See beyond the structure



4DMedical Limited (ASX:4DX)

Investor Presentation

27 May 2025

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Current lung diagnostics are failing us

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Lung health screening
(COPD, silicosis, black lung, lung cancer)



- COPD – 4th largest cause of mortality in world[1]
- Silicosis – 600,000 Australian workers exposed to silica dust per annum

Unexplained dyspnoea
(shortness of breath)



- $12.2bn cost of breathlessness in Australia[2]
- 9.5% of Australians have clinically relevant breathlessness

Burn Pits & DRRD
(Deployment-related Respiratory Disease)



- >6million service personnel exposed to airborne toxic hazards[3]
- No standard diagnostics detecting presence or absence of DRRD

[1] thelancet.com/lancetgh, Vol11 August 2023 | [2] 'The health and economic burden of breathlessness, Australia, 2019: a national survey', A. Sunjaya, et al. | [3] publichealth.va.gov/exposures/burnpits/index.asp

Regulatory clearance – product portfolio

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	Product		Regulatory Clearance			
			US	Canada	Europe	Australia
Pulmonary Function	XV LVAS®	Dynamic Ventilation Analysis (Fluoroscopy)	✓			✓
	CT LVAS™	CT-based Ventilation Analysis	✓	✓		✓
	CT:VQ™	Ventilation + Perfusion from routine non contrast CT*				
	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 for UIP pattern	✓			
	Lung Nodules	Lung Cancer (Partner Solution)	✓	✓	✓	✓
Cardio-vascular	CAC™	Coronary Calcification/Heart Disease	✓		✓	
	PHA™	Hypertension (RV/LV, MPA, Pa/Ao)	✓		✓	

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Revolutionizing Lung Imaging & Major Company Milestone

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CT:VQ™
FDA 510(k) Submission
Clinical evidence validation



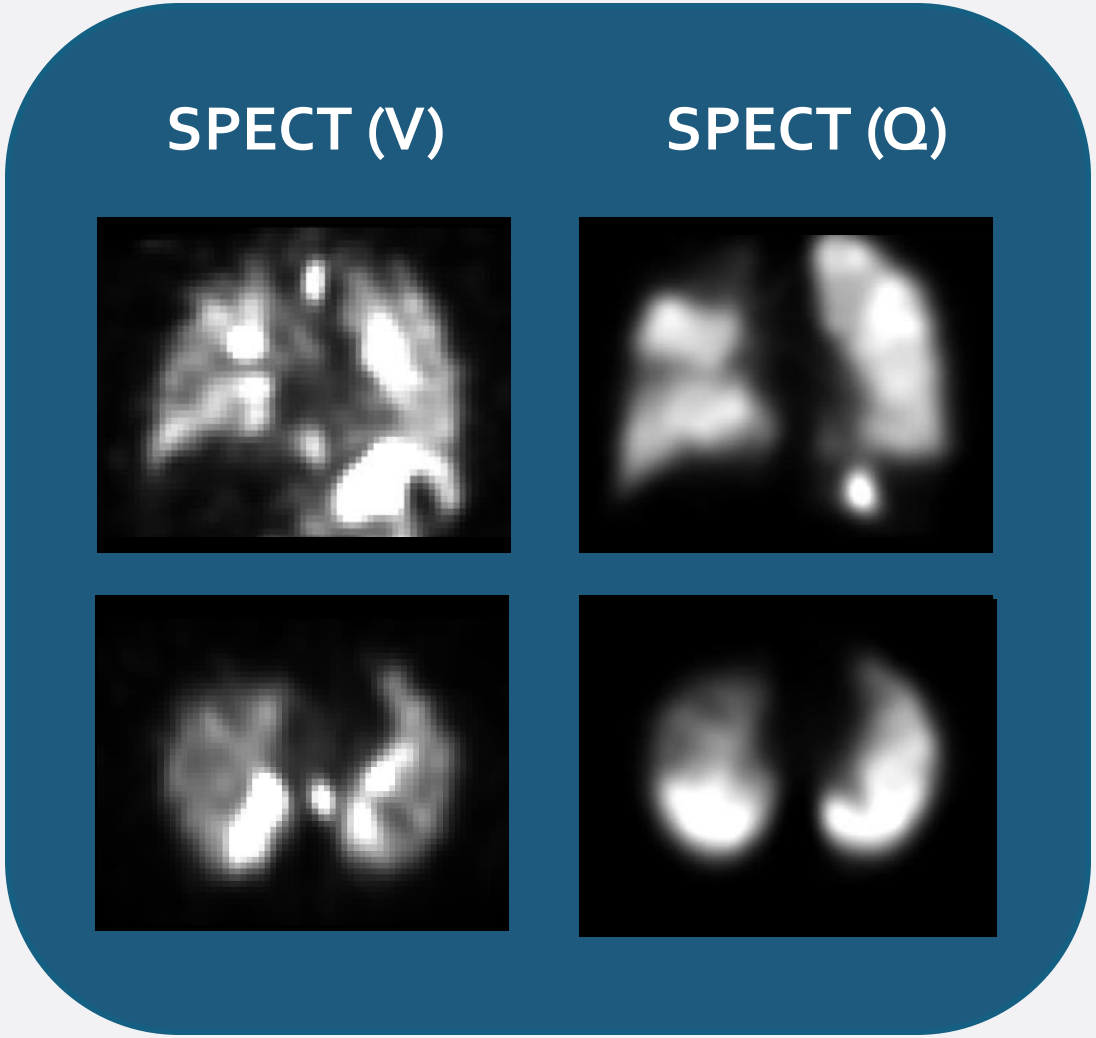


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NUC:VQ has logistical and technical challenges

- Nuclear VQ is slow, logistically complex, expensive & delivers low resolution results.
- This multi billion-dollar procedure is ripe for disruption.



Existing technology used has logistical and technical challenges

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NUCLEAR MEDICINE CURRENT STATE

- HIGH-COST PROCEDURE
- POOR RESOLUTION OF OUTPUTS
- TIME CONSUMING PROCEDURE FOR RADIOLOGISTS AND PATIENTS
- HIGH PATIENT COMPLIANCE
- EXPENSIVE TESTING EQUIPMENT NEEDED
- COMPLEX PROCEDURE

CT:VQ™ FOCUSES ON ADDRESSING THREE CRITICAL ISSUES:

1. REDUCING COSTS AND INCREASING PRODUCTIVITY
2. IMPROVING THE PATIENT EXPERIENCE
3. INCREASING EQUITY THROUGH GREATER HEALTHCARE ACCESSIBILITY

CT:VQ™ – PROVIDING ENHANCED PATIENT EXPERIENCE AND EFFICIENCIES

1. ENHANCED PHYSICIAN EXPERIENCE
2. INCREASED EFFICIENCY AND COST REDUCTION TO HOSPITALS
3. ENHANCED PATIENT AND CAREGIVER CARE
4. WITHOUT RADIOACTIVE MATERIALS OR CONTRAST INJECTIONS

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CT:VQ™ has an immediate opportunity to displace NUC: VQ (and grow considerably through uptake on CT)

$1.1B

NUC:VQ - USA

+ organic growth through superior access

Reimbursed study

$2.6B

NUC:VQ - GLOBAL

+ organic growth through enhanced access

Superior economics

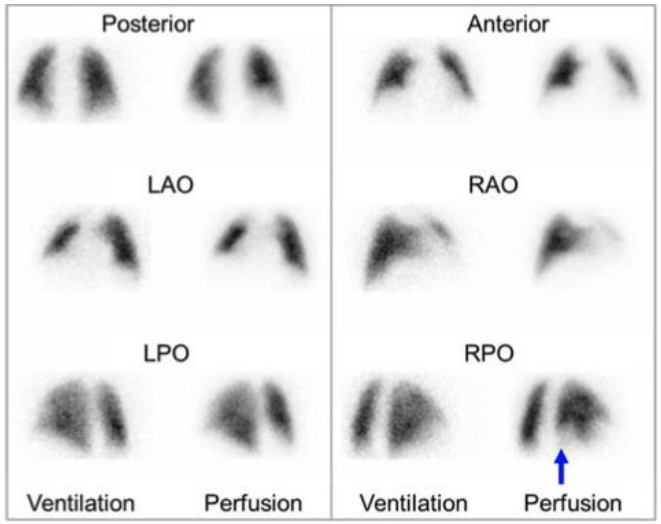
1. Figures adapted from Frost and Sullivan Report 2020 USD $31.3 billion global spend annually

