Earables as Medical Devices: Opportunities and Challenges

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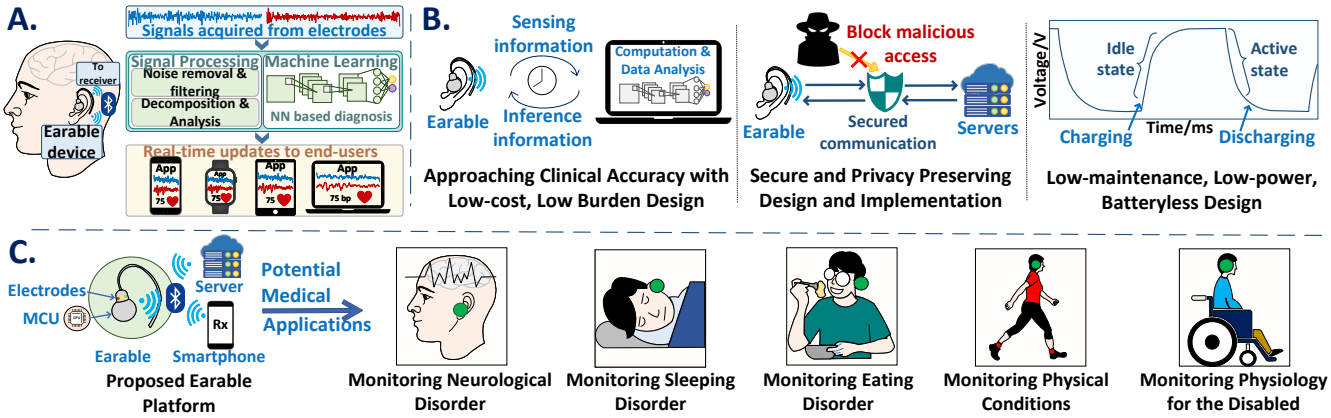

Figure 1: Earables as medical devices: A) The end-to-end earable concept of sensing signals from in and around the ear locations. B) Some key focus areas of the current state of earable research. C) The future of earables as medical devices

CCS Concepts

• **Human-centered computing → Ubiquitous and mobile computing**.

Keywords

ubiquitous computing, wearable computing, earables

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1 INTRODUCTION

The recent advancements in remote healthcare monitoring have revolutionized clinical practices. They provide reliable and affordable solutions to monitor physiological and neural signals in various environments instead of having to rely solely on on-site clinical monitoring in hospitals and medical centers. Wearable devices, particularly *earables*, computers placed in or around the ear, have gained considerable attention for their convenience, social acceptability, comfort, and minimal disruption to daily activities.

The development of earable devices has been propelled through the recent technological advancements in edge and fog computing, battery technology, and energy harvesting methods [11]. Earables allow us to capture important signals from the upper part of the human body, especially the human head. Equipped with the right sensors (e.g., accelerometers, IMU, PPG), these devices have the potential to monitor various biometrics such as heart and respiratory rate [12], blood pressure [2] and muscle movements [8]. Electrochemical sensors in earables can even open up novel possibilities to investigate alternative body fluids such as sweat [13]. Moreover, their proximity to the brain and eyes enables the detection of complex modalities like EEG [6], and EOG [9] making earables promising for health monitoring [7, 10]. They are also less affected by motion noise compared to smartwatches, which are prone to disruptions from wrist movements [4]. The portable, discreet, and unobtrusive nature of these devices allows them to monitor patient vitals for extended periods in any setting and environment [1].

However, there are inherent challenges associated with earable technologies and the use of the ear as a sensor location. Interference from motion and physiological artifacts, limitations in electrode placement area, and the trade-off between signal resolution and wearability pose obstacles to reliable and accurate monitoring [5]. Factors such as battery failures, computation latency, and RF interference can introduce errors in measurements leading to wrong treatment. Additionally, as wearable medical technology becomes

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more interconnected, security and data privacy mechanisms to protect patients from theft or malicious actions must be considered [3]. In addition to addressing technical complexities, sustainability considerations play a vital role in the development of earable computers as a growing field. This involves reducing waste throughout the entire value chain and contributing towards designing a more circular device lifecycle. Overcoming these challenges is crucial to fully leverage the potential of earables in medical applications.

