PROJECT PROFILE

19017

Frequent biomarker monitoring by an autonomous wearable patch as practical tool for clinicians and nurses to improve early warning. Reducing critical complications, improving patient care and quality of life [Sentinel]

Hospitals lack an essential facility to monitor – in a semi-continuous fashion – biomarkers, in combination with physiological and contextual ones, without causing a major disruption to a hospital's workflow. Responding to this problem, the Sentinel project will significantly improve the hospital's' early warning system (EWS) targeting a reduction of serious complications and disabilities after their discharge.

According to the National Institute for Health and Care Excellence and the European Resuscitation Council (ERC) patients should be monitored to help identify those with a deteriorating clinical condition, or one at risk of deterioration. Regrettably, despite the deployment of early warning systems (EWSs), adverse events are currently estimated to affect a significant number of hospitalised patients, and to cause thousands of patient deaths every year – in the European Union (EU) alone.

Current EWSs are based on measuring physiological vital signs and consciousness levels. However, clinicians consider biomolecule markers to be valuable indicators of disorders. Efforts have been made to include these markers to improve EWSs, by either point-of-care (POC) testing or increased central lab testing. However, they have not been widely accepted, primarily because of poor integration into the workflow of the caregiver.

Therefore, to obtain a clinical-relevant scoring methodology with improved specificity to quantify the severity of these adverse effects, a technology should be available that:

- Simultaneously and in a timely manner measures relevant factors, hence in a semi-continuous way;
- Operates autonomously with minimum disruption to a nurse's workflow;
- Provides signal analysis and data analytics to discover clinically relevant relationships between the measured parameters and the above-mentioned health indicators.

Developing wearable device with hybrid marker sensing

The Sentinel project will address and resolve these issues by developing technologies which will result in a wearable solution – a hybrid patch – that integrates semi-continuous quantitative hybrid sensing of physiological, contextual and biomolecule markers, including affiliated algorithms, manufacturing technology and verified prototypes.

These technologies will be demonstrated in the area of patient monitoring by two clinical use cases: sepsis (including reduced peripheral perfusion) and delirium (including monitoring of stress). New developments in micro-nano technology will be needed, combined with microfluidics to interface with the person's bio-liquids and allow for (semi)continuous measurements for a week.

Sentinel will focus on seven areas:

1. Wearing formats:

- For many patients, an adhesive patch is acceptable, aided by the limited duration of use. For ones with frail skin, an attachment module will be developed that offers the wearer pressure relief.

2. Biomarker sample methods:

- Sweat is a non-invasive rich source of biomarkers. Since most patients do not undergo excessive physical strain, they have a low sweat rate of approximately 0.2 nl/min/gland. A complicating factor is that the concentration of so-called actively resorbed biomarkers not only depends on a disorder but also on the sweat rate per gland, not addressed by the state-of-the-art. Sentinel will develop high-end microfluidic designs for sampling sweat, capable of handling nanolitre volumes of bio-fluid.
- A small number of biomarkers may require sampling of interstitial fluid (ISF). If required, Sentinel will utilize miniature sensors for ISF sensing.

3. Sample methods for physiological and contextual markers:

- For sampling physiological and contextual markers, existing technology is used. This technology will be applied in synergistically manner for biomarker sample methods as well.

4. Sensor platform:

- Different use-cases will require the measurement of different markers in a semi-continuous manner, hence the need for semi-continuous and interchangeable sensors. Sweat and ISF sensor modules will be developed to accommodate various sensors without changing the architecture of the particular module.

5. Microfluidic flow:

- A previously developed continuous-flow-operation principle, is the starting point for the development of a hybrid patch; capable of semi-continuous monitoring patients for at least four days.

6. Signal acquisition and Data Analytics:

- An algorithm will be developed to improve the signal-to-noise ratio of biomarker detection

KEY APPLICATION AREAS

Health & Well-Being

ESSENTIAL CAPABILITIES

Systems and Components Architecture, Design & Integration

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KEY PROJECT DATES

01 April 2020 to 31 March 2023

in sweat by considering physiological characteristics of sweat secretion in time and frequency;

- Data analytics algorithms will be developed to enhance the specificity and accuracy utilising the combination and synchronisation of physiological, contextual and biomarker signals; enabling studies to quantify the multifactorial phenomena;
- A data-quality Index toolbox will be built to produce a quality-scoring model for vital signs time series data through machine learning.

7. Manufacturing platform:

- Scalable and cost-effective foundry technologies will be applied for cost-effective manufacturing of the modules;
- Conflicting requirements, like cost price and use-case adaptability, will be addressed by standardising the module (miniaturised) dimensions, allowing various types of sensor modules to be integrated seamlessly on the so-called frames.

Advantageous position

Project partners are specialised in components (sensors and materials), integration (microfluidics and assembly), as well as, the signal chain (electronics, software, analytics, and clinical decision-support) of the Sentinel patch. This expertise combination puts them in an advantageous position to deal with user requirement provided by the clinical and medical industry, and to leverage existing state-of-the-art technologies around vital signs monitoring patches (energy, materials, and systems). Involvement of the end-user (clinical party) in the early phases of this project will improve the quality of the wearable patch requirements, as well as, provide relevant clinical results. These are essential and distinct advantages for market introduction and acceptance.

Impacting patients and the economy

Despite the use of EWS, adverse events are currently estimated to affect up to 12% of hospitalised patients and to cause up to 95,000 patient deaths per year in the European Union alone. In addition, infections associated with healthcare institutions affect an estimated 4.1 M patients. The United Kingdom National Audit Office estimates the cost of such conditions at £1 billion (US$1.2 billion) per year. Infections that are detected late will lead to fast patient deterioration. Similar numbers are seen in the United States. In ensuring semi-continuous monitoring in an autonomous and hybrid manner, Sentinel will decrease complications & mortality in hospitals and will reduce the number of permanent disabilities. This will not only improve the quality of life for patients after discharge, but will also reduce healthcare costs.

Promising market developments

Sentinel will target its products at these four market segments:

1. POC diagnostic market;
2. Healthcare wearable market;
3. Electrochemical-sensor technology market;
4. Main diagnostics market.

The global market for POC diagnostics in 2015 was valued at nearly US$18 billion. This market is predicted to grow from US$19.3 billion in 2016 to US$28.3 billion in 2021, at a CARG of 8%. This growth, which is expected to continue for the coming years, is substantially fuelling the growth in the entire in-vitro diagnostics industry.

The global market for wearable healthcare devices is anticipated to reach a revenue of US$18.9 billion in 2020, growing at a CAGR of about 30%. The consumer health market, including wellness, fitness, and sport-wearable segment, is expected to grow at a CAGR of 27.8% (2015-2020). Medical and clinical-grade wearables, the most promising product segment within healthcare wearables, is expected to grow with a CAGR of 32.9% (2015-2020).

Electrochemical sensors show strong growth due to the unique properties of continuous sensing (low cost per measurement). Moreover, the concentration range fits in well with the markers Sentinel is planning to measure. The rising ageing population and the increasing incidence of chronic ailments will boost the demand for precise diagnosis, and drive investments and adoption of use in other application domains, for example such as safe driving in the automotive market and promoting healthy living. The global biochemical sensor market is forecasted to reach US$58.48 billion by end-2025, a CAGR of 14.7% between 2016 and 2025.

Finally, main markets in clinical diagnostics (besides the already-mentioned POC one) are microbiology, molecular diagnostics, immunoassays, and flow cytometry, especially in preventing deterioration in the case of sepsis. This market is expected to grow at a CAGR of about 10% (2015-2022).

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