Quality Management

As a manufacturer of medical equipment which is responsible for saving lives, we aim to supply products and services that provide customers with safety and peace of mind.

Message from Operating Officer



Yoshiyuki Fujita
Senior Operating Officer,
Chief Quality & Regulatory Officer,
General Manager of Corporate Quality Management Operations

Quality is an essential element in ensuring the safety and performance of products and is a key management factor that supports customer confidence and trust. At the same time, it serves as one of the foundations of management's commitment to "keeping healthcare running without interruption." In recent years, the quality requirements for medical equipment have expanded to encompass areas such as cybersecurity and environmental sustainability, and the regulations related to medical equipment are rapidly becoming more sophisticated and complex.
Furthermore, rising geopolitical tensions, particularly in the Middle East, have further increased uncertainty in the business environment, affecting areas such as raw material procurement, logistics, and energy costs. Under these circumstances, design changes and component substitutions—which are essential for compliance with medical equipment regulations—directly lead to procurement risk and supply constraints. The product supply disruptions caused by delays in responding to regulatory requirements that became apparent in FY2025 clearly demonstrated that ensuring quality solely through the production process is not sufficient to support a stable product supply. In addition to our traditional efforts to build quality into products at the development stage, it has become essential to incorporate resilience against changes in the external environment from a much earlier stage.
Through my experience as the Chief Quality & Regulatory Officer (CQRO) responsible for overseeing quality and regulatory compliance, I have come to strongly recognize that quality is a management element essential for sustaining both product compliance and product supply in the face of changes in the external environment.
Rather than relying solely on the ability to respond to on-site situations in individual development and production processes, I believe it is essential to take a comprehensive view of the entire product lifecycle from the product planning stage onward and embed quality and regulatory compliance considerations into each process—design, procurement, production, and supply—as a means of mitigating potential risks.
Accordingly, the Company does not leave quality solely to frontline operations; rather, we view it as a key priority that management must proactively address while focusing on shortening Time to Market (TTM: the period from product planning to market launch).
As we move toward the culmination of our Long-term Vision, BEACON 2030, we will evolve quality management from "a management system for maintaining compliance" into "a management foundation for continuing to support healthcare even amid changes." Through this transformation, we will lay the groundwork for the next Three-year Business Plan. By proactively addressing regulatory requirements, enhancing cross-functional visibility of quality risks, and strengthening business continuity with geopolitical risks in mind, we will continue to refine quality as a source of medium- to long-term corporate value creation.
"Continuing to provide peace of mind to healthcare professionals, even in an era where uncertainty has become the norm." This is precisely our responsibility as we regard quality as a core element of our management foundation.

Quality Policy

Medical devices used in advanced medical care require the highest level of quality and safety. Nihon Kohden has set the following quality policy.

Quality Policy

Maintaining high customer satisfaction with the purchase of a Nihon Kohden product through its entire life cycle.

Quality Management

Quality Targets

In FY2025, Nihon Kohden conducted one recall for products manufactured and distributed in Japan, resulting in inconvenience to medical professionals.
We will continue making company-wide efforts to prevent the recurrence and build up a record of "Zero Recall Days."
In FY2026, the following initiatives will be implemented as quality targets.

(1) We will build a global quality management system to strengthen regulatory compliance and post-marketing monitoring in each country.

In response to the increasing demand for high-quality medical equipment at the global level, Nihon Kohden has established its QMS that has strengthened legal and regulatory compliance and post-marketing monitoring in each country or region where its products are sold. We will continue to thoroughly collect and share information on medical equipment-related laws and regulations in each country/region to shorten the time required for global product registration and ensure the timely supply of products. We will also further upgrade our post-marketing monitoring system and provide feedback on the information obtained for the improvement of internal processes and products to improve the quality of our products and services more rapidly.

(2) We will improve software design quality and manufacturing quality to enhance Customer Experience (CX).

To enhance CX, we will work to improve daily operations, increase efficiency as well as speed, and respond to customer feedback in an appropriate and timely manner. In addition to third-party evaluations of software design, we will continue to work to reduce product failures after shipment by analyzing problems in the product manufacturing process and taking measures to prevent their recurrence.
Nihon Kohden has obtained ISO 9001:2015 certification for its quality management system and ISO 13485:2016 certification for medical devices and in vitro diagnostic medical devices. The Company has also obtained numerous certifications and accreditations including the Medical Device Single Audit Program (MDSAP)* certification. Our Reliability Center has obtained laboratory accreditation in accordance with ISO 17025:2017. In addition, the Company complies with the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) in Europe.

