PHILIPS

# Vue PACS

## Lesion Management

## User Guide

**Part # 6K9834**

# Preface

## Intended Use

The Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. The system is to be used by trained professionals including, but not limited to, physicians and medical technicians.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.

## Application Specific Intended Use

The Lesion Management Application is a module that works with Vue PACS for measurement of lesions or regions of interest identified by trained users, tabulation of measurements, categorization of tumor response in accordance with user-selected standards, and follow-up record of findings.

Note: Lesion Management Application is not to be used for mammography.

## Indications for Use

The Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems. This includes the display of structured reports from CAD systems with DICOM "for presentation" mammography images. The system is to be used by trained professionals including, but not limited to, physicians and medical technicians.

The system contains interactive tools in order to ease the process of analyzing and comparing three-dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.

The system contains a Perfusion module with interactive tools to analyze and compare Computed Tomography Perfusion (CTP) and MR Perfusion (MRP) images of adult patients. Blood perfusion parameters are automatically calculated and displayed as a set of perfusion maps and perfusion tables. The perfusion tables include the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

The system contains a Diffusion Module with interactive tools to ease the process of analyzing and comparing MR Diffusion Weighted images (DWI) and MR Diffusion Tensor Imaging (DTI) of adult patients. This module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

The system supports Subtraction with interactive tools to aid with the analysis of Digital Subtraction Angiography (DSA) images in both interventional radiology and cardiology. Subtraction automatically subtracts a mask from contrast frames of an X-Ray Angiography study for visualization of vascular anatomy and pathology of adult patients.

The Lesion Management Application is a module that works with Vue PACS for measurement of lesions or regions of interest identified by trained users; tabulation of measurements, categorization of tumor response in accordance with user-selected standards, and follow-up record of findings. Lesion Management Application is not to be used for mammography.

The Vue Motion software program is used for patient management by clinicians in order to access and display patient data, medical reports, medical data, and medical images for diagnosis from different modalities including CR, DR, CT, MR, NM, ECG, and US.

Vue Motion provides wireless and portable access to medical images for remote reading or referral purposes from web browsers including usage with validated mobile devices. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography.

## Contraindications

There are no contraindications identified as Vue PACS is a software medical device and is not exposed to the patient or user.

## Safety

WARNING

Warnings are directions, which if not followed, could cause injury to an operator, patient or any other person, or could lead to a misdiagnosis or mistreatment.

CAUTION

Cautions are directions, which if not followed, could cause damage to the equipment described in this Instructions for Use and/or any other equipment or goods, and/or cause environmental pollution.

## General Limitations of Use

| | |
|---|---|
|  | WARNING<br>Do not use the Vue PACS for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this equipment safely and effectively DO NOT USE IT. Operation of this equipment without proper and adequate training could lead to clinical misdiagnosis. |
|  | WARNING<br>Vue PACS must be operated in an environment where the minimum specified requirements for hardware and network performance are met. |
|  | WARNING<br>Do not use the Vue PACS for any purpose other than those for which it is intended. Operation of the Vue PACS for unintended purposes, or with incompatible equipment, could lead to clinical misdiagnosis. |
|  | WARNING<br>Use of this product in a way not described in these Instructions for Use, could lead to clinical misdiagnosis. |
|  | WARNING<br>The Vue PACS system can display both lossless and lossy compressed images. The user's ability to analyze images depends on the quality of the image data the user intends to analyze. Lossy/irreversible compression affects the quality of the image. The user is responsible to ensure that the image's quality is adequate enough for the review purpose. |
|  | WARNING<br>When running Vue PACS Client with a virtualization solution (Citrix XenDesktop®), a degradation in image quality, as well as skipped frames, may occur, based on the network bandwidth and virtual machine configuration. |
|  | WARNING<br>Before the study is closed, verify that images are copied or backed up successfully. |
|  | WARNING<br>Before the study is deleted, verify that images are copied, archived, or backed up successfully. |

| | |
|---|---|
|  | WARNING<br>Be careful when editing the Report. In some parts of the report it is possible to change the information created automatically. |
|  | WARNING<br>Make sure that you are using appropriate monitors, and that they are properly configured and calibrated prior to using Vue PACS especially for clinical application such as Mammography. |
|  | WARNING<br>Never switch the IT equipment off using the POWER ON/OFF switch while the software product is still running, as this may damage data integrity, which can lead to loss/damage of patient-related data. Always exit the software product before switching off the IT equipment. |
|  | WARNING<br>Do not install unsupported software on the Vue PACS system as this could interfere with diagnosis/interpretation, and/or cause loss of or damage to patient-related data, and/or introduce computer viruses. |
|  | WARNING<br>Hardware Characteristics, resolution settings, and viewing environment all affect the displayed image quality. It is the responsibility of the user to ensure that the displayed image quality is fit for purpose. Incorrect monitor setup can lead to misdiagnosis/misinterpretation. Check the display performance regularly. |

## Application Specific Limitations of Use

| | |
|---|---|
|  | WARNING<br>When loading data into any application, verify that the image orientation shown is consistent with the image appearance. This precaution is required for data that contains incorrect orientation information and therefore, will be incorrectly presented within the application. For example: Legacy nuclear medicine volume data (PET), reconstructed using cardiac orientations, may not encode the orientation information correctly. |
|  | WARNING<br>Verify the correctness of the volume segmentation and edit as required. |
|  | WARNING<br>Do not use the Lesion Management Tool for Mammography applications. |

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# Introduction

The application offers tools for the evaluation and monitoring of cancerous and other lesions identified in Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) images.

Lesion Management volumetrically measures and segments lung lesions, liver lesions (or other types of masses), lymph nodes, and other lesions and Regions of Interest (ROIs) based on input such as a drawn line or a drawn contour. It allows pairing of lesions from prior and subsequent studies and performs follow-up calculations to assess size and volume changes over time. Drawing tools are available for measuring lesions two-dimensionally by their diameters.

