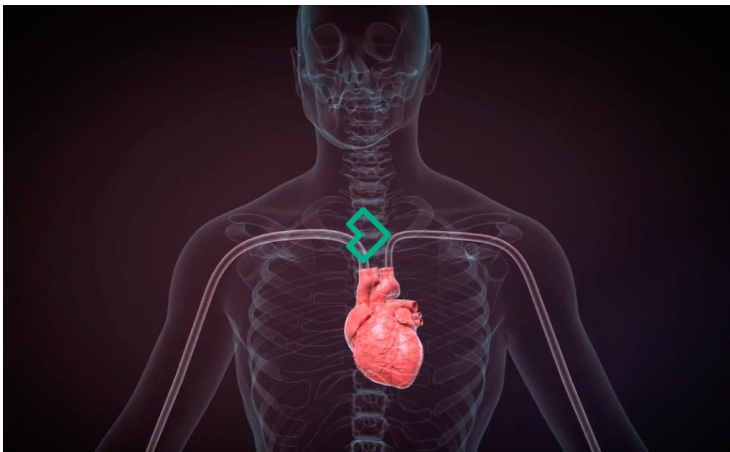


Japan gives nod to Israeli startup MedHub-AI's coronary physiology diagnostic software

June 20, 2025 | News

Generating results in just 37 seconds, the system provides fast, reproducible, and operator-independent decision support



Israel-based startup MedHub-AI, a global leader in artificial intelligence (AI)-powered cardiovascular diagnostics, has announced that the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan has approved AutocathFFR, the company's non-invasive, AI-driven software solution for evaluating coronary physiology.

AutocathFFR is the first fully automated Software as a Medical Device (SaMD) that calculates Fractional Flow Reserve (FFR) values directly from standard X-ray coronary angiograms without the need for guidewires or vasodilatory agents.

Generating results in just 37 seconds, the system provides interventional cardiologists with fast, reproducible, and operator-independent decision support in the cath lab.

Fractional Flow Reserve (FFR) is a commonly used technique in cardiac catheterisation for assessing the extent of blood flow reduction in narrowed coronary arteries.

Traditionally, this procedure involves administering a vasodilatory drug to dilate the blood vessels, followed by the insertion of a guidewire equipped with a pressure sensor into the coronary artery. The sensor measures intravascular pressure changes to determine the FFR value, enabling physicians to assess the severity of arterial blockages.

AutocathFFR revolutionises this standard of care by calculating precise FFR values, fully automatically, directly from routine X-ray coronary angiograms using advanced AI algorithms, eliminating the need for invasive guidewires with a pressure sensor or drug-induced vessel dilation.

The approval coincides with MedHub-AI's strategic partnership with Terumo Corporation, Japan's leading cardiovascular device company. Together the companies will deliver this breakthrough platform across Japan and accelerate adoption of AI driven clinical tools.

In July, MedHub-AI will unveil its non invasive iFR pullback solution, expanding its real time physiology suite and moving one step closer to fully wire free coronary assessment.