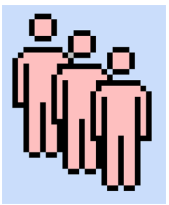
4 Multimodality Tumor Tracking



Introduction

Philips Medical Systems' Multimodality Tumor Tracking (MMTT) application is a post-processing software. It is non-organ specific, multimodality application which is intended to function as an advanced visualization application. The MMTT application is intended for displaying, processing, analyzing, quantifying and manipulating anatomical and functional images, from multimodality of CT, MR PET/CT and SPECT/CT scans.

The Multimodality Tumor Tracking (MMTT) application allows the user to view imaging, perform segmentation and measurements and provides quantitative and characterizing information of oncology lesions, such as solid tumor and lymph node, for a single study or over the time course of several studies (multiple time-points). Based on the measurements, the MMTT application provides an automatic calculation of the different oncology response criteria. The results obtained may be used as a tool by clinicians in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structure.

Indications for Use

Multimodality Tumor Tracking (MMTT) application is a multimodality post processing application used to display, process, analyze, quantify (in 2D and 3D) anatomical and functional images for a single study or over the course of multiple time points for CT, MR, PET/CT and SPECT/CT, Dual Energy CT, and Spectral CT.

It assists the clinician to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.

Intended User Population

The software provides Radiologists and technicians with a robust application to display, process, analyze, quantify and create reports on solid tumor and lymph nodes. The expected users of the application are Radiologists (performing the diagnosis or the treatment response assessment) or 3D image processing technologists (preparing a case, not concluding).

This application may be used as a tool by clinicians in diagnosis, management and surveillance of solid tumors and lymph node.

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Limitation for Use

NOTICE

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

WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

WARNING

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 (SPECT or PET), reconstructed using cardiac orientations, may not encode the orientation information correctly.

WARNING

When selecting an option that includes resolution reduction, please be aware that image resolution and quality will be reduced.

WARNING

The review of conventional images is recommended prior to finalizing diagnosis. Spectral Images should not be used as the sole source for clinical diagnosis.

WARNING

It is recommended that you review conventional images prior to finalizing diagnosis. Spectral Images should not be used as the sole source for clinical diagnosis.

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Multi Modality Tumor Tracking Application Description

The Multimodality Tumor Tracking (MMTT) application is a post-processing software package application intended for use as a patient imaging tool by visualizing and analyzing radiology images from multimodality of CT, MR PET/CT and SPECT/CT scans.

The MMTT application allows:

- The user to define a lesion by identifying a region of interest by using a manual or semi-automatic segmentation tool.
- The user to manually label the lesion (in a lesion-property dialog):
  - Target or non-target lesion
  - Lesion type: tumor, lymph node, not set (only for non-target)
- The user to monitor changes over time and assess the disease response after treatment.
- The user to measure relevant lesion properties on anatomical and functional images.
- The user to manage the set of defined lesions.
- The user to review the measurements in tabular and graphical formats that may help the user to detect trends.
- The user to select an oncology response criterion preset and provide a tool to calculate it according to well established guidelines.

The application supports:

- Adding **Priors** to running applications.
- Loading results from CT Liver, CT Viewer and CT LNA. Findings that were marked in the Liver Analysis or CT Viewer or CT LNA application appear in the Tumor Tracking Findings List and on the image (as Non-target tumors, with the name that was assigned in the saved application). Results from the Tumor Tracking application can also be loaded to the Liver Analysis application.

Key Features

The MMTT application has the following key features:

1. Longitudinal follow-up for oncology.
2. Multimodality support: CT, MR PET/CT and SPECT/CT scans.
3. Load up multiple concurrent studies for temporal measurements.
4. Automatic and manual registration between studies and between series within study (same patient, different time-point).
5. Identify pre-defined data types (pre-sets) and user created hanging layouts.
6. Semi-automatic and manual volumetric tissue segmentation and editing tools.
7. Findings management of the identified lesions (lesion properties, Join, Match, un-match, delete)
8. Automatic software calculation of the following measurements for each segmented lesions:

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  - Long Axis- Longest diameter on an axial slice, between two points on the lesion contour in 2D dimensions (mm)
  - Short axis (mm)- shortest diameter in an axial slice, perpendicular to the long axis (mm)
  - Long axis*short axis- the multiplication result of the longest diameter in axial slice with the short diameter of the same slice o Max 3D diameter (mm)- longest diameter that can be drawn in the 3D volume o Lesion Volume (cm^3)
  - Max Area (cm^2)- maximal area of lesion an axial slice in the volume
  - Mean/Max/Min/SD values of all functional volumes
  - Doubling time (days)- the time it takes for the volume to double
  - Density- the mean density of all target tumor (only for CT data)
  - Enhanced volume/Enhanced Percentage/Enhanced Mean/Enhanced SD (available only for qEASL preset).

9. Support oncology response criteria such as RECIST 1.0, RECIST 1.1, WHO, CHOI, PERCIST, irRC, mRECIST, qEASL.
10. Support SUV calculation for PET scans, such as: SUV Body Weight (the default option); SUV Lean Body Mass; SUV Body Surface Area; and SUV Body Mass Index
11. Results displayed in tabular and graphical formats.
12. Export results in many formats.

Functionality Scenes and Workflow

The Multimodality Tumor Tracking (MMTT) application supports anatomical and functional images, from multimodality scans: PET/CT, SPECT/CT, MR, and CT.