Lesion Management also includes bookmarking tools designed to assist with navigation through segmentations and other marked findings and to facilitate the monitoring of changes over time.

Various correction tools allow further input and segmentations in order to better measure lesions and observe changes.

# Lesion Segmentation

The Lesion Management segmentation tools let you volumetrically segment lesions found in various tissues. Some of the tools are optimized for lesion identification and segmentation in specific tissues and modalities. For example, the algorithm activated by the Lung Segmentation tool is optimized for identifying lung lesions in CT scans, while the algorithm activated by the Liver Segmentation tool is designed to identify liver lesions in CT scans.

You can also use a two-dimensional drawing tool, a semi-automatic contour-drawing tool, and a lesion tracking tool that identifies lesions in a new study based on the existence of lesions in a prior study.

## Segmentation Ribbon


| # | Description |
|---|---|
| 1 | **Lung Lesion Segmentation**<br>Volumetrically segment a lung lesion based on your drawn line (long diameter). |
| 2 | **Liver Lesion Segmentation**<br>Volumetrically segment a liver lesion based on your drawn line (long diameter). |
| 3 | **Lymph Node Segmentation**<br>Volumetrically segment a lymph node based on your drawn line (short diameter). |
| 4 | **Threshold Segmentation**<br>Volumetrically segment a lesion located inside your drawn sphere (or spheroid). The segmentation threshold is based on the maximum value point inside the volume boundaries (when the threshold type option is set to Percentage) or on a fixed value (when the threshold type option is set to Fixed). Set threshold type options in **Application Settings**. See Section Determining Threshold Segmentation Options. |
| 5 | **Generic Lesion Segmentation**<br>Volumetrically segment any lesion based on your drawn line (long diameter). |
| 6 | **Two Diameters Measurement**<br>Activate a drawing mode that allows you to draw the long and short lesion diameters for a two-dimensional Response Evaluation Criteria in Solid Tumors (RECIST) measurement. |
| 7 | **Livewire Mode Segmentation**<br>Define a lesion's contour in a semi-automatic manner in order to volumetrically measure the lesion. |
| 8 | **Add Segmentation**<br>Create a new segmentation from scratch using the disk tool.<br>The disk's diameter can be changed by pressing the shift key along with the arrow keys. The SHIFT+LEFT ARROW decreases its size and SHIFT+RIGHT ARROW increases its size.<br>A single mouse click starts the segmentation creation and another click stops the segmentation, to allow moving to a new location and continue the segmentation from there.<br>The ESC key or double-clicking the image finishes the segmentation. |

## Segmenting Lung Lesions

1. Click the **Lung Lesion Segmentation** icon  .

   The cursor changes its shape to signify segmentation mode.

2. Draw a line across the lesion along the lesion's long diameter. To draw the line, click at the line's starting point and then at its end point.

The application draws a contour around the lesion boundaries in all relevant slices (images) and measures the lesion's volume. The calculated volume appears next to the lesion (as well as in the bookmark list).

Note that the application also draws lines reflecting the longest axial diameter and longest perpendicular diameter of the lesion. The diameters are displayed when you hover with the mouse over the segmented lesion in the slice that was calculated to have the longest diameter.

The lung tool is intended for marking small nodules (< 2 cm). When measuring larger lesions other lesion tools may yield better results.

# Segmenting Liver Lesions

1. Click the **Liver Lesion Segmentation** icon  .

   The cursor changes its shape to signify segmentation mode.

2. Draw a line across the lesion along the lesion's long diameter. To draw the line, click at the line's starting point and then at its end point.

   The application draws a contour around the lesion boundaries in all relevant slices (images), and measures the lesion's volume. The calculated volume appears next to the lesion (as well as in the bookmark list).

   The application also draws lines reflecting the longest axial diameter and longest perpendicular diameter of the lesion. The diameters are displayed when you hover with the mouse over the segmented lesion in the slice that was calculated to have the longest diameter.

# Segmenting Lymph Lesions

1. Click the **Lymph Lesion Segmentation** icon  .

   The cursor changes its shape to signify segmentation mode.

2. Draw a line across the lesion along the lesion's short diameter. To draw the line, click at the line's starting point and then at its end point.

   The application draws a contour around the lesion boundaries in all relevant slices (images) and measures the lesion's volume. The calculated volume appears next to the lesion (as well as in the bookmark list).

   The application also draws lines reflecting the longest axial diameter and longest perpendicular diameter of the lesion. The diameters are displayed when you hover with the mouse over the segmented lesion in the slice that was calculated to have the longest diameter.

# Using the Threshold Segmentation Tool

## Using the Threshold Segmentation Tool

1. Click the **Threshold Segmentation** icon  .

   The cursor changes its shape to signify circle drawing.

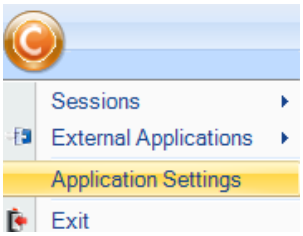
2. Draw a sphere around the lesion by clicking a point inside the lesion, then clicking again at a second point outside the lesion. The application draws a contour using the distance between the two points as the radius of the sphere. A second contour is drawn automatically inside that sphere to represent an inner segmentation. This segmentation is drawn around a volume with pixel values higher than a threshold defined in the application settings. The two contours are shown on all relevant slices (images), along with the calculated volume of the inner segmentation.

For Positron Emission Tomography (PET) images, the application also shows the average and maximum Standardized Uptake Value (SUV) values calculated from the inner segmentation. For any other images it draws lines reflecting the longest axial diameter and longest perpendicular diameter of the lesion. The diameters are displayed when you hover with the mouse over the segmented lesion in the slice that was calculated to have the longest diameter.

