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

As the Operating Officer in charge of quality management and regulatory compliance at Nihon Kohden, my role is to ensure that our medical devices and services continue to be provided smoothly on a global scale by promptly adhering to the laws and regulations related to medical equipment in each country without delay, which includes maintaining the quality of safe and effective medical equipment, services, and solutions in healthcare. We support the R&D, production, sales, and maintenance departments through our Quality Management System (QMS), to achieve this.

In the previous Three-year Business Plan, BEACON 2030 Phase I, we restructured the organization of the departments involved in quality management and established the Corporate Quality Management Operations. This reorganization has enhanced the exchange of information and personnel, allowing us to build an organization capable of rapid analysis and decision-making. Three supervisory divisions are responsible for Maintenance and improvement of QMS, Quality improvement of medical equipment and services, and Collaboration with Group companies based on QMS. We coordinate with the departments involved in the realization of products and services, striving to collect information on global laws as well as regulations and establishing a system that prompts us to respond without delay.

The Nihon Kohden Group employees, guided by our Management Philosophy, are actively working towards achieving the quality goals set by their respective departments. This dedication is reflected in the quality of our products and services. Corporate Quality Management Operations members adhere to the Core Values and incorporate perspectives from quality engineering. They drive improvements in product development and customer service based on the analysis and judgment of laws, regulations, and post-market information.

In the new Three-year Business Plan, BEACON 2030 Phase II, while advancing the quality improvement of in-house products, we will further concretize the structure of Nihon Kohden's QMS, aiming to achieve the highest quality standards in the world.

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 FY2023, Nihon Kohden conducted two recalls for products introduced to the domestic market, causing inconvenience to medical professionals. We set the "Zero Recall Days" goal at over 200 days, but we only achieved 76 days.
We are making company-wide efforts to prevent any reoccurrence and pursue the highest level of quality in the world across the value chain.
In FY2024, we will take actions to achieve the following 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 deploy 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.
Cyber-attacks on medical institutions have been increasing in recent years and are posing a growing threat. In addition to cyber-risk mitigation measures and the early detection of security incidents, we have established a Product Security Incident Response Team (PSIRT) to provide appropriate support for early recovery in the event of a security incident. We will continue to strengthen our cyber security response.

(2) We will improve customer service as well as software 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 has responded to the Medical Device Regulation (MDR) effective in May 2021 and the In Vitro Diagnostic Medical Device Regulation (IVDR) effective in May 2022 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.

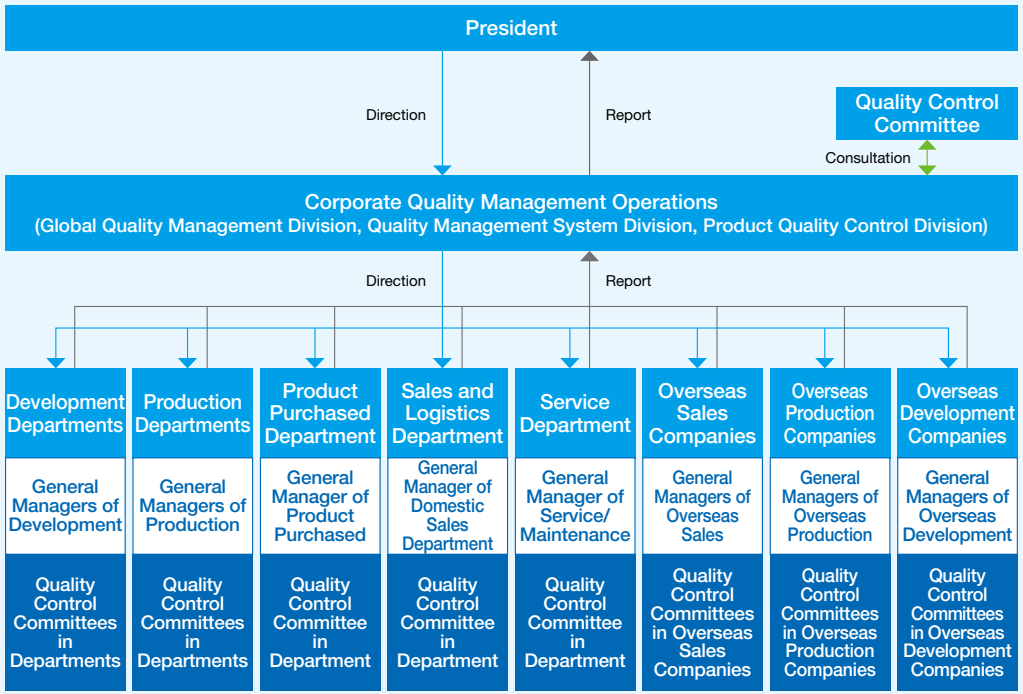
Quality Management

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
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.

