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THE IMPLANTABLE INTERNET OF MEDICAL THINGS:
Toward Lifelong Remote Monitoring and Treatment of Chronic Diseases

Excerpted from "U-Verse: a miniaturized platform for end-to-end closed-loop implantable internet of medical things systems," from *Proceedings of the 17th Conference on Embedded Networked Sensor Systems* (SenSys '19) with permission. https://dl.acm.org/doi/10.1145/3356250.3360026 ©ACM 2019

The promise of real-time detection and response to life-crippling diseases brought by the Implantable Internet of Medical Things (IIoMT) has recently spurred substantial advances in implantable technologies. Yet, existing medical devices do not provide at once the miniaturized end-to-end body monitoring, wireless communication and remote powering capabilities to implement IIoMT applications. This paper fills the existing research gap by presenting U-Verse, the first FDA-compliant rechargeable IIoMT platform packing sensing, computation, communication, and recharging circuits into a penny-scale platform. Extensive experimental evaluation indicates that U-Verse (i) can be wirelessly recharged and can store energy several orders of magnitude more than state-of-the-art capacity in tens of minutes; (ii) with one single charge, it can operate from few hours to several days. Finally, U-Verse is demonstrated through (i) a closed-loop application that sends data via ultrasounds through real porcine meat; and (ii) a real-time reconfigurable pacemaker.

Connecting medical devices and personnel to networks and patients is rapidly becoming big business. Experts forecast the Internet of Medical Things (IoMT) market will exceed $534.3B by 2025, expanding at a CAGR of 20.2% per year [6]. From a medical perspective, the opportunities that implantable IoMT (IIoMT) platforms will offer to both doctors and patients are unprecedented in healthcare history. Through the implantation of tiny networked devices inside our bodies, healthcare professionals will be able to perform 24/7 *in situ* monitoring of critical physiological conditions without being in proximity of the patient [14].This promise comes at a moment when healthcare expenditures in the United States have reached more than $3T a year [4], urging widespread marketization of platforms that can not only detect, but also react in real time to abnormal medical conditions. The IIoMT is expected to radically transform the healthcare landscape by allowing (i) early diagnosis and prevention of diseases through remote patient monitoring; (ii) faster delivery of healthcare services and response to sudden life-threatening events [12]; (iii) reducing health care expenditure drastically.

Motivation

Millions of people would benefit from IIoMT systems where blood pressure and glucose sensors detect arrhythmia, hypertension and diabetes [10, 13] and implantable pumps deliver hypertension and insulin medication only when most needed [18] – for example, through remote real-time intervention by healthcare professionals. Our vision, simply put, is to realize end-to-end implantable systems able to finally bridge the existing gap between doctors and real-time sensing/actuation of health-critical functions. The harsh reality, indeed, is that the above (and similar) IIoMT systems do not yet exist. Despite the numerous recent advances in intra-body communications and implantable medical devices (IMDs), most of the existing devices focus on small-scale ad hoc design, wireless charging, passive communications and extremely low power consumption [1, 2, 3, 17], while other platforms [15] focus on the computation/communication side, but come short on the recharging aspect. In other words, we still lack end-to-end IIoMT systems where sensing, computation, communication, and actuation work smoothly together to implement end-to-end, real-time, long-lasting, closed-loop, miniaturized IIoMT platforms.

Novelty

This paper addresses the current research gap with the U-Verse platform [7]. U-Verse has been specifically designed to enable highly demanding next-generation IIoMT functionalities such as muscle/nerve stimulation, pacemaking, distributed intra-body sensing and multi-point actuation, among others. Figure 1 depicts an overview of the integration of U-Verse in the IIoMT context. The board can be interfaced with sensors to detect specific bio-markers. The measurement data, processed on the board, are sent through the ultrasonic interface to an external receiver enabled with Internet connectivity to forward health data to a healthcare facility or a doctor. Based on the received data, actuation commands can be sent back to U-Verse instructing the implant with the specific actuation settings. Figure 2 shows a miniaturized, penny-scale prototype. In a nutshell, U-Verse implements a platform where (i) a single ultrasonic transducer is used for data transfer and wireless charging; (ii) a miniaturized field-programmable gate-array (FPGA) and micro-controller (MCU) provide the necessary computation/communication needs. The novelty of U-Verse with respect to existing implantable devices is that it provides the first demonstration of a multi-purpose integrated and modular implantable ultrasonic IIoMT platform with sensing/communication/computation/energy harvesting. These unique capabilities enable U-Verse to achieve the following key IIoMT objectives: (i) periodically transmit outside the body critical health-related statistics measured by implantable sensors; and (ii) control appropriate actuation to health-critical events – establishing the opportunity to implement pacing devices, smart drug pumps, and other IIoMT medical devices. To the best of our knowledge, no other IIoMT platform provides at once wireless charging, connectivity, and reconfigurability both at the communication and computation levels. Therefore, the overarching target of this project is to provide a blueprint for next-generation IIoMT platforms.