## Determining Threshold Segmentation Options

Use Application Settings to determine the threshold type, threshold units, display mode and threshold values.

1. Click the round icon at the top left corner of the screen and click **Application Settings**.




2. Expand the **Clinical Applications** node in the left pane and click **Lesion Management**.

You can set the following options:

| Option | Description |
|---|---|
| Threshold Type | Select a threshold type. Possible values are:<br>• **Fixed**<br>Segmentation is based on fixed values. In PET studies, set the value in the **Fixed SUV Threshold** option. In CT studies, set the maximum and minimum values in the **Fixed HU Maximum Threshold** and **Fixed HU Minimum Threshold** option.<br>• **Percentage**<br>The system looks for the maximum value point inside the spheroid. All voxels with values above the set percentage (of the maximum value point) is included in the segmentation. |
| Threshold Units | Select threshold units. Possible values are:<br>• **SUV BW**<br>SUV Body Weight<br>• **SUV LBM**<br>SUV Lean Body Mass<br>• **SUV BSA**<br>SUV Body Surface Area |
| Display Mode | Select a display mode. Possible values are:<br>• **Overlay**<br>The segmented area is marked by a contour and an overlay.<br>• **Contour**<br>The segmented area is marked by a contour only. |
| Fixed SUV Threshold | Select a value for the fixed threshold type in PET studies. |
| Fixed HU Maximum Threshold | Select a maximum value for the fixed threshold type for CT studies. |
| Fixed HU Minimum Threshold | Select a minimum value for the fixed threshold type for CT studies. |

| Option | Description |
|---|---|
| SUV Marker | Select a method to enable the SUV Peak or the SUV Max calculation and marker. |
| PET Segmentation Measurements | Select one or more threshold segmentation enhanced annotations. |
| Segment only single component around the max pixel | Segment only the component that contains the maximum pixel within the threshold area. |

## Segmenting Generic Lesions

1. Click the **Generic Lesion Segmentation** icon  .

   The cursor changes its shape to signify segmentation mode.

2. Draw a line across the lesion along the lesion's long diameter. To draw the line, click at the line's starting point, and then at the end point of the line.

   The application draws a contour around the lesion boundaries in all relevant slices (images), and measures the lesion's volume. The calculated volume appears next to the lesion (as well as in the bookmark list).

   The application also draws lines reflecting the longest axial diameter and longest perpendicular diameter of the lesion. The diameters are displayed when you hover with the mouse over the segmented lesion in the slice that was calculated to have the longest diameter.

## Measuring Diameters

The **Diameter Measurement** tool allows you to draw two diameters for a lesion (normally the longest axial diameter and longest perpendicular diameter).

1. Click the **Two Diameters Measurements** icon  .

   The cursor changes its shape to signify the two-dimensional line-drawing mode.

2. Draw a line across the lesion. To draw the line, click the line's starting point and then the end point of the line. Then draw a second line. The lengths of the lines (in mm) appear next to the lines (as well as in the bookmark list).

   When you have drawn the lines, you may move them around or drag their vertices, the same way you change any line measurement. Bring the mouse over to the line and when the cursor changes to a four-headed arrow, press the left mouse button and while pressed move the line to the desired place.

## Defining Livewire Lesion Contours

The **Livewire Mode Segmentation** tool is designed to measure a lesion volumetrically based on semi-automatic contour drawing.

1. Click the **Livewire Mode Segmentation** icon  .

   The **Livewire Contour** ribbon displays.


| # | Description |
|---|---|
| 1 | **Livewire Mode Segmentation**<br>Define a lesion's contour in a semi-automatic manner in order to volumetrically measure the lesion. |
| 2 | **Livewire Windowing Parameters**<br>Take into account the image's windowing features. |
| 3 | **Delete Current Contour**<br>Delete the currently displayed user contour. |
| 4 | **Accept Lesion Segmentation**<br>Accept the lesion segmentation and calculated measurements. |
| 5 | **Cancel Lesion Segmentation**<br>Cancel all of the operations performed with the livewire tool. |

2. While the **Livewire Mode Segmentation** icon is selected, click the **Livewire Windowing Parameters** icon if you want the segmentation operation to take into consideration the windowing attributes of the image. If this icon is not chosen, the segmentation tools ignore windowing information and looks at the entire range of intensity values.
3. Click once on the lesion boundary and then hover with the mouse cursor around the lesion (no clicking). The contour is drawn as you progress while changing to follow the lesion boundaries.

   You can click several points along the lesion's boundaries. The clicks serve as control points that determine the contour's route.

   You can also draw the contour by pressing the mouse continuously along the lesion's boundaries. In this method, the application does not change the line to follow the lesion's boundaries, but rather bases the contours on your drawing.

   When you draw the contour by hovering with the mouse or by adding control points, the application suggests an automatic closure of the contour when the drawing is near completion.

   While defining a lesion's contour for the first time, you may use correction actions by using the livewire correction tools. See Section Correcting Contours in Livewire Mode.
4. Double-click to complete the contour drawing. If an automatic completion of the contour has been suggested by the application, you can complete the contour by a single click as well.

   The lesion's volume (in cc) appears next to the segmented lesion.

   You may repeat the drawing on several slices along the lesion.

   The application interpolates the missing contours between every two consecutive user-defined contours and draws interpolated contours on those images. User contours appear as a thicker line compared with the interpolated contours, which are marked with a thinner line.

   NOTE: If you draw a livewire contour on a single image only, the resulting volume calculation will represent the thickness of the image on which the contour was drawn.

5. Click the **Accept Lesion Segmentation** icon to accept all segmentations and calculations and have the diameters of the lesion displayed next to the lesion.