The Multimodality Tumor Tracking (MMTT) application includes two main stages:

- Stage #1: Set-up and segmentation
- Stage #2: Results

Stage #1: Set-up and Segmentation:

- This is the initial stage which allows the user to load the studies of the same patient which are relevant for the follow-up session.
- The user should select a preset, based on the modality and criteria, from the list of predefined presets. The selected preset defines the hanging layout, the selected criterion (i.e. RECIST 1.1, WHO), target tumor default parameters (volume, diameter density and etc.) and the results display (graphs, table and etc.).
- When the application is loaded, automatic registration between the studies and between series is initiated. The user can apply manual registration, if required.
- Explore the scans to find new lesions.
- Segmentation of the lesions using the application 3D and 2D segmentation tool. Semi-automatic and manual volumetric tissue segmentation and editing tools to segment lesions:

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  - The segmentation of the physician indicated lesions is initiated manually by clicking on the lesion or by drawing the boundary or contour of the lesions; the lesions are detected and marked by the user. Segmentation of lesions is performed by the designated 3D or 2D dedicated tools. The following segmentation tools are available: One Click Segmentation and Smart ROI.
  - Segmentation, MR Threshold segmentation and NM segmentation.
  - Edit the segmentation using the editing tools. Manual editing of the lesions segmentation contour lines in volume or slice, with automatic recalculation of geometric measurements post-editing is available.
- Finding List- The Finding list includes target and non-target lesions. According to the National Cancer Institute of the United States and the Organization of European Cancer Institutes (OECI), Target lesions are lesions that have been specifically measured. Non-target lesions are lesions whose presences have been noted, but whose measurements have not been taken. The findings provides the following:
  - Allow the user to have an overview of the segmented lesion status, how many target and non-target lesion exists, in which organs etc.
  - Allow the user to navigate between segmented lesions.
  - Allow the user to select lesions in order to perform operations on them.

Stage #2: Results:

- **Table and Graphs**: Results can be displayed in th Results table and in graph format. The graphs display the change of selected parameters from study to study. When the selected table is functional parameters, the user can toggle between graph and histogram on the distribution of measured units of the selected tumor instead of the graph. The table and graphs are divided into three parts:
  - **Criteria results**- Display the criterion measured values over the time points presented as numeric and graphical value as relative to baseline (%), relative to previous (%) or relative to Nadir (%).
  - **Target lesions measurements**- Displays all of the measurements that were selected for target lesions, as absolute value, relative to baseline (%), or relative to previous (%).
  - **Non- target lesions summary**- Displays only a table with the status of each of the non-target lesions with dates and a summary.

Information on Results

Notes About Obtaining Results

The results that are displayed in the result table can be calculated following different methods: RECIST 1.0, RECIST 1.1, WHO, PERCIST, mRECIST, CHOI and irRC. The calculation logic is based on the selected method and the type and number of the marked lesion. The general definition of each of the methods is as follows:

RECIST 1.0

The RECIST 1.0 value is calculated as the sum of the longest axial diameters of all the target lesions.

RECIST 1.1

The RECIST 1.1 value is calculated as the sum of the longest axial diameter of the target tumors and the shortest axial diameter of the target lymph nodes.

WHO

The WHO value is calculated as the sum of the product between the two longest diameters in the perpendicular dimensions in the axial orientation.

PERCIST

The PERCIST is based on the SUL Peak, which is the largest possible mean value of a 1 cm 3 spherical VOI positioned within a tumor or hotspot, using SUL (or SUVlbm) as the reported unit. The application uses the sum of the SUL Peak of the target tumors for the decision calculation.

mRECIST

The mRECIST value equals the sum of the longest axial diameters of all the enhanced parts of the target tumors This is the same as RECIST 1.0.

CHOI

- For CHOI, the RECIST value is calculated based on RECIST 1.1 (the sum of the longest axial diameters of all the target tumors and the shortest diameter of the target lymph node).
- Tumor density is calculated as the mean density of all target tumors.
- The mean density is calculated as the average of segmented tumors.

irRC

The irRC value is calculated as the sum of the product between the two longest diameters in the perpendicular dimensions in axial orientation.

qEASL (cm^3)

The **qEASL (cm^3)** value is calculated as the sum of the volume of the enhancing tumor.

qEASL%

The **qEASL%** is calculated as the sum of the percentage in the volume of the enhancing part of the tumor compared to the total volume of tumor.

EASL

The **EASL** value is calculated as the sum of the product between the two enhanced longest diameters in the perpendicular dimensions in axial orientation.

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NOTICE

This application does not check the number of target lesions. It is up to the user to follow the RECIST 1.0 or 1.1 guidelines regarding the number of target tumors in total and per organ.

Notes About Obtaining SUV Calculations

Tumor Tracking supports the following SUV calculation methods:

- SUV Body Weight (the default option);
- SUV Lean Body Mass;
- SUV Body Surface Area; and
- SUV Body Mass Index.

SUV calculation methods may be changed in the Preferences menu. Go to **Directory Preferences > Regional Settings** and **Measurements**.

SUV Calculation Dependency

If the required patient information for the selected SUV method is missing (for example the selected method is SUVlbm, but patient height tag is missing), the voxel value will be provided only as counts.

CAUTION

The Tumor Tracking application uses the James formula for calculating SUV Lean Body Mass. This formula may not be accurate for female patients with a high body weight (above 264lbs/120KG).

