Health Care Sensor – Based Systems for Point of Care Monitoring and Diagnostic Applications: A brief survey

Michail Tsakalakis- *Student Member, IEEE, EMBS*, and Nicolaos G. Bourbakis-*IEEE fellow*

*Abstract***— Continuous, real-time remote monitoring through medical point – of – care (POC) systems appears to draw the interest of the scientific community for healthcare monitoring and diagnostic applications the last decades. Towards this direction a significant merit has been due to the advancements in several scientific fields. Portable, wearable and implantable apparatus may contribute to the betterment of today's healthcare system which suffers from fundamental hindrances. The number and heterogeneity of such devices and systems regarding both software and hardware components, i.e sensors, antennas, acquisition circuits, as well as the medical applications that are designed for, is impressive. Objective of the current study is to present the major technological advancements that are considered to be the driving forces in the design of such systems, to briefly state the new aspects they can deliver in healthcare and finally, the identification, categorization and a first level evaluation of them.**

I. INTRODUCTION

Given the continuous rising cost for monitoring, management and treatment of various diseases with current approaches, [1] the major problem of the "Ageing" of the population [2], and the current methods utilized for management and supervision of chronically ill people, there is an urgent need for novel low cost practical and feasible solutions to be found. Beside this, a recent concept that promotes the customization of healthcare upon the individual's needs has attracted significant attention. Personalized medicine is considered as one of the most emerging approaches for effective treatment and management [3], being driven by the notion that clinicians can deliver more effective and targeted treatment to their patients by monitoring each individual and keeping track of their clinically readable habits. Significant innovations towards individualized medicine are driven by advances in biocompatible materials [4], biomarkers [5] and biosensors [6]. Finally, it is generally admitted that different preventive medicine strategies can significantly reduce the overall cost spent in healthcare, depending on the level of prevention. Preventive strategies and methods can be used for diagnosing and treating at early stages or even to avoid the occurrence of a disease. All the previously discussed issues can be alleviated or even resolved with low cost intelligent and sophisticated POC medical monitors of various physiological and biochemical signals.

 Advancements in certain key technologies have promoted the burst increase in development of those systems. Evolution in microelectronics and digital electronics have led to the development of low cost, low

Michail Tsakalakis and Nikolaos Bourbakis are with Computer Engineering and Computer Science, Wright State University. (tsakalakis.2@wright.edu, nikolaos.bourbakis@wright.edu).

power consumption circuits such as microprocessors, Application Specific Integrated circuits (ASICs) and Field Programmable Gate Arrays (FPFAs) that can provide portable real-time, continuous monitoring solutions for signals acquisition and analysis. Innovations to integrated sensors and Micro-Electro-Mechanical Systems (MEMS) pose new challenges for the future sensory systems [7]. New wireless communication schemes such as Industrial and Scientific Medical (ISM) radio bands and Medical Implant Communication Services (MICS) band have been reserved for a variety of industrial, scientific and medical applications. Finally, "the illusion of infinite computing resources" that cloud computing can offer as it is stated in [8] can be extremely beneficial for the computational demanding medical applications where huge amount of data need to be stored for further off – line processing.

The following of the paper is organized as follow: In section II a brief review on different POC systems is presented. In Section III a maturity evaluation procedure is conducted for sensor – based systems. Finally in Section IV we conclude the paper.

II. POINT OF CARE HEALTHCARE MONITORING SYSTEMS

A high level categorization of POC medical systems is illustrated in Figure 1. In the present survey we will review only the part of the devices that are dedicated for physiological monitoring purposes.

Figure 1: High level categorization of POC healthcare systems

It is important though to briefly mention some of the devices dedicated for medical intervention. Retinal [9] and cochlear [10] implants rise the expectations of visually and hearing impaired patients. Spinal Cord Stimulators (SCS) [11], deep brain stimulators (DBS) [12], intravesical stimulators and gastric electrical stimulators are few of the systems extensively used for the management of neurological disorders. Last but not least, drug release reservoirs [13] can deliver very effective and targeted treatment to groups of people suffering from chronic diseases, cancer and cardiovascular disease (CVD) related disorders.

