

Brainomix 360[®] e-Lung

User Manual

Version 2.3

e-Lung-MAN-2.3 - 2026-06-22

e-Lung is part of Brainomix 360

Historic revisions (<https://www.brainomix.com/docs/>)

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Regulatory Information

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1 Introduction

1.1 Overview

Brainomix 360 e-Lung is a software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server. e-Lung is a CT processing module which operates within the integrated Brainomix 360 platform.

Brainomix 360 e-Lung is a stand-alone software device which uses a set of image processing algorithms to perform evaluation (3D segmentation and isolation of sub-compartments, volumetric measurements, and density evaluations), editing, and reporting tools which are combined with a dedicated workflow.

e-Lung can be used to support the physician in the examination of radiological findings that may be indicative of chest diseases e.g. when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses.

e-Lung is designed to analyze pulmonary CT slice data and display analysis results. Each voxel of the scan is measured by Hounsfield units (HU), a measurement of x-ray attenuation that is applied to each volume element in three-dimensional space. The HU are utilized to distinguish between air, water, tissue and bone, such distinction is common in the industry.

e-Lung provides computed tomography (CT) viewing, and parenchymal density analysis in one application. e-Lung provides quantitative measurements and tabulates quantitative properties.

e-Lung focuses on what is visible to the eye and applies volumetric methods that might otherwise be too time consuming to use. The software does not perform any function which cannot be accomplished by a trained user utilizing manual tracing methods; the software does not reconstruct a 3D rendering image of the lung; the intent of the software is to enhance the workflow by saving time and automating potential error prone manual tasks.

e-Lung has functions for loading, analyzing, and saving datasets, and will generate screen displays, computations and aggregate statistics. e-Lung data output may be exported to a CSV, Excel or PDF file.

1.2 e-Lung Analysis

e-Lung will process an input chest CT scan to compute a lung segmentation, followed by any structural density filters and density histogram filters that have been set by an administrative user as part of the e-Lung workflow.

Output	Description
Lung Segmentation	The left and right lung are segmented and displayed as an overlay in the scan viewer. The volume of the left, right, and total lungs are displayed within the data tab in ml. The lung segmentation is used for subsequent stages of processing.

Output	Description
Periphery	The periphery of the lungs is displayed as an overlay in the scan viewer based on the lung segmentation and the periphery thickness selected by the user. The volume of the left, right, and total periphery are displayed within the data tab in ml.
Structural Density Filter	The Structural Density Filter extracts homogeneous patterns that are brighter (i.e. denser) or darker (i.e. less dense) than their surround (i.e. local minima or maxima) with a range of thicknesses specified by an administrative user. These are displayed as an overlay in the scan viewer. The volume (ml) and percentage of these are displayed in chart format within the e-Lung display and can be summarized as a volume/percentage of the total lungs or the periphery.
Density Histogram Filter	The Density Histogram Filter extracts coarse-scale fluctuations in amplitude within up to 5 non-overlapping ranges or bins, that can be configured by an administrative user. These are displayed as an overlay in the scan viewer. The volume (ml) and percentage of these are displayed in chart format within the e-Lung display and can be summarized as a volume/percentage of the total lungs or the periphery.

2 Intended Use / Indications for Use

The e-Lung software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support in the examination of radiological findings. These radiological findings can then be evaluated by the physician in conjunction with a range of ancillary information to form a potential diagnosis or list of likely diagnoses. The e-Lung software package is intended to be a workflow enhancement and visualization tool for the assessment of CT thoracic datasets. e-Lung can be used to support the physician when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets. 3D segmentation and isolation of sub-divisions, volumetric measurements, density evaluations, and reporting tools are combined with a dedicated workflow.

2.1 Intended User and Patient Population

Brainomix 360 e-Lung is intended to be used by radiologists on scans from adult populations who have received a chest CT (see Scanner and Image Compatibility) as part of their clinical care.

2.2 Limitations

- Brainomix 360 e-Lung is not intended for diagnostic use.
- Brainomix 360 e-Lung has been validated and is intended to be used on Siemens, Philips, GE and TOSHIBA scanners.

2.3 Contraindications

Brainomix 360 e-Lung is not suitable for use with scan data containing image features associated with:

- Pneumonectomy, lobectomy, or resection

2.4 Warnings

	Brainomix 360 e-Lung should not be used for diagnosis or as a diagnostic conclusion tool. It should only be used by a trained professional with an understanding of CT image interpretation.
	Brainomix 360 e-Lung should only be used by professionals who have received adequate training on the use of the software by qualified trainers of Brainomix or authorized third parties.
	Brainomix 360 e-Lung should only be installed within a secure network which is subject to appropriate protective measures including antivirus, antimalware and firewall protection.
	To minimize the risk of unauthorized use of Brainomix 360 e-Lung, users should not share access credentials and should log-off when not using the system.

2.5 Precautions

	The performance of Brainomix 360 e-Lung is limited by the quality of the input CT image. If Brainomix 360 e-Lung receives poor quality, invalid or corrupted data, it may affect the system's ability to process results effectively. The user should therefore manually inspect the image for scanner artifacts and poor-quality images and cross-check processed results with the original data to avoid incorrect results.
	Brainomix 360 e-Lung is dependent on the correct functioning of the underlying server platform on which it is installed and is not intended to be used as a data store. Results and original data should be stored in a PACS system and backed up appropriately.
	Brainomix 360 e-Lung has only been validated in adult populations. Safety and effectiveness in pediatric cases has not been established.

