14 Lung Nodule Assessment

Introduction

The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

The user interface and automated tools help to determine growth patterns and compose comparative reviews. The Lung Nodule Assessment and Comparison Option requires the user to identify a nodule and to determine the type of nodule in order to use the appropriate characterization tool. Lung Nodule Assessment and Comparison Option may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening.*

CAUTION

***Screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.**

Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409), NELSON trial "Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial" Koning et al, N Engl J Med 2020; 382(6):503-513 and subsequent literature, for further information.

Results of this application include nodule measurements, clinical decision-support tools and category calculations based Lung-RADS™ guidelines.

The LNA application features include nodule identification using single click segmentation, nodule volume calculation and an optional Lung Nodule Computer Aided Detection (CAD) feature.

NOTICE

There are two lung CAD options. Only one option can be enabled. The user interface for the two algorithms is similar. The algorithm used is dependent on geographic location:

- The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.
- The CT LNA ClearRead CAD is FDA cleared and commercially available in the United States, as well as other markets.

Indications for Use

The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

Intended Users

The software provides radiologists and technicians with a robust application to locate, identify, segment, measure, characterize and create reports on lung nodules including nodule types.

This application allows for the preparation of nodule comparison studies.

Comment: Lung Nodule Assessment and Comparison Option may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening.*****

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Limitations for Use

WARNING

When loading images into Lung Nodule Assessment, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

Supported Scan Types

The application supports chest volumetric CT data with Axial orientation. The application supports loading of multiple time-points, with a single series in each time-point.

LNA only supports Supine scans.

Device Description

Philips Medical Systems enhanced Lung Nodule Assessment (LNA) and Comparison Option application is intended for use as a diagnostic patient-imaging tool for reviewing and analyzing thoracic CT images for Lung Nodule assessment and characteristics.

The Philips Medical Systems enhanced Lung Nodule Assessment (LNA) and Comparison Option application is a software package used with Phillips IntelliSpace Portal.

Using the LNA application, the user can identify nodules and measure their volumes in a single study and, using the follow-up mode with subsequent studies, compare matching nodules in two studies. The Lung Nodule CAD Option may be used to assist in nodule detection. The growth of nodules can be tracked over time.

The application features volumetric quantitative measurement tools and a set of advanced editing tools.

In addition, the application consists of a Risk Calculator tool that uses image-based features and clinical information and a Lung RADS™ calculator, according to ACR guidance, which can assist the physician when making decisions regarding the next treatment steps.

The LNA application may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening*.

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Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) NELSON trial "Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial" Koning et al, N Engl J Med 2020; 382(6):503-513 and subsequent literature, for further information.

Key Features

- Automatic Lung and Lobe segmentation
- Single-click lung nodule segmentation
- Manual nodule segmentation editing tools
- Loads at least 8 concurrent studies for temporal measurements
- Restores previously segmented nodules from prior studies for comparison
- Enhanced comparison feature that allows matching and correspondence between pre-identified nodules in two studies
- Synchronization between studies from different time-points
- 3D or MIP visualization of segmented nodules
- Reporting based on Lung-RADS™ Version 1.0 and 1.1 guidelines. An option enables exporting to Clipboard

- Risk Calculator tool based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013)*. Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919.
- Reporting based on Fleischner Society Guidelines. An option enables exporting to Clipboard
- Automatic software calculation of the following measurements for each segmented nodule:
  - Quantification of nodule parameters
    - Long Axis- Longest diameter on an axial/coronal/sagittal slice (mm)s
    - Short axis- Longest diameter perpendicular to the long axis on the same slice (mm)
    - Average \ Max 3D \ Effective diameter (mm)
    - Volume (mm3)
    - Mean densities (HU)
    - Nodule Mass (mg)
  - Manual editing of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing
  - **Specification of the following characteristics for each nodule in configurable presets**
    - Nodule type (solid, part-solid, ground glass, calcified)
    - Lobe location
    - Nodule shape (Circular/Oval/Triangular)
    - Nodule Spiculation
  - Comparison and matching feature automatic calculation of the following measurements between each follow-up scan and the previous scan:
    - Doubling time in days
    - Percent (%) and absolute change of all numerical parameters (growth in nodule long axis, short axis, average diameter, max 3D diameter, effective diameter, volume and mean HU).

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

The CT LNA ClearRead CAD is FDA cleared and commercially available in the United States as well as other markets.

Functionality Workflow

The Lung Nodule Assessment (LNA) and Comparison Option application may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening.*****

***The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.**

Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409); NELSON trial "Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial" Koning et al, N Engl J Med 2020; 382(6):503-513 and subsequent literature, for further information.

Main LNA application Workflow And Stages

The Lung Nodule Assessment (LNA) and Comparison Option application includes three main scenes:

1. **Scene 1: Detect & Segment**

   This is the initial stage, which allows the user to perform the following:

   - Explore a single study in order to find nodules
   - **Segmentations of nodules** - Single-click lung nodule segmentation - segmentation of the physician indicated lung nodules is initiated manually by clicking on the nodule, and the nodules are detected and marked by the user. Segmentation of nodules is performed by the designated 3D tools.

     2D segmentation of the physician indicated lung nodules is also available and is being performed with dedicated 2D segmentation tools. 2D segmentation is performed manually.

     Edit the segmentation by enhanced editing tools. Manual edit of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing is available.
   - **Characterization of nodule** – Including automatic measurements as well as suggesting nodule characteristics in configurable presets. User needs to confirm the suggestion or to manually select another value.

2. **Scene 2: Compare & Match**

   This workflow stage is available when performing a follow-up Lung Nodule Assessment (LNA) and Comparison Option procedure. This scene purpose is to compare between studies (initial and follow-up) in order to assess nodule characterization changes over the course of time of several thoracic studies. This scene includes all the available options of scene #1, presented above, with the addition of the following features:

   - Loading the follow up studies.
   - Synchronization between studies from different time-points. User can disable and/or override using the “Link” tool.

- **Matching** - An automatic matching suggestion of lung nodules between studies. The user needs to decide whether to accept the suggested match of the two nodules or to create a new un-matched nodule.
- **Propagation** - Propagation functionality could be automatic and manually done by the user. Automatic suggestion and presentation of a potentially matching nodule, based on an already segmented nodule from another time-point.

The user reviews suggested matches and nodule propagation and either accepts or rejects them.

3. **Scene 3: Results**

The Results work stage consists of the following:

- **Population of patient related information** – Patient and family history of lung cancer. User fills in the patient related information manually.
- **Nodule result table** – This table includes all the confirmed by the user lung nodules that were identified in the first two scenes, scenes #1 and #2. Each nodule with the characteristics that are available per each specific nodule, such as identified nodules number, characteristics and measurement, as well, changes over time (for follow-up studies). If a characteristic was left empty or unconfirmed- it will we displayed as "undefined" in the table.
- **Additional finding** – Allows the user to add manually further patient related information when a patient has an additional finding, related or unrelated to lung cancer.
- **Lung-RADS™** – Both Lung-RADS™ Versions 1.0 and 1.1 are available for the user. According to the version selected, the Lung-RADS reporting criteria provide automatic Lung-RADS calculation according to the American College of Radiology (ACR) guidelines, including: category, suggested management and a rationale. The user has to confirm or reject the suggestion and can override it by manual selection of Lung-RADS category.
- **Risk Calculator tool** based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919*. The subject Lung Nodule Assessment and Comparison Option provides this additional feature to assist and support user decision.
- **Fleischner Society Guidelines Calculation** provides management suggestion based on rev. 2017 of the Fleischner Society guidelines.
- Different results management options are available to the user:
  - Copy results to Clipboard
  - Save results as image series
  - Export results to PDF
  - Send results to report
  - Save option – the tables could be saved as HTML or Text file

Single Study (Single time point) work flow

The following flow presents the main stages in Single study (single time point) operation work flow:

Data Loading → Chest Inspection → Nodule Segmentation and Editing → Nodule Characteristics → Review Results → Export Results

Follow-up (multiple time-points) workflow

The following flow shows the main stages in Follow-up (multiple time-points) operation workflow:

Data Loading → Chest Inspection → Nodule Segmentation and Editing → Nodule Characteristics → Propagate and Match Nodules →Review Results → Export Results

NOTICE

Depending on your Portal configuration, this application may not be available.

Validation Activities

For the Lung Nodule Assessment and Comparison Option (LNA), validation activities were conducted to provide objective evidence that the design meets user needs and intended use.

These validation activities assure that the lung and lobe segmentation, the comparison, as well as the nodule matching and propagation functionality, and the Prefill functionality for the Lung-RADS score and the risk prediction are adequate from an overall product perspective.

Recommended Scan Parameters

When using the Lung Nodule Assessment clinical application, there are recommended parameters that should be used to insure accurate and reproducible results.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

If the radiologist prefers different parameters based on preference or clinical indication, certain guidelines should be followed if the case is intended to be processed with the LNA application. In these instances, if guidelines cannot be met, it is suggested to perform a second reconstruction from raw data with the recommended parameters for use in the Lung Nodule Assessment package.

Scanning Parameter	Follow These Guidelines When Creating a Protocol for Lung Nodule
Resolution	Standard resolution
Filter	Filter C • The B filter can be used • Never use the D, L, or Y filters • Do not add any additional enhancements
Slice thickness	Slice thickness 3mm or less with a 50% overlap • The slice thickness is related to the size of the nodule. If the nodule is small, then the thinnest slice thickness available should be used to make volumetric measurements • There are several factors that can affect the segmentation of the nodule: – Scan parameters (slice thickness, filters) – Nature of the nodule (shape, homogeneity)

NOTICE

Please refer to Physician’s Training Manual “459801861791_A_ClearRead CT Console IFU” for ClearRead CAD details.

