

# High-Confidence Platforms for Personalized Continuous Care

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**Abstract**– Designing bug-free medical device software is difficult, especially in complex on-body and implantable devices that may be used in unanticipated contexts. Safety recalls of pacemakers and implantable cardioverter defibrillators due to firmware (i.e. software) problems between 1990 and 2000 affected over 200,000 devices, comprising 41% of the devices recalled and are increasing in frequency. Our goal is to develop high-confidence medical device software for ‘long-term wear on-body’ embedded wireless platforms which are able to adapt to the patient’s condition. The Adaptive Real-Time Systems for Medical Sensor Networks (medARTS) project is composed of three components: (a) sub-\$50 disposable on-body hardware-based Health-strip, (b) adaptive real-time operating system design for runtime programmable control and (c) long-term context-based medical sensor data interpretation. The Health-strip is a flexible-circuit based disposable ECG and accelerometer sensor patch for non-invasive detection of risk patterns according to a programmable criterion. The adaptive RTOS on each Health-strip will allow for runtime remote firmware updates, software attestation and event-triggered task partitioning between the node and centralized database. We are currently collaborating with IMEC, Netherlands to develop software for a low-power integrated ECG, processor and radio ASIC. The results of medARTS will contribute open hardware and software platforms towards: rapid development of medical systems with certifiable software components, economical on-body continuous care for disease management across large patient populations, long-term evaluation of cardioactive drugs, and context-aware ECG interpretation.

## 1. Problem Statement

The rapidly increasing use of software to control medical devices makes the development and production of medical-device software and systems (MDSS) a crucial issue, both for device vendors and for ensuring safe advances in healthcare delivery. Current approaches to MDSS design and evaluation are ad hoc and will not scale as devices grow more complex and rely much more on embedded software to achieve critical functionality [1]. With the ultimate goal of designing certifiable plug-and-play software components for medical devices, we look at four specific problem areas:

### 1.1 The Need for High-Confidence Medical Device Software and Systems

Between 1990 and 2000, safety recalls of pacemakers and implantable cardioverter defibrillators due to firmware (i.e. software) problems affected over 200,000 devices, comprising 41% of the devices recalled and are increasing in frequency [2]. In the 20-year period from 1985 to 2005, the FDA's Maude database records almost 30,000 deaths and almost 600,000 injuries from device failures [3]. In addition to the human cost, such large-scale impact of software errors severely dampens the adoption of on-body and implantable medical devices and introduces longer approval processes by the FDA. With the increasing demand for mobile healthcare and the low-cost of portable electronics, rapid medical device development requires standardized, certifiable software components for embedded systems, networking, diagnosis and reporting. We believe this can be facilitated to a significant extent by patient-device model-based development, MDSS component frameworks, adaptive patient-specific algorithms and provenance protocols for evidence-based design.

### 1.2 The Need for Adaptive Real-Time Medical Sensor Networks

Most embedded software in on-body and implantable medical devices run at a single operating point (in terms of number of tasks, sampling/reporting rates, process execution times and type of diagnosis algorithms), which is determined when the device is manufactured. Such a system makes it difficult to (a) rollout firmware updates remotely, (b) personalize the device to the patient’s body, medical history,

medication, age and environment and (c) adapt the device and network’s operating point to the patient’s activity level and urgency of the medical event such as a stroke. In a study the FDA conducted between 1992 and 1998, 242 out of 3,140 device recalls (7.7%) were found to be due to faulty software. Of these, 192 -- almost 80 percent -- were caused by defects introduced during software maintenance [1]. There is a need for adaptive real-time operating systems for medical devices where processing, algorithms and communication are attested, triggered and tuned at runtime to the patient’s ‘normal’ medical and physical state.

