

imbio

LDA

v5.1.1

Contents

| | | |
|----------|---|-----------|
| 1 | Introduction | 3 |
| 1.1 | Prescription Use Statement | 3 |
| 1.2 | Manual Scope | 3 |
| 1.3 | Product Overview | 3 |
| 1.4 | Hardware Requirements | 3 |
| 1.5 | Contact Imbio | 3 |
| 2 | Indications for Use and Requirements | 4 |
| 2.1 | Intended Users | 4 |
| 2.2 | Scan Protocol Requirements | 4 |
| 2.2.1 | Breathing Instructions | 5 |
| 2.2.2 | Subject Positioning | 5 |
| 2.2.3 | Scan Coverage | 5 |
| 3 | Quality Assessment | 6 |
| 3.1 | Precautions | 6 |
| 4 | LDA Software | 7 |
| 4.1 | Input | 7 |
| 4.2 | Optional Feature: Fitlering | 7 |
| 4.3 | Outputs | 7 |
| 4.3.1 | LDA Summary Report | 7 |
| 4.3.2 | SeleCT Inspiration Assessment Map | 10 |
| 4.3.3 | Fissure Completeness Map | 11 |
| 4.3.4 | Segmentation Map | 12 |
| 4.3.5 | Screening Outputs | 12 |
| 4.3.6 | Input Check Failure Report | 13 |
| 5 | Quality Assessment of Segmentation Outputs | 14 |
| 6 | Software Label | 15 |

1 Introduction

1.1 Prescription Use Statement

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

1.2 Manual Scope

Imbio'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.

1.3 Product Overview

Imbio's 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 2.2).

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

1.4 Hardware Requirements

Hardware requirements for running LDA are as follows:

- 8 CPU Cores
- 32 GB RAM
- 50 GB

1.5 Contact Imbio



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2 Indications for Use and Requirements

The Imbio CT Lung Density Analysis™ Software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. The Imbio 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.

2.1 Intended Users

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

2.2 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..

| | 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 | | | |

Table 1: Recommended protocol for LDA input images.

2 INDICATIONS FOR USE AND REQUIREMENTS

2.2.1 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

Breathe 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

2.2.2 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.

2.2.3 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.

3 QUALITY ASSESSMENT



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

3 Quality Assessment

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

3.1 Precautions

This software is designed to run on any input data that satisfies the criteria in Section 2.2 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.

4 LDA Software

4.1 Input

The LDA Software requires one DICOM format high resolution CT image series as input. Reference Section 2.2 for more information.

4.2 Optional Feature: Filtering

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.

4.3 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.

4.3.1 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:

4 LDA OUTPUTS

- **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.

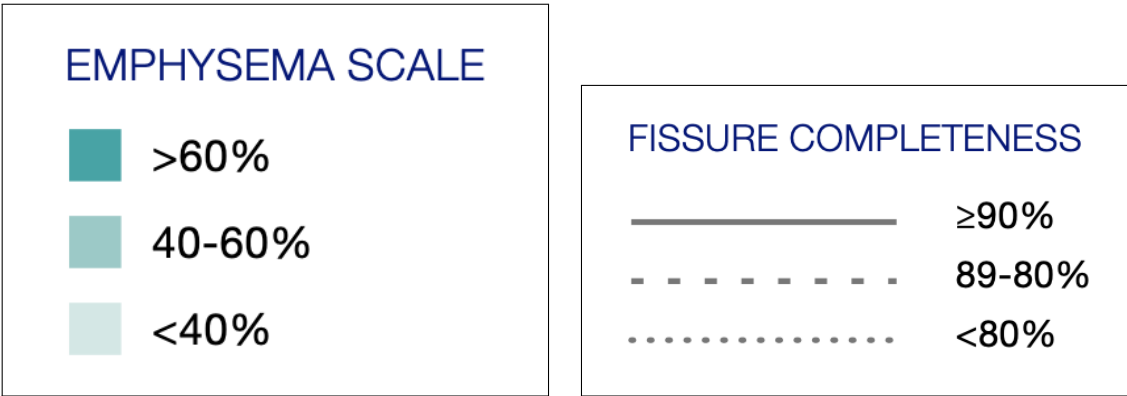


Figure 2: Keys on the report to aide in interpretation of the results.