Volume and diameters for the completed lesion are calculated and displayed as for the other lesion segmentation tools.

NOTE: You can change the orientation of the image after you have drawn contours. If you then draw a contour in a new orientation, the application accepts the segmentation and treats the new contour and any following contours as correction to that segmentation. Clicking **Cancel** dismisses the whole process, including the contours drawn in the original orientation.

## Moving the Segmentation Contour Text

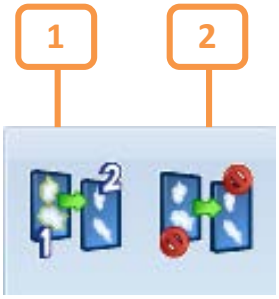
The segmentation contour text can be moved from one point to another. Moving the segmentation contour text on one slice moves the segmentation text to that point in all slices.

When the text is moved from its default location, a dotted line is drawn connecting the text to the segmentation.

This is the same behavior as 2D measurements, including resetting to the default location.

# Tracking Lesions

## Lesion Tracking Ribbon




| # | Description |
|---|---|
| 1 | **Lesion Tracking Tool**<br>Locate and segment lesions in a destination study based on the location of existing lesions in a source study. |
| 2 | **Stop Lesion Tracking**<br>Stop lesions in the destination group from being segmented based on the existence of source group lesions. |

## Using the Lesion Tracking Tool

The **Lesion Tracking** tool locates lesions in a destination group, based on existing lesions in a source group. Typically, the destination group belongs to the current study while the source group is of a prior study. For each lesion in the source group, the tool searches for a corresponding lesion in the destination group. It then segments the new lesion and creates a Follow-Up set from the source and destination lesions.

To use the tool when the source study is the prior study and the destination study is the current study –

1. Click the **Lesion Tracking** tool icon.

   The cursor changes its shape, displaying the digit 1.

2. Click anywhere on the image group that is to be the source group.

   The cursor changes its shape, displaying the digit 2.

3. Click the image group that is to be the destination group.

   If these groups are not already registered, the application registers (volumetrically matches) them and, based on the registration and on the location of each lesion in the source group, looks for lesions in the destination group. The algorithm then segments the newly found lesions and associates between the source and destination lesions, creating Follow-Up sets.

4. Click the **Stop Lesion Tracking** tool to stop lesions in the destination group from being segmented based on the existence of source group lesions.

NOTE: Once the **Lesion Tracking** tool has been activated, any new lesion that is marked at a later stage on the source study is located, segmented, and associated with a lesion in the destination study. This mode is retained until **Stop Lesion Tracking** is activated, or until **Lesion Tracking** is activated on a new group.

In cases when an already segmented lesion exists in the destination group in a location corresponding to a lesion in the source group, the existing segmentation is retained.

If the two lesions were not associated in a Follow-Up set, the application creates a Follow-Up set containing the two lesions. However, in cases when the newly located lesion in the destination group overlaps an existing segmented lesion, the following occurs:

- If the overlap covers 90 % (configurable) or more of the existing lesion, the application retains the already existing segmentation and defines a new Follow-Up set if one did not exist. No new segmentation is created and a dialog box alerts the user that no new lesion has been created.
- If the overlap covers less than 90 %, both segmentations (the existing one and the newly located one) are retained. The Follow-Up set is created with the newly segmented lesion.

At the end of the run a dialog box lets you know how many lesions have been successfully transferred from the source group to the destination group.

NOTE: The lesion tracking tool only tracks lesions of type lung or liver.

# Using Correction Tools

The Lesion Management application offers you tools for correcting already existing segmentations. Correction tools are available in a right-click context-sensitive menu, as well as in the **Correction** ribbon.


| # | Description |
|---|---|
| 1 | **Livewire Correction**<br>Correct a drawn contour using the livewire mode. |
| 2 | **Merge Lesions**<br>Treat two different lesions as a single one. |
| 3 | **Crop Lesion Using Line**<br>Crop a lesion based on a drawn line representing a plane perpendicular to the displayed plane. |
| 4 | **Edit Segmentation**<br>Edits an existing segmentation by adding or removing part of the segmentation using a brush tool, similar to the one used in the **Add Segmentation** tool. |

## Correcting Contours in Livewire Mode

The **Livewire Correction** tool allows you to correct segmentation contours of volumetric lesions using a livewire-mode correction tool.

1. Click on the **Livewire Correction** icon  in the Correction ribbon or right-click on a contour and select **Correct with Livewire**.
2. The **Livewire Contour** ribbon displays.


| # | Description |
|---|---|
| 1 | **Livewire Mode Segmentation**<br>Define a lesion's contour in a semi-automatic manner in order to volumetrically measure the lesion. |
| 2 | **Livewire Windowing Parameters**<br>Take into account the image's windowing features. |
| 3 | **Delete Current Contour**<br>Delete the currently displayed contour. |
| 4 | **Accept Lesion Segmentation**<br>Accept the lesion segmentation and calculated measurements. |
| 5 | **Cancel Lesion Segmentation**<br>Cancel all of the operations performed with the livewire tool. |

3. While the **Livewire Contour Drawing** icon is selected, click the **Livewire Windowing Parameters** icon if you want the segmentation correction operation to take into consideration the windowing attributes of the image.
4. If you have started the process by clicking the **Livewire Correction** icon rather than by right-clicking a contour, click the image.
5. Start correcting the contour. You may choose any of the following methods:
   - Click a point on the image. The contour changes to accommodate the new point. This method changes the shape and size of the contour based on your clicks.
   - Click the line of the contour and draw the correction to the existing contour. The contour changes its shape to include the new part you draw.
   - Double-click the image and draw a new contour. The newly drawn contour replaces the existing contour.

