Lung Density Analysis Software

Fissure Completeness Configuration

Instructions for Use US

This edition is valid for Device release from 5.2.x

LDA Instructions for Use

US

Contents

1 Introduction

1.1 Manual Scope

4DMedical's Lung Density Analysis™ Software is capable of running in multiple modes with various configurations. This User Manual covers the mode that analyzes fissure integrity in addition to quantifying low density. This is the mode that powers the SeleCT analysis for users of the Spiration Valve manufactured by Olympus.

1.2 Product Overview

The LDA Software is a set of image post-processing algorithms designed to help radiologists and pulmonologists determine the location and extent of tissue damage in patients with COPD, by providing visualization and quantification of areas with abnormal CT tissue density. The LDA Software runs automatically on the input CT series, with no user input or intervention.

The LDA software analyses high resolution CT DICOM images of the lung at inspiration. The specific input requirements are given in the Scan Protocol section of this document (Section 3.2).

The LDA algorithm provides a DICOM or PDF summary report with the results of the analysis.

1.3 Hardware Requirements

Hardware requirements for running LDA are as follows:

- 8 CPU Cores
- 32 GB RAM
- 50 GB

2 Symbols

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


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 Indications for Use and Requirements

The CT Lung Density Analysis™ Software provides reproducible CT values for pulmonary tissue, which are essential for providing quantitative support for diagnosis and follow up examinations. The CT Lung Density Analysis™ Software can be used to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, and reporting tools are provided.

3.1 Intended Users

The intended users for the LDA Software are pulmonologists, radiologists, and radiology technicians under the supervision of a pulmonologist or radiologist.

3.2 Scan Protocol Requirements

To ensure an optimal QCT Analysis, please adhere to the following guidelines. It is important that the patient fully understands the breathhold and scanning procedure, and that any concerns are addressed prior to performing the CT scan.

Table 1: Recommended protocol for LDA input images.

	SIEMENS	PHILIPS	TOSHIBA	GE
Smooth Kernel Reconstruction	≤B45, ≤I45	B, C	≤FC08, FC10-FC18	Standard
Breathhold at	TLC, Full Inspiration			
Slice Thickness	≤1.5 mm			
Slice Spacing	Consistently spaced, no gaps, and ≤1.5 mm			
Anatomic Coverage	Full coverage of the lungs			
Severe Motion Artifact	Absent			
Contrast Enhanced	None			

3.2.1 Breathing Instructions

The patient should be coached to achieve and hold full inspiration, with several practice attempts prior to scan acquisition. If the patient is unable to hold their breath for the scan period, such as the case for a severely ill patient, a faster scanner needs to be utilized. Below is a suggested script of how to coach a patient for a successful breathhold.

Breathing Instructions Script

Inspiratory CT

For the first part of this scan, I am going to ask you to take a deep breath in and hold it

First let's practice:

Take a deep breath in

Hold it - do not breathe

Breathe and relax

Take a deep breath in

Let it out

Take a deep breath in

Let it out

Breath all the way IN…IN…IN…

Keep holding your breath - DO NOT BREATHE!

At end of scan: Breathe and relax

Start scan at bottom of lungs; end at top of lungs

3.2.2 Subject Positioning

The patient should be in the supine position. Arms should be positioned comfortably above the head in a head-arm rest, lower legs supported. Using the laser positioning lights, line up the patient so the chest is at the isocenter of the CT gantry. Move the table so the patient is in the correct position for a chest CT scan.

3.2.3 Scan Coverage

The scan should completely cover the entire lungs in all directions. Failure to capture the full extent of the lungs could result in analysis failure.

Figure 1: Images showing proper scan coverage in axial, coronal and sagittal orientations.

4 Quality Assessment

The scan quality and possible artifacts must be assessed before utilizing the results produced by the LDA Software.

This software is designed to run on any input data that satisfies the criteria in Section 3.2 and it does not perform any additional quality checking. **It is the responsibility of the medical professional who is using the application (i.e., the Thoracic Radiologist or General Radiologist) to ensure that the input data is of adequate quality**. If the input data is not of adequate quality, the application's results should be disregarded.

