

VectorCAST Introduced to Improve Vision Unit Development Efficiency of the Made-in-Japan "hinotori™ Surgical Robot System"

Medicaroid Corp., a joint venture between Kawasaki Heavy Industries, Ltd. and Sysmex Corp., has introduced Vector's unit testing tool VectorCAST in the development of the vision unit software of the Japan made robotic-assisted surgery system called "hinotori™ Surgical Robot System". VectorCAST is ideal for this development as it is certified to IEC 62304, an international standard for the development of medical device software.

5 Years Spent to Develop the hinotori™

A U.S. company had dominated the market for robotic-assisted surgery system used in laparoscopic and thoracoscopic surgeries for years. However, the expiration of many patents held by the company in 2019-2020, allowed new entrants to enter the business.

Medicaroid Corp. (Medicaroid), headquartered in Port Island, Kobe, Hyogo Prefecture, is one such company. It was founded in August 2013 by Kawasaki Heavy Industries, Ltd. (Kawasaki Heavy Industries), which specializes in industrial robots, and Sysmex Corp. (Sysmex), which focuses on clinical testing devices such as sample testing, to make medical contribution with their technologies.

In cooperation with Kobe University Hospital and other medical institutions, Medicaroid started developing the robotic-assisted surgery system in 2015 after conducting market research and examining technology. Medicaroid then obtained manufacturing and marketing approval from the Ministry of Health, Labour and Welfare (MHLW) for the "hinotori™ Surgical Robot System (hinotori™)" in August 2020 and started selling it in December that year. It has obtained MHLW approval in urology, gastroenterologi-cal surgery, gynecology, and thoracic surgery (respi-ratory surgery). As of the end of December 2024, the cumulative total shipments of the hinotori™ in Japan amounted to 71 units, and cumulative total surgeries conducted using the system were 7,890[*1].

The hinotori™ consists of the operation unit, which is equipped with four operation arms with an 8-axis configuration, the surgeon cockpit, which features controls such as the hand control unit and a three-dimensional (3D)



Figure 1. The hinotori™ Surgical Robot System consists of the operation unit (on the left), surgeon cockpit (in the middle), and the monitor cart that includes the vision unit (on the right)

viewer, and the monitor cart, which includes a monitor that shows images to surgical staff and nurses in the operating room and an electric scalpel generator (Figure 1).

A surgeon is seated in front of the surgeon cockpit and controls the operation arms by using hand controls and a foot pedal while watching 3D endoscopic images on the viewer.

Instruments such as an endoscopic camera, grasper, dissector, scissor-type forceps, and ligature forceps can be attached to the operation arms. The surgeon conducts medical treatments such as separating, removing, or inosculating tissues by inserting the tips of forceps through small incisions around 1cm made in the patient's body.

The endoscopic image shown on the surgeon's cockpit viewer can also be displayed on the LCD display on the monitor cart, allowing the surgical team in the operating room to review it.

The unit that controls audio and image is the vision unit (inside the frame on the right in Figure 1). It consists of hardware (FPGA: Field Programmable Gate Array) that displays endoscopic images like a pass-through without delay, and an image processing part that overlays the types of attached instruments and their status on the image. The image on the external monitor is displayed in 2D or 3D, and surgical assistants wear 3D glasses to view the 3D image.

VectorCAST Selected for Unit Testing of the Vision Unit

Medicaroid introduced Vector's unit testing tool, VectorCAST, in the development of control software for the vision unit. Mr. Hirofumi Yamamori, Manager, Medical Robot Section 2, Medical Robot Department, Medical Robot Group, Robot Business Division, Precision Machinery & Robot Company, Kawasaki Heavy Industries, explained the reason for selecting VectorCAST as follows: "The hinotori™ is a medical device, so it was necessary to proceed with the development in compliance with IEC 62304, a standard for the development of medical device software. While there are a variety of unit testing tools, we have selected VectorCAST as a testing tool as we evaluated highly for certification to IEC 62304."

Mr. Akito Nakano, Development Dept., Medicaroid, who handles the unit testing of the vision unit by using VectorCAST, said, "I used various functions of VectorCAST such as coverage measurement."

As introduced in "Introduction to VectorCAST" [*2], a document made available by Vector, in addition to automated unit testing and coverage measurement, VectorCAST features various functions including automated output of test reports in HTML format, automated generation of test cases, and change-based testing that conducts regression testing by extracting only the changed part when a source code is changed. Mr. Nakano said he found all functions easy to use.