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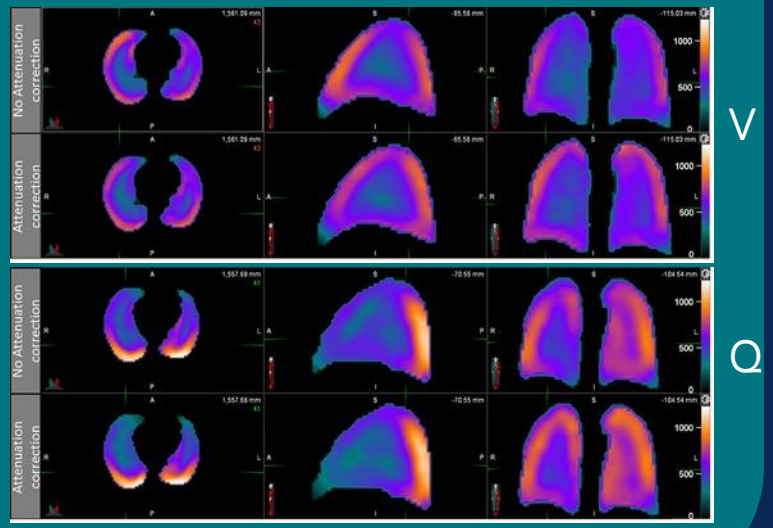
‘NUC:VQ’ refers to Planar Scintigraphy, SPECT and SPECT/CT

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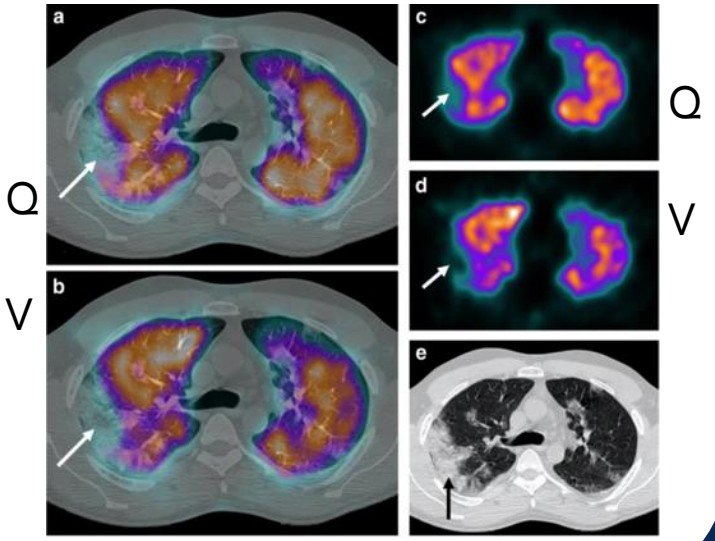
Planar Scintigraphy acquisition is a 2-dimensional technique obtained through a dual-head gamma camera for ventilation and perfusion scans. Limited patient movement between the 2 scans is crucial. Both series uses at least 4 views



SPECT (Single-photon emission computed tomography) obtains the image through multidetector gamma-cameras to generate 3-dimensional images. SPECT shows higher sensitivity than the planar technique



SPECT/CT integrates a low-dose CT scan with the functional SPECT to provide more detailed anatomic information. The CT image (without contrast) is usually taken after the perfusion scan



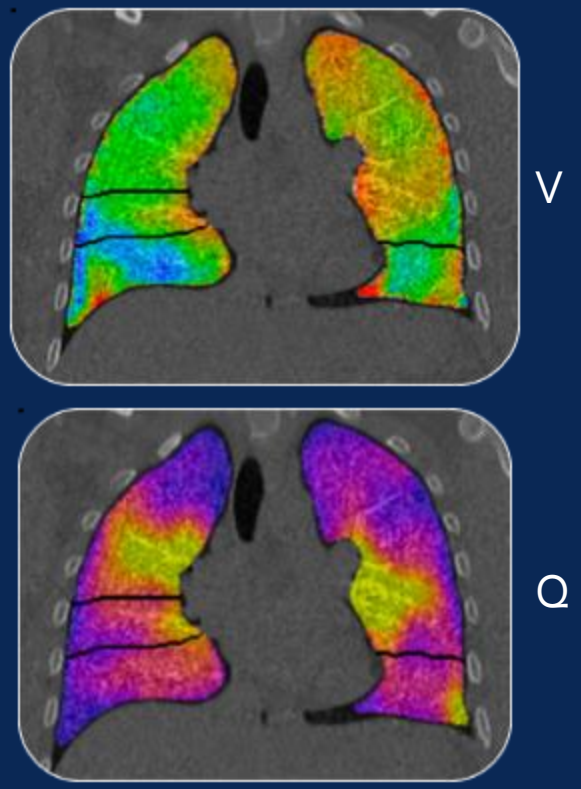
Images for illustrative purposes only – sourced from;
Journal of Nuclear Medicine Technology Vol. 51 No. 1 March 2023 | V/Q SPECT for the Assessment of Regional Lung Function: Generation of Normal Mean and Standard Deviation 3-D Maps. Front. Med. 7:143. (2020) | Eur J Nucl Med Mol Imaging47, 2453–2460 (2020)

CT:VQ™ - how is it delivered?

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- CT:VQ™ is a software layer applied to a non-contrast CT scan of the lungs
- The CT scan, referred to as HRCT (High-Resolution Computed Tomography), provides detailed images of the lungs, captured in both peak inspiration and expiration
- Analysis of ventilation and perfusion through CT:VQ™ is provided through DICOM-fused images registered to the underlying CT scan
- Images are delivered into the reporting radiologists PACS queue as part of the patient's CT series

CT:VQ™ - Coronal CT images of ventilation and perfusion



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CT:VQ™ - additional growth opportunities and reimbursement

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Beyond displacing existing NUC:VQ, **additional growth opportunities** arise by extending VQ analysis to non-contrast CT-based imaging.

Access to pulmonary perfusion is dramatically increased;

- to facilities that do not offer Nuclear Imaging
- cannot release more booking slots for Nuclear lung imaging
- and CT departments where contrast enhancement / CT perfusion is not available

Reimbursement considerations

CT:VQ™ aligns with the existing CT LVAS™ CPT code (USD $650), supporting rapid clinical adoption upon receipt of regulatory clearance

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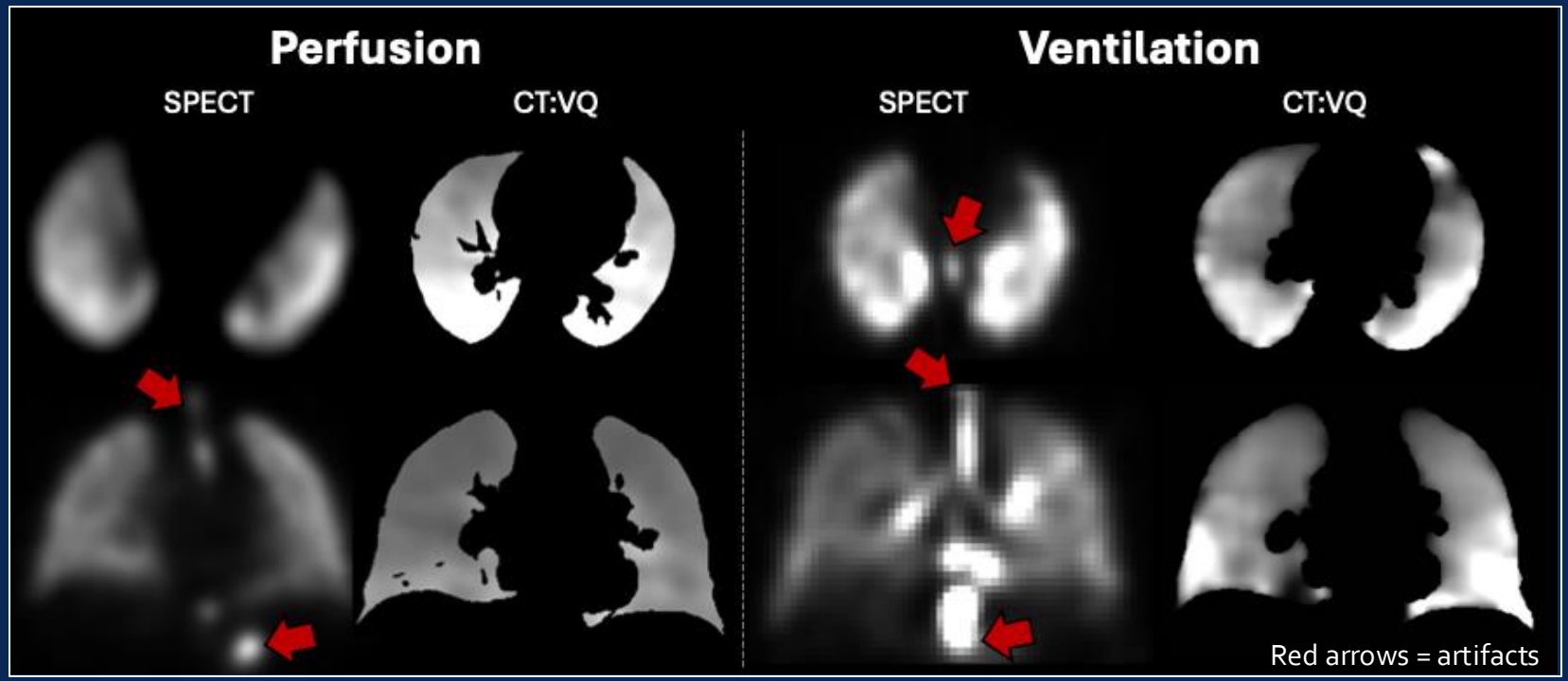
A More Convenient and Non-invasive Lung Imaging Technology