LDA was designed and validated on adult chest CT images and has not been validated on children.

5 LDA Software

5.1 Input

The LDA Software requires one DICOM format high resolution CT image series as input. Reference Section 3.2 for more information.

5.2 Optional Feature: Fitlering

If both RevolutionTime (0018,9305) and XRayTubeCurrent (0018,1151) are present in the input metadata and the average series mAs is < 80 mAs, a noise reducing filter is applied to the lung datasets before classification. Filtering options can be configured at installation or upon request.

There are tradeoffs between the two options, unfiltered and filtered. Filtering before classification allows for robust classification of low signal-to-noise ratio (SNR) images (high specificity) at the expense of missing small areas of low attenuation (reduced sensitivity). Not filtering before classification allows for identification of small areas of low attenuation areas (high sensitivity) at the expense of small erroneous classifications of low attenuation areas in noisy images (reduced specificity).

The user is allowed to determine if filtering is appropriate for classification for the input images based on the patient of interest and the noise level of the scans.

5.3 Outputs

When run with appropriate input data, the LDA Software generates a Summary Report, Inspiration Assessment Map, Fissure Completeness Map, and Segmentation Map. More information about these outputs are provided below. In the event that input data fails the input check process, an Input Check Failure Report will be generated.

5.3.1 LDA Summary Report

The LDA Summary Report contains the results from the LDA Software analysis. It can be provided in several formats: PDF file, DICOM encapsulated PDF, or a DICOM Secondary Capture Storage.

The two key quantitative measures reported in the LDA report include:

- **Fissure Completeness**: Has been used as a surrogate for collateral ventilation expressed as a percent of fissure completeness[1].
- **Emphysema Severity**: Measure of emphysema defined as the percent of tissue below a threshold of -920 HU[1].

Keys are included on each report to help providers interpret information in the graphics, see Figure 2.

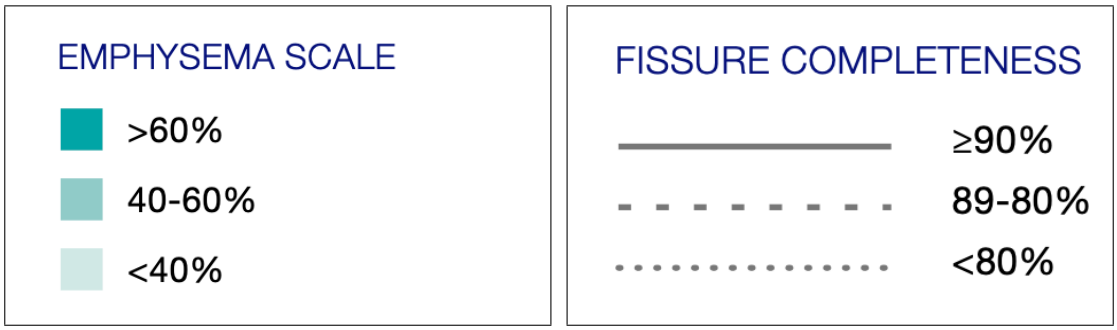


Figure 2: Keys on the report to aide in interpretation of the results.

Each lobe (excluding the RML) has a circle that contains values for (E)mphysema Severity, and (F)issure Completeness, pertaining to that lobe. There is also a circle that contains the quantitative results for the RML + RUL, as shown in Figure 3.