BACKGROUND

Thanks to the myriad of potentially life-saving applications, the design and development of technologies for implantable medical devices(IMDs) has received a surge of interest from the research community over the last few years [1, 2, 11, 15, 16, 17]. Charthad et al. [2] recently proposed an ultrasound-powered IMD having a 2×3×6.5mm dimension for wireless electrical stimulation. However, the extremely constrained nature of the passive device prohibits IIoMT scenarios where communication, computation and actuation requirements are more than what passive devices can offer. The devices in [1,2, 17] can provide power in the order of a few milliwatts at best, and are not able to last more than few milliseconds, since their storage capability is extremely limited. Passive RFID-based IMDs based on radiofrequency (RF) backscatter communications have also been proposed [11, 16]. For example, Ma et al. [11] proposed an RF-based beamforming to enable powering up and communicating with RFID devices implanted in deep tissues. Vasisht et al. [16] proposed a backscatter design for localization of deep tissue devices. Although the above work introduces new communication strategies and technologies, ultimately, they cannot implement IIoMT applications, since the generated backscatter power is of one-two orders of magnitude less than what is needed. In other words, the above devices were made for "power-

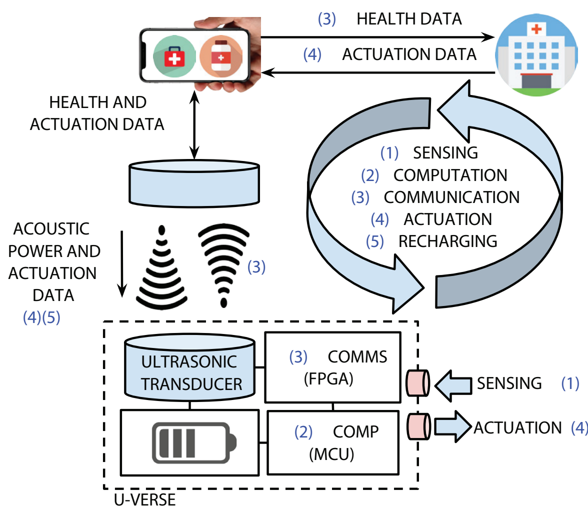

FIGURE 1. U-Verse enables end-to-end closed-loop long-lasting Internet of Implantable Medical Things applications.

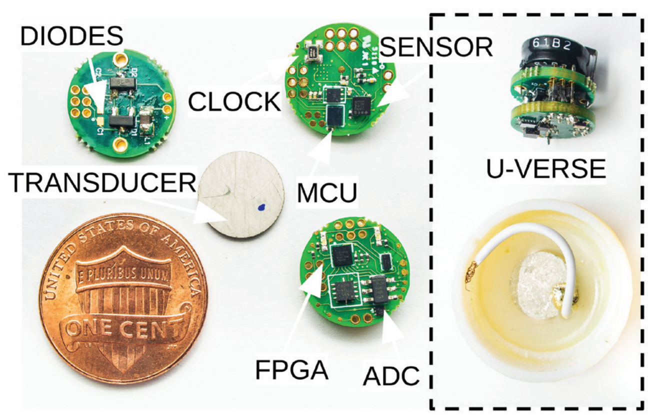

FIGURE 2. From top left, clockwise: energy harvesting unit (EHU), processing and communication unit (PCU) top and bottom side, penny, and ultrasonic transducer. The dashed box shows the full stack-up with a supercapacitor as power storage, as well as the transducer location.