NOTICE

If patient weight is not available, SUV cannot be calculated. The results will be reported in native units (for example, counts) for those studies.

Missing information should be added to patient details before running the tumor tracking application if specific SUV method is desired.

Bookmark and Results will be displayed with the units they were originally calculated with.

SUV Peak Calculation

To generate SUV Peak (PERCIST criteria), SUV must be calculated based on the Lean Body Mass (SUV LBM) method.

If any of the following information is missing, SUV LBM cannot be calculated and SUV peak will not be generated:

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- patient weight;
- patient height;
- patient gender; and
- injected activity.

Missing information should be added to patient details before running the Tumor Tracking application if these parameters are desired.

PERCIST Support of Peak SUV

- PERCIST support in Tumor Tracking includes calculation of Peak SUV.
- Peak SUV is defined as: The largest mean value of a $1cm^3$ spherical ROI positioned within a tumor.
- PERCIST criteria Peak SUV can be used as a guide for assessing response to therapy. For more information, please refer to:

  Wahl, R.; Jacene, H.; Kasamon, Y.; Lodge, M. (May 2009), From RECIST to PERCIST: Evolving Considerations for PET response Criteria in solid Tumors. The Journal of Nuclear Medicine, Vol 50 No 5 (Suppl) May 2009.
- SUV max can also be generated. SUV max is defined as: The value of a single voxel within the segmented lesion that has the maximum intensity.

Notes about SUV Glucose Correction

The application calculates glucose corrected SUV values. Glucose values are input (either mg/dL or mmol/L) via the blood glucose icon in the task guidance panel.

To input patient blood glucose values:

1. Select the  **Patient Blood Glucose** icon.

   The **Patient blood glucose level** window opens.
2. Select the relevant glucose measurement unit (either mg/dL or mmol/L).
3. Enter the patient's blood glucose level that was measured before the exam.
4. Click **OK**.

The **Patient blood glucose level** icon in the task guidance panel changes depending on the status.

	Indicates that blood glucose values need to be added.
	Indicates that partial blood glucose values were added.
	Indicates that all blood glucose values were added.

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The glucose correction is displayed in the Results stage as scaled SUV values in conjunction with the previous method of reference region. The scaled results are shown with **SUVxx_glu**, where xx is the calculation method (**bw** or **lbm**).

When glucose correction is selected, all of the SUV calculated parameters are shown scaled SUV values based on glucose using the following equation:

*SUV Glu=suv value * blood glucose (mg/dL) /100(mg/dL)*

NOTICE

If the blood glucose value is provided in mmol/L, the value is converted to mg/dL by a multiplying factor of 18.

Saving Tumor Tracking Results for Later Use

When you use Save Results As... (in Common Tools) after finishing a Tumor Tracking work session, all the data produced during the work session is saved, including registration, tumor segmentation, graphs, histograms and calculations.

Save as RT Struct

This allows the saving of Lesion contours as a standard **Radiotherapy Structure Set** (RTSTRUCT) object which can be transferred to the radio therapy planning system.

Tumor Tracking Workflow

Loading

1. Select the latest study and any prior studies of the same patient which are relevant for the follow-up session. See section “Loading Patient Studies” on page 181.

CAUTION

If the studies are not identified as belonging to the same patient, a warning message appears. If the user continues, the application assumes that all studies belong to the same patient.

2. *Optional (recommended)*: Within the series area, select the relevant series from each study to be loaded to the application.
3. Select the **Multimodality Tumor Tracking** application to load the data.

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Segmentation

1. Select a Preset from the list of predefined **Presets**. The selected preset defines the hanging layouts, the selected criterion and the results. See section “Workspace Preparation” on page 182 and section “Preset Editor” on page 183.
2. If a change in series selection is needed, use the Series List and adjust series selection by dragging the series to the correct position(s). See section “Series List” on page 192.
3. When the application is loaded, Automatic Registration, between the studies, runs in the background and is automatically applied. If registration fails, use Manual Registration to align the studies. If a series is replaced after Automatic Registration is applied, use the **Re-run registration** button. See section “Automatic Registration” on page 193
4. If Manual Registration is required, click on **Manual Registration** and mark the same anatomy landmark on all studies (all study types). See section “Manual Registration” on page 194. After the same anatomy is marked on all studies, click on **Apply Registration** to accept the registration.
5. **Review the lesions** - Use the Viewing Tools to review the images and previous findings. See section “Viewing Tools” on page 190. Use the following tools:
   – Single time point
   – Focus mode
   – Standard viewing options
6. **Mark new finding** - The segmentation tool bar is always located over the selected viewport and allows the user to select the appropriate tool. There is a set of segmentation tools which varies according to the modality used. There are volumetric segmentation tools that allow segmentation to the lesion as a volume, and a 2D tool that allows marking the long and short axes on a single slice. See section “Mark New Finding” on page 197 and section “Segmentation Settings” on page 202.

   Use the provided segmentation tools to mark the finding on the latest study and then:
   – Continue editing the lesion until satisfied. See section “Lesion Editing Tools” on page 203.
   – Match the new lesion to previously segmented lesions, if relevant. See section “Operations on Findings” on page 207.
   – Use the Properties dialog to label lesions, select the lesion type and mark changes. See section “Lesion Properties” on page 201.