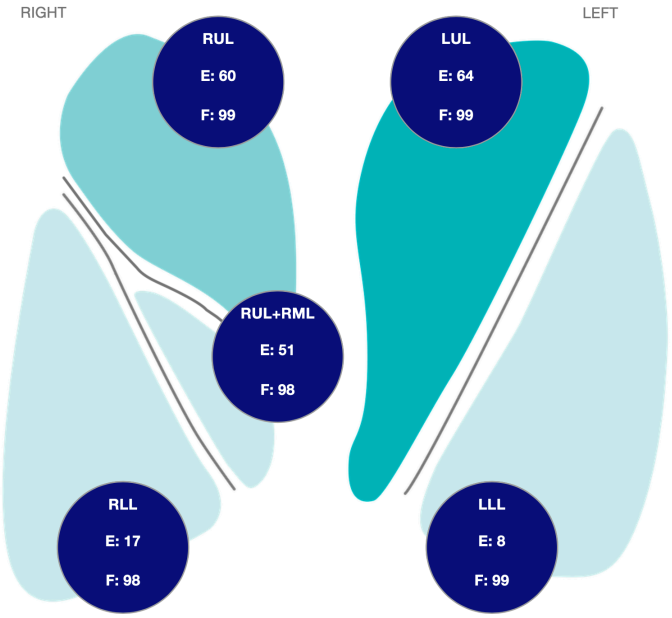


Figure 3: Visualizations of the lungs showing results of the analysis.

The key metrics for each lobe, as well as for the right middle and right upper lobes combined, are displayed in a table on the report, along with lobar volume, see Figure 4.

	RUL	RML	RUL+RML	RLL	LUL	LLL
EMPHYSEMA (% -920 HU)	**60**	**22**	**51**	**17**	**64**	**8**
FISSURE COMPLETENESS	**99**	**NA**	**98**	**98**	**99**	**99**
EMPHYSEMA (% -950 HU)	**40**	**4**	**32**	**5**	**44**	**2**
VOLUME	**1116**	**330**	**1446**	**980**	**1456**	**686**

Figure 4: Key metrics and lobar volume.

Lastly, on the bottom of the report are 3D renderings showing the fissure completeness of each fissure: right oblique, right horizontal and left oblique. The blue color indicates regions of complete fissures, while the red indicates regions with imaging features that suggest an incomplete fissure. Notice the orientation of the right horizontal fissure rendering is slightly rotated such that an unobstructed view of the fissure is achieved.

