# 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.**

## Message from Operating Officer

**Yoshiyuki Fujita**
Operating Officer,
General Manager of Corporate
Quality Management Operations

The role of the Operating Officer in charge of Quality Management is to provide safe and effective medical equipment and services to customers by supporting and providing guidance to individual departments, such as R&D, production, sales, and maintenance, based on the Quality Management System (QMS) required of medical equipment manufacturers by laws and regulations related to medical equipment in each country.

To ensure that the world envisioned in Nihon Kohden's Long-term Vision, BEACON 2030, underpins and realizes "high quality as a matter of course," I will develop a system that enables the Group to maximize its functions. As shown in our QMS, in Corporate Quality Management Operations, which was newly established in April 2023, three divisions share the duty to "maintain and enhance the QMS," "build quality into medical equipment and services," and "contribute cross-functional QMS of the Group companies," while mutually sharing information and providing feedback to management.

All employees of the Nihon Kohden Group work to achieve the quality targets set by each department based on our Management Philosophy. Minimizing the number of repairs and recalls will help provide customers with safety and peace of mind when using our medical equipment and services.

Unfortunately, two software recalls were conducted in FY2022. Although the recalls did not result in the replacement or disposal of products or parts, I realize that quality improvement is also a sustainability promotion activity that contributes to reducing $CO_2$ emissions. We will continue our efforts to realize our Long-term Vision through sophisticated quality activities throughout the entire Nihon Kohden Group.

## 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 FY2022, Nihon Kohden conducted two 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 FY2023, 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 strengthened its regulatory compliance in each country where its products are sold, improved its global post-marketing monitoring, and enhanced its QMS in April 2023. Under the new structure, we will thoroughly collect and deploy information on medical device-related laws and regulations in each country to shorten the time required for global product registration and ensure the timely supply of products. We will also continue to improve our post-marketing monitoring system and use the information obtained to improve internal processes and provide feedback to design teams 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 PSIRT (Product Security Incident Response Team) to provide appropriate support for early recovery in the event of a security incident. We will continue to strengthen our cyber security response.

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### (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 and speed, and respond to customer feedback in an appropriate and timely manner. In addition to third-party evaluations of software design, we will 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: 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 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.

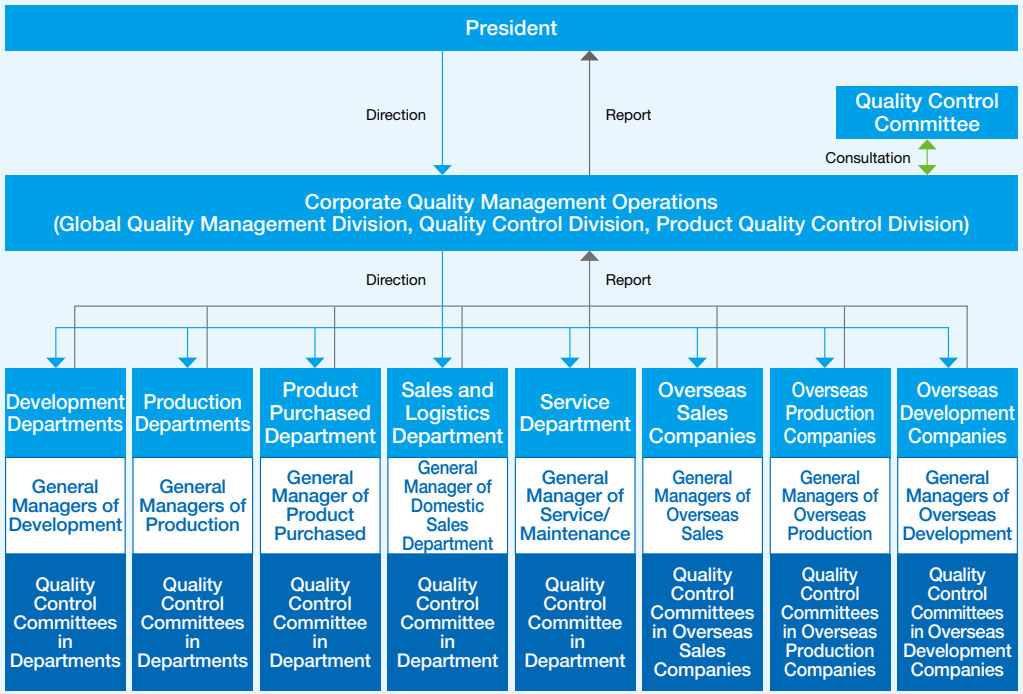
To achieve the above quality targets and pursue customer value, we will develop human resources by providing practical training across all Nihon Kohden departments.

