



2024/12/10

Company: CYBERDYNE Inc.
Name of Representative: Yoshiyuki Sankai,
President and CEO
Code: 7779 (Growth Section of the Tokyo
Stock Exchange)
Contact: Shinji Honda,
Director and COO
(Tel. +81-29-869-9981)

Announcement on the new product Medical Vital Sensor “Cyvis M100” ~Cleared as a medical device and public health insurance coverage in Japan~

CYBERDYNE Inc. (The “Company”) obtained certification as a medical device for Japan from a third-party certifier for its Medical Vital Sensor “Cyvis M100 (Cyvis)” on November 27, 2024. The Ministry of Health, Labor, and Welfare (MHLW) also accepted the Company’s request for insurance coverage as of today.

1. Overview of the initiative and the product

The Company is promoting “Cybernetics Medical Health Innovation” to realize comprehensive medical healthcare through IoH/IoT (Internet of Human and Things) Cybernetics Devices and Interfaces, where medical and non-medical fields are mutually linked and integrated. As part of this initiative, the Company is working on developing and commercializing the “Cyvis” series, which collects, analyzes, and processes medical and healthcare data daily using AI. This system will enable optimized programs to prevent, diagnose, and treat various diseases for each individual.

This product includes a component compatible with Holter electrocardiography examination. Cyvis can continuously record cardiac activity and detect arrhythmias and other cardiac disorders. Its lightweight and compact design allows easy handling and continuous measurement for up to 10 days on a single charge. Remote monitoring is also possible by transmitting the collected data to an integrated Cybernetic System available on the cloud.

After January 1, 2025, the insurance coverage will be available for the Holter electrocardiography examination using this product (D210 Holter electrocardiography examination exceeding 8 hours) for 1,750 points (17,500 yen).

Holter electrocardiography is used to diagnose a wide variety of cardiac diseases, and in particular, early detection of atrial fibrillation is critical in the prevention of stroke. Stroke is one of the main causes that lead a person to the need for nursing care in Japan, and cardiogenic stroke caused by atrial fibrillation is particularly likely to be severe and carries a high risk of death, sequelae, and recurrence. The product's long-time measurement function increases the possibility of early detection of paroxysmal atrial fibrillation, which has been challenging to detect with ordinary 24-hour measurements. Cyvis is expected to contribute to the prevention of severe disease and recurrence of diseases such as stroke through early treatment.

In addition to cardiac activity data, the Company plans to gradually expand the “Cyvis” series to include brain activity data, body temperature, SpO2, and respiratory status. The Company will continue to develop and commercialize new devices capable of collecting other medical and healthcare data, thereby contributing to the realization of medical health innovation.

Outline of the product

Product name: Small Holter Electrocardiography Examination Device Medical Vital Sensor Cyvis M100
General Name: Cardiac Monitor for Long-term Data Acquisition
Certification number: 306AIBZX00028000

2. Overview of the initiative and the product

The product will be launched in phases starting in January 2025. The impact of this matter on the Company's consolidated business results for the fiscal year ending March 31, 2025, is expected to be negligible. The Company will promptly disclose such information as soon as it arises.



<About CYBERDYNE Inc.>

CYBERDYNE Inc. is a future pioneering company that simultaneously creates innovative technologies, creates new industries, and fosters human resources through these challenges by utilizing Cybernics (*) that fuse “Human” and “Cyber Physical space” (HCPS) to solve various issues facing society. Through these challenges, the Company promotes a virtuous cycle of innovation. One key example of Cybernics Technology is the world's first Wearable Cyborg, HAL. The technology has been highly evaluated for its efficacy and safety in promoting functional regeneration through Cybernics Treatment. The technology has been deployed in more than 20 countries and regions worldwide. The Group is committed to creating a safe and secure society in which people of all generations can increase their independence and freedom and solve various problems in their lives, mental and physical, targeting people with health, physical function, cognitive and psychological problems, as well as people working in society at large.

<https://www.cyberdyne.jp/english/>