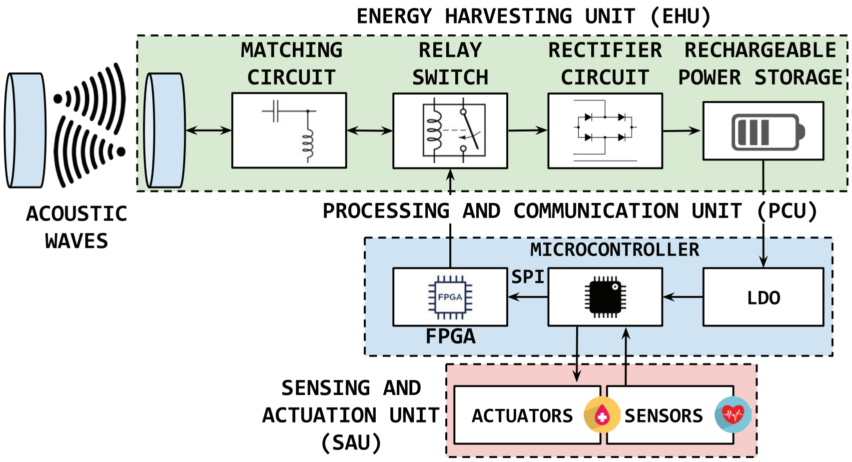

FIGURE 3. U-Verse is logically divided into an energy harvesting unit (EHU), a processing and communication unit (PCU), and a sensing and actuation unit (SAU).

and-play" applications, where the IMD is powered up for a very short period, performs very specific, low-power tasks, and then goes to sleep. U-Verse, instead, can execute sensing/actuation applications that take longer than just few milliseconds and it can repeat them several times with a single charge. We investigated the idea of using ultrasonic waves for intra-body wireless charging in previous work [9]. The closest work to ours is [15], where the authors propose an IIoMT system based on ultrasound communications that has similar computational and communication capabilities to U-Verse. However, the platforms proposed suffer from the following core limitations: (i) they were early-stage prototypes made with off-the-shelf evaluation boards; (ii) the recharging problem was neglected.

Design Challenges

Instead of using electromagnetic (EM) waves, U-Verse leverages ultrasound-based recharging and communication. This is because ultrasound waves have significantly lower absorption in human tissues, e.g., around 70 dB less attenuation for a 1 MHz ultrasonic link vs a 2.45 GHz RF link [5], making them significantly more reliable than EM waves. On the other hand, achieving miniaturized ultrasonic wireless recharging and communications is extremely challenging and requires careful design choices to optimize the way U-Verse receives, stores, and manages the energy with its resource-limited components. Part of our efforts included utilizing strictly commercial off-the-shelf (COTS) components and materials. COTS components facilitate the re-producibility of the device, limit its fabrication costs, but require extra design efforts since they do not provide enough margin for customization. Last but not least, another concern of ours was the platform's versatility – indeed, an IIoMT platform should be amenable to be reconfigured on both the application and the hardware fabric sides. For this reason, we struggled to find the "sweet spot" between flexibility and efficiency.

U-VERSE: SYSTEM OVERVIEW

Figure 3 depicts a high-level overview of the main blocks of U-Verse and the interactions among them. U-Verse realizes the vision of a self-contained IIoMT platform where sensing, computation, wireless communication and charging coexist with each other yet kept logically and physically separated for modularity purposes. Perhaps the most fundamental design feature of U-Verse is its capability to go beyond the highly specialized designs and architectures crippling most of the existing implantable devices – and provide a "blueprint" for future IIoMT-ready devices that use ultrasound technologies to communicate wirelessly through body tissues. This is required to consider modularity and extendability as top priority in designing U-Verse, which obviously trades off size and power to achieve the high levels of flexibility required by the IIoMT environment.

Main Modules and Operations

U-Verse is composed by (i) an energy harvesting unit (EHU), tasked with powering the computational and sensing components of U-Verse; (ii) a processing and communication (PCU) unit, which handles networking and computation tasks; and (iii) a sensing and actuation unit (SAU), which includes the circuitry necessary to implement applications such as telemetry and remote delivery of health-care services.

