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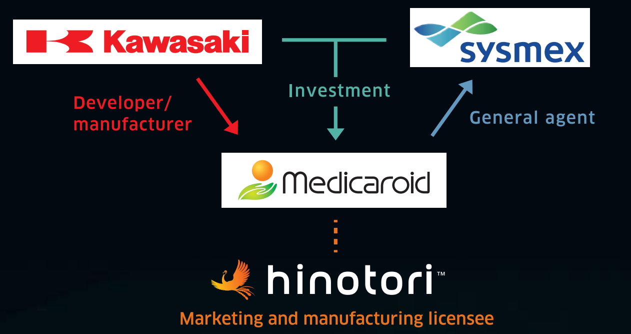
Contents

About the Cover

About the cover: A scene from the operational demonstration of the hinotori™. See *Special Feature* for details. (this page)

Flying High in Achieving a Medical Revolution: The hinotori*™ Robotic-Assisted Surgery System

On December 14, 2020, a milestone was reached in the history of Japanese medicine. It was the day the first made-in-Japan robotic-assisted surgery system hinotori™ was successfully utilized for the first time, marking the debut of a patient-friendly, Japanese product at the forefront of a medical revolution.



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What Is "Medicaroid"?

Headquartered in Kobe City, Medicaroid Corporation is a medical robot manufacturing and sales company, formed in 2013 as a joint venture by Kawasaki and Sysmex Corporation, a leading manufacturer of clinical laboratory diagnostic systems. Medicaroid, Kawasaki, and Sysmex were all involved in the development of the hinotori™, with the first two developing the system itself, and the last developing its network support service platform. Medicaroid now acts as the Marketing Authorization Holder of the product, Kawasaki develops and manufactures the product at Akashi Works, and Sysmex acts as general agent for domestic and overseas markets.

A scene from the debut surgery conducted on December 14, 2020, at ICCRC (above). The photo which forms the background for these pages is a scene from the press conference introducing the hinotori™, held in November 2020. Many reporters and investment analysts attended, reflecting a strong interest in Japan's newly-developed technology.

Collaborating with Physicians in Life-Saving Missions

The hinotori™ is a robotic-assisted surgery system whose development was led by Medicaroid**, utilizing the industrial robot technologies of Kawasaki and the medical expertise of Sysmex, a global manufacturer of clinical laboratory diagnostic systems.

Its initial surgery, which was to assist with a total prostatectomy for a patient with prostate cancer, was carried out at the International Clinical Cancer Research Center (ICCRC) of Kobe University Hospital. Speaking about the accomplishment, the surgeon, Dr. Masato Fujisawa, President of Kobe University and advisor for the hinotori™'s development, comments, "It got a perfect score. I'm extremely moved by the fact that we've achieved societal implementation of a new medical device."

Robotic-assisted surgery is an advanced form of laparoscopic surgery, which involves the insertion of cylindrical surgical instruments into multiple incisions (ports) in a patient's body, through which the laparoscope (a type of endoscopic camera), forceps,

