

Connected Medical Device Manufacturer Gains Ultra-reliability for Fetal Health Monitoring App



Challenges

Ensure ultra-reliability of life-critical fetal medical device.

App needed to simulate subtle fetal behaviors while simultaneously maintaining wide coverage.



Solutions

Performance testing software, physical IoT device and with simulators.

Tri-phase test strategy breaks mammoth undertaking into systematic granular project gates.



Results

Test coverage expanded by 40% by using innovative synthetic data.

Simulation expanded from just the client's experienced data footprints into additional and plausible hypothetical data combinations.



Client overview

Our client is in the prenatal health products business. Their platform combines IP-protected fetal monitoring with data analytics to provide accurate tracking of the health of the mother and the fetus. This technology-enabled prenatal care platform can be used at home, at the clinic, or in the hospital during pregnancy and childbirth.

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How to maximize test coverage with data known unknowns

Performance testing such a life-critical medical device becomes challenging due to its requirement for a wide range of test coverage running in parallel with the need to simulate a fetus’ behavior. Qualitest needed to fully understand the platform and its required data exhaust in order to come up with a cost-effective and comprehensive testing strategy. It meant Qualitest’s IoT team needed to first intensively develop an understanding of ECG, services and characteristics used in the BLE components of the IoT device under test while exploring the possibility of simulating synthetic data to improve the test coverage of the device.

Tri-phase test strategy delivers ultra-reliability

1. Testing software component

As part of the discovery process, Qualitest conducted in-depth investigations and fact-finding excursions into the client’s platform to better understand its hardware and software functionality. The Qualitest team gained a detailed understanding of the workflows that could be achieved via software and mandatory physical device interactions. We provided a targeted testing strategy for the independent functionalities of the software components to support existing feature development on the software and setup regression testing suites.

During the sprints, Quality Engineers participated in all sprint meetings and acted as an extended team for performing estimations, assisting ongoing testing during sprints, accessing client tools so that they could create testing artifacts, submitting summaries reports, and generating metrics and reports.

2. Testing involving physical IoT device

Having established a clear testing strategy for the software component, Qualitest collaborated with customer teams to establish an IoT devices lab. This included devices for monitoring testing at our offshore delivery center. During this phase, hardware tests were identified and a test suite with firmware and physical device integration was put in place.

Below are a few features of the strategy:

- BLE Pairing of the device
- Power consumption and battery life tests



- Device performance at different battery levels
- Interoperability of the device with different mobile
- OS/form factors
- Data transmission from the device to the software

3. Testing using simulators

Part of the platform's functionality is the transmission of ECG data about the mother and the fetus to the companion app. To rigorously test the ECG data functionality there would be a need for a wider variety of combinations than existed within the available live data.

Qualitest, as a company with a strong background in medical devices and IoT, recommended using simulators to create a variety of new testing data sets. What a simulator can do is to load and replay multi-channel ECG waveforms that replicate a much wider range of fetus and mother heart rate combinations. The simulation also took input as data files to reproduce various types of ECG waveforms and replace the actual test fetus data to cover a wider variety of test scenarios.

The simulator setup is compliant with safety and essential performance requirements of medical equipment – IEC 60601, protocol for a reproducible test with realistic clinical requirements ANSI / AAMI EC57.

Key benefits

Within the timeframe given, Qualitest engineers were able to meet all the client's stated goals:

- Our quality engineering practices enabled the client's product to be ready for FDA approval.
- Testing coverage improved 40% with tests involving in physical device and simulators.
- A formal testing process was established and implemented for the client.
- The test strategy involves both software and IoT devices and where these intersect.
- Simulator set up to test the widest possible variety of ECG scenarios.

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