

# **Lung Image Analysis (LIA)**

## **USER MANUAL**



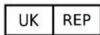
Manufacturer:

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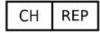
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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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### 1. Device Description

The Lung Image Analysis (LIA) software is designed to aid in the interpretation of Computed Tomography (CT) scans of the thorax that may contain pulmonary abnormalities. Lung Image Analysis has both a graphical user interface and command-line software which can be run as a Windows application or from a command-line interpreter.

### 2. Intended Purpose/Indications for Use

The Lung Image Analysis (LIA) software provides CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examination. The LIA software can be used to support 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 (including lung structures), volumetric analysis, density evaluations, fissure evaluation, and reporting tools are provided.

### 3. Contraindications

None.

### 4. Warnings and Precautions

None.

### 5. Required Technical Specifications

The software has the following minimum hardware requirements:

- Memory: 16GB of RAM (per process)
- CPU: Intel Core i7 or later (or AMD equivalent). Higher CPU frequencies and more cores can increase
  performance.
- GPU: Optional (but for a smoother image display Nvidia GTX 1050 TI or better is recommended)
- Hard Disk: for each processed CT series, allow for three times its space.

The software has the following minimum software requirements:

• Windows 10

### 6. Clinical Benefits

The LIA software is a diagnostic tool, the results of which are used together with other clinical information by a medical professional. The software does not provide any direct clinical benefit.

### 7. Performance Characteristics

Software verification and validation (V&V) were conducted to ensure that the LIA software met its intended use and software requirements. The V&V testing included subsystem integration testing, unit testing, module testing, and code reviews. The Lung Image Analysis software successfully passed the verification and validation.

An equivalence study was conducted to compare data from 30 scans that were analyzed by a predicate device and Lung Image Analysis. Each device computed 120 fissure calculations, 180 lobar volumes, and 360 voxel density scores from 30 scans. Results from the two devices were similar, meeting the acceptance criteria.

### 8. Cybersecurity and data confidentiality (PHI and PII)

### 8.1 Cybersecurity

The Lung Image Analysis (LIA) software has been designed to have the lowest possible cybersecurity footprint. The software does not establish or accept wired or wireless outbound network connections and only interacts with file storage locations configured on the system it is installed on. It is the user's responsibility to have appropriate cybersecurity controls in place. Because of the nature of the output that the LIA software generates (quantitative CT analysis results), we recommend implementing the following security controls on the system where the LIA software is installed:

- The system should require users to authenticate with a username and password.
- The system should require users to change their passwords at least every 6 months.
- The system should automatically logout the user, lock the system, or switch to a password protected screen saver after 10 minutes of idle time.
- The user should manage their case folders on a file storage location that only they can read and write on, except for other users with similar authorization.
- The user should move or copy their case folder to a read-only location as soon as possible to prevent tampering with quantitative analysis results.
- The user should only have local administrator or network administrator rights when necessary.
- The system should be running an up-to-date anti-virus monitoring software.
- The system should be running an up-to-date ant-malware monitoring software.
- The system should be accessible only through physical access with access control on place (e.g., badge, keys, etc.) or via a secured network (e.g., corporate network, VPN).
- The system or user should *not* bridge the loop back ethernet device to the network ethernet device (e.g., 127.0.0.1 to 0.0.0.0 or assigned network IP address). This will expose an Inter Process Communication port to the network.
- The user should periodically check (e.g., every quarter) for users and their authorization for correctness.
- The user should periodically review the LIA log files (located in the user's home directory) for signs of tampering (e.g., error messages that say: "Error: file has no valid signature").
- The user should periodically (e.g., once per year) refresh the operating system and installation of the LIA software by reverting to a preconfigured image or by performing a clean installation. This activity will remove any undetected viruses or malware from the operating system.