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.

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.

4 LDA OUTPUTS

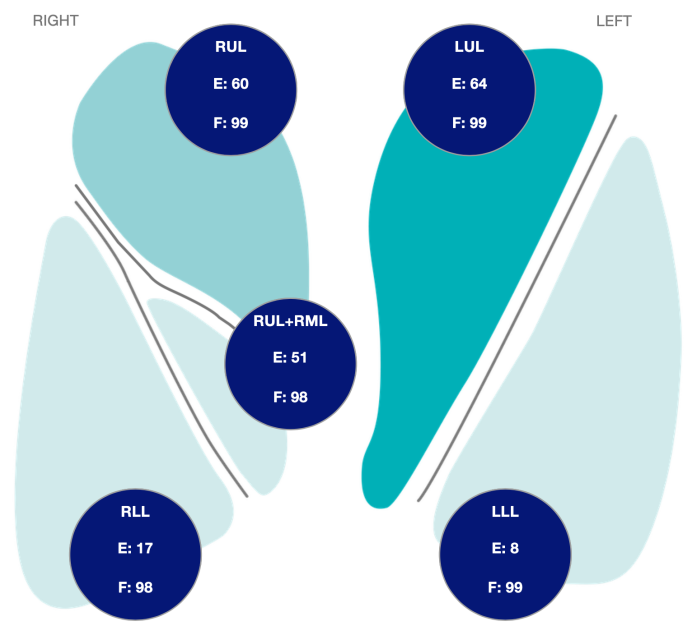


Figure 3: Visualizations of the lungs showing results of the analysis.

| | 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.