CAUTION

If the recommended parameters are not used the accuracy of the results cannot be assured.

When performing follow-up studies it is important to use the same parameters as the original case to get a consistent volumetric comparison between current and previous studies.

Loading Studies

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

From the IntelliSpace Portal Patient Directory, locate the LNA study you want to work with.

NOTICE

If performing a follow-up procedure, load at least two studies (at least eight studies can be loaded) at this time. The follow-up procedure is described in the section “Compare & Match Work Stage” on page 370. Although you can load multiple studies, only two studies are displayed at a time. The remaining studies are loaded and can be used within the application.

Select Lung Nodule Assessment from the Analysis tab. The LNA study loads.

- LNA supports the loading of multiple time-points, with a single series in each time-point.
- By default, images are loaded with Lung windowing, original slice thickness and MIP rendering mode.
- When loading a single time-point to the application, the **Detect & Segment** stage is active by default and the **Compare & Match** scene is unavailable.
- When loading multiple time-points to LNA, the **Compare & Match** stage is active by default. It is possible to navigate back to the **Detect & Segment** stage if needed.
- When attempting to load more than one axial series within a time-point, a **Series Selection** window appears. The user must select a single representative series for each timepoint.

NOTICE

One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.

Workflow

1. Detect & Segment Work Stage

The initial workflow stage, **Detect & Segment**, allows you to perform the following:

- Lung and lobe segmentation on the CT image (pre-processing performed automatically).
- Use the Lung Nodule CAD option as an adjunct detection process (if available).
- Explore a single study in order to find nodules.
- Select and segment nodules using 3D or 2D segmentation tools.
- Edit the segmentation using the enhanced editing tool.
- Calculate nodule measurements and fill in nodule characteristics via by automatic pre-fill option or manually.

2. Compare & Match Work Stage

Use the additional workflow stage, Compare & Match, when performing a follow-up LNA procedure.

Use the Compare & Match stage to compare the two studies (initial and follow-up) and assess changes over time. After you have matched nodules between the studies, you can generate a report that includes calculations of nodule measurement changes and projected doubling time.

3. Results

A Summary table is created, showing all identified nodules, with characteristics and measurements that include Maximum 3D diameter, volume, effective diameter, Long & Short Axes and mean Hounsfield units, as well as calculations of percentage of growth and doubling days.

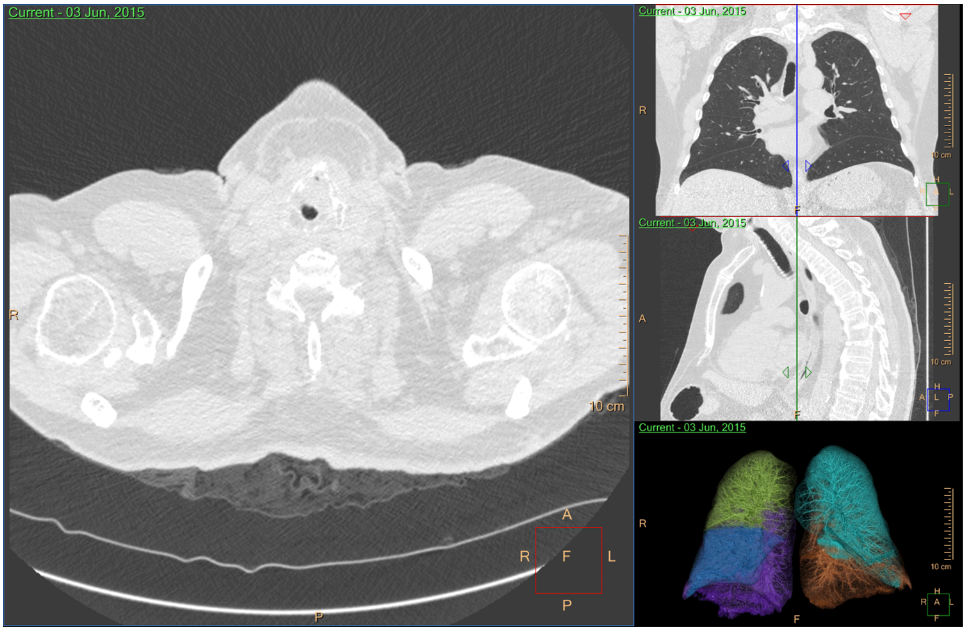
In addition, the LNA application provides Lung RADS calculation both Version 1.0 and 1.1 according to ACR guidelines and a Risk calculator result of the calculation of the probability of malignancy based on Risk Calculator tool based on patient information and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919.

Images can be sent to film or report at any time during the analysis. After segmentation has been done, the identified nodules and results can be saved, filmed, and sent to report.

Detect & Segment Work Stage

When loading a single study into the Lung Nodule Assessment application, it defaults to the **Detect & Segment** workflow stage.

The main viewport displays the axial slab image (using the original thickness it was reconstructed with). Use this image to look for nodules. It can be manipulated like any slab image.

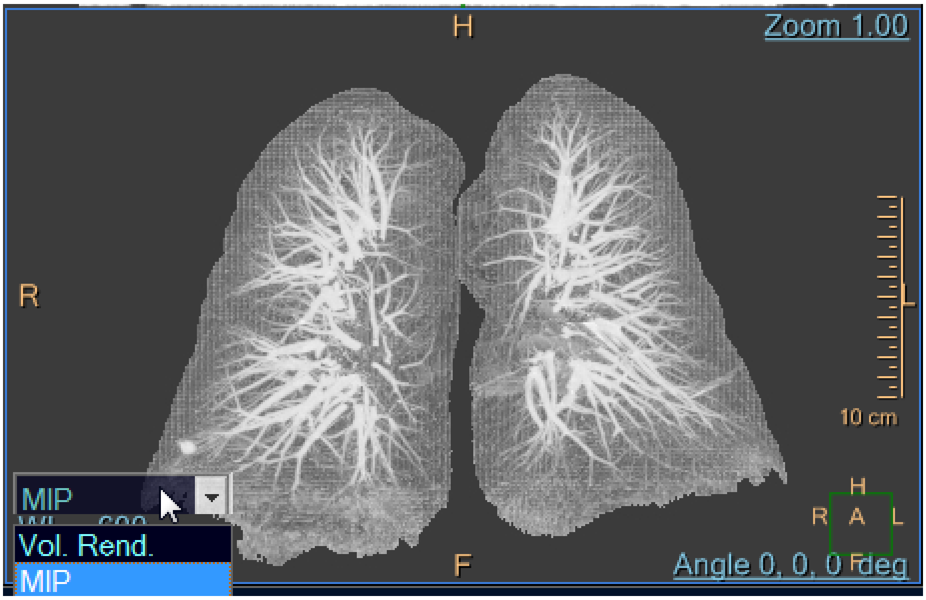


Reference Images, Coronal and Sagittal

Reference images are displayed in the minimum slice thickness. After nodules are marked and accepted, these images visually indicate the locations of the nodules by surrounding each of them with a blue circle and a Finding number.

Mode

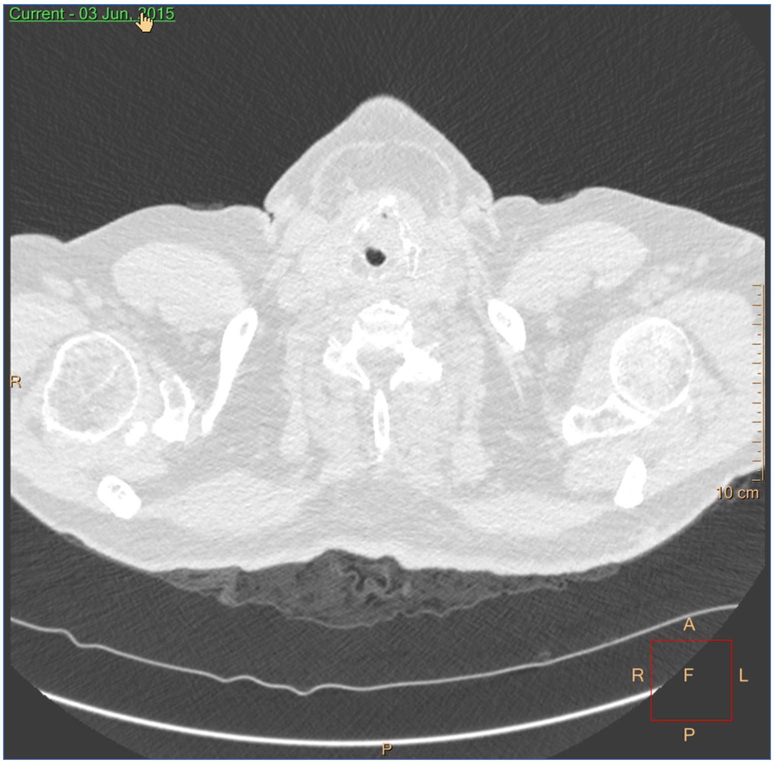
To change a VR image to MIP Rendering mode, use the viewport control.



Switching Between Time Points

When loading multiple timepoints and navigating to the Detect & Segment work stage, it is possible to switch between the time points using either:

- The series selection viewport control.



- The Next and Previous series button in the upper toolbox.

CT Common Tools

These are the tools that are common to other IntelliSpace Portal applications.

See **Report**, **Film**, **CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Image Review Tools

Various viewing techniques and tools are provided to assist in your image viewing, nodule detection, and matching process.