# Improving Safety and Reliability

## 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 OrangeMed, Inc. | - | June 2019 |
| Nihon Kohden America, LLC | - | March 2016 |
| Defibtech, LLC | - | February 2004 |
| 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.

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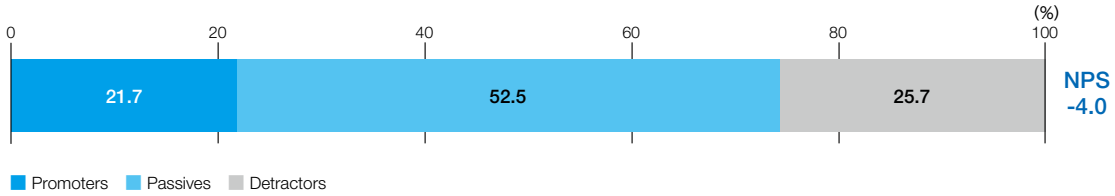
## Net Promoter Score (NPS) Surveys

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 FY2022, we conducted the second survey. The overall NPS survey score in FY2022 improved by 1.3 points to -4.0 from -5.3 points in FY2021.

In terms of individual scores, the score for Contribution to Operational Efficiency improved by 0.1 points and the score for Cost-effectiveness of After-sales Service worsened by 0.2 points, indicating that improvement is needed. Through the NPS survey, we will make continuous improvements by analyzing areas that need improvement and taking measures to address then, including those areas that have been highly evaluated by our customers. As a partner to medical institutions and 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 FY2022 (Overall Score)

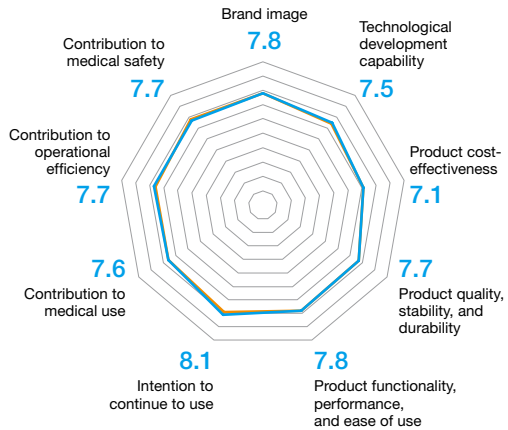



### NPS Survey Results in FY2022 (Individual Scores)

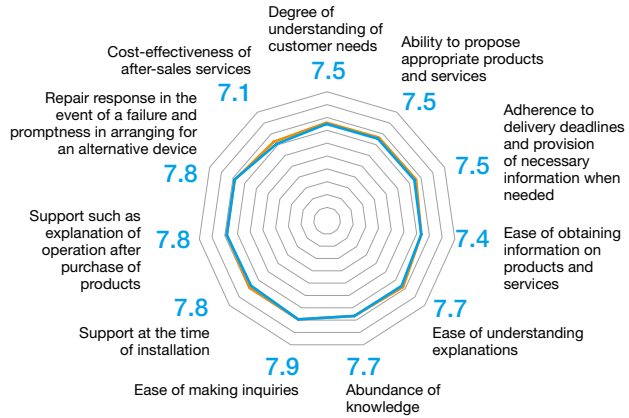
* 10-point scale for each item

FY2022 FY2021

#### Corporate Image and Contribution to Customer Value




#### Satisfaction with Sales and Services



# Improving Safety and Reliability

## 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 FY2022, 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.

(FY2022 results: 716 workshops, educational materials provided to 261 facilities)

### Main workshop topics

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

* 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 regarding infection prevention raising. 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 introduction of mandatory pre- and post-driving alcohol checks and record-keeping, all of our domestic sales offices use alcohol checkers to check and record alcohol consumption.