imbio

LDA+

v4.1.0

SOFTWARE USER MANUAL

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Contents

1 Introduction

1.1 Manual Scope

Imbio's Lung Density Analysis™ Software is capable of running in multiple modes with various configurations. This User Manual covers LDA+, the mode that analyzes lung density by quantifying low and high density areas of the lung.

1.2 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 lung diseases 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.

1.3 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	CANON/TOSHIBA	GE
Smooth Kernel Reconstruction	≤B45, ≤I45	B, C	FC12	Standard
Breathhold at	TLC, Full Inspiration			
Slice Thickness	≤2.5 mm			
Slice Spacing	Consistently spaced, no gaps, and ≤2.5 mm			
Anatomic Coverage	Full coverage of the lungs			
Severe Motion Artifact	Absent			
Contrast Enhanced	None			

Table 1: Recommended protocol for LDA+ input images.

2.2.1 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

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.

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 CT 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 Outputs

When run with appropriate input data, the LDA+ Software generates a Summary Report and a RGB image with color overlay classifying lung voxels into three categories: Low Density, High Density, and Very High Density. 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.

4.2.1 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 three key density measures reported in the LDA+ report include:

- **Very High Density (VHD)**: Percent of tissue above a threshold of -200 HU. Has been shown to be indicative of consolidation. [1].
- **High Density (HD)**: Percent of tissue above a threshold of -700 HU and below a threshold of -200 HU. Has been shown to be indicative of ground glass. [1].
- **Low Density (LD)**: Percent of tissue below a threshold of -950 HU. Has been shown to be indicative of emphysema. [2].

The default settings for the thresholds can be changed. Contact Imbio Support for more information.

The report includes 3D renderings showing the distribution of each density measure and a plot of percentages by lung total. See figure 2

The key metrics for each lung, as well as for each lung third, are displayed in a table on the report, along with lung volumes, see Figure 3.

4 LDA+ OUTPUTS

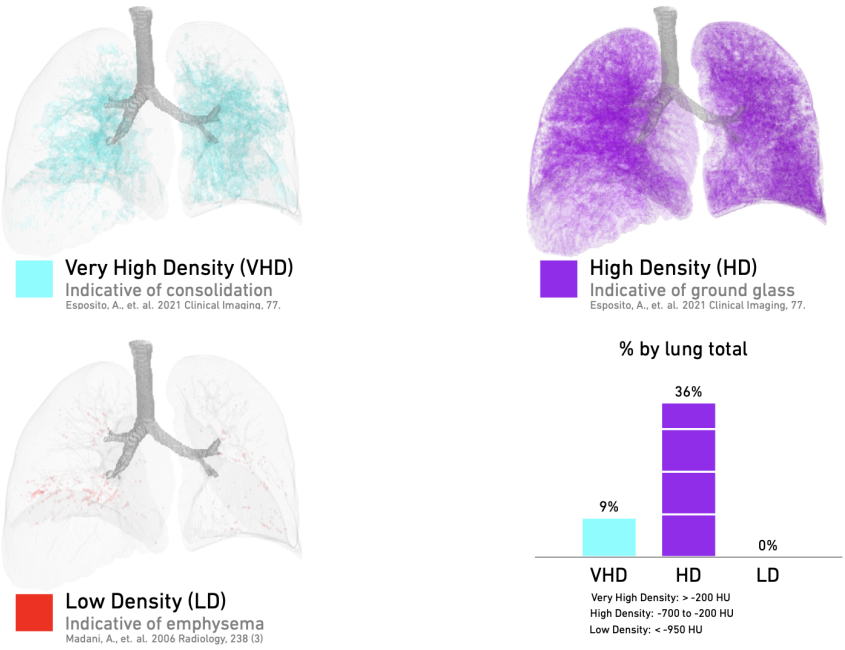


Figure 2: 3D renderings of each density measure.