3 Performance

3.1 Software Verification and Validation Testing

Brainomix 360 e-Lung complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association NEMA PS 3.1 - 3.20.

Brainomix 360 e-Lung is tested against its user needs and intended use by the successful execution of planned software verification and validation testing.

Algorithm validation testing has additionally been performed using phantom data with known properties.

The results of software verification and validation and algorithmic testing demonstrate that Brainomix 360 e-Lung has met all design requirements and specifications associated with the intended use of the software.

3.2 Lung Segmentation

A retrospective study has been carried out to validate the lung segmentation functionality of e-Lung. The study evaluated the accuracy of the e-Lung lung mask generation compared to a ground truth mask generated from the consensus of three experienced US board certified radiologists, who segmented the lungs following their usual standard of care. The similarity between the device lung masks and the ground truth lung masks was evaluated using Dice Similarity Coefficients (DSC), which index the amount of overlap between the two masks. The acceptability criterion for the study was an average DSC across all cases of over 0.95 (defined by the lower bound of the confidence interval).

All cases showed a DSC of above the acceptability criterion (DSC=0.95) and lung segmentation performance of the device was consistent across all subgroups assessed.

3.3 Digital Phantom Testing

Specific validation has been carried out to test the density analysis outputs (structural density filtering and density histogram evaluation). This testing made use of synthetic digital phantom data that was representative of a real-world CT dataset through a data bridging study created to provide a ground truth against which the performance of the density evaluations can be assessed and demonstrated.

For structural density filters, the ground truth was defined by target structural density patterns, with rounded and linear structural densities labelled differently. For histogram density filters, the ground truth was defined by applying two Hounsfield Unit (HU) cutoffs and masking all voxels within the amplitude range.

The performance of the density filters were validated by ensuring a Dice score greater than 80% between the output images from e-Lung structural density and histogram density filters and the ground-truth images generated in the digital phantom dataset.

4 System Specifications

4.1 Server

The following should be considered recommended specifications for reliable use of the application.

Processor	x86-64 compatible processor with 4 cores at 3.5+ GHz supporting AVX instructions (e.g. Intel Xeon, AMD EPYC)
Memory	16GB RAM
Disk	500GB SSD
Network	1Gb Ethernet
Operating System	Ubuntu Linux 24.04

4.2 Clients

The following web browsers and platforms should be considered recommended requirements for reliable operation of the web user interface.

Web Browser	Minimum Version
Google Chrome	Latest version
Mozilla Firefox	Latest version
Microsoft Edge	Latest version

Platform	Minimum Specifications
PC (desktop or laptop)	Memory: 4GB RAM Screen size: 13.3 inches and above Screen resolution: 1024 x 768 Processor: Intel or AMD CPU

4.3 Languages

The following languages are supported in the current version of the software.

- German (de)
- English (en)

5 Scanner and Image Compatibility

The e-Lung software is designed to work with chest CT scans sent via the DICOM protocol. These scans should have the following characteristics:

Slice thickness	≤5mm slice thickness
Acquisition volume	CT images should include the entire lung volume without any missing slices and with consistent pixel spacing and Field Of View (FOV).
Reconstruction method	Standard Filtered Back Projection (FBP), Iterative Reconstruction (IR), or deep learning image reconstruction (DLIR) as recommended for Lung/Chest CT protocols.
Reconstruction Spacing	For helical scans, the reconstruction interval should be at least equal the slice thickness. Overlapping reconstruction are not necessary for helical scans but acceptable. For incremental scanners, the CT scans should be reconstructed at contiguous interval.
Matrix Size	512x512 recommended
Coverage	Lung apex to below the lung bases. The coverage can be extended down to abdominal region.
Field of View (FOV)	FOV as small as possible while ensuring a complete capture of the lung/chest.

6 Cybersecurity

Brainomix 360 e-Lung is installed on a server (either physical or virtual) within the hospital network and as such is potentially vulnerable to any malware or viruses penetrating the hospital network in which Brainomix 360 e-Lung is embedded, or to any other form of unauthorized access.

Brainomix 360 e-Lung does not present a specific vulnerability to the hospital network in which it is embedded and is unlikely to be intentionally exploited. However, should such risks occur they could potentially result in corruption or loss of processing data being received, stored or sent, corruption, loss or damage to stored configuration data or interruption or prevention of normal operation.

In the event your organization discovers a vulnerability in Brainomix 360 e-Lung, please get in contact with our support team without any hesitation via support@brainomix.com.

Brainomix 360 e-Lung has been designed and developed with features and requirements to mitigate these cybersecurity risks. In particular the system has been designed such that:

- User access can be restricted and controlled
- Data storage components are not accessible over a network other than through Brainomix web-service components
- Only the minimum number of ports required for all functionality are left open
- Data transmission across untrusted connections is secured and encrypted
- Brainomix can remotely monitor the system and securely install security updates as needed.

