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

In order for Nihon Kohden to provide solutions to global medical issues, Chief Quality & Regulatory Officer (CQRO) is responsible for maintaining the Company's compliance with laws and regulations related to medical devices in each country and ensuring the safe and effective solution delivery processes and product quality.
To enhance the agility of the organizational structure established in the previous Three-year Business Plan, we have dissolved the three supervisory divisions under the Corporate Quality Management Operations, which were responsible for maintaining the Quality Management System (QMS), improving product quality, and monitoring the quality of our globally operating subsidiaries, in the second year of the Three-year Business Plan, BEACON 2030 Phase II. This reorganization has resulted in a more open and flat organization.
Underlying this reorganization is the need to strengthen resilience against unforeseen events that may occur in the course of our quality-related activities. Personnel assignments have also been revised to strengthen the functions regarding audits by each country's government and certification bodies, checks on Nihon Kohden Group companies, and post-marketing monitoring of products. In addition, the sections that evaluate the safety and reliability of developed products, which had been placed in the Technology Development Department, were reorganized into the Corporate Quality Management Operations. This will promote the exchange of human resources, with a view to handling the new Tsurugashima Factory. It will also strengthen the overall structure of the Corporate Quality Management Operations to improve product quality and shorten the Time to Market (TTM), time from product planning to market launch, required for the supply of products and services to the market.
There are continuing concerns about the impact on product quality due to changes in distribution channels of manufacturing materials, triggered by tariff policies in the U.S., as well as the tightening of regulations related to move to prefer domestically produced products in some countries. In order to respond flexibly to these various situation changes, we need to make prompt decisions and refine our quality monitoring at manufacturing sites in each country.
Within the Company, we have undergone QMS audits by the governments in various countries and are committed to continual quality improvement. Unfortunately, we had to recall our patient monitors, ventilators, and automated chest compression devices. We apologize for the concern and inconvenience caused to our customers. While company-wide efforts were made to promptly repair and improve the products and prevent any health issues from occurring, we will continue to correct the product development process and upgrade the QMS to prevent the recurrence of recalls.
To realize Nihon Kohden's Quality Policy shown below, we will operate an appropriate QMS, ensure compliance with laws and regulations in our development, production, sales, and maintenance activities, and promote the sustainability of continuous improvement. These actions of each employee are based on Nihon Kohden's pursuit of the highest level of quality in the world, and we are confident that this will be reflected in our products.

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 FY2024, Nihon Kohden conducted three recalls for products manufactured and distributed in Japan, resulting inconvenience to medical professionals.
We are making company-wide efforts to prevent the recurrence and to build up a record of "Zero Recall Days".
In FY2025, 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 devices at the global level, Nihon Kohden has established its QMS that has strengthened 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 device-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 customer service as well as software design and manufacturing quality to pursue customer value.

To enhance services for our customers, 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 its medical devices and in vitro diagnostics. 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 shorten downtime and reduce failure rates to achieve high product availability.

To increase the utilization rates of products used by our customers, we will continue to work to reduce the failure and re-repair rates. We will also promote the prompt provision of replacement devices in the event of malfunctions and the reduction of delivery times of repair parts and repair times.

(4) We will work on human resource development to achieve quality targets and pursue customer value.

