



Press Release

Astellas, Nitto, and M. Heart Partnering for ECG testing service

*-Total Solution for Early Detection of Atrial Fibrillation Using
Disposable Holter ECG device and AI-Based Analysis Service-*

TOKYO, OSAKA, and IWATE, September 2nd, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”), Nitto Denko Corporation (TSE: 6988, President; Hideo Takasaki, “Nitto”), and M. Heart Co., Ltd. (President and CEO: Yoshimi Mizunuma, “M. Heart”) today announced that the three companies concluded a memorandum of understanding on September 1st concerning an ECG testing service.

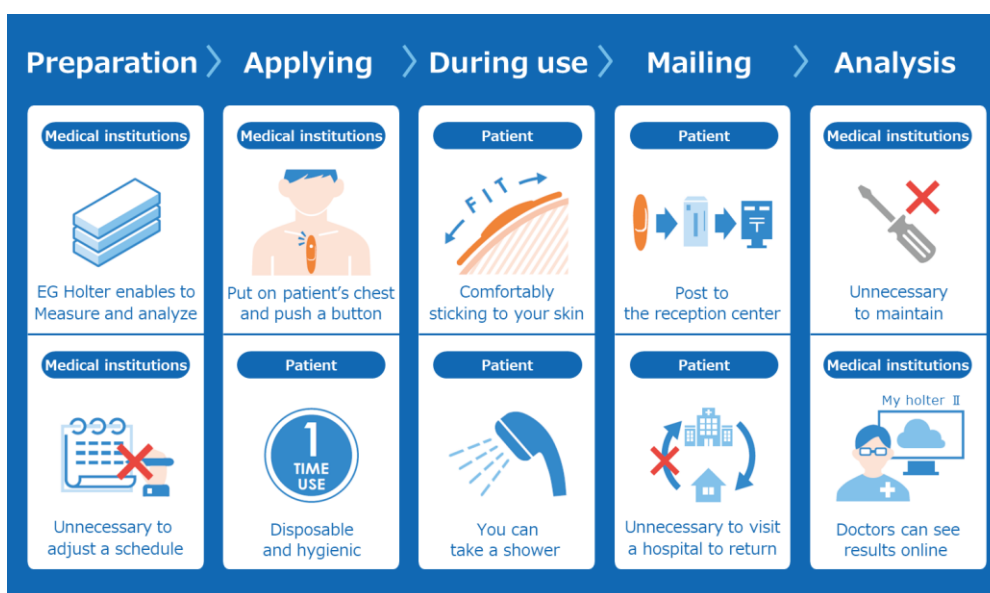
Based on this memorandum of understanding, Astellas, Nitto, and M. Heart will continue to look into Nitto developing and manufacturing the “EG Holter” a novel disposable holter ECG device, and Astellas exclusively selling it in Japan. M. Heart will play the role of marketing authorization holder of the EG Holter following from its background of providing development support and regulatory affairs consultations and be responsible for providing the service that will analyze the data obtained from the EG Holter through “MYHOLTER II,” a software for the Holter analyzer (“The ECG testing service”). In the future, Astellas will aim to provide EG Holter nationwide following pilot-sales .

The EG Holter is disposable and hygienic. It is 6 millimeters thick, 11 grams in weight, has no cords, and is waterproof (IPX4). Patients thus can wear it more comfortably. M. Heart obtained certification for the EG Holter as a medical device (Class II) in August 2021.



Disposable Holter ECG device “EG Holter”

Astellas and M. Heart have developed “MYHOLTER II”¹ jointly and built it into M. Heart’s cloud-type Holter ECG analysis service² in July for provision to healthcare professionals. MYHOLTER II is a system that analyzes Holter ECG data efficiently with high accuracy using unique artificial intelligence (AI). With the ECG testing service, after measurement, patients return it to the reception center by postal mail, eliminating the need to return the equipment back to a medical institution. Medical institutions can also see results online via MYHOLTER II, resulting in the reducing of the burden on both patients and medical institutions.



The process for analysis by EG Holter

Medical costs for heart diseases and other cardiovascular diseases in Japan exceed 6 trillion yen per year—the highest of any disease category¹. Of particular concern is cardiogenic cerebral embolism, which occurs when a thrombus that formed in the heart blocks an artery in the brain or neck. This has a high mortality rate (20%) and often results in severe sequelae, such as a bedridden state (40%)¹. Atrial fibrillation is said to be the cause of cardiogenic cerebral embolism in 3 out of 4 cases². Early detection of atrial fibrillation is an important social issue.

By providing a total solution that involves the combining of convenient ECG testing using the EG Holter and the effective and highly accurate data analysis using MYHOLTER II, Astellas, Nitto, and M. Heart are hoping that by promoting early detection and appropriate treatment of atrial fibrillation, a condition estimated to affect

approximately 700,000 patients in Japan² they can contribute to the prolongation of healthy life expectancy.

*1 Press release “Begun Providing Holter ECG Analysis Service using AI”

<https://www.astellas.com/jp/en/news/17076>

*2 Holter ECG: An exam that continuously records ECGs, 24 hours a day. An electrode is attached to the chest and ECGs are continuously recorded on a small portable recorder to detect pulse irregularities.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

About Nitto

Nitto is a Japanese manufacturer of high-performance materials. Since its founding in 1918, they provide a wide range of products based on four core technologies: adhesion, coating, polymer function control, and polymer analysis & evaluation. A few examples are polarizing film, indispensable for displays of smartphones and TVs, industrial adhesive tape, automobile parts and medical supplies. Remaining faithful to the brand slogan, “Innovation for Customers,” Nitto continues to contribute to a better society and environment through its innovative products and services and delivers technologies that shapes the future. For further information, please visit [Nitto’s official website](#).

About M. Heart

M.Heart is a MedTech venture that provides the cloud-type Holter ECG analysis service to medical institutions nationwide using the program “My holter”.

Since the data to be analyzed complies with the international standard MFER, it enables collaboration with domestic and overseas electrocardiograph manufacturers and system manufacturers.

Our staff includes doctors, clinical laboratory engineers, IT engineers, marketers, and pharmaceutical consultants, and we will realize business transformation of medical services with innovative technology and diverse imagination.

For more information on M-Heart, please visit our website at <https://www.emheart.co.jp/>

Cautionary Notes (Astellas)

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Advocacy & Relations
TEL: +81-3-3244-3201

Nitto Denko Corporation
Brand Strategy Dept.
TEL: +81-6-7632-2101 FAX: +81-6-7632-2568

M.Heart Co.,Ltd

<https://www.emheart.co.jp/contact/>

1: From Japan Stroke Association, Japanese Heart Rhythm Society, Atrial Fibrillation Weekly Website

2: Ministry of Health, Labour and Welfare, 2018 Summary of National Medical Care Expenditures