See **Report**, **Film**, **CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Orientation

You can select from three viewing orientations: Axial, Coronal, Sagittal, and Flip. The Flip button becomes available when you select the Volume image or MIP Overview image. You can use the orientation buttons, the keyboard shortcuts (A, C, S, or O for Flip), or select from the right mouse menu (right click in any viewport and select from the menu’s Orientation list).

Layouts

There are three layout selections available from the factory:

- 1 +2
- 1 +3 (default)
- 2 x 2

You can also create and save your own layouts with **Layout Manager**, a common process function.

Rotation Center

If a marked nodule is selected, when selecting the Rotation center box, the rotation center appears on that nodule.

If no nodule is marked when checking the Rotation center box, the rotation center defaults to the middle of the image. You can move the center of rotation to any location in the image (left click on the center and drag it to the desired location).

The Rotation Center icon is a dropdown, sharing the same location as the **Show Crosshair** and **Center Cursor** icons.

Center Cursor

Click on this icon to move the rotation center cursor to the center of the viewport.

The Center Cursor icon is a dropdown, sharing the same location as the **Show Crosshair** and **Center Cursor** icons.

Show Crosshair

Click on this icon to show crosshairs on reference images.

The Show Crosshair icon is a dropdown, sharing the same location as the **Center Cursor** and **Rotation Center** icons.

Inspect Chest

Windowing

There are three windowing preset buttons which allow toggling between the following presets:

- Lung
- Mediast. (Mediastinum)
- Bone

These buttons affect all slab images (including focus viewports, when they are displayed).

Slab Thickness

- The two **Slab Thickness** buttons allow toggling between the original slice thickness of the images and the value displayed on the left button.
- Use the drop down menu on the left button to select a different Slab Thickness value.
- Select the **Other…** option in the drop down menu to type-in thickness values.
- Select **Original** to return to the original slice thickness.
- The default thickness for the slab image is the original slice thickness of the images and the reference images are defaulted to the minimum slice thickness available. The slice thickness, a common process function, can be controlled for the slab image and reference images.
- The minimum slice thickness depends on the scan parameters and the maximum slice thickness is 200 mm.
- The Slab Thickness buttons affect the main slab viewport only.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use** > **Directory** > **Key Image Notes** for more information.

Key Images can be used to save images of findings that are not lung nodules.

Show Findings

This function controls the display of the blue circle (or orange for unconfirmed findings) around a marked finding, and is ON by default.

To display findings on the different viewports, including the focus viewports, place a check mark in the **Show Findings** checkbox.

If there is no check mark in the checkbox, all finding indications, including the contours from the focus viewports, are hidden.

Mark Nodules

When a nodule is observed, it can be marked using one of the following tools:

- Mark Nodule 3D
- Mark Nodule 2D

When a nodule is segmented using the Mark Nodule 3D or Mark Nodule 2D tools, it is treated as a confirmed nodule.

Once a nodule is segmented, it appears in the Findings list and on the different viewports, including the focus viewports.

Mark Nodule 3D

WARNING

Verify the correctness of the segmentation and labels (manual visualization). If needed, correct them manually using the correction tools provided by the application.

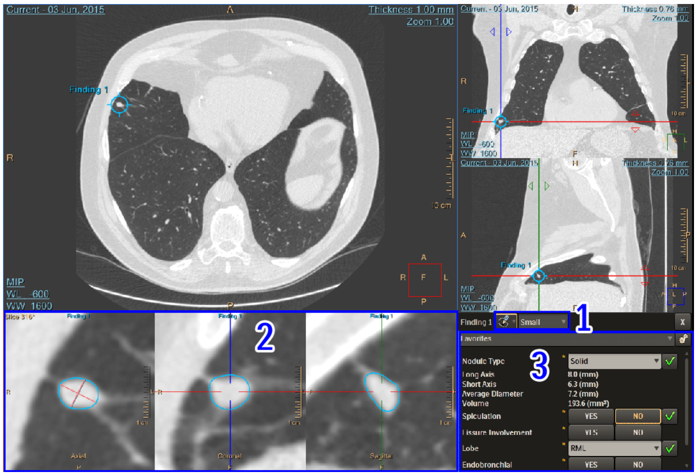
Mark Nodule 3D Tool

The Mark Nodule 3D tool provides one-click volumetric segmentation.

To segment a nodule using the Mark Nodule 3D tool:

1. Select the **Mark Nodule 3D** button.
2. Click on a nodule in any of the Slab viewports (axial, coronal or sagittal).

   Once segmentation is performed, focus viewports are added based on the current layout.
3. Review all slices of the nodule to verify the correctness of the segmentation. Use the editing tools (#3 in below image) to correct the segmentation if needed. For additional information, see section “3D Segmentation Correction or Editing ” on page 353.



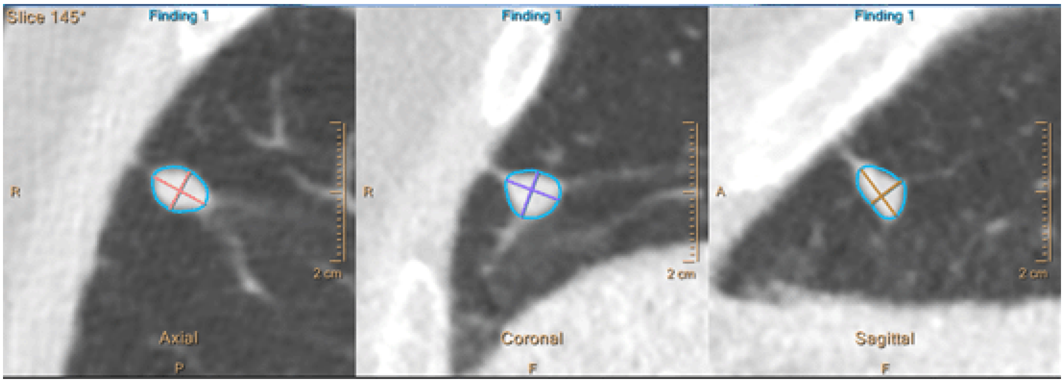
Nodule Type	Solid ✓
Long Axis	8.0 (mm)
Short Axis	6.3 (mm)
Average Diameter	7.2 (mm)
Volume	193.6 (mm³)
Spiculation	YES [✓ NO] ✓
Fissure Involvement	YES NO
Lobe	RML ✓
Endobronchial	YES NO

The segmentation’s contour is displayed on each of the focus viewports.

Each finding is added to the Findings List. If the **Show Findings** checkbox is enabled, findings appear in the viewports (#2 in above image).

The nodule's characteristics are displayed next to the nodule's focus viewports (#3 in above image). For additional information, see section “Characteristics Table” on page 365.

The Long Axis and Short Axis are automatically extracted from the segmentation and are displayed on the Axial, Coronal and Sagittal focus viewports.



Nodule Volumetric Display

To change the focus axial display of a selected nodule (confirmed or unconfirmed) to a volume rendering image (and back), use the **Show 3D Cube** button (located in the upper toolbox).

To change the display using the context menu, right click in the axial focus viewport and select **Show 3D Cube**.

3D Segmentation Correction or Editing

The editing tools are only displayed for accepted nodules.

There are two types of Editing Tools for 3D segmentation:

- **Drag to Edit**
- **Click to Edit**

When a nodule is segmented using the **Mark Nodule 3D** tool, the **Drag to Edit** tool is activated by default.

Drag to Edit Tool

To use the **Drag to Edit** tool:

1. Hover over the contour in any of the focus viewports and correct the contour by dragging it.
2. Review all slices to verify the correctness of the segmentation after editing.

Click to Edit Tool

The **Click to Edit** tool can be selected from the Editing Tools dropdown menu (located next to the name of the finding in the Characteristics table).

To use the **Click to Edit** tool:

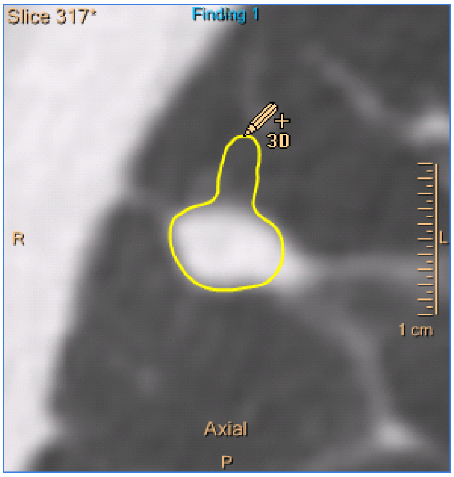
1. Select the **Click to Edit** tool from the Editing Tools dropdown list.
2. Click the desired location.

   The contour is relocated to this location. This can be done on any of the focus viewports.
3. Review all slices to verify the correctness of the segmentation after editing.

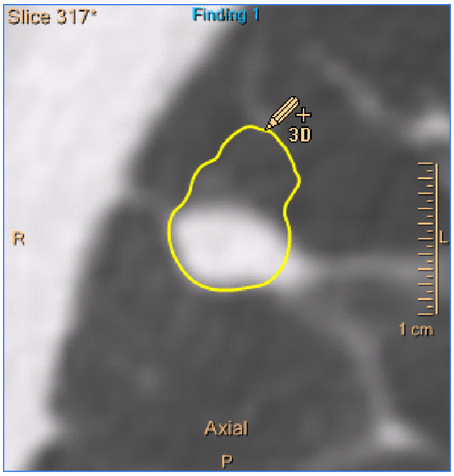
Editing Radius Size

The area of the contour to be affected by the editing tool can be adjusted using the size dropdown menu. The available options are:

- Small



- Medium
- Large



Mark Nodule 2D

Mark nodule 2D

This tool allows you to manually draw the Long and Short Axis on the focus viewports.

