Product Responsibility

Quality Assurance

Basic Approach and Policy

Olympus has established its Olympus Group Quality Policy based on the Olympus Group Corporate Philosophy and the Olympus Group Corporate Conduct Charter. The policy was revised in October 2017 to define the Group's basic policy direction in activities aimed at improving quality and safety, and to define a code of conduct to ensure the utmost focus on quality, which defines the fundamental direction of the Group's quality activities to provide products and services for society that are beneficial, safe and of high quality.

Olympus Group Quality Policy

The Olympus Group will pursue value that is genuinely wanted by our customers, act with the utmost focus on quality and will sustainably deliver safe products and services that are useful to society.
To this end, the Olympus Group will continue to maintain and improve the effectiveness of its quality management system in full conformance with regulatory requirements.

Code of conduct for ensuring the utmost focus on quality

1. Customer-centric approach
   We will keep our customers and patients in mind, fully focus on their safety and need, and act in a sincere manner.
2. Ensuring compliance with laws, regulations and social norms
   We will strive to fully and correctly understand and comply with all relevant laws, regulations and social norms, as this understanding and compliance forms the foundation for the delivery of safe, reliable products and services to our customers and patients.
3. Constant quest for quality
   We will never be content with the status quo when it comes to the quality of all relevant business processes, which will boost the safety and quality of our products and services.
4. Appropriate communication
   We will provide useful and accurate information in an appropriate manner to our customers and patients in order to ensure their safety and peace of mind.

In fiscal 2017, the second year of the Group's medium-term management plan adopted in 2016, efforts were directed to reorganizing the quality management system for the entire Olympus Group, including revising the Olympus Group Quality Policy, and reinforcing its global compliance organization by providing quality and product regulations. In fiscal 2018 we will focus on greater employee awareness of quality and improvements in business operations to ensure products that are safe and of high quality and to strengthen the product-related statutory compliance process.

Quality Management System

Each business unit and group company in the Olympus Group actively seek certification under an international quality control standard—either ISO 9001 or ISO13485. They also build individual quality management systems that comply with the legal requirements in each country, while accurately understanding the quality demands of our markets, maintaining and improving the quality of existing products, and aiming to enhance customer satisfaction toward further global business expansion.

Quality Improvement Activities

Our medical, scientific solutions, and imaging business units are improving their quality management system across the globe. They gather data concerning customer inquiries and quality-related issues and utilize the data analysis results in making quality improvements.

The Olympus Group also vigorously invests in human resource development through quality management seminars focused on ISO9001, ISO13485, and the relevant laws and regulations of each country, as well as utilization of an e-learning system. We also utilize external consultants aiming at better quality management through their assessments and reviews.

Improvement in Product Usability and Safe Usage

The Olympus Group manages risks concerning product safety, providing information for customers on using our products safely and effectively through instruction manuals and product labeling, in conformance with the laws and regulations of each country. We also have our own medical product usage training centers in Tokyo, Germany, China (Shanghai, Beijing, and Guangzhou), Thailand and Korea. These provide training on endoscope knowledge and handling for medical staff so that they can use our medical equipment safely. We established Olympus Korea Medical Training & Education Center (K-TEC) in 2017 to offer product demonstrations and training sessions for medical staff in Korea and contribute to the development of medical industry.

Efforts in Health and Safety

The Olympus Group publishes the "Olympus Group Control Rules for Chemical Substances Used in Products," based on the latest information concerning chemical substance handling and the legal frameworks in each country. These rules clarify the chemical substance standards used in Olympus Group products to ensure the health and safety of customers and patients who use the products. The latest version of the Control Rules, updated in fiscal 2018 is Edition 12 and is available on the following website:

Olympus Group Control Rules for Chemical Substances Used in Products
https://www.olympus.co.jp/csr/effort/pdf/annexA_Ver12_en.pdf?page=ir

Example of Quality Evaluation at the Development Stage

As a part of quality evaluation during the development phase of Olympus products, our intra-company test and evaluation center conducts calibrations, Electromagnetic Compatibility (EMC), product safety testing, usability evaluations, mechanical and environmental tests, material analyses, electronic component analyses, and failure analyses. As these tests and evaluations are important for ensuring our products' quality and safety, we insist that they are conducted in a fair and reliable manner. To verify this, our test center has obtained certification as a third-party testing laboratory.