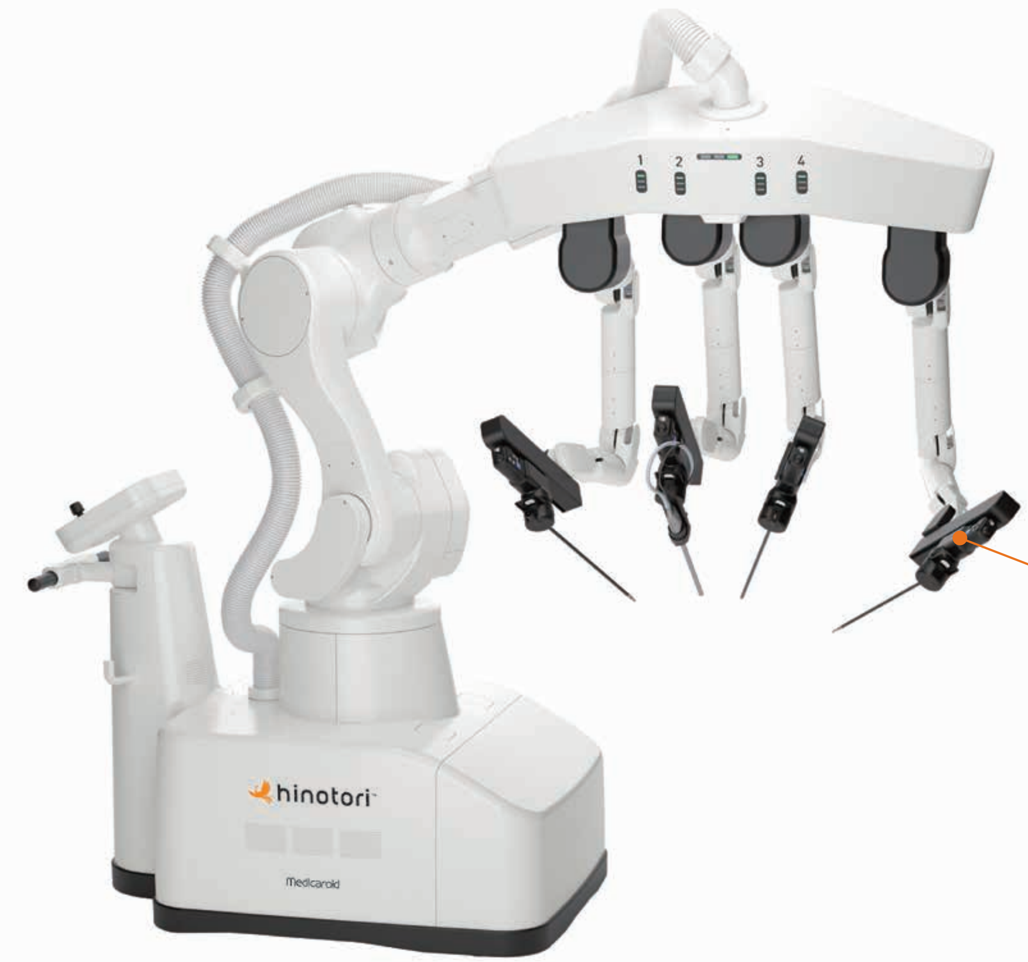
* "Hinotori" means "phoenix" in Japanese. ** A joint venture company funded by Kawasaki Heavy Industries and Sysmex Corporation. See *"What's Medicaroid?"*

and other surgical instruments are inserted to perform operations, benefitting from the view from the laparoscope. This procedure became popular because it is not an open surgery and requires only small incisions, achieving minimal invasiveness and reduced physical impact on patients. However, the movement of a conventional laparoscope is linear, provides only a two-dimensional image, and surgeons must operate with the reversed movement of laparoscopic instruments.

The robotic-assisted surgery system, on the other hand, has robotic arms equipped with an endoscope or forceps which can move freely, and it provides a three-dimensional (3D) image, resulting in movements closer to those of human arms and hands, which conventional laparoscopic surgery was unable to achieve. Such precise, dexterous movements enabled the system's debut to be in assisting with a urological surgery, which requires sophisticated skills for operating on intricately-positioned pelvic organs. A reduced risk of complications is another advantage.

Currently, da Vinci Surgical Systems, manufactured by Intuitive Surgical, Inc. of the United States, almost dominates the robotic-assisted surgery systems market. It was approved by the U.S. Food and Drug Administration in 2000, and about 5,500 units are in operation worldwide, with 7.2 million procedures having been completed as of the end of 2019 (source: Intuitive Surgical website). Regarding its endeavor to tap into this challenging market, Medicaroid President Kaoru Asano says, "Japan holds a global share of more than 50% of the industrial robot market, but zero percent in the robotic-assisted surgery systems market. We would like to take an approach which differs from the da Vinci, and contribute to improving global health by applying our excellent robotic technologies to the healthcare market."

The hinotori™ was named after the masterpiece manga series, *Hi no Tori (Phoenix)*, created by Osamu Tezuka, a manga legend who was also a licensed physician. Inspired by Tezuka's portrayal of the preciousness of life, the hinotori™ was produced as the first made-in-Japan robotic-assisted surgery system with the mission of supporting healthcare professionals who constantly deal with matters of life and death.



