4DMedical™

CT:VQ™

Instructions for Use US

This edition is valid for all releases within V2 of the Device

CT:VQ™ Instructions for Use US

Contents

1 Preface

These Instructions for Use (IFU) describe the operation of CT:VQ™. 4DMedical recommends that the requesting physician takes note of all advice and precautionary statements included in this manual. Prior to use, please read this entire document.

2 Symbols

The meaning of the symbols shown on the labeling and/or instructions for use are as follows:

CAUTION for information related to patient safety

Consult Electronic Instructions for Use

Manufacturer

Date of Manufacture (YYYY-MM-DD)

Medical Device

Unique Device Identifier

Batch Code (Device Version)

Caution: Federal law restricts this Device to sale by or on the order of a physician.

3 Acronyms

CT	Computed Tomography
CT:VQ	Computed Tomography Ventilation Perfusion
DICOM	Digital Imaging and Communications in Medicine
FOV	Field of View
Q	Perfusion
SaaS	Software as a Service
V	Ventilation

4 Product Overview

CT:VQ is a software analysis technology, which can be used in the analysis of two non-contrast thoracic CT reconstructed volume scans (one at inspiratory phase and one at expiratory phase). It is designed to quantify regional ventilation (V) and regional perfusion (Q) in the lungs of adult patients.

The Device provides quantitative information to aid in the assessment of thoracic diseases. These regional ventilation measures are derived from the lung tissue displacement and the lung volume change between the paired inspiration-expiration chest CT, and the regional perfusion measures are derived from the pulmonary vasculature and the lung tissue density.

4.1 Indications for Use

CT:VQ software is a non-invasive image post-processing technology, using CT lung images to provide clinical decision support for thoracic disease diagnosis and management in adult patients. It utilizes two non-contrast chest CT studies to quantify and visualize ventilation and perfusion.

Quantification and visualizations are provided as DICOM Images. CT:VQ may be used when Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians need a better understanding of a patient's lung function and/or respiratory condition.

4.2 Intended Use

CT:VQ is intended to be used by referral from Radiologists Pulmonologists, and/or Nuclear Medicine Physicians or equivalent. The CT:VQ software can be used to provide these physicians with additional supporting clinical data regarding pulmonary ventilation and perfusion for use in adult patients.

5 Radiation Safety

Acquisition of CT:VQ inputs involves exposure to radiation. A paired inspiration-expiration chest CT is required for the analysis. The requesting physician must use their judgement to assess the risk to the patient before proceeding with acquisition of images. For more information on the image acquisition protocol please refer to Section 8.

6 Result Interpretation and Considerations

The output containing image and quantitative data will be made available to the ordering physician and a trained diagnostic specialist (e.g., Radiologist or other physician). This software is designed to run on any input data that satisfies the criteria in Section 7. It is the responsibility of the medical professional who is acquiring the images (i.e., Radiologic Technologist) to ensure that the input data is of adequate quality. The quality of the input data directly affects the output results; areas with artifacts or anomalies may lead to undesired outcome. Either CT:VQ will be unable to create an output or the output may be non-optimal, but within an acceptable deviation. Thus, when an output is received, the receiving physician must interpret CT:VQ results with clinical judgment. Note that quantification is based only on measured areas shown in the visual representation.

7 Device Input Requirements

The Device requires a paired inspiration-expiration thoracic CT, captured in a single study on a CT scanner, and a lung mask (which does not need to be provided by the customer). The software is designed for inputs acquired from equipment maintained and calibrated to the manufacturer's specifications. If the input images do not meet the following criteria, the images will be rejected by the Device, and no analysis will be undertaken.

7.1 CT Resolution

To produce a output, the minimum resolution for the CT images must meet the following requirements:

Name	Required Value
Pixel Spacing	≤1.00 mm
Slice Spacing	≤2.5 mm
Slice Thickness	≤2.5 mm

7.2 Lung Volume Difference

NOTICE: The total lung volume difference between the inspiratory and expiratory CT images must be more than 0.5 liters (or more than 10% of the expiration CT volume). If the measured volume is less than 0.5 liters or 10% of the expiration CT volume, then no output will be generated.

NOTICE: If the expiratory to inspiratory volume change is less than 0.8 Liters and 20% of expiratory volume, the low values may be related to the image acquisition process and may not be representative of the patient's actual lung function.

If a notice is present in the output and is not believed to be due to an error in the image acquisition, please contact 4DMedical using the information in Section 12.

7.3 CT: Filetype

The CT images must be in DICOM (Digital Imaging and Communications in Medicine) format. An uncompressed DICOM format is preferred, however, a lossless compression algorithm is acceptable.