### The user should be aware that:

- The integrity of the installer can be validated by calculating a SHA256 checksum on the installer executable file and comparing it with the Pulmonx published SHA256 checksum. If these do not match, the installer might have lost its integrity while downloading, or it might have been tampered with.
- If the installer shows the message "NSIS error: Error launching installer", the installer might have lost its integrity while downloading, or it might have been tampered with.
- The integrity of the results written to a file storage location by LIA can be validated by reviewing the data integrity hashes in metadata.json, in the field dataIntegrityHashes. The hashes are based on the SHA512 algorithm.

### 8.2 Protected Health Information (PHI) and Personally Identifiable Information (PII)

Patient information is private, confidential, and subject to various regulations. LIA does not establish wired, wireless network or wireless communications (e.g., Bluetooth, RFID, NFC) connections and only reads/writes data on file storage locations provided by the local operating environment

(computer system) it runs on. If the data read by LIA contains PHI or PII, the written data will therefore also contain PHI or PII.

It is the user's responsibility to have appropriate controls around sensitive data in the operating environment. On the suspicion that you are processing and viewing data that falls under PHI or PII and you are not supposed to have exposure to this kind of information, notify your supervisor immediately.

### 9. Reporting Incidents

Please report any serious incidents related to LIA to Pulmonx at <a href="mailto:customerservice@pulmonx.com">customerservice@pulmonx.com</a> and if applicable, the competent authority of your European Union Member State.

### 10. Symbols

In this manual, displayed on device labels or the device itself, the following symbols are used:

Symbol	Meaning
***	Manufacturer
	Importer
EC REP	European Authorized Representative
UK REP	UK Responsible Person
CH REP	Swiss Authorized Representative
UDI	Unique Device Identifier
REF	Catalog Number
سا	Manufacture Date
i	See accompanying documentation. The supplied documentation must be consulted for operating, cautionary or safety information before using the device.

Symbol	Meaning
MD	Medical Device
Ronly	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

### 11. Input Specifications

The following CT scan radiographic parameters have been optimized to provide appropriate inputs to the LIA platform:

- 1. Ensure all files are in standard .DICOM format
- 2. Only SUPINE position chest CT scans with arms positioned above the head are supported. Scans obtained in PRONE position can NOT be analyzed.
- 3. The CT scans must have a slice thickness of 1.5mm or less (smaller slices provide more information for fissure completeness).
- 4. The input image should NOT be reconstructed with a slice spacing larger than the slice thickness (slice spacing should be less than or equal to slice thickness, no gaps in the 3D volume are allowed).
- 5. The complete lung must be present on the CT scan. If parts of the lung are missing, the output parameters will be compromised.
- 6. Only non-contrast TLC (inspiration) scans are accepted for analysis.
- 7. Technologist should instruct the patient to take a full inspiration breath and hold. The scan should start once the patient has reached breath hold and relaxed their body.
- 8. Ensure the CT scan is not of poor quality (e.g., movement artifacts, artifacts due to metal, high noise levels due to dose level, etc.).
- 9. Please ensure the CT scan does NOT suffer from image artifacts such as streak artifacts from implants.
- 10. Scans taken from CT scanners with less than 16 detector rows are not recommended.
- 11. Any series containing less than 120 images will be automatically removed by the system.

### 12. Getting Started

### 12.1 Installation

### 12.1.1 Installation using the command line interface (CLI)

The Lung Image Analysis (LIA) software can be installed using the CLI. Locate the installation executable (e.g., LIA\_1.0.exe), and execute the following statement on a command prompt:

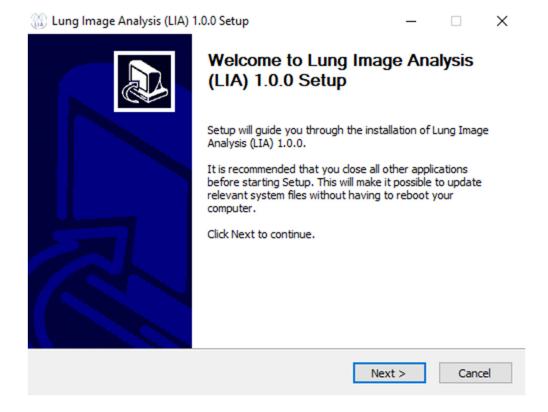
This will install LIA and all its dependencies without requiring user input in its default directory: C:\Program Files\Lung Image Analysis (LIA)\. The command prompt will return once the software is installed.

