

Flexible biosensor for continuous monitoring

ESE Senior Design Team 6 Interdisciplinary with BE

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I. Executive Summary

Doctors and nurses rely on vital sign monitoring to provide accurate diagnosis and best treatment. Currently, physicians rely on electrical vital monitors or handheld devices to manually measure and document patient vitals. This has been identified as the major source of inefficiencies as nurses can spend up to 35% of their time on these repetitive tasks. Also, patients bear the risk of delayed emergency response and high error rate, when nurses fail to capture changes or develop alarm fatigue. Therefore, we saw needs in developing an automated patient monitoring device that improves efficiency, reduces cost for hospitals, and enhances bedside vigilance and patient safety.

The goal of this project is to develop a stretchable, wirelessly rechargeable device that provides continuous monitoring of patient vitals. Wireless power transmission from a power device to the wearable sensor charges the onboard sensor battery. Currently, the inductive WPT system operates at 1.3 MHz and delivers 100 mW power.

To maximize patient comfort, the sensor system is embedded in a silicone wristband or patch. Rigid circuit board area is optimized down to 2 cm by 3 cm. The power receiving circuit is manufactured with non-toxic liquid metal (Ga-In alloy) for flexibility. The size of the entire finished sensor node to be around 5cm * 8cm, with high stretchability and increased lifetime.

The sensor communicates with a smartphone via bluetooth, and the team also develops an app for user interface. Continuous data collection will be run in the background and all the data will be pushed and stored in the cloud. The app will display the readings and alert the users of abnormalities.

II. Project Overview

We are building a stretchable, wirelessly rechargeable biometric monitoring platform to enable nonstop monitoring of high risk patients for weeks. We envision the end product to be a multipurpose platform where the sensors can be customized based on each user's need for a variety of purposes, including inpatient use and home care, and the data collected will be analyzed on a smartphone app. Current monitoring devices require regular recharges, which can cause interruptions in data collection. Continuous sensing and real-time data transmission will allow patients to construct a biological profile over time, and such baseline-setting is crucial in temperature or heart rate monitoring when individual differences can lead to inaccuracies. For demonstration purposes, we will be using a temperature monitoring sensor.

Potential application cases include: electrophysiology studies with EKG monitoring; temperature monitoring for fever, autoimmune diseases, infection and sepsis; body position and movement tracking using accelerometry for athletic training / physical therapy.

III. Technical Description

The project is divided into 4 parts: flexible electronics, wireless charging, embedded controller and user connectivity. Xiaoya Song is responsible for flexible electronics, Hanming Zu is responsible for wireless charging, Hyun Ji Jung is responsible for embedded controller, Zetong Jia is responsible for user connectivity.



Specification

Mechanical: Weight: < 50g Dimension: 7cm X 5cm X 1.5mm Strain: 120% longitudinal elongation

Electrical: Battery life: 2 days (100 mAh, 3.7V) Temperature accuracy: ±0.05 °C Microcontroller: nRF52833 (ARM M4) Communication: Bluetooth 4.0 LE

Wireless charging: Distance: > 1 cm Maximum power transfer to load: > 100 mW Frequency: 1.3 MHz

Flexible electronics

Design

We are using EcoFlex to manufacture silicone pads to embed the electronics, because silicone is easily accessible, nontoxic and widely used in medical applications. The initial design was a 3D printed spiral mold of the WPT coil. A silicone patch with channels was made then a bonding process was performed to seal the channels for liquid metal injection. The timing of the bonding was particularly challenging, and the double-layer coil design added manufacturing complexity. In the second semester, we used an alternative method, which is to create channels with silicone tubing. Silicone tubings are pre-made medical-graded tubes that can be shaped in a certain geometry. We 3D printed a mold to make a 10-turn WPT coil, and poured uncured silicone into the mold. This significantly simplifies the process by eliminating the bonding step, and also reduces the risk of leaking because the tubing serves as a container. A syringe and needle is used to inject the liquid metal (Figure 2). This part is extremely flexible, it conforms with the skin, and is light weight and more comfortable than rigid wearables (Figure 1).



Figure 1. 4.5cm diameter power coil prototype, connected to PCB with copper wire.

