

Deep Breathe Secures FDA Clearance for Groundbreaking AI Lung Ultrasound Diagnostic

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Deep Breathe Inc., a leader in AI-powered respiratory diagnostics, has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Software as a Medical Device (SaMD) that autonomously assesses lung health from ultrasound images.

This marks Deep Breathe's first FDA clearance and represents a major milestone in the evolution of lung diagnostics. The cleared AI model interprets ultrasound artifacts to determine the state of lung tissue, supporting the detection of conditions such as heart failure, pneumonia, occupational lung disease, and lung contusion.

Deep Breathe's model has been proven to be more accurate than trained experts and is hardware-agnostic, operating seamlessly across any ultrasound platform. This flexibility eliminates barriers to advanced lung diagnostics in all environments, from the battlefield to the emergency room.

"This clearance validates years of scientific and clinical development," said Dr. Robert Arntfield, CEO and Founder of Deep Breathe. "By removing hardware dependence and automating diagnosis, we're empowering frontline providers to deliver sophisticated lung diagnostics wherever patients are—whether in hospitals, ambulances, or the field."

The model forms part of Deep Breathe's expanding Respiratory Diagnostic Ecosystem—a suite of AI tools designed to make lung ultrasound a routine, low-cost, and portable diagnostic option. Applications span hospital, military, EMS, and veterinary settings, enabling earlier detection and management of respiratory disease and injury in ways that were previously out of reach.

About Deep Breathe Inc.

Deep Breathe Inc. is a Canadian medical technology company developing AI software that transforms portable ultrasound imaging into an autonomous diagnostic platform for lung health. Its mission is to make respiratory diagnostics universally accessible through intelligent, vendor-agnostic design.

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