Calibration

Calibration is a process used to maintain the accuracy of measuring instruments by ensuring that all components are functioning correctly. The precision of measuring instruments can vary from day to day in response to changes in environmental conditions. Olympus is accredited as an ILAC-MRA*1 member and carefully monitors errors caused by these changes and applies approved calibration methods to its measuring equipment.

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) testing is carried out to ensure that electrical and electronic equipment will not emit electromagnetic noise that exceeds acceptable levels and could affect other equipment, and that it will not malfunction when exposed to such emissions. The significance of EMC is being recognized more widely in recent years, and related regulations were enforced in various countries. We test our products in a 10 m anechoic chamber*2 and an electromagnetic field immunity test chamber*3.

*1 ILAC-MRA International Laboratory Accreditation Cooperation—Mutual Recognition Agreement

*2 10 m anechoic chamber
Olympus has three 10 m anechoic chambers that were certified for use in electromagnetic testing under the National Voluntary Laboratory Accreditation Program (NVLAP) of the United States.

*3 Electromagnetic field immunity test chamber
This chamber is used to confirm that electrical and electronic devices do not malfunction by exposing them to specific electromagnetic fields. With the dissemination of wireless communication devices, action is underway to expand the test frequency range and upgrade testing levels. The chamber at Olympus is capable of testing at frequency ranges of 80 MHz–6 GHz and a maximum test level of 30 V/m.

Product Safety Testing

For medical equipment, it is particularly important to conduct product safety tests. Olympus conducts safety tests, including a conformity assessment test (compliant with IEC 60601-1), as a third-party testing laboratory.

Mechanical and Environmental Testing

Taking account of various conditions of usage, storage, and transportation, mechanical tests assess product strength and life expectancy. Tests include a vibration test, drop test, and environmental tests, including operational humidity and temperature, to confirm that products will maintain their performance and have sufficient strength and life.

Materials Analysis

Olympus not only analyzes and assesses parts and materials, but also uses various analytical systems to identify defects and other issues through detailed analyses carried out after products have been brought to market. Findings from these analyses are used to eliminate the causes of problems and prevent recurrences.

Electronic Component Analysis and Failure Analysis

We conduct electronic component analyses to prevent the components used in a new product from causing failures. We also analyze failures that have occurred in test products and commercialized products.

Valuing Bioethics in Evaluating of Product Efficacy and Safety

Olympus conducts animal research as required to develop medical equipment and evaluate equipment efficacy and safety. We are keen to ensure that the research we carry out is ethical from both the scientific and animal welfare viewpoints, because we value the lives of animals.

Olympus introduced its animal research corporate rules based on the Act on Welfare and Management of Animals, Basic Guidelines for Animal Research in Institutions under Management of the Ministry of Health, Labour and Welfare and other related laws and guidelines. We established our Animal Research Ethical Committee based on the animal research corporate rules to rigorously review all our animal research plans and ensure that they are based on the 3Rs of animal welfare —Replacement (of animal testing with alternative methods), Reduction (of the number of animals to be used), and Refinement (of the testing method to minimize animals' suffering). We are committed to handling all the animals used in our research ethically and humanely, paying extra attention to animal welfare. We also conduct regular self-inspections to ensure that our animal research is carried out appropriately and our practice is accredited under the Accreditation for Laboratory Animal Care and Use by the Japan Health Sciences Foundation.