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Multi-center clinical evaluation complete.

CT:VQ™ to has the potential to quickly displace nuclear medicine VQ without having to change clinical practice or replace existing infrastructure. It could reduce patient exposure to radioactive material and increase diagnostic accuracy, ultimately improving patient care and workflows.

Comparative analysis CT:VQ™ and NUC:VQ



A case study for suspected subacute subacute/chronic pulmonary thromboembolic disease subject showing selected axial (top row) and coronal (bottom row) perfusion (left panels) and ventilation (right panels) images from SPECT and CT:VQ.

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FDA 510(k) Submission – Clinical Evaluation Studies

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To thoroughly assess the performance of CT:VQ™, the Company employed three complementary approaches:

1. **Standalone Device Performance: *Quantitative Assessment***
   Regional correlation analyses were performed between CT:VQ and SPECT VQ perfusion and ventilation maps.

2. **Reader Performance: *Clinical Assessment***
   Expert radiologists and nuclear medicine physicians rated the regional distribution of function on CT:VQ and SPECT VQ using a standardized 5-point ordinal scale.

3. **Case-Based Review: *Qualitative Assessment***
   A subset of cases was reviewed in depth to highlight areas of agreement and discrepancy. These illustrative examples demonstrate clinical interpretability of CT:VQ and support its equivalence (or superiority) in identifying perfusion and ventilation defects relevant to clinical decision-making.

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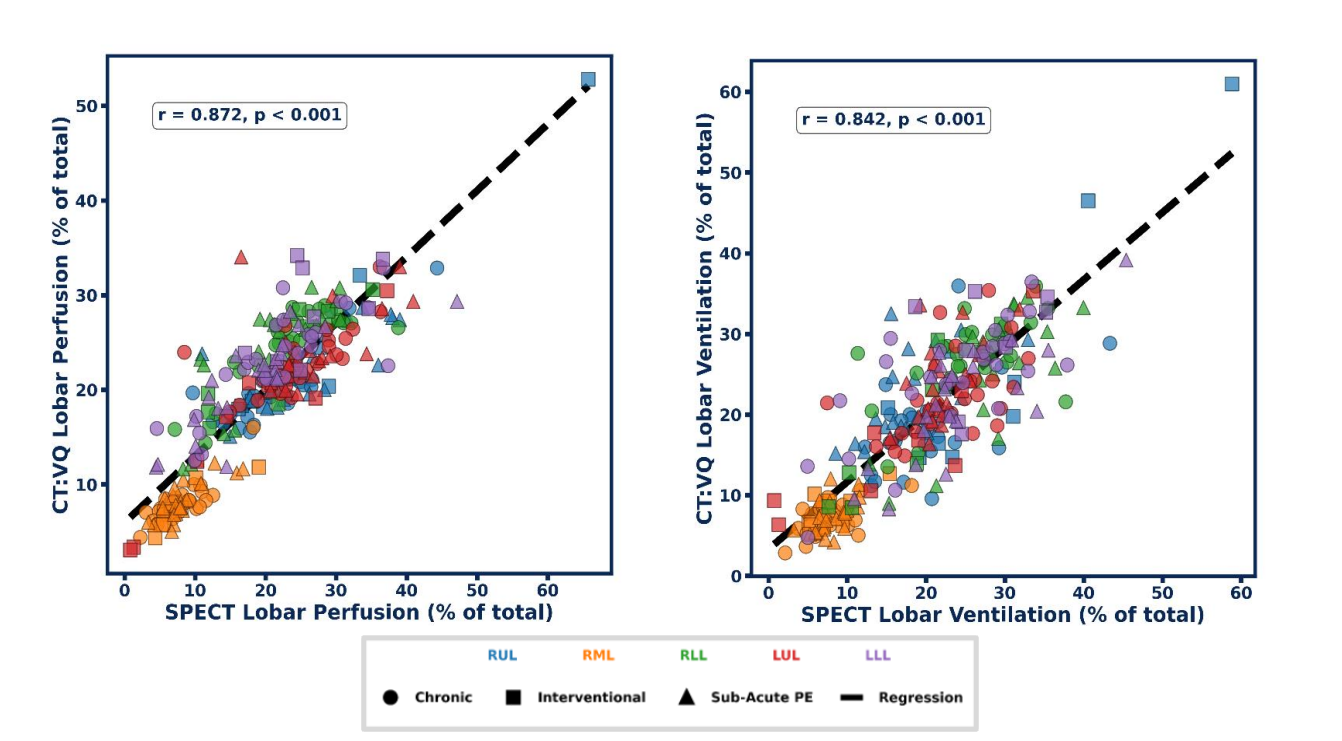
Quantitative assessment demonstrated that *CT:VQ™ strongly correlates with those from SPECT*

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Quantitative comparison of perfusion (A) and ventilation (B) between SPECT and CT:VQ™:

- Each data point represents the ventilation or perfusion in a lobe as a percentage of the total ventilation or perfusion in the lungs.
- Different lobe regions are indicated by marker color and each cohort is indicated by marker style.
- The dashed line represents the linear regression fit.

Both perfusion and ventilation display strong positive correlation (r=0.872 and r=0.842) with high statistical significance (p<0.001).



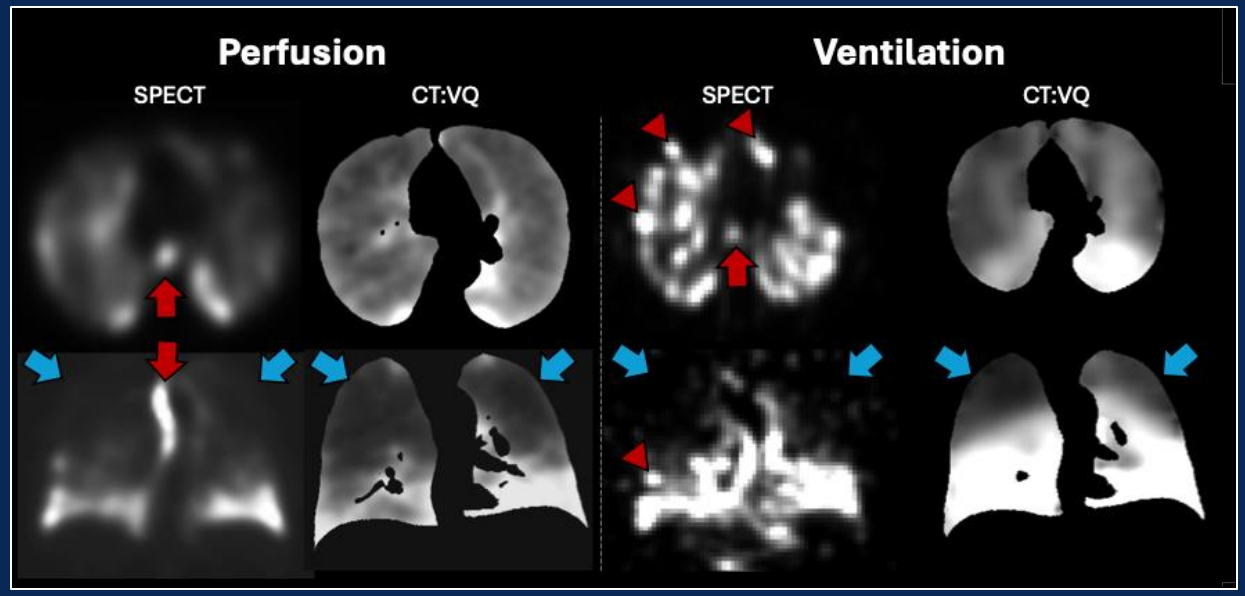
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Reader Study and Case Review

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The reader study confirmed that clinicians consistently rated CT:VQ™ perfusion images as having good to excellent agreement with SPECT across all lung zones, with very strong inter-modality correlation.