### 12.1.2 Installation using the graphical user interface (GUI)

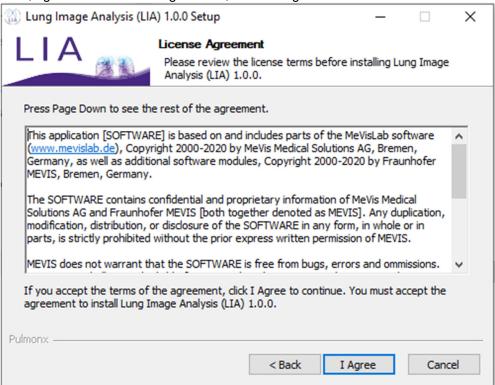
The Lung Image Analysis (LIA) software can also be installed using the GUI. Locate the installation executable (e.g., LIA\_1.0.exe), and double click the file to start the installation process.

A dialogue box will appear asking "Do you want to allow this app from an unknown publisher to make changes to your device?" Select "Yes."

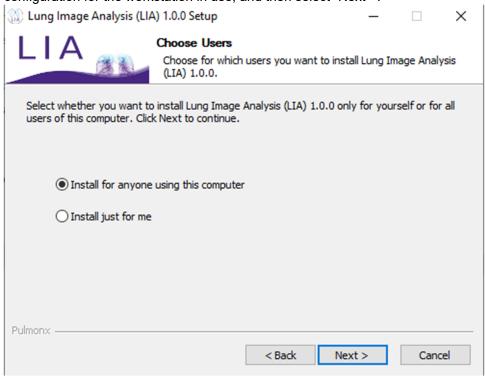
Immediately following this, the installer will be launched, select "Next >"



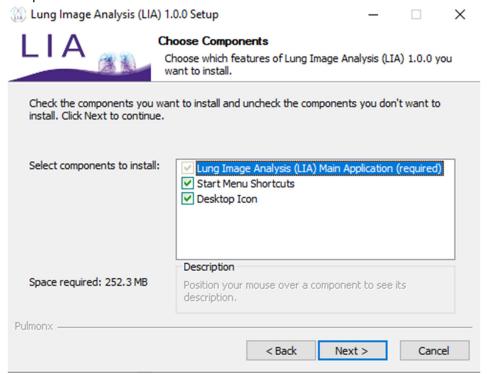
Next, agree to the License Agreement, select "I Agree."



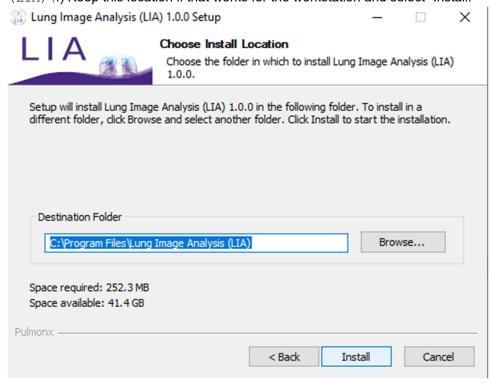
Now select who should be allowed to launch this application, select either depending on the best configuration for the workstation in use, and then select "Next >."



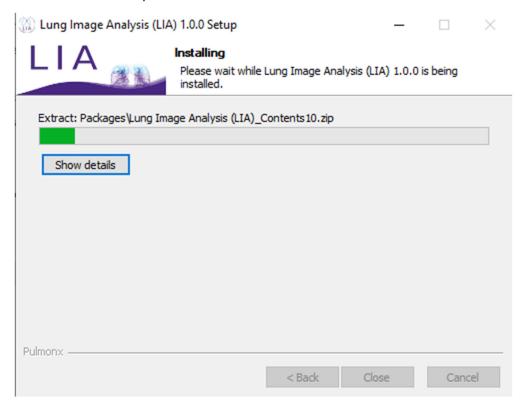
To create all menu shortcuts and have the application appear on the workstation Desktop, keep all options selected and select "Next >."