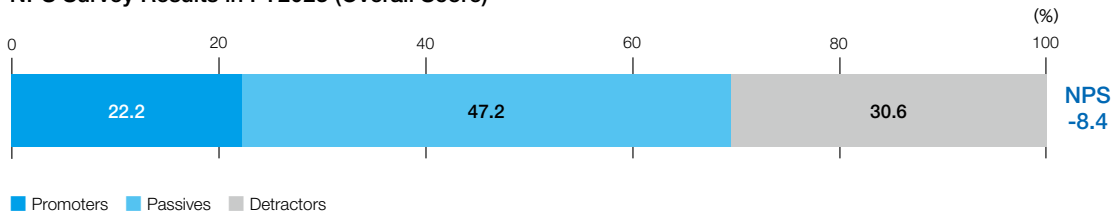
Quality Management

Net Promoter Score (NPS) Surveys

Nihon Kohden had set one of the material issues in the previous Three-year Business Plan, BEACON 2030 Phase I, as "Pursue the highest level of quality in the world across the value chain," and established the Net Promoter Score* as a KPI, beginning surveys in FY2021.
In FY2023, we conducted the third survey. The overall NPS survey score was -5.3 points in FY2021, and -4.0 points in FY2022 but decreased to -8.4 points in FY2023. The evaluation of individual scores showed a decrease of more than 0.5 points in Technological development capability and Product cost-effectiveness in the corporate image, indicating that improvement is needed. Through the NPS survey, we will continue to enhance the points that are highly evaluated by our customers and actively improve the points that need improvement. As a partner to medical professionals, we will continue to work together with them to solve healthcare issues.

* 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 FY2023 (Overall Score)

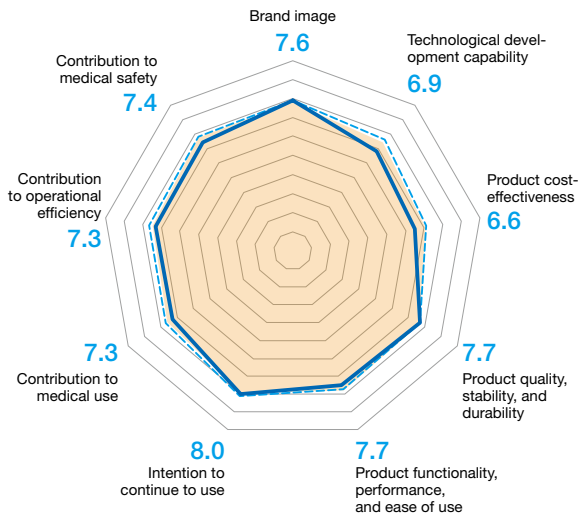


NPS Survey Results in FY2023 (Individual Scores)

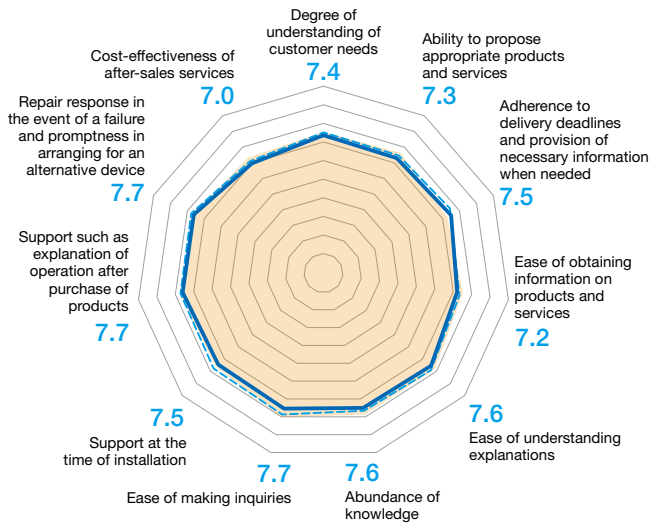
FY2023 FY2022 FY2021

* 10-point scale for each item

Corporate Image and Contribution to Customer Value



Satisfaction with Sales and Services



Quality Management

Support for Customers' Safety Management

Nihon Kohden not only strives to improve the quality and safety of its products, but also supports customers' safety management and helps spread medical technologies, to ensure safety after delivery of the product.

In Japan, Nihon Kohden deploys specialized Medical Equipment Safety Advisers (MESA) nationwide who have received accreditation as Medical Device Information Communicators (MDIC).* We also organize safety workshops to ensure that customers use our products correctly.

In FY2023, following the reclassification of COVID-19 to Category 5, we had more opportunities for in-person training sessions. However, there was still significant demand for educational content such as online training and slide materials with audio that were introduced during the pandemic. To meet these needs, we provided essential safety information to numerous medical facilities and healthcare professionals.

FY2023 Results	
1,253 sessions (In-person training: 998 times, providing materials (including video files): 240 times, web-based training sessions: 15 times)	28,661 participants (In-person training: 18,118 participants, non-in-person training: 10,543 participants) 561 facilities

Main workshop 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.

Employee Safety

Nihon Kohden has established the Safety and Health Committee to promote accident prevention and the development of a healthy environment in compliance with the Labor Standards Act and the Industrial Safety and Health Act. At monthly meetings, the Safety and Health Committee deliberates on health and safety proposals submitted by each department as well as 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 facilitate activities to prevent infectious diseases. The Infectious Disease Prevention Committee has executed employee training, surveys, discussions, and awareness raising regarding infection prevention. Company vehicles used by employees are equipped with collision avoidance assist systems, lane departure warning systems, automatic high-beam switching systems, and drive recorders as standard equipment, and studless tires are provided as needed. In addition, for employees who work in areas subject to severe cold weather, we promote the reduction of traffic accidents by arranging for cold-weather-specification vehicles. In response 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, record-keeping, and pre- and post-driving alcohol checks.