Case reviews further highlighted CT:VQ™ advantages, including higher spatial resolution and the absence of common SPECT artifacts, demonstrating its diagnostic equivalence and enhanced image quality for assessing regional lung function.



Concordance of defects (blue arrows); Artifacts (red arrows)

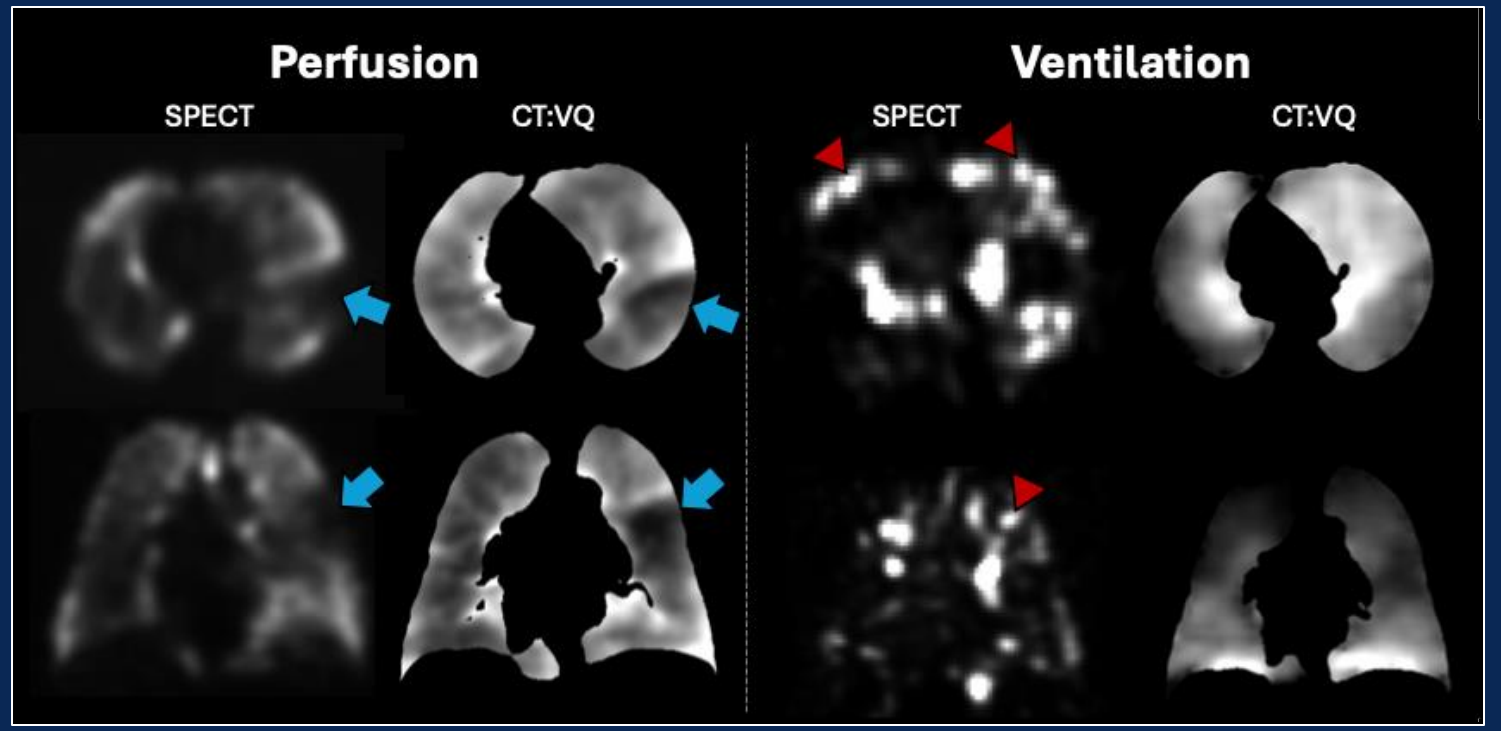
A case study for COPD subject showing selected axial (top row) and coronal (bottom row) perfusion (left panels) and ventilation (right panels) images from SPECT and the CT:VQ™

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Reader Study and Case Review

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- Case study shows clear modality agreement providing comprehensive functional information valuable for clinical management and therapeutic planning in this complex patient.
- A well-defined segmental perfusion defect in the upper portion of the left lower lobe (blue arrows) as well as more uniformly reduced perfusion throughout the entire right versus left lung.
- The SPECT ventilation images exhibit technical limitations rendering this portion of the study non-diagnostic due to extensive radiotracer deposition artifacts (red arrowheads).



Concordance of defects (blue arrows); Artifacts (red arrows)

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CT:VQ™ a Superior, Non-nuclear Alternative for Regional Lung Function Imaging

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Lung Zone	All Readers	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5	Reader 6
Upper-Left	τ = 0.743	0.709	0.706	0.800	0.578	0.715	0.760
Middle-Left	0.758	0.758	0.707	0.814	0.528	0.775	0.753
Lower-Left	0.712	0.767	0.694	0.677	0.449	0.771	0.644
Upper-Right	0.765	0.774	0.720	0.852	0.514	0.816	0.748
Middle-Right	0.734	0.690	0.749	0.808	0.547	0.770	0.698
Lower-Right	0.702	0.667	0.692	0.722	0.423	0.754	0.694

Strength	Kendall's tau correlation
Negligible	0.00
Weak	0.06
Moderate	0.26
Strong	0.49
Very Strong	0.71

The reader performance study confirmed clinicians consistently rated CT:VQ outputs as having good to excellent agreement with SPECT across all lung regions. These findings affirm that CT:VQ outputs are interpretable and clinically actionable by intended users.

FDA targeted a correlation of 0.40 for our submission | CT:VQ achieved >0.7

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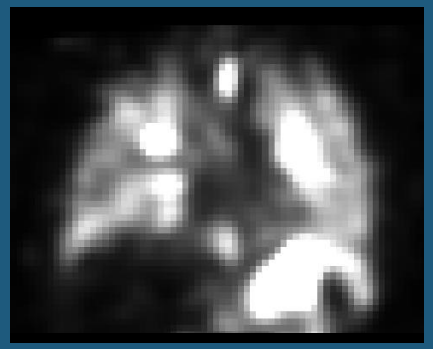
CT:VQ™ clinical cases

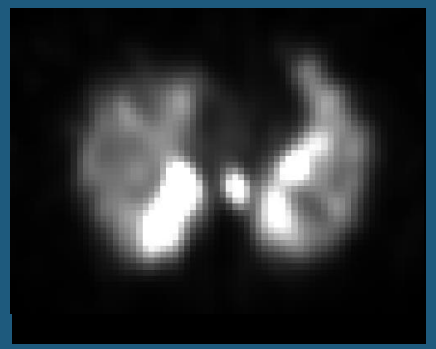
CT:VQ™ cases collected during validation study and at Royal Brompton Hospital COPD meeting