To segment a nodule using the Mark Nodule 2D tool:

1. Select the Mark Nodule 2D tool.
2. Click on a nodule in any of the Slab viewports (axial, coronal or sagittal).

   Three focus viewports are added, displaying the clicked location: axial, coronal and sagittal.
3. Manually draw the Long and Short Axes on any of the focus viewports, as required.

2D Segmentation Editing Tools

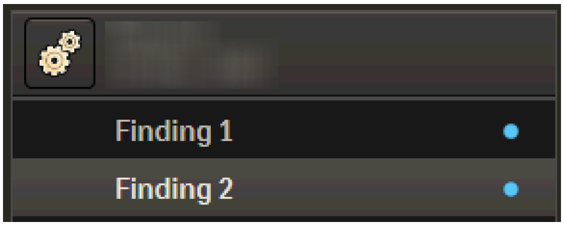
It is possible to edit diameters by hovering over a line’s edges and dragging. Dragging:

- in the line’s direction changes its length
- in any other direction rotates the diameters, while keeping them perpendicular

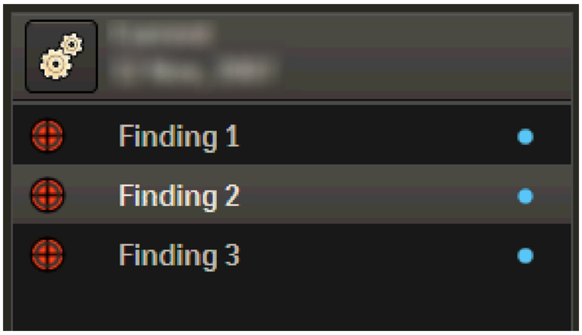
It is possible to redraw the diameters by selecting the **Redraw diameter** tool (located in the Characteristics table) and drawing new/additional diameters on any of the focus viewports. If diameters already existed on a specific focus viewport, the new diameters are updated, replacing the old ones.

Findings List

Each finding, confirmed or unconfirmed, is added to the Findings List.



- Manually segmented nodules or confirmed nodules are displayed with a blue dot to the right of the name of the finding.
- If the CAD licensed option is available and **Show CAD Suggestions** is enabled, a red icon is displayed for nodules that were segmented manually, but were also detected by the CAD algorithm. For additional information on this option, see section “Philips Lung Nodule CAD Option” on page 357,



Navigating Between Findings

To navigate between Findings:

1. Select a finding from the Findings list or click on the finding’s indication on any of the slab viewports or volume images.

   Once a finding is activated, all viewports display this finding. The finding’s focus viewports and characteristics table are displayed.
2. To select more than one finding from the Findings list, hold the **Ctrl** button on your keyboard while selecting findings.

Deleting a Finding

To delete a confirmed nodule in the Findings list:

1. Select the finding and right click on the nodule in the Findings list.
2. Select **Delete**.

It is also possible to right click on the nodule in the slab/volume viewport and select **Delete**.

Philips Lung Nodule CAD Option

NOTICE

The Philips Lung Nodule CAD Option requires an additional license key.

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

Philips Lung Nodule CAD Software Option is a Computer Aided Detection (CAD) software option designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector CT (MDCT) scans of the chest. It is intended to be used as an adjunct by the radiologist to identify regions of interest following the initial reading of the study. Upon further assessment of each CAD-suggested region, the radiologist may either accept the CAD result as a nodule, or reject it.

The device is intended for use as an aid for image evaluation, only after the radiologist has performed an initial interpretation of the diagnostic images and it improves the radiologist's ability to detect lung nodules. It assists the radiologist in minimizing observational oversights.

Philips Lung CAD Option Warnings

WARNING

Before using the CAD option, review the entire study and use your own radiological interpretation to identify and mark your findings. The CAD option does not detect all pulmonary nodules. You may miss nodules if you do not review the entire study before using the CAD option.

Do not change your initial interpretation based on the results of the CAD option. Since the CAD option does not detect all pulmonary nodules, changing your initial interpretation may result in misdiagnosis.

Use the CAD option only as an adjunct for detecting lung nodules. Use your own independent interpretation to distinguish between true nodules and false positives.

The CAD option also detects structures that are not true nodules (false positives). Use your radiological interpretation to reject false positives that may lead to misdiagnosis.

Do not use the CAD option to detect the following: ground-glass opacities, semi-solid nodules, and pulmonary parenchymal abnormalities that do not represent solid nodules. The CAD option does not reliably detect these abnormalities, which may cause misdiagnosis.

Do not use the CAD option for patients with diffuse interstitial lung disease or extensive granulomatous disease. Using the CAD option for these patients may reduce detection performance.

Do not use the CAD option for patients with prior thoracotomy or radiation therapy involving lung parenchyma. Using the CAD option for these patients may reduce detection performance.

Use the CAD option only on CT images that were acquired with the recommended scan protocol parameters presented later in this section.

Using the CAD option on images that were acquired with non-recommended parameters may reduce detection performance, which may cause misdiagnosis.

Do not use the CAD option on CT images that exhibit patient motion, such as exams not performed during a single breath-hold period. Patient motion may contribute to false positive readings, which may cause misdiagnosis.

The Lung Nodule CAD option should not be used as the SOLE incontrovertible basis for clinical diagnosis

Philips Lung CAD Scan Parameters and Specifications

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

The following parameters need to be met for optimal image reconstruction. Additionally, good imaging practices for lung/chest studies need to be followed, as outlined in the scanner instructions for use.

Scanners	Philips or other vendor multislice CT scanners
Detector rows	4 or more
Scan area	The entire thorax should be in scan area but it is not required
Exposure	up to 365 mAs
Voltage	120 kV
Slice width	0.9 (submillimeter) to 3 mm
Slice overlap	0 - 50% overlap
Number of images	Up to 1,200
Contrast	Intravenous contrast is optional

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

CAD Results

When the CAD algorithm’s results are available, the **Show CAD Suggestions** checkbox is enabled and can be checked.

To view the CAD results, place a check mark in the **Show CAD Suggestions** check box. The below warning appears.

⚠ **WARNING**

CAD results should not be used as a SOLE basis for clinical diagnosis.

After clicking **OK** on the warning message, the nodules suggested by CAD are surrounded by orange circles in the Slab image, reference images and Volume Rendering image. The CAD suggested findings are added to the Findings list and are labeled CAD 1, CAD 2, and etc.

It is possible to configure the order of the CAD suggestions in the list according to location or size, by clicking on the ⚙ **CAD Suggestions Settings** button and selecting an option from the dialog:

- Location (cranial to caudal)
- Size (large to small)

The selected order is used the next time the CAD algorithm is run.

The Philips CAD algorithm can detect 30 Nodules by default. If a study contains more than 30 nodules, a note is displayed in the warning **A large number of CAD suggestions were detected, only 30 candidates are shown**.

CAD Findings List

Unconfirmed nodules are displayed with a ? icon and there is an **Unconfirmed** label.

CAD 8

Unconfirmed

?

A finding that was detected by CAD is marked with the CAD icon.

The icon is also displayed for nodules that were segmented manually, but were detected by the CAD algorithm as well.

Accepting CAD Suggestions

To accept a CAD suggestion: either:

- Right click on the CAD indication (orange circle) on the slab viewports and choose **Accept CAD x as a nodule** (where x is the number assigned to the CAD suggestion).
- Click the **Accept as nodule** button in the nodule's Characteristics table.

Once a CAD suggestion is accepted:

- The nodule becomes a confirmed finding. The ? icon and the **Unconfirmed** label are replaced with a "confirmed" icon.

  Finding 2

- The contour editing tools become visible and it is possible to edit the contours.
- It is possible to edit the nodule characteristics.

WARNING

Verify the correctness of the segmentation and labels (manual visualization). If needed, correct them manually using the correction tools provided by the application.

Rejecting CAD Suggestions

To reject a CAD suggestion:

- Right click on the CAD indication (orange circle) on the slab viewports and choose **Reject**.
- Click on the **Reject** button in the nodule's characteristics table.

When a CAD suggestion is rejected, the suggestion is deleted from the viewports and Findings list.

Re-running the CAD Algorithm

To re-run the CAD algorithm for a selected series, use the context menu from the viewport to select the **Run CAD algorithm for active series** option.

CT LNA ClearRead CAD Option

NOTICE

The CT LNA ClearRead CAD Option requires an additional license key

The CT LNA ClearRead CAD is FDA cleared and is commercially available in the United States, as well as other markets.

The CT LNA ClearRead CAD option is a third party CAD algorithm manufactured by Riverain Technologies.

The option is comprised of computer assisted reading tools designed to aid radiologists in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population, as well as in already diagnosed patients. [1]

The nodule detection component identifies regions of interest associated with solid, sub-solid, and/or ground glass nodules.

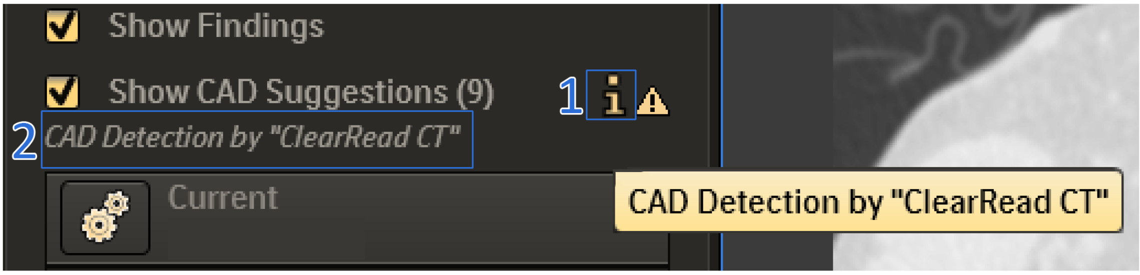
ClearRead CAD provides adjunctive information and is not intended to be used without the original CT series.

