4DMedical receives FDA clearance for CT:VQ™

1 September 2025

Highlights

- 4DMedical's ventilation-perfusion product, CT:VQ™, receives U.S. Food and Drug Administration (FDA) 510(k) clearance
- FDA submission for CT:VQ™ was supported by a compelling clinical validation package across multiple lung conditions
- CT:VQ™ is the world's first and only non-contrast, CT-based ventilation-perfusion imaging technology
- With over one million nuclear VQ scans performed annually in the U.S., CT:VQ has an initial addressable market of USD $1.1 billion
- 4DMedical believes it can rapidly capture a significant part of this market, and over time expects to displace 100% of all nuclear VQ scans
- Potential to grow the current ventilation-perfusion market into new applications in disease monitoring and screening, due to the wide availability of CT infrastructure globally
- 4DMedical will hold an investor webinar tomorrow, Tuesday 2 September 2025 at 11am AEST

Melbourne, Australia, 1 September 2025 – 4DMedical Limited (ASX: 4DX, "4DMedical" or the "Company"), a global leader in respiratory imaging technology, today announces that its ventilation-perfusion product, CT:VQ™, has received U.S. Food and Drug Administration (FDA) 510(k) clearance. This represents a historic moment in respiratory diagnostics, as CT:VQ™ becomes the world's first non-contrast imaging modality capable of delivering quantitative ventilation and perfusion analysis directly from standard chest CT scans.

Ventilation-perfusion (VQ) scans

A VQ scan is a specialised nuclear medicine procedure that evaluates both airflow (ventilation) and blood flow (perfusion) in the lungs. The test creates images showing how well airflow and blood flow are distributed throughout the lungs, helping doctors identify areas of imbalance.

VQ scans are primarily used to diagnose pulmonary embolism (blood clots in the lungs), a potentially life-threatening condition requiring prompt treatment. They also help evaluate chronic thromboembolic pulmonary hypertension (CTEPH), regional lung function in COPD and asthma patients, and other airway diseases by showing areas of poor ventilation or altered blood flow. VQ scans are also regularly used as part of preoperative planning for lung surgeries, such as lobectomy, and other lung procedures such as endobronchial valve placement.

Currently, the VQ imaging procedure involves two scans performed in a single appointment: patients first breathe in a radiotracer to image airflow distribution, then receive an injected radiotracer to image blood flow patterns. A specialised gamma camera captures both sets of images. The entire process takes 45-90 minutes.

4DMedical's ventilation-perfusion scan – CT:VQ™

4DMedical's CT:VQ™ revolutionises ventilation-perfusion imaging, as the world's first technology capable of extracting quantitative VQ data and visualisations from routine CT scans without requiring radiotracers or contrast agents. The technology measures regional lung tissue motion and local density changes to generate comprehensive ventilation and perfusion maps.

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CT:VQ™ addresses critical clinical and operational challenges inherent in traditional nuclear VQ imaging. The elimination of radiotracers streamlines scheduling and improves patient access by removing the associated complex handling requirements and regulatory constraints. Traditional nuclear VQ imaging workflows are simplified through CT:VQ™ by seamless integration with existing CT protocols, requiring no additional infrastructure or specialised equipment. CT:VQ™ delivers superior image resolution and precise quantification while eliminating artifacts commonly associated with radiotracer clumping or contrast leakage.

Most significantly, CT:VQ™ leverages the extensive installation base of approximately 14,500 CT scanners across the U.S. healthcare system. This broad accessibility extends advanced VQ imaging capabilities to rural and smaller healthcare facilities that may lack nuclear medicine infrastructure, democratising access to this critical diagnostic tool, and offering improved patient outcomes.

Commercial opportunity for CT:VQ™

Over one million nuclear VQ scans are performed annually in the U.S. alone, with an average reimbursement rate of approximately USD $1,150 per scan. This translates to an initial addressable market of more than USD $1.1 billion annually in the U.S., and estimated at over USD $2.6 billion globally.

With the clinical and logistical advantages that CT:VQ™ has over traditional nuclear VQ imaging modalities, 4DMedical believes it can rapidly capture a significant part of this market, and over time expects to displace 100% of all nuclear VQ scans. Management also anticipates that the introduction of CT:VQ™ into the market will drive long-term growth in demand for ventilation-perfusion scans beyond the traditional nuclear VQ indications.