Using non-toxic room temperature liquid metals to replace the power receiving coil can achieve large cross sections while maintaining stretchability. More specifically, we will be using Gallium-Indium alloy. It has a special property of forming an oxide layer that maintains shape and restricts fluidity, therefore reduces the risk of leakage. The viscosity of the liquid metal is similar to water, a syringe and needle will be used to inject. The melting point is -19 degrees celsius, and electrical conductivity is 3.46×10[^]6 S/m.



Figure 2. Liquid metal injecting into silicone tubing with a syringe.

The sensors will be manufactured onto a flexible PCB and embedded into the silicone patch, alongside the power receiving circuit, for wireless charging. We are expecting the size of the entire finished sensor node to be around 5cm * 8cm, with high stretchability and increased lifespan.

The sensor node (substrate and adhesive) needs to be manufactured with hypoallergenic material. Electronic risk factors should also be considered and addressed in the design. We will use lead free flexible PCB enclosed in silicone for flexible circuitry to minimize contact of toxic materials. For human testing, approvals from IRB will be needed.

Final status

The power coil is 4.5cm in diameter with 10 turns, filled with Ga-In alloy. It is able to connect with the rest of the electronics and transfer power at a desirable efficiency.

Wireless charging

Design

For the 1 MHz inductive charging design, a RC cross coupled oscillator is designed to power the transmitter coil. It is selected because of high efficiency driving inductive load. Regular power electronics are used because they are cheap and sufficient at 1 MHz. The receiver consists of a series LC resonator and rectifier.



Figure 3. WPT circuit diagram and system architecture

Final status

The WPT system has a source impedance of 150 Ω . When 2 coils are at contact distance, maximum power transmitted is 1.0 W. Parasitic capacitance of the 2 SQ1922EEH MOSFET is 50 pF measured by the VNA. The transmitter coil made with AWG 22 copper wire has inductance of 4.8 uH and capacitance of 5.15 pF. The resonant frequency is 1.5 MHz.

The power receiver coil is simulated with a hand wrapped coil with AWG 30 wire with a diameter of 4.5 cm and 10 turns. Its inductance is 4 uH. AWG 30 wire conductance corresponds to the conductance of a Galinstan wire of 0.86 mm² cross sectional area. The resistance of galinstan coil is 2 ohm, so the quality factor at 1.5 MHz is about 10.

The power system is able to stabilize a wide range of input voltage, depending on the distance to the transmitter coil. The power receiver can receive 100 mW when the receiver coil is directly on top of the transmitter coil at 1 cm distance. We do not detect any sensible heating of the receiver coil when the sensor is charging on our skin.

Embedded controller

Design

A module that is capable of both BLE communication and basic ADC/SPI capabilities was chosen to minimize the size of the sensor node. nRF52832 is a cost-effective and popular BLE module used in several DIY bluetooth kits. Since no advanced functionalities of the chip are needed besides SPI communication, the reference circuit from the datasheet was used.

We chose a TMP117 high-accuracy digital temperature sensor. Designed for wearable devices, this sensor provides up to $\pm 0.1^{\circ}$ C accuracy and 0.0078° C resolution which is suitable for

medical applications as well. The sensor is placed at the back of the board so that it can maintain close contact with the patient's skin.

Current draw during BLE transmission is about 7mA, and idle current draw is \sim 30µA. With a small 50 mAh lithium ion battery, the sensor can last for about 1.5 days assuming that temperature data is transmitted every 5 seconds.

Final status

We were able to successfully connect to the board and utilize all peripherals such as Bluetooth, I2C for temp sensor communication, and ADC for battery level detection. Currently, the board is able to advertise itself and establish Bluetooth connection with smartphones. The chip can transmit temperature data in a standardized format, but development was halted before we could calibrate the sensors and regularly transmit the updated values. While the MCU development kit does provide the functionality, encryption of the data over the Bluetooth channel has not been implemented yet and remains a challenge.



7cm

Figure 4. MCU on rigid PCB and connected to liquid metal coil.