Ensure that the PACs and/or DICOM routing configuration preserves the original metadata, as this data is required for analysis. See *DOC-8968 DICOM Conformance Statement* for details on integration requirements with your PACS.

8 Imaging Protocol

The imaging protocol for a CT:VQ output is documented in *DOC-8898 CTVQ Imaging Protocol*.

8.1 Image Transfer, Analysis Ordering and Output Delivery

4DMedical utilizes data transfer and sharing systems to facilitate the transfer of CT series from healthcare facilities to the Device for processing. To order a CT:VQ output, follow these steps:

1. **Create an Order:** At your institution, create an Exam with CT:VQ procedure code.
2. **Acquire Images:** Acquire images required for input as per the Imaging Protocol documented in *DOC-8898 CTVQ Imaging Protocol*, also refer to Section 7 for Device Input Requirements.
3. **Initiate Data Transfer:** Once the images have been acquired, initiate the data transfer at your facility. The images will be transmitted to the Device for processing. For technical details about data sharing, consult your facility's *Guide to Data Transfer*.
4. **Receive the Output:** After the Device completes analysis, the CT:VQ output will be returned to your facility via the same data transfer system.

Need Assistance?

If your institution requires help setting up the data transfer process to 4DMedical's platform, please contact your local 4DMedical representative.

9 Device Outputs

The primary outputs of the software are the regional ventilation measurements and the regional perfusion measurements calculated from the paired inspiration-expiration chest CT. A DICOM output is provided of regional ventilation, regional perfusion, quantifications and the label. Output data is provided for the masked lung region only.

9.1 Regional Ventilation

Regional ventilation measurements are derived from the lung tissue displacement and the lung volume change between the paired inspiration-expiration chest CT, and are presented as DICOM outputs of the same alignment and spatial resolution as the input expiratory CT DICOM image. The intensity (grayscale) values of each pixel values represent the specific ventilation at the corresponding location on the expiratory CT.

9.2 Regional Perfusion

Regional perfusion measurements are derived from the lung tissue displacement and density field, and are presented as DICOM outputs of the same alignment and spatial resolution as the input expiratory CT DICOM image. The intensity (grayscale) values of each pixel values represent relative perfusion magnitude at the corresponding location on the expiratory CT.

9.3 Volume

Inspiration Volume The total volume (L) of lung tissue at deep inspiration.

Expiration Volume The total volume (L) of lung tissue at deep expiration.

Change in Volume The difference in the volume (ΔL) between deep inspriation and deep expiration.

10 Testing

10.1 Summary of Verification

4DMedical has conducted performance testing of CT:VQ on a broad combination of synthetically generated phantom images and clinically-acquired datasets. The clinically-acquired data included paired chest CTs acquired on CT scanners across a range of manufacturers and models and at different institutions, across a diverse range of patients. It also included inspiration and expiration CTs of varying lung volume and image properties. The input CT properties most affecting the quantitative measurements are voxel size and signal-to-noise-ratio (SNR). The verification testing demonstrated that the Device was robust within acceptable performance limits across the entire range of these inputs.

10.2 Summary of Clinical Studies

The performance of CT:VQ was assessed across multiple clinical studies, and across the diverse patient population typically referred for nuclear VQ imaging. The studies included patients across the spectrum of lung health and included subjects with pulmonary thromboembolic disease, chronic pulmonary disease (such as Chronic Obstructive Pulmonary Disease and small airways disease), and subjects awaiting pulmonary interventions (such as lung volume reduction therapy). The studies compared the regional ventilation and perfusion measurements output by CT:VQ with gold-standard and best practice measures for respiratory diagnosis. Specifically, the performance of the Device was assessed quantitatively and qualitatively to determine consistency of the Device's outputs with Nuclear Medicine Imaging (Single photon emission computed tomography, SPECT) and pulmonary function tests (Diffusing capacity of the lung for carbon monoxide (DLCO) and FEV1/FVC ratio).

A Reader Performance Study was performed with n=77, while a Standalone Performance Assessment was performed with a subset of 58.

In the **Standalone Performance Assessment**, CT:VQ showed strong regional agreement with SPECT VQ across lobar distributions of ventilation and perfusion. Quantitative perfusion heterogeneity metrics derived from CT:VQ demonstrated stronger associations with gas transfer impairment (DLCO) than those derived from SPECT, suggesting improved physiological sensitivity. Similarly, ventilation heterogeneity metrics from CT:VQ correlated well with FEV1 and FEV1/FVC % predicted, further supporting the clinical relevance of the CT-based outputs.