Operation Unit

This unit is comprised of the cart (the base underneath the robot's body), the positioner (middle section), the arm base (upper section), and four operation arms. The cart contains the Central Control Unit, which coordinates with the four controllers of the arms. The four arms are comprised of an endoscope, two forceps for dissection and suturing, and a forceps for securing organs or lifting them up and out of the way.

Operation Arms

These eight-axis arms of the hinotori™ are capable of various movements on a par with those of human arms. At the ends of the arms, instruments (e.g., an endoscope and forceps) are attached, which are themselves capable of four-axis movements.

Surgeon Cockpit

This is a console where the surgeon operates the robot, using two hand controls and a foot switch, with the 3D endoscopic image displayed on a monitor. The cockpit can adjust its position according to the posture the surgeon takes.

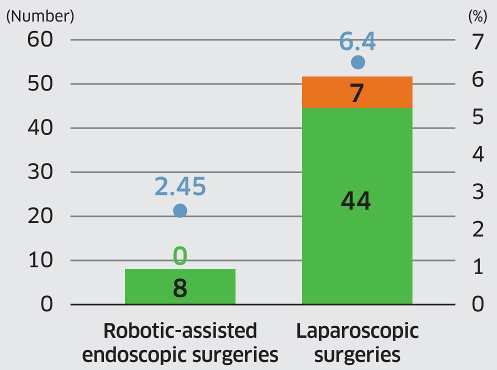
Microphone/speaker

3D Viewer
This viewer can be adjusted to the surgeon's preferred position.

Hand Control
Scaling can be changed using a touchscreen.

Foot Unit
Its position is adjustable.

Number and Rate of Occurrence of Post-Gastrectomy Complications in Robotic-Assisted Endoscopic Surgeries and Laparoscopic Surgeries



Local complications Systemic complications
Rate of occurrence

Source: Research by the Department of Surgery at Fujita Health University. *Rinsho Geka (Journal of Clinical Surgery)*, No. 74, Vol. 3. March 2019.

The Power of Engineering Achieves Exact Tactile Sensations Experienced by Surgeons

Industrial robot engineers at Kawasaki were responsible for developing and manufacturing the hinotori™. The development project began in 2015, and engineers quickly achieved a level of dexterity which enabled the system to peel a grape, utilizing the expertise and knowledge accumulated at Kawasaki over half a century. That initial success, however, was followed by a multitude of challenges.

Raizo Yamaguchi, Vice Director of ICCRC, who is a urologist with extensive expertise in robotic-assisted surgeries, recalls, "What was challenging was getting the engineers to understand what surgeons feel and experience when they operate." On the Kawasaki side, Tsuyoshi Tojo, the Senior Staff Officer who led the development project, says, "We had a hard time understanding the exact tactile sensation the physicians' hands experience during surgeries, and replicating the sensory feel mechanically." To enlighten the perplexed engineers, Yamaguchi told a "parable" in explaining what should be achieved, using a helicopter and a sports car. "If an industrial robot fails, we can just deactivate it, but can we do the same for a helicopter in flight? Even faced with troubles, a pilot must be able to maintain control of the aircraft as long as possible. The same goes for the robotic-assisted surgery system."

Raizo Yamaguchi
Vice Director
Kobe University Hospital International Clinical Cancer Research Center

He continues, "Engineers tend to be conservative, thinking, 'It's dangerous if a knife is too sharp,' but surgeons are confident in their ability to control sharp knives. We want a robot to be like a luxurious, high-performance, highly-responsive sports car, but safeguarded by a redundancy that permits the driver to use as many driving techniques as possible."

This parable aided the engineers by specifically identifying which key technological challenges had to be resolved. Tojo explains, "In the end, we decided on three key concepts for development, which were 'compactness,' 'high-level safety,' and 'maximum maneuverability'."