**1.3 The Need for Long-term Continuous Medical Care**

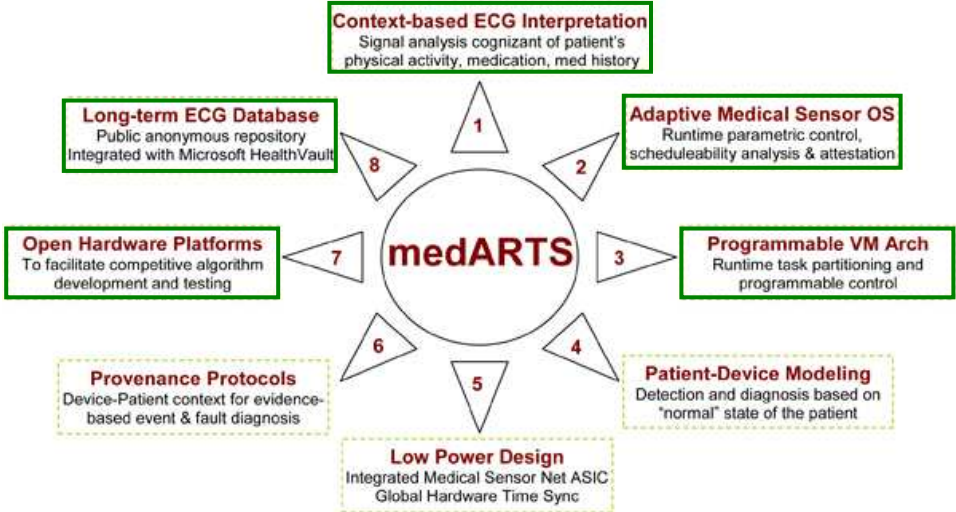
The US health system is primarily a reactive one with a focus on care *after* the occurrence of a significant adverse medical event and after the patient has experienced considerable pain. With non-intrusive, on-body continuous care medical devices, preemptive and preventive care can be provided at a lower pain threshold, lower cost and potentially with less severe treatment. Furthermore, such devices enable longer-term quantifiable monitoring of the effects and side-effects of certain medications. This is especially important for cardioactive drugs such as Vioxx® and Celebrex®, which were widely prescribed for arthritis patients but adversely affected the heart. The current generation of electrocardiogram (ECG) and Holter devices are largely for patients “at rest” and make it challenging for doctors to prescribe medication which control a patient’s heart rate.

**1.4 The Need for Long-term Medical Data**

The majority of patient-trial data is not easily available to the public and most open medical databases provide data for very short time frames (i.e. minutes to a few hours). For example, the MIT-BIH Arrhythmia Database [4], a valuable resource for ECG device manufacturers, mostly provides ECG data up to 30 minutes and only for resting patients. The introduction of disposable on-body medical devices will allow for economical long-term monitoring across large population groups. They will be able to detect subtle changes in ECG patterns such as ST segment shifts, wandering atrial pacemaker and premature atrial contraction which are early-warning signs of cardiovascular disease.

**2. Proposed Research & Technical Approach**

Our development of High-confidence Medical Software and Systems is conducted in framework of the medARTS project, as shown in Fig. 1. We plant attack three components over the near term: development of 2<sup>nd</sup> and 3<sup>rd</sup> generation on-body ECG-Accelerometer hardware platforms, development of adaptive real-time operating system for parametric and programmable control of the hardware platform and patient context-aware ECG data interpretation.

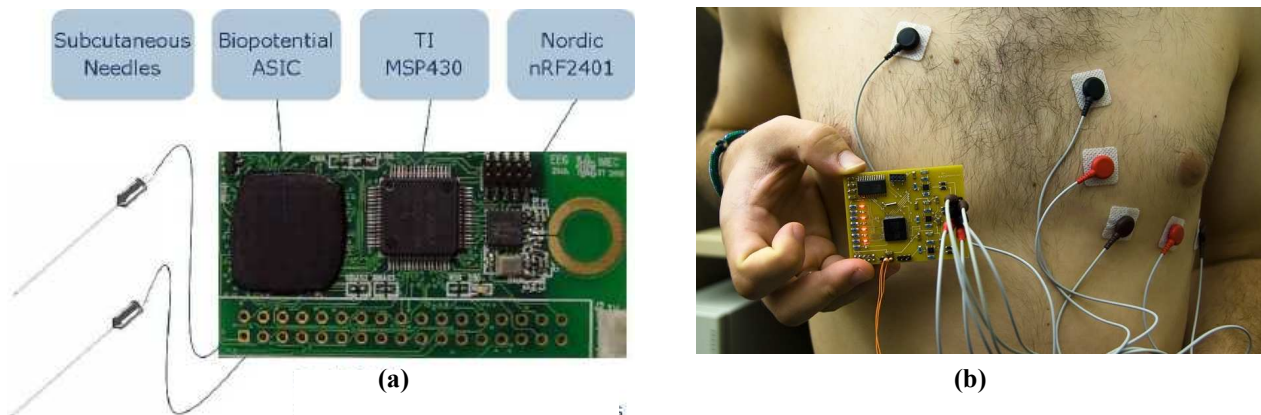


**Fig. 1.** Components of the Adaptive Real-Time Software for Medical Sensor Networks (medARTS) project.

The three components provide a low-cost embedded platform for investigation of Patient-Device Modeling, Provenance Network Protocols for evidence-based fault/event diagnosis and runtime verification and validation of embedded medical software.