For more information, including warnings, please refer to Riverain Technologies' “Physician’s Training Manual “459801861791_A_ClearRead CT Console IFU” for ClearRead CAD details”.

[1] The intended population for ClearRead CT differs in different markets. Please contact your representative for more details. In the United States, ClearRead CT is cleared for the asymptomatic population only.

CT LNA ClearRead CAD Results

This section provides information on the ClearRead CT algorithm.



When the ClearRead CAD algorithm is enabled, if the ℹ icon (#1) is selected, the following ClearRead information appears:

CAD detection algorithm is "ClearReadCT". The algorithm displays up to 25 nodules. If more than 25 nodules are detected-the rest of the nodules are being filtered out. Note: Nodules segmentation and quantification are based on Philips algorithms.

- When there are more than 25 suggestions, a note is added to the CAD warning if **Show CAD Suggestions** is checked.

⚠ **WARNING**

CAD results should not be used as a SOLE basis for clinical diagnosis.

Note: A large number of CAD Suggestions were detected, only 25 candidates are shown.

- **CAD Detection by “ClearRead CT** (#2) is displayed below the **Show CAD Suggestions** checkbox on the left panel.

Automatic CT LNA ClearRead CAD Results to PACS

NOTICE

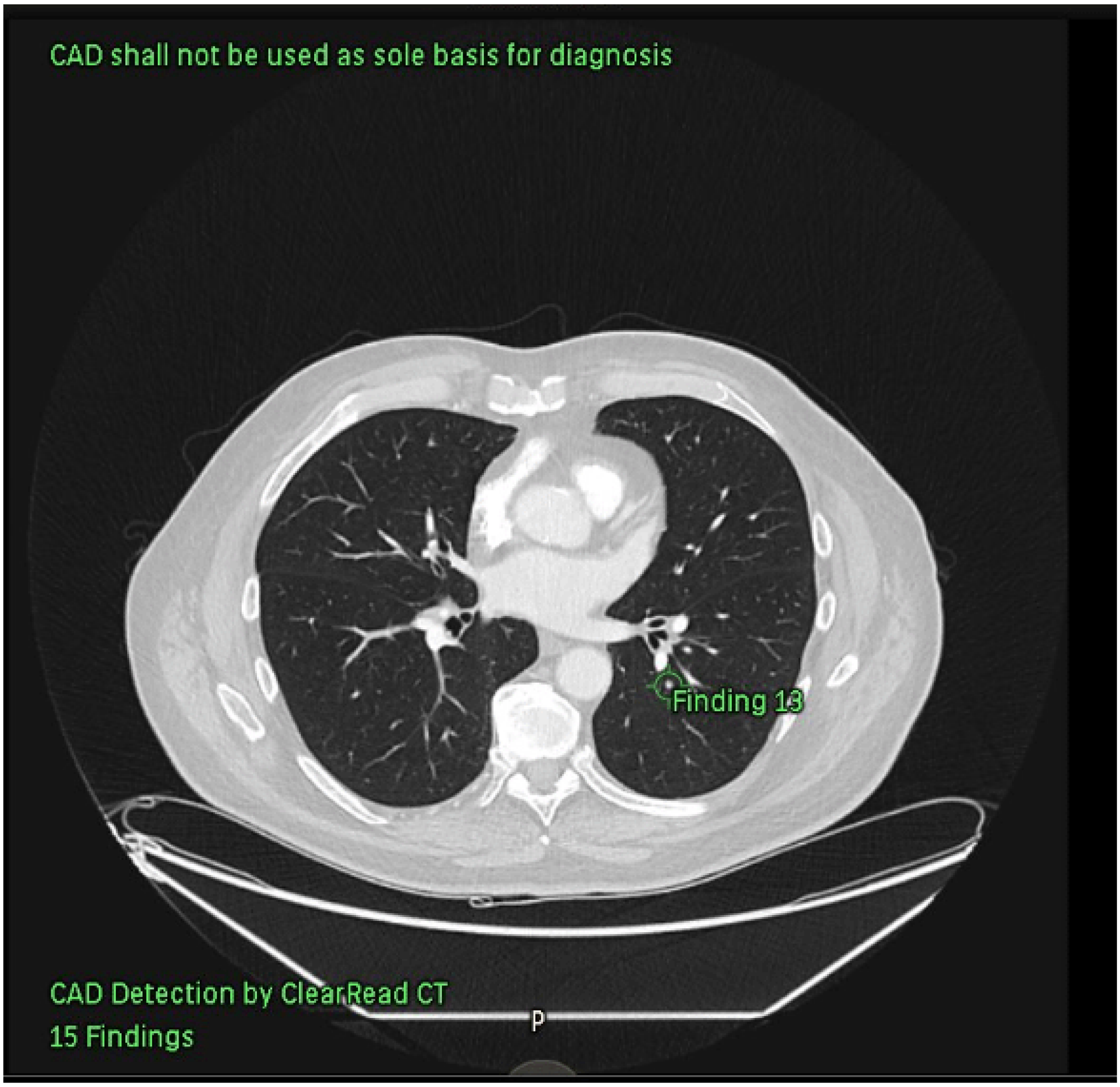
The Automatic CAD Results to PACS option are available only when the **CT LNA ClearRead CAD** license key is enabled.

The Automatic CT LNA ClearRead CT CAD suggestions are limited to only 25 findings/ suggestions.

The Automatic CAD result creation is triggered by preprocessing, based on the preprocessing rules defined in Preferences (or Manual preprocessing from right-click context menu on a series).

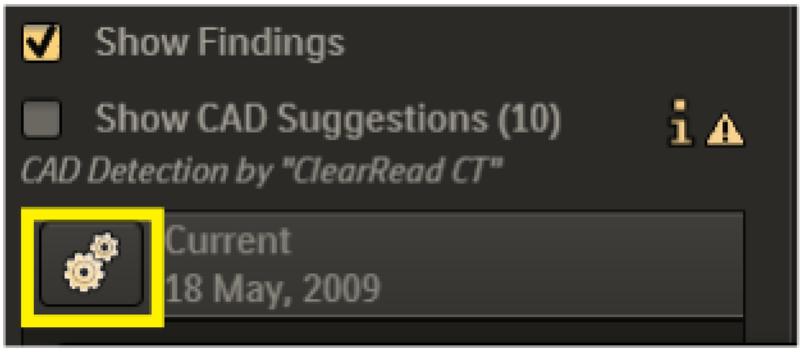
Automatic CAD Results Suggestions

- The automatic CAD results are Grayscale Softcopy Presentation State (GSPS) objects received from ClearRead CT CAD.
- The Result Series is named **Automatic ClearRead CT Suggestions**.
- Each Suggestion is displayed as a detection sign (ring around the suggestion)
- The CAD suggestions are named as Findings 1, Findings 2, Findings 3....



Enable Automatic CAD Results and Configuration of PACS

The Configuration of the PACS destination is done within the LNA application in **CAD Suggestions Settings** dialog.



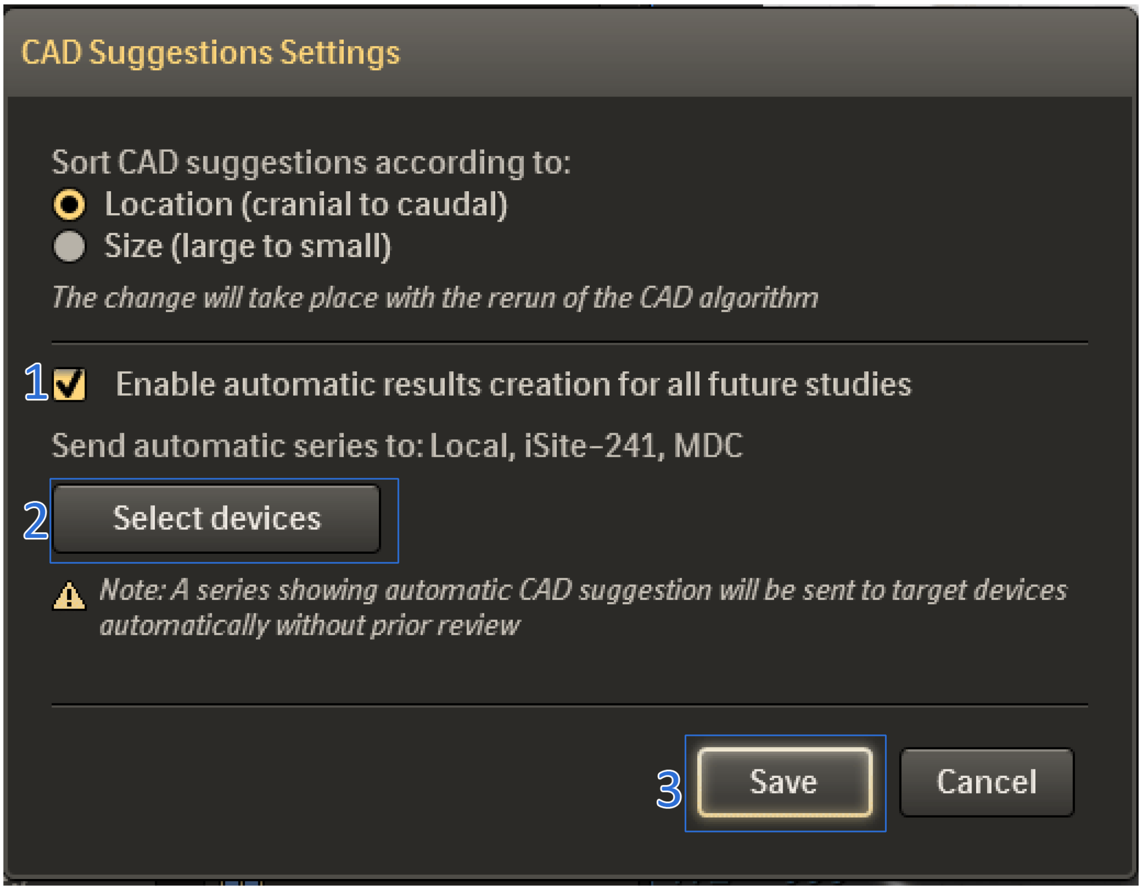
☑ Show Findings

☐ Show CAD Suggestions (10)

