the ambient temperatures [5]. Studies have suggested that 3.1–36.6 mW of power can be harvest form chest of a human body [6]. However, only 10.2 μ W/cm² has been reported for TEG placed on the chest at room temperature (291.3 K) while walking at a speed of 1.1 m/s. This device was fabricated using powder sintered bismuth telluride based p and n-type materials [7], and does not generate enough power for the SmartVista application.

Thereby, the aim for the development of thermoelectric energy harvester is twofold, firstly: the development of energy harvesting devices using thermoelectric module to convert body heat into usable electrical power using the existing state of the art electroplated material; and secondly: Improving the efficiency (Figure of merit, ZT) of electroplated p an n-type thermoelectric materials by introducing a multilayer doping strategy to develop mesoscale materials [8]. This innovative multilayer strategy will enable the transfer of this technology to a cost effective and semiconductor fab compatible process with an aim to bridge the gap between research and industrial production of efficient thermoelectric devices for SmartVista application.

4.2 Printed Battery Technology

Batteries, as they exist today, are limited to standard form-factors, which limit their compatibility with future human-centric device designs. Removing the bulk and weight of current batteries may allow product designs that were previously not thought possible. By incorporating and networking batteries within the structure of the wearable device itself, as needed, it may be possible to enable massive-scale personalization of battery technology. The missing innovation involves the rethinking of the design and manufacture of batteries

so that they are no longer separate to the devices they power. The volume of the battery is much larger than the volume of ultra-small sensor devices, limiting further miniaturization of the whole system. State of the art in advancement beyond standard Li-ion batteries involves new materials and electrolyte developments primarily [9]. For non-convention designs of cells, some flexible and stretchable batteries are possible, but have limited volumetric energy density and capacity. In both these approaches, the primary issue remains: the batteries are separate from the device, and remain a single power source for the entire device.

With the proliferation of smart electronics and continued miniaturization of these devices for the Internet of Things (IoT) applications, accommodating the rising power requirements is of the utmost importance [10]. Li-ion batteries are the dominant rechargeable or secondary power sources within the smart and consumer electronics industry, offering not only high capacity but also high energy density for power-hungry devices and applications [11]. Li-ion cells cannot be ‘clicked’ together to match or adapt to the desired form factor, which is very important when size and volume constraints are a primary technology driver. Alternative designs for wearables may require power sources with particular volume or shape, particularly for human-centric technologies where the device must overcome form factor limitations caused in part, by the space required for the battery. We are developing a 3D printing approach to all-plastic battery construction that operates as an aqueous Li-ion rechargeable battery. The battery cell is made using an FDM and PolyJET 3D printing for the cell architecture, including carbon-impregnated conductive polylactic acid (PLA) current collectors within an acrylonitrile butadiene styrene (ABS) plastic cell, and an aqueous gel electrolyte for the cell chemistry without a separator. Cathode and anode materials uniformly coat PLA current collectors. These batteries currently exhibit good specific capacities of between 30 mAh g⁻¹ (1C rate) to 90 mAh g⁻¹ (0.1C rate) for at least 100 charge/discharge cycles, and gravimetric and volumetric energy densities of ~110 Wh kg⁻¹ and 0.36 Wh L⁻¹, following a voltammetric priming step to enhance pre-lithiation and to balance capacity during cycling. In SmartVista, the battery will be designed to be the outer casing of the wearable multimodal sensor, integrated with thermoelectric harvesting for continual charging.

4.3 Strain Sensors for Bio-Signals Monitoring

Commercially available strain sensors often use solid-state devices, such as piezoelectric, capacitive and resistive materials. However, they are generally not flexible and stretchable. Thus, recently more advanced materials are continually being explored such as carbon-based nanomaterials, nanofibers or nanowires. Carbon-based nanomaterials (i.e., 1D nanomaterial) offer superior sensitivity owing to their remarkable electrical and mechanical properties. More recently, 2D nanomaterials (such as graphene, MoS₂) are also being explored for sensing applications including biomolecules, chemical, mechanical strain, and pressure. The tunability of the physical properties of these nanomaterials is one of the most promising features for their implementation as a versatile sensing platform. The principle of strain sensing can be explained based on the percolation theory due to the resistance change on nanomaterials. Carbon nanotubes (CNTs), after being dispersed in small amounts into an insulating polymer matrix can connect to each other through CNT junctions to form conductive networks for electrons and phonons, which, in turn, transform the insulating polymer into an electrical conductor. On semiconducting monolayer MoS₂, the piezoresistivity phenomenon is due to the generation of electrical polarization when a strain gradient (i.e., curvature) is introduced in a material.

In this project, we aim to go beyond state of the art and develop novel strain biosensors based on 1D and 2D nanomaterials. We will develop novel multi-modal strain biosensors where we can simultaneously obtain the heart rate, blood pressure, temperature, and respiratory flow. By having **multi-modal biosensors** ensures continuous bio-signals monitoring, correlations between different vital signs, remote patient monitoring and early diagnosis of cardiovascular problems.

4.4 Sensor for Chemical Analysis of Human Sweat Composition

A wearable non-invasive sweat sensor based on transition metal dichalcogenides (TMD) such as WSe_2 , MoSe_2 , etc. is being targeted in the framework of this project. The principle of operation is dependent on being able to harness to achieve piezo-electrical properties from thin layers of these materials which will allow sensitivities in range that is compatible with the common analyte composition of human sweat [12]. The key challenge to enable such a system is in being able to create near perfect reproducible layers by the usage of a Plasma Enhanced Chemical Vapour Deposition (PECVD) process such that the resulting piezoelectric values and crystallinity of the TMD layers permit the desired application requirements. Thereby, investigation concentrates on deposition of TMD layers on insulating materials in combination with seed layers.