Tsuyoshi Tojo
Senior Staff Officer, Medical Robot Section 2
Medical Robot Department
Medical Robot Group
Robot Business Division
Precision Machinery & Robot Company

18 Trillion Simulations Conducted

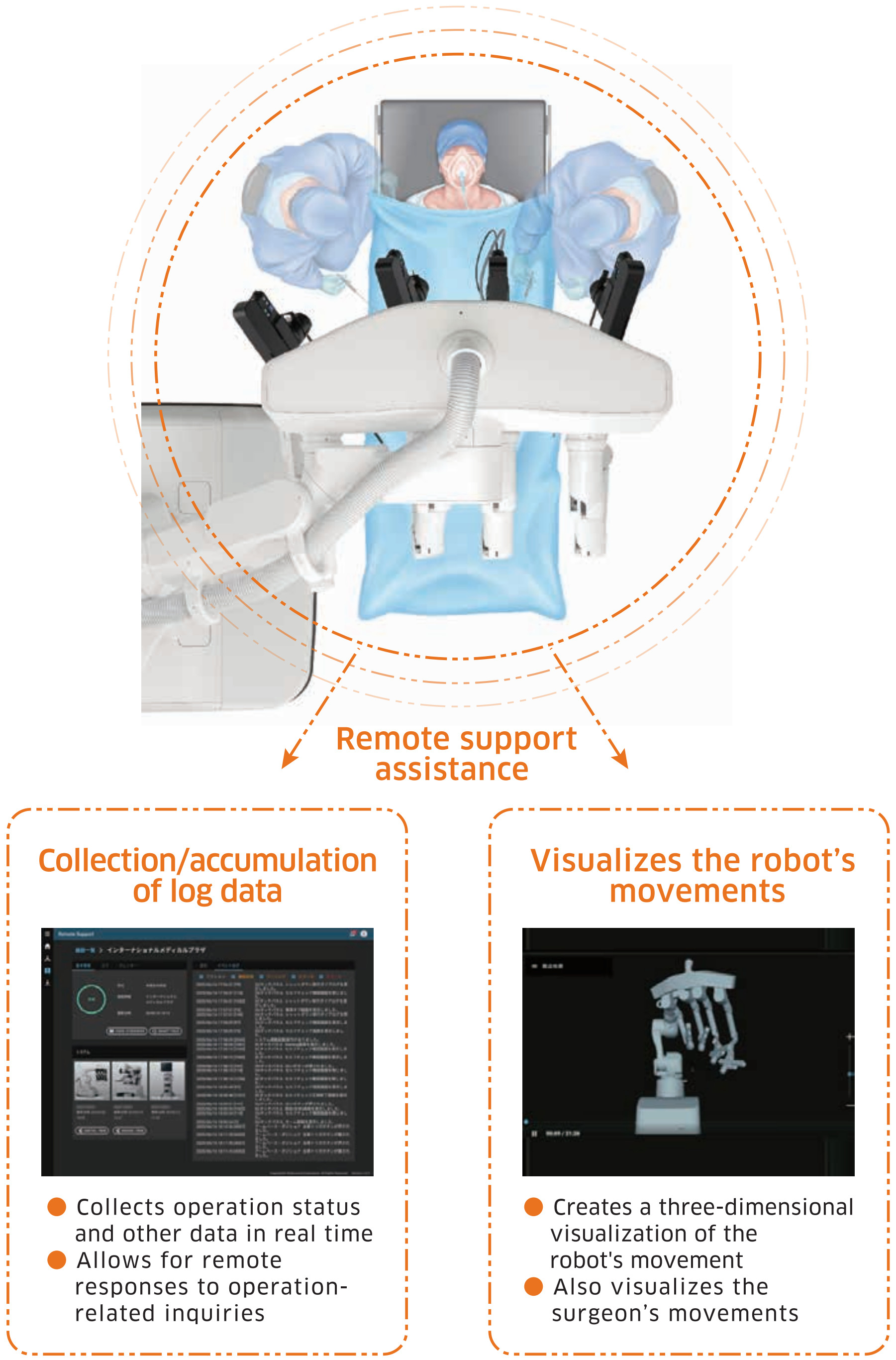
Three major components comprise the hinotori™: 1) the Operation Unit, composed of the robotic arms with various instruments attached to their tips; 2) the Surgeon's Cockpit, where the surgeon operates; and 3) the Vision Unit, which sends high-definition, 3D endoscopic images to the Surgeon Cockpit and supports communications between surgeon and assistants.