Brainomix 360 e-Lung has been designed to employ a layered authorization model based on user roles. This includes standard users who access and use the system and Administrators who have additional privileges to enable them to:

- Access patient data or system configuration
- Set and manage security options
- Delete patient data/scans
- Modify or remove users

The installation package for Brainomix 360 e-Lung includes local firewall, antivirus and antimalware protection for the server. These can be changed or amended to suit local security policies; however, **it is important that Administrators contact Brainomix support before removing or re-configuring these default protections to avoid compromising the security of the system.**

To prevent unauthorized access, Brainomix 360 e-Lung includes inbuilt username/password and two-factor authentication mechanisms which are described in the Access Control section of this user manual.

If users or administrators suspect that a user's log-on credentials have been compromised, the password should be changed immediately, or the account disabled.

Passwords can be set and re-set by users and/or administrators but must meet minimum password complexity requirements. Minimum password complexity requirements are set to a default but can be configured by Administrators to facilitate options for more complexity where this is required or mandated by local security policies.

These options include setting the mandatory use of special characters, creating blacklists of passwords which may not be used and setting the maximum age for re-setting passwords. Two-factor authentication is optional by default but may also be enforced by Administrators.

Brainomix 360 e-Lung can be set to automatically disable user accounts that have had no activity for a defined period and, for active users, also includes an automatic time-out feature which will log out users after a period of inactivity.

To minimize the risk of unauthorized use of Brainomix 360 e-Lung, users should not share access credentials and should log-off immediately when not using the system.

Administrators can also opt to use Active Directory user accounts (via LDAP) in place of the default Brainomix authentication system.

Although various cybersecurity measures have been designed and implemented, the successful mitigation against security vulnerabilities for Brainomix 360 e-Lung depends on the security infrastructure of the hospital network environment, best practice by users and management by Administrators.

Brainomix 360 e-Lung should only be installed within a secure hospital network which is protected by a network level firewall, antivirus and antimalware software and, ideally, Intrusion Detection Software (IDS).

Client machines used to access the server hosting Brainomix 360 e-Lung should also be protected by antivirus/antimalware software and IDS and should be kept up to date with security patches and updates.

Note: a separate technical data sheet (TDS) for the Brainomix 360 platform with information relevant for your organization's IT department is provided at the time of first installation and is also available upon request. Refer to this document for important security information that ensures continued safety and security of Brainomix 360 e-Lung.

7 Installation and Training

7.1 Installation

Prior to first use of Brainomix 360 e-Lung, installation of the software is required. Brainomix 360 can be installed for your organization either via a cloud-based server deployment or a local server installation. Prior to the installation, Brainomix (or an authorized distributor) collects all necessary installation information, including location, power and networking requirements and any third-party systems that may interact with the e-Lung software. Liaise with Brainomix or authorized distributor with regards to the method and requirements for installation.

7.2 Training

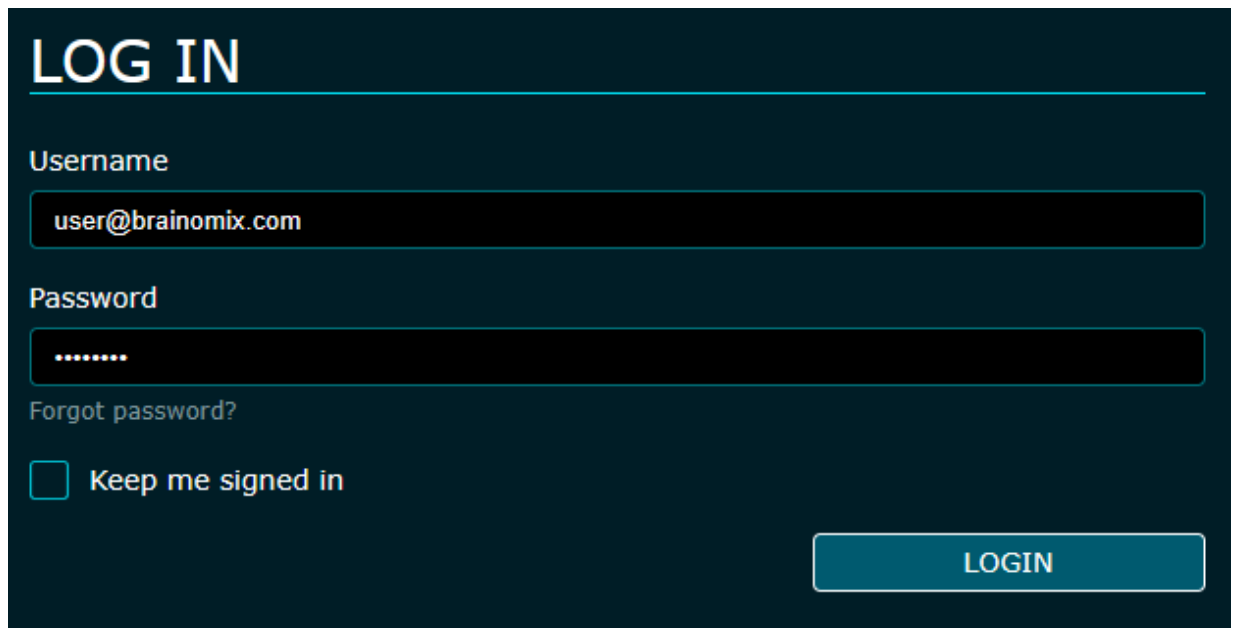
The use of Brainomix 360 e-Lung requires competency in the analysis and interpretation of chest CT scans. Training in the use of the software is required prior to first use of the software. The training is organised in advance and delivered by qualified trainers of Brainomix (or third-party trainers appointed by Brainomix) at the time of the initial installation to the clinical and/or IT representative(s) of your organisation. Subsequently, new users may be trained in the use of the software by the designated lead trainer(s) of your organisation. Brainomix will communicate if any new training is required following the initial deployment. For any questions related to training, please contact the lead trainer(s) of your or organisation or contact Brainomix at support@brainomix.com (<mailto:support@brainomix.com>)