User and connectivity

Design

This Android app will be running in the background on the smartphone, and all the data collected will be pushed and stored in the cloud (Firebase). When the user first opens the app, they will see the current temperature reading. The user will be able to select symptoms that the patient is experiencing with each corresponding time and temperature. On the second tab a graph displaying the temperature changes for the past 8 hours. On the third tab, the user will

save its basic information such as weight, height, and contact information to share with the doctor.



Figure 5. Simulated app interface

Final status

All designed features are successfully implemented. This android app runs it's backend on Firebase. Users first sign up with email and password, and their information will be saved in the Firebase database. Once users enter, there are three tabs shown. The first one shows the current temperature. If the number is in red, that shows that the temperature is out of the normal range. If the number is displayed in black, it is within the normal range. The user can also enter the medication and dose taken along with the symptoms. This information will be saved in Firebase with a timestamp, and doctors can access it to help with better diagnosis. On the second tab, a temperature graph is shown that displays the temperature changes. Users can toggle the graph to zoom in and zoom out, and also slide left and right. The graph will update real time based on the time frame shown. On the third tab, users will enter some basic information and this is mainly for doctors to use. Users can also update these information anytime.

IV. Business Model

Problem Statement and Value Proposition

FlexiSense's target users are hospital clinicians - physicians, nurses and technicians. It delivers significant value to three stakeholders: hospitals, nurses and patients. Bedside monitoring is so essential to patient care, yet current practices are manual and inefficient. Nurses are often saddled with this repetitive task, resulting in low efficiency. And without real-time monitoring for

non-critical patients, it can cause delays in patient treatment due to a lack of insight into the patient's potential decline in health. For pediatric, elderly, ICU or fragile patients, having nurses coming into the rooms and take measurements could be interruptive and decrease comfort. Another challenge with vital monitoring that emerged with current COVID-19 pandemic is to protect the safety of physicians from infectious pathogens. Therefore, FlexiSense could be used in such settings where contactless technology could ensure the safety of patients and physicians.

FlexiSense delivers value to the hospitals by reducing costs associated with expensive machines, inefficient labor and fail-to-response cases, to the nurses by alleviating workload and allowing them to provide high quality of care to patients more efficiently and safely, and to the patients by enhancing experience and safety.

Competitive Analysis

As shown in Figure 6, current patient monitoring products and practices generate many unmet needs, which can be solved by FlexiSense. For example, compared to the traditional bedside monitor, FlexiSense not only provides continuous readings, but also automates the documentation process to reduce patient disturbance and nurse workload.



Figure 6. Benefits of FlexiSense compared to current practices.

Market Size

FlexiSense targets the hospital medical device market, which is a rapid growing market both in the U.S. and globally. As one of the leading countries in the healthcare industry, there are around 1 million staffed beds nationwide that could incorporate FlexiSense technology. The global patient monitoring devices market is valued around \$19.5BN in 2019 and shows strong growth with >5% CAGR.



Figure 7. Global market size and CAGR

We also plan to expand beyond the hospital segments into adjacent markets such as homecare, physical therapy, and even military use (as this project is in collaboration with Army Research Lab). Figure 8 shows a brief summary of potential adjacent markets for FlexiSense.

	Military / Combat	Physical Therapy	Rare Disease
Pain points / needs	Real time monitoring of soldiers with flexible, durable device	Monitoring of patient muscle condition, movement, etc	Monitoring risks of medica emergency due to rare disease ; monitoring of recovery / progression
Market Size	LARGE	LARGE	SMALL-MEDIUM
Distribution Channels	Contracting with government agencies	Contracting with physical therapy centers and sale through physicians	Contracting with research centers and sale through physicians / patient caregivers
Entry Barrier	HIGH	LOW	MEDIUM



Financial Analysis

The two most important purchase decision drivers for healthcare providers are cost reduction, and efficiency enhancement. To calculate the annual cost saving per hospital, we assume 200 beds in a hospital and 70% occupancy rate at any moment, with an average hospital stay of 14

days for each patient. Figure 8 shows a cost comparison between FlexiSense and traditional vital monitors. A traditional vital signs monitor without analytics has an unit cost of average \$5000, and our device has a unit cost of \$100. FlexiSense has higher overheads especially in the first year, due to more ordering cycles, holding, and disposal costs, one time software installation.