In the **Reader Performance Study**, clinicians with expertise in thoracic imaging and pulmonary care consistently rated CT:VQ outputs as having good to excellent agreement with SPECT across all lung regions. Inter-reader variability was not significantly different for CT:VQ than for SPECT, adding to the overall very strong inter-modality agreement. These findings affirm that CT:VQ outputs are interpretable and clinically actionable by intended users.

Case Studies further illustrated key advantages of CT:VQ, including higher spatial resolution and the absence of common SPECT-related artifacts such as esophageal contamination and central airway deposition. In each case, CT:VQ successfully replicated the diagnostic findings of SPECT while offering enhanced image clarity and anatomical fidelity.

The clinical studies conducted for the Device successfully demonstrated the feasibility of generating valid data that is reliable and consistent with Nuclear Medicine Ventilation imaging results. The studies demonstrated strong correlation between CT:VQ and SPECT in the assessment of regional distribution of ventilation and perfusion and that there was a statistically significant correlation between the CT:VQ and PFT outputs.Based on the clinical performance documented in the clinical studies, CT:VQ was found to have a safety and effectiveness profile that is similar to the primary predicate Device. Further, it demonstrated the capability of the Device to provide this information without the use of contrast agents utilized by alternative methods.

11 Information Security Statement

CT:VQ and the results can be delivered through different deployment approaches. Depending on the implementation, certain components, such as a DICOM Router or virtual machines (VMs), may need to be managed by your local institution's IT support. Information security is a shared responsibility, please follow your institutions information security protocols. 4DMedical will follow the appropriate jurisdictional requirements in communicating with your institution regarding information security, as required.

11.1 Cybersecurity Recommendations

When deploying systems on which this application will run, please consider the following technical security guidelines:

- Ensure only permitted users are able to sign into the system, using at minimum, a username and strong password;
- Ensure that system firewalls are configured in such a way as to only allow needed traffic to ingress the system;
- Ensure that all system patches are kept up-to-date, and monitor the system's vendor communication for security and patching-related announcements; and
- The Device will only be available when the cloud service or network connection is available.

12 Support

12.1 Support

For support, contact 4DMedical using the details below during standard business hours.

Contact 4DMedical U.S.

Phone: +1 833 VQ SCANS (+1 833 877 2267)
Address: 21255 Burbank Blvd. Suite 120
Woodland Hills, California
91367
U.S.A
Email: support@4DMedical.com | 4DMedical.com/support

12.2 Regulatory Information

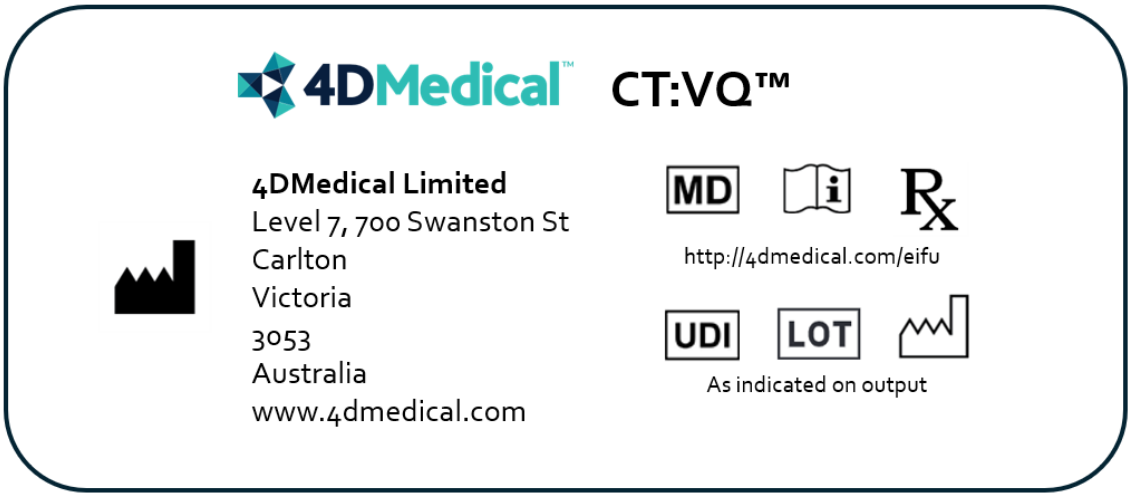

Figure 1: Device Label

The information provided is intended to support physicians with their assessment of patients with lung diseases. CT:VQ and the resulting output does not, in itself, provide a diagnosis of lung health. 4DMedical assumes no responsibility for the improper use of, or self-diagnosis using, CT:VQ and the resulting DICOM.