

Improving Safety and Reliability

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

Quality Policy and Quality Targets

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

To have the customers feel continuous satisfaction with their purchase of Nihon Kohden products.

In FY2021, Nihon Kohden conducted six product recalls, causing inconvenience to those in clinical practice. We are making company-wide efforts to prevent any reoccurrence and are pursuing the world's highest quality levels throughout the entire value chain.

In FY2022, we will take actions to achieve the following quality targets.

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

Healthcare systems in every country are being overwhelmed as a result of the COVID-19 pandemic, and demand for high-quality medical devices is rising worldwide. Nihon Kohden is gathering information on medical device related laws and regulations in each country and comprehensively disseminating it within the Company, reducing global product registration times, and achieving timely launch of products to global markets. We are also improving post-marketing monitoring systems and using the acquired information to enhance internal processes and provide feedback that is useful for products, leading to higher product quality.

(2) Establish a product supply and service system that results in greater customer satisfaction, and achieve high rates of utilization by customers

To have the customers feel continuous satisfaction with their purchase of Nihon Kohden products, we are continuing our efforts to design and manufacture products with low failure rates. To achieve this goal, we set quantitative targets for utilization rates, periodically review them, and provide feedback for use in design, production and service activities. In addition, we employ new technologies for remotely monitoring the status of product utilization rates, which lead to the prevention of failures. We are also working to reduce the time from receipt of products for repair to the provision of loaner devices as well as reducing repair times.

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 Survey 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.

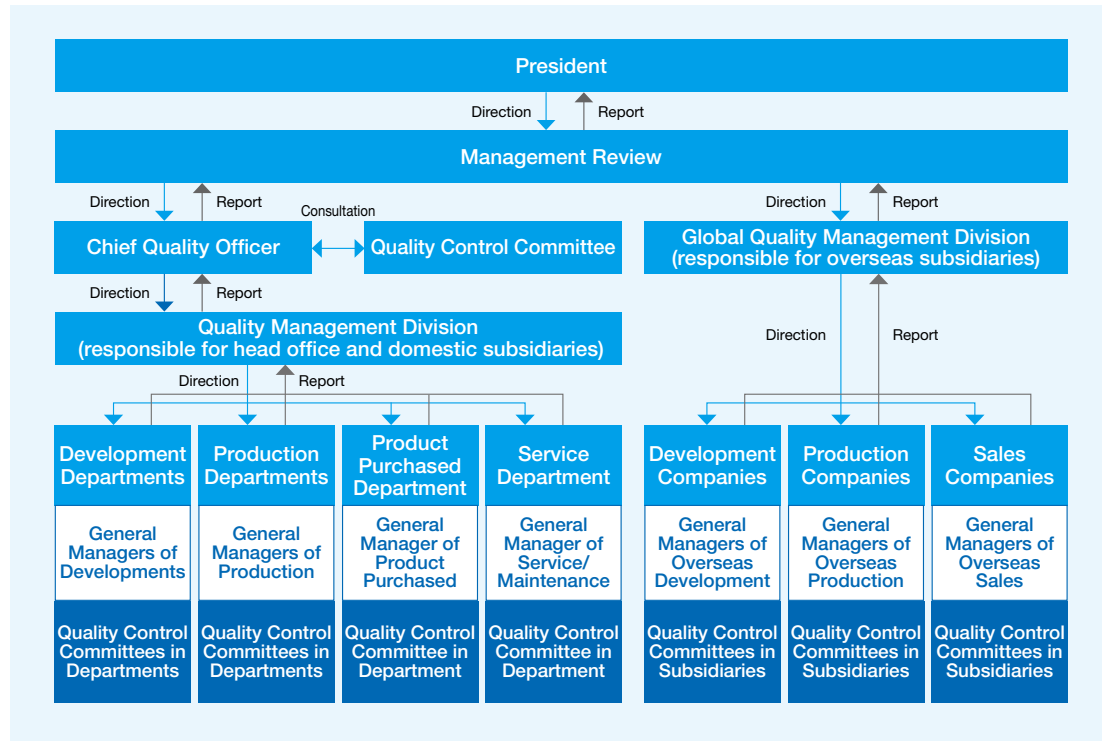
* MDSAP is a third party Auditing Organization's program for conducting a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements.

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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, Inc.	-	March 2016
Defibtech, LLC	-	February 2004
Neurotronics, Inc.	-	October 2009
Nihon Kohden OrangeMed, Inc.	-	June 2019
Nihon Kohden Digital Health Solutions, Inc.	-	June 2022
Nihon Kohden Europe GmbH	November 1995	November 1995
Nihon Kohden Firenze S.r.l.	December 1995	December 1999
Shanghai Kohden Medical Electronic Instrument Corp.	December 2003	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.

