

4DMedical receives FDA clearance for lung imaging technology

29 May 2020 | News

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4DMedical, an Australian medical technology company specializing in medical imaging innovation software, announced it has received clearance from the U.S. Food & Drug Administration to market its XV Technology™, a patented four-dimensional lung imaging process that rapidly and automatically analyses any functional lung impairment from a single X-ray. 4DMedical's U.S. operations are based in Woodland Hills, California.

"Our XV Technology™ is a valuable new respiratory diagnostic tool," said 4DMedical founder and CEO, Andreas Fouras, Ph.D. "It provides critical information about the functional and structural state of a patient's lungs in the treatment of illnesses such as COVID-19, asthma, chronic obstructive pulmonary disease, cystic fibrosis and lung cancer."

The clearance comes at a time when there has never been a greater focus on respiratory health around the world, as countries deal with the COVID-19 pandemic.

4DMedical's XV Technology™ process is a software-as-a-service (SaaS) diagnostic tool, available through secure cloud subscription, and can be implemented immediately, utilizing existing hospital and clinical infrastructure with no capital expenditure or training required. Imaging departments simply electronically send an X-ray (using existing fluoroscopy equipment) to 4DMedical.

XV Technology™ is not intended to replace molecular tests as the primary diagnosis method for COVID-19; however, 4DMedical believes its ventilation reports will prove essential in providing quantitative support for diagnosis and follow up examinations for patients with, or recovering from COVID-19.

4DMedical software then rapidly and automatically analyzes and applies its proprietary algorithms to identify and quantify any functional impairment. The software generates a ventilation report and sends it to the hospital to enable clinicians to determine the most effective treatment course of action and allocation of finite hospital resources. The end-to-end process can be completed and a report generated within three hours.