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Japan approves iRhythm Technologies' AI-based ECG monitoring system

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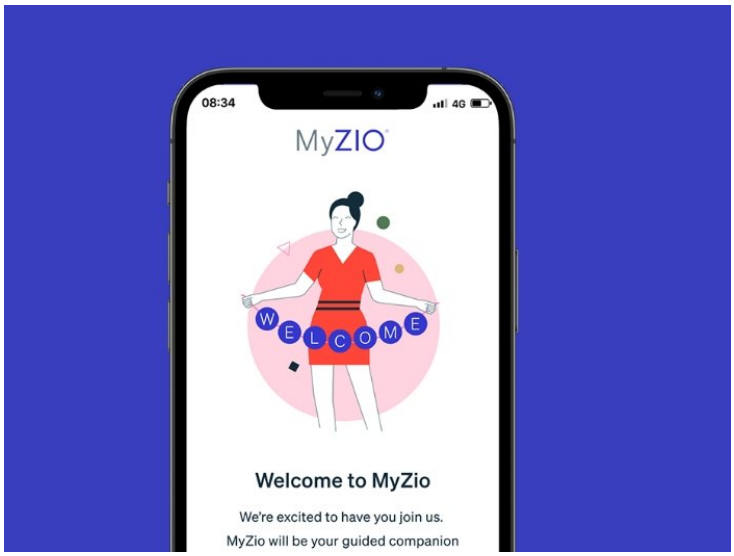
First product to deliver arrhythmia monitoring service utilising Artificial Intelligence



US-based iRhythm Technologies, Inc., a leading digital healthcare company focused on creating trusted solutions that detect, predict, and prevent disease, has received regulatory approval from the Japanese Pharmaceutical and Medical Device Agency (PMDA) for the Zio fourteen-day, long-term continuous ECG monitoring system.

With regulatory approval in hand, iRhythm intends to work towards a reimbursement decision for the Zio ECG monitoring system with the Japanese Ministry of Health, Labour, and Welfare (MHLW).

Zio long-term continuous monitoring (LTCM) service consists of a prescription only patch ECG monitoring device (Zio monitor) worn for up to 14 days and the ZEUS (Zio ECG Utilisation Software) System (iRhythm's advanced AI algorithm) that generates a comprehensive end-of-wear report reviewed and curated by certified cardiographic technicians.

The Zio system represents a significant advancement in cardiac arrhythmia diagnostics compared to traditional Holter monitoring and is designed to deliver high clinical accuracy to help enable doctors in making the right diagnosis the first time. iRhythm's deep learning approach can classify a broad range of distinct arrhythmias with high diagnostic performance similar to that of cardiologists and, in clinical settings, this service could reduce the amount of misdiagnosed computerised ECG interpretations and improve clinical efficiency.

Japan is the second largest ambulatory cardiac monitoring market in the world with an estimated 1.6 million tests prescribed annually, a number that is expected to continue to increase based on stroke and cardiovascular disease burden in an aging population. However, Japanese patients are forced to use Holter monitoring, the traditional standard of care, as patch-based technology, like the Zio service, has not been adopted.