     For methods of drawing, see Section Defining Livewire Lesion Contours.

## Merging Two Lesions

Use this capability to have the application treat two lesions as a single one. This is useful, for example, in cases when two separate lesions have grown and have been merged into a single lesion.

Or in cases when a lesion has decreased over time and has been split into two separate ones. To follow-up the lesions' change in size over time by creating a Follow-Up set, you may want to treat the two lesions as a single one.

This capability is also useful in cases when the lesion has an idiosyncratic shape as often happens in brain lesions. Because it is difficult to segment such lesions in a single segmentation, it is customary to "split" the segmentation to several individual ones but treat the split lesions as a single one.

1. Click the **Merge Lesions** icon  in the **Correction** ribbon and hover with the mouse over the first of the two lesions you wish to combine.

   The cursor changes its shape, displaying the digit 1.

2. Click the first lesion and hover over the second lesion.

   The cursor changes its shape, displaying the digit 2.

   Alternatively, you can right-click the first of the two lesions to be combined and select **Merge Lesion With Another**. The cursor changes its shape, displaying the digit 2.

3. Click the second lesion.

The size of the two lesions is calculated as a single lesion. If the two lesions overlap, the segmentation also changes to a single segmentation.

NOTE: If each of the merged lesions belonged to a Follow-Up set before the merging operation, then this set is removed after the merging has taken place. If only one of the pre-merged lesions belonged to a Follow-Up set, then the follow-up attribute is retained for the merged lesion.

NOTE: If the lesion is composed of several disconnected components, each of the components has two diameters associated with it. The reported value for the two diameters of the merged lesion is the sum of respective long and perpendicular diameters.

## Cropping a Lesion Using a Line

Use the **Crop Lesion Using Line** tool to crop a lesion based on a line you draw.

1. Click the **Crop Lesion Using Line** icon in the **Correction** ribbon.
2. Draw a line on the lesion to be cropped. The line represents a plane perpendicular to the displayed plane.

The lesion is cropped, retaining the part containing the point where you clicked to mark the lesion. If such a point does not exist, the larger part of the lesion remains. If the segmentation is a line, the midpoint of the line serves as the determining factor.

## Cropping a Lesion from the Current Plane

Use the **Crop Lesion from This Plane** feature to crop a lesion from the displayed plane onwards or backwards.

Right-click the segmented lesion and select **Crop Lesion from This Plane**.

In axial images, the cropping removes the part of the lesion either above or below the displayed image. In coronal images, the cropping removes the part that is either in front or behind the currently displayed image.

The lesion is cropped, retaining the part containing the point where you clicked to mark the lesion. If such a point does not exist, the larger part of the lesion remains. If the segmentation is a line, the midpoint of the line serves as the determining factor.

## Correcting a Single Diameter

Use this correction tool to correct the long diameter calculated and drawn by the application.

1. Right-click a segmented lesion and select **Correct Single Diameter**.

   You may click on any image containing segmentation, not necessarily on the image showing the long and short diameters calculated by the application.

2. Draw the long diameter. To draw the line, click at the line's starting point and then at the end point of the line. The diameters calculated and drawn by the application disappear and are replaced by your manually drawn long diameter.

## Correcting Both Diameters

Use this correction tool to correct the long and short diameters calculated and drawn by the application.

1. Right-click a segmented lesion and select Correct Both Diameters. You may click any image containing segmentation, not necessarily on the image showing the long and short diameters calculated by the application.
2. Draw the long and short diameters. The diameters calculated and drawn by the application disappear and are replaced by your manually drawn diameters.

## Editing a Segmentation

You can edit an existing segmentation, which can be applied to all segmentations even created by another tool such as the liver segmentation. This tool enables you to add or remove part of the segmentation using a brush tool, similar to the one used in the Add Segmentation tool.

To edit a segmentation:

1. Click the drop-down arrow on the Edit Segmentation button.


2. Click **Add** to add part of a segmentation or click **Remove** to remove part of a segmentation.
3. Left-click to enter the drawing mode to create a new segmentation. Moving the mouse continues adding disk-like elements to the segmentation. A second mouse click pauses the segmentation allowing you to move to a new location or to a new slice.
4. Press the SHIFT+LEFT ARROW key to decrease its size and SHIFT+RIGHT ARROW key to increase its size.
5. Press the ESC key or double-click the image to complete the segmentation.

# Bookmarking

Use bookmarks to mark measurement graphics that are of interest for easy retrieval at a later stage.

NOTE: Typically, you mark graphics that serve to measure a lesion in both the prior and the current study. It is recommended to register the two studies before you perform the bookmarking, so that when you view a bookmark in one study, the other study displays the matching image and bookmark.

Lesion segmentations are marked as bookmarks. In addition, the following graphics can be marked as bookmarks: line, ROI, square, rectangle, oval, freehand, curve measurement and arrow.

All bookmarks created in a study are stored when the study is dismissed and will be available when the study is loaded again in the future.

## Bookmark Ribbon


| # | Description |
|---|---|
| 1 | **Bookmark List**<br>Show and hide the **Bookmark List** window**.** |
| 2 | **Define Follow-Up Set**<br>Define an association between two bookmarks marking two occurrences of the same lesion or general finding in two different studies. |
| 3 | **Previous Bookmark**<br>Navigate to the previous bookmark on the bookmark list. The viewer focuses on the previous bookmark of the selected study. |
| 4 | **Next Bookmark**<br>Navigate to the next bookmark on the bookmark list. The viewer focuses on the next bookmark of the selected study. |
| 5 | **Synchronize Bookmarks**<br>Use Synchronize Bookmarks to synchronize the study bookmarks in the database without the need to dismiss and reload the study. |
| 6 | **Automatically Mark as Bookmark**<br>Automatically mark graphic as bookmark. When this icon is activated (highlighted yellow), graphics you draw, including line, ROI, square, rectangle, oval, freehand, curve measurement and arrow, are automatically marked as bookmarks. |

NOTE: The **Bookmark** ribbon also appears in the **Graphics** tab.