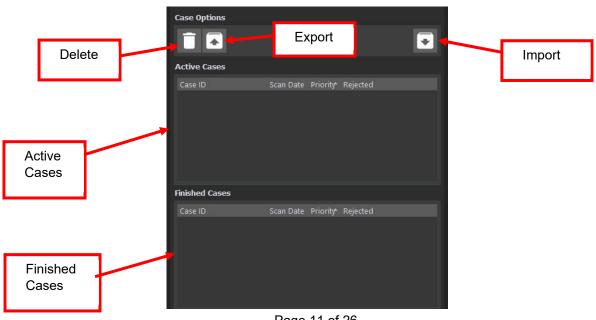
For the Install location, the default location will be C:\Program Files\Lung Image Analysis (LIA) \.) Keep this location if that works for the workstation and select "Install."



After selecting "Install" the Installer will begin with a progress bar indicator showing how much time is left in the installation process.



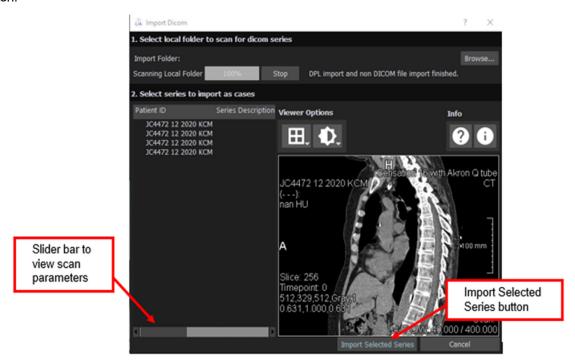
# 12.2 Importing files (selecting the correct series)12.2.1 DICOM Images



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To import images for analysis, select the "Import" button, and a pop-up dialogue box will appear to select the DICOM images to be uploaded. Navigate to the location on your workstation where the DICOM images are stored. Click "Select." A pop-up will appear to select the DICOM series to import, use the slider bar to view the various scan parameters for the different image series imported. If many series were imported, select one or many of the series to upload, and click "Import Selected Series" button.

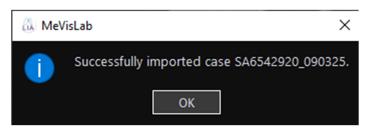


The series will then be uploaded into the Case Menu under "Active Cases."



### 12.2.2 Pre-processed images

Select the "Import" button, a pop-up dialogue box will appear to select the LIA case. The LIA case to be uploaded contains the original DICOM images and the pre-processed images. Navigate to the location or folder on your workstation where the pre-processed or analyzed images have been stored. Once this folder is selected a loading dialogue will appear. Once loading has finished an application pop-up will appear saying "Successfully imported case XXXXXXX\_XXXXXXX." The XXXXXXXX\_XXXXXX naming convention follows the format of Patient ID\_Scan ID for the study uploaded.



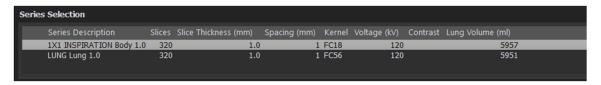
The series will then be uploaded into the Case Menu under "Active Cases." Once the case is selected the pre-processed images can be viewed.



# Series Selection Process Scan button Scan Orientation CT Image CT Image CT Image Lut Cw.-350-800 / 1000 8000

### 12.3.1 Series Selection

In the top right portion of the viewing window, the Series Selection field is shown. If multiple series were imported, toggle between the series prior to selecting one. Review the various scan parameters for the different series uploaded and select the correct series for analysis.



