

# Product Responsibility

## Quality Assurance

### Basic Approach and Policy

The Olympus Group has established its Quality Policy based on the Olympus Group Corporate Philosophy. 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.

### 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 2018, we implemented actions based on our Corporate Strategic Plan to strengthen both the organizational and system aspects of the quality regulation functions. Global action has been taken to increase the number of employees in the quality regulation divisions, mainly for the Medical Business, in addition to reinforcing the compliance for regulations, product registration and post market surveillance. We are also continuing activities to build a group-wide corporate culture with a greater focus on safety and quality.

Based on our Corporate Strategic Plan and our corporate transformation plan Transform Olympus, we will take actions to establish and implement compliance and governance systems worthy of a truly global company in 2019.

### ■ Improving our business performance quality

The Olympus Group believes that a high level of performance quality will lead to improvements in our corporate value. Hence, the Quality Policy has been established not only for organizations directly linked to products (development and manufacturing, etc.) but as an Olympus Global Rules. We plan to upgrade our business performance quality based on the actions of each employee in the Group under our Quality Policy and to provide products and services that are safe and beneficial to society and support our contributions to society.

### ■ From the customer perspective

To ensure that products in the Medical Business are used safely, we have set up training centers for healthcare professionals to provide education and training of endoscope in Japan, Germany, China (Shanghai, Beijing and Guangzhou), South Korea and Thailand. In the Scientific Solutions Business, videos on product use and applications are available on our website to provide various information suited to customer needs.

### ■ Strict compliance with laws and social norms

The Olympus Group is encouraging its business divisions and group companies to obtain ISO 9001 and ISO 13485 certification, the international standards for quality management. At the same time, we have established quality management systems adapted to local laws and regulations to assess the status of market quality. We are thus promoting measures to maintain and improve product quality and increase customer satisfaction. We have also organized seminars and e-learning programs for training in quality management systems adapted to local laws and regulations.

### ■ Pursuit of quality

The Olympus Group will never be satisfied with the status quo and continues to pursue advancement in the quality of its operational processes. In Imaging business, for example, it was this policy that encouraged Olympus in February 2019 to introduce the OM-D E-MIX, a model with the world's highest\* image stabilization equivalent to 7.5 shutter speed. This was achieved through the Development Group's determination to create new value, combined not only with joint development with suppliers of the materials and services but also as a result of our pursuing quality in our performance evaluation methods and manufacturing processes as we develop new technology.

\*As of February 2019

### ■ Appropriate information disclosure

The Olympus Group has gathered information on handling environment-related substances, regulatory trends, etc., in countries around the world and established Control Rules for Environment-Related Substances Used in Products, which are published on our corporate website. We explicitly define the criteria for environment-related substances found in Olympus Group products to assure safe product use by our customers and patients.

Olympus Group Control Rules for Environment-Related Substances Used in Products  
[https://www.olympus.co.jp/csr/effort/pdf/annexA\\_Ver12\\_en.pdf?page=ir](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 Group 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.

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

## ■ 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 of other equipment, and that it will not malfunction in the presence of such emissions. As the significance of EMC is being recognized more widely in recent years, its related regulations were enforced in various countries. We test our products in a 10 m anechoic chamber\*<sup>2</sup> and an electromagnetic field immunity test chamber\*<sup>3</sup>.

### \*<sup>2</sup> 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.

### \*<sup>3</sup> 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.

We own two test chambers, and both chambers at Olympus are 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.

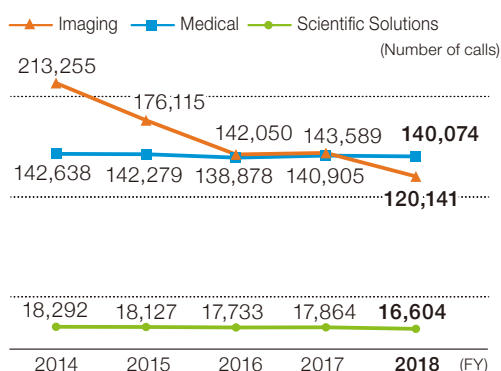
Olympus introduced its animal research corporate rules based on the Act on Welfare and Management of Animals, Basic Guidelines for Animal Research in Institutions under Management of the Ministry of Health, Labour and Welfare and other related laws and guidelines. We established our Animal Research Ethical 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)

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

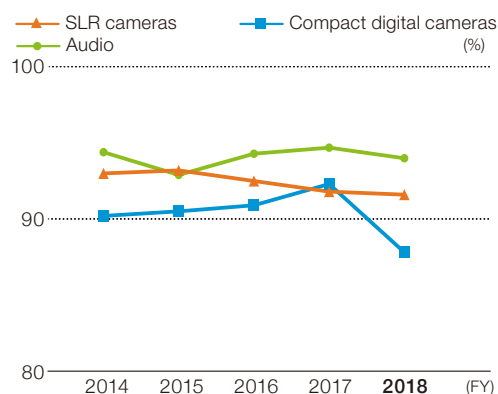
We have developed a repair service network to meet user needs in each region and product category. Outlines of customer response activities in each business field and of the efforts of the repair service network are set out below.

### ○ Calls Received at Customer Support Centers (in Japan)



\* In Medical Business, the number of calls only by telephone until FY2017. The number has been including inquiries at website since FY2018.