CT:VQ™ Comparison to SPECT Ventilation and Perfusion

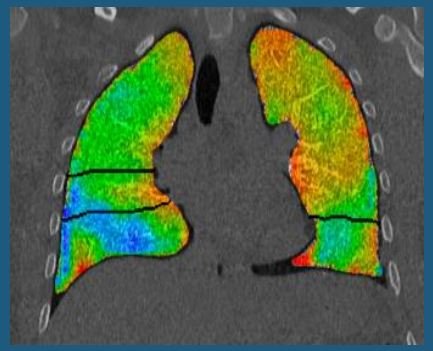
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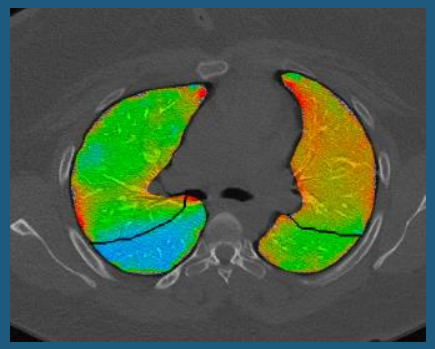
SPECT (V)





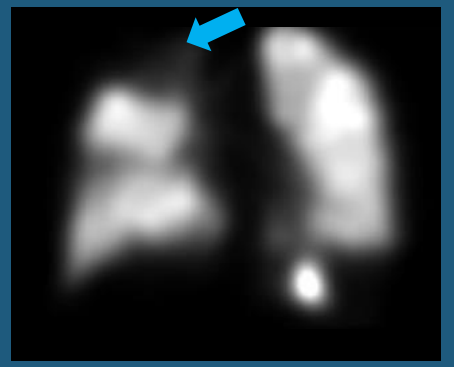
CT:VQ (V)

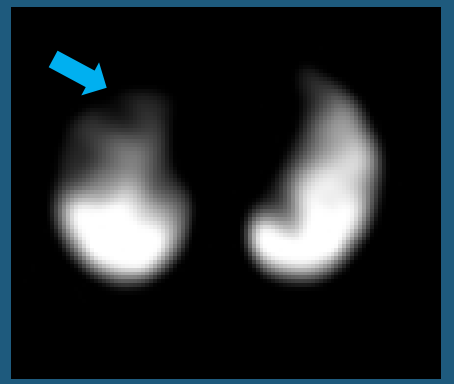




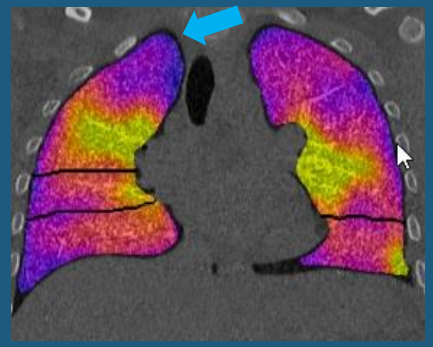
Less More

SPECT (Q)





CT:VQ (Q)





Concordance of defects (blue arrows)

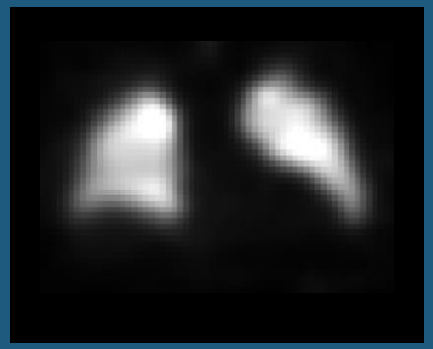
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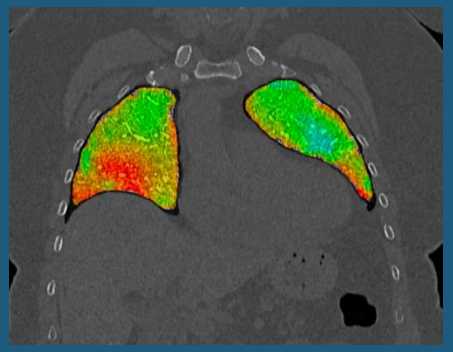
CT:VQ™ Comparison to SPECT Ventilation and Perfusion

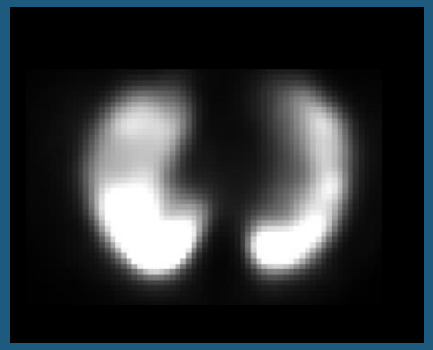
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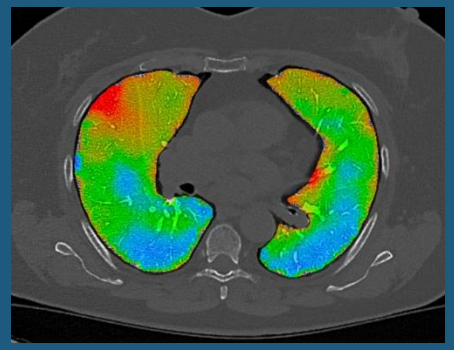
SPECT (V)



CT:VQ (V)

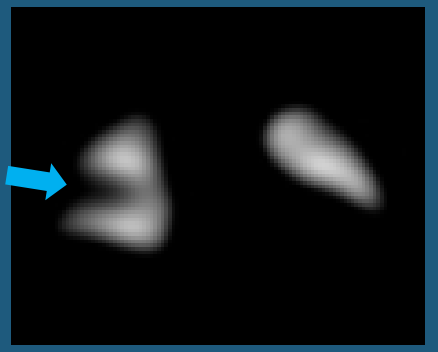




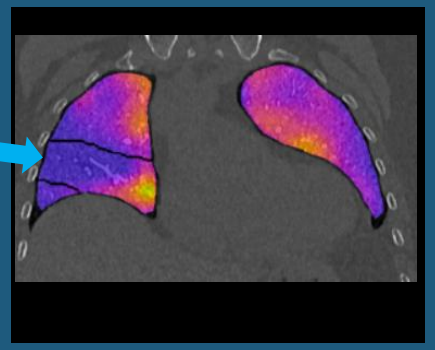


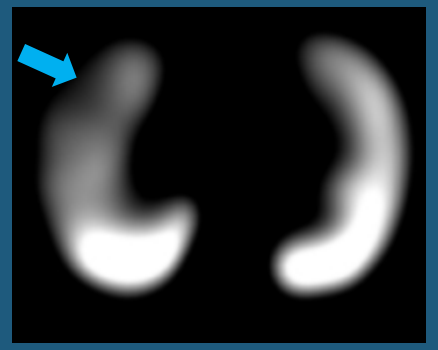
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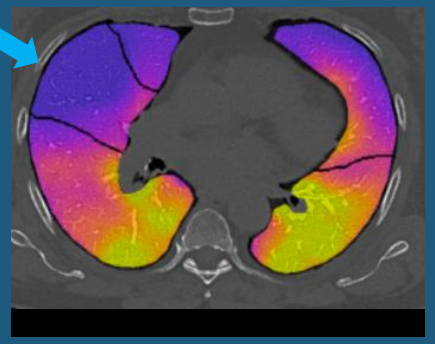
SPECT (Q)



CT:VQ (Q)







Concordance of defects (blue arrows)

