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## **M3DICINE Receives U.S. FDA Regulatory 510(k) Clearance for World's First AI-Enabled Wireless Stethoscope System for Cardiac and Respiratory Vital Signs Detection**

*Stethee Pro 1 System non-invasively captures cardiac and respiratory vital signs, providing data to aid in early detection of COVID-19\* and other acute respiratory or cardiac conditions*

**Brisbane, Australia, Dec. 8, 2020** -- [M3DICINE](#), a medical device company democratizing healthcare through artificial intelligence-enabled medical devices, today announced that it has received regulatory 510(k) clearance from the U.S. Food and Drug Administration (FDA), for its electronic stethoscope system, Stethee Pro 1.

The Stethee Pro 1 System is comprised of an elegant wireless electronic stethoscope and powerful companion machine learning-based artificial intelligence (AI) software. It is the first device to be cleared with AI algorithms that are clinically validated to accurately measure systole, diastole, and heart cycle durations in milliseconds, and respiration rate in just 20 seconds. The Stethee Pro mobile app and HIPAA compliant Central Web Portal provide healthcare professionals with the ability to capture and share an unprecedented level of vital sign data in real-time, allowing for deeper insights, analysis and collaboration.

Healthcare professionals around the world use stethoscopes during the examination of vital signs. It takes clinicians years of experience to be able to differentiate the subtle sounds and nuances of heart and lung sounds. It also takes precious, valuable clinical time and resources to perform these subjective examinations and there is no way to easily capture, share, compare or baseline the data on the next visit – until now.

“Stethee Pro is a simple to use, beautifully designed, novel stethoscope technology that moves beyond standard electronic stethoscope capabilities,” said Dr. Ed Nicol, cardiologist, Royal Air Force and Royal Brompton Hospital. “It is a disruptive technology that has the potential to revolutionize clinical practice in many areas of healthcare, creating a new standard for screening and monitoring of acute and chronic health conditions.”

Diseases like heart failure, asthma, COPD, pneumonia and conditions caused by respiratory viruses such as COVID-19\* require close and careful monitoring of respiratory rate. Dr. Nayyar Hussain, CEO of M3DICINE said, “With the clearance of our respiratory rate algorithm, the stethoscope is no longer a purely cardiac-focused tool; it can offer broader vital sign monitoring capability, enabling healthcare professionals to better screen and manage patients’ cardiac and respiratory health.”

The capture of a patient’s respiratory rate has eluded previous stethoscope technologies on the market. Stethee Pro provides a respiratory rate in just 20 seconds. Typically, hospital ICUs and

wards use capnography machines to accurately capture respiratory rate, but these devices are expensive and invasive, requiring nasal tubes to be placed on the patient. During clinical validation testing, the accuracy of Stethee Pro respiration rate detection algorithm was assessed against capnography and results indicated equivalence with 99.9% correlation. Additionally, Stethee Pro 1 System's software spectrogram view for lung function provides a unique visual display of the respiration cycles, enabling clinicians to listen and "see" lung sounds. This feature allows the clinician to quantitatively locate the timing, duration and position of lung sounds such as wheezes and crackles during inspiration and expiration cycles to track and monitor severity and disease progression or to establish baseline datasets.

M3DICINE is currently working with [UCSF Health](#) and leading academic partners in 11 countries on a global initiative funded by the National Institutes of Health (NIH) to more quickly and accurately screen for drug-susceptible and drug-resistant tuberculosis (TB). Researchers in the trial will use the superior respiratory capability of the Stethee Pro 1 device as a screening tool and the goal is to develop new AI algorithms for detecting TB.

### **Stethee Pro Automatically Visualizes, Records and Saves Lung and Heart Vital Sign Data**

Stethee Pro has been designed for the new era of remote, personalized and precision medicine. Five proprietary heart and lung filters are designed with the system, delivering a powerful listening experience with superior acoustics, to help increase confidence in auscultation during clinical examinations using wired or Bluetooth® wireless headphones.

"We are at an inflection point in healthcare as mobile, IOT devices and artificial intelligence fundamentally change how we screen and examine patients," said M3DICINE CEO & Founder, Dr Nayyar Hussain. "Every engagement point by a healthcare professional is potentially an opportunity to capture a baseline to track vital signs over time so we can start to predict disease outcomes. Stethee Pro empowers healthcare professionals to effortlessly capture both respiratory and cardiac data to deliver the highest quality of care."

Stethee Pro is the only comprehensive, point-of-care platform that capture and measure systole and diastole durations (how long the heart contracts and relaxes during each heartbeat), heart rate and respiratory rate in 20 seconds (compared to industry standard of 4.5 minutes with a traditional stethoscope).

This provides healthcare professionals with an unprecedented level of detailed insight into cardiac function, health and performance and allows clinicians to establish a comprehensive baseline of vital signs to track condition progression of individual patients and similar cohorts of patients by correlating data over time.

Stethee Pro 1 System is now available in the United States for \$499 USD with a limited-time free subscription to the Central Web Portal.

Please visit [www.m3dicine.com](http://www.m3dicine.com) for ordering and more information.

## **About M3DICINE**

Founded in 2015, M3DICINE is a medical device platform company, focused on democratizing healthcare through the design of connected, elegant products, powered by intelligent and intuitive software. The '3' in the M3DICINE name stands for the company's core competencies in hardware, software, and artificial intelligence (AI).

M3DICINE is based in Brisbane, Australia and San Francisco, USA, with early stage seed funding from U.S. and Australian investors. M3DICINE has partnerships and advisors at leading institutions in the United States and the United Kingdom, include Mayo Clinic, UCSF Health, MIT, Cleveland Clinic and Royal Brompton Hospital.

For more information, please visit [www.m3dicine.com](http://www.m3dicine.com)

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