### ○ 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	<p>[Japan]</p> <ul style="list-style-type: none"> <li>● Olympus has developed service systems designed to ensure the safety and reliability of healthcare environment.               <ul style="list-style-type: none"> <li>• Establishment of Endoscopes Customer Support Center, a call center dedicated to providing an information service for healthcare professionals.</li> <li>• Formation of a special team for offering information on how to handle medical devices, troubleshooting, etc.</li> <li>• More than 95% immediate telephone connection rate</li> <li>• Major medical devices are retained inside the call center so we can provide accurate answers to inquiries</li> <li>• Introducing advanced technologies such as AI to improve quality of response</li> <li>• Immediate response system based on coordination and interaction among call centers and Olympus sales/ service personnel or authorized vendors in various area.</li> <li>• Medical Town, a membership website that offers up-to-date information on medical endoscopes and related medical treatment for healthcare professionals.</li> <li>• Share call center inquiry contents inside the company for the purpose of product and service improvements</li> </ul> </li> </ul> <p>[Overseas]</p> <ul style="list-style-type: none"> <li>● Olympus has established call centers in major cities.               <ul style="list-style-type: none"> <li>• Call centers have also been set up in major cities in the USA, China, and Europe for localized and extensive services.</li> </ul> </li> </ul>
Scientific Solutions	<p>[Japan]</p> <ul style="list-style-type: none"> <li>● Call Center               <ul style="list-style-type: none"> <li>• Running Customer Support Center to solve customers' problems in using our products</li> </ul> </li> <li>● Technical assistance               <ul style="list-style-type: none"> <li>• Running the Olympus Techno Lab for customers to experience our products and evaluate their performance</li> <li>• Holding Microscope Training Program for customers to learn how to use the product correctly</li> </ul> </li> </ul> <p>[USA]</p> <ul style="list-style-type: none"> <li>● Expanding training opportunities               <ul style="list-style-type: none"> <li>• In addition to training programs for customers in the safe use of Olympus products, a program has been created to train engineers in nondestructive inspection. Because nondestructive inspection devices are widely used in the inspection of petroleum pipelines, etc., Olympus products have been donated to a university in Pasadena, Texas, known prominently for its ties with the petroleum industry, for training in the use of our products.</li> </ul> </li> </ul> <p>[Europe]</p> <ul style="list-style-type: none"> <li>● Olympus Academy activities               <ul style="list-style-type: none"> <li>• Manned by specialist staff, the Olympus Academy provides training in products and applications for subsidiaries and sales distributors in various countries. Product and application seminars are then held for customers by the subsidiaries and sales distributors that have undergone such training themselves.</li> </ul> </li> </ul>
Imaging	<p>[Japan]</p> <ul style="list-style-type: none"> <li>● Call center staffed seven days a week, including national holidays (Note: Excluding system maintenance days and year-end/New Year holidays)</li> <li>● Consolidating telephone responses by the various service bases in a call center to integrate inquiries on product repair and usage. The customer support system has been strengthened as a one-stop service operation.</li> <li>● The communication skills and product knowledge required by the personnel handling product inquiries by phone or email have been strengthened to upgrade service quality through email questionnaire surveys and "mystery shopper" surveys by external organizations.</li> <li>● Q&amp;As and other information have been published on the corporate website. Chat Support was introduced in December 2018.</li> <li>● Supervision and management of global response results</li> </ul> <p>[Overseas]</p> <ul style="list-style-type: none"> <li>● Olympus has established call centers in major cities.               <ul style="list-style-type: none"> <li>• 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.</li> </ul> </li> </ul>

## Repair System per Business Field and Improvement Efforts

Business Field	Outline of Activities
Medical	<p><b>Minimizing downtime of endoscope</b> 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.</p> <p><b>Endoscope service networks</b> 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</p>
Scientific Solutions	<p><b>Providing repair services to the same high level at service bases across the world</b> The following services are provided at domestic and overseas manufacturing sites, service bases, sales subsidiaries and contracted agents</p> <ul style="list-style-type: none"> <li>• Microscopes: Back-to-base repairs, on-site repair services, function inspections, calibration, service contracts, delivery installation</li> <li>• Industrial endoscopes: Back-to-base repairs, function inspections, service contracts</li> <li>• Non-destructive testing devices: Back-to-base repairs, on-site repair services, function inspections, precision calibration</li> <li>• X-ray analytical systems: Back-to-base repairs, function inspections</li> </ul> <p><b>Back-to-base repair services</b> 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 almost one month of receipt.</p> <p><b>On-site repair services</b> For installation-type products, technical staff is dispatched to provide on-site services, including repairs, calibration and maintenance inspections.</p> <p><b>Service contracts</b> Depending on the product, Olympus offers a number of maintenance service contracts.</p>
Imaging	<p><b>Greater repair service convenience with a variety of services and schemes</b> 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:</p> <ol style="list-style-type: none"> <li>(1) Pickup service via website and telephone</li> <li>(2) On-line repair booking and estimating service Internet-based repair service offering applications for servicing and information on repair fees and repair status</li> <li>(3) Quick Repair Service (Applied to mirrorless SLR camera bodies and interchangeable lenses) Service for reducing repair time</li> <li>(4) Camera cleaning service (Applied to Olympus digital cameras and interchangeable lenses)</li> <li>(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.</li> <li>(6) Olympus Owners Care Plus (OOC+) The OOC+ service offers Olympus camera owners functional diagnoses, maintenance services, and rental lenses. A Maintenance Package service for the E-M1X also started to coincide with the commencement of sales. The long-term maintenance services for E-M1X and E-M1 Mark II are provided, and we offer customers safety for our products.</li> </ol> <p><b>For worldwide overseas repairs</b> 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.</p> <p><b>Improving the on-time rate for back-to-base repairs</b> 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.</p>