4 LDA OUTPUTS

LUNG FISSURE VISUALIZATION

■ Complete ■ Incomplete

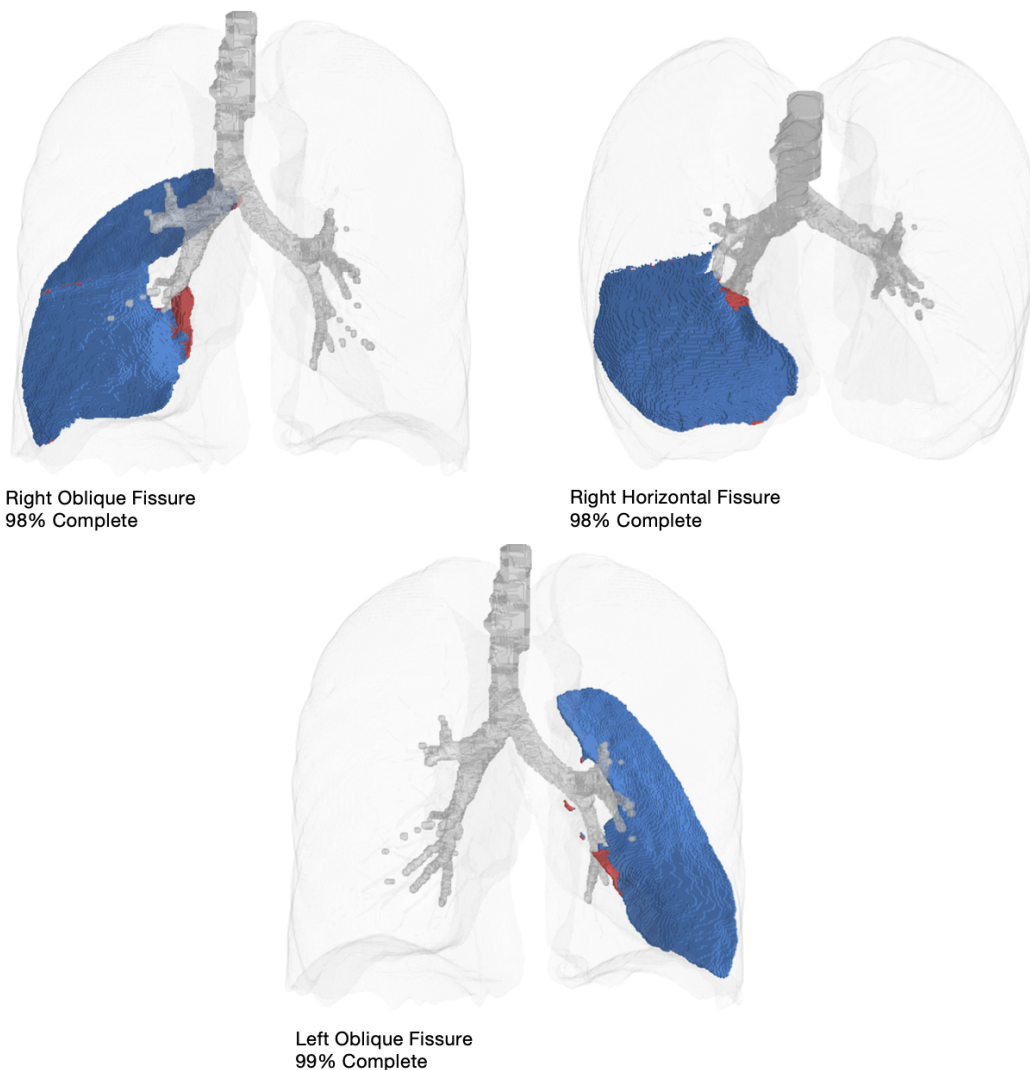


Figure 5: 3D rendering of the fissure completeness per fissure.

4.3.2 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.

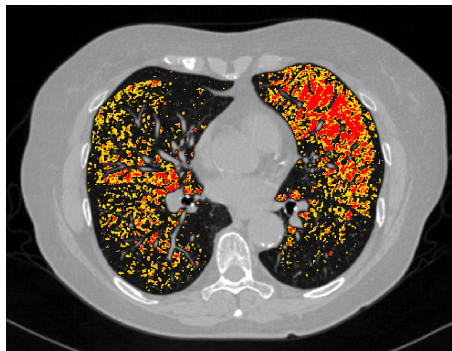


Figure 6: Slice of Inspiration Assessment Map

4.3.3 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 opaque blue color indicates regions of complete fissures, while the opaque 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 5 for more details on how to interpret the images.

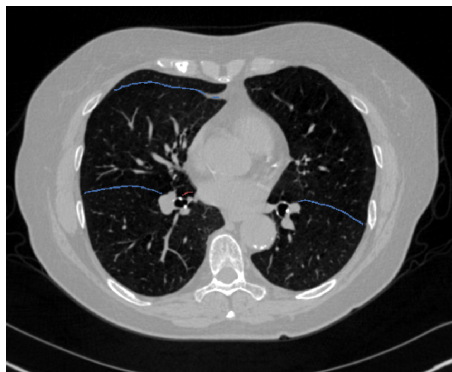


Figure 7: Slice of Fissure Completeness Map

4.3.4 Segmentation Map

Imbio 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 5 for more details on how to interpret the images.

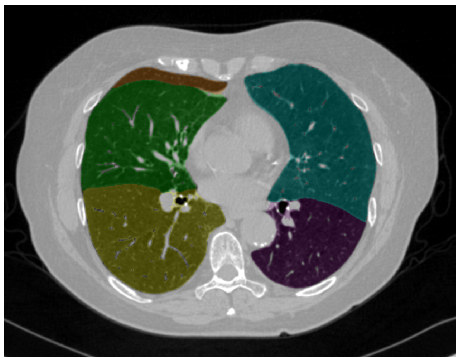


Figure 8: Slice of Segmentation Map






| Lung Lobe Segmentation | |
|------------------------|--|
| Upper Right |  |
| Middle Right |  |
| Lower Right |  |
| Upper Left |  |
| Lower Left |  |

Figure 9: Lung Segmentation Label Colors

4.3.5 Screening Outputs

If Imbio 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 Imbio LDA Software manual.

4 LDA OUTPUTS

4.3.6 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


5 Quality Assessment of Segmentation Outputs

The Imbio 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 Imbio 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 especially helpful for detecting segmentation errors.


6 Software Label


 **imbio**

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 2025-01-14
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References

- [1] Gerard J Criner, et. al. 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. Vol 200, Issue 11, pp 1354--1362. 2019.