CAD Detection by "ClearRead CT"

Current
18 May, 2009

1. Place a check mark in the **Enable automatic results creation for all future studies** checkbox (#1).



CAD Suggestions Settings

Sort CAD suggestions according to:
● Location (cranial to caudal)
○ Size (large to small)

The change will take place with the rerun of the CAD algorithm

1 ☑ Enable automatic results creation for all future studies

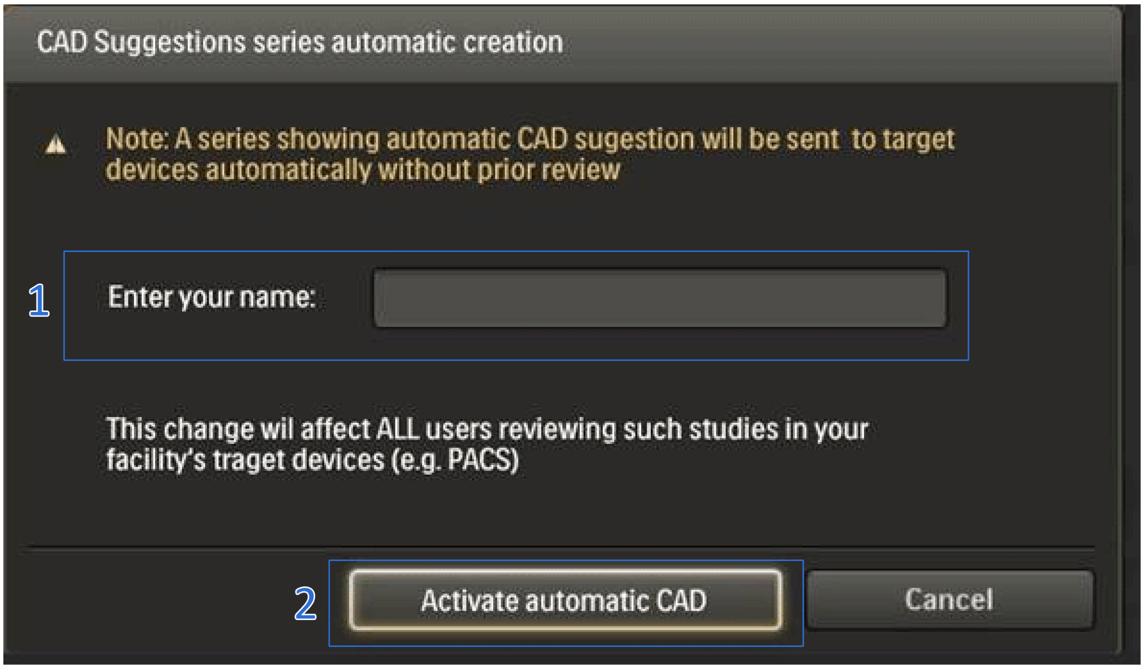
Send automatic series to: Local, iSite-241, MDC

Note: A series showing automatic CAD suggestion will be sent to target devices automatically without prior review

2. Select the **Select devices** button (#2) to choose from a list of all configured remote devices. The automatic CAD results are sent to the selected device when created.

   After selecting **Save** (#3), the following dialog is displayed.

3. Enter your name (#1) and select **Activate automatic CAD** (#2).



CAD Suggestions series automatic creation

Note: A series showing automatic CAD sugestion will be sent to target devices automatically without prior review

1 Enter your name:

This change wil affect ALL users reviewing such studies in your facility's traget devices (e.g. PACS)

Once done, the CAD Suggestion Results are shared to the PACS devices configured.

Characteristics Table

- Each nodule has a characteristics table (located next to the focus viewports), with all the parameters related to this nodule.

Nodule Type: Ground Glass

Axial Average Diameter: 5.1 (mm)

Coronal Average Diameter: 5.2 (mm)

Sagittal Average Diameter: 5.2 (mm)

Volume: 66.5 (mm³)

Spiculation * YES NO

Perifissural * YES NO

Subpleural * YES NO

Lobe: RUL

/881 * 2021-06-30

- The characteristics table allows filling in the different characteristics of accepted nodules.
- Part of the characteristics are automatically extracted from the segmentation:
  - For 2D segmentation: Long Axis, Short Axis and Average Diameter
  - For 3D segmentation: Long Axis, Short Axis, Average Diameter, Volume, Max 3D Diameter, Effective Diameter and Mean HU.
- Empty characteristics are marked with a yellow asterisk.
- The characteristics are grouped into four presets that can be selected from the dropdown menu:
  - **Lungs-RADS™** - Includes all the characteristics that are mandatory for the Lung-RADS category calculation.
  - **Risk Calculator** - Used to calculate the probability of lung nodule malignancy.
  - **Fleischner Society** - Used to suggest an appropriate management for follow-up based on the 2017 revision of the Fleischner Society guidelines for management of incidental pulmonary nodules.
  - **Favorites** - Allows user-defined configuration of the displayed characteristics.

- If the Pre-fill option is available, some of the parameters are automatically filled in by the application. For additional information, see section “Characteristics Prefill (Licensed Option)” on page 368.
- Once all values are selected, check for missing parameters. For additional information, see section “Checking For Missing Parameters” on page 369.

Configuring Favorites

To configure the **Favorites** preset:

1. Select **Favorites** from the drop down list.
2. Click on the ⚙ Favorites Preset Settings button, which opens the configuration dialog.

   The **Select Measurements, Characteristics and Information for display** window opens.

   The four buttons at the top of the dialog function as shortcuts for characteristic selection:
   - **All** - Selects all parameters.
   - **None** - Deselects all parameters.
   - **Lung-RADS™** - Selects all characteristics that are mandatory for the Lung-RADS™ calculation, in addition to the characteristics that are already selected.
   - **Risk Calculator** - Selects all characteristics that are mandatory for the probability of lung nodule malignancy, in addition to the characteristics that are already selected.
   - **Fleischner** - Selects all characteristics that are mandatory for the Fleischner calculation, in addition to the characteristics that are already selected.
3. Select the appropriate options as described below:
   - To exclusively select only **Lung-RADS™** or **Risk Calculator** or **Fleischner**, select **None** first and then select one of the shortcuts.
   - To select more than one of the shortcuts (**Lung-RADS™**, **Risk Calculator** a or **Fleischner**), select **None** first and then select the relevant shortcuts.
   - Place a check mark on additional characteristics as desired.
   - Select **Save** to save the **Favorite**.
4. The **Doubling days** parameter appears if it was selected in the **Favorites** preset.

NOTICE

The **Doubling Days** option at the bottom of the dialog controls whether the Doubling Days value is displayed in the **Compare and Match** step and the **Results** work stage for follow-up cases.

Characteristics Prefill (Licensed Option)

NOTICE

Characteristics Prefill requires an additional license key.

When the Pre-fill license key is available, the following parameters are automatically filled-in by the application:

- Nodule Type
- Spiculation
- Lobe (once the lobe segmentation is available)
- Shape
- Endobronchial
- Perfissural
- Subpleural

Values that are automatically filled-in by the application must be confirmed. Click on ✓ for each parameter or select **Confirm all suggestions*** to confirm all of the pre-fill parameters. If the pre-fill is not correct, replace it with a different selection.

*The **Confirm all suggestions** button is only enabled if:

- All pre-fill values are set (i.e. Lung & Lobe segmentation finished running).
- There are at least two unconfirmed pre-fill values in the displayed preset.

Finding 1

Fleischner Society

Nodule Type	Ground Glass
Axial Average Diameter	5.1 (mm)
Coronal Average Diameter	5.2 (mm)
Sagittal Average Diameter	5.2 (mm)
Volume	66.5 (mm³)
Spiculation *	YES NO
Perifissural	YES [✓ NO]
Subpleural	YES [✓ NO]
Lobe *	RUL ✓

A value that is automatically filled-in by the application and that is not confirmed is considered an empty/undefined field.

Once all values are confirmed (or manually replaced by another value), check for missing parameters. For additional information, see section “Checking For Missing Parameters” on page 369.