## Defining a Follow-Up Set

You can associate bookmarked occurrences of the same lesion in different studies to create a Follow-Up set. Follow-Up sets allow you to follow and accurately assess changes in a lesion's size and volume over time.

NOTE: The number of studies participating in a Follow-Up set is not limited.

1. Display the two studies with the two occurrences of the bookmarked lesion.
2. Click the **Define Follow-Up Set** icon  . The cursor changes its shape, displaying the digit 1.
3. Bring the mouse over to the bookmark of the first study. The cursor changes its shape.
4. Click the bookmark once. The cursor indicates FII.
5. Bring the mouse over to the second bookmark in the second study. The cursor changes its shape, displaying the digit 2.
6. Click the bookmark.

An annotation appears next to the bookmarks indicating the Follow-Up set name.

Alternatively, you can right-click a bookmark, select **Define Follow-Up Set** and select a bookmark in another study.

NOTE: Bookmarks of different types may be associated in a Follow-Up set (e.g., graphic line and a liver lesion). The graphic line type is changed to Lesion and the line's length is considered as the lesion's long diameter.

NOTE: It is not possible to create Follow-Up sets of bookmarks that are part of the same study

NOTE: It is possible to merge two Follow-Up sets provided that the sets do not contain common studies.

Once the bookmarked lesions are associated, the **Follow-Up** column in the **Bookmark List** window is populated with the name of the Follow-Up set.

When the bookmarks in the **Bookmark List** window are displayed in a follow-up layout, the bookmarks are arranged by Follow-Up set. Bookmarks that are not part of any Follow-Up set do not appear in that layout).

NOTE: Similar to bookmarks, Follow-Up sets are also stored for later use.

NOTE: If Follow-Up sets exist between the current study and prior studies, loading only the current study to the viewer will also retrieve all bookmarks from prior studies that participate in these Follow-Up sets.

## Automatic Follow-Up Set Creation

When you add a measurement (bookmark) to one of two registered groups and then add another measurement in the same anatomical area in the other registered group, the system creates an automatic follow-up set. The first time you perform this action, a message appears, allowing you to enable or disable this automatic linking feature. Subsequently, messages appear every time an automatic follow-up set is created to inform you that the system has created the set. You may then view the follow-up set details in the Bookmark List.

## Detaching a Bookmark from a Follow-Up Set

To break a Follow-Up set by detaching a bookmark from it, right-click a bookmark and select **Detach from Follow-Up**. The bookmark itself is not deleted and the graphic/lesion does not change in any way.

## Synchronizing Bookmarks

Click the Synchronize Bookmarks icon  to synchronize the study bookmarks in the database without the need to dismiss and reload the study.

When synchronizing bookmarks, the system:

- Saves new or modified bookmarks to the database
- Loads and displays any bookmark added or changed since the study was loaded.

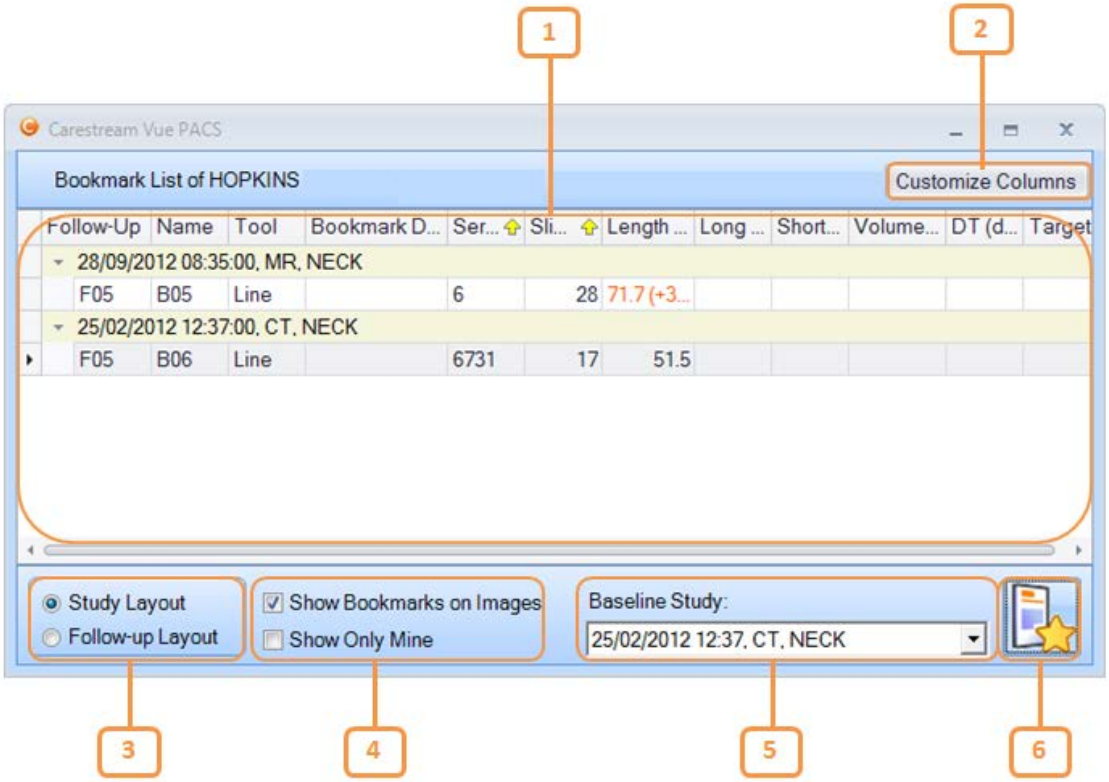
This feature is useful when more than one user is working on a study and one user wants to see changes made by the other user.