The chemical sensor will be on thin and flexible substrate where the laterally structured electrodes are in-plane. In this way, a three-electrode concept including a pseudo-reference electrode for chemical signal acquisition is possible. The three-electrode concept enables active and passive signal circuitry. The sensing layers will be the same as investigated for piezo resistive response, for it is to be expected, that poly-crystalline layers appear first during deposition development. These will replace the nano-particle layers used in the actual status. To avoid direct contact to the skin, porous cover layers open for water diffusion will be added. Silicon as substrate enables the implementation of additional active and passive elements like transistors, resistors or capacitors. Chalcogenides TiO_2 and WO_3 will also be investigated for chemical signal extraction. The reason for these additional materials lies in the safety data information for MoS_2 or WS_2 . While for MoS_2 no hazardous risks are reported, other molybdenum compounds are classified as poisonous. This means it should not be in contact with the skin to avoid any risk.

4.5 Flexible Packaging and System Integration on Flex

In this project, a flexible hybrid electronics (FHE) integration approach will be implemented to enable fully flexible, quasi iso-planar packaging with bio-compatible encapsulation and/or planarization of sensor components conforming to current wearable patch technologies produced in a roll-to-roll process.

The key challenge here is to enable the complex heterogeneous co-integration of silicon (standard SMD, housed passives & ultra-thin) components together with 1D/2D Sensors, which are based on non-conventional substrates, together with the existing setup of a standard Holter ECG in a System in Package (SiP) on a wearable platform (Fig. 2). This is level of integration will be based on the process developed in the FP7 Project “Interflex” (Grant agreement no: 247710) with the augmentation of adaptive correction for lithography and mounting techniques being developed in the nationally funded BMBF project

“ADAMOS” on Adaptive laser lithography on film substrates in roll-to-roll technology. Additionally, in regards to the packaging of the individual IC and sub-system components, a strategy based on the results of the EnSO project will be developed. For a detailed overview of the packaging process, please refer to the SSI 2019 publication by Erwin Yacoub-George et al. On “Ultra-thin flexible interposer – a flexible hybrid integration approach to replace wire bonds” [13].

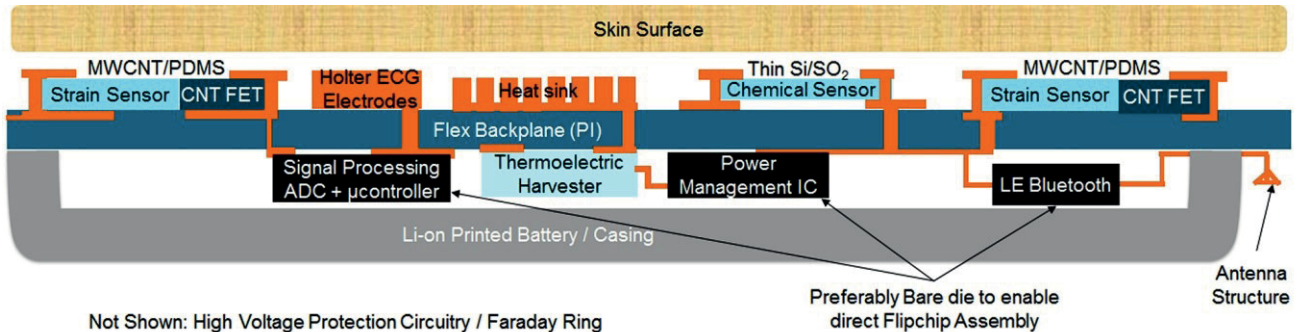


Fig. 2: Schematic cross-section of the provisioned demonstrator.

4.6 Ultra-Low Power Wireless Body Sensor Platform

Novosense is developing their first line of products named as *CardioSenseSystem*, which is designed to replace stationary as well as portable monitoring ECG systems used in hospitals. The basic idea is to measure ECGs entirely wirelessly with low-cost disposable units in the same way as today's wired disposable electrodes. The difference is that no wires have to be connected, thus eliminating the problems with electrodes or wires coming loose. Novosense's patented ECG measurement technology makes it possible to measure all forms of ECG with disposable self-contained units. The targeted applications in SmartVista project are Holter ECG and monitoring of sleep apnea. The key competitive advantaged with the SmartVista system would be:

- **Miniaturisation:** The SmartVista encapsulated sensor will only be 2-3 mm on the thickest sections. This is only possible to achieve using thermoelectric energy harvesting technology to reduce the required size of the battery. Competitors have much more bulky solutions.
- **Weight:** Due to the same reason as above the sensor would be drastically lighter.
- **Improved reliability and adhesiveness:** Due to the drastically reduced weight and thickness of the sensor, the likelihood of sensors being pulled off or unintentionally knocked off will be reduced. The adhesiveness is further improved due to the flexibility and inherent adhesiveness of the 1D/2D nanomaterials based sensors.
- **Improved monitor duration:** For the Holter ECG, a longer monitoring duration will increase the physician's possibilities to make the correct diagnosis. This long time monitoring will be accomplished by converting the body heat into electricity by the energy harvesting module, which can recharge the thin film battery to provide continuous power to achieve improved reliability though longer monitoring durations.

These four key competitive advantages can be translated into more effective methods for the physician to generate reliable data for making a correct diagnosis. Thereby, the increased reliability of SmartVista system should eventually translates into health care savings.

5 Conclusion

SmartVista will develop the first nano/micro sensor-based vital sign monitoring system through comprehensive design, 3D integration, and packaging as a cost-effective and widespread application of wireless autonomous multimodal sensor system to reduce the sudden death due to cardiovascular disease.

6 Acknowledgements

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