Checking For Missing Parameters

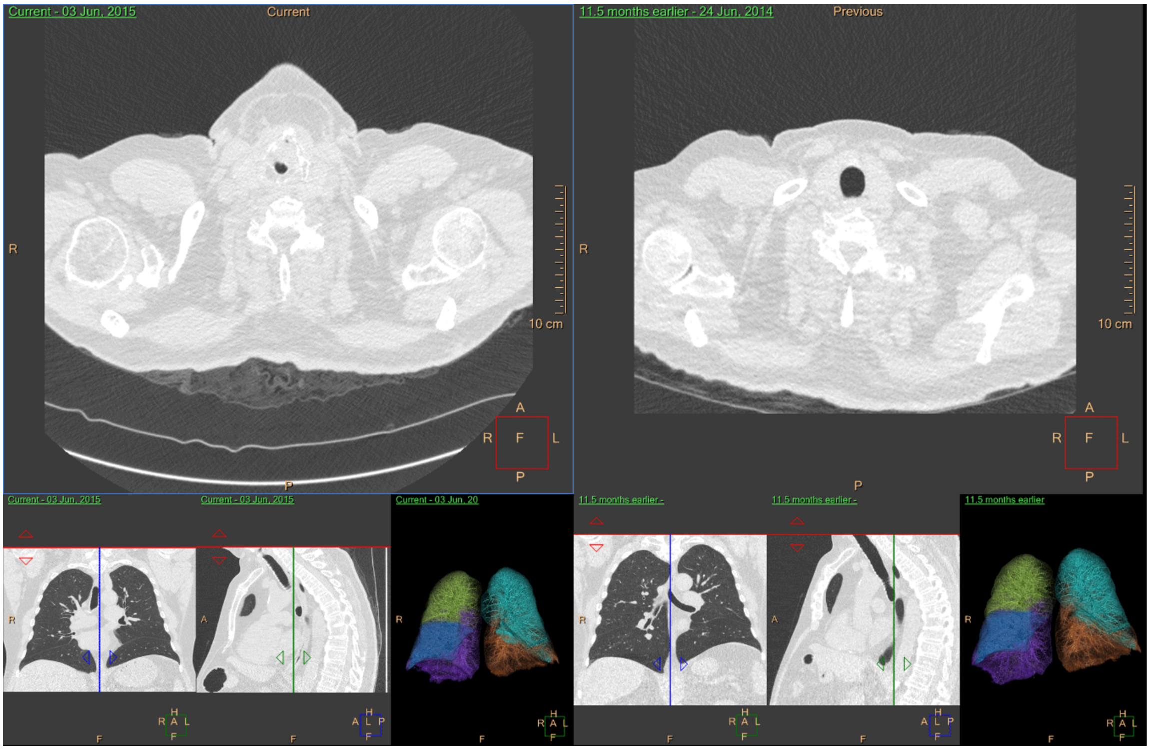
- Once all nodules are segmented and matched, and before proceeding to the Results Scene, verify that all characteristics are filled in and confirmed.
- Leaving empty/unconfirmed characteristics may result in partial data displayed in the Results stage, or an inability to use the decision support tools.
- To check which characteristics are missing, click on the ☆ **Check if there are missing parameters in any of the findings** button located below the Findings list. The **Missing Parameters** dialog opens.
- The **Missing Parameters** dialog details all of the missing parameters for all accepted nodules, according to the currently selected preset.

- It is possible to check the missing parameters for another preset, by selecting the required preset from the dropdown menu.
- It is possible to fill-in the characteristics for the different nodules while keeping the dialog open. To refresh the list, click on the **Refresh** button.
- To close the dialog, click on the **OK** button.

Compare & Match Work Stage

The **Compare & Match** workflow stage allows matching nodules for follow-up.

- This stage provides quick tools for chest inspection, nodule detection, comparison and matching.
- This stage displays two timepoints side by side. The most recent timepoint is displayed on the left side, with a **Current** label. The previous timepoint is displayed on the right side with a **Previous** label.
- To switch between the previous time-points, use the 1◀ ▶1 **Previous/Next Series** buttons from the upper toolbox (or select another timepoint from the timepoints viewport control).
- The current time-point is always displayed and cannot be replaced.
- The default layout of the **Compare & Match** work stage is shown below.



Load Follow-up Studies

1. From the Patient Directory of IntelliSpace Portal, locate the original and follow-up studies you want to work with.
2. Hold down the **<Ctrl>** key on the keyboard and click both studies to select them.
3. In the Series folder, make sure that only the Original series and the results series, along with the follow-up series are selected.
4. From the Directory, under the Analysis tab, select Lung Nodule Assessment.

   A message displays, requiring you to verify the two studies.
5. Click **OK** if you have selected the correct studies. Both studies load.

Apply Registration

The automatic registration algorithm runs between the different series on start up.

Once registration is available, it is applied automatically and the **Apply Registration** button is "selected".

If registration is unsatisfactory, de-select the **Apply Registration** button.

Scroll through the series to the desired slices and press the 🔗 **Link** button, to scroll side by side according to the link.

Matching Findings

Matching is only possible between two single accepted nodules that are segmented on two different timepoints.

Automatic Matching

- Once a nodule is manually segmented or when a CAD suggestion is accepted (see section “Philips Lung Nodule CAD Option” on page 357), the application looks for a potential match for this nodule in the second timepoint.
- When a potential match is found, a message is displayed, allowing either:
  - Matching between the two nodules.
  - Creating a new un-matched nodule.

Matching Nodules

To manually match two nodules:

1. Select the two nodules from the list, while holding the keyboard **Ctrl** key.
2. Click the **Match** button, located below the Findings list.

   The nodules are matched and appear in the same line of the list.

The table below provides an example for a Confirmed Match, Unconfirmed Match and an Un-matched nodule.

● ●	Confirmed Match
? ●	Unconfirmed Match
●	Un-matched

Unmatching Nodules

To un-match a nodule:

1. Select the matched nodule in the Findings list.
2. Select the **Un-Match** button, located below the Findings list.

   The nodules are un-matched and appear in separate lines with separate names.

Manual Propagation

To manually propagate a single (un-matched) nodule from one timepoint to another, select the **Propagate** option from the nodule’s context menu.

If the propagation succeeds, a new unconfirmed match is created.

The match can be accepted or rejected using the **Yes, Finding X is a match** and **No, this is not a match** buttons, in the dialog that is displayed while the nodule is selected.

⚠ **WARNING**

When propagation is applied, verify the accuracy of segmentation of the propagated finding.

Automatic Propagation From Saved Results

When loading multiple time-points and when the previous time-point has saved results, the application automatically propagates the previously segmented nodules from the results to the most recent time-point.

To view these suggestions, check the **Show suggestions from previous** checkbox (checked by default when propagation from results is available).

When the checkbox is checked, the suggestions are displayed on the current time-point’s viewports and in the Findings list, as unconfirmed matches of the nodules they originated from.

⚠ **WARNING**

When propagation is applied, verify the accuracy of segmentation of the propagated finding.

To accept the match, click on the **Yes, Finding X is a match** button. Accepting the match automatically accepts the propagated nodule as well.

To reject the match, click on the **No, this is not a match** button. This deletes the propagated nodule.

Characteristics Table

- For the current timepoint, an additional parameter **New Nodule** is available.

- If the nodule has a match in a previous timepoint, then the **New Nodule** is assigned the value **No** and this value cannot be changed.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use** > **Directory** > **Key Image Notes** for more information.

Results Work Stage

The Results work stage consists of the following:

- **History of Lung Cancer Inquiries** - The top of the screen includes two inquiries regarding:
  - **Patient information**

    Options include: **Positive**, **Negative** or **Undefined**.
  - **Family history of lung cancer**

    Options include: **Positive**, **Negative** or **Undefined**.
  - Patient Risk

  Options include: **High**, **Low** or **Undefined**.
- **Nodules Table** - See section “Nodules Table” on page 373.
- **Additional Findings** - See section “Additional Findings” on page 374.
- **Lung-RADS™ Assessment** -See section “Lung-RADS™ Category Calculation” on page 374.
- **Risk Calculator** - See section “Risk Calculator” on page 376.
- **Fleischner Society** - See section “Fleischner Society Guidelines Calculation” on page 379.

Nodules Table

- If there are unconfirmed suggestions that were not accepted or rejected, they are excluded from the Nodules Table. In addition, a message appears above the Nodules Table.
- All accepted nodules are displayed in the nodules table, with their characteristics, as filled-in during previous stages.

- The characteristics that are displayed in the nodules table are based on the last set of characteristics used in the previous stages (i.e. last selected preset).
- Each nodule has a thumbnail of the slice with the long and short axes from the most recent timepoint.
- When multiple timepoints are loaded:
  - The **Current** and **Previous** timepoint columns display side-by-side parameters.
  - The change is displayed in the **Change** column, for each parameter.
- To change the **Previous** timepoint when more than two timepoints are loaded for comparison, select the desired timepoint from the dropdown menu below the **Previous** column heading.

Nodule Selection

By default, all nodules are selected for calculation.

To choose which nodules will be used for the calculation of the different decision support tools:

- Remove/Place a checkmark in the **Use for calculations** checkbox.
- Select the **None** button to deselect all nodules.
- Select the **All** button to reselect all nodules.

When calculating one of the decision support guidelines, only the selected nodules are considered in the calculation. If any of the unselected nodules are missing mandatory parameters for calculation, this is disregarded, as the calculation is performed based only on the selected nodules.

Additional Findings

This section allows the addition of further information when a patient has additional findings, related or unrelated to Lung Cancer. When **Yes** is selected, a textbox appears, allowing text input. **Additional Findings** parameters include:

- **Other cancer related findings that increase the suspicion of Lung Cancer (Lung-RADS™ Category 4X)**
- **Emphysema** - A suggestion is provided (Yes/No). Confirm or change the suggestion.

