



Case Study



Smart wearable medical device and implant for patient monitoring

End-to-end hardware & software solution generating real time diagnostic data about multiple health parameters



Executive Summary

There is a revolution happening in the digital health space. Special purpose remote monitoring and evidence-based applications are on the rise. Our customer wanted to design & develop an innovative medical device which would monitor key health parameters of critical patients in real-time. Great Software Laboratory was chosen to be a key product development partner for our rich experience and expertise in embedded systems, IoT and software engineering.

Overview

Our customer is a start-up focused on medical devices. Designing medical systems requires an interdisciplinary approach cognizant of certification considerations. Our customer's devices consisted of embedded electronic systems, complex hardware modules, firmware, physical products, communications & backend infrastructure and mobile & web apps. The customer led mechanical product design with their technology & domain expertise in engineering. GS Lab was their partner of choice for electronics and software development.

Our customer needed a partner who had:

- Knowledge of embedded hardware and firmware
- Ability to architect, design and develop an end-to-end technology solution under one roof
- Understanding of medical device development requirements, regulations and compliance standards
- Understanding of startup challenges such as defining the right Minimum Viable Product (MVP) and proving its usefulness in the market in quick time
- Flexibility in the product development process to optimize for a robust & scalable design

Challenge

The customer wanted to develop a medical implant and wearable miniature device to monitor body vitals like body temperature, pulse rate, respiration rate, oxygen saturation and body activity. The medical device had to be designed and developed while keeping in mind the needs of medical practitioners and had to comply with all medical standards.

The collection of data was valuable for users/patients as it would warn them of any potential health issues allowing them to seek adequate medical assistance in time. We had to develop an embedded system for the implant and the wearable device, the communication & backend infrastructure and a mobile application that would seamlessly connect the software and the hardware components.

- The embedded system had to fit perfectly in the prescribed industrial grade enclosure.
- The miniature size of the device posed severe design challenges.
- The device had to synchronize and communicate with the patient's mobile device.
- The device needed to collect data from each of the sensors and store it locally before transmitting it to the app and then onto the cloud-based systems.
- The device size, battery life and frequency had to conform to medical standards.
- The app had to collect and store data with time stamps in CSV format.
- The app had to set the frequency, sampling rate and data transmission requests for the wearable device



Solution

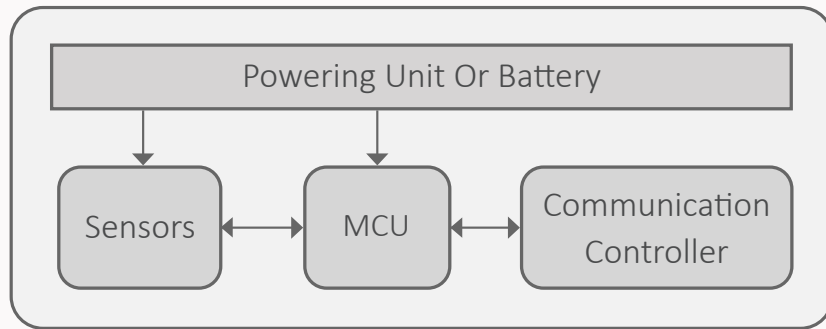
The complete solution consisted of both embedded hardware systems as well as the mobile application. With prior experience in the designing & development of industrial & medical IoT ecosystems (physical, networked, software and human-interactive systems), we adopted an iterative approach focusing on 'design-test-learn-design' strategy. As a development partner, GS Lab was responsible for the electronics, instrumentation and software components while our customer looked after mechanical design and integration. GS Lab's approach of focusing on the problem statement first and then choosing the right technology components simplified the process of finding an optimal solution.

Solution Implemented

Embedded System Design	System Development	Certification Support
<ul style="list-style-type: none"> Define right architecture Study and select sensors, MCU units & right communication protocols Optimize power management 	<ul style="list-style-type: none"> Electronic hardware Firmware codes 	<ul style="list-style-type: none"> Pre-compliance tests Design & development documentation

Hardware And Firmware Architecture

We considered and recommended iterative and agile engineering. As a result of the hardware and firmware systems used, we not only met the miniature device and medical compliance challenges, but also conformed to the size, power consumption and reliability constraints.