Figure 9. Cost comparison and analysis for hospitals

FlexiSense's first year costs totaled to 370K, which is still significantly lower than the 701K, a cost reduction of over 40%. There is also long-term, operational benefits FlexiSense could bring - the improved nurse efficiency and satisfaction. Quantitatively, nurses will spend less time on checking and charting for vitals (107.5 seconds / patient with wireless method and 203.7 seconds/patient with manual documentation), and automatic data upload will reduce error rates by 10%. Based on a study, the annual cost of wasted time for one hospital can be around 21K. Qualitatively, nurses workload will be reduced as they could focus on caring for the patients, thus improving efficiency and satisfaction. Summing up, the first year cost saving per hospital is over 500K, and more importantly, with FlexiSense, providers are investing in patient centric, and value based care.

With a price of \$100/device, the unit economics analysis for FlexiSense shows a projected profit margin of 21% and steady growth (Figure 10). On the operations side, we expect a high economy of scale in production. On the sales side, we expect hospital procurement to be done in bulks, and high customer stickiness once the technology is integrated into the infrastructure.



Figure 10. Financial projection and cost of goods

Market Entry Strategy

The health provider market could be very challenging to break into. Our market entry strategy has four parts: licensing, partnership, adoption and expansion. First we need to obtain FDA approval to conduct evaluation; the device is classified as class I so the process should be relatively easy with 510K submission. We plan to partner with our advisors and penn hc system to obtain data on clinical impacts of the product. Academic partners can offer credibility especially for early stage startups who do not have many customers. After validation of the device and more development iterations, we will be ready to enter the high growth market and expand. As discussed previously, to enter the healthcare provider market, we need to influence the decision makers. The device needs to be integrated into the existing IT system and become part of many workflows, from ER to nursing station. With the success of pilot programs, we expect to scale rapidly to enter hospitals across the nation, and expand to more profitable markets. Figure 11 provides a summary of the strategy roadmap.



Figure 11. Market entry roadmap

We plan to adopt a dual distribution strategy. For our core market (hospitals, clinics), we will sell directly to customers to ensure quality of the product and service, and collect feedback for further product development iterations. Marketing and sales will constitute a large portion of OPEX. For the adjacent markets such as homecare and consumer markets, we plan to license the technology to existing companies or form joint ventures. This strategy will create synergies and reduce costs of marketing and product development.

Social Impact

We believe FlexiSense is a life saving technology that should make an impact outside of U.S. and promote universal healthcare in low income low resource countries, such as sub-Saharan Africa. Some low income countries receive up to 80% of medical devices as donations, but they face the challenges of lack of trained nurses, incompatible/unstable energy sources. FlexiSense is highly autonomous, relies on low energy supply, and is affordable and easy to use. One strategy is to integrate into the existing mobile health networks to promote telemedicine, where doctors can receive real-time patient data and tailor diagnosis. In the long term, corporate social responsibilities could help build company image and stimulate revenue growth. We believe FlexiSense can make a real difference serving the population in low-middle income countries.

V. Ethics and professional responsibility

We will clear all ethics/regulatory issues once we obtain the IRB/FDA approval for testing on human volunteers. We will test on ourselves before testing on volunteers. We will investigate the likelihood of liquid metal leakage, and prepare the industry standard way of cleaning up liquid metal for users.

Potential ethics issues are mainly related to data and privacy. We plan to integrate the device with the hospital electronic medical record system, such as Epic, and encrypt patient data with industry standard methods. This would be cost efficient without adding complexity.

VI. Standards and Compliance

Hardware

- IEEE C95.1-2005 Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz
- IEEE 802.15.1 Bluetooth
- ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- FCC CFR Part 15.205 Restricted bands of operation
- FCC regulation on intentional radiators
- FDA class 1 medical device, exemption from PMA

Software

• Patient data compliance

Device Testing

• IRB (Institutional Review Board) approval for human subject testing

In addition, biometric data is encrypted before bluetooth transmission. Standard library for SHA128 is implemented on the microcontroller. Using asymmetric encryption, the sensor and smartphone are authenticated with the database.