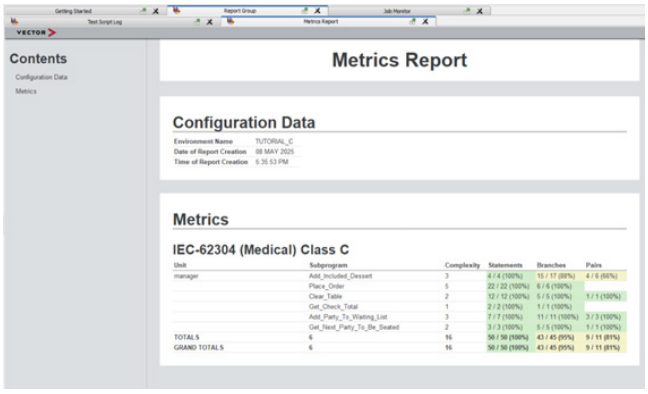


Figure 2. Example of VectorCAST metrics report for Class C

Certification to Standards other than IEC 62304 also Obtained

IEC 62304 (Medical device software - Software life cycle processes) and Vector's response to it are briefly explained below.

IEC 62304 is an international standard for medical device software development, maintenance, risk management, configuration management, and problem-solving processes and requirements. In Japan, a similar standard is issued as JIS T2304.

IEC 62304 identifies three safety classes for medical devices under development, and items to be dealt with are defined for each class: Class A (no possibility of injury or damage to health), Class B (no possibility of death or serious injury), and Class C (possibility of death or serious injury). In the development of Class A to Class C medical device software, VectorCAST supports structural coverage and code coverage collection and reporting recommended by IEC 62304 (Figure 2).

VectorCAST is also IEC 62304:2015 certified by TÜV SÜD, a third-party certification organization based in Germany [*3]. Furthermore, to support customers in establishing the IEC 62304 process, Vector provides Tool Operation Requirements (TOR), Tool Qualification Data (TQD), test cases, manuals, outcomes, and other relevant documents as the VectorCAST medical device software compliance kit for FDA/IEC 62304 [*4]. In addition to IEC 62304:2015, VectorCAST is certified to