Our Position: In this vision paper, we reflect on the growth of earable computing and make an attempt to chart its near and long-term challenges and opportunities, particularly in a medical context. Our vision covers three broad areas – technological capabilities, user experience, and clinical implementation. Each of the three areas is critical if we expect earables to move from an invention in the lab to a medical device in the clinic to a tracker in the home.

Given the broad range of expertise in earables in the workshop, we aim to present our vision and build on it as a community. We welcome input from other earable researchers on the challenges, opportunities, and the path to translation we imagine.

2 CURRENT EARABLE RESEARCH

Current and Future Opportunities for Earables Research. For earables to grow as a community, we need to take a step back and look at the broader medical infrastructure and understand where and how it fits in. There are regulatory bodies (e.g., the Food and Drug Administration in the USA) that determine whether a new device or technology is fit for medical use. The primary focus of such agencies is to ensure that any new technology being introduced in the medical system meets the minimum standard of safety and does what it is advertised to do. For earables to be widely adopted, they will need to not only comply with these minimum requirements but go beyond them to overcome the various barriers to adoption. These barriers span technological capabilities, user experience, and implementation. Below we enumerate various ongoing and potential future areas of research that the earable community will need to conduct to improve its adoption in medicine:

- *Regulatory Compliance and Reliability:* Medical-grade wearables must comply with relevant regulatory standards and certifications specific to medical devices which ensures that they can be used in healthcare settings with confidence. They must provide reliable and consistent data to ensure accurate diagnosis, monitoring, and treatment decisions. There should also be strategies to detect and remove noise, understand uncertainty, and mitigate artifacts' impact on outcomes.
- *Computation and Latency:* Head-worn wearables operate on battery power and should prioritize energy-efficient sensing techniques and adapt algorithms based on the available energy. Efficient scheduling methods that adapt sensing algorithms based on the available energy envelope are important. While prediction accuracy is essential, latency of operation becomes critical in real-time scenarios. Mobile health platforms must carefully consider the tradeoffs between accuracy and latency, particularly in continuous sensing applications.
- *Privacy and Security:* The sensitive health information collected by medical-grade wearables must be handled securely and protected from unauthorized data access or breaches. While data transfer to the cloud or accompanying devices might be necessary due to device size constraints, privacy-preserving measures should be implemented. Encryption, data anonymization, and secure transmission protocols are essential to safeguard patient privacy and maintain data confidentiality.
- *Safety and Comfort:* Earable devices need to be designed for user comfort with ergonomic form factors and hypoallergenic materials for safe contact with the skin for prolonged periods. The form factor should be ergonomic, allowing for extended use without causing discomfort. Materials used should be hypoallergenic and safe for prolonged contact with the skin. Risk assessments and usability studies are necessary to determine the optimal shape and functional design and mitigate potential safety hazards. Acceptability considerations, especially for conspicuous devices like headbands, should also be addressed.
- *Usability and User Experience:* Medical-grade wearables should have intuitive user interfaces and clear instructions for use as user experience plays a vital role in ensuring device adoption, compliance, and engagement. As with any new piece of technology, earables will need to scaffold the onboarding experience for new users and provide consistent value to ensure easy and sustained adoption. Considerations such as ease of setup, data visualization, and actionable insights are important for enhancing usability and user satisfaction. Human-centered design methods and tools such as participatory design, interviews, and usability measures will provide critical insights on how to best improve earables each step of the way.
- *Clinical Validation and Evidence:* Medical-grade wearables should undergo rigorous clinical validation and evidence-based evaluation to demonstrate their effectiveness and safety. Clinical studies involving patient populations and collaboration with healthcare professionals can provide valuable insights into the device's performance, benefits, and limitations.
- *Implementability:* Assuming the end goal of earables is for them to be adopted in medical practice, we need to onboard clinicians on how to use the device, how to operationalize the outputs into actionable treatment plans and devise ways to integrate the data with EHRs. Even after a technology has been demonstrated to be useful, accurate, and usable, we need to be mindful of the implementation challenges that will need to be overcome in addition to the technical and user experience challenges. Additionally, we will also need earable experts to guide policy around the safe and effective use of earables.

Open Challenges for Earables Research.

