



CASE STUDY

WHILL Delivers FDA-Approved
& IEC 62304-Compliant Smart
Mobility Vehicles



OVERVIEW

Established in 2012, WHILL, Inc. provides products and services for short-distance mobility in the smart mobility market. This market aims to evolve vehicles like cars, bicycles, wheelchairs, and electric carts into more convenient, comfortable, and safe forms of transportation through the power of technology.

WHILL offers its products and services for short-distance travel in more than 20 countries and regions around the world. People can purchase the smart mobility vehicles at car dealerships, bicycle shops, and electronic retailers, or rent them for leisure activities. WHILL's mission is to make everyone's movement fun and smart.

The design, functionality, and operability of the company's short-distance mobility vehicles set them apart from traditional electric wheelchairs and senior carts. Anybody can enjoy using this new means of transportation casually and daily, including those who have difficulty moving due to disabilities, seniors who have surrendered their driver's licenses, and seniors who experience difficulty walking due to physical decline.

Industry:
Smart Mobility

Company Size:
300

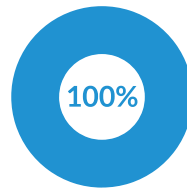
Location:
Tokyo, Japan

Solution:
C/C++test

KEY RESULTS



**Achieved FDA
approval.**



**Achieved 100%
compliance with
IEC 62304.**



**Improved testing
efficiency.**



THE CHALLENGES

WHILL produces all of the software related to the controls of its own products with a goal of developing convenient and safe products. Its team of engineers works in a system where they can internally produce both hardware and software, making it faster and easier to deliver enhancements for existing functionality and develop new functionality including integrating features with smartphone apps.

In addition to building a product that WHILL's customers will fully enjoy, it's crucial that the team build software that operates reliably and meets medical device safety requirements per regulations in each country. Achieving IEC 62304 compliance and obtaining FDA Class II medical device approval for WHILL Model C2 enables physicians to prescribe it as a medical device to mobility-impaired consumers with a broader range of medical conditions in the U.S. healthcare system.

The team faced the following challenges in trying to achieve their goals.

- » Creating an efficient system to improve product quality.
- » Ensuring the functional safety of embedded software for smart mobility.
- » Establishing a process to efficiently reuse legacy code assets and ensure their quality.

“One of the technical features of WHILL's product is the Omni wheel. Unlike a typical wheel, it's composed of 10 small rollers, which allows us to achieve both high offroad performance and maneuverability,” said Tsuyoshi Iriyama, Chief Officer of the Quality Headquarters and Head of the Regulatory and Certification Department.

Adopted in the flagship WHILL Model C2, the patented Omni wheel, allows the rollers to rotate both vertically and individually horizontally, enabling the device to pivot in a very small radius. The high offroad performance effortlessly overcomes steps that are five centimeters high.

This is just one example of WHILL's unique devices that must meet requirement specifications. The demand for software to comply with specific requirements increases as the team develops new devices, which often entail new interfaces. The team might create new code or reuse existing code from other products.



“In addition to new code, it was an urgent issue to establish a process to efficiently reuse legacy code assets while ensuring quality. At the same time, we needed to work on compliance with international standards related to software quality, such as IEC 62304, an international standard on the life cycle process for medical device software, and the U.S. FDA, which are necessary for selling WHILL products overseas. With these in mind, we planned to introduce a static analysis tool with the aim of visualizing code quality [through reporting metrics] and achieving higher quality development,” said Yoshizo Mihara from Personal Mobility Development Section 4 at WHILL.

THE APPROACH

With code quality top of mind, WHILL considered multiple static analysis tools, including commercial and open source software (OSS). The tool they selected had to meet the following five points:

- » Provide guidance for quality and standards compliance such as IEC 62304.
- » Offer scalable licensing and affordable pricing for WHILL's needs.
- » Opportunity to expand and continually improve code quality.
- » Provide exceptional maintenance and support.
- » Compatible with the IDE used in development with low learning cost.

THE SOLUTION

Based on WHILL's established five points, the team selected Parasoft's C/C++test along with TechMatrix's provision system in Japan. Initially, the team used C/C++test for two existing software modules and conducted code checks based primarily on MISRA C.

"In order to understand our own capabilities, we initially conducted checks with strict filtering conditions, which resulted in thousands of rule deviation notices. Reviewing these notices with our own eyes, including the parts reused from past assets, we were able to visualize the overall code quality from the objective perspective of the tool, and deepen our understanding of our own code. We feel that was a great achievement," said Mr. Mihara.

The WHILL team gained a comprehensive view of all the test results from C/C++test.



THE RESULTS

At WHILL, development for the release of new products and services is ongoing. The team has been able to establish a system where C/C++test efficiently performs code checks to ensure compliance with various functional safety, security, and coding standards and deliver high-quality software. It's a great advantage in terms of enhancing the competitiveness of their products and services.

"Being able to create an environment where we can quickly pick up code issues [with C/C++test] within a limited development period and focus on the areas that need concentration has been a very meaningful effort in improving software quality and, in turn, the quality of WHILL's products and services."

—Tsuyoshi Iriyama, Chief Officer of the Quality Headquarters and Head of the Regulatory and Certification Department

The WHILL team also expressed satisfaction with TechMatrix's support system.

With goals of developing new products on the horizon, WHILL aims to continuously improve the quality of its products using Parasoft C/C++test.

TAKE THE NEXT STEP

[Talk to a compliance expert](#) to learn how your embedded software development team can automate software testing to deliver high-quality, compliant software.

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.