* MDSAP is a program to realize a single survey on the compliance and validity of QMS surveys introduced by medical device regulatory authorities in five countries: the U.S., Canada, Brazil, Australia, and Japan.

(3) We will work to reduce the repair rate to ensure stable operation of our products.

To ensure the stable operation of products used by our customers, we will continue our efforts to reduce repair and re-repair rates. We will also provide replacement devices promptly during repairs and work to shorten lead times for repair parts and repair turnaround times.

(4) We will work on human resource development to achieve quality targets and improve CX.

To achieve the above quality targets and improve CX, we will develop human resources by providing practical training across all Nihon Kohden departments.

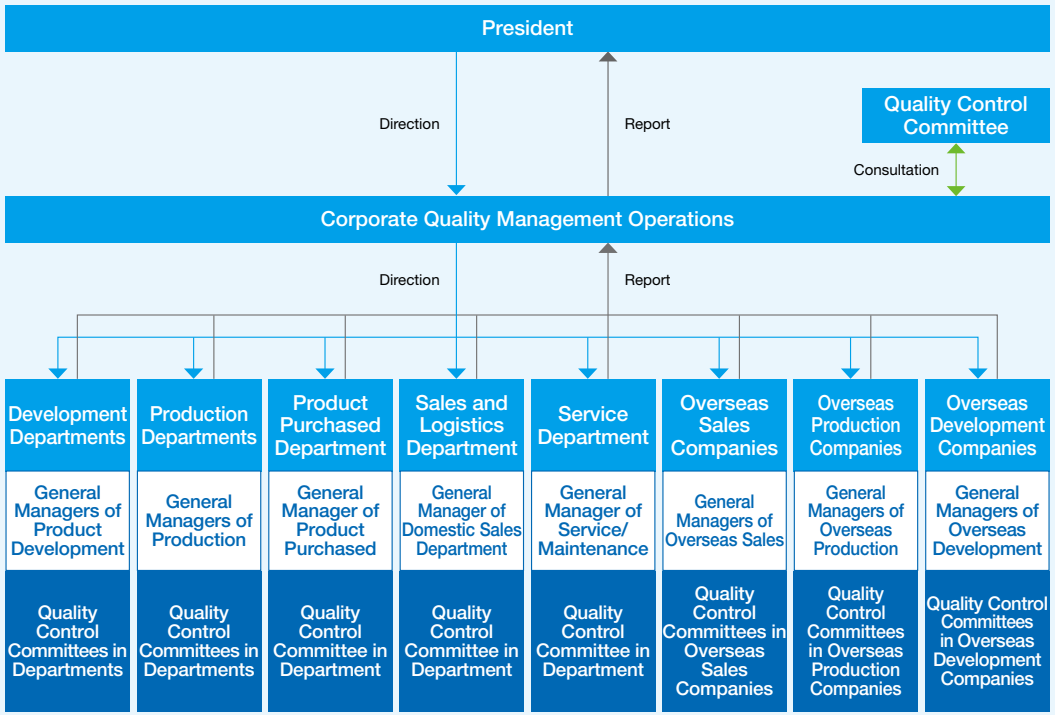
Quality Management

Management System

■ **Strengthen Our Global Quality Management System**

Nihon Kohden is working to strengthen its quality management system and regulatory affairs functions for obtaining approval in each country in order to supply products globally in a timely manner.

Quality Management System



ISO 9001/ISO 13485 Certification in the Nihon Kohden Group

	ISO 9001 Quality Management System	ISO 13485 Medical Device Sector Standard
Nihon Kohden Corporation*	○	○
Nippon Bio-Test Laboratories Inc.	○	-
DOWELL Co., Ltd.	○	-
Nihon Kohden America, LLC	-	○
Defibtech, LLC	-	○
Nihon Kohden OrangeMed, LLC	-	○
Neurotronics, LLC	-	○
Nihon Kohden Digital Health Solutions, LLC	-	○
Ad-Tech Medical Instrument Corporation	○	○
Nihon Kohden Europe GmbH	-	○
Nihon Kohden Firenze S.r.l.	○	○
Software Team Srl	○	○
Shanghai Kohden Medical Electronic Instrument Corp.	○	○
Nihon Kohden Malaysia Sdn. Bhd.	-	○
Nihon Kohden India Pvt. Ltd.	○	○
Nihon Kohden Middle East FZE	○	○

* Including Nihon Kohden Tomioka in the scope of certification.