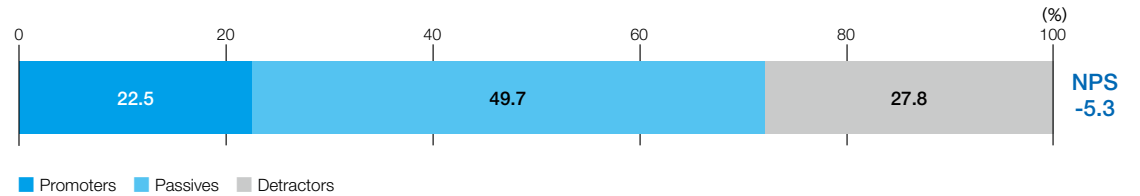
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Net Promoter Score (NPS) Surveys

One of the material issues in sustainability at Nihon Kohden is to pursue the highest level of quality in the world across the value chain. We set Net Promoter Score* as a KPI and started the survey in FY2021. In the 2021 NPS survey, the overall score was -5.3 points. Individual scores averaged 7.6 points for Corporate Image and Contribution and 7.7 points for Satisfaction with Sales and Service. Through this NPS survey, we hope to understand and analyze what our customer value and what we need to improve in order to further enhance our quality and continue to be a partner with medical institutions and medical professionals, working together to solve the issues facing healthcare.

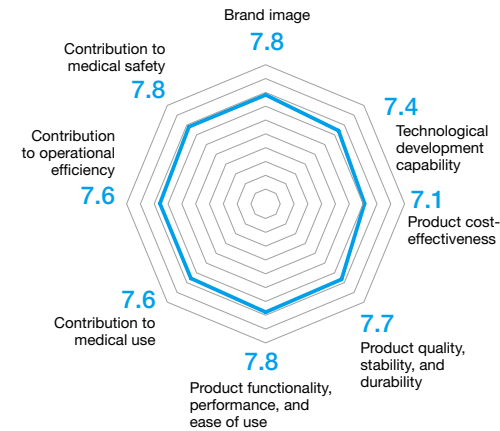
* The NPS® survey is conducted to quantify the degree of attachment to and trust in a company or brand, which has traditionally been difficult to measure, in order to evaluate the customer's experience at the point of contact with the company and apply it to improvements through future business activities. 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 FY2021 (Overall Score)

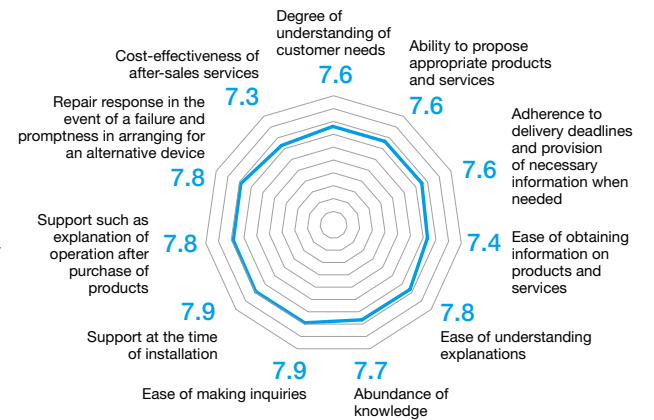


NPS Survey Results in FY2021 (Individual Scores) * 10-point scale for each item

Corporate Image and Contribution to Customer Value



Satisfaction with Sales and Services



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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 safety managers 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 FY2021, as in the previous fiscal year, it remained difficult to hold face-to-face workshops in the resurgence of the COVID-19. We held remote workshops and provided safety information needed in clinical practice using educational materials such as DVDs and slide presentations with voice-overs.

(FY2021 results: 610 workshops, educational materials provided to 290 facilities)

Main workshop topics

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

* MDIC is an accreditation program established by the Japan 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. The Company has promoted reduction of traffic accidents by providing sales and services personnel with company vehicles equipped with collision avoidance support systems, lane departure warning systems, automatic high-beam switching systems and drive recorders as standard equipment, and studded tires as required. Vehicles equipped with cold weather specification are also provided for employees working in extremely cold areas to promote reduction of traffic accidents. In addition, due to the revision of the enforcement regulations of the Road Traffic Act in Japan that is effective from April 2022, it becomes mandatory to check the influence of alcohol before and after driving and keep a record of the check. Nihon Kohden is working to establish operation systems to respond to this regulation at all domestic offices.