PARASOFT®

CASE STUDY

Kitea Health Achieves 30-Minute Test Cycles Developing Safety-Critical, First-in-World Brain Implant

Overview

Kitea Health is a pioneering MedTech company dedicated to revolutionizing the management of hydrocephalus, a life-threatening condition involving fluid buildup in the brain. Their innovative system includes:

- An implantable intracranial pressure sensor, the Kitea Sensor
- A handheld reader, the Kitea Wand, reads data from the implant

The Kitea Wand provides doctors with critical, real-time insights directly from the patient's brain. This technology replaces uncertainty with data, empowering clinicians to make informed decisions and giving patients their lives back from a cycle of fear and emergency room visits.

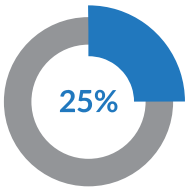
Industry:
Medical

Company Size:
23

Location:
Auckland,
New Zealand

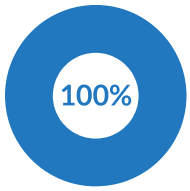
Solution:
C/C++test

Key results



Reduced firmware development timeline by 25%

Transformed test execution from impossible to 30 minutes for 1,000+ cases



Consistently achieves 99-100% code coverage

The Challenge

For patients with hydrocephalus, common symptoms like headaches and nausea can signal a dangerous pressure spike in the brain. Traditionally, doctors had no way to see inside the brain outside of a clinical setting, forcing them to make reactive—and sometimes risky—decisions based on symptoms alone.

Technically, delivering a solution that was both innovative and inherently safe presented a monumental software challenge. Masahiro Kondo, embedded system principal engineer at Kitea Health, was tasked with developing firmware for both the implantable Kitea Sensor and the Kitea Wand. The core business challenges he faced:

- **Achieving systematic risk control.** Adhering to IEC 62304 Class B was critical to ensure demonstrable reliability and mitigate hazards where software failure could lead to patient harm.
- **Managing immense complexity.** Manually creating, managing, and executing over 1,000 unit test cases for more than 35,000 lines of C code was an impossible task prone to human error.
- **Automating a complex test environment.** Free testing tools could not manage the firmware's deep system calls and library dependencies, resulting in persistent configuration errors and stalling development.

The Approach

Kitea Health needed a robust, automated testing solution that could integrate seamlessly into their development environment. Their key requirements were:

1. A unified tool for both comprehensive unit testing and static code analysis
2. Support for medical device coding standards
3. The ability to achieve high code coverage metrics essential for regulatory submission
4. Professional support to overcome technical hurdles quickly

After a competitive evaluation, they selected Parasoft C/C++test based on its comprehensive functionality, suitability for medical devices, and reasonable cost.

The Solution

Kitea Health implemented Parasoft C/C++test to verify the firmware for its entire system.

"For any embedded development team having trouble getting unit tests done in a comprehensive and manageable way, it's critical to find the right tool to help with the process. Parasoft C/C++test saves a lot of time. I would most certainly recommend it," said Masahiro Kondo, principal engineer.

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The solution provided:

- **A unified testing platform.** A single environment for creating unit tests and performing static analysis, ensuring code compliance with industry standards.
- **Efficiency and power.** The Test Case Editor allowed Kondo to easily configure stubs and parameterize values, making test creation and management straightforward.
- **World-class support.** When technical challenges arose, Parasoft's support team replicated the test environment to diagnose and resolve issues—a level of service unavailable with free tools.

> *"Managing test suites and performing tests to the level required for medical devices was not achievable with free unit test tools," said Kondo. "The improvement of unit tests and static analysis by using Parasoft C/C++test is immeasurable since it wasn't even possible before. Now we run our entire suite of over 1,000 test cases in just 30 minutes."*

“Parasoft C/C++test accelerated our firmware development and tests by over one month, which was critical for our clinical trial timeline.”

The Results

The integration of Parasoft C/C++test fundamentally transformed Kitea Health’s firmware development process, accelerating time to market while establishing a foundation of verifiable safety and quality.

- **Accelerated time to market by over 1 month.** The compressed firmware development cycle ensured the project stayed on track for clinical trials and future FDA submission.
- **Comprehensive, rapid testing.** The entire suite of over 1,000 test cases now runs in just 30 minutes, enabling frequent, test-driven development.
- **Verifiable code quality and coverage.** The team consistently validates its firmware for high coverage, providing the documented proof required for regulatory audits.
    - 99-100% statement
    - More than 90% branch
    - 80-90% MC/DC
- **Demonstrable reliability.** This thorough approach has resulted in zero firmware-related bugs found in the field, ensuring patient safety.
- **Proven regulatory readiness.** Parasoft generates the necessary pass/fail reports and traceability evidence, building a strong case for FDA and other regulatory approvals.

“Parasoft C/C++test accelerated our firmware development and tests by over one month, which was critical for our clinical trial timeline,” said Kondo. “It will be one of the key tools we use for our success in the future.”

Through a rigorous focus on software quality and reliability, the Kitea Health system provides patients with the data-driven clarity and confidence needed to take control of their health journey.

Take the Next Step

Request a demo to see how your embedded development team can consistently deliver high-quality code with Parasoft C/C++ testing solutions.

About Parasoft

Parasoft helps organizations continuously deliver high-quality software with its AI-powered software testing platform and automated test solutions. Supporting the embedded, enterprise, and IoT markets, Parasoft's proven technologies reduce the time, effort, and cost of delivering secure, reliable, and compliant software by integrating everything from deep code analysis and unit testing to web UI and API testing, plus service virtualization and complete code coverage, into the delivery pipeline. Bringing all this together, Parasoft's award-winning reporting and analytics dashboard provides a centralized view of quality, enabling organizations to deliver with confidence and succeed in today's most strategic ecosystems and development initiatives—security, safety-critical, Agile, DevOps, and continuous testing.