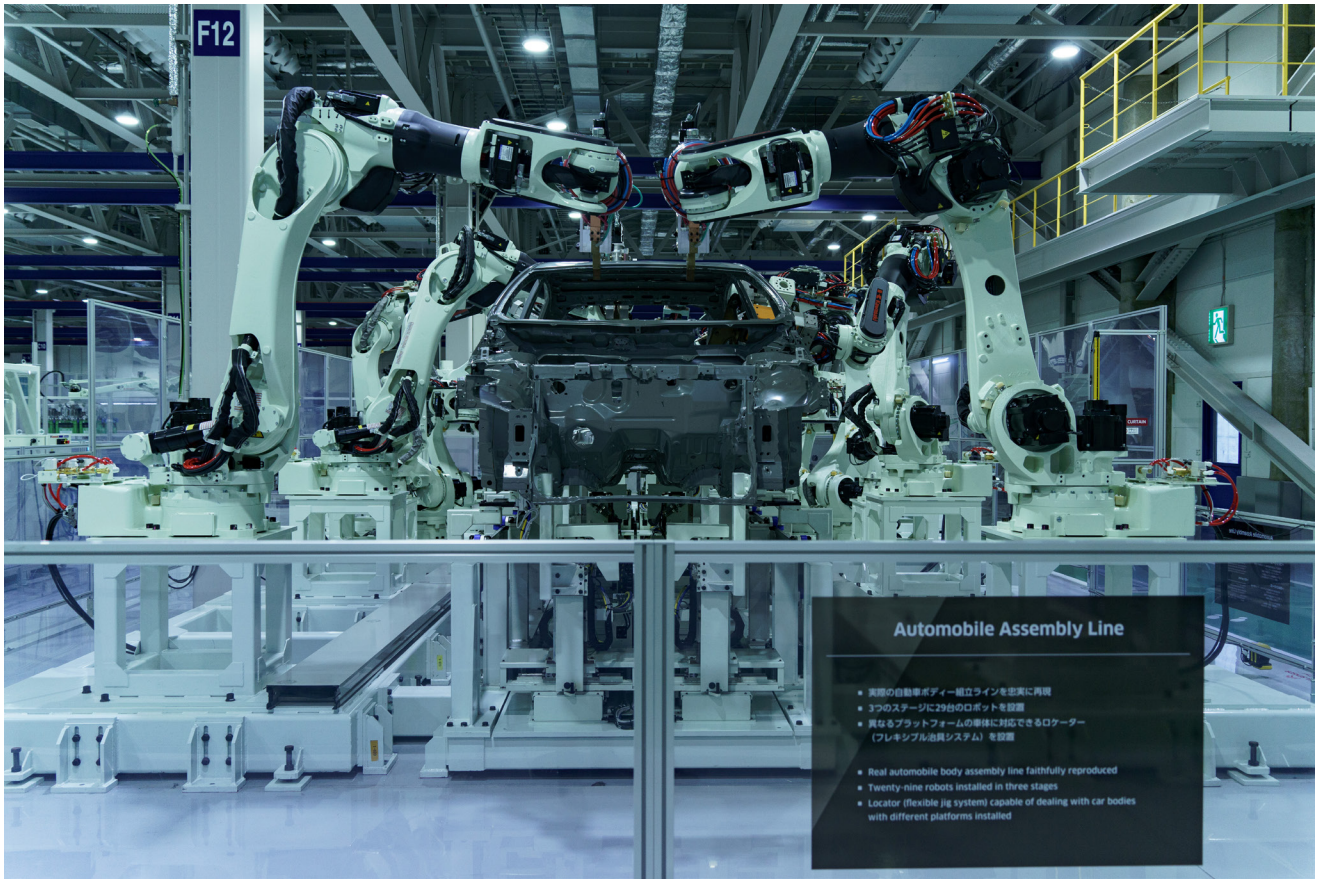


Figure 3. The use of VectorCAST in the development of welding robots for automobile production lines, Kawasaki Heavy Industries' forte, is being considered

the industrial devices functional safety standard IEC 61508-3:2010, the road vehicles functional safety standard ISO 26262-8:2018, the railway functional safety standard EN 50716:2023, the nuclear power plant software standard IEC 60880:2006, and tractors and machinery for agriculture and forestry safety standard ISO 25119-3:2018/AMD1:2020. Therefore, VectorCAST is an effective solution for the development of software in diverse areas where safety is crucial, such as industrial devices, automobiles, trains and railway equipment, and farming and forestry machinery, as well as medical devices.

Use of VectorCAST in CI Automation and Industrial Robots under Consideration

Medicaroid is considering CI/CT (Continuous Integration/ Continuous Testing) automation in preparation for future development.

"To improve efficiency in future development, we believe it will become necessary to have a system that automatically conducts unit testing when a source code put in a server is updated," said Mr. Yuichi Mizohata, Medical Robot Section 2, Medical Robot Department, Medical Robot Group, Robot Business Division, Precision Machinery & Robot Company, Kawasaki Heavy Industries. "Given that VectorCAST is also compatible with CI/CT using Jenkins, an open-source tool, we expect it to be used effectively."

Furthermore, adjustments are being made so that VectorCAST will be used in the development of industrial robots, in which Kawasaki Heavy Industries excels (Figure 3). "We have already introduced VectorCAST to the department that handles welding robots for automobiles," said Mr. Yamamori. "They are keen on the idea of the use as it could help improve unit testing efficiency."

Made-in-Japan robotic-assisted surgery system Makes Advanced Medical Care More Accessible

The market for robotic-assisted surgery system that enables minimally invasive surgery to help ease the burden on patients is forecast to grow by over ten percent annually in the future, not only making a medical contribution but also drawing attention as a business. Kawasaki Heavy Industries, known for its industrial robots, Sysmex, which specializes in medical devices, and Medicaroid, a joint venture between Kawasaki Heavy Industries and Sysmex, plan to enhance the hinotori™. They aim to do this by better understanding the specific needs of healthcare professionals.

Mr. Yamamori has this to say about the outlook: "Since the release of the hinotori™ in December 2020, we have continued to improve the software and mechanism by reflecting requests from healthcare professionals. At the beginning, our activity was mainly catching up with the leading U.S. company, but now that we have been receiving high evaluations from doctors in Japan, we are considering proceeding with the activity to overtake the leading company."

Meanwhile, demonstrative experiments of remote surgeries are underway, bringing us closer to the future in which anyone can receive an advanced operation anywhere.

Named after "Hinotori (Phoenix)," the masterpiece manga series on an epic scale created by the renowned manga artist Osamu Tezuka, the made-in-Japan robotic-assisted surgery system hinotori™ continues to fly high into the future of medical care.

[*1] Sysmex' Summary of Consolidated Financial Results for the First Nine Months of the Fiscal Year Ending March 31, 2025, released on February 12, 2025

[*2] "Introduction to VectorCAST" and ""Introduction to Unit Testing" (Japanese Title : " はじめての VectorCAST" and " はじめての単体テスト "):
https://www.vector.com/jp/ja/know-how/vj-beginners/

[*3] IEC 62304 certification and TÜV SÜD certification:
https://www.vector.com/int/en/products/products-a-z/software/vectorcast/iec61508-iec62304-en50128-iso26262-certification/

[*4] VectorCAST medical device software compliance kit for FDA/IEC 62304:
https://www.vector.com/int/en/products/products-a-z/software/vectorcast/fda-iec-62304-compliance/

Sources for images:
Figure 1: Medicaroid Corp.
Figure 2: Vector Japan Co., Ltd.
Figure 3, cover page: Kawasaki Heavy Industries, Ltd.

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Contact information:
https://www.vector.com/contact