# B Further Strengthen Leadership in Endoscopy

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## **Operating Environment / Priorities for Business Growth**

### **Operating Environment**

- Rising case numbers due to aging populations in developed countries
- and higher cancer prevention awareness
- Wider range of business opportunities accompanying economic growth and need for training to spread procedure usage in emerging
- countries
- Higher requirements for quality and efficiency
- Increased concern for cleaning, disinfection and sterilization processes

 Growing maturity of 3D system market over the medium term and normalization of imaging sensors and data transferring technology compatible with 4K systems driving acceleration of full 4K system introduction

 Distinctive R&D activities related to special light imaging technologies being advanced by various companies and permeating the market

## **Priorities for Business Growth**

- Maintenance of endoscope market share and improvement of profitability
- Establishment of new de facto standard in surgical endoscopes market
- Significant upside in single-use endoscope
  Evolve the commercial model of endoscopes
- (Shift toward value-based payment)
- Contributions to development of endoscopic medicine in emerging countries

## Target and Measures (FY2021–FY2023)

Maintain Leadership in Reusable Endoscopes	Product Innovation	<ul> <li>Contribute to professionals irregular lesior</li> <li>Introduce Al-e</li> </ul>
	Commercial Excellence	<ul> <li>Build value pro new Olympus</li> </ul>
	Regional Growth	<ul> <li>Continue to gr markets</li> </ul>
Complement Portfolio with Single-Use Endoscopes	Prioritizing Focus Areas	• Target scopes
	Strengthening R&D and Manufacturing	<ul> <li>Strategic investigation</li> </ul>
Evolve the Commercial Model of Endoscopes	<ul> <li>Initiate trials of evidence or procedu</li> <li>Scale up pilot programs of wrap-are</li> </ul>	



## Progress

- Successful launch of next-generation EVIS X1 GI endoscopy system in EMEA, Japan and Asia Pacific introducing innovative imaging features like RDI/TXI/EDOF
- Launch of Medpresence SW solution to allow "medical virtual presence" in hospitals in times of global COVID-19 pandemic crisis
- Finalizing AI system for CAD (detection and characterization) applications in GI endoscopy
- Launch preparation on going ORBEYE (surgical microscope) IR/BL feature in the United States

## **Future Priority Measures**

- Complement our portfolio with single-use endoscopes to provide a comprehensive set of product offerings
- Evolve the commercial model towards service-based and procedure-based offerings
- Enabling cloud based data collection from wide range of installed devices for improved service contract offers
- VISERA ELITE II launch in the United States and China market

b improving quality of endoscopic procedure by supporting healthcare s (HCPs) in the detection, characterization, staging, and treatment of ons by NBI/RDI/TXI/EDOF function of EVIS X1 -enabled CAD (computer-aided diagnosis) to EVIS X1

roposition by clinical evidence to demonstrate the positive impact of s product features on the quality of endoscopic diagnosis

grow the pool of qualified HCPs in underpenetrated high-growth

es for duodenum, biliary duct and urinary duct

estment in R&D and manufacturing for single-use endoscopes

lure-based payment models for targeted products and regions round services



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## **Business Strategy**

# Introduced Next-Generation **EVIS X1 Endoscopy System**

The launch of the EVIS X1 system further strengthens Olympus' leadership in endoscopy, as the Company aims to continue contributing to society by making people's lives healthier, safer and more fulfilling.



# EVIS X1

Olympus launched the EVIS X1 endoscopy system in EMEA. Australia, India and Hong Kong in April 2020 and commenced sales in Japan in July 2020. Our most advanced endoscopy system to date, EVIS X1 has undergone a model change from the previous EVIS EXERA III and EVIS LUCERA ELITE models for the first time in about eight years. The global key message for EVIS X1 is "Let's Be Clear-Elevating the Standard of Endoscopy." Aiming to improve the quality of endoscopic procedure in the detection, characterization, staging, and treatment of irregular lesions, as well as examination efficiency by endoscopy, the EVIS X1 system contributes to early detection, early diagnosis, and minimally invasive treatment of gastrointestinal diseases such as cancer by being equipped with a variety of new technologies that embody this message.

## HISTORY

Through the introduction of EVIS 1, our first production model, we found that the needs of endoscopists differ by country. We have subsequently been meeting the needs of each country with two systems: the 100 series, which prioritizes real-time images and the reproduction of smooth and natural movements; and the 200 series, which prioritizes color reproducibility and the highest quality still images. The EVIS X1 is a model that meets these needs in one product.