To overcome the highest hurdle in this development project, which was to realize both compactness and a large operating range, the developers made the robot compact so that it was less overwhelming to the patient, and designed the robotic arm to match the width of a human arm.

The system's four arms and the instruments at their tips serve as the surgeon's eyes and hands, going deep inside the body to grasp, cut, suture, and perform other tasks. These actions are supported by eight-axis motion control of each arm and four-axis motion control of each instrument, achieving a total of 48-axis motions with the four arms. Having multiple axes (i.e., multiple joints) provides excellent redundancy. However, the close configuration of the four arms increases the risk of interference and may result in serious incidents if the arms lock up following a collision.

Hirofumi Yamamori, who was in charge of developing the controls, comments, "The standard configuration for industrial robots is six axes. With the hinotori™, each arm alone with its instrument provides 12-axis motion. Because each arm must reach the target area through the incision without any misalignment, it must have a large operating range. Even when moving an arm straight forward, the control process is still very complex, given the positions of other arms and the angles of their joints. It took a lot of trial and error and input by surgeons to establish a control method that would achieve reduced risk of collisions, since an optimization that worked locally didn't necessarily work for the whole." To tackle the challenge, the developers visited operating rooms to observe how surgeons move their arms and hands, and conducted various computerized simulations — amounting to 18 trillion sessions — to identify the optimal control algorithms.

The compactness of the hinotori™ provides for a large, surgically clean area of movement around the operating table (left below). To ensure a high level of safety, the world's first technology providing remote support using high-speed communication lines is being used to respond in real time to problems during surgical procedures (above).



Balancing compactness and a large operating range entailed various challenges in mechanical design as well. Senior Staff Officer at Kawasaki, Wataru Doi, recalls, "If we make the arm thin to keep the device compact, the arm's instrument easily becomes unsteady. If we try to use a long, thin part to make the operating range greater, its thinness makes the arm unable to support its own weight. It took repeated efforts to find the optimal balance between the mechanical aspects of the system and the software controls."

The combination of a high-output motor and reduction gear jointly developed by Kawasaki and a parts manufacturer resolved the challenge of achieving both compactness and a large operating range. Tojo adds, "The compact design optimizes lines of movement around the operating table and provides ample space around the surgeon's hands. We were able to generate advantages that benefit not only the surgeons but also the entire operating team."

Hirofumi Yamamori
Manager, Medical Robot Section 2
Medical Robot Department
Medical Robot Group
Robot Business Division
Precision Machinery & Robot Company

A scene from an evaluation session for the prototype of the hinotori™.
The prototype was repeatedly evaluated, modified, and upgraded.

A Leader's Voice

Kaoru Asano
President, Medicaroid Corporation

Striving to Realize the Ideal Embodied in hinotori™'s Name

The development of the hinotori™ resulted from the collective passion of Kawasaki President Yasuhiko Hashimoto, Sysmex CEO Hisashi Ietsugu, and many others. We had long been frustrated that its world-class industrial robot technologies had not yet been applied in the healthcare industry.

In fact, the industry was eager for the arrival of domestically-produced medical robots, as was evidenced in business feasibility studies in which many physicians expressed support, making such comments as, "Existing robots are too costly and make procedures unprofitable," and, "Producing robots in Japan will allow us to work with manufacturers to continue upgrading them." The steady advancement in minimally-invasive surgeries — as seen in the transition from open surgery to laparoscopic surgery to robotic surgery — also propelled us to initiate development.

Once the decision was made, the engineers at Kawasaki, Sysmex, and Medicaroid worked very hard, day and night. Another driver was Kobe City's plan to build its "Biochemical Industrial Cluster," in which Medicaroid was a partnering firm. This facilitated our collaboration with the ICCRC and the manufacturers of medical equipment parts, which are located on Kobe's Port Island along with Medicaroid. A marketing and manufacturing license from the Ministry of Health, Labour and Welfare was granted in August 2020, which was followed by our successful first surgery in December. Putting us at the forefront of this medical revolution, 2020 therefore turned out to be a year filled with great excitement.