Hardware:

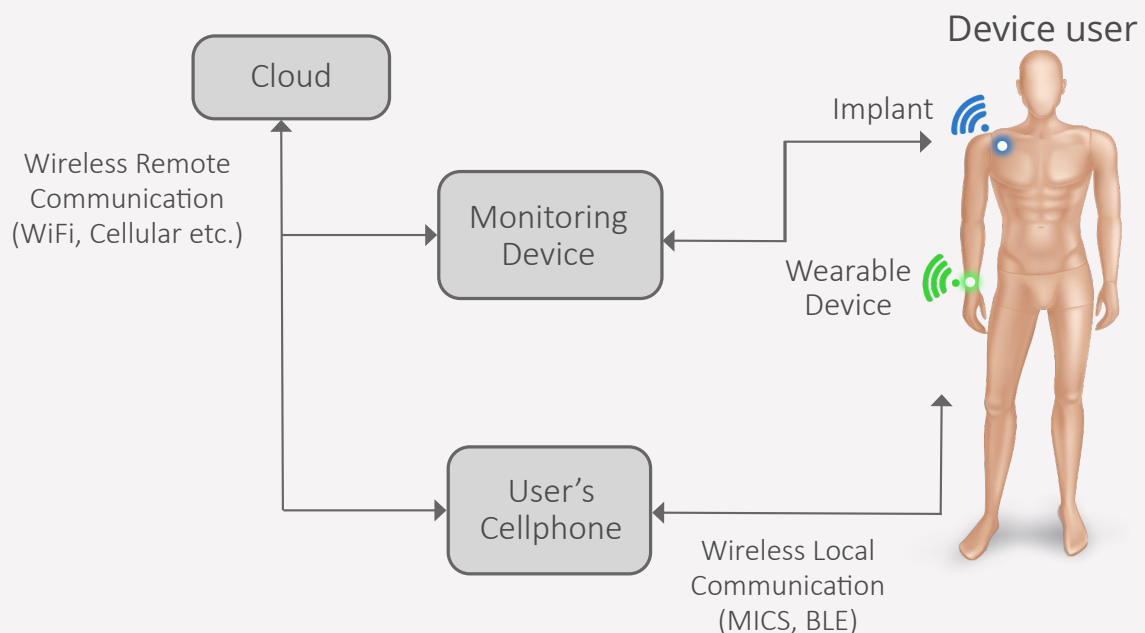
- Micro-controller-based circuit
- Sensors: Temp, SpO2, Activity
- BLE-based communication module
- NFC based triggering commands

Firmware:

- Power-optimized circuit operations
- Sensing & communication routines
- Medical grade, robust application flow

Supported Certification Standards:

The medical devices needed FDA/FCC approvals. The implant had to comply with the right medical or industrial grade certifications. GS Lab supported and fulfilled all the necessary design & development documentation prerequisites.



Device Communication Model:

Considering the design of the implant, the data from the sensor had to be synchronized with the mobile application and then with the cloud-based management systems. The app worked as an edge-computing device, which cleansed, standardized, transformed, integrated and analyzed the data to derive diagnostics for real-time monitoring.

Impact



**Reduced
Costs**



**Improved
Scalability**



**Architecture
Extended To
Platform**

- **Faster goto market:** Working closely with the partner, GS Lab defined the MVP. The product was ready for launch in only nine months.
- **Reduced risks:** We not only helped flag possible hazards but also mitigated and minimized risks.
- **One-Stop compliant solution:** We developed a smart IoT driven medical device combining both hardware and firmware. The solution met all FCC/FDA regulations and compliance standards to facilitate device certification. This software-defined approach also helped quickly iterate on the software, having frozen the key sensor & hardware elements.
- **Low manufacturing costs:** The embedded devices were designed keeping manufacturing processes in mind. The choices made during the design resulted in significant cost savings for our partner.

Great Software Laboratory (GS Lab) has been the technology partner of choice to 100+ organizations across North America, Europe and Asia-Pacific for over 16 years. Leveraging our expertise in 130+ tools & technologies, we have created 300+ 'first-of-its-kind' solutions to real-world problems. Our 'Beyond code' philosophy ensures that we not only push boundaries of existing technologies but also try out newer problem solving approaches to keep our customers one step ahead of their competitors. Our global team of 1200+ employees is adept at creating 'real value' at each stage of the customer growth journey, right from proof-of-concepts to completely scaled up products. For more information about our solutions & offerings, please visit www.gslab.com

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