The above opportunities we highlight are based on our experiences working with earables. Based on the same experiences, we also want to take a deeper dive into some key challenges that we are experiencing across three key areas of technological innovation, user experience, and implementation.

- *Thinking Beyond Traditional Manufacturing*. With the rising popularity of wearable medical devices, it has become imperative that we think beyond computing complexities and focus on sustainable development as well. Building wearable medical devices with a sustainable approach encompasses considerations of power efficiency, materials, and environmental impact. Additive manufacturing processes, flexible electronics, and stretchable materials [14] enable cheap and rapid production methods while allowing

the creation of intricate and customized designs that perfectly fit the ear. Adopting eco-friendly materials and modular designs can promote reusability and harvesting energy from the environment can facilitate the development of battery-free systems reducing the reliance on disposable or rechargeable batteries. However, further research needs to be done to address challenges such as energy efficiency, power fluctuations, and continuous operation under varying conditions. The community should encourage prioritizing sustainability as a design principle so that it may lead to unlocking the full potential of earable healthcare solutions.

- *Thinking Beyond the Single User.* It is common in SIGMOBILE (UbiComp, MobiSys, MobiCom, SenSys, etc.) research to focus on the end-user being a single individual. If we want earables to be adopted in medicine, we need to broaden our understanding of who we consider to be the stakeholders. Beyond the end-user, often a patient, we need to think about the clinicians – nurses and doctors, the medical tech, the EHR admin, policymakers, and regulators among others. Essentially, understanding who interacts with the system at what points in the care will be critical to improving the likelihood of earables seeing a successful adoption. While patients may care about ergonomics and form factors, clinicians will be concerned with data reliability and interpretability, technicians will be concerned about ease of setup and integration with hospital IT systems.
- *Thinking Beyond A Single Device.* In contrast to the above two challenges we want to imagine a farther-out future for wearable health sensing. A vision of wearables that we want to offer is that of seamless interoperability. Similar to Weiser's vision for computing to disappear in the background, we imagine a world in which sensing becomes a secondary activity. In a world where all devices you interact with can sense a range of health signals, a person does not need to consciously think about what sensor they are wearing, its battery level, or if it will be comfortable during a particular activity. We can build a standard for interoperability where the sensing can be handed off between devices as a user moves around in an environment interacting with different things (e.g., smartphone, TV, keyboard, mouse, toothbrush, car steering). In such an environment, a person can decide to wear dedicated wearables for higher accuracy or choose to be more fluid and settle for slightly lower accuracy.

Towards realizing such a vision of ubiquitous health sensing, we need to not only think about different wearable form factors but also think about leveraging materials to make day-to-day objects capable of capturing health signals and propose universal standards for health sensing among other steps. Earables provide the next leap toward this vision by providing a new form factor for sensing neurological artifacts, EEG, EMG, EOG, HRV, EDA, PPG, SpO2, and even blood glucose levels or biomarkers of dehydration or stress.

As stated earlier, the above is an abridged version of the challenges that we see in our work with earables. Balancing clinical effectiveness and user experience is another vital consideration that will ensure earables effectively contribute to medical diagnostics while offering a positive user experience. We are excited to hear if these resonate with other earable researchers and also look forward to hearing what additional challenges they experience in their research that we did not touch upon here.

3 CALL TO ACTION

We have listed a broad range of opportunities and challenges for earable research. The expectation is not for any single researcher or team to solve all the problems on their own. Instead, we want people to take a broader view of the earables research, and reach out to other experts in human-centered design, implementation science, sustainable materials, public policy, etc. to enrich the community. By being inclusive of various perspectives and types of contributions, the earable community can not only realize its goal of positive impact on medicine but also act as an example of how to grow a new community. Sustainability is a crucial aspect of the development and adoption of earable computers as medical devices. By focusing on material selection, energy efficiency, repairability, and responsible disposal, sustainable practices can be integrated into the manufacturing and lifecycle of earable devices. Moreover, considerations such as battery lifetime, user willingness, user comfort, and usability play vital roles in ensuring the long-term sustainability and acceptance of earable computers in healthcare applications. By addressing these challenges and embracing sustainable design principles, earable computers can contribute to improved healthcare outcomes while minimizing their environmental impact.

We are excited to participate in this workshop and look forward to engaging with our peers on their thoughts and vision for the Earables community.

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