There are still many challenges to overcome in order for the hinotori™ to be implemented widely and to make further technological advancements. We must devise flexible programs to encourage adoption of the system by middle-sized and small hospitals, such as leasing programs and pay-per-use systems. We also need to have more training centers and to train proctors (physicians who act as instructors). Formation of a "users' club" for collection of enhancement ideas is also needed, so that we can upgrade the hinotori™ to an even more physician-friendly system and make more robotic procedures subject to insurance coverage. An initiative utilizing AI-based systems to reproduce the expert skills of surgeons and another realizing telesurgeries using high-speed communication lines are underway, as are preparations to obtain approval from the U.S. Food and Drug Administration.

In addition to surgical robots, we are now strengthening our "applied robotics" business, whereby industrial robots are used for medical applications without major alterations to their basic structure. One such example would be a robotic polymerase chain reaction (PCR) testing system. Medicaroid, Kawasaki, and Sysmex are committed to working together with healthcare professionals to enhance the dignity of life — the ideal embodied in the name "hinotori™."

The Control Experience: "Light as Air with No Constraints"

The hand control in the Surgeon Cockpit is a vital component, enabling the surgeon to manipulate the system at will. However, this also became a challenge, as Doi recalls: "Surgeons requested that the hand control 'give the tactile sensation of being as light as air.' It was a challenge, as at first, we didn't know how to realize such a request from a mechanical perspective."

Key to resolving this issue was the gear reduction ratio. Because the hand control transmits a sense of "heaviness" when friction between the motor and the reduction gear increases, the developers lowered the gear reduction ratio to reduce the friction. In addition, to better assist the surgeon's operations, they improved the sensory aspect of the hand control by making mechanical modifications and upgrading the software.

Wataru Doi
Senior Staff Officer, Medical Robot Section 1
Medical Robot Department
Medical Robot Group
Robot Business Division
Precision Machinery & Robot Company

To ensure its operational safety, the robotic system is equipped with multiple monitoring systems, including a function which keeps the system deactivated unless the sensor of the 3D viewer detects the surgeon's gaze in the viewer. Yamamori continues, "If the arms interfere with each other, an alarm is set off, but even if they were to collide, or an arm reaches the limit of its operating range, the system is designed in such a way that the surgeon can continue with the procedure.

Next Step: Improving Navigation

Regarding the future evolution of surgical robots, Yamaguchi of the ICCRC predicts that three navigational features will be subject to critical improvements: "One will be to enhance the level of procedural precision using accurately-visualized images of the affected area, obtained by injecting fluorescent dye into the surgical field. Another will be to accumulate and analyze data from robotic surgeries performed by expert surgeons, so that their expertise can be leveraged as best-practice examples. Finally, the advancement of telesurgery using 5G and 6G (5th- and 6th-generation) communication systems is also vital."

On the same topic, Tojo comments, "We still have many challenges to overcome, but focused on the common goal of 'contributing to improving global health from the perspective of patients and medical professionals,' we would like to keep improving the hinotori™ through an open platform, utilizing the collective input of expertise from the stakeholders. These enhancements include virtual pre-operation simulations incorporating CT-scan images; the automation of simple suturing; and the transferring of seasoned surgeons' skills to those with less experience."

The hinotori™ has already begun its flight toward the next stage of this medical revolution.

SUPPORTING LIFE WITH TECHNOLOGY

Kawasaki Develops Automated Polymerase Chain Reaction (PCR) Testing System to Ensure the Safety of Our Mobile Society

The world's first automated PCR testing system utilizing robots was recently developed by Kawasaki for the COVID-19 pandemic. As it is designed to increase protection for healthcare workers and improve mobility — which should facilitate economic recovery — the Company is encouraging various entities to consider adopting the system.