Please note that only after clicking the "Process Scan" button and then navigating back to the Case Menu will the calculated lung volumes appear for the selected series.

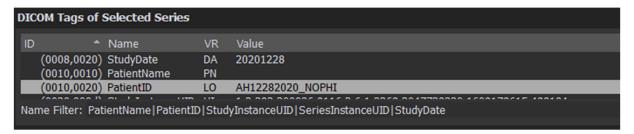
### 12.3.2 Process Scan button

To process an image for LIA automatic segmentation, select the correct series (indicated by

being highlighted in lighter grey color) and press the \_\_\_\_\_ "Process Scan" button. After pressing the "Process Scan" button the Quantitative Results window will appear.

### 12.3.3 DICOM Tag viewer

In the viewing window, next to the Process Scan button is the DICOM Tags of Selected Series, scroll through the DICOM tags to view the various scan parameters. To add an additional DICOM tag to the viewing window, click the "Name Filter" field and type "|" followed by the DICOM tag description. For example, to view the study date simply type "|StudyDate."



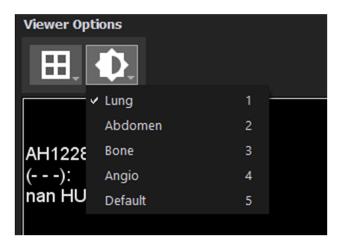
### 12.3.4 Scan Orientation

Under viewer options, select the scan orientation to view the CT scan in the window. The options include Axial, Coronal, and Sagittal. During analysis, the "Sagittal" orientation is predominantly used.



### 12.3.5 Image Window

Under the viewer options, select the image window to view the CT scan in the window. The options include Lung, Abdomen, Bone, Angio, and Default. The default image window is defined in the original DICOM images, if that definition is missing, the LIA software will select the "Lung" window as default.

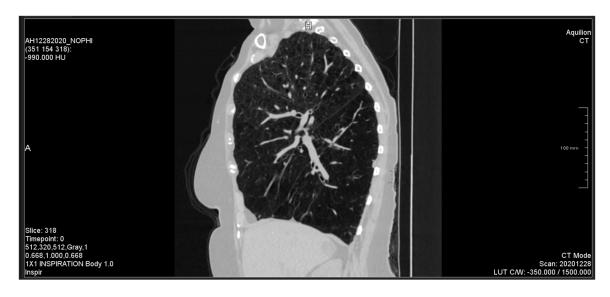


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The Numbers located on the right side of the Viewer options, indicate the shortcuts that are available to toggle between the various image windows. These shortcuts are outlined in 12.4.1.3.

### 12.3.6 CT Image

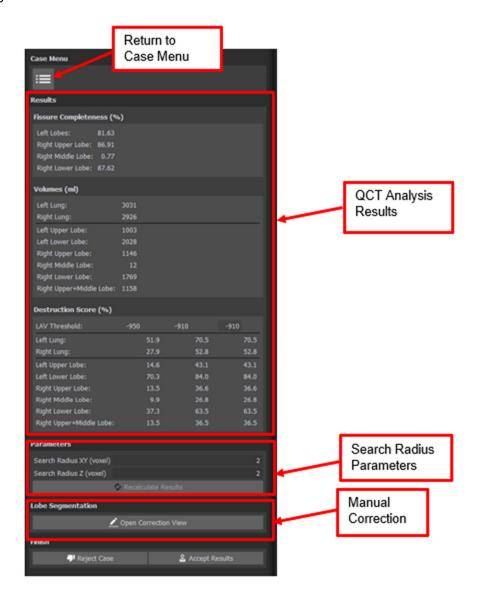
In the center portion of the viewing window is the CT image. Place cursor in the CT image window portion and scroll through the CT image slices in the orientation selected. To move through the images quickly, click inside the CT window with the scroll button on your mouse and slide the cursor up to move forward and down to move backward.