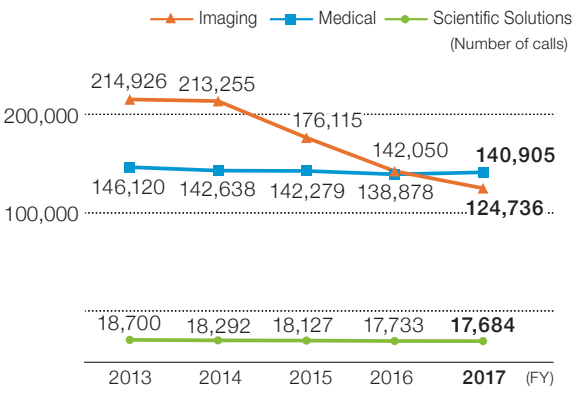
Improvement of Sales/After-Sales Service Quality (Responses to Inquiries/Repairs)

Olympus has systems in place to respond to customer inquiries and repairs in Japan and overseas for different product fields and in different regions. As regards points of contact for inquiries, information relating to after-sales services in general is provided via a Product Support link on our website. Important information concerning safety or consumer protection is made known via Important Announcements for Customers on our website.

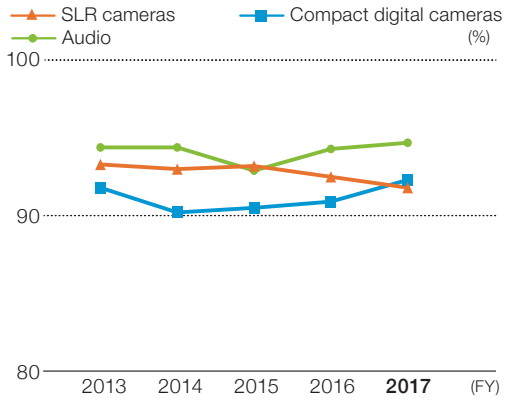
We have developed a repair service network to meet user needs in each region and product category.

Outlines of customer response activities in each business field and of the efforts of the repair service network are set out below.

◎Calls Received at Customer Support Centers (in Japan)



◎Percentage of Repairs Completed within the Allotted Time in Imaging Business (in Japan)



◎Customer Response Structures in Each Business

Business Field	Outline of Activities
Medical	[Japan] ● Olympus has developed service systems designed to ensure the safety and reliability of healthcare environment. • Establishment of Medical Customer Information Center, a call center dedicated to providing an information service for medical specialists. • Formation of a team for specialist services offering information on how to handle medical treatment devices, troubleshooting, etc. • More than 95% telephone connection rate • Major medical devices are retained inside the call center so we can provide accurate answers to inquiries • Immediate response system based on coordination and interaction among call centers and Olympus sales/service personnel or authorized vendors in various regions. • Medical Town, a special website that offers up-to-date information on medical endoscopes and related medical treatment for medical specialists. • Share call center inquiry contents inside the company leading to product and service improvements • Advanced efforts utilizing AI to improve customer responses [Overseas] ● Olympus has established call centers in major cities. • Call centers have also been set up in major cities in the USA, China, and Europe for localized and extensive services.
Scientific Solutions	[Japan] ● Call Center • Running Customer Support Center to solve customers' problems in using our products ● Technical assistance • Running the Olympus Techno Lab for customers to experience our products and evaluate their performance • Held Microscope Training Program for customers to learn how to use the product correctly [USA] ● Opening of Olympus Discovery Center in the University of Texas at Dallas • Under collaboration with the University of Texas at Dallas, we opened a product training center for users. ● Offering support for Mexican Navy and a rescue team • After the 2017 Central Mexico earthquake, Olympus donated an industrial videoscope to the Mexican Navy and the Topos de Tlatelolco, a non-profit emergency rescue team, to help in the search for survivors who may be trapped under collapsed buildings and rubble. [Europe] ● Olympus Academy activities • Manned by specialist staff, the Olympus Academy provides training in products and applications for subsidiaries and sales agents in various countries. Product and application seminars are then held for customers by the subsidiaries and sales agents that have undergone such training themselves.
Imaging	[Japan] ● Call center staffed seven days a week, including national holidays (Note: Excluding system maintenance days and year-end/New Year holidays) ● Enhanced telephone and e-mail support per product category ● Enhancing responses at call center • Enhancing the quality of telephone responses by various means, including improving the communication skills and product knowledge of call center staff members, through "mystery shopper" surveys undertaken by external organizations and by e-mailing customer questionnaires • From August 2015, lines into the call center changed to a nationwide call-handling service ● Q&A and other information made public via our website ● Supervision and management of global response results [Overseas] ● Olympus has established call centers in major cities. • Call centers have also been set up in major cities in the USA, China, and Europe to provide detailed responses tailored to the areas they cover.