A. Wearable/Portable (W/P) Sensor – Based Monitoring Systems

The major categories of such systems are: a) *Electrocardiogram* (ECG) sensors/platforms [14],[15] for monitoring of cardiac activity and CVD pathologies, b) *Electroencephalogram* (EEG) sensors/platforms [16] for brain activity screening and brain disorders identification, c) *Electromyogram* (EMG) sensors for measuring the electrical activity of muscles for muscular dystrophy, inflammation of muscles, pinched nerves, peripheral nerve damage, d) *Blood pressure* sensors for heart related diseases, e) *motion sensors* such as accelerometers for fall detection and Parkinson's related problems [17], f) *other* sensors such as oxygen saturation, temperature and heart rate that can provide clinicians with valuable complementary information about the general health state of the subject. Other systems utilize sensors to capture the electrodermal activity [18] which is highly related with sympathetic nervous system activity, pulse detection sensor for detecting loss of radial pulse in order to prevent Sudden Cardiac Death (SCD) [19] and g) *ultrasound* sensory systems [20] for internal organs imaging.

B. Implantable Sensor – Based Monitoring Systems

In this category we examine the implantable medical devices (IMDs) designed for screening and diagnostic applications. The major categories can be divided in: a) *Blood Flow* sensors [21] usually integrated with vascular prosthetic grafts for early detection of graft degradation or failure, b) *Blood Pressure* sensors [22][23][24] for heart failure and CVD detection, c) *Intraocular Pressure* sensors [25] for managing visual related disorders, d) *Intracranial Pressure* [26][27] sensors for diagnosis or management of neurological disorders such as hydrocephalus and Traumatic Brain Injury (TBI), e) *Bladder Pressure* [28] sensors for monitoring of the intravesical pressure, that can be informative about kidney's state or detect the manifestation of urinary tract infections, f) *Wireless endoscopy pills* [29] that transmit images of gastrointestinal tract (GI tract) and g) *other* sensors that can measure temperature and oxygen saturation for complementary information.

C. Portable and Implantable Biosensor – Based Systems

Biosensor based systems are more sophisticated and complex systems capable of measuring certain biomarkers. Biomarkers are certain substances in human's organism such as biomolecules, analytes or certain biochemical reactions that can be objectively measured and act as indicators for normal or abnormal health state. The main difference between a sensor and a biosensor is the bio-recognition element that is responsible for immobilizing the correct substance to be measured. Measurement of biomarkers is performed in highly equipped laboratories from trained personnel. With the advent of MEMS and the progress observed in biomaterials and tissue engineering new technologies such as $Lab - on - a - Chip (LoC)$ [30] or System – on – a – Chip (SoC) can enable POC biosensors for monitoring and treatment of outpatients. Glucose meters [31] for managing diabetes and lactate biosensors for CVD management are the two most widely systems used today.

III. MATURITY EVALUATION OF SENSOR-BASED MONITORING SYSTEMS

In this section a comparative study was undertaken; selected devices/papers from the literature were evaluated based on their "maturity" to be part of the medical market. Each one of those systems/papers was selected to fulfil certain criteria; a) to compose a complete well described system for a certain application, b) to have an impact in the scientific community and c) adequate information about their performance to be provided by the authors. At this point, we would like to mention that the purpose of the maturity metric is not criticize and compare system's performance, but on the contrary to reveal potential shortcomings and deficiencies that can be the driving force for further improvements. We adopted a similar methodology to the one presented in [32] and applied it in the two main categories (wearable/portable and Implantable sensor – based devices) for monitoring applications with appropriate modifications

A. Description of Maturity Evaluation Procedure

The process can be divided into three basic steps: a) feature selection, b) weighting of features c) score assignment and maturity evaluation.

1) Feature Selection

The first and most important step for the evaluation of "maturity" was the selection of appropriate features that can fully characterize the performance of a particular device. Wearable/portable devices poses different restrictions than implantable devices, thus different features must be selected in each category (table 1 and table 2).

2) Weighting of Features

Due to the fact that different parties are involved in the chain from designing to vendition of POC medical systems, we tried to take into account their opinion about the significance of each feature. We considered three groups: a) patients, b) physicians and c) manufactures. We assigned values from 1 to 5 (1 = not interested, $5 =$ maximum interested) to each feature for each group. The average of those values for each feature i was calculated and used as weight (impact factor, IF) of each feature (formula 1).

$$
IF_i = (PP_i + CP_i + MP_i) / 3
$$
 (1)

Where i represents the $i - th$ feature from tables 1 and 2 (eg, i=3 represents the feature *Ease of use* for wearable and *Biocompatibility* for implantable devices). PPi, CPi and MPi represent the opinion of patients, physicians and manufactures regarding feature i (importance of feature).