### 12.4 Segmentation

By clicking the "Process Scan" button, the software performs automated segmentation of the

lungs, lobes, airways, and major blood vessels. To return to the Case Menu, select The Quantitative Results Window appears to review the QCT analysis results. To modify the search radius, select either "Search Radius XY" textbox or "Search Radius Z" textbox under the Parameters section. Select "Recalculate Results" for the quantitative results to refresh and reflect any changes. If manual correction is needed, select "Open Correction View" under Lobe Segmentation.



### 12.4.1 Manual Correction Mode

After selecting "Open Correction Mode," to correct the lobe segmentation boundaries, on the left side of the screen, select which lobe boundary to correct: Right Major Boundary, Right Minor

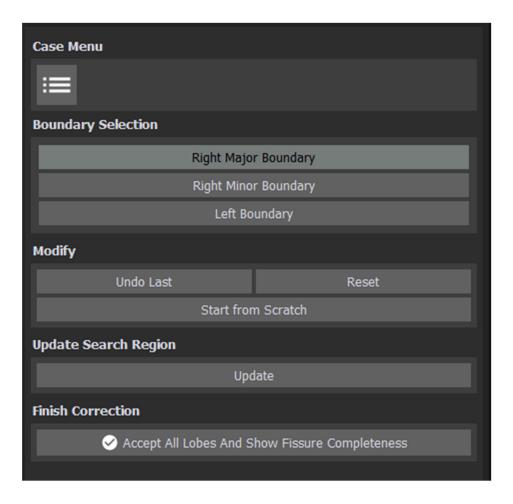
Boundary, or Left Boundary. At the top portion of the screen, under Overlays, select

toggle on or off the lobar boundary line during correction. From the overlay menu, select to toggle on or off the search region during correction. From the overlay menu, select the

to view fissure candidate voxels during correction. (The white box around each button indicates that the button was recently selected. The greyed-out button indicates that the overlay is enabled).



Use the left hand menu to modify the lobar boundary lines once any corrections are made. To undo the previous correction, click "Undo Last." To reset all manual corrections and return to the original automated results, click "Reset." To manually correct the study without the automated results, click "Start From Scratch." Once corrections are made, to view the updated search region, under Update Search Region click "Update." To accept all manual corrections select "Accept All Lobes And Show Fissure Completeness."



### 12.4.1.1 Edit Lobar Boundary

Edit Mode must be enabled to edit the lobar boundary line. To enable edit-mode navigate to the

top of the screen and click Figure 1 shows the automated boundary line. Once in Edit Mode draw seed points to create a new lobar boundary line across the true right major fissure. Once the line is drawn double click to ensure the line is accepted. Continue to scroll through the scan, correcting the lobar boundary line as needed to match the true lung fissure anatomy.

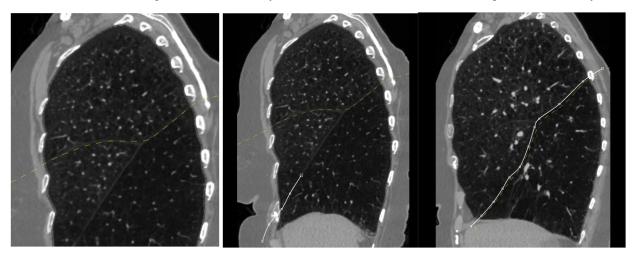


Figure 1: Automated Boundary Line

Figure 2/3: Edit Mode, Manual Correction of Boundary Line

### 12.4.1.2 Erase Seed Points

To erase the seed boundary points the user will need to be in Erase Seed Point Mode, the user

will enable Erase Seed Point Mode by going to the top of the screen and clicking . This will enable the view of the seed points. The user may then draw in yellow using the orange cursor along the seed points they would like to delete, once all the seed points are selected, the seed