SUMMARY	VOL	VHD	HD	LD
TOTAL LUNG:	2.3 L	9 %	36 %	0 %
Left Lung:	1.1 L	12 %	40 %	0 %
Left Upper		4 %	23 %	0 %
Left Middle		18 %	44 %	0 %
Left Lower		12 %	49 %	0 %
Right Lung:	1.3 L	6 %	33 %	0 %
Right Upper		3 %	25 %	0 %
Right Middle		8 %	31 %	0 %
Right Lower		4 %	46 %	0 %

Figure 3: Key metrics and lung volumes.

4.2.2 LDA+ Map

The LDA+ Map is a DICOM Secondary Capture Image with voxel data that is the original expiration image with an RGB overlay. The RGB overlay color codes each lung tissue voxel, identifying the lung tissue as one of three classification categories. Below are the definitions of the classification categories and the corresponding color of the Functional Assessment Map voxel data.

BLUE - **Very High Density Area**
Voxels with HU higher than -200 HU

PURPLE - **High Density Area**
Voxels with HU higher than -700 HU and lower than -200 HU

RED - **Low Density Area**
Voxels with HU lower than -950 HU

An example axial slice from the LDA+ Map is shown below in Figure 4.

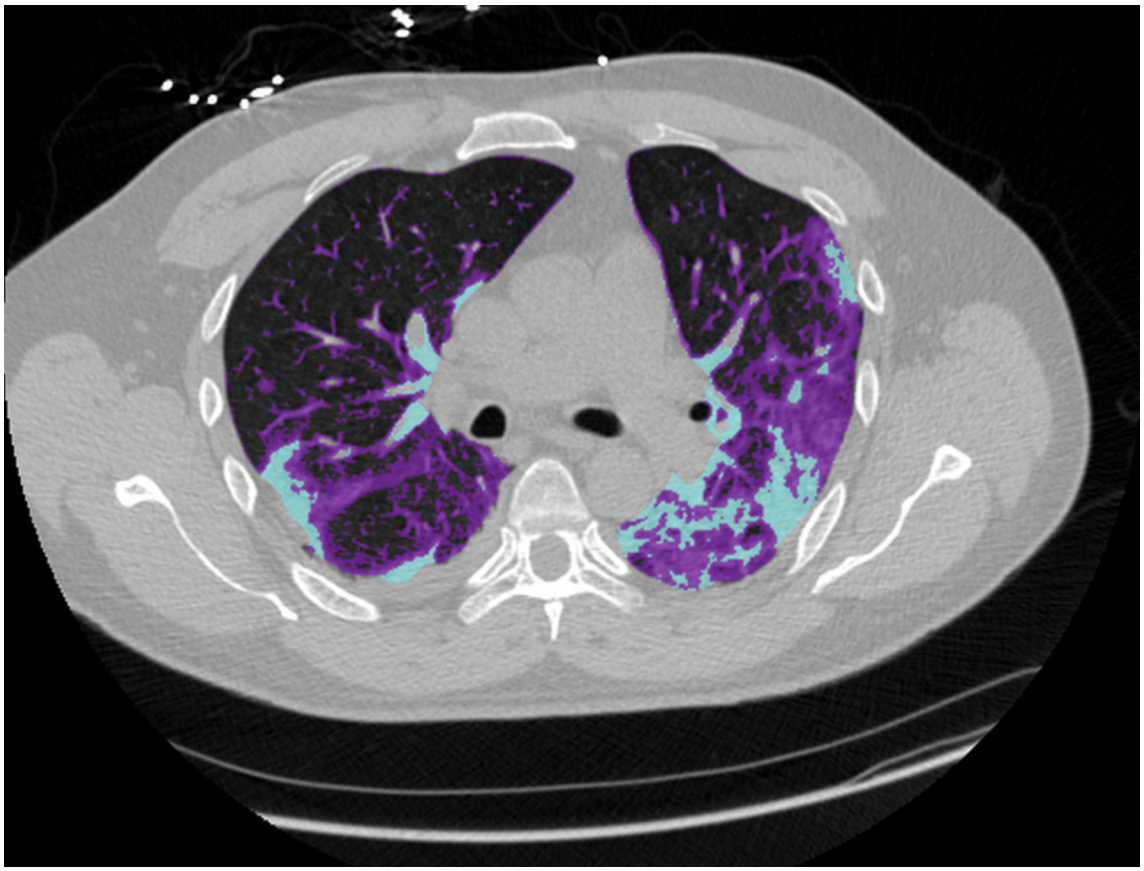


Figure 4: Slice of LDA+ Map.