For example, an attending doctor adds bookmarks to a study from their station and has the resident see these changes to create hyperlinks to the new bookmarks in the report without closing the study.

## Using the Bookmark List

All bookmarks you create are listed in the bookmark list. Clicking a bookmark in the bookmark list displays the image that contains that bookmark in the viewer.

To open the bookmark list, click the **Bookmark List** icon  . The **Bookmark List** window displays a list of all bookmarks created in the current session or in the past in the loaded studies (current and prior).




| # | Description |
|---|---|
| 1 | List of bookmarks created in the loaded studies. Click a column header to sort the list by that column (in ascending or descending order). Drag a column to a different location in the window to change the columns' order. Drag a column above the table to hide it. |
| 2 | **Customize Columns**<br>Click **Customize Columns** to display a list of possible column headers you may add to the bookmark list. |
| 3 | **Layout**<br>Select the **Study Layout** option to arrange the bookmarks in the list by study. The yellow title row displays information about the study, including study date, study description, time from baseline, and total Metabolic Tumor Volume (MTV) of the study. Select the **Follow-up** option to arrange the bookmarks in the list by Follow-Up sets. Expand the Follow-Up set (click the minus sign near the Follow-Up set name) to display the bookmarks constituting that set. |
| 4 | Select **Show Bookmarks on Images** to display all bookmarks created in the study on the viewer images. Select **Show Only Mine** to show only those bookmarks created by you. |

| # | Description |
|---|---|
| 5 | **Baseline Study**<br>The study with which length and volume measurements are compared. By default, the earliest study serves as the baseline and the bookmarks are compared with bookmarks in that study. Click the drop-down menu to change the baseline study, that is, determine a later study as the study with which measurements are compared. |
| 6 | **Bookmark Report**<br>Click the **Bookmark Report** icon to open the bookmark report, which presents summary information about all bookmarked findings, including size, volume, and changes over time compared with the baseline study. |

### Bookmark List Columns

The following fields display as columns in the **Bookmark List** window.

| Field | Description and Additional Information |
|---|---|
| **Creator** | Name of physician who created the bookmark. |
| **Type** | An indication of whether the bookmark marks a lesion or another type of graphic. Categories can be either **General** or **Lesion**. |
| **Sub-type** | Bookmarks belonging to the Lesion type can be sub-classified to **Liver**, **Lung**, **Lymph** or **Other** (that is, lesions that are not tissue-specific).<br>You may change the sub-type to a different one. For example, you may change **Other** to **Liver**. |
| **Tool** | The tool that was used to create the bookmark (for example, line, oval, segmentation). |
| **Date** | The date on which the bookmark was created or modified. |
| **Bookmark Name** | The name given by the system to the bookmark. |
| **Slice #** | The number of the slice on which the bookmark was created. |
| **Series** | The series containing the slice with the bookmark. |
| **Long Diameter** | The length of the lesion's long diameter. |
| **Short Diameter** | The length of the lesion's short diameter. The short diameter is the axis drawn perpendicularly to the long axis at the point of the longest possible short diameter. |
| **RECIST Diameter** | The reported diameter (either the long or the short diameter). |
| **Volume** | The lesion's volume. |
| **Volume Error** | The percentage of error, based on inclusion or exclusion of the lesion surface volume. |
| **HU Mean** | The mean Hounsfied value in the ROI. |
| **SUV Max** | The maximal SUV in the ROI. |
| **SUV Mean** | The mean SUV in the ROI. |
| **SUV Peak** | The mean SUV value of voxels contained in a one cubic centimeter volume around the hottest voxel in the VOI structure or the mean SUV value of the hottest one cubic centimeter constrained inside the VOI. |

| Field | Description and Additional Information |
|---|---|
| **Days from Baseline** | For bookmarks that are part of a follow-up, this column shows the number of days elapsed from the date of the baseline study and the date of the study containing this bookmark. |
| **TLG** | Shows the Total Lesion Glycolysis (TLG) value of the lesion (mean SUV multiplied by the Volume).<br>NOTE: For TLG calculation, SUV is calculated using the Lean Body Mass (LBM) method. |
| **MTV** | Indication of whether or not this bookmark should be included in the MTV value. |
| **DT (days)** | The calculated doubling time of the lesion's volume. |
| **Target** | RECIST classification of lesions signifies lesions as Target (a measured lesion to be examined in the study), Non-Target (lesions whose presence has been noted but are not included in the clinical study) and as Non-Target Non-Measureable (lesions that cannot or are not measured). |
| **Area** | Calculated two-dimensional area of a lesion. |
| **Bookmark Description** | A general free description. (A default is given by the system.) |
| **Length** | The length of a line bookmark. |
| **Report** | Indication of whether or not this bookmark should be included in the report. |
| **Reviewed** | An indication of whether or not this bookmark has been reviewed by the user.<br>Manually created bookmarks are marked as Reviewed.<br>Lesions created by the Lesion Tracking tool are initially marked as Non-reviewed.<br>Editing a non-reviewed lesion marks it as Reviewed. |
| **Study Date** | Date of study creation |

### Customizing the Bookmark List Columns

You may change the order of the columns or add columns to those displayed in the list window by default.

1. Click **Customize Columns** at the top right corner of the window. The **Customization** window appears.
2. From the **Customization** window, drag the desired column to the column header area of the **Bookmark List** window.

### Sorting the Bookmark List

By default, the list of bookmarks within each study is sorted by series number and then by the number of the slice (image) carrying the bookmark in the series. However, you may change this default by clicking any of the column headers. The list is sorted by that column.