Energy Harvesting Unit (EHU)

To recharge the platform, a signal is generated at ultrasonic frequencies (*i.e.*, >20 kHz) from an external charger. The ultrasonic waves propagate through human tissues and are received by U-Verse, which efficiently extracts the energy from them and stores it. It is crucial to control the transmit power to ensure that the system is compliant with the FDA exposure limitations. In the United States, the FDA sets the exposure limits of the human body to720 mW/cm^2 for acoustic waves and to 10 mW/cm^2 for EM waves. This considerable difference is due to the fact that ultrasonic waves propagate better in aqueous media, resulting in smaller absorption when compared to RF [8, 15]. Figure 4 shows the transmitted power and the corresponding intensity to recharge U-Verse for varying input voltage. In particular, Figure 4 shows that even when transmitting at the highest voltage, the acoustic intensity is well below the FDA limit.

Processing and Communication Unit (PCU)

The PCU is composed of an MCU and an FPGA, which together offer the required low-power small-area hardware and software computation and communication capabilities. The FPGA is tasked with implementing an ultrasonic wide-band (USWB) physical-layer communication scheme [15]. The usage of an FPGA instead of an application-specific integrated circuit (ASIC) guarantees physical-layer reconfigurability, which is critical for the following reasons. First, the IIoMT is still in its infancy – therefore, major wireless-related advances are expected to happen between now and a few years. Therefore, we need to be able to radically change the physical-layer fabric of the IIoMT platform to keep the pace of innovation. Second, intra-body channels are extremely hard to model, which may require the real-time modification of physical-layer parameters.

Sensing and Actuation Unit (SAU)

U-Verse can be interfaced with a wide variety of sensors and actuators through standardized analog and digital interfaces. This crucial aspect indeed realizes a "plug-n-sense" vision where IIoMT platforms are flexible enough to connect with different sensors depending on the application and therapy requirements.

Prototyping U-Verse

To demonstrate that U-Verse can be miniaturized within acceptable implant physical constraints, we designed, implemented, and fabricated an ultra-small (i.e., 1 cm diameter) stack-up prototype printed circuit board (PCB) for U-Verse. The current prototype presents 2 PCBs, one for the PCU (top and bottom layouts respectively shown on the left and center portions of Figure 2) and one for the EHU (shown on the right side of Figure 2). The EHU PCB presents a diode bridge rectifier and a matching circuit as well as a single supercapacitor and six breakouts to interface with external sensors and actuation functions, such as adaptive pacemaking.

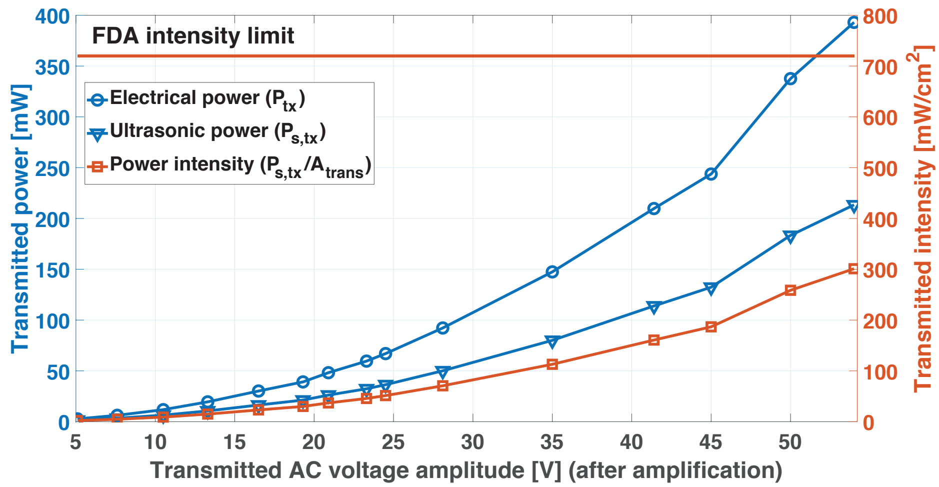

FIGURE 4. Transmitted power vs FDA limits.