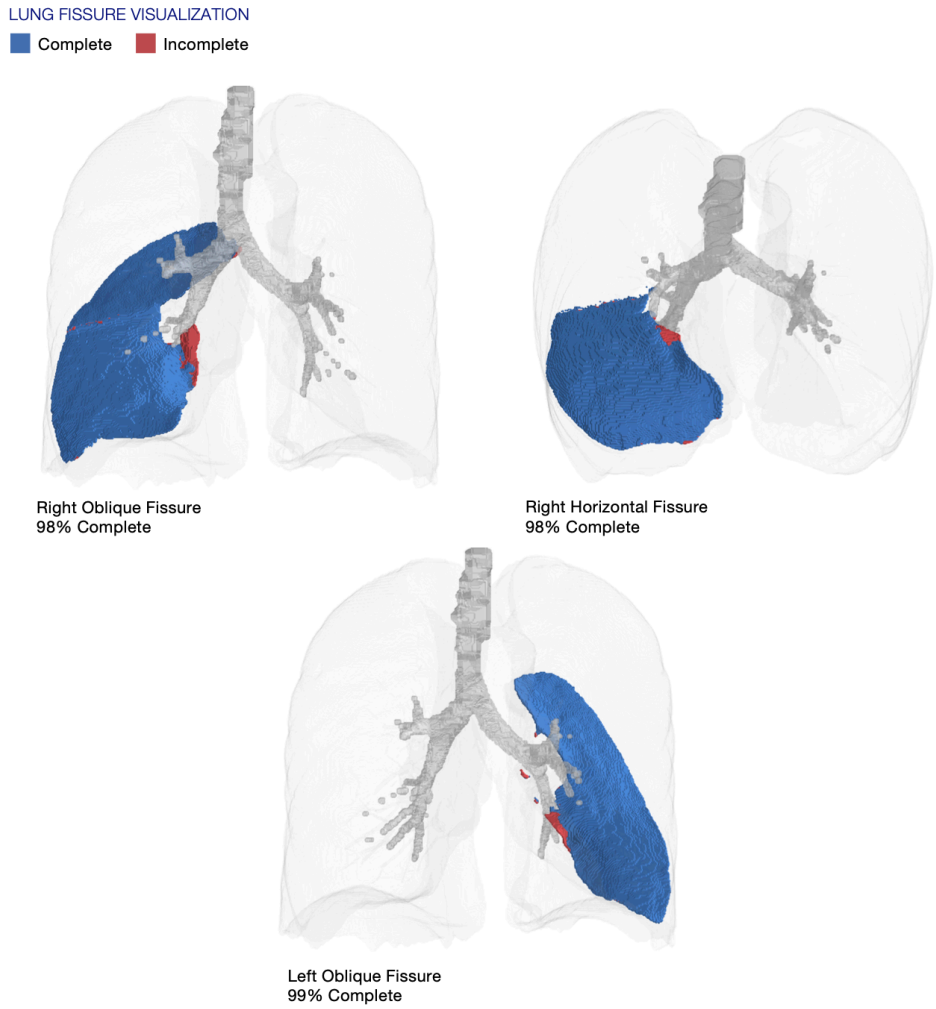


Figure 5: 3D rendering of the fissure completeness per fissure.

5.3.2 SeleCT Inspiration Assessment Map

The Inspiration Assessment Map is a DICOM Secondary Capture Image with voxel data that is the original inspiration image with an RGB overlay. Voxels that are labeled as lung tissue by the segmentation algorithm and have a HU value below the inhalation thresholds are identified by an opaque red color for the -950 HU threshold and an opaque yellow color for the -920 HU threshold.
An example of a slice from the SeleCT Inspiration Assessment Map is shown below in Figure 6.

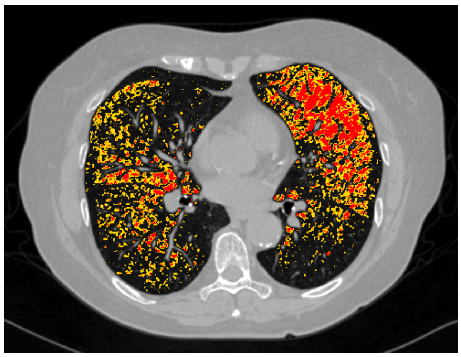


Figure 6: Slice of Inspiration Assessment Map

5.3.3 Fissure Completeness Map

The Fissure Completeness Map is a DICOM Secondary Capture Image with voxel data that is the original inspiration image with an RGB overlay. Voxels that are labeled as a pulmonary fissure by segmentation algorithm are identified in the RGB overlay. the The opaque blue color indicates regions of complete fissures, while the opague red indicates regions with imaging features that suggest an incomplete fissure.
An example of a slice from the Fissure Completeness Map is shown below in Figure 7. See section 6 for more details on how to interpret the images.

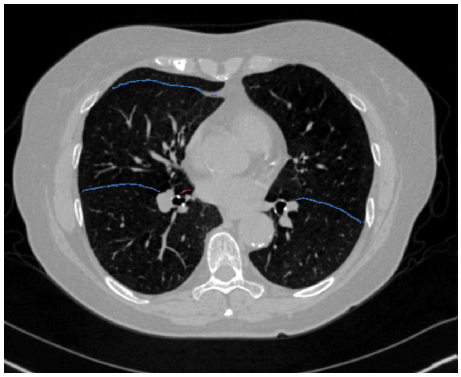


Figure 7: Slice of Fissure Completeness Map

5.3.4 Segmentation Map

The LDA Software produces a segmentation DICOM series so that users can assess the quality of segmentation. The Segmentation Map is a DICOM Secondary Capture Image with voxel data that is the original inspiration image with an RGB overlay. The upper right, middle right, lower right, upper left, and lower left lobes are labeled.
An example of a slice from the Segmentation Map is shown below in Figure 8. See Figure 9 for a list of the colors used for anatomical labeling. See section 6 for more details on how to interpret the images.