### Deleting a Bookmark from the List

Right-click a bookmark in the **Bookmark List** window and select **Delete Bookmark** or select the bookmark itself in the viewer, right-click, and select **Delete**. You can also select more than one bookmark, right-click, and select **Delete Selected Bookmarks**.

## Marking a Graphic as a Bookmark

1. Draw the graphic on the image.
2. Right-click the graphic and select **Mark Graphic as Bookmark**.

Or

1. Click **Automatically Mark as Bookmark**  in the toolbar.
2. Draw the graphic.

An annotation with the bookmark name appears next to the graphic.

NOTE: Graphics drawn with the **Automatically Mark as Bookmark** icon activated (highlighted yellow) are always marked automatically as bookmarks.

## Cancelling Changes

If you are not interested in saving changes you have made to bookmarks (e.g., you have moved a graphic inadvertently), you may dismiss the study without saving the changes.

To dismiss the study without saving changes to bookmarks, clear the **Save Bookmarks** option in the **Dismiss Study** menu in the **Workflow** tab.

# Reports

Reports provide summarized information regarding all bookmarked findings in the currently loaded studies.

1. To display the report, click the **Bookmark Report** icon  in the **Bookmarks List** window. The Bookmark report window displays in preview form, showing the report data.
2. To see a preview of the final report, click **Preview Report**.
3. To save the report to the server, click **Save Report**. You can then access the report via the Archive Explorer.
4. The report (in its Preview form) includes the following sections.

## Patient and Study Details

Following the patient details, the report displays study information (e.g., study date).

Underneath the study date and name, the report displays the following figures:

- Number of days that have passed since the date of the study that was designated as the baseline study (see Section Using the Bookmark List for details on the baseline study).
- Number of days that have passed since the previous exam.

## Target Lesions

The **Target Lesions** section presents summarized information of all bookmarked lesions designated as Target in the current study (see Section Bookmark List Columns for details on target lesions).

The **Sum of Target lesions** figure is a summation of all lengths of all long diameters in these lesions.

## Other Lesions

The **Other Lesions** section presents summarized information of all bookmarked lesions that were not designated as Target lesions.

## Findings

The **Findings** section displays summarized information of bookmarked findings that are not lesions (that is, bookmarked findings created by a graphic tool such as line or oval and not by the Lesions tools).

## Graphic Summary – Target Lesions (Sum)

The graphical presentation of the Target lesions shows the sums of all long diameters in the current and prior studies. The Y axis displays the diameters' lengths sum and the X axis displays the prior and study dates.

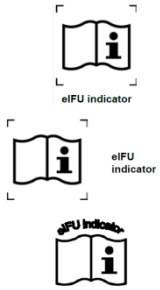
## Change Over Time

This section displays follow-up information. Each row in the table represents a Follow-Up set and the lesion measurement data of each study included in the Follow-Up set is presented in a separate column. The data presented is volume, long diameter length, short diameter length and doubling time. For each of these parameters, the table presents the value and the percentage of change relative to the baseline study. For each study, the comparison is always with the values of the baseline study.

# Symbols Glossary

The following symbols may appear in the product documentation or on the labels attached to the product.

| Symbol | Symbol Name | Symbol Description | Standard / Regulation Number & Name | Symbol Reference Number |
|---|---|---|---|---|
|  | Manufacturer | Indicates the name and address of the manufacturer | EN ISO 15223-1:2016[1] | 5.1.1 |
|  | Date of manufacture | Indicates the date when the device was manufactured. | EN ISO 15223-1:2016[1] | 5.1.3 |
|   | Batch code | Indicates the full Software Release/Version number. | EN ISO 15223-1:2016[1] | 5.1.5 |
|   | Catalogue number | Indicates the manufacturer's catalogue number so that the device can be identified. | EN ISO 15223-1:2016[1] | 5.1.6 |
|  | Consult instructions for use | Indicates the need for the user to consult the instructions for use or electronic instructions for use (eIFU).<br><br>When a symbol is accompanied by additional text, it denotes the location of the instructions for use. | EN ISO 15223-1:2016[1] | 5.4.3 |

| Symbol | Symbol Name | Symbol Description | Standard / Regulation Number & Name | Symbol Reference Number |
|---|---|---|---|---|
|  | eIFU Indicator | When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or any other appropriate indication on the use of eIFU (e.g. "Refer to IFU Kit"). The indicator may be placed either alongside, beneath or surrounding the symbol. | EN ISO 15223-1:2016[1] | 5.4.3 |
|  | Caution<br>and/or<br>Warning | WARNINGS aredirections which if not followed could cause fatal or serious injury to a user, patient or other person, or could lead to clinical misdiagnosis, and/or loss or damage of patient- related data.<br><br>**Also:**<br>This symbol is used on the device label to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. | EN ISO 15223-1:2016[1] | 5.4.4 |

| Symbol | Symbol Name | Symbol Description | Standard / Regulation Number & Name | Symbol Reference Number |
|---|---|---|---|---|
| CE | CE Marking of Conformity | A marking by which a manufacturer indicates that a product is in conformity with applicable requirements out in European Union's harmonization, legislation providing for its affixing. | COUNCIL DIRECTIVE 93/42/EEC concerning medical devices, as amended. | Annex XII |
| Rx only | Prescription Device in USA | Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner | 21 CFR 801.109(b)(1) Prescription Devices | Not Applicable |

[1] EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements

Philips Medical Systems Nederland B.V.

Veepluis 6, 5684 PC  Best, The Netherlands

**Australian Sponsor Details**

Philips Electronics Australia Ltd.

65 Epping Road

North Ryde

NSW 2113

Australia

Rx only

CE 0197



6K9834_D/ * 2021-01-20  - en-US