Results

1. Change to the **Results** tab by clicking on the arrow next to **Segmentation.**
2. Review the tables and graphs.
3. Table reports can be exported to Microsoft Word® or CSV.
4. Optional: Send Findings to a report.
5. Save the results. (The segmentation and registration are saved for the next usage or follow-up study.)

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Please refer to the following sections of the IntelliSpace Portal Spectral Applications IFU for information on spectral results and processes:

- Understanding Spectral Results
- Common Spectral Processes

Loading Patient Studies

NOTICE

Multiple studies can be selected for loading into the Tumor Tracking application.

Make sure that all studies belong to the same patient before launching the Tumor Tracking application.

The application displays a warning message if you approve loading studies with different patient identification (may occur due to different spellings of patient name) to the application. The studies are treated as belonging to the same patient.

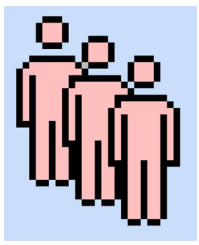
NOTICE

When you launch Tumor Tracking, the application is opened in the last used protocol for a specific combination of modalities.

1. Select appropriate studies from the Patient Directory.

   Up to 8 volumetric studies can be loaded and displayed for modalities that include CT, MR, PET, PET/CT and SPECT.

2. Click the Tumor Tracking icon to load the studies.

   The application opens in the Segmentation work stage with the Setup tab displayed.

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.

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Segmentation Work Stage

Tumor Tracking opens in the Segmentation Work Stage.

In the Segmentation Work Stage you will:

- Select the Preset, based on the modality, and then register the loaded exams (Setup Phase).
- Perform various operations on lesions.

WARNING

Verify the correctness of the volume segmentation and edit as required.

Segmentation Function Tabs

The following Function Tabs appear in the Segmentation work stage:

Findings - The Findings tab contains the Findings List. This list is used for navigating between the finding and operations on the finding, including: Un-Match, Match, Join, Mark as reference region, Assign Properties and Delete.

Bookmarks and Batch functions - Instructions for using the Bookmarks and Batch functions are provided in the Common Processes chapter.

Fusion - The Fusion Viewer allows refining the registration between an underlay and overlay that are fused in one viewport.

NOTICE

Instructions for using the Fusion function are provided in the Fusion Viewer (NM) section.

Key Images - Instructions for using Key Images are provided in the Directory chapter.

Workspace Preparation

NOTICE

Tools that are not relevant to the loaded data (for example Automatic Registration in NM) will be disabled.

Before starting segmentation, prepare your workspace using the following functions:

- Select the relevant Preset from the drop down list (or select Edit Preset)

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- If necessary, use the Series List to change the series selection. See section “Series List” on page 192.
- Register between the examinations - You can perform **Automatic Registration (CT and MR studies only)**, (see section “Automatic Registration” on page 193) or **Manual Registration** (see section “Manual Registration” on page 194).

Edit Preset- The Edit Protocol function allows you to create your own customized preset protocols, to handle exceptions. See section “Preset Editor” on page 183.

Select Preset

When a study is loaded, the application associates each of the loaded series to a data type based on modality, DICOM tags and series description. The application displays the series in a hanging layout based on the Preset and data type identified.

A preset specifies the settings of the Tumor Tracking application, including:

- **Hanging layout** - Defines the number of viewports and which data type should be displayed. It is possible to define several hanging layouts per Preset.
- **Treatment Response Evaluation** - Determines the selected treatment response evaluation method (example: RECIST).
- **Application Calculated Output** – Determines which measurements should be included in the result tables (table and graph).

Press on the **Presets** button to access the Preset list or to the edit preset button.

In this step, you select a Preset from a drop-down list of predefined (factory) application presets.

The Tumor Tracking application accommodates numerous studies in numerous modalities. By using the pre-defined presets, the operator does not need to setup the Tumor Tracking application for every possible case.

To create a new Preset, see section “Editing Presets” on page 187.

Preset Editor

Presets in Tumor Tracking provide an easy way to customize the application to your needs. The **Edit Preset** function allows you to create preset behavior of the application, that changes according to the loaded data.

Shared Presets

IntelliSpace Portal can be set up with two user types: the individual User and the Clinical Administrator.

- Admin Users (with the proper permissions) can create “Site” protocols (both modified and New). **Site protocols are available to all portal users**.
- In Tumor Tracking, individual users can copy and modify existing presets and create new private presets, **only for their own use**.

NOTICE

Factory presets cannot be edited or deleted. They are displayed in gray text in the Presets page.

The Preset Editor consists of two main pages:

- Data Types
- Presets

Data Types

The Data Type Association table displays all of the series that were loaded in the session and the associated data type. The application identifies all standard data types, based on their DICOM attributes, including derived MR maps, AC, NAC, Spectral data types etc. The user can change the associated data type for a series to another existing and valid data type, using the combo box in the table, or create a new data type which would be associated to the selected series.

The **Data Type** identification can be used for the definition of a dedicated hanging layout per preset.

The data type association table includes the following columns:

- **Series Number** - Series number
- **Modality** - The modality of the series
- **Description** - The full series description that was loaded to the session.
- **Data Type** - The associated data type according to existing configuration.
- **Functional** checkbox - a checkmark appears if the data type can be used for functional measurements. Functional measurements are only calculated for “functional” data types.

It is possible to associate a series to an existing data type as long as there is no contradiction between the series and the data type attributes (such as CT series to an MR data type). Based on these data types definitions, the user can design layouts for the preset. The user can also create new datatype based on the series description for specific hanging layouts.