EXPERIMENTAL RESULTS

U-Verse Charge and Discharge Performance

U-Verse performances were extensively evaluated through experiments. The first type of experiments that we conducted was the measure of the charging and discharging times of U-Verse, proving that the system can be wirelessly recharged with ultrasounds at 5 cm of distance. The recharge time remains within acceptable limits – between 10 minutes and 2 hours (depending on the energy capacity size) when transmitting at maximum power. In a real-world implantation of U-Verse, for example, the storage unit could be recharged overnight with a strap-on transducer attached to the skin of the patient. Furthermore, we would like to point out, however, that since the transmitted electrical power is still about half the amount of power allowed by the FDA (see Figure 4), the charging time of the EHU could be further decreased. As well, the energy storage discharge time strongly depends on the computation/communication/sensing burden that the IIoMT application imposes on U-Verse and on the power consumption of each of these operations. For this reason, we have experimentally evaluated the power consumption U-Verse, over several closed-loop sensing/processing/transmission/reception application tasks.

Although it is intuitive that due to the increased acoustic power loss between the transducers, a deeper IIoMT platform will require more charging time (or equivalently, more transmission power), it is paramount to provide accurate recharge/discharge times to the patient so that U-Verse can operate continuously. Experimental results show that U-Verse is able to support discharge duration of up to 610 and 40 hours when it is powered by a rechargeable battery or a 15 F supercapacitor, respectively, when a very low duty-cycle is used in the application. When the tasks are running continuously, U-Verse still supports operations up to 100 and 20 minutes, respectively.

U-Verse End-to-End Applications Demo

We then demonstrate U-Verse in an end-to-end closed-loop application. This experiment demonstrates (i) the wireless charging of the EHU through two types of real porcine tissue, (ii) the periodic transmission of sensor data for several minutes through porcine meat; (iii) the reception of sensed data with another U-Verse PCU board; (iv) the real-time processing; and (v) the reception of data by U-Verse. To execute this demo, we used porcine meat as propagation media because it has similar properties to human muscular tissues at ultrasound frequencies. We tested the remote charging of the EHU along two distances, namely 3 cm and 5 cm through two different types of porcine meat, one homogeneous and the other (pork belly) composed of different layers, including skin, fat and other soft tissues. Data communication is possible at longer distances because it requires less power than wireless charging. Therefore, as showed in Figure 5, we placed a U-Verse device and wirelessly powered it to a fully charged 15 F supercapacitor on the left side of a 12 cm long porcine meat. Another processing and communication unit (PCU) was placed on the right side of the porcine meat and was connected to (i) another transducer similar to the one used by U-Verse, and (ii) to a PC.

The transducer on the right side is used both to transmit/receive data and for wireless power transfer. We used an off-the-shelf oscilloscope to probe the data communication interfaces of the two PCUs measuring the transmitted and received voltages ("TX" and "RX" respectively, in Figure 5). We finally demonstrate the versatility of U-Verse in an application-specific implementation of a reconfigurable pacemaker. The MCU implements three major functions: exchanging data with the internal FPGA, sensing and processing the readings from a pressure sensor, and

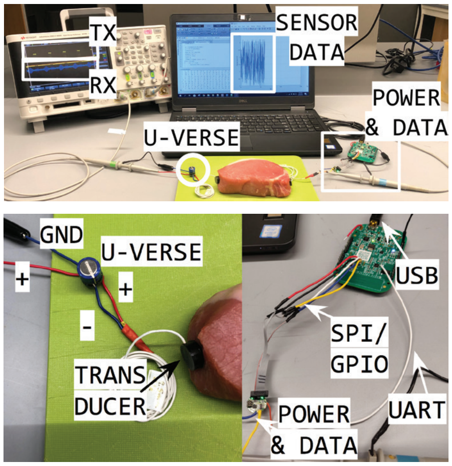

FIGURE 5. Closed-Loop U-Verse Application Demo.

producing the pacing pulses. The results of this experiment are fundamental because they show (i) the actuation capabilities of U-Verse, (ii) that therapy specific parameters (pacing frequency and pulse duration in this case) can be reprogrammed during operation without interruption, (iii) that the prototype can pace continuously for about 40 minutes.

CONCLUSION

Thanks to the myriad of potentially life-saving applications, the design and development of technologies for implantable medical devices (IMDs) has received a surge of interest from the research community over the last few years. However, these devices cannot support the highly efficient and highly demanding functionalities of future IIoMT devices in a miniaturized environment. For the first time, U-Verse addresses the above issues by presenting a rechargeable, miniaturized IIoMT platform able to support end-to-end closed-loop applications in real-time. We believe that for these reasons, U-Verse provides unique contributions as it makes a substantial step toward autonomous, long-lasting IIoMT systems. ■

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