

Case Study

PORTABLE AND RAPID DISEASE DETECTION DEVICE

Executive Summary

A US healthcare innovator specializing in early detection of diseases like COVID-19 and early-stage cancers sought an engineering partner to create a high-throughput device for widespread testing. The client aimed for controlled access in public areas like hospitals, stadiums, offices, and mass transit.

The eInfochips team, with its deep engineering expertise in medical device development, helped the client with the design and development of the system - including hardware, firmware, FPGA components and mechanical enclosure. The team facilitated the seamless transition of the client's research and Proof of Concept (POC) product into a fully-fledged commercial system. Notably, this system was meticulously crafted to adhere to stringent medical regulatory standards, namely ISO 13485 and IEC 62304.

The result of this collaborative effort is a cutting-edge solution that not only aligns with the client's vision of proactive disease detection but also meets the rigorous demands of the medical regulatory landscape.



**Filter circuit design
to meet 1.5 μ V
peak-to-peak noise**



**Accurate
measurement of all
band EEG signals**



**STM32 controller
firmware
development**



**ISO 13485
and PDMA
compliant design**



Client

A pioneering US healthcare firm specializes in the early detection of major illnesses like COVID-19 and early-stage cancers. Their mission involves using portable devices to sense VOCs (Volatile Organic Compounds) in liquid samples, palm skin, and various skin surfaces for disease detection, aiming to enhance survivability and reduce healthcare expenses.



Challenge

The customer aimed to transform their research and proof-of-concept device into a commercially viable and innovative medical product for the market. However, they lacked an internal engineering department capable of creating a comprehensive system that would adhere to the necessary medical regulatory guidelines. There were also other challenges such as,

- Swiftly identifying individuals infected with COVID-19 and providing immediate alerts through both auditory and visual cues.
- Utilizing a shared implementation approach based on the i.MX8M processor and FPGA, accommodating various product versions.
- Adhering to the requirements of ISO 13485, IEC 62304, and IEC 60601-1-2 standards to ensure compliance.



Solution

The einfochips team undertook full responsibility for the design and development of a portable disease detection device, encompassing the following essential solution elements:

- Schematics design, BOM selection, electro-mechanical analysis
- PCB, layout design, prototyping, fabrication, and assembly
- Detailed mechanical design, DFMA, fitment check
- NXP i.MX8 firmware development using Linux OS
- Intel Cyclone FPGA code development
- Test case development, execution, and reporting
- Bring-up and functional testing, EDVT testing and validation



Key Highlights

- ▶ **The Main Board**
 - iMX8M Quad core CPU
 - 4GB LPDDR4 and 64GB eMMC storage
 - Yocto Linux system to process and run AI/ML algorithm
 - Intel Cyclone 10 FPGA to capture data coming from ADC from sensor board and drive DAC to generate bias voltages required for VOC (Volatile Organic Compound) sensor operation
 - Gigabit Ethernet interface
 - Dual band WiFi / BT module
 - LED bar for user indication
- ▶ **The Sensor Board:**
 - 24-bit high speed ADC to capture dual VOC (VOLATILE ORGANIC COMPOUND) sensor output from 256 channels
 - 16-bit DAC to generate voltage outputs to bias the dual VOC (VOLATILE ORGANIC COMPOUND) sensor for 64 channels
 - Temperature and humidity sensors and proximity sensors for palm detection and ambient condition capture
- ▶ **AWS Cloud to connect with the device, capture measured files, device firmware OTA updates and provisioning**
- ▶ **ISO 13485 medical processes, IEC 62304 software processes, ISO 14971 risk management followed during throughout the project life cycle**
- ▶ **IEC 60601-1 and IEC-60601-1-2 are followed for device safety and EMI/EMC pre-compliance**



Tools/Technologies

- Schematic and Layout: OrCAD, Allegro
- Mechanical Design: Solidworks
- FPGA: Quartus Prime Pro, ARM development studio, Intel SoC FPGA Edition



Benefits

- Enhancing Time-to-Market through Strategic Alliances: leveraging einfochips' collaborations with NXP and Intel, empowered by EVM and SOM Technologies
- Pioneering Commercialization: The platform will be used to develop multiple devices for lab and hospital use in medical domains
- Revolutionizing Disease Detection:
 - Enables the non-contact identification of numerous diseases. By employing this operational concept, we enhance the early detection of illnesses through analysis of human VOC (Volatile Organic Compound) emissions.
 - Elevates education and patient record-keeping by enabling the digital capture of patients' VOC (Volatile Organic Compound) profiles. The system successfully identifies diseases like COVID-19 and ovarian cancer by analyzing VOC (Volatile Organic Compound) patterns.

About einfochips

einfochips, an Arrow Electronics company, is a leading provider of digital transformation and product engineering services. einfochips accelerates time to market for its customers with its expertise in the areas of IoT, AI/ML, security, sensors, wireless, cloud, and power. einfochips has been recognized as a leader in Engineering R&D services by many top analysts and industry bodies, including Gartner, Zinnov, ISG, IDC, Nasscom and others.

USA – 2025 Gateway Place, Suite #238, San Jose, CA 95110.

INDIA – Block-E, Ratna, 3rd Eye Voice, Ognaj, Daskroi, Ahmedabad - 380060, Gujarat

FOLLOW US



/einfochips



/einfochipsltd



/einfochips



/einfochipsindia