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US FDA clears world's first mobile app for contactless pulse rate measurement

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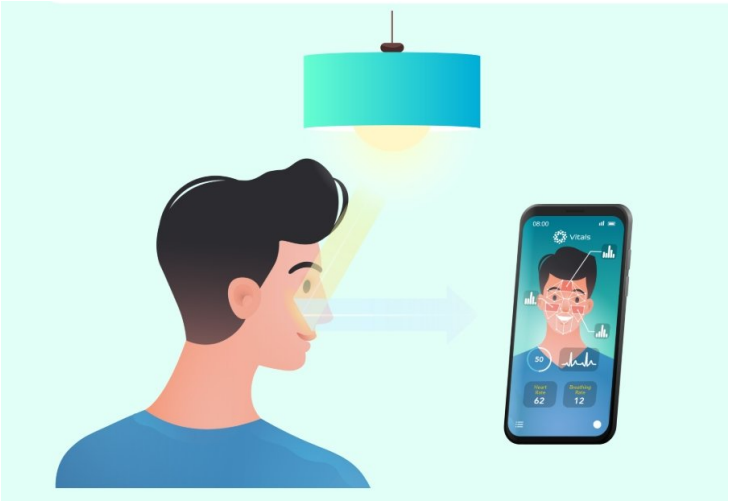
PanopticAI is the first Hong Kong-based company to achieve FDA clearance for a Software as a Medical Device



PanopticAI, a leading innovator in remote patient monitoring, has received 510(k) clearance from the US Food and Drug Administration (FDA) for its contactless vital signs monitoring software.

The PanopticAI Vital Signs app is the first FDA-cleared mobile application for contactless pulse rate measurement using the built-in camera of iPhones and iPads. This also distinguishes PanopticAI as the first Hong Kong-based company to achieve FDA clearance for a Software as a Medical Device (SaMD).

PanopticAI's technology leverages proprietary remote photoplethysmography (rPPG) algorithms to transform readily available smartphones and tablets into medical-grade vital sign monitors. Advanced AI and signal processing techniques are used to analyse subtle coloUr changes in the skin captured by the device's camera, accurately measuring vital signs like pulse rate in just 30 seconds.

This FDA clearance represents a significant milestone in PanopticAI's mission to make healthcare more accessible and scalable. By leveraging the ubiquity of smartphones, PanopticAI's technology eliminates the need for specialized equipment, significantly reducing costs and expanding access to vital sign monitoring for a wider population. The company's contactless vital signs monitoring technology is already used by hospitals, insurance providers and pharmacies. Its customers include Gleneagles Hospital Hong Kong (part of IHH Healthcare, one of the world's largest healthcare providers), Mannings (Hong Kong's leading health and beauty chain) and Bupa (multinational health insurer).

Clinical testing was conducted on a diverse patient population reflecting US census data to ensure the accuracy and reliability of the PanopticAI Vital Signs app across a broad range of users. Rigorous non-clinical testing evaluated the app's performance under various conditions, including different lighting, distances, and user characteristics, to ensure reliable operation in real-world settings. The PanopticAI Vital Signs app also underwent rigorous cybersecurity and human factors testing to ensure patient safety and ease of use.