8 Access Control

8.1 Logging In

1. Go to the Brainomix 360 or Brainomix 360 Cloud server address in your web browser.
2. You will be prompted to log in if you have not used the application recently from your current web browser. Your system administrator can provide login credentials.

Brainomix 360:

The image shows a login form for Brainomix 360. It has a dark blue background with white text. The title 'LOG IN' is at the top. Below it are two input fields: 'Username' with the value 'user@brainomix.com' and 'Password' with masked characters. There is a link 'Forgot password?' and a checkbox 'Keep me signed in'. A 'LOGIN' button is at the bottom right.

LOG IN

Username

user@brainomix.com

Password

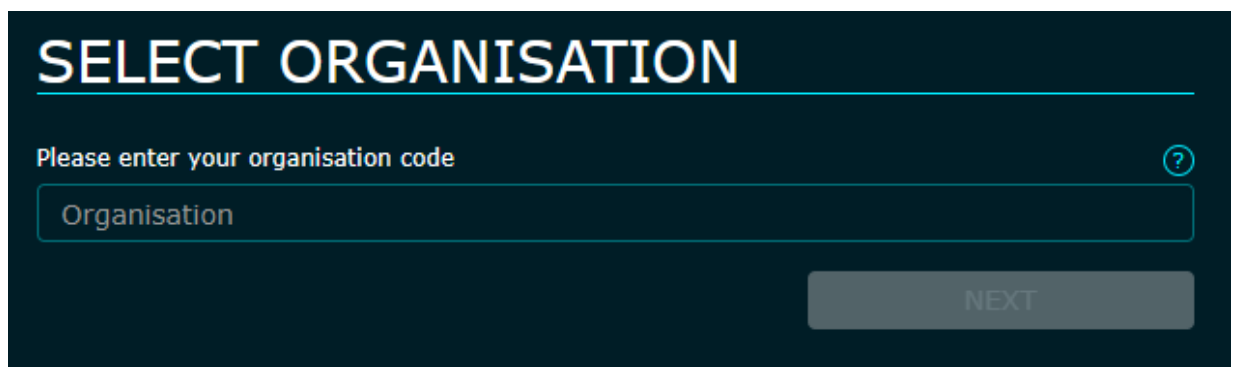
.....

[Forgot password?](#)

☐ Keep me signed in

LOGIN

Brainomix 360 Cloud:

The image shows a 'SELECT ORGANISATION' form for Brainomix 360 Cloud. It has a dark blue background with white text. The title 'SELECT ORGANISATION' is at the top. Below it is a text input field with the placeholder 'Organisation' and a question mark icon. A 'NEXT' button is at the bottom right.

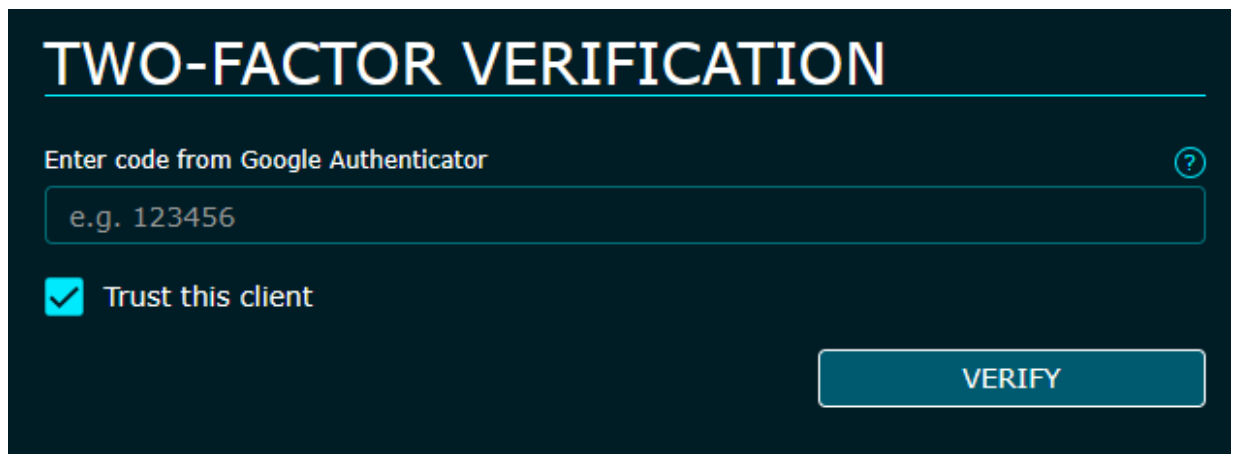
SELECT ORGANISATION

Please enter your organisation code [?](#)