EVIS 1

### 1989

EVIS 100/130 series EVIS 200/230 series

### Introduction of First Olympus Video Endoscopy System\*

\* A video endoscope is a system whereby a charge-coupled device (CCD) is used to convert images into electrical signals transmitted to the monitor. This enables minations while looking at the monito

100 Series: Simultaneous method Excellent real-time images,

## 200 Series: Sequential-frame method Excellent image reproducibility, high-quality still images

## 2006-2007

100 Series EVIS EXERA 200 Series EVIS LUCERA

### Downsized CCD

2000-2002

 Introduction of endoscopes with HD technology

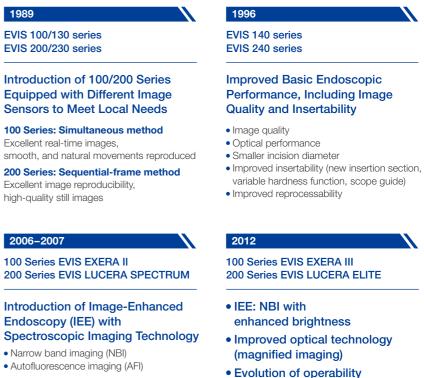
## • Narrow band imaging (NBI)

• Autofluorescence imaging (AFI)

## STRATEGY

## **Developing a Rich Product Portfolio Based** on a Globally Unified Platform

EVIS X1 is a system that achieves global integration while maintaining compatibility with existing systems. Olympus provides a wide variety of scopes by maintaining compatibility with scopes developed for existing endoscopy systems, in addition to the special scopes for EVIS X1, by best utilizing the globally unified platform of EVIS X1. This makes it possible for physicians to use scopes that were not previously available in their regions and had been deployed to other regions. For example, the PowerSpiral small intestine endoscope system was available only with the EXERA series, while the ultra high-magnifying Endocyto endoscope was available only with the LUCERA series. This is because we selected the products to introduce to meet the different needs of each region. However, to meet endoscopists' needs, which have been diversifying in recent years, we will develop a rich product portfolio based on a globally unified platform.



# **Creating Clinical Value with**

## the New Features of EVIS X1

Olympus has been developing technologies that contribute to improving the quality of endoscopy, such as narrow band imaging (NBI). This time, we have developed three new imaging technologies that support the provision of new diagnoses and treatments: Texture and Color Enhancement Imaging (TXI), Red Dichromatic Imaging (RDI), and Extended Depth of Field (EDOF). Going forward, we will strengthen activities to pursue clinical usefulness by adapting these technologies to each stage, such as detection,

technologies

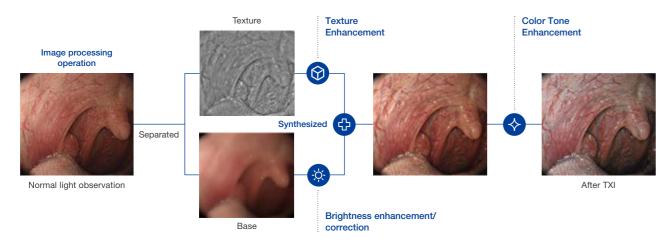
characterization, staging, and treatment. Specifically, we will use TXI for detection and the combination of EDOF and NBI for characterization and staging, as the gold standard procedure to contribute to endoscopy medical services around the world.

## TECHNOLOGY

## **Innovative Imaging Technologies**

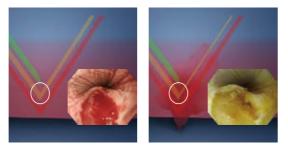
# **Texture and Color Enhancement Imaging**

TXI supports better visibility of potential lesions (such as areas of inflammation, flat or depressed lesions, or even tiny precursor lesions) through enhancing texture, brightness, and color to define subtle tissue differences more clearly. With its advanced imaging technology, TXI holds the potential to reinvent white light in endoscopy. By supporting better visibility of potential and extant lesions, TXI aims to contribute to higher detection rates and improve qualitative diagnosis.



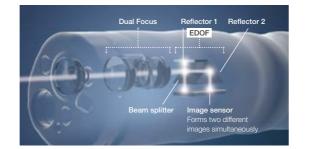
# **Red Dichromatic Imaging**

Gastrointestinal bleeding is a serious challenge, potentially involving considerable mortality risks and management costs. RDI enhances the visibility of deep blood vessels and gastrointestinal bleeding sources, thereby helping to identify blood vessels that could require immediate treatment. It utilizes green, amber, and red wavelengths to visualize deep blood vessels. Easier identification of bleeding spots makes hemostasis quicker and easier while potentially improving the efficiency of any corresponding treatment. This minimally invasive technology could also be expected to help reduce physician stress during endoscopic therapy.