## 2.1 Medical Sensor Hardware: On-body disposable programmable ECG

Over the past half-year, we have been actively developing the 1<sup>st</sup> generation of the on-body disposable (sub-\$50) programmable ECG Health-strip. The Health-strip comprises a low-power microcontroller, three or more ECG electrodes, ECG amplifiers, an accelerometer and a microSD slot for local data storage. The Health-strip also incorporates a wireless transceiver for receiving programming signals from an external programming device and a 3V mini Li-ion battery. The Health-strip is programmed to detect multiple specific risk patterns in the ECG of an individual. The current generation of the Health-strip is shown in Fig. 2(a) (with a 24-channel EEG/ECG bio-potential ASIC from IMEC, Netherlands) and Fig. 2(b) (with a 3-channel ECG and 3-axis accelerometer for the context of the patient's physical activity.) Our goal is to develop the 2<sup>nd</sup> and 3<sup>rd</sup> generation prototypes of the Health-strip on a flexible-circuit so it may be placed directly on the body as shown in the models in Fig. 4. This will involve integration and extension of the nano-RK real-time sensor network kernel [6] and RT-Link wireless link protocol [6] which is capable of near-optimal node lifetime.



**Fig 2.** (a) Current-generation smart health-strip with the 24-channel EEG/ECG sensor from IMEC.  
(b) Current generation 3-ch ECG node with 3-axis accelerometer for activity-aware interpretation.

## 2.2 Medical Sensor RTOS: Adaptive Virtual Machine with Runtime Programmable Control

As most patients are under 'normal' conditions for a majority of the time (~95%), the node may operate in low-power mode. However, when an event is detected potentially indicating the onset of an adverse health attack, the node needs to adapt by controlling the operating point both parametrically and in programmability -- from increasing the low-level duty cycles for sampling sensors, activation of additional tasks (or tasks with larger execution budgets) for event analysis, data summarizing and reporting, adaptation of the network schedule to include more throughput with bounded delays and finally at the high-level, policy negotiation of data aggregation across the network.

In order to support runtime programmable control, we will embed a light-weight FORTH-like virtual machine within and around the nano-RK sensor RTOS kernel. As shown in Fig. 3, the services supported by the Adaptive Runtime System include parametric control for heart rate limits, ST segment position and shift, QT intervals, and pacing. Programmable control includes task partitioning when a high-risk event is detected so that a majority of data processing may be outsourced to the gateway or remote database. Programmable control will incorporate runtime scheduleability analysis, software attestation of all firmware updates, dynamic algorithm activation to detect risk patterns relating to arrhythmia, syncope, myocardial infraction and transient ischemic attack.

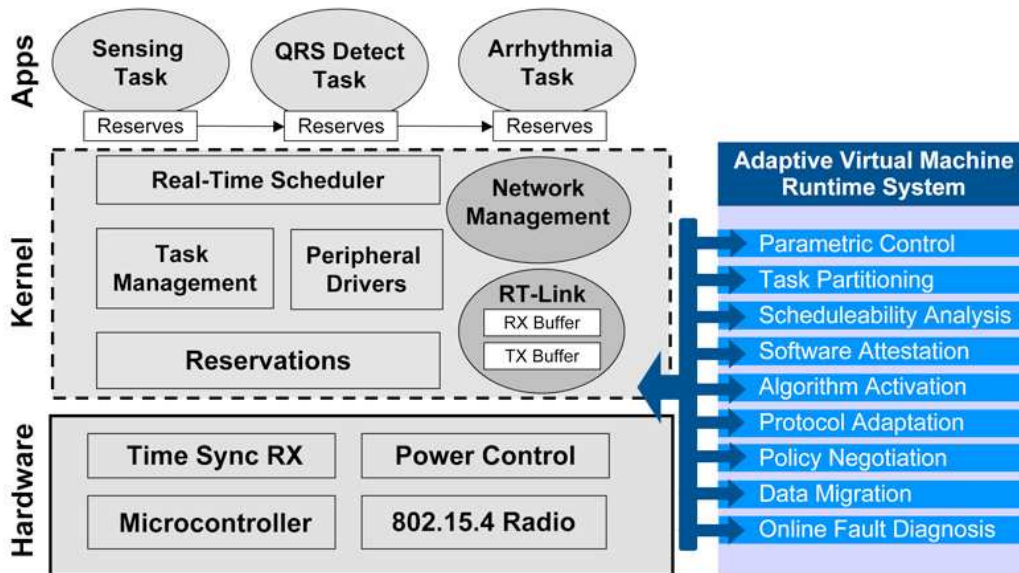


Fig 3. High-confidence Medical Sensor node architecture with runtime parametric and programmable control