Less More

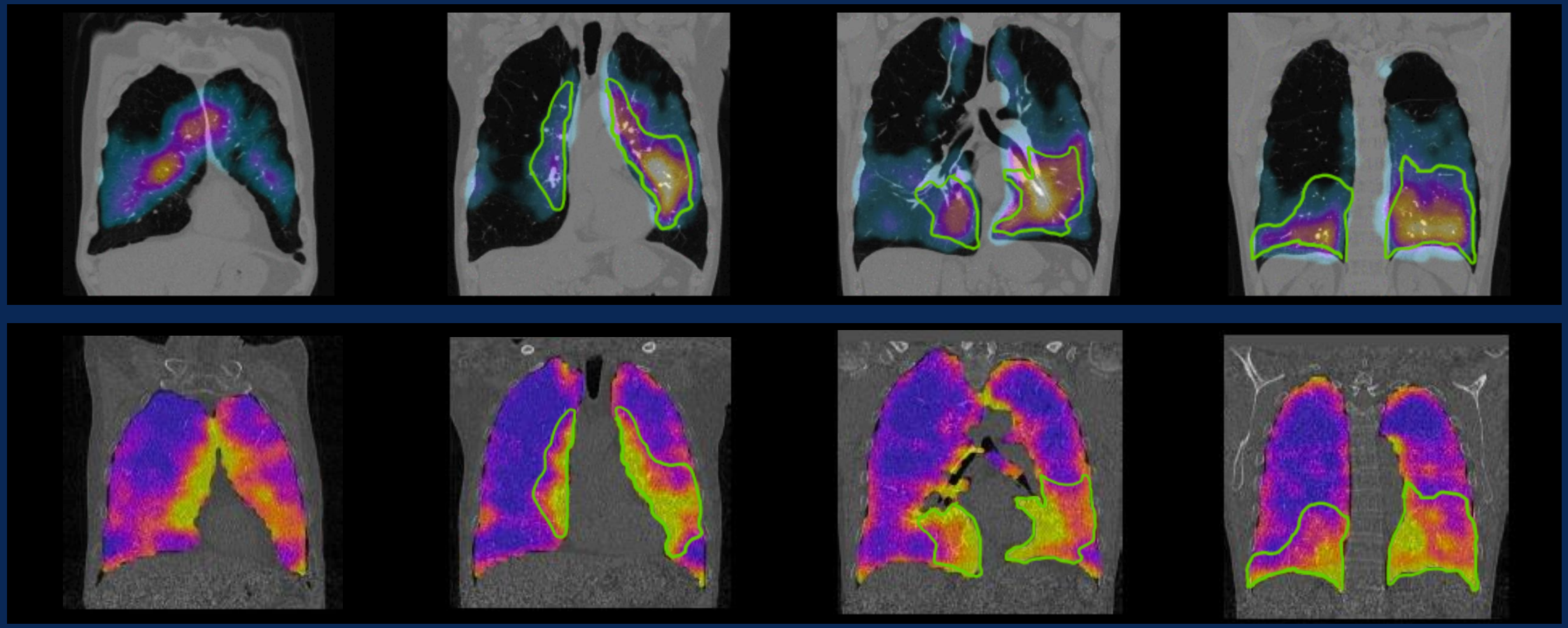
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CT:VQ™ Detailed comparison to SPECT Perfusion

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Nuclear Perfusion

CT:VQ Perfusion



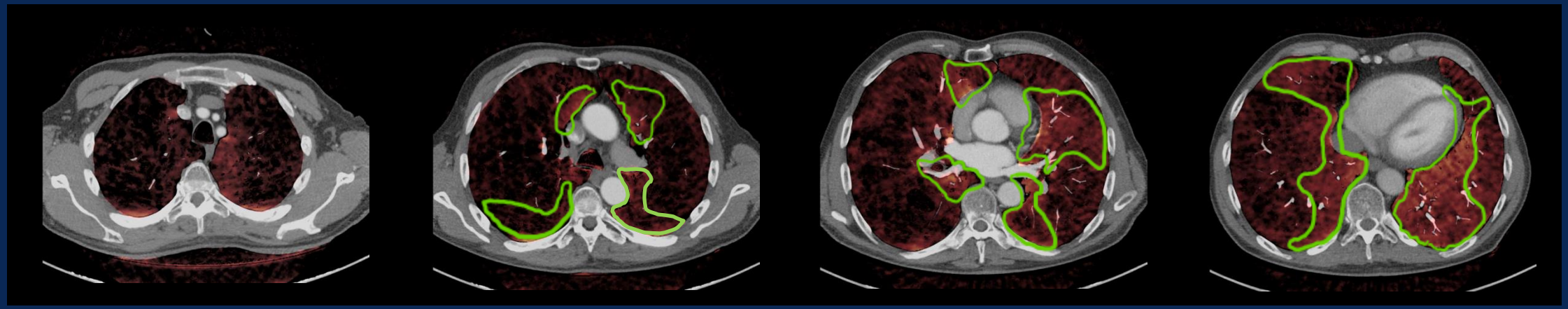
Good visual alignment despite different scans and analysis technology.

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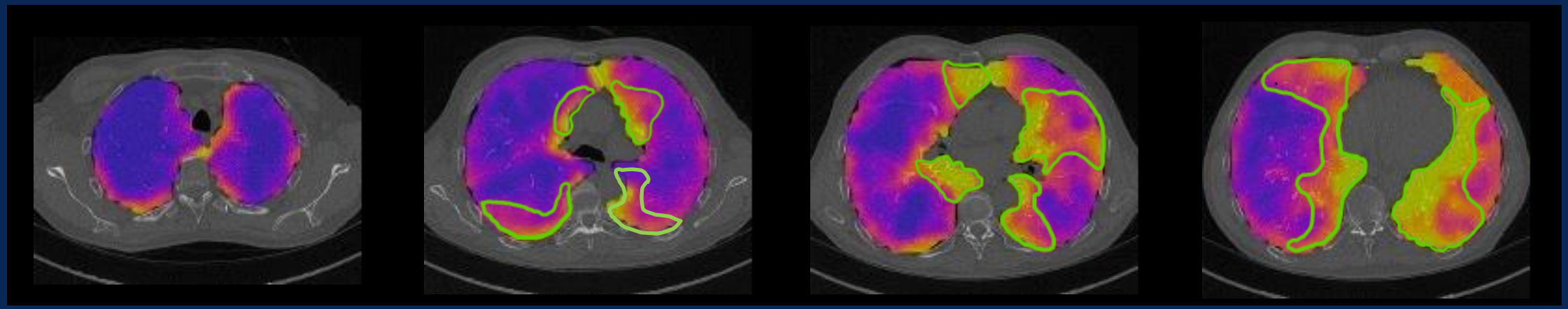
CT:VQ™ Comparison to Dual Energy CT Perfusion

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DECT Perfusion



CT:VQ Perfusion



Good visual alignment again, despite different CT scans and technology.

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CT:VQ™ vs SPECT compared with lung function from PFT

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DLCO an important functional assessment

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DLCO

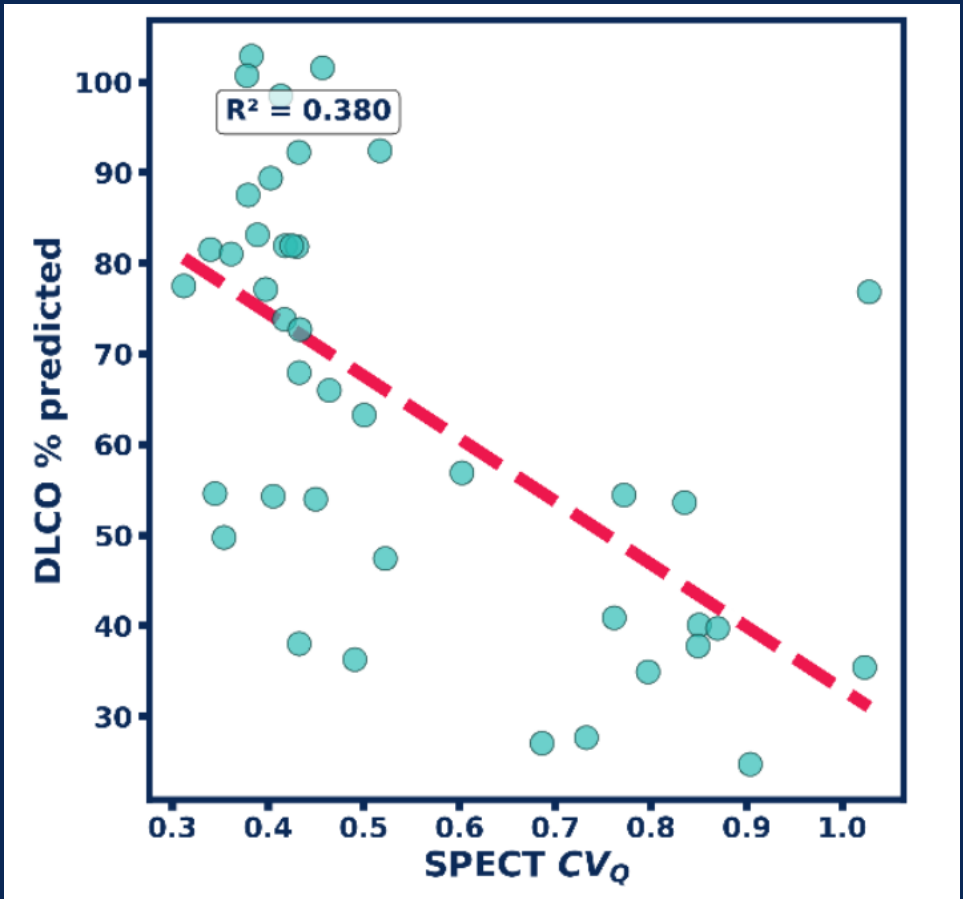
- Diffusion capacity of the lungs for carbon monoxide
- Utilises delivery of small amounts of CO (Carbon Monoxide) during PFT (pulmonary function test)
- Used as a surrogate measure of total lung function – not unlike a VQ test

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DLCO compared to SPECT

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Heterogeneity of SPECT perfusion vs DLCO



Heterogeneity of SPECT perfusion (measured by CV; co-efficient of variation) correlates with DLCO (R^2 = 0.38).