EDOF combines two images at different focus distances into one perfect image to help aid diagnosis and confidant decision-making. It delivers observational excellence through continuous broad focus and seamless magnification. At the same time, the established Dual Focus function provides high magnification, which can be activated by the push of a button. This improved visibility and continuously sharp image has been developed to reduce the necessity for focal adjustments and could be expected to improve efficiency and decrease the oversight rate.



## **A Doctor's Perspective**

In 2020, Olympus introduced EVIS X1

To tell what kind of impact the EVIS X1 system is having on the medical field, we interviewed Dr. Haruhiro Inoue, Professor and Director of the Digestive Diseases Center at Showa University Koto Toyosu Hospital.

which is the globally unified platform. It was about 35 years ago that Olympus introduced the first video endoscope system that allowed us to see lumens, such as those of the stomach and colon, in real time and share those images with an entire team of doctors and nurses via a monitor. I recall that, at that time, doctors in Europe and the United States preferred the simultaneous method, which enabled smooth and natural movements to be reproduced, and Japanese doctors preferred the sequential-frame method, which featured excellent image reproducibility and high-quality still images. Olympus subsequently fulfilled each need by introducing two complete endoscope systems. However, as Japanese doctors specializing in endoscopy gradually became more active internationally, they had to use different endoscope systems in Japan and overseas, which caused some confusion. Following requests from endoscopists-not only from Japan, but also from Europe and the United States-who have said that they would like endoscope system integration, Olympus has introduced the globally unified platform EVIS X1, which is compatible with the two existing systems.

The EVIS X1 system incorporates a variety of new functions. First, the video signal is now 4K, so the images are clear and bright. Since endoscopy is performed while looking at a monitor, the improved image quality is expected to lead more precise manipulation, which may shorten examination time. The Narrow Band Imaging (NBI) that was installed in the conventional system was previously a little dark, but that has also become a lot brighter. In



addition to NBI, a new enhanced image function has been included. A structural color enhancement function, Texture and Color Enhancement Imaging (TXI) emphasize surface irregularities and changes, such as lesions and polyps, in color tone. In contrast to normal lighting, this helps prevent things from being overlooked. Next, there is Red Dichromatic Imaging (RDI), which features the ability to make any areas with bleeding appear yellow, thereby making them easier to discern than red blood. Using RDI makes it easier to see where the bleeding is coming from and assists hemostasis in endoscopic treatments. In addition, the built-in Extended Depth of Field (EDOF) function allows a greater range of focus depth and makes it possible to focus at the push

## From screening to early-stage cancer diagnosis and treatment, EVIS X1 contributes to a wide range of endoscope diagnoses."

of a button. We hope that this EDOF function will promote the standardization of magnified imaging in the years to come. Until now, magnified imaging was not as common in the United States as it is in Japan, due to differences in medical systems and ways of thinking. However, with the advent of new technology that makes focusing easy, I believe that magnified image diagnostics could come to be accepted in the United States as well.

In this way, the EVIS X1 system can cover a wide range of functions, from diagnosis to treatment, in one scope. I believe that the diagnosis and treatment of early stage cancers will become easier not only for expert endoscopists but also for doctors who handle endoscopy in general clinics.

## **Business Strategy**

# Business Growth in Endoscopy Driven by the Chinese Market

The Chinese market has continued to record double-digit growth in recent years. In this section, we outline Olympus' strengths and describe the market conditions and future growth potential.

Olympus' Strengths and Leading Position in China



Prof. Chen Minzhang (second from left), who was then head of the Department of Gastroenterology at Peking Union Medical College Hospital, performs the first endoscopic examination in China in 1972 under the instruction of Prof. Rikiya Fujita (left), an assistant professor at the University of Tokyo 50 years

Around

been expanding in the Chinese market and building relationships of trust with local doctors Number of doctors who have participated in Olympus training programs over the

past five years\*

Approx.

23,000 people

\* FY2016 to FY2020

### BUSINESS

## Leveraging Long-standing Relationships of Trust while Strengthening Business Foundations

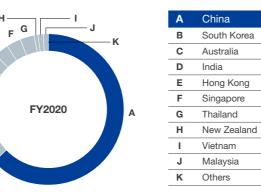
In 1972, the year when diplomatic relations between Japan and China were normalized, an Olympus endoscope was first used in China, and in the almost 50 years since, Olympus has been strengthening its business base in China ahead of other companies. As we expanded our business, it was very important to increase the number of doctors who could operate endoscopes. Since endoscopes are difficult to operate and training is essential, we utilized our own training centers, supported the training of endoscopists and actively cooperated with hospitals and academic societies in the effort to make endoscopy procedures and treatment more widespread. By setting up service sites and strengthening the after-sales services, we also responded to the demand for endoscope maintenance and repair services. In the years to come, we would like to achieve growth in our business domain by continuing to strengthen these efforts.

