

4DMedical gains regulatory approval for CT LVAS™ in Canada

25 February 2025

Highlights

- Canadian regulatory approval granted for CT LVAS™
- Adds to the existing Canadian approvals for Pulmonary Structure portfolio products: LDA, LTA and Lung Nodules
- Increases 4DMedical’s access to the large and valuable Canadian healthcare market

Melbourne, Australia, 20 February 2025: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, “4DMedical”, or the “Company”) today announces that it has received regulatory approval for its CT Lung Ventilation Analysis Software (CT LVAS™) in Canada. The Medical Device Licence has been granted by the Health Canada Medical Devices Directorate in accordance with the Medical Devices Regulations, Section 36, as a Class 2 medical device.

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The approval of CT LVAS™ in Canada adds to the existing approvals for Lung Density Analysis (LDA), Lung Texture Analysis (LTA) and Lung Nodules in Canada, reinforcing 4DMedical’s commitment to delivering cutting-edge respiratory imaging technology to patients and healthcare providers. The regulatory status of the Company’s portfolio of products is presented below:

Regulatory status

| | Product | Jurisdiction | | | | |
|---------------------|------------------------------|--|--------|--------|-----------|---|
| | | US | Canada | Europe | Australia | |
| Pulmonary Function | XV LVAS® | Dynamic Ventilation Analysis (Fluoroscopy) | ✓ | | | ✓ |
| | CT LVAS™ | CT-based Ventilation Analysis | ✓ | ✓ | | ✓ |
| | CT:VQ™ | Next Gen VQ (Ventilation + Perfusion) | | | | |
| | Functional LDA (LDAf) | Air Trapping + Emphysema | ✓ | ✓ | ✓ | ✓ |
| Pulmonary Structure | Lung Density Analysis (LDAi) | Emphysema, HAA, Fissures | ✓ | ✓ | ✓ | ✓ |
| | Lung Texture Analysis (LTA) | ILD’s/ Fibrosis | | ✓ | ✓ | ✓ |
| | IQ-UIP | IPF Screening | ✓ | | | |
| | Lung Nodules | Lung Cancer (Partner Solution) | ✓ | ✓ | ✓ | ✓ |
| Cardiovascular | CAC | Coronary Calcification/Heart Disease | ✓ | | ✓ | |
| | PH Assessment | Hypertension (RV/LV, MPA, Pa/Ao) | ✓ | | ✓ | |

Canada spends 63% more on healthcare than Australia. With a population of over 40 million people, the Canadian GDP is over US\$ 2.1 trillion and is ranked 10th in the world. Within Canada, there are 560 CT scanners, predominantly located within hospitals (94%), with 12.7% of 6.4 million total CT examinations per annum relating to respiratory imaging. This significant opportunity lies within easy reach of our US-based sales teams, with 70% of Canada’s population living below the 49th parallel and a further 20% living within 160 km of the US border.

The future of
lung health

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CT LVAS™ enables clinicians to assess lung ventilation using standard CT scans, providing valuable insights into lung function without the need for additional imaging or contrast agents. The software is designed to improve the diagnosis and monitoring of lung diseases, including chronic obstructive pulmonary disease (COPD) and other respiratory conditions, ultimately enhancing patient outcomes.

With the addition of CT LVAS™ to 4DMedical's portfolio of cleared products in Canada, the Company is well-positioned for the potential future approval of its CT:VQ™ imaging technology. CT:VQ™, once cleared, would further enhance diagnostic capabilities by integrating ventilation and perfusion imaging for a more comprehensive assessment of lung function.

The Company will continue to pursue regulatory approvals in Canada as part of its strategy to drive commercial adoption and improve respiratory care across North America.

4DMedical MD/CEO and Founder Andreas Fouras said:

I am excited to be able to add functional imaging technology through CT LVAS™ to our structural imaging portfolio in Canada. With the vast majority of Canadians living near the north-east corner of the US and with easy travel and shared culture no region is more accessible to our US-based sales team.

In the last half we grew our number of sites by 24%, scans per site at over 10% and average fee per scan by 12%. With our team having cracked the code on how to drive adoption, now is a great time to have CT:LVAS™ approved in Canada.

–ENDS–

Authorised by the 4DMedical Board of Directors.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a cutting-edge global medical technology company revolutionizing respiratory care. By harnessing advanced imaging and AI-powered solutions, 4DMedical delivers unprecedented insights into lung function, enabling earlier and more precise diagnoses of respiratory diseases.

At the heart of 4DMedical's innovation is its patented XV Technology®, a groundbreaking platform that dynamically quantifies ventilation throughout the lungs as patients breathe. This technology underpins the company's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®) and its CT LVAS™, empowering physicians to detect and monitor regional airflow abnormalities with unparalleled sensitivity.

4DMedical's solutions integrate seamlessly into existing hospital infrastructure via its Software as a Service (SaaS) model, transforming routine imaging into powerful diagnostic tools.



In December 2023, 4DMedical expanded its leadership in medical imaging with the acquisition of **Imbio**, a pioneer in artificial intelligence solutions for chronic lung and cardiothoracic diseases. Imbio's AI-driven platforms enhance physician productivity, improve diagnostic precision, and support personalized care, aligning seamlessly with 4DMedical's mission to redefine respiratory healthcare.

To learn more, please visit www.4dmedical.com

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