3) Score Assignment and Maturity Evaluation

The final step was to assign for each device involved in the review process a certain score (Fji) for each feature. This score was estimated based on author's statements and results provided in theirs paper. The final total score was calculated using the following formula.

$$
Maturity = NTS_{j} = (\sum_{i=1}^{n} IF_{i} * F_{j,i}) / \sum_{i=1}^{n} IF_{i}
$$
 (2)

Where \mathbf{j} is the \mathbf{j} – th system under consideration, Fit is the score assigned for device j in respect to feature i.

Finally, the average score per feature (FS_i) divided by the factor of 2 was calculated (using equation 3) as an intention to capture and localize technological shortcomings.

$$
FS_{i} = \left(\sum_{j=1}^{k} F_{j,i}\right) / 2 * k \tag{3}
$$

For wearable/portable systems $n = 15$ and $k = 6$ while for implantable systems $n = 17$ and $k = 6$.

B. Wearable/Portable Sensor – Based Systems

Selected features in this category are presented in Table 1. The final maturity score for the selected papers and the average score of each feature are depicted in Figure 2 and 3.

TABLE 1: SELECTED FEATURES FOR W/P SYSTEMS (STEP 1)

F1	Accuracy	F6	Reliability	F11	Resolution
F2	Application's Impact	F7	Power consumption	F12	Security
F3	Ease of Use	F8	Portability/ Wearability	F13	Decision Support
F ₄	Operational lifetime	F9	Real time Application	F14	Cost
F ₅	Clinical Evaluation	F10	Continuous monitoring	F15	Size

Figure 2: Maturity level for w/p systems (using eq. 1-2)

Figure 3: Average score per feature for w/p systems (using eq. 3)

C. Implantable Sensor – Based Systems

Selected features in this category are presented in Table 2. The final maturity score for the selected papers and the average score of each feature are depicted in Figure 4 and 5.

TABLE 2: SELECTED FEATURES FOR IMPLANTABLE SYSTEMS (STEP 1)

F1	Accuracy	F7	Reliability	F13	Resolution
F ₂	Application's	F8	Power	F14	Security
	Impact		consumption		
F3	Biocompatibility	F9	Method of	F15	Decision

Figure 4: Maturity level for implantable systems (using eq. 1-2)

Figure 5: Average score per feature for implantable systems (using eq. 3)

D. Comment on the Results

Observing Figure 2 and 4 none of the systems reviewed achieved the maximum possible maturity score. Despite the evolution throughout the last decades, there is still room for improvements and issues need to be addressed for prolonged real time, ambulatory monitoring in both categories. From Figure 3 and 5 we were able to specify and localize the technical characteristics of such systems that require further attention. More careful examination can reveal trade – offs and compromises among those technical features.

For w/p systems the triplet power consumption – operational lifetime – continuous recording is very critical for the designers. The required performance in one of them directly affects the performance of the other two. In addition, very few systems support decision making algorithms. Ongoing research is focused on the development of completely autonomous systems with diagnostic capabilities.

Developing implantable systems is a completely different problem and set more restrictions and challenges to researchers. Size – power consumption – continuous monitoring – implants lifetime are technical features closely related. Ongoing research is focused on reducing the size of implant through different methods of power supply. Energy harvesting and remotely transmission of power through inductive link are the main fields of interest. Finally, new biocompatible material are required not only to ensure patient's safety but also for reliable and robust monitoring.

IV. CONCLUSION

The state of the art POC systems used in medical applications were discussed and a brief review of sensor based systems were presented. Concluding, we would like to emphasize on two important issues; the high heterogeneity of systems targeting in the management and monitoring of various diseases and the new features that can attach to the current healthcare system. Development of POC systems, either simple or more sophisticated can deliver faster and more effective management for a wide range of pathologies. In addition, combination of biosensor-based systems with drug delivery reservoirs can potentially become a very powerful diagnostic and interventional tool. Besides this, the overall expenditures for healthcare and the total cost spent from patients for medical care will be significantly reduced. In order those devices to be smoothly embodied in the current system, researchers should focus their efforts on addressing the issues discussed in the previous section and Food and Drug Administration (FDA) should exhaustively analyze feedback coming from current bearers and revise current regulations and standards if necessary.

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