  If the suggestion is **Yes**, a **Preview** button is displayed. Selecting **Preview** opens a thumbnail of a slice on which Emphysema is suspected, according to the pre-fill algorithm.
- **Non Lung Cancer Related Incidentals (Lung-RADS™ Category S)**
- **Other Incidentals**

Lung-RADS™ Category Calculation

The Lung-RADS™ Assessment tab provides an automatic Lung-RADS™ calculation for both Lung-RADS Versions 1.0 and 1.1, according to the ACR guidelines. In addition, it provides a manual selection option.

Automatic Lung-RADS™ Calculation

The Lung-RADS V1.1 Assessment tab provides an automatic calculation method based on the nodules' average diameter or based on volume options.

NOTICE

The Automatic Lung-RADS™ Calculation requires an additional license key.

NOTICE

The Volume Based Calculation for Lung-RADS™ V1.1 for Part-solid nodules is performed based on the volume of the entire nodule and the average diameter of the solid component.

Use the Manual Lung-RADS™ Calculation (see below), if a license key is not available.

1. Click **Calculate** to use the automatic calculation option.
2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

   If parameters are missing:

   - Return to one of the previous stages.
   - Fill in the missing parameters.
   - Return to Results stage.
   - Click **Calculate** again.
3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with the automatic calculation suggestion.
4. Select **Approve** to accept the automatic calculation. Select **Reject** to reject the automatic calculation.

   Once the suggestion is approved, the **Lung-RADS™ Assessment** tab is populated with the approved information.

- The calculation is based on the approved nodule's characteristics, general information and additional information that was input per nodule.
- The suggestion is based on the nodule(s) with the highest category from the automatic calculation.

Manual Lung-RADS™ Calculation

To manually select the Lung-RADS™ category:

1. Click the **Select Manually** button.

   The **Lung-RADS™ Category and Management Manual Selection** window opens.
2. Select a category from the drop down list.
3. Place a check mark in the **Suspicious** or **Significant** check boxes if required.

4. Input a **Rationale**.
5. Select **Approve**.

Risk Calculator

NOTICE

The Risk Calculator requires an additional license key.

The Risk Calculator suggestion provides a calculation of the probability of malignancy based on the McWilliams Lung Cancer Risk Calculator for probability of malignancy.

NOTICE

Indication: The Risk Calculator feature of the IntelliSpace Portal LNA application is intended to be used on baseline screening low-dose CT scans.

Contra-indication: The Risk Calculator feature of the IntelliSpace Portal LNA application is not to be used with regular dose CT or follow-up CT scans.

NOTICE

The radiologist must explicitly verify and correct if necessary, all proposed measurements (suggested by the LNA algorithms or prepared by a technician) before they can be used as inputs to the Risk Calculator and the LUNG RADS report.

The Risk Calculator is available from the dropdown menu (the same drop down menu as Lung-RADS™ Assessment).

The Risk Calculator can only be used for the first (baseline) screening low-dose CT.

To use the automatic calculation:

1. Select the **Calculate** button.
2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

   If parameters are missing:

   - Return to one of the previous stages.
   - Fill in the missing parameters.
   - Return to Results stage.
   - Click **Calculate** again.

3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with general parameters that are mandatory for the calculation.
4. Verify that all of the parameters in the **Risk Calculator Assessment - Verify Parameters** window are correct. Update values if necessary. These parameters are essential for accurate calculation.

   The **Total number of nodules** value must be equal to the total number of nodules found, excluding the ones that are marked as:

   - Nodule Type = Calcification
   - Nodule Type = Fat Containing
   - Perifissural/Subpleural = Yes
5. Click **Calculate**.

   The calculation is performed and the probability of malignancy of the nodule with the highest probability is displayed. In addition, the probability of malignancy is added to each of the nodules in the nodules results table.

   If the **Family history of lung cancer** is unknown (marked as **Undefined**), it is still possible to calculate the probability of malignancy. In this case, the probability is displayed as a range, with the low value assuming a negative family history and the high value assuming a positive family history.

   A traffic light is displayed next to the nodule with the highest probability of malignancy, according to the following:

0-5%	Green	🟢
5-10%	Yellow	🟡
Above 10%	Red	🔴

Manual Selection

To manually select another nodule to be displayed, along with its probability of malignancy and traffic light visualization:

1. Click the **Select Manually** option.

   A window with all nodules and their probability of malignancy appears, allowing the selection of a representative nodule.
2. Select a nodule.
3. Input text if relevant.
4. Click **Approve**.

Additional Information for Risk Calculator

The Risk Calculator feature in LNA is based on the full model with spiculation developed by Brock University as described in *McWilliams, et al (2013)*. This model allows to estimate the probability that lung nodules detected on baseline screening low-dose CT scans are malignant. The model's performance was validated using two large population-based prospective studies: the Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and the chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute.

Below is the Abstract of the *McWilliams, et al (2013)* article:

BACKGROUND—Major issues in the implementation of screening for lung cancer by means of low-dose computed tomography (CT) are the definition of a positive result and the management of lung nodules detected on the scans. We conducted a population-based prospective study to determine factors predicting the probability that lung nodules detected on the first screening low-dose CT scans are malignant or will be found to be malignant on follow-up.

METHODS—We analyzed data from two cohorts of participants undergoing low-dose CT screening. The development data set included participants in the Pan-Canadian Early Detection of Lung Cancer Study (PanCan). The validation data set included participants involved in chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute. The final outcomes of all nodules of any size that were detected on baseline low-dose CT scans were tracked. Parsimonious and fuller multivariable logistic regression models were prepared to estimate the probability of lung cancer.

RESULTS—In the PanCan data set, 1871 persons had 7008 nodules, of which 102 were malignant, and in the BCCA data set, 1090 persons had 5021 nodules, of which 42 were malignant. Among persons with nodules, the rates of cancer in the two data sets were 5.5% and 3.7%, respectively. Predictors of cancer in the model included older age, female sex, family history of lung cancer, emphysema, larger nodule size, location of the nodule in the upper lobe, part-solid nodule type, lower nodule count, and spiculation. Our final parsimonious and full models showed excellent discrimination and calibration, with areas under the receiver-operating-characteristic curve of more than 0.90, even for nodules that were 10 mm or smaller in the validation set.

CONCLUSIONS—Predictive tools based on patient and nodule characteristics can be used to accurately estimate the probability that lung nodules detected on baseline screening low-dose CT scans are malignant. (Funded by the Terry Fox Research Institute and others; ClinicalTrials.gov number, NCT00751660.)

Further details can be found in *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919*.

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Fleischner Society Guidelines Calculation

NOTICE

The Fleischner Society Guidelines Calculation requires an additional license key.

The Fleischner Society tab provides automatic calculation based on the 2017 revision of the Fleischner Society guidelines for management of incidental pulmonary nodules. These recommendations do not apply to lung cancer screening, patients with immunosuppression or patients with known primary cancer. A **Select Manually** option is also available in the Fleischner Society tab.

- Automatic calculation can only be performed when a single time-point is loaded to the application.
- When multiple time-points are loaded to the application, use the **Select Manually** option.
- Automatic calculation can be performed based on the nodules’ average diameter or volume.
  - The calculation method can be selected using the **Based on average diameter** or **Based on volume** options at the top of the Fleischner Society tab.
  - When the **Based on average diameter** calculation option is selected, the average diameter used per nodule is the greatest average diameter that is available for this nodule on the three planes: Axial, Coronal or Sagittal.
  - The **Based on volume** calculation option is available only when all selected nodules are marked using 3D segmentation, since for nodules that are marked using the 2D tool, volume measurement is not available.

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Calculation Information

- The calculation is based on the approved nodule’s characteristics, general information and additional information that was input per nodule.
- The suggestion is based on the nodule(s) with the highest category from the automatic calculation.
- The calculation is performed according to patient risk, nodule characteristics that are extracted from the segmentation and that are manually filled-in for each nodule, and the selected method (average diameter of volume).
- Separate suggestions are provided for solid nodules and subsolid nodules.

Automatic Fleischner Society Calculation

1. Click **Calculate** to use the automatic calculation option.
2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

   If parameters are missing:

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- Return to one of the previous stages.
- Fill in the missing parameters.
- Return to Results stage.
- Click **Calculate** again.

3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with the automatic calculation suggestion.
4. Select **Approve** to accept the automatic calculation. Select **Reject** to reject the automatic calculation.

   Once the suggestion is approved, the **Fleischner Society** tab is populated with the approved information.

Manual Fleischner Society Calculation

To manually select the Fleischner Society Guidelines:

1. Click the **Select Manually** button.

   The **Fleischner Society Guidelines Manual Selection** window opens.
2. Place check marks in the relevant check boxes.
3. Input a **Rationale**.
4. Select **Approve**.

Results Management

The following Results Management options are available:

- Copy Results to Clipboard
- **Save results as image series**
- **Export Results to PDF**
- **Send Results to Report**
- **Save all tables as...**
- **Save findings and lungs as RT Structures**

Copy Results to Clipboard

To copy the content of the following sections to the clipboard, use either the context menu (from the selected section) or click on a section and use the **<Ctrl+C>** keyboard shortcut.

- Nodules Table
- Lung-RADS™ Assessment tab
- Risk Calculator tab
- Fleischner Society

Once copied, paste the content into another document, including Word, Excel, NotePad, etc.

Save results as image series

To save the results as an Image Series, select the option from the **Manage Results** toolbox (or from the common tools area).

The series of images contains the following items:

- General information section (patient information related to lung cancer)
- Nodule parameters table, including a thumbnail for each nodule as a separate image
- Additional findings tab
- Lung-RADS™ V1.0 Assessment tab or Lung-RADS™ V1.1 Assessment tab
- Risk Calculator tab
- Fleischner Society