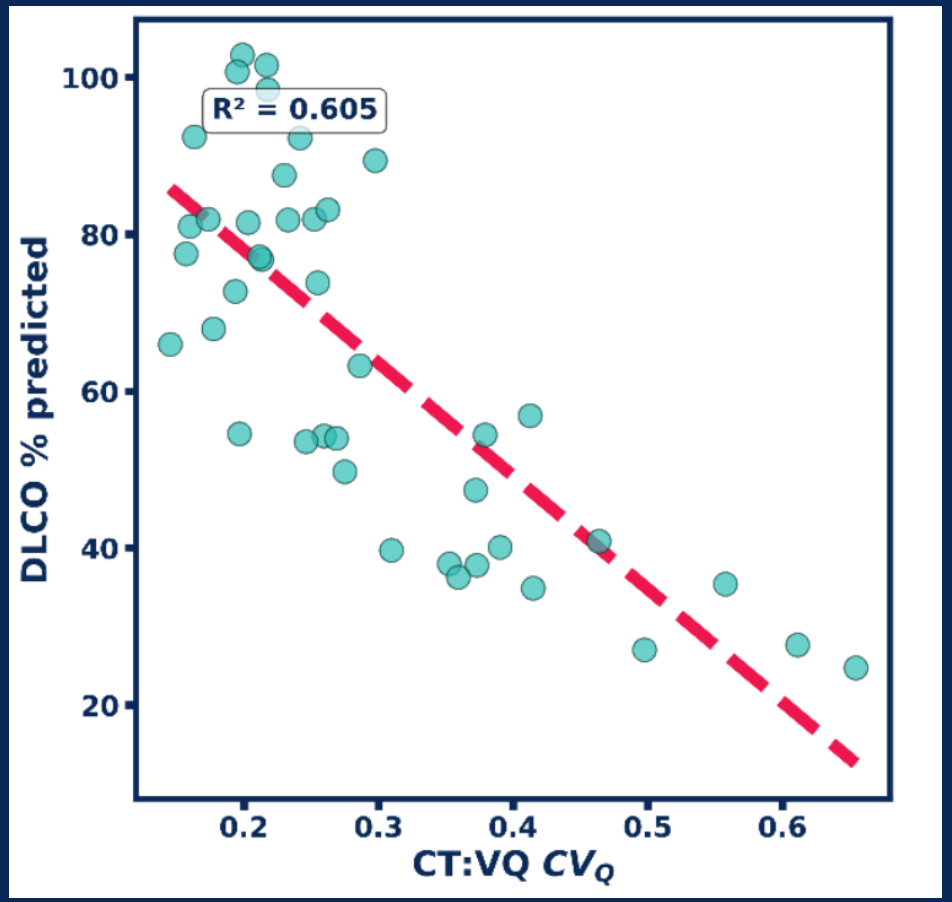
This is an expected result - significant heterogeneity of perfusion is linked to a loss of lung function.

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CT:VQ™ demonstrates a higher correlation to DLCO

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Heterogeneity of CT:VQ™ perfusion vs DLCO



The CV (co-efficient of variation) of CT:VQ perfusion correlates with DLCO (R2 = 0.557).

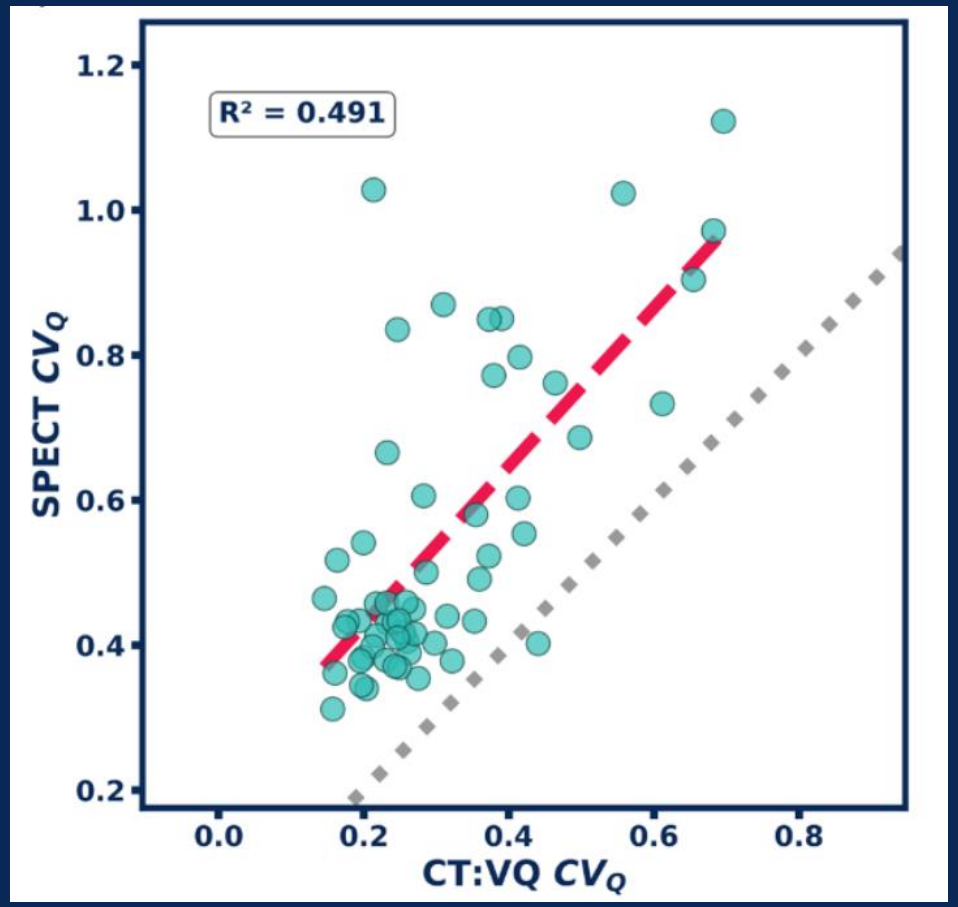
The substantially higher correlation coefficient (when compared to the SPECT derived measure) suggests either a higher SNR (signal-to-noise ratio) or a closer physiologic link.

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CT:VQ™ vs SPECT

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SPECT vs CT:VQ



When plotted against each other, all CV data lies above the line of unity, indicating that in all images the CV of SPECT perfusion is above the CV of CT:VQ perfusion.

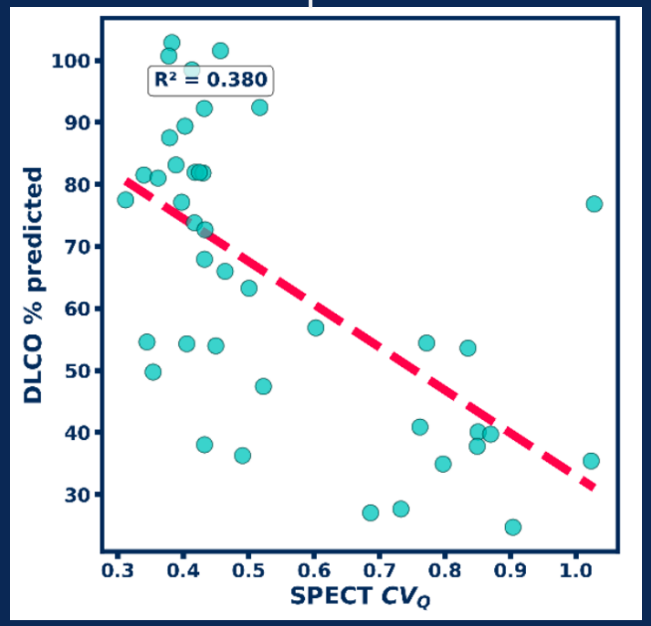
When combined with the fact that the correlation with DLCO is much higher with CT:VQ derived data, this is highly suggestive that CT:VQ perfusion, has less uncorrelated noise, or has a much higher SNR than SPECT perfusion.

