CT LVAS
Instructions for Use US

Contents

1. Preface

These Instructions for Use (IFU) describe the operation of the CT LVAS Software, and CT LVAS Ventilation Report. 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 labelling and/or the instructions for use are as follows:

CAUTION
For information related to patient safety.

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

Consult Electronic Instructions for Use

Manufacturer

Date of Manufacture (YYYY-MM-DD)

Medical Device

Unique Device Identifier

3. Acronyms

CT	Computed Tomography
CT LVAS	Computed Tomography Lung Ventilation Analysis Software
DICOM	Digital Imaging and Communications in Medicine
FOV	Field of View
SaaS	Software as a Service

4. Product Overview

CT LVAS is a software-based image processing technology that analyzes two non-contrast CT images, reporting detailed ventilation information of pulmonary tissue, at regional locations of the lungs between inspiratory and expiratory volumes. Quantification and statistics are provided in the form of a CT LVAS Ventilation Report, including:

- The volume of ventilation, presented as three values;
- Visualization of lung ventilation with color-defined specific ventilation ranges overlaid on the CT slices;
- The heterogeneity of lung ventilation, presented as three values, which quantifies the regional variability of the ventilation; and
- Ventilation histogram of lung voxels' relative frequencies showing the frequency distribution of regional specific ventilation measured across the entire lung, including ventilation defect percentage which shows the volume of lung with low ventilation.

4.1 Indications for Use

CT LVAS software is a non-invasive image processing technology that utilizes a paired inspiration-expiration CT to quantify and visualize regional and global ventilation within the lungs. The device provides physicians with additional clinical data to support management of pulmonary disease. Quantification and visualizations are provided in the form of a report.

4.1.1 Intended Use

The CT LVAS is intended to be used by referral from thoracic radiologists, pulmonologists or equivalent. The CT LVAS software can be used to provide these physicians with additional supporting clinical data regarding pulmonary ventilation for use in adult patients.

5. Safety and Regulatory

The CT LVAS Ventilation Report is intended to be interpreted by the requesting physician and they must ultimately use their clinical judgement in making decisions that concern patient management (See Section 6 for detailed information about acceptable datasets). Areas with artefacts and anomalies within the imaging may give unpredictable results, and therefore, the CT LVAS results should be interpreted with appropriate clinical judgement.

This software is designed to run on any input data that satisfies the criteria in Section 6. It is the responsibility of the medical professional who is using the software (i.e., Radiologic Technologist) to ensure that the input data is of adequate quality. If the input data is not of adequate quality, the output CT LVAS Ventilation Report results will reflect the quality of the input data.

Read all safety information prior to prescribing acquisition of input data.

5.1 Precautions

CAUTION Acquisition of CT LVAS 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 7.

CAUTION Values presented in the CT LVAS Ventilation Report are dependent on the correct information being supplied in the input data and associated metadata. The requesting physician is responsible for the suitability of the input images.

CAUTION The CT LVAS Ventilation Report output is dependent on the quality of input images. Images containing motion artifacts or the presence of foreign objects (e.g., metallic components) may impact the quality of the Report outputs.

6. Device Input Requirements

CT LVAS requires a pair of inspiratory and expiratory chest CT images, captured in a single study.

6.1 Image Requirements

6.1.1 CT: Resolution

To produce a CT LVAS Ventilation Report, the inspiration and expiration CT images must meet the following requirements:

Name	Required Value
Pixel Spacing	≤2.5mm
Slice Spacing (Interval/Increment)	≤2.5mm
Slice Thickness	≤2.5mm

6.1.2 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.

If the input images do not meet the above criteria, the images will be rejected, and no analysis will be undertaken.

7. Imaging Protocol

For the chest CT scans, the radiologic technologist shall acquire a paired inspiration-expiration chest CT of the patient. A standard non-contrast CT Chest protocol is recommended, with CT scans acquired at deep inspiration and at deep expiration.

Sections 7.1 and 7.2 provide instructions for acquiring suitable chest CT scans.

7.1 Patient Setup and Configuration

- The paired inspiration-expiration CT shall be captured in a single study.
- Scan patient in a supine position aligning longitudinal axis of the body with longitudinal axis of the CT scanning bed.
- Use imaging and reconstruction parameters consistent with a standard non-contrast CT Chest protocol.
- Ensure patient's arms are out of the Field of View (FOV), for example, by placing them above the head.

7.2 Imaging Requirements

7.2.1 Inspiration CT

- Ensure image resolution settings meet the requirements outlined in Section 6.1.1
- Position patient in **supine position**
- Capture a breath hold CT image at **deep inspiration**
- Ensure coverage is cranial-caudal lung apices through to lung bases
- FOV shall include the entire lungs (e.g., 1cm beyond the edge of the patient)

7.2.2 Expiration CT

- Use the **same resolution settings** as the inspiration CT
- Keep the patient in **supine position**
- Capture a breath hold CT image at **deep expiration**
- Ensure coverage is cranial-caudal from lung apices through to lung bases
- FOV shall include the entire lungs (e.g., 1cm beyond the edge of the patient)

7.3 Image Transfer and CT LVAS Ventilation Report Delivery

4DMedical utilizes a DICOM routing system to transfer the CT scan to 4DMedical's SaaS platform for processing, that is managed by your institution. If your institution requires assistance establishing a connection to 4DMedical's SaaS platform, please contact your local 4DMedical representative.

8. Information Security Statement

CT LVAS and the resulting CT LVAS Ventilation Report are delivered using a Software as a Service (SaaS) model, with one main component, commonly referred to as a DICOM Router, which needs 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.

9. Support and Notice

9.1 Support

To contact 4DMedical please use the details below. Support will be available during 4DMedical's standard business hours.

Contact 4DMedical

4DMedical
21255 Burbank Blvd. Suite #120
Woodland Hills, California, 91367
USA

Phone: +1-833-XV-SCAN (+1-833-98-72267)
Email: support@4DMedical.com | 4DMedical.com/ventilation-support

9.2 Notice

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

10. Glossary

See below for more information regarding terms found in the CT LVAS Ventilation Report. For a more detailed explanation of these terms, refer to the how-to-read section of the CT LVAS Ventilation Report.

Expiration Volume	The total volume (L) of lung tissue at deep expiration.
Inspiration Volume	The total volume (L) of lung tissue at deep inspiration.
Specific ventilation	Defined as the ratio of the change in volume of a region of the lung (ΔV) following an inspiration, divided by the end-expiratory volume (V_0) of that same lung region. Presented values are normalized by mean specific ventilation (i.e. normalized by the average of the specific ventilation values).
Ventilation defect percentage	The percentage of ventilation volume below 60% of the mean specific ventilation.
Ventilation Heterogeneity	The regional variability of the ventilation. This is the ratio of the interquartile range to the mean of the specific ventilation. Low Ventilation Heterogeneity values are associated with uniform ventilation throughout the lung, while high Ventilation Heterogeneity values represent significant variability in the lung.
Ventilation heterogeneity: large scale	The degree of heterogeneity within larger regions of the lung (e.g. lobar and larger), calculated after first filtering out small scale variations (i.e. scales smaller than 64 mm / 2.5”).
Ventilation heterogeneity: small scale	The degree of heterogeneity within local regions of the lung (e.g. alveolar to lobar size), calculated after first filtering out large scale variations (i.e. scales larger than 64 mm / 2.5”).
Ventilation heterogeneity: total	The overall value of heterogeneity, calculated using all regional specific ventilation data (as displayed in the Ventilation Report Regional Ventilation Visualizations)
Change in Volume	The difference in the volume (L) between deep inspiration and deep expiration.