### Number of Endoscopists per Million People

China	22
Malaysia	17
Vietnam	6
India	5
Thailand	4
Philippines	4
Indonesia	2
(Reference) Japan	250

Source: Olympus Corporation (based on publicly available data)

## Distribution of Revenue by Country in Asia / Oceania



## **Chinese Sales Growth Trends in the Medical Field**



## PERFORMANCE

## Achieved High Growth with Strong Sales to Class II Hospitals

In China, healthcare standards vary according to the classification of hospitals, and patients tend to concentrate in large hospitals, or class III hospitals. The Chinese government has implemented a variety of measures with the aim of resolving this situation. For example, according to the "12th Five-Year Plan" announced in 2011 and the "Healthy China 2030" agenda, as well as the "13th Five-Year Plan" announced in 2016, policies have been adopted for the standardization of local medical institutions, for improvements in medical standards, and to strengthen preventive medicine. In 2019, a working plan for improving the comprehensive capabilities of county-level hospitals was released. This plan aims to raise the healthcare standards of 500 county-level hospitals and 500 Traditional Chinese Medicine (TCM) hospitals to the same level as a class III hospital or class III TCM hospital. In line with this trend to strengthen preventive healthcare, new budgets have been allocated to these class II hospitals, and construction of new hospitals and capital investments are being actively carried out. As a result, Olympus sales have increased, and remarkable growth has been achieved in recent years. (Growth rate by local currency in Endoscopic Solutions Division for FY2020 +28%)

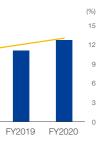
### COLUMN



Online equipment training

COVID-19 spread rapidly beginning late January 2020. In Wuhan, China, a hospital was built in just 10 days to accommodate COVID-19 patients. To install an endoscope system at this hospital, Olympus dispatched employees and created an environment in which examinations and treatment could be performed with endoscopes. For the purpose of providing training suitable to the "new normal," we are strengthening our support system so that hospital staff can receive training on the safe and effective use of equipment in a timely manner by establishing a room for online training in our training center and connecting it with hospitals.

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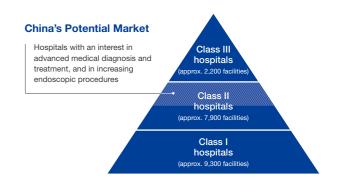




## STRATEGY

## **Business Strategy for the Future**

In China, the early detection and treatment of gastric and esophageal cancers, which have high incidence and mortality rates, can contribute significantly to improving the quality of life of patients and reducing medical costs. Therefore, Olympus is focusing on early-stage cancer diagnosis, which has led to the purchase of high-end equipment for Class II hospitals, and believes that there is considerable room for future market growth. To meet the needs of the healthcare professionals in each region, we have launched a dedicated website for products and procedures and are strengthening the provision of online information. In the years to come, we will continue to provide consistent value, from early detection and early diagnosis with endoscopes to minimally invasive treatments by endoscopy and laparoscopy through collaboration with hospitals and academic societies.



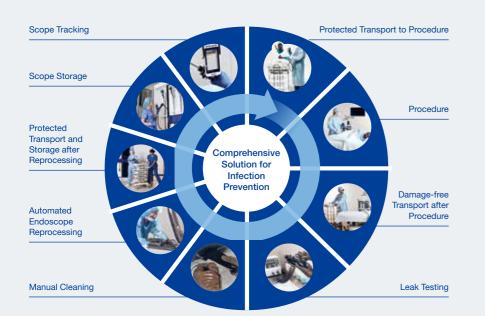
## **Olympus' Response to COVID-19**

## **Reprocessing (CDS: Cleaning, Disinfection, and Sterilization)** Enhancements for Reusable Medical Devices to Promote Patient and Healthcare Professional Safety

Olympus has delivered high performance medical devices across multiple diagnostic and therapeutic areas throughout its long history in endoscopy. Further, Olympus believes that advancements in endoscopic technologies play an important role in patient care. As a key component to the safe and effective use of reusable endoscopes, endoscope reprocessing is gathering more attention from regulatory authorities and hospitals owing in large part to reports of infection events associated with endoscopes. Moreover, novel bacteria and viruses, e.g., multidrug-resistant bacteria and the COVID-19 virus, have recently appeared, leading to increasing awareness of, and attention to, infection risks within the medical community. Olympus is committed to playing an important role in infection prevention and pushing ourselves to ensure that safe, effective products reach healthcare professionals.