Using this dialog, it is possible to review all Spectral image types and to define all Spectral data types as part of a user defined preset.

The table below provides a list of factory data types that can be selected:

Data Type	Modality
ADC	MR
PET_AC	PET
PET_NAC	PET
SPECT_AC	SPECT
SPECT_NAC	SPECT

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EADC	MR
FA	MR
Diffusion	MR
Dynamic	MR
CT Contrast	CT
ANY	
relCBF	MR
relCBV	MR
MTT	MR
TTP	MR
T0	MR
Delay	MR
RELENH	MR
MAXENH	MR
MAXRELENH	MR
WASHIN	MR
WASHOUT	MR
KTRANS	MR
KEP	MR
BREVENH	MR
AUC	MR
VE	MR
VP	MR
Diffusion Coefficient D	MR
Pseudo Diffusion coefficient (D*)	MR
Perfusion Fraction f	MR
Goodness of Fit	MR
Kurtosis K	MR

Create New Data Type

Select a series and press the **Create New Data Type** button. A dialog opens with the following fields:

- **Description**

- **Modality**
- **Data Type** - Add the new data type you want to create.
- **Access level** - User or Site
- **Functional** - Place a check mark in the check box if this data should be used for functional measurements.

Once a new data type is created and associated with a series description (and same modality) and is saved, all series with this description will be associated with the new data type.

Manage Data Types

The **Manage Data Types** button opens a dialog that enables the review of the list of user data types along with their associated description.

Select a series and press the **Manage Data Types** button. A dialog opens with the following fields:

- **Access Level** drop down list - Allows you to select the user type.
- **Data Type** list - displays a list of data types
- **Descriptions** - list of associated data type descriptions

This dialog allows you to delete either a Data Type or an associated description.

Presets

The Presets page is divided into two sections.

Preset Information - The left side of the screen includes a table with the existing Preset Names, Modalities and Sharing Status (User, Factory or Site). It is possible, create a new preset, duplicate an existing preset or delete a preset.

Layout/Properties - The right of the screen displays two tabs, **Layouts** and **Properties**.

- **Layouts** - This allows you to define the hanging layout that belongs to a preset. Set the number of viewports (either one, two, or three) and which data type appears in which viewport and which combination data you see together as part of a Preset. You can also choose a valid layout as the default layout by placing a check mark in the **Set this layout as default** check box. A valid layout has at least one other data type other than spectral. A valid layout is represented by a green check mark in the layout display.
- **Properties** - This allows you to choose the following properties:
  - **Choose Criterion** - This determines the treatment response criteria. The setting selected here will impact the default result settings and guidelines. Available options are WHO, RECIST (1.0 and 1.1), PERCIST, CHOI mRECIST, irRC, qEASL (cm^3), qEASL (%), EASL and None.
  - **Segmentation Tools** – Basic 2D Tools and 3D Volumetric Tools. This determines what tools are available during the reading session. Individual tools can be selected.
  - **Results View** - This setting determines the default graphs and histograms to be included in the results. This parameter is automatically set based upon the **Choose Criterion** parameter.

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- **Target Tumors Default Parameter** - Options includes Volume, Long Axis and Long Axis * Short Axis.
- **Show Advanced Results** - Clicking this parameter displays the Results table with the Generic, Criterion and Functional parameters.

Editing Presets

Editing Data Types

1. Click the  **Edit Preset** button. The editor opens to the **Data Types** tab of the **Preset Editor** page with the Data Type Association table.
2. If necessary, change a data type by selecting a different data type in the Data Type drop down list. Press **Save** when done.
3. If necessary, create a new data type. To create a new data type:
   - Click the **Create New Data Type** button.

     The **Create New Data Type** dialog appears.
   - Type a **Data Type** name.
   - Choose the **Access Level** from the drop-down list (User or Site).
   - Place a checkmark in the **Functional** checkbox if the data is Functional data.
   - Press **Save**.

   The Data Type table is updated with the newly created data definition. If the series description is identical in two or more rows , the associated data type is automatically updated for all relevant data series when **Save** is pressed.

Managing Data Types

1. Select a series and press the **Manage Data Types** button.
2. Select the **Access Level** from the drop down list (if relevant).
3. To delete a Data Type, select the relevant Data Type and click **Delete Data Type**.
4. To delete an associated data description, select the relevant description and click **Delete Description**.
5. Click **Save** to save your changes. The changes are reflected in the Data Type and Presets pages.

A user with no administrative privileges can only view, delete or modify data types that were created by him.

A user with administrative privileges is allowed to delete or modify "Site" data type.

Creating a New Preset

To create a new Preset:

1. Click on the **Presets** tab.

2. Click on the Preset you want to modify and click **+Duplicate**.

   -- OR –

3. Click **+New Preset** to create a new preset
4. Click on the Preset Name and type a name for the new preset.
5. In the **Sharing** column, choose either **User** or **Site** in the drop down list. Selecting **User** means that this preset is private and **Site** means that the preset can be used by all portal users.

Modifying a Preset Layout

To modify or create a new Preset:

1. Select the Preset that you want to modify.
2. In the Layout section, select **+Create New Layout**.
3. Select the number of required viewports in the combo box (either one, two or three).
4. For each viewport define the underlay data type.
5. For fused viewport – Define the overlay datatype (mainly for PET/CT).
6. **Optional** - Select the data orientation. This is good for MR series that are acquired for a specific orientation.
7. To set a layout as the default layout, place a check mark in the **Set this layout as default** check box.

