For Immediate Release
January 29, 2020
Cybernet Systems Co., Ltd.

Cybernet Systems Co., Ltd. (head office: Tokyo, President & CEO: Reiko Yasue, hereinafter “Cybernet”) is pleased to announce that it has jointly developed EndoBRAIN®-EYE, the software to support the detection of colorectal polyps and other lesions in endoscopy using artificial intelligence (AI)*1, with the group led by Professor Shinee Kudo at the Digestive Disease Center at Showa University Northern Yokohama Hospital and Professor Kensaku Mori at the Department of Intelligent Science, Graduate School of Informatics, Nagoya University, and obtained approval for the software as a Controlled Medical Device (Class II)*2 under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act)*3 on January 24, 2020.

EndoBRAIN®-EYE is the software that assists doctors in detecting lesions by using AI to analyze endoscopic images captured in a colonoscopy and alerting if a polyp or other lesion is detected. The software does not go as far as specifying the site of the detected lesion and is only designed to alert the doctor through sounds and colors on the screen. In this way, EndoBRAIN®-EYE is a diagnostic tool that supports the detection of lesions whilst leaving room for diagnosis by the doctor. The software can be used in Olympus general purpose colonoscopes (featuring higher image quality than High-definition television) and can be used in combination with many endoscope models.

EndoBRAIN®-EYE employs a branch of AI known as deep learning*5, and incorporates algorithm knowhow obtained through research by the Mori Laboratory at the Nagoya University Graduate School of Informatics, which has a long track record of research at the cutting edge of AI. The AI studied around 3.95 million images extracted from videos collected from five centers in Japan as described earlier and, in the clinical performance studies, was able to...
accurately detect lesions with sensitivity of 95% and specificity of 89%,¹⁶, achieving a sufficient level of accuracy to support endoscopists. Although there will be no post-marketing improvement in the product’s performance through autonomous learning, if improvement in performance through an increase in the number of studied images and improvements to the algorithm can be expected, Cybernet plans to apply to the Pharmaceuticals and Medical Devices Agency (PMDA) for approval.

Background to development

In Japan, colorectal cancer has the highest mortality in women and the third highest in men,⁷ and it is a type of cancer that requires effective countermeasures. Among such countermeasures, the removal of neoplastic polyps, which are early stage cancer or pre-cancerous lesions, at colonoscopy is known to significantly reduce (by 53-68%) mortality from colorectal cancer (Zauber et al. N Engl J Med 2012, Nishihara et al. N Engl J Med 2014). However, it has been found that around 22% of neoplastic polyps are missed during a colonoscopy (van Rijn JC et al. Am J Gastroenterol 2012). Sometimes polyps are not detected because they are hidden behind folds of the large intestine or stools and sometimes polyps show up on the screen but are missed by human error. Since 2013, Cybernet has been collaborating with the Digestive Disease Center at Showa University Northern Yokohama Hospital and the Mori Laboratory at the Nagoya University Graduate School of Informatics over the research and development of AI to assist doctors in performing endoscopies, with particular focus on preventing polyps from being missed through human error.

Significance of development

Colorectal endoscopy is considered to be difficult and its procedure is complex for even the most experienced doctors. Use of EndoBRAIN®-EYE is expected to support doctors in making endoscopic observations and improve the detection rate of lesions. Furthermore, integration of EndoBRAIN®-EYE with EndoBRAIN®, which is already on the market, will put in place an environment in which AI supports the process from detection to diagnosis of lesions. This can be expected to reduce the workload of medical staff involved in endoscopies and increase the detection rate of polyps and other lesions.

Initiatives by Cybernet in the field of medicine

Cybernet has been involved in the development and sale of software products for medical use for many years, including DirectPath for virtual bronchoscope navigation, the INTAGE Station series of general purpose DICOM³⁸ data 3D editors, SlimVision for visceral fat surface area measurement, and LungVision for lung measurement. Since 2016, Cybernet has received a commission from the Japan Agency for Medical Research and Development (AMED) and has been working with Showa University and Nagoya University on joint research into highly accurate image diagnosis support software using AI.