4.3 Segmentation Map

Imbio CT LDA+ Software produces a segmentation DICOM series so that users can assess the quality of the lung segmentation. See Figure 5 for an example segmentation DICOM series image.

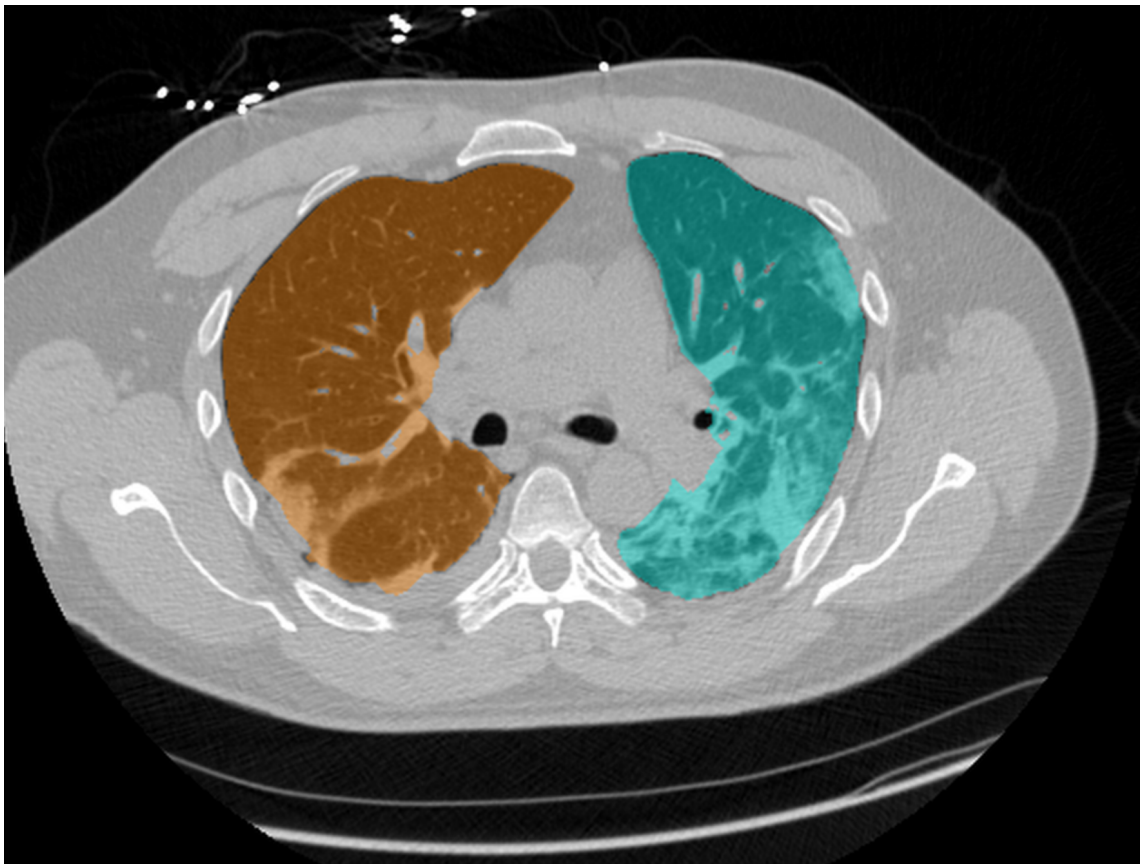


Figure 5: Example segmentation map.

4.3.1 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 6. The cause(s) of the input check failure can be identified by the red 'X' mark in the Result column. In Figure 6, 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.