Organisation

NEXT

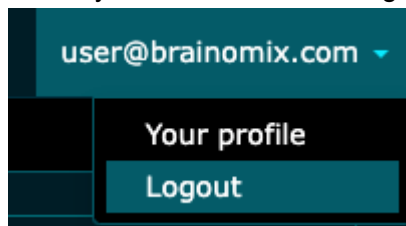
1. If logging into Brainomix 360 Cloud, enter your organisation ID
 2. Enter your username
 3. Enter your password
 4. Leave the box unchecked if you want to be automatically logged out after 1 hour, or when you quit the browser. Check the box if you want to remain signed in on this computer until you sign out.
 5. Click the submit button or press enter
3. If you have forgotten your password, you can request a password reset email by clicking the "Forgot password?" text.

A dark-themed interface for two-factor verification. At the top, the title "TWO-FACTOR VERIFICATION" is displayed in large, white, sans-serif capital letters. Below the title, the instruction "Enter code from Google Authenticator" is shown in a smaller white font, followed by a small circular help icon containing a question mark. A text input field with a light gray border contains the placeholder text "e.g. 123456" in a light gray font. Below the input field, there is a checkbox with a blue checkmark and the text "Trust this client" in white. At the bottom right, a blue rectangular button with the word "VERIFY" in white capital letters is positioned.

4. If you have enrolled in two-factor authentication, you may be prompted to enter a token code from your authenticator app.
 - Select "Trust this client" to avoid being asked for a token code again on this device or browser. Do not use this option on shared devices.
 - If you cannot get a token code from your authenticator app, you can enter an unused recovery code from the list given when enrolling in two-factor authentication.

8.2 Logging Out

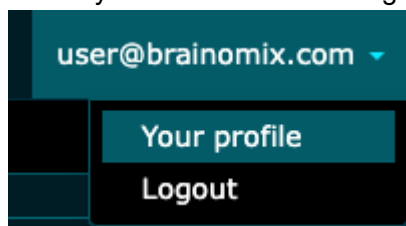
1. Select your username at the right hand side of the navigation bar.



2. Click **Logout**.

8.3 Changing Your Password

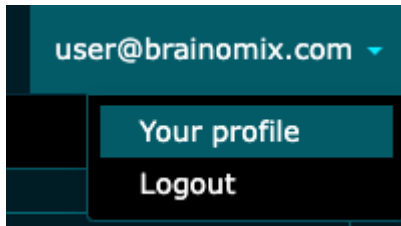
1. Select your username at the right hand side of the navigation bar.



2. Click **Your profile**.
3. Click on the tab labelled **Change password**.
4. Enter your old and new passwords (Passwords must meet minimum complexity requirements set by your system administrator).
5. Click **Save** or press enter.

8.4 Two-factor Authentication

1. Select your username at the right hand side of the navigation bar.

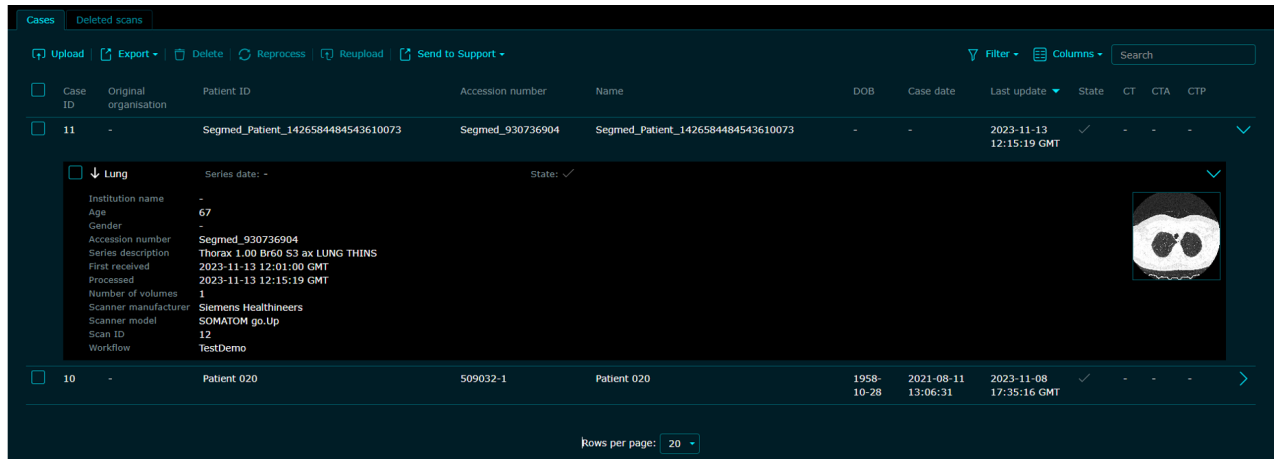


2. Click **Your profile**.
3. Click on the tab labelled **Two-factor authentication**.
4. Click the **enroll** button.
5. Follow the on screen enrollment instructions.