A robot performing opening and dispensing of specimens. Using robots for the process, which poses a high risk of infection, contributes greatly to reducing the burden on healthcare professionals.

The entire system is housed in a 40-foot container (12 meters long, 2.5 meters wide), and its robot conducts the entire testing process: 1) Centrifugation of specimens, 2) Opening of specimen containers and dispensing specimens into separate containers, 3) Nucleic acid extraction, 4) Reagent preparation, and 5) PCR measurement.

Because it requires no human intervention, the system ensures the safety of healthcare professionals while achieving simplified operations. It is the world's first container-housed mobile system utilizing robots that allows for automated mass processing of specimens.

With a conventional PCR testing system, the PCR measurement — performed after opening/dispensing of specimens and nucleic acid extraction — takes 210 minutes. Given the additional time and work needed for transporting specimens to a testing site, it has been a laborious undertaking. With Kawasaki's system, it takes only 80 minutes to receive results following specimen collection. This shortened time is attributable to limiting the number of specimens in each testing unit to eight, compared to 96 in conventional PCR testing, which reduces the time needed to raise and lower the temperature evenly across the specimens.

Assuming that it operates 16 hours a day, the system is capable of testing about 2,500 specimens per day, and capacity can be increased by adding more units of the system.

For example, in an airport with a testing facility using our system, a traveler could be tested and receive his/her results in 80 minutes. If the test is negative, a physician could verify the result and issue a certificate for the traveler to present upon entering the country of destination. (This might require a prior agreement between Japan and the destination country.)

The development project for this system was already underway in March 2020. In August 2020, the project was upgraded to a cross-divisional one led by the Presidential Project Management Division, and in February 2021, the testing business using this system was launched. Project leader Hirotoshi Tsuji of the Project Division, says, "Recovery of international business travel is an urgent matter to which Japanese and other governments, as well as industries across the world, are paying close attention. By checking passengers' status of infection immediately before they board, we are trying to ensure that everyone can board worry free, and enter their country of destination using a certificate of negative result."

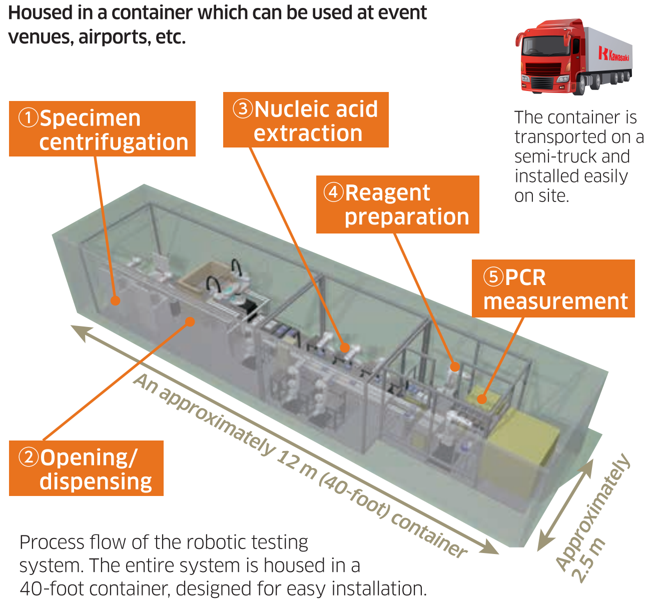
For the system, Kawasaki manufactures and systematizes the product, Sysmex acts as general agent for selling the PCR testing device and reagents, and Medicaroid serves as the Marketing Authorization Holder of the system. We anticipate that it will be used not only at airports but also at large sporting events.

Currently, Kawasaki is also developing a robotic system to collect nasal swab samples, and is working on obtaining approval for the system as medical equipment from the Ministry of Health, Labour and Welfare.

Robots can contribute significantly to creating a safe environment for travelers by reducing the risk of infection in any situation, thereby achieving new heights in technology's contributions to society.

■ Kawasaki's PCR Testing System

Housed in a container which can be used at event venues, airports, etc.



Process flow of the robotic testing system. The entire system is housed in a 40-foot container, designed for easy installation.