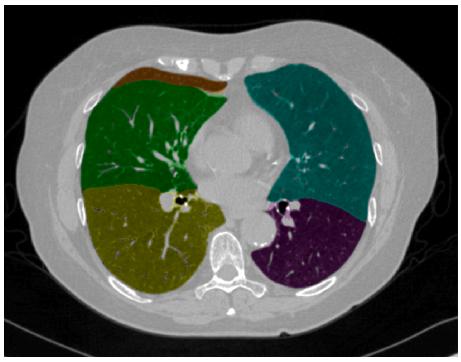


Figure 8: Slice of Segmentation Map

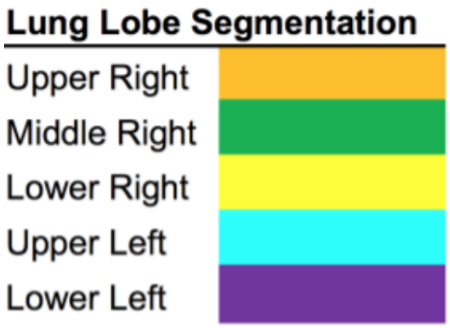


Figure 9: Lung Segmentation Label Colors

5.3.5 Screening Outputs

If the LDA software is used in screening mode, outputs from LDA Inspiration Analysis will also be created, including reports and an inspiration assessment map. These outputs are described in the LDA Software manual.

5.3.6 Input Check Failure Report

In the event that the input data is determined to not meet the minimum requirements, the algorithm will output an Input Check Failure Report indicating the reason why the input data was deemed unacceptable. An example Input Check Failure Report is shown in Figure 10. The cause(s) of the input check failure can be identified by the red 'X' mark in the Result column. In Figure 10, the offending parameter is the slice thickness. Note the yellow triangle warning signs indicate sub-optimal parameters (Convolution Kernel) or parameters that are missing from the input meta data (Revolution Time). These warnings will not result in an input check failure, but should be noted nonetheless.

SCAN ID:	SERIES:	SERIES INSTANCE UID:	STUDY DATE:	ORDER DATE:
6789	5348	1.3.6.1.4.1.19291.2.1.2.16413	December 3, 2009	July 5, 2023

KERNEL: X BONE – This kernel is NOT recommended.

	ACCEPTABLE RANGE	VALUE	ASSESSMENT
MODALITY	CT	CT	✓
REVOLUTION TIME (S)	<= 1.0	Not Present	⚠
PIXEL SPACING (MM)	<= [2.0, 2.0]	[0.607, 0.607]	✓
FOV (MM)	>= (100, 100, 200)	(311, 311, 295)	✓
IMAGE ORIENTATION	(±1,0,0,0,±1,0)	(1.0, 0.0, 0.0, 0.0, 1.0, 0.0)	✓
SLICE SPACING (MM)	<= 1.5	2.5	X
SLICE THICKNESS (MM)	<= 1.5	5.0	X
RESCALE TYPE	HU	HU	✓
PATIENT AGE (YEARS)	>= 18	52	✓
CONTRAST BOLUS AGENT	Missing	Missing	✓
TRANSFER SYNTAX UID	Non-Big-Endian	OK	✓
STATUS			REJECTED

Figure 10: Input check failure report

6 Quality Assessment of Segmentation Outputs

The LDA Software uses advanced image processing techniques to segment the lungs from thoracic CT images. The software produces a segmentation DICOM and fissure completeness DICOM series so that users can assess the quality of segmentation.

In order to detect segmentation errors, LDA software checks input parameters and lung segmentation statistics, and notifies users with warning or error messages if potential problems are discovered. Even so, there may be a small number of cases where poor segmentation quality is not automatically detected and the output report is generated with potentially misleading results. These cases can be categorized as one of the following:

- Lung inclusion errors. This includes but is not limited to the following:
  - Air outside of the body is categorized as lung.
  - Air in the gut is categorized as lung.
  - Air in the esophagus is categorized as lung.