9 Desktop Interface

9.1 The Case List

Standard usage



- The case list page shows all cases available to you. By default, they are listed in order of the latest case date. Cases being processed will show a percentage completed in the State column.
- Move through the pages of cases by clicking on the page numbers below the list.
- Click on a case to open it in the case viewer (see the Case Viewer section).
- Click on the  icon to expand the case details and expand each scan to see scan details and a preview thumbnail of the scan.
- Click on the  icon to mark a case as a favorite, or on the  icon to unmark a favorite.
- To customize the displayed columns, click on the "Columns" button. An administrator can change the default set of columns for your organization.

9.2 Finding Cases

Sorting

Sort the case list by clicking on the required column heading; click on the title again to reverse the order, as shown below:

Name ▲	Name ▼
Example 1	Example 4
Example 2	Example 3
Example 3	Example 2
Example 4	Example 1

Search

Search for a patient by name, accession number or ID by entering text into the search box above the table.

Filtering

Filter the cases using the available options. Once the option is selected, choose the values to filter by in the dropdown. If any scan in a case matches the selection, all scans in the same case will be shown.

Filter ▼

Columns ▼

☒ State

☐ Favorite

☐ Workflow

☐ Institution name

☐ Scanner

State: 1 item selected ▼

✕

☒ ✓ This scan has completed processing

☐ ⚙ This scan is being processed

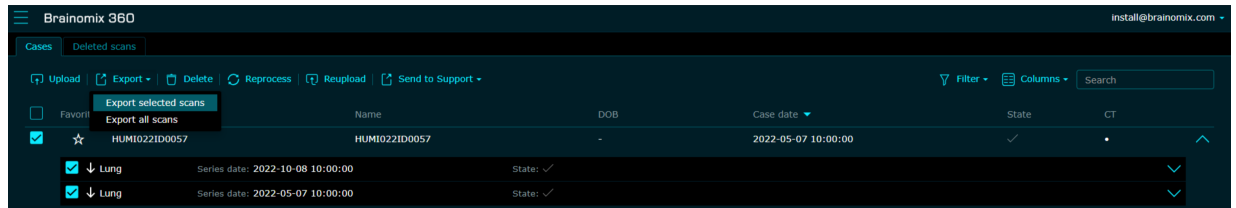
☐ ⚙ Waiting to be processed (Paused)

☐ ⌛ Waiting to be processed

☐ ! Processing for this scan has failed

9.3 Exporting Results

1. Select all the cases you wish to include by clicking on their tick-boxes. Repeat for all relevant pages of the list.



Tip: To select all the cases on a page, click the tick-box in the header row.

Tip: You can change the "rows per page" setting at the bottom of the table to view more scans on each page.

Tip: You can open a case and select only some scans within the case if you want to export them.

2. Click on the **Export** button, and choose to export only the selected scans, or all scans on all pages.
3. Click the appropriate button in the window to export in CSV or XLSX format.
 - These file types can be opened in a variety of applications, including Microsoft Excel.
 - The downloaded files contain a row for each case with identifying information, scoring results, and instructions on how to interpret the exported information.

9.4 The Case Viewer

The case viewer contains all the information for a given case. Each primary scan in the case will be displayed in a separate tab.

Patient Details

This section at the top summarizes the personally identifying information for the patient. These details are taken from the source DICOM series tags.

Additional Scans

Additional scans or DICOM series may be linked to the case if CT viewer or DICOM storage workflows have been configured. These can be accessed from the Report tab.

9.5 Report

The Report includes an imaging summary of all imaging for a patient, which can be sorted using the sort options. Each displayed slice in the case report is a link to the full slice viewer for the relevant scan.

The detailed information for every scan in the case is displayed after the imaging summaries.

 Patient ID: Patient 020
Name: Patient 020

Case date: 2022-01-08 15:26:46
Case ID: 6

Report

e-Lung

Accession number: -
DOB: 1959-01-01
Age: 61
Gender: Unknown

All scans



Open scan

Scan type: Lung

Study description: 01_Chest_HRCT_PH(Adult)

Series description: HRCT 1.00 Br64 S1 ax Lung

Scanned: 2020-08-17 13:40:51

Accession number: -

First received: 2025-03-05 15:43:47 GMT

Processed: 2025-03-05 15:50:37 GMT

Processing time: 321 seconds

Cloud sync: -

Workflow: eLung

Slice thickness (as processed): 2.4 mm

Slice thickness: 1.0 mm

Number of volumes: 1

Algorithm version: 2.0.0

Institution name: -

Scanner manufacturer: SIEMENS

Scanner model: SOMATOM go.Now

Scanner serial no.: 137070

Scan ID: 8



Open scan

Scan type: Lung

Study description: Thorax^JIC_THORAX_PLAIN (Adult)