   Only a valid layout can be set as a default layout. A valid hanging layout must have at least one other data type other than spectral. A valid layout is represented by a green check mark in the layout display.

Editing Preset Properties

To set the treatment response criteria, segmentation tools displayed and results calculated and displayed for this preset, perform the following:

1. Select the **Properties** tab to modify the properties of a preset.
2. In the **Choose Criterion:** drop-down list, choose a treatment response criteria. The guidelines for the criteria that you select are available by clicking on the  **Guidelines** button. These guidelines can also be reviewed in section “Criterion Guidelines” on page 214.
3. In the **Segmentation Tools** area, select the 2D and 3D segmentation tools to be available during the session. Individual segmentation tools can be selected.
4. In the **Results View** area, it Is possible to define the default result to be displayed on the result page, for the criterion parameters and for the target tumor parameters as described below.

Criterion Default parameter – If you requested the calculation of more than one value (i.e. RECIST 1.1, WHO, Density), you can choose the default result. Normally it would be the value that belongs to the selected criterion.

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Target Tumors Default parameter - You can select several values to be calculated for target tumors such as Volume, Diameters, Density etc. Select an option from the drop down list to define which parameter is displayed in the **Results Table**.

Select **Show Advanced Results** to modify how the Generic (Anatomical), Criterion and Functional Parameters are displayed in the Results table.

- **Generic parameters** - The following values can be calculated by the application for Target tumors:
  - **Max 3D Diameter** – Longest diameter that can be drawn in the 3D volume.
  - **Long Axis** - Longest diameter in an axial slice found in the segmented volume.
  - **Short axis** – Shortest diameter in an axial slice found in the segmented volume.
  - **Long axis*Short Axis** – the multiplication result of the longest diameter in axial slice with the short diameter of the same slice found in the segmented volume.
  - **Max area** – Maximal area of an axial slice in the volume.
  - **Volume (cm^3)**
  - **Doubling days** – The time it takes for the volume to double.
  - Enhanced Percentage
  - **Enhanced Volume (cm^3)**
  - **Enhanced Mean**
  - **Enhanced SD**
  - **Enhanced Long Axis (mm)**
  - **Enhanced Short Axis (mm)**
  - **Enhanced Long Axis * Enhanced Short Axis (MM^2)**

  To define the display of Generic (Anatomical) parameters (the physical properties of the lesion) in the Results table, click the corresponding **Value** checkbox. Note that volumetric measurements can be calculated by the application only when 3D segmentation tools are used.
- **Criterion parameters** - You can get additional values calculated by the application, which represent the tumor burden of the target tumors. The application can calculate the following values:
  - **RECIST 1.0 (mm)** - Sum of the longest axial diameters of all the target lesions.
  - **RECIST 1.1 (mm)** - Sum of the longest axial diameter of the target tumors and the shortest axial diameter of the target lymph nodes.
  - **mRECIST** - Sum of the longest axial diameters of all the enhanced part of the target tumors.
  - **SPD (mm^2)** - Product between the two longest diameters in the perpendicular dimensions in the axial orientation.
  - **EASL (mm^2)** - Sum of the product between the two enhanced longest diameters in the perpendicular dimensions in axial orientation.

  - **Total Peak SUV** - SUL Peak of the Target tumors for the decision calculation. (Relevant only for PET data).
  - **CT Density (HU)** - The mean density of all Target tumors (Valid only for CT data).
  - **Total Volume** – Sum of all Target tumor volumes.
  - **qEASL (cm^3)**
  - **qEASL (%)**

  To define the display of Criterion parameters in the Result table, click the corresponding **Value** checkbox.

- **Functional parameters** - To define the display of Functional parameters of the lesion in the Results table, click the corresponding Mean/ Minimum / Maximum checkbox. Note that functional values can only be calculated for data types that are defined as “functional". It is possible to select Spectral data as a measured functional parameter.

Deleting a Preset

To delete a preset, select a preset and use the **X Remove** button to remove the selected preset.

Philips installed factory protocols cannot be removed or edited.

Viewing Tools

You can select from three viewing orientations, Axial, Coronal, and Sagittal.

The **Layout** icon opens the Layout dialog, which allows you to select either the hanging layout or the viewport layout.

The hanging layouts options are displayed according the selected preset.

To save the layout contents of the currently selected timepoint as an additional hanging layout in the preset, click the **Save Hanging From View** button. This button is enabled only when a user preset is selected.

Single time point toggles between the display of a single study (with large images) and a comparison display between multiple studies. When the button is depressed, only one study will be displayed on the full screen.

Next time point (available only in the Single time point mode) moves to the next time point in time.

Previous time point (available only in the Single time point mode) moves to the previous time point in time.

When **Link** is clicked, viewport navigation is linked between all displayed data, according to the registration method used.

Spread Mode toggles between a single monitor display and a dual monitor display of the application.

Show Series List toggles between show and hide the series list. For additional information see section “Series List” on page 192.

Relate Viewports - Allows you to relate a location on one image of the patient to the same location on other image(s) of the patient. Use the Relate Viewports button to mark a specific location of interest in one viewport and see it on other images in the display.

NOTICE

Relate between studies is functional only when the studies are registered.