◎Repair System per Business Field and Improvement Efforts

Business Field	Outline of Activities
Medical	**Minimizing downtime of endoscope** To minimize endoscope downtime during malfunction or repair work, both Shirakawa and Nagano service centers (Domestic Repair Division) collectively control and carry out repair operations as well as handling of loaners. **Endoscope service networks** Major repairs (Repairs in need of overhaul) Japan: Medical Equipment Service Operation Centers located in Shirakawa and Nagano Overseas: Service centers in the United States, Germany, France, Czech Republic, United Kingdom, Russia, China, India, etc. Simple repairs (to endoscopes and peripherals): Available through a worldwide network of approx. 170 repair bases
Scientific Solutions	**Providing repair services to the same high level at service bases across the world** The following services are provided at domestic and overseas manufacturing sites, sales subsidiaries and contracted agents • Microscopes: Back-to-base repairs, on-site repair services, function inspections, precision calibration, service contracts, delivery installation • Industrial endoscopes: Back-to-base repairs, function inspections, service contracts • Non-destructive testing devices: Back-to-base repairs, on-site repair services, function inspections, precision calibration • X-ray analytical systems: Back-to-base repairs, function inspections
	Back-to-base repair services Portable devices and those that may require extensive repairs are collected and repaired in an environment equivalent to the production line. Devices that are collected for repair are normally returned within one month of receipt.
	On-site repair services For installation-type products, technical staff is dispatched to provide on-site services, including repairs, calibration and maintenance inspections. **Service contracts** Depending on the product, Olympus offers a number of maintenance service contracts.
Imaging	**Greater repair service convenience with a variety of services and schemes** In Japan, the following services are provided by the Hachioji Repair Center, Olympus Plaza Tokyo, Olympus Plaza Osaka and the service stations in Sapporo and Fukuoka: (1) Pickup service via website and telephone (2) On-line repair booking and estimating service Internet-based repair service offering applications for servicing and information on repair fees and repair status (3) Quick Repair Service (Applied to mirrorless SLR camera bodies and interchangeable lenses) Service for reducing repair time (4) Camera cleaning service (Applied to Olympus digital cameras and interchangeable lenses) (5) Digital Camera Maintenance Seminar Hands-on-style seminars for digital camera owners on cleaning their cameras and interchangeable lenses under instruction were held in Olympus Plaza in Tokyo and Osaka, and other service stations in Sapporo and Fukuoka. (6) Olympus Owners Care Plus (OOC+) The OOC+ service offers Olympus camera owners functional diagnoses and camera servicing, customization (e.g. changing colors of external parts), and rental lenses. A Maintenance Package service for our flagship model, the E-M1 Mark II, also started to coincide with the commencement of sales. **For worldwide overseas repairs** Overseas, repair services tailored to the areas they cover are provided by repair bases in the USA, Portugal, Czech, Republic, Russia, Australia, China, South Korea, Hong Kong, Singapore, Thailand and Malaysia.
	Improving the on-time rate for back-to-base repairs One of our target indicators for customer satisfaction is the on-time rate for back-to-base repairs, the achievement rate of which we verify on an annual basis.