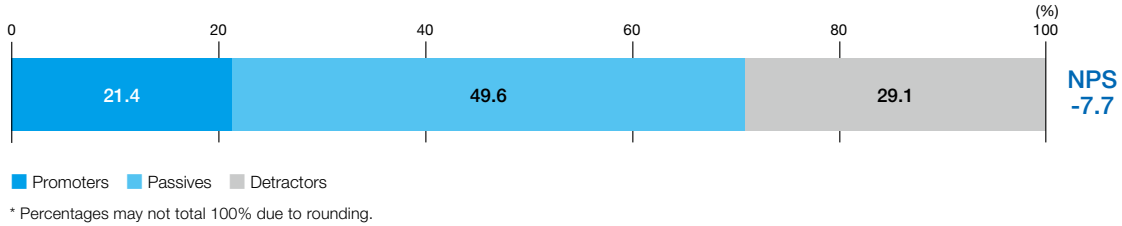
Quality Management

Net Promoter Score (NPS®) Surveys

Nihon Kohden had set one of the material issues in the Three-year Business Plan, BEACON 2030 Phase II, as "Pursue the highest level of quality in the world," and established the Net Promoter Score (NPS®) as a KPI. The improvement of NPS® has been a KPI since the period of the previous Three-year Business Plan, and the NPS® survey was conducted for the fifth time in FY2025. The overall NPS® survey score was -5.3 points in FY2021, -4.0 points in FY2022, -8.4 points in FY2023, -4.1 points in FY2024, and -7.7 points in FY2025, a decrease of 3.6 points from the previous fiscal year. In particular, the scores in areas such as "Brand image" and "Degree of understanding of customer needs" indicated that further improvement is needed. On the other hand, the score for categories such as "Ease of obtaining information on products and services" and "Support at the time of delivery and installation" received high ratings.
Through the NPS® survey, we will continue to further enhance the points that have been highly evaluated by our customers and actively improve the points that need improvement. As a partner to medical professionals, we will continue to be a company that works together with them to solve issues facing the medical field.

* The NPS® survey is conducted to quantify the degree of attachment to and trust in a company or brand, which has traditionally been difficult to measure, in order to evaluate the customer's experience at the point of contact with the company and apply it to improvements through future business activities. Since the NPS® survey has a high correlation with business growth rates, it is used by listed companies in the U.S. and Europe and is attracting attention in Japan as a new indicator alongside customer satisfaction.
NPS® is calculated by the following method.
Customers were asked to rate the service on a 10-point scale, with 9 to 10 being "promoters," 7 to 8 being "passives," and 0 to 6 being "detractors." The percentage of promoters (%) to the total number of respondents was subtracted from the percentage of detractors (%), and the resulting number is the NPS® value, which is expressed between -100 and +100.
NPS® is a registered trademark of Bain & Company, Fred Reichheld, and NICE Systems, Inc.
Net Promoter System, Bain & Company's Website
https://www.bain.com/consulting-services/customer-strategy-and-marketing/customer-loyalty/

NPS® Survey Results in FY2025 (Overall Score)

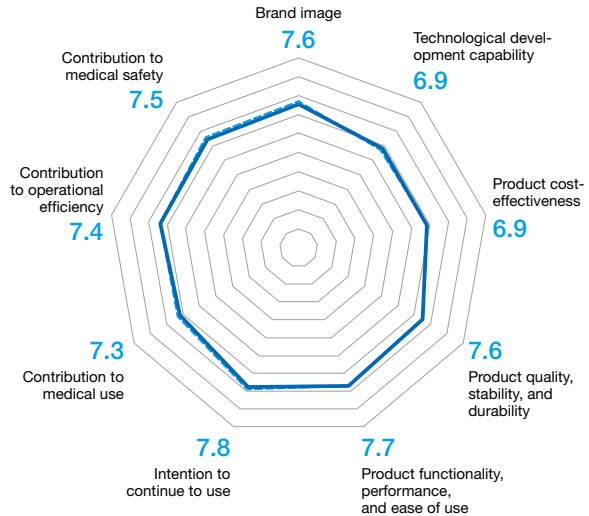


* Percentages may not total 100% due to rounding.