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

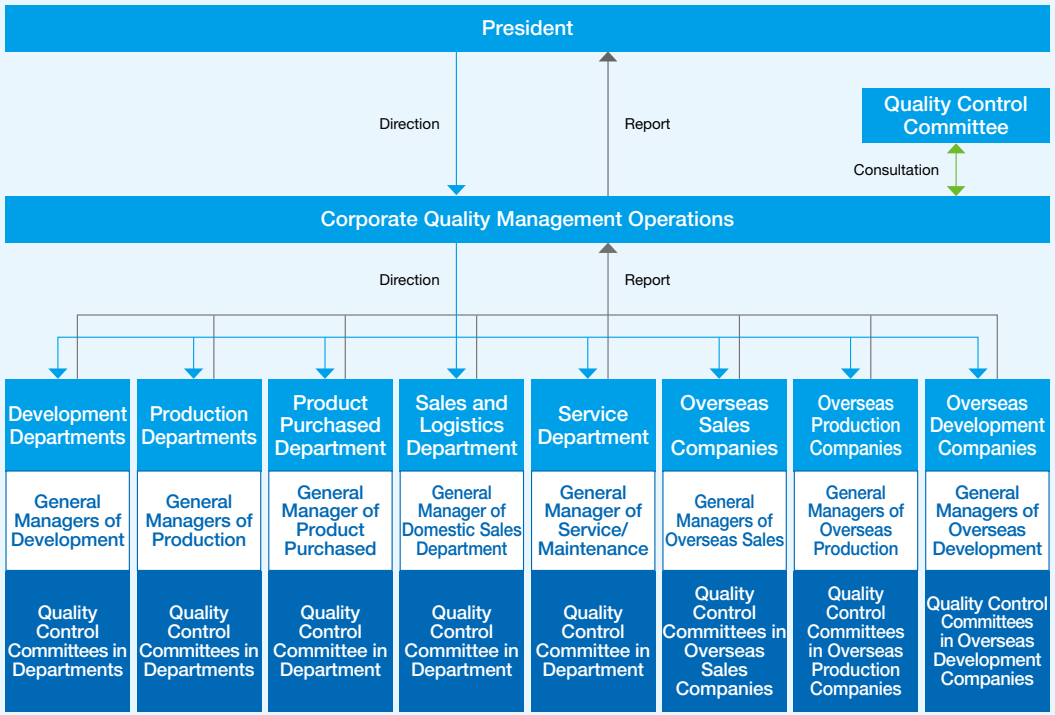
Quality Management

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
	Certification Date	Certification Date
Nihon Kohden Corporation*	January 1995	February 2003
Nippon Bio-Test Laboratories Inc.	May 2014	-
Nihon Kohden America, LLC	-	March 2016
Defibtech, LLC	-	February 2004
Nihon Kohden OrangeMed, LLC	-	June 2019
Neurotronics, LLC	-	October 2009
Nihon Kohden Digital Health Solutions, LLC	-	June 2022
Ad-Tech Medical Instrument Corporation	July 1999	September 2000
Nihon Kohden Europe GmbH	November 1995	November 1995
Nihon Kohden Firenze S.r.l.	December 1995	December 1999
Software Team Srl	July 2013	July 2013
Shanghai Kohden Medical Electronic Instrument Corp.	December 1995	December 2003
Nihon Kohden Malaysia Sdn. Bhd.	-	April 2015
Nihon Kohden India Pvt. Ltd.	August 2018	August 2018
Nihon Kohden Middle East FZE	July 2020	June 2020

* Including Nihon Kohden Tomioka in the scope of certification.

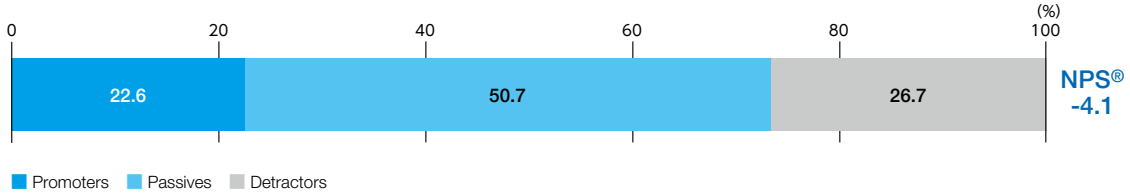
Quality Management

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 fourth time in FY2024. The overall NPS® survey score was -5.3 points in FY2021, -4.0 points in FY2022, and temporarily declined to -8.4 points in FY2023, but improved to -4.1 points in FY2024. In the evaluation of individual scores related to "Corporate Image and Contribution to Customer Value," the score for "Product cost effectiveness" was improved. On the other hand, the score for "Technology development capability" continued to need improvement. Survey items are reviewed from time to time in light of changes in social demands and customer needs. Beginning with the FY2024 survey, we have added "Environmental considerations such as resource and energy conservation" and "Product design and appearance" to the survey items in an effort to more accurately grasp customer opinions and requests. 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 Satmetrix Systems (now NICE).
Net Promoter System, Bain & Company's Website
https://www.bain.com/consulting-services/customer-strategy-and-marketing/customer-loyalty/

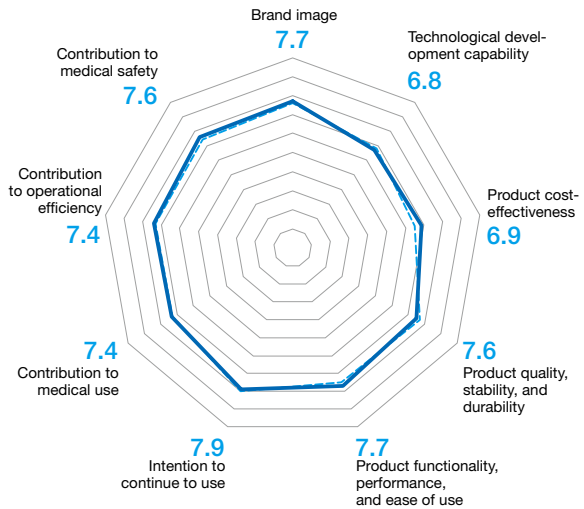
NPS® Survey Results in FY2024 (Overall Score)



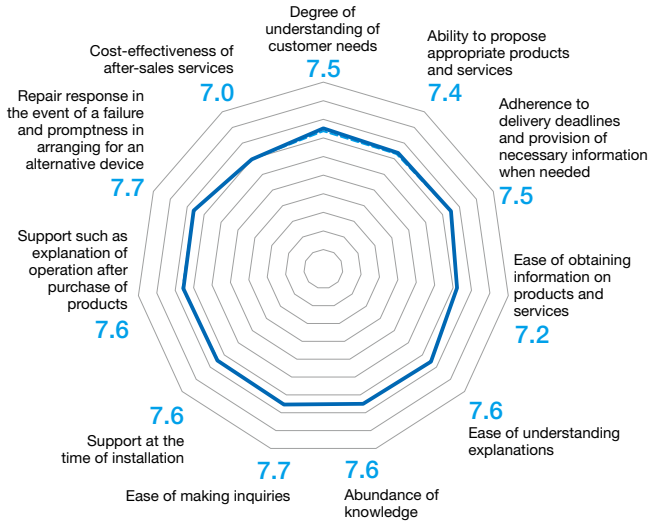
NPS® Survey Results in FY2024 (Individual Scores) * 10-point scale for each item

FY2024 FY2023

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 FY2024.

FY2024 Results	
1,535 sessions (In-person training: 1,239 times, providing materials (including video files): 284 times, online-based training sessions: 12 times)	29,425 participants (In-person training: 23,537 participants, non-in-person training: 5,888 participants) 691 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

To realize our Quality Policy, Nihon Kohden has established and is implementing a basic policy to ensure cybersecurity throughout the total product life cycle from development to production, sales, and after sales service.

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

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.
Through these efforts, Nihon Kohden strives to ensure both employee safety and environmental friendliness.