Compelling clinical validation package across multiple lung conditions

4DMedical conducted extensive clinical testing to prove that CT:VQ™ produces the same diagnostic results as SPECT, the current gold standard for nuclear ventilation-perfusion imaging, while offering significant practical advantages:

- **Head-to-Head performance testing:** The Company directly compared CT:VQ™ to SPECT across a wide range of patients, measuring how well each technology assessed lung ventilation and perfusion. The results showed strong agreement between the two methods, confirming that CT:VQ™ delivers equivalent diagnostic accuracy to the established standard;
- **Expert physician validation:** Experienced radiologists and lung specialists reviewed images from both technologies and consistently rated CT:VQ™ as having excellent agreement with SPECT results. This provides doctors with the confidence that CT:VQ™ affords the same clinical information they currently rely on from SPECT imaging; and
- **Real-world clinical cases:** The validation included actual patient cases demonstrating that CT:VQ™ identifies the same lung problems as SPECT, such as blockages in COPD patients, while producing clearer, higher-quality images, without the artifacts that can interfere with SPECT diagnosis.

Overall, this comprehensive validation package demonstrates that CT:VQ™ is a clinically proven alternative that matches current standards while eliminating the logistical challenges, radiation exposure, and infrastructure requirements of nuclear imaging. The robust clinical evidence positions CT:VQ™ for broad market adoption across the 14,500+ CT scanners already installed in U.S. healthcare facilities.

Early customer engagement with CT:VQ™

As previously announced, the Company already has commercial contracts for CT:VQ™ for research use at leading U.S. healthcare facilities such as Stanford University and Brooke Army Medical Center (the U.S. Department of Defense's largest medical centre).

Results from these early clinical evaluations have been presented at major international conferences including the 2025 American Thoracic Society (ATS) meeting, demonstrating the potential of CT:VQ™ to not only match existing nuclear medicine capabilities, but to also expand the clinical utility of ventilation-perfusion imaging into disease monitoring, treatment planning, and population health screening.

Investor Webinar, tomorrow 11am

4DMedical will hold an investor webinar tomorrow, Tuesday 2 September 2025 at 11am AEST, where Andreas Fouras will provide further information, and host a Q&A session, in relation to CT:VQ™.

Please register in advance using the following links:

Phone registration: https://s1.c-conf.com/diamondpass/10049972-ghs765.html

Webcast: https://ccmediaframe.com/?id=3NSdjKq1

After registering, you will receive a confirmation email containing information about joining the webinar or dial-in details for those who would prefer to join by telephone.

4DMedical MD/CEO and Founder Andreas Fouras said:

FDA clearance of CT:VQ™ is a defining milestone for 4DMedical and for lung health. For the first time in history, doctors can order a lung perfusion scan without requiring their patients to be injected with any radioactive tracer or contrast media. And unlike historical advancements in medical imaging, such as the introduction of MRI, this technology is instantly compatible with an install base of 14,500 CT scanners already deployed across the United States.

This innovation delivers safer, faster, and more accessible functional lung imaging to patients, while also streamlining workflows for clinicians and radiologists. CT:VQ™ represents not just an incremental improvement, but a complete redefinition of the standard of care in pulmonary imaging.

With FDA clearance now secured, 4DMedical is positioned to accelerate the commercial rollout of CT:VQ™ across the United States. The Company will engage with leading healthcare providers, academic centres, and strategic partners, to integrate this groundbreaking technology into clinical practice, supporting a shift toward safer, more efficient, and more accessible respiratory care.

–ENDS–

Authorised by the 4DMedical Board of Directors.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company revolutionizing respiratory care with advanced imaging and artificial intelligence. Its patented **XV Technology®** transforms standard scans into rich, functional insights that allow physicians to detect, diagnose, and monitor lung disease earlier and with greater precision.

4DMedical's expanding software portfolio includes the FDA-cleared **XV Lung Ventilation Analysis Software (XV LVAS®)**, **CT LVAS™**, and the ground-breaking **CT:VQ™** solution designed to set new benchmarks in cardiothoracic imaging by combining ventilation and perfusion analysis.

Delivered seamlessly through a Software-as-a-Service (SaaS) model, 4DMedical's solutions integrate into existing hospital infrastructure, enhancing physician productivity and enabling more personalized patient care. With the addition of advanced AI capabilities from its 2023 acquisition of **Imbio**, 4DMedical continues to push the boundaries of medical imaging to redefine how respiratory disease is understood and treated worldwide.

Learn more at www.4dmedical.com