Support for this research

The research and development described here was carried out with support from the Japan Agency for Medical Research and Development (AMED)’s medical device development promotion and research project entitled Innovative Shifts in Colorectal Endoscopy Achieved through Artificial intelligence and Massive Data Circulation (leader of R&D: Professor Shinei Kudo).

Notes

*1: Artificial intelligence (AI): The AI employed by EndoBRAIN®-EYE is a form of machine learning called deep learning, and is not the type of AI where after purchasing the learning is repeatedly performed by itself to improve performance.

*2: Due to their wide diversity, medical devices are classified as a General Medical Device (Class I), Controlled Medical Device (Class II), or a Speciality Controlled Device (Class III and Class IV) depending on the risk to patients. A Controlled Medical Device (Class II) is considered to be comparatively low risk even in the event of malfunction and x-rays, electrocardiographs, hypodermic needles, and diagnosis support programs such as EndoBRAIN®-EYE fall into this category.

*3: Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceutical and Medical Devices (Pharmaceutical and Medical Device Act): Also called the PMD Act, this law ensures the quality, effectiveness, and safety of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medicine products, and covers the enhancement of safety measures on medical devices as well as the approval and regulation of pharmaceuticals, medical devices, regenerative medicine, and other such products. This law also covers software for diagnosis and treatment.

*4: EndoBRAIN®: A software application that uses AI on images from a super-magnifying endoscope to identify neoplastic polyps that are precancerous lesions and non-neoplastic polyps during colorectal endoscopy, and present them to a doctor along with the potential for a tumor as a percentage. Cybernet is in charge of product development/commercialization and Olympus commenced sales of the product in March 2019. Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceutical and Medical Devices (Pharmaceutical and Medical Device Act) Class III / Advanced Management Medical Device Approval (Approval No.: 23000BZX00372000).
PRESS RELEASE

About Cybernet
As a leading CAE technology services company, Cybernet Systems Co., Ltd. has provided software, training services, technical support, and consulting services to a wide variety of fields, including the research and development and design-related sectors of the manufacturing industry and the research institutions of universities and governments, for more than 30 years. Meanwhile, in the ICT sector, the company provides not only the most advanced security solutions but also IT asset management tools and IT operation and management tools that are essential for improving the security level of companies. In recent years, the company has also been proposing solutions that combine CAE with AR and VR in areas such as the IoT, digital twins, big data analysis, and AI.
Cybernet’s brand message is “Energy for your innovation” and it aims to be a company that customers turn to when faced with increasingly diverse and complex technological problems.
Details of Cybernet Systems Co., Ltd. are available on the following website:
https://www.cybernet.jp/english/

Contacts for inquiries at Cybernet Systems Co., Ltd.

- **For further information, contact**
  - Masahiro Sugai
  - Medical Visualization Department
  - Phone: 03-5297-3819
  - E-mail: med-info@cybernet.co.jp

- **Press Contact**
  - Masatoshi Niidome
  - Corporate Marketing Department
  - Phone: 03-5297-3094
  - E-mail: prdreq@cybernet.co.jp

- **Investors Contact**
  - Naotaka Meguro
  - IR Department
  - Phone: 03-5297-3066
  - E-mail: irquery@cybernet.co.jp

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*5: Deep learning: A machine learning method that makes computers learn to perform tasks normally performed by humans, such as voice recognition and image identification. By entering a large volume of image, text, audio, and other such data into a multi-layer neural network that mimics human brain cells, it makes automatic learning of data characteristics possible in each layer. A technology that supports the development and progress of AI.

*6: Sensitivity is the probability that AI can correctly detect a lesion in an endoscopic image that shows the presence of a lesion. Specificity is the probability that AI can correctly determine the absence of a lesion in an endoscopic image where a lesion is not present. The higher the sensitivity, the less oversight by AI. The higher the specificity, the fewer false detections.


*8: DICOM: Digital Imaging and Communications in Medicine. A standard that defines the format for medical images captured with CT, MRI, CR or other such methods, and the communication protocols for medical imaging devices that handle the images.

*9: Precancerous lesion: Lesions that are in the process of becoming cancerous or are in the initial stages of cancer, and can be cured with treatment.

*All company names and product names in this press release are trademarks or registered trademarks of the relevant company.