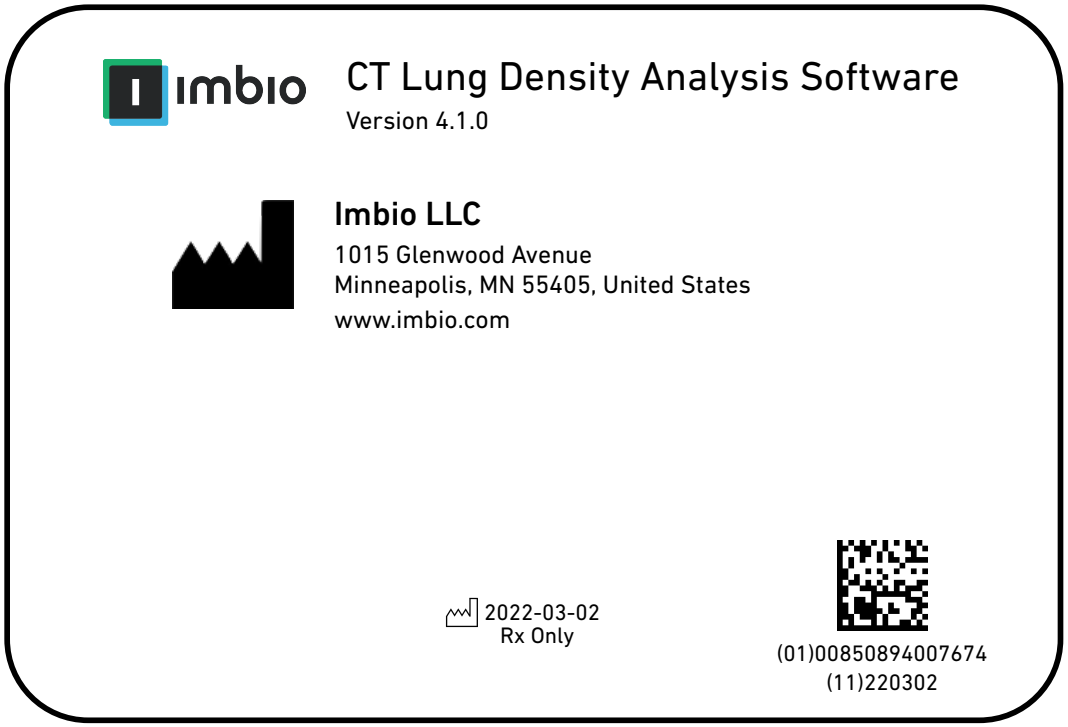
4 LDA+ OUTPUTS

ACCESSION NUMBER: **6789**	MANUFACTURER: **GE MEDICAL SYSTEMS**	KERNEL: **BONE**
STATION NAME: **Unknown**	MODEL: **Horos**	TUBE CURRENT AVG ($\frac{max}{min}$), KVP: **300 ($\frac{300}{300}$) mA, 140 kV**

	Requirement	Value	Result
Series Description: ER AAA 3.0 B30f - THICK **Series Instance UID:** 1.3.6.1.4.1.19291.2.1.2.164131231142152106123722058 83			
Modality	CT	CT	✓
Revolution Time (sec)	≤ 1	Not Present	⚠
Pixel Spacing (mm)	≤ 2	N/A	✓
Column Spacing (mm)	≤ 2	0.607422	✓
Row Spacing (mm)	≤ 2	0.607422	✓
Slice Spacing (mm)	≤ 2.5	2.5	✓
FOV (mm)	≥ (200, 100, 100)	(295.0, 311.000064, 311.000064)	✓
Slice Thickness (mm)	≤ 2.5	5.0	✗
Image Orientation	(±1,0,0,0,±1,0)	(1.0, 0.0, 0.0, 0.0, 1.0, 0.0)	✓
Patient's Age (years)	≥ 18	52	✓
Rescale Type	HU	HU	✓
Convolution Kernel	Non-edge-enhancing	BONE	⚠

Figure 6: Input check failure report.

5 Software Label



References

[1] Antonio Esposito, et. al. Quantitative assessment of lung involvement on chest CT at admission: Impact on hypoxia and outcome in COVID-19 patients. Clinical Imaging. Vol 77, pp 194--201. 2021.

[2] Afarine Madani, et. al. Pulmonary emphysema: objective quantification at multi-detector row CT--comparison with macroscopic and microscopic morphometry. Radiology. Vol 238, Issue 3, pp 1036--1043. 2006.