points may be deleted once the user clicks

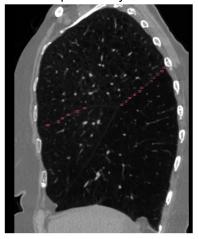


Figure 4: Seed points

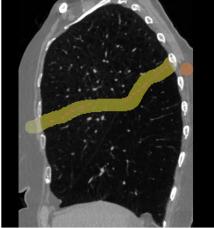


Figure 5: Selection to erase

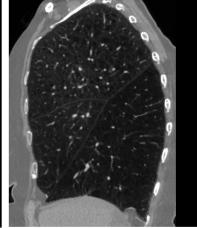


Figure 6: Deletion of seed points

### 12.4.1.3 Keyboard Shortcuts

Keyboard Shortcut	Description
d	Erase seed points
0	View Boundary Line
f	View Fissure Candidate
	Voxels
S	View Search Region
1	Show Lung Image Window
2	Show Abdomen Image
	Window
3	Show Bone Image Window
4	Show Angio Image Window
5	Show Default Image Window

### 12.4.1.4 Tips for successful Analysis

Following these tips during analysis will ensure optimal results.

- 1. Start on the slice with the largest error between true lung boundary and the automated boundary line.
- 2. Always draw the boundary line beyond the lung boundary, extend the line outside of the true lung and into the body tissue.
- Once analysis is complete, review all slices to confirm the lobar boundary lines are correct for all slices, since edits made in one slice may impact lobar boundary lines drawn in previous slices.
- 4. For right minor boundary corrections, the lobar boundary line should extend into the right lower lung (RLL), bisecting the RLL and NOT follow the right major fissure. Please refer to Figure 8 for the suggested correct correction. Figure 7 illustrates what would constitute an incorrect right minor boundary line.

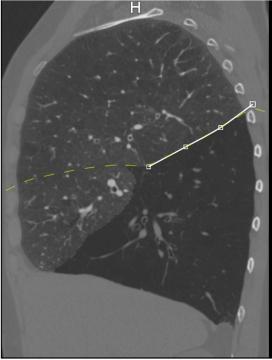


Figure 7: Incorrect Correction Example

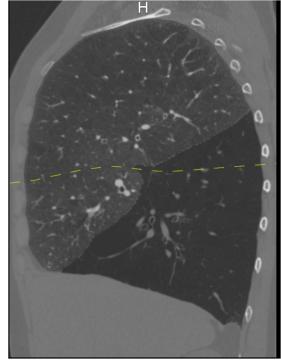


Figure 8: Correct Correction Example

### 12.5 Quantitative Analysis

After selecting "Accept All Lobes And Show Fissure Completeness," the LIA software will automatically calculate fissure completeness scores for all lobes. On the left side of the screen, the software displays quantitative outputs for the fissure completeness score by lobe, volumes per lobe, and % voxel density destruction scores for all lobes at -910HU and -950HU threshold. Under the destruction score field, there is a manual entry field to calculate destruction score for a third user specified HU threshold.

On the right side of the screen display of the lung image is shown with indicators on how well the fissure completeness voxels matched the lobar boundary lines. The orange portion of the fissure indicates that the fissure completeness voxels matched the lobar boundary lines drawn. The red portion of the fissure indicates that the lobar boundary line did not match the fissure completeness voxels. Scroll through the images to determine if any additional corrections are needed to accurately trace the lung boundary lines along the lung fissure anatomy. Once finished, under the Finish header select "Accept Results." If the case cannot be accepted for analysis for any reason (including image artifacts), select "Reject Case."



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### 12.6 Exporting LIA case

Once the user has selected "Accept Results" the case will be moved to the Finished Cases

section. Select the case and click the Export" button. The user will then be prompted with a file explorer to select an export location.

### 12.7 Deleting Cases

To delete a case from the "Active Cases" list or "Finished Cases" list, select the case and click

"delete" button to delete the case. The user will then be prompted with a pop-up dialogue to confirm that the case should be deleted.