### 2.3. Context-based ECG Interpretation

ECG signals obtained from stress examinations are diagnostically significant in detecting a number of heart diseases, which may not be apparent when the patient is at rest. There are currently no low-cost on-body ECG monitors which can be used for a duration spanning several weeks. Our goal is to determine the ‘normal’ state of the patient in different activity modes so that each set of ECG readings may then be interpreted within the context of the patient’s current physical activity. To determine the current state of physical activity, we integrated a 3-axis accelerometer within the Health-strip. In addition, we bias our data interpretation with other aspects of the patient profile characteristics such as medical history, medication and its effect on cardio activity and physiological side-effects, patient’s age and environmental conditions (i.e. humidity and temperature). With the availability of long-term ECG and physical activity data, we will be able to competitively decide on classification algorithms which can best determine the status of the patient and suggest recommendations based on physical exertions or lack of physical activity.

### 3. Expected Outcomes

As a final result, we will demonstrate 2<sup>nd</sup> and 3<sup>rd</sup> generation prototypes of the on-body Health-strip as modeled in Fig. 4. Each Health-strip will run the adaptive RTOS and runtime system for parametric and programmable control. We will implement classification algorithms for context-aware ECG data interpretation based on our experiments. The results of medARTS will contribute open hardware and software platforms towards: rapid development of medical systems with certifiable software components, economical long-term on-body continuous care for disease management across large patient populations, long-term evaluation of cardioactive drugs, and context-aware ECG interpretation.



Fig 4. Models of the proposed on-body smart health-strip for contextual electrocardiogram monitoring. The health-strip will feature a multi-channel ECG sensor, accelerometer, microSD slot and wireless radio.

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6. A. Rowe, R. Mangharam, R. Rajkumar, "RT-Link: A Time-Synchronized Link Protocol for Energy-Constrained Multi-hop Wireless Networks", *Third IEEE International Conference on Sensors, Mesh and Ad Hoc Communications and Networks - IEEE SECON*, 2006.

## Biographical Sketch – Rahul Mangharam

Rahul Mangharam is the Stephen J Angello Chair and Assistant Professor in the Dept. of Electrical and Systems Engineering, with a secondary appointment in the Dept. of Computer and Information Systems, at the University of Pennsylvania. His interests are in scheduling algorithms for wireless and embedded systems with applications in Medical Sensor Networks, Vehicular-to-Vehicle Networking and industrial control networks.

He received his Ph.D. in Electrical & Computer Engineering from Carnegie Mellon University where he also received his MS and BS. in Electrical & Computer Engineering in 2007, 2002 and 2000 respectively. In 2002, he was a member of technical staff in the Ultra-Wide Band Wireless Group at Intel Labs. He was an international scholar in the Wireless Systems Group at IMEC, Belgium in 2003. He has worked on ASIC chip design at Marconi Communications (1999) and Gigabit Ethernet at Apple Computer Inc. (2000). He was a visiting researcher at Athens Institute of Technology, Greece in the summer of 2006.

## Selected Publications

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1. **FireFly: A Cross-Layer Platform for Wireless Sensor Networks**  
Rahul Mangharam, Anthony Rowe and Raj Rajkumar  
*Real-Time Systems Journal*, Sp. Issue on Real-Time Wireless Sensor Networks, 2007
2. **MEERA: Cross-Layer Methodology for Energy-Efficient Resource Allocation for Wireless Networks**  
Rahul Mangharam, Sofie Pollin, Bruno Bougard, Raj Rajkumar and Francky Catthoor  
INFOCOM 2005 and in *Journal Transactions on Communications*.
3. **GrooveNet: A Hybrid Simulator for Vehicle-to-Vehicle Networks**  
Rahul Mangharam, D. S. Weller, R. Rajkumar, P. Mudalige and F. Bai  
*Proceedings of Second ACM International Workshop on Vehicular Ad hoc Networks. Mobicom/VANET 2005*
4. **RT-Link: A Time-Synchronized Link Protocol for Energy Constrained Multi-hop Wireless Networks**  
Anthony Rowe, Rahul Mangharam and Raj Rajkumar

Third IEEE International Conference on Sensors, Mesh and Ad Hoc Communications and Networks Reston, VA, September 2006. IEEE SECON 2006 *Best Paper Award*