- Lung exclusion errors. This includes but is not limited to the following:
  - Part of the lung is categorized as belonging to the airway tree, removing that part of the lung from the analysis.
  - The apex of the lung is categorized as part of the trachea.
  - High-density areas of the lung parenchyma are excluded from the segmentation.
- Left/right lung labeling error.
  - Part of the left lung is incorrectly classified as belonging to the right lung, or vice versa.
  - Either the left or right lung is excluded from the segmentation.
- Lung lobe labeling error. This includes but is not limited to the following:
  - A lung lobe is missing from segmentation.
  - Part of a lung lobe is incorrectly classified as belonging to another lung lobe.

Users of the software should review the segmentation and fissure completeness outputs to assure that segmentation accurately represents the underlying lobar anatomy. If segmentation errors are present, the results should not be used. The 4DMedical Lung Density Analysis™ Software should only be used by Pulmonologists, Radiologists, and Radiology Technicians under the supervision of a Pulmonologist or Radiologist.

NOTE: Viewing the lobar segmentation and fissure maps in the sagittal plane may be be especially helpful for detecting segmentation errors.

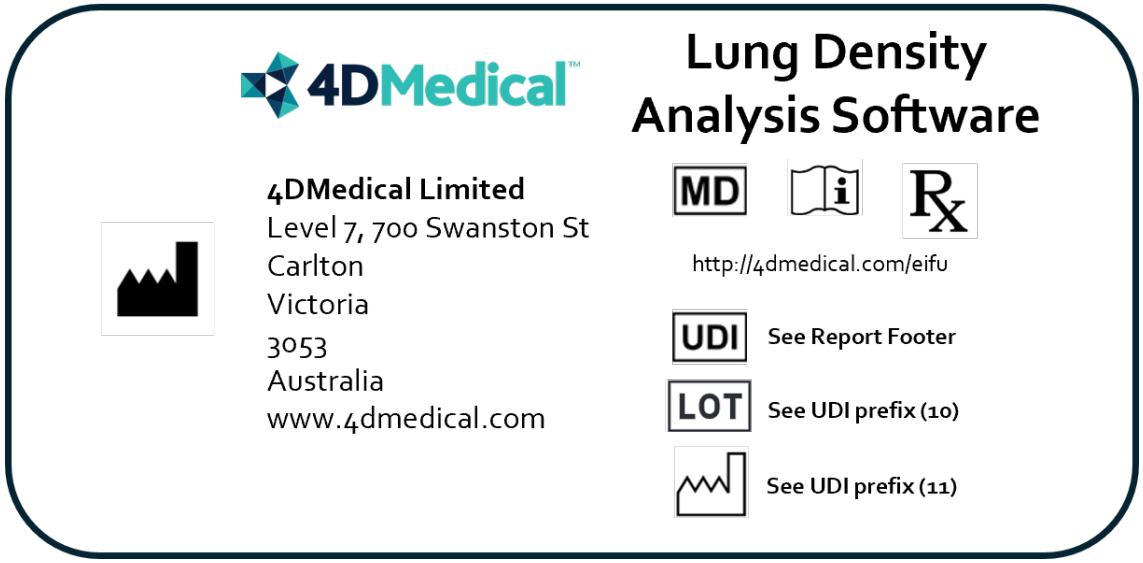
7 Regulatory Information

7.1 Contact 4DMedical

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

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

7.2 Software Label



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References

[1] Gerard J Criner, Antoine Delage, Kirk Voelker, D Kyle Hogarth, Adnan Majid, Michael Zgoda, Donald R Lazarus, Roberto Casal, Sadia B Benzaquen, and Robert C Holladay. Improving lung function in severe heterogenous emphysema with the spiration valve system (EMPROVE). A multicenter, open-label randomized controlled clinical trial. *American journal of respiratory and critical care medicine*, 200(11):1354–1362, 2019.