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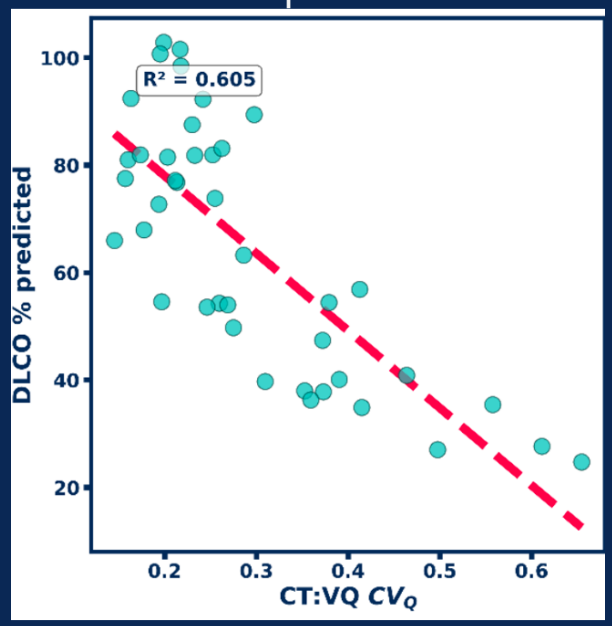
CT:VQ™ demonstrates lower noise than SPECT

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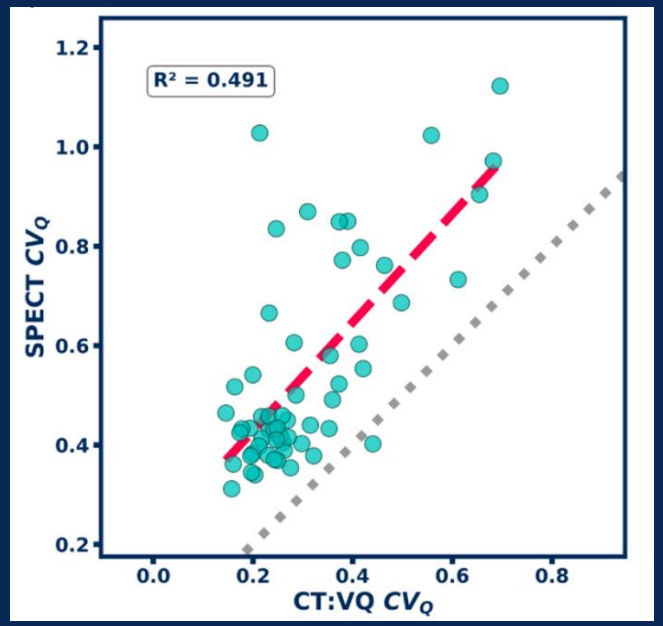
SPECT perfusion



CT:VQ perfusion



SPECT vs CT:VQ



The combination of stronger correlation with DLCO and lower heterogeneity, the differences in CV are highly suggestive that CT:VQ perfusion has a substantially higher SNR compared to SPECT perfusion.

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FDA timeline of communication during 510(k) review

Day 1
FDA receives **510(k) application**

By Day 7
FDA sends **Acknowledgement Letter**

By Day 15
FDA conducts **Acceptance Review**.
FDA informs applicant if 510(k) is accepted for **Substantive Review**

By Day 60
FDA conducts **Substantive Review**
FDA communicates proceeding to **Interactive Review** or Asks for **Additional Information**

By Day 90
FDA sends **final decision on 510(k)**

Important Notes:

- Days are Calendar Days
- The timeline is based on the performance goals set by Medical Device User Fee Amendments of 2012 (MDUFA III)
- When FDA asks for 'Additional Information' the review clock stops while applicant prepares response
- For 510(k) submissions received in 2024, the average 'Shared Outcome' Total Time to Decision goal for FDA and industry (including applicant response time) is 112 calendar days

Modified from: https://www.emergobyul.com/news/how-long-fda-review-process-510k-medical-device-submissions

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Key Takeaways of FDA submission

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With clear advantages in logistics, workflow, patient experience, and provider economics **CT:VQ™** must only **meet** clinical equivalence **to win** the initial $1B U.S. NUC:VQ market:

- CT:VQ™ has demonstrated **equivalence in quantitative stand-alone comparison** to SPECT; and
- CT:VQ™ has demonstrated **equivalence in clinical reader study** head-to-head with SPECT

Additionally:

- CT:VQ™ has demonstrated **superiority** through absence of contrast related artefacts that impact SPECT perfusion and significantly impact SPECT ventilation; and
- CT:VQ™ has demonstrated **lower noise and higher correlation with physiology** as measured by DLCO

No need for Radio-pharmaceuticals

Support clearer and faster diagnostic capability

Enhance accessibility through existing CT Scanners

Improved patient experience and cost of care

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1 million NUC:VQ scans in the US alone can be immediately displaced by CT:VQ™

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4DMedical intends to capture 100% of the 1 million NUC:VQ scans performed today AND grow this market organically by increasing the accessibility through a more-widely available modality as **the only non-contrast lung perfusion study**.

In discussions with key U.S. referrers, doctors have been overwhelmingly supportive of CT:VQ™:

Doctor 1 – *"I can't get (Nuc) VQ scans for all my patients due to the imaging department capping the number of VQ scans slots available. I would like to have that clinical information, and I am already getting CT scans. Combining the tests could be impactful to the way I manage their care"*

Doctor 2 – *"SPECT VQ is not available in our hospital, and we are still reliant on using Planar Scintigraphy for lung studies, but we have multiple CT scanners I can access. Shifting from Planar Scintigraphy to CT:VQ is a no-brainer"*

Doctor 3 – *"My facility has patients waiting for (Nuc) VQ outpatient scans 2-3 weeks before I can schedule my valve procedure, and often this requires a whole separate trip back to have the nuclear scan. I could add CT:VQ to the CT done as part of their regular clinical workup"*

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Clinical expert comment from Key Opinion Leader (KOL)

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"I am excited about being able to image perfusion in my patients without the delays and logistical challenges of nuclear imaging. I'm already ordering a non-contrast CT on these patients: I want to maximize the data from each scan, and this allows me to do that."

Professor D. Kyle Hogarth

- Professor of Medicine at the University of Chicago. He directs the Interventional Pulmonary and Advanced Bronchoscopy Program and co-leads the Lung Cancer Screening Program at UChicago Medicine.
- Dr. Hogarth pioneered the use of robotic bronchoscopy originally with the Monarch Platform and advanced imaging tools like LungVision® to improve early lung cancer diagnosis. His robotic program upgraded to the Noah Galaxy and he was the first to use this device in the United States. He runs one of the largest Bronchoscopic lung volume reduction programs (BLVR) in the country and the largest in the Midwest.
- An active researcher and educator, he lectures all over the world and has published extensively in premier journals such as the NEJM, Chest, AJRCCM, and others.

Built the fundamentals, significant multipliers in play during 2025

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…2025 → **Foundations established** → **Multiplier #1 Philips agreement** → **Multiplier #2 CT:VQ™ displacing NUC:VQ** → **2026….**

- ✓ Commercialisation of comprehensive lung function portfolio established, with >$6m run-rate
- ✓ Cost controls activated with OPEX reduction >$6.5m pa
- ✓ Key opinion leaders and reference sites on-boarded.
- ✓ Commercial–payers, VA, DoD and AMCs activated
- ✓ CMS Reimbursement granted for key products at $650 & $311 (USD)
- ✓ Extensive regulatory clearances, including 8 FDA cleared products

\+ **25 x** Sales personnel

>25x increases sales coverage

Current activation of Agreement creates large commercial coverage across all sectors in US healthcare

\+ **>$1b** US market opportunity

Better resolution, lower cost and a more integrated approach to workflow, CT:VQ™ can displace existing $1b market for NUC:VQ and grow the market through increased accessibility of CT

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4DMedical Limited (ASX:4DX)
27 May 2025

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