Show Crosshair - This is used to show/hide crosshairs on all images. When Link is on, all crosshairs move as one. When Link is off, they can be moved independently.

Display Lesion Settings - Opens a dialog with a **Show lesion diameters** and a **Show lesion rim** checkbox and a **Lesion opacity** slider. Use the slider to control the opacity of the segmented lesions on the images.

- For **Show lesion rim**, the visibility of the lesion boundary is enhanced by setting the Lesion opacity slider to zero. When enabled, it is applicable for all lesions displayed in the application.
- In addition to placing a check mark in the check box, it is also possible to enable/disable the feature by:
  - using the **<Ctrl >+ <R>** keys.
  - right-clicking on the viewport and clicking on **Show lesion rim**.

Same Anatomy Size - Use this tool to make the images from two different studies the same size.

Focus Mode - This button allows the user to closely inspect a previously segmented lesion. Clicking on the Focus Mode button will automatically pan and zoom on the selection lesion in all of the displayed viewports.

- If studies are linked, this impacts all of the studies that the selected lesion is segmented to. If the studies are not linked, the focus impacts only the selected viewport.
- Once this button is pressed, the user can navigate between the lesions in the Results Table and the display automatically zooms into the new lesions in all the viewports.
- The focus mode displays the viewport zoomed and the lesion will be centered in the viewport. All of the related images are zoomed and panned accordingly.

- If the “Link” state is active, the largest lesion is identified and centered. The other linked viewports will have the same pan and zoom factor.
- The user can still edit the lesion and do any other operations when in focus mode.
- The images return to their original pan and zoom once the Focus Mode button is unselected.

Show/Hide Time Points

The Hide operation allows you to hide a time point. To hide a time point, right-click on the title of the time point and select **Hide this time point**. The Hide option is only available when there is more than one time point.

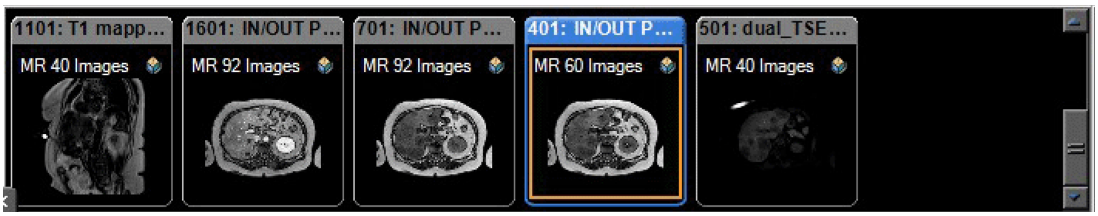
To display the hidden time point, right-click on the title of the time point and select **Show time point**

Series List

The Series List provides tools to choose the studies and series to be displayed in the viewing area.

1. Click the **Show Series List** icon.

   The series list is displayed above each study.

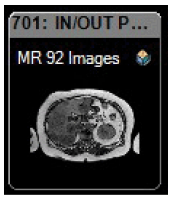


2. Click the Show Series List again to hide the series list.

Pictorial Color Codes		
	Blue title and frame	This series is displayed

	Gray title and frame	This study is not displayed
	Blue title and orange frame	This is the active series

Working with the Show Series List



Dragging a series with a gray title and frame to a viewport of the same study will replace the current series with a different one.

Dragging a series with the right mouse pressed onto another image, will create a fused image in the viewport.

Right clicking on a series with a gray title and frame displays the context menu with the **Replace** option. When the mouse is moved over **Replace**, a list of studies that can be replaced in the viewport appears. Selecting a study creates a fused image.

Register Examinations

After loading the desired patient studies, the first step is to register the image datasets to one another.

Automatic Registration

NOTICE

When using the Automatic Registration option, verify accuracy of the registration.

If you deselect the Automatic Registration button, the previous registration status is restored.

NOTICE

When automatic registration is ON, manual registration is overridden.

Automatic Registration is a non-rigid registration. It maps voxel to voxel between the series, without distorting the displayed slices. When the Relate Viewports function is used, the image jumps to the matching slice where the related voxel is located.

Automatic Registration runs in the background for the loaded studies. The type of registration is dependent on the type of loaded data.

For CT volumes, Automatic Registration uses a non-rigid registration.

For MR data, Automatic Registration is based on a rigid registration algorithm between the anatomical series.

1. The **Automatic Registration** button is applied automatically as soon as registration succeeded.

2. Turn off Automatic Registration by clicking the Automatic Registration button.

Rerun Registration

When an application is loaded with multiple studies, Automatic Registration runs based on the default series that are display in the hanging layout. If a new preset is selected or another series is dragged to the viewport and the new series covers different areas of the body, then it may be necessary to re-apply registration.

1. Click **Rerun Registration** to activate the function.

The anatomies in the CT studies are correlated and the calculated registration is applied.

Manual Registration

NOTICE

When the studies are launched, all studies are automatically linked: if you scroll one image, all other images also scroll. (The Link button appears depressed.) Once Manual Registration is selected, the studies are automatically unlinked, until Manual Registration is completed, to allow separate scrolling.

Use Manual Registration if Automatic Registration failed or is not sufficiently accurate. Manual Registration requires you to mark the same anatomical landmark in all of the studies and match between them. Once the registration is applied, the registration is rigid and is based on the defined landmark.