### 12.8 File Management

Users have the ability to:

- 1. Import CT DICOM files or existing LIA case from local and network locations
- Export LIA case (DICOM images and the pre-processed images) to a local or network location
- 3. Delete studies from the application
- 4. Distinguish between active cases and finished cases

### 12.9 Command Line Interface

LIA can be operated by an automated or unattended process by utilizing the Command Line Interface (CLI). These CLI operations are limited to automatic pre-processing of DICOM CT series and managing case data. The CLI does not allow approval, rejection or review of cases. The CLI can be used in a traditional Windows command prompt. The CLI has not been validated using the Windows PowerShell.

The following section will provide the Command Line Interface commands available to the user. These instructions are based on the LIA application being installed in its default directory: C:\Program Files\Lung Image Analysis (LIA)\Packages\MeVisLab\IDE\bin\. If the LIA application has been installed in a different directory, the following commands should be updated with the appropriate path where the LIA application can be found.

CLI Functionality	Error state/message	
Preprocessing	"Not all series could be processed" (Processing failed at least for one series)	
	- "Workflow Step X has failed" (A specific workflow step processing failed)	
Copy case	- "Failed to copy case directory, because it could not be locked: <directory_name>" - "Failed to copy case directory, because it could not be locked:  <directory_name>" - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it could not be locked:  - "Failed to copy case directory, because it case directory, because it case directory, because it case directory, because it case di</directory_name></directory_name>	
	<ul> <li>"Failed to copy case directory, because no case was found in <directory_name>"</directory_name></li> </ul>	
Move case	<ul> <li>"Failed to move case directory, because it could not be locked: <directory_name>"</directory_name></li> </ul>	
	<ul> <li>"Failed to copy move directory, because no case was found in <directory_name>"</directory_name></li> </ul>	

CLI Functionality	Error state/message		
Delete Case	<ul> <li>"Failed to delete case directory, because it could not be locked: <directory_name>"</directory_name></li> </ul>		
	<ul> <li>"Failed to delete case directory, because no case was found in <directory_name>"</directory_name></li> </ul>		
General	<ul> <li>"An exception occurred: <exception_description>"</exception_description></li> <li>(An internal exception occurred that was not handled explicitly)</li> </ul>		

### **Generic Command Line Command (without parameters):**

"c:\ProgramFiles\LIA\Packages\MeVisLab\IDE\bin\MeVisLabAppConsole.exe"-console runappbatch LIA

### **Parameters:**

Parameter Name (one is required)	Description
lock <destination_case_directory></destination_case_directory>	Locks the case, waits until SIGINT signal is received, then unlocks the case again
preprocess <dicom_source_directory> <destination_case_directory></destination_case_directory></dicom_source_directory>	Preprocess the dicom files in the dicom source directory and stores the case in the destination case directory
import-case <target_directory></target_directory>	Imports the case without locking (for example from a read-only file system) and copies it to the target directory
copy-case <target_directory> <source_case_directory></source_case_directory></target_directory>	Locks the case in the case directory, copies it to the target directory and then unlocks it again
move-case <target_directory> <source_case_directory></source_case_directory></target_directory>	Locks the case in the case directory, moves it to the target directory and then unlocks it again
delete-case <target_directory> <source_case_directory></source_case_directory></target_directory>	Locks the case and deletes it entirely from its location
help	Prints the detected hardware and CLI parameters to screen

Optional Parameters		
loglevel <level></level>	Specifies the log level. Accepted values are:	
	Debug, info, warning, error (default)	
lock-timeout	Specify timeout when locking a case.  If a case is already locked by a different process, the command will wait until the case becomes unlocked by the other process and then executes the command, or until the lock-time-out expires and immediately terminates without performing the command	

### **Example (Preprocess):**

C:\>C:\Program Files\Lung Image Analysis (LIA)\Packages\MeVisLab\IDE\bin\MeVisLabAppConsole.exe"
-console

<sup>-</sup>runappbatch LIA -loglevel error -preprocess "c:\dicom\_source" "c:\case\_dir"