

Case Study

Rapid Development of COVID-19 Testing Solution

Accelerated Prototyping for a Novel Testing Solution

OVERVIEW

Digital Health Solutions partnered with a startup diagnostics company to develop an at-home COVID-19 testing device specifically designed for individuals with visual or physical impairments. The device utilizes a magnetic sensing platform that enables precise, electronic test result detection and audio indicators rather than relying exclusively on visual cues. Our multidisciplinary team led a human factors-first design approach for the mechanical housing and custom sensor design. All sensors, electronics, firmware, user and physician-facing mobile applications and cloud portals were developed into a fully integrated diagnostic reader for future commercialization.

CHALLENGES

- Accessibility Requirements: Ensure usability for individuals with limited vision or hearing, requiring non-visual feedback and simplified operation.
- Sensor & Electronics Design: Designing highsensitivity magnetic coil sensors and compact analog reader electronics for precise signal capture.
- Usability & Cost Constraints: Creating a costeffective, single-use cartridge and accessible enclosure system for home-use environments.

IMPACT

- System Integration: Fully integrated system (coils, PCB, firmware, housing) delivered by the fourth prototype, ready for internal testing.
- **Diagnostic Innovation:** Enabled the client to evaluate a novel diagnostic workflow optimized for accessibility.
- Point-of-Care Success: Successfully incorporated clientdeveloped lateral flow-assay, building on extensive team knowledge in diagnostic instruments for both clinical and home settings

APPROACH

- Hardware & Firmware Engineering: Engineered custom magnetic coils and analog/digital electronics with rapid firmware iterations for signal processing.
- Mechanical & Industrial Design: Developed multiple industrial and mechanical prototypes, integrating usability and accessibility considerations.
- Rapid Prototyping & Testing: Delivered four full prototype generations, each improving sensor integration, performance, and user experience.

About Digital Health Solutions

DHS, located near Boston, MA, provides key engineering, testing, documentation & regulatory services for Medical Device, Diagnostics, Healthcare and Life Science industries. Our expertise & services include:

- End-to-end Product Development
- Firmware/Software Engineering (AI/ML)
- · Systems Engineering
- Quality & Regulatory Guidance
- Cybersecurity
- ISO 13485 Contract Manufacturing
- Verification and Validation Testing/Documentation

Accelerating MedTech Innovation

Let's build something together.

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