Series description: Thorax-Plain 1.0 THIN

Scanned: 2021-08-11 13:09:29

Accession number: 509032-1

First received: 2025-03-05 15:43:47 GMT

Processed: 2025-03-05 15:53:35 GMT

Processing time: 162 seconds

Cloud sync: -

Slice thickness (as processed): 2.5 mm

Slice thickness: 1.0 mm

Number of volumes: 1

Algorithm version: 2.0.0

Institution name: -

Scanner manufacturer: SIEMENS

Scanner model: SOMATOM Definition Edge

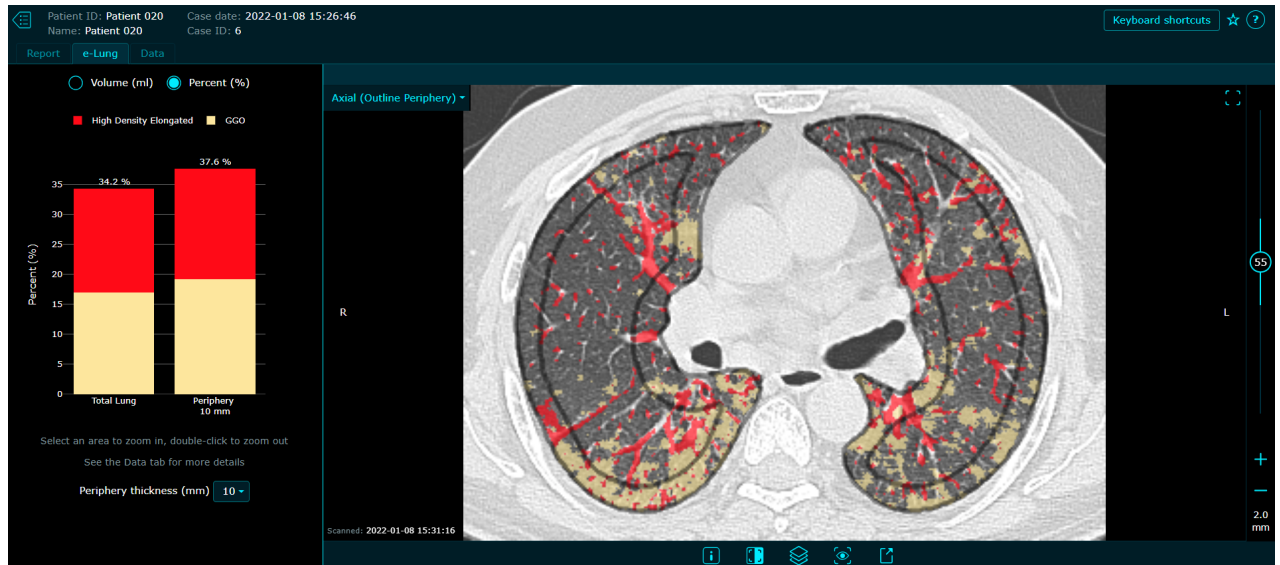
Scanner serial no.: 83280

Scan ID: 9

9.6 e-Lung Display

Result

For a single scan



User defined metrics are displayed on the left hand side of the e-Lung case viewer, in bar chart format and as either volume (ml) or percentage.

For multiple scans



User defined metrics are displayed on the left hand side of the e-Lung case viewer in a line graph format and as either volume (ml) or percentage. Individual bar charts for each scan available can also be selected from the drop down menu.

MPRs



Multipanar reconstructions can be viewed for each scan by pressing the 3D button.

Scan Details

The scan time is located on the bottom left corner of the scan. Additional scan details are located in the Info button on the bottom toolbar, and in the Report tab. Some details are taken from the source DICOM series tags (e.g. study description) while others are derived from the software itself (e.g. algorithm version).

Warnings

If there are warning messages displayed above the scan from e-Lung, they may affect the accuracy of the results.

Menus

In the **Export** menu are buttons to:

- Download images in DICOM format.
- Send the results to Brainomix support.

In the **View** menu are buttons to:

- Choose whether to view the original scan.
- Reset zoom, to fit the whole scan into view.
- View the scan at 1:1 ratio.
- View the Minimum, Mean, or Maximum Intensity Projection.

Scrolling through slices

To scroll through slices:

- You can use your mouse wheel or hold down the left mouse button while moving the mouse up and down on the scan.
- You can move the slider up and down.
- You can use the **+** and **-** buttons to change which slice is displayed.

Windowing

Pixels in a CT scan are measured in Hounsfield Units (HU), which must be converted to grey levels for display. The windowing level and width controls in the **Windowing** menu allow you to adjust the range of HU values which are displayed.

These preset windows are provided to help you manually assess the scan:

- **Brain:** Provides a good overall view of brain tissue.
- **High-contrast:** Provides a high contrast view to make early hypodense changes more easily visible.
- **CTA:** Provides a better contrast to make enhanced vessels more easily visible.
- **Lung:** Good for viewing lung images.
- **Mediastinum:** Good for viewing soft tissue on chest CT.
- **CTPA:** Good for viewing pulmonary angiograms.
- **Bone:** Good for viewing bone structures.

You can add up to three custom windowing presets for your own use, which will be available in the same preset list.

Window width and level can also be adjusted by pressing and holding the middle mouse button over the viewer, while moving the mouse up/down (to change level) or left/right (to change width).