VII. Learning, meeting and teamwork

The interdisciplinary nature of this project facilitates learning in material science, electrical engineering and programming. Xiaoya has learned about silicone molding. Hanming has learned RF power circuit design and layout in megahertz range, building on analog circuit class (ESE 419). Hyun has learned PCB design for microcontroller and programming with an ICSP programmer, building on embedded systems class (ESE 350). Overall, the project introduces us to medical devices, an important field of electrical engineering that often represents the best technology in sensing and circuitry. By applying for IRB approval to test our prototype, we learned about the IRB process and specific concerns regarding medical devices.

Feedbacks for our presentation include possible heating of device and human skin when charging, possible form factor of the wearable silicone (e.g. adhesive patch vs a sleeve), cost, and safety. It is helpful to consider user experience and comfort early in design and hear feedback across iterations. We will investigate durability and comfort of various 3M adhesive samples, as well as manufacture a sleeve, to test both methods.

We have weekly calls with our US army lab advisor Dr. Nathan Lazarus on Monday, and regular check-ins with Dr. Olcay Jones and Professor Weimer. Our advisors have been extremely helpful to us in different dimensions. Nathan is always available and willing to guide us on the technical side, and Professor Weimer helps us figure out our target users and market.

Even though each team member has a slightly different focus, we meet every week to keep each other updated on our progress. We use messenger to communicate and set up times to meet. We have very clear task delegation among team members. We have completed most of the goals and milestones for this semester, and everyone is contributing to the success of the project.

VIII. Budget

Part	Estimate unit cost	Quantity	Source of funding	Subtotal
РСВ	\$50 per board	2	ESE	100
Wireless power components	\$20	2	ESE	40
MCU	\$16	2	ESE	32
MCU PCB components	\$20	2	ESE	40
Silicone material	\$20	1	BE	20
Gallium and Indium	\$100	1	ARL	100
1 mm Silicone tubing	\$80	1 (50feet)	ESE	80
Total				410

Table 1. Budget

IX. Timeline

Date	Event	Work Item
Oct 1		Need finding Microcontroller and sensor selection Investigate wireless charging technology
Oct 14	MVP 1	Practice making silicone mold Wireless charging at 200 kHz on breadboard. Microcontroller with temp sensor working on breadboard.
Nov 11	MVP 2	Wireless charging at 1 MHz on PCB Microcontroller PCB manufactured
Nov 25	Fall demo	Silicone microtubing for flexible coil Investigate AirFuel wireless charging at 6.78 MHz Program Microcontroller Source app functionality needs from doctors
Jan 1		Combine microcontroller and charging circuit on PCB Designed app with mockup tool
Jan 20		Manufacture PCB, program microcontroller

Feb 5		Microcontroller link with phone Adhesive or physical design for wearable sensor Finished user log in and sign up
Feb 25		Manufacture flexible PCB, combine with silicone Test on ourselves
March 25		Test and iterations Finished app
April 3	Demo	

Table 2. Timeline

X. Work done since last semester

In the fall semester, our primary goal was to verify technologies. We manufactured silicone coil, designed PCB and app as individual components. The emphasis for the spring semester is system integration. The wireless power system, flexible coil and microcontroller are integrated into a small circuit board in a silicone patch. Bluetooth connectivity between sensor and phone app is established and data is transmitted. Pairing and database features of the phone app are enhanced for user experience.

XI. Conclusion

Flexisense prototype works as intended. Digital temperature sensor, microcontroller, bluetooth connection, wireless power, phone app and overall form factor all functions according to design requirement. Because of the coronavirus lock down, we did not calibrate the temperature sensor with a medical thermometer. Nevertheless, we have designed and implemented a wirelessly rechargeable wearable sensor, which can be used as a platform for a wide range of digital sensors serving medical needs.

Smooth collaboration among team members and regular consultation with advisors helped us stay on track and flexible in our approach. We would like to thank our advisors, Dr. Lazarus, Dr. Jones, Dr. Weimer for their valuable advice, and ESE teaching staff, Sid and Prof. Van der Spiegel for countless support. Overall, we are satisfied with our design and learning experience.

Appendix

PCB design



Poster