## Nothing Is More Important than the Health and Safety of Patients

Olympus' number one priority is the health and safety of patients. Infection prevention is a critical challenge not only for healthcare professionals, but also for medical industry societies, and Olympus strives to support the entire process of endoscope reprocessing to help healthcare professionals focus on patient care. Olympus diligently works to provide maintenance service and training for customers so that our products are used safely, effectively, and as intended. Olympus continues to improve reprocessing procedures by enhancing partnerships with medical and industry societies that likewise seek to enhance product safety. Furthermore, Olympus is exploring design innovations for enhanced safety and plans to continue offering innovative and trusted products in future generations.





Olympus offers products supporting infection prevention while simplifying reprocessing and maximizing efficiency from pre-cleaning, leakage testing, manual cleaning, automated disinfection drying, and transport to storage



Olympus offers customized education and training programs, comprehensive service packages, a wide-ranging support network, and the power of cutting-edge workflow connectivity

## Sharing Information with Hospitals to Further Improvements

After the commercialization of endoscopes, Olympus conducts its own investigations and surveillance on actual usage and reprocessing in clinical environments. Olympus obtains findings for potential improvements to endoscopes and endoscope reprocessing that enable healthcare professionals to use Olympus products more safely and effectively in order to maximize patient outcomes.

For a class of endoscopes referred to as duodenoscopes, based on an order from the Food and Drug Administration (FDA), a regulatory authority in the United States, Olympus conducted thorough investigations, called post-market surveillance, on endoscope reprocessing by collaborating with 15+ hospitals from throughout the United States over the course of approximately three years, obtaining more than 2,000 samples.



2,000+ samples from across the United States

## **Working Together with Hospitals**

In the post-market surveillance study for duodenoscopes, Olympus visited hospitals and investigated endoscope conditions and reprocessing in clinical environments, residual bacteria in samples after reprocessing, genetic analysis of residual bacteria found after reprocessing, and root cause analyses.



## **Analyzing Residual Bacteria at Hospitals**

The post-market surveillance study confirmed that duodenoscopes are reprocessed to a condition that is considered to be safe in most cases. Further, the analyses of residual bacteria from clinically used and reprocessed duodenoscopes that cultured positive for contamination during the study can contribute to strengthening reprocessing processes to improve infection prevention. While contamination does not mean patient infection, and there was not a single patient infection reported in the post-market surveillance study, detailed analyses revealed that insufficient cleaning was considered to be a cause of the residual contamination in more than 50% of cases. Further, the same analyses provided valuable data for future improvements. It is important to note that the actual patient infection rate in the US associated with duodenoscopes is decreasing, and remains a very small percentage of the overall duodenoscope procedures conducted in the United States and worldwide.\*

\*FDA.gov <https://www.fda.gov/media/132346/download> [Accessed Oct. 2, 2020]; based on 2018 patient infection data

## **Bring Improvements Back to Hospitals**

Olympus has initiated several affirmative steps to further enhance endoscope reprocessing at hospitals. Examples include an enhanced regular maintenance service program to maintain the endoscope quality and functionality, enhanced reprocessing training to healthcare professionals, improvements on instructions for use, and development of easier-to-clean endoscopes. Olympus is committed to patient safety in endoscopy and will continue closely working with healthcare professionals to achieve our shared goal of improving patients' lives healthier, safer.





**Regular Maintenance** Service Program

**Reprocessing Training** to Healthcare Professionals

## COLUMN





Olympus recently launched a new duodenoscope with a removable distal-end cover. This allows healthcare professionals to visualize and access a detailed structure at the distal end of duodenoscopes more easily. Olympus already introduced this duodenoscope to markets in Europe, Asia, and Japan, but now can offer this in the United States as well after obtaining a 510(k)-clearance from FDA in January 2020. Although Olympus believes existing duodenoscopes can be safely used, in the interest of furthering infection prevention efforts, Olympus has initiated voluntary actions to facilitate duodenoscope upgrades to the new, easier-to-clean duodenoscope by collaboratively working with regulatory authorities in each market.



Sampling at hospitals



Sampling from endoscope distal end



Bacteria analysis from a sample





## For More Access to the Latest Duodenoscope