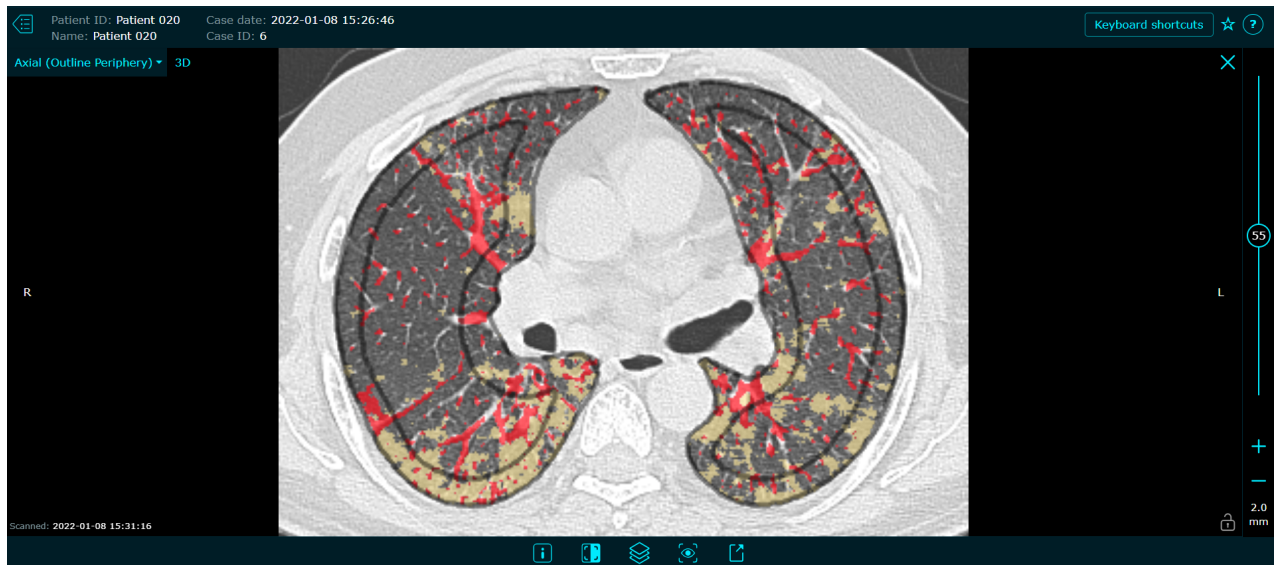
9.7 Help

The case viewer has a lot of functionality to aid in the assessment of the scans. You can access the help at any time by clicking the **Help** button. Each feature will be annotated with a button you can click to view the additional help. The additional help allows you to familiarize yourself with the controls and the various features available to you.

It is recommended that you view the help after major updates of the Brainomix 360 software to make yourself familiar with new features as they are added.



9.8 Maximizing



Any of the windows can be maximized to view them larger, one at a time. The relevant menus are available beneath the maximized window. Press X to return to the normal view.

10 Administration

Administrator users have extra features available to them for managing users, deleting scans and configuring the integration of the Brainomix 360 system into the clinical workflow. In general, these settings will not need to be changed and incorrect settings may result in data loss, incorrect operation or compromised security. If you require assistance with the integration of your Brainomix 360 system into your clinical workflow, please contact your local distributor or Brainomix support.

11 Troubleshooting

In case of any issues encountered during use or if presented with any error messages, contact your local administrator or Brainomix support at one of the contact options indicated in the Regulatory Information section.

12 Service Maintenance and Upgrades

In the event of a planned maintenance, Brainomix will inform impacted users in advance that maintenance work is being carried out and what level of interruption to service is expected. User access may be denied during the maintenance window. If the Brainomix 360 Mobile app is installed on a mobile device, ensure to update to the latest version when prompted or made available on the Google Play or the Apple App Store.

13 Incident Reporting

Please contact us via support@brainomix.com (<mailto:support@brainomix.com>) if you have discovered a potential issue with any of our Brainomix 360 suite services. Note that any information you submit will be governed by our Privacy Policy (<https://www.brainomix.com/privacy-eu/#:~:text=For%20users%20of%20Brainomix%20products,in%20order%20to%20provide%20support>). If a serious incident has occurred in relation to any of our products, please also report it to the local competent authority of your country:

- Member States of the European Union (<https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human>)
- United Kingdom of Great Britain and Northern Ireland (<https://www.gov.uk/report-problem-medicine-medical-device>)
- Turkey (<https://www.titck.gov.tr/>)

14 Decommissioning

In the event of discontinuation and removal of service, Brainomix will coordinate the process with the relevant stakeholders at your organization to ensure smooth and complete removal of the Brainomix 360 system, including any assets and data. The impact of removal will be assessed to determine whether it will result in changes to your clinical workflow and/or the configuration of other systems. Any assets owned by Brainomix will be reclaimed and integrations will be removed from the system to ensure there is no more data transfer taking place to or from the to be decommissioned asset(s). For more information on the process of decommissioning of your Brainomix 360 system, please contact your local distributor or Brainomix support.

15 Symbols

Symbol	Description of symbol
	Indicates the medical device manufacturer's name and address.
	Indicates the date when the medical device was manufactured.
	Indicates the carrier that contains unique device identifier information.
	Indicates the authorized representative in the European Community.
	Indicates the entity importing the medical device into the locale.
	Indicates the need for the user to consult the instructions for use.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicates the item is a medical device.
	CE marking indicates that a product complies with the applicable European Union regulations.

16 Request a Paper Copy

Should you require a printed hard copy of this revision of the user manual of Brainomix 360 e-Lung, please consider printing out this webpage (right click + Print or download the latest revision from our website (<https://www.brainomix.com/docs/>)). If this option is not available for you, please contact us via support@brainomix.com (<mailto:support@brainomix.com>) with your request and a printed copy will be sent to you within 7 calendar days of the receipt of request. This service is provided free of charge.