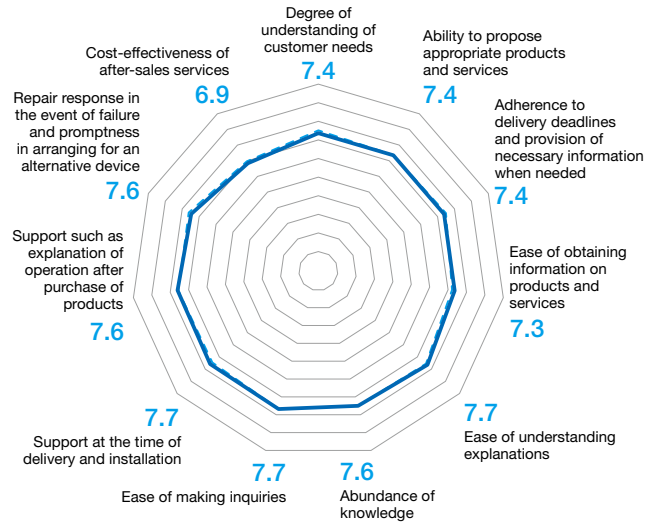
NPS® Survey Results in FY2025 (Individual Scores) * 10-point scale for each item

FY2025 FY2024

Corporate Image and Contribution to Customer Value



Satisfaction with Sales and Services



Quality Management

Support for Customers' Safety Management

Nihon Kohden strives to ensure safety even after product delivery by supporting customers' safety management and the dissemination of medical technologies.
The Company has assigned specialized Medical Equipment Safety Advisers (MESA) throughout Japan, who have received accreditation as Medical Device Information Communicators (MDIC)*, to hold training sessions on the proper use of its products. In addition to in-person training sessions, we also provide online-based training and audio-narrated slide materials. Through the training materials, we delivered essential safety information to many medical facilities and healthcare professionals in FY2025.

FY2025 Results

- 1,390 sessions (In-person training: 1,172 times, providing materials (including video files): 218 times)
- 26,045 participants
  (In-person training: 23,485 participants, non-in-person training: 2,560 participants)
- 669 facilities

Main training topics

- Safety workshops for use of patient monitors, defibrillators, ventilators and AEDs
- Safety workshops for electrical safety, safety management of medical devices, and alarm report for patient monitors

* MDIC is an accreditation program established by the Japanese Society of Medical Instrumentation (JSMI) to cultivate personnel who can contribute to patient safety and the improvement of healthcare quality.

Product Cybersecurity

■ Product and Service Safety Program

Nihon Kohden implements its Product Security Policy throughout the entire product lifecycle, from development to post-sales support. By providing customers with information advisories and information on the End of Life (EOL) and the End of Support (EOS), we help ensure that customers can use our products safely and securely throughout their lifecycle.

For further details, please refer to **the Information Risk Management page** and our website.

Product Security Measures

Information System Risk Management

Employee Safety

Nihon Kohden has established the Safety and Health Committee to promote accident prevention and the development of a healthy environment in the workplace, in compliance with the Labor Standards Act and the Industrial Safety and Health Act. The Safety and Health Committee holds monthly meetings to deliberate on health and safety proposals submitted by each department and engages in activities for safety and health improvement.
In addition to the Safety and Health Committee, the Company has also established the Infectious Disease Prevention Committee to conduct employee training, surveys, discussions, and awareness raising activities regarding infection prevention.
Company vehicles used by employees are equipped with collision avoidance systems, lane departure warning systems, automatic high-beam switching systems, and drive recorders as standard equipment, and studless tires are provided as needed. All company vehicles are generally leased for a period of five years, and are updated with the latest safety equipment, while also promoting the use of hybrid vehicles to reduce environmental impact.
In addition, for employees working in regions with severe cold weather, we promote the reduction of traffic accidents by arranging vehicles equipped for cold climates. Due to the revision of the Road Traffic Act enforcement regulations, which mandates alcohol checks using breathalyzers before and after driving from December 2023, we have implemented a vehicle management system at all domestic business sites. This system ensures the proper operation of driver's license verification, driving logs, and pre- and post-driving alcohol checks.
Beginning in FY2026, we will revise the repair and management framework for company vehicles to ensure vehicle safety and establish a more responsive maintenance system. Through these efforts, we aim to further reduce traffic accident risks and enhance employee safety.
In addition, we have introduced an employee safety confirmation system that enables us to quickly verify the safety of our employees in the event of a disaster. This system enhances our initial emergency response capabilities and strengthens our business continuity plan (BCP) framework. By establishing a system that enables the rapid confirmation of employees' safety and the prompt issuance of response instructions in the event of a disaster, we enhance both employee safety and business continuity, thereby strengthening the Company's overall resilience.
Through these initiatives, Nihon Kohden will continue to ensure the safety and well-being of its employees while strengthening its business foundation and earning the trust of society through a robust business continuity framework.