1. Select the **Begin Manual Registration** button .

NOTICE

When Manual Registration is selected, the state of various buttons is automatically changed. The link button is automatically disabled to allow the user to scroll each image to the required point. The Relate Viewport button is disabled.

Previously applied landmarks are preserved and displayed on the image. The Apply registration button is only enabled when there is a selected landmark location in each of the studies.

2. Scroll each study to a slice image so that each slice shows the same anatomical landmark. In each study, click on the same anatomical landmark.
3. If needed, drag the registration point(s) to a better location (or just click on a new location).
4. When all points show the same anatomy, select the **Apply manual registration** option by clicking on the arrow.

   To cancel Manual Registration, click the **Manual Registration** button.

NOTICE

You can edit the Manual Registration whenever desired by repeating the above procedure.

Inter-series Registration

Inter-series registration is applicable per time point, to register all the series to the anatomical series within that time point. The anatomical series for inter-series registration reference is selected automatically by the application. Inter-series registration is applied automatically when the application is loaded, for all time points. The progress of inter-series registration is shown in the progress bar in the bottom right corner. Once completed, a **Registration completed** message is shown in the status bar. Once Inter-series registration is completed in the background, the button is “enabled” and registration gets applied to the images.

If inter-series registration is not successfully applied, the  inter-series registration icon is disabled.

NOTICE

Inter-series registration can be performed on any loaded MR or CT study with more than one MR or CT series. Inter-series registration is applied automatically when the application is loaded, for all time points. The user can control the status of inter-series registration per time point individually. Inter-series registration matches the position and orientation of volumes as closely as possible. It works best when there is only a small mismatch between the registering series and the reference series. Inspect the registration thoroughly before continuing.

To enable inter-series registration for a time-point:

1. Click the inter-series registration icon  to activate the function.
2. Turn off inter-series registration by clicking the inter-series registration button again.

Inter-series registration for MR studies uses the “Rigid” registration method, using the “Normalized Mutual Information” algorithm.

- It is best used to perform multimodality registration in cases where there is limited anatomical data or large misalignments.
- Inter-series registration uses a histogram-based method.
- The probability distribution of gray values is calculated in each data set and uses this in the mutual information equation.
- Inter-series registration does not rely on a functional relationship between the gray values in the data sets.
- Inter-series registration for CT studies uses the "Elastic" registration method.
- When using elastic registration between series, the lesions that are segmented on one series and are projected onto the other series based on registration, appear deformed. The diameter annotations are not displayed on these lesions. The annotations are only shown on the original segmented or last edited series. Elastic registration is disabled if it is corrected manually using fusion registration.

Findings Management

The Findings List provides the following:

- An overview of the current status of the marked findings.
- Navigation between segmented findings.
- Selection of a finding.
- Operations on findings.

As you mark lesions to segment them, they appear in the Findings list.

The Findings List is divided in to two sections: **Target Lesions** (upper area) **Non- target Lesions** (lower area). Newly created lesions are listed under **Non- target Lesions**.

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Lesions can be moved between the two areas. Drag and and drop the lesions between the two areas.

It is possible to select multiple lesions at one time and to perform the following operations:

- Join Lesions
- Update lesion properties
- Delete lesions

Findings can be marked as 2D objects or 3D objects, depending on the segmentation tool that was used.

Each finding is represented in the table with an appropriate icon. The icons represent the type of the finding (Tumor, Lymph node, Target etc). In addition, there is an indication of how many follow-ups are matched to a specific finding, which organ it is related to and if it was marked on the latest study in the session.

Right-clicking context menus allow you to manage the list, including the Match, Un-match, Delete and Rename operations.

Mark New Finding

When a viewport is clicked, the segmentation tools are displayed as a floating tool bar.

The Preset that is currently selected determines what segmentation tools are displayed in the floating tool bar. Only tools that are valid for the selected modality are included.

Use the tools described in this section to mark new findings.

- When a new lesion is segmented, the segmentation tool remains selected in the segmentation tool bar for the following tools: **Smart ROI** (for CT and MR) and **One Click Segmentation** (for CT and MR). Continue to mark additional findings. When you have finished, click the segmentation tool.
- When marking new findings, if a finding overlaps with a previously defined finding on the same volume, a dialog appears allowing the user to choose whether to combine the new lesion with existing findings (merge) or create a new lesion.

Automatic Propagation

Automatic propagation  is available on the segmentation tool bar on selection of a lesion and on the right-click context menu of selected lesion on view port. The user can select to propagate only one lesion at a time; selecting more than one lesion disables the automatic propagation option. Lesion propagation is based on registration across studies for MR to MR and CT to CT and is performed using the Smart propagation algorithm.

It is possible to propagate lesions after the segmentation of a lesion is completed. The user can load lesions saved for priors from loaded results or from bookmarks and can choose if the lesion changes are smaller or larger, for better results. Only one lesion at a time can be propagated, and to one adjacent study at a time in order to review the lesion immediately after propagation.

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The application shows the mid slice of the propagated lesion by default for review, with a warning message. The user can complete the lesion on baseline and then propagate for best propagated lesion results. Propagation is possible on priors.

NOTICE

When segmenting without propagation: after segmenting or editing a lesion, verify accuracy of the segmentation. When segmenting with automatic propagation: verify accuracy of segmentation on propagated study.

Lesions segmented on one Spectral data type are propagated (by default) to all other linked spectral data types from the same time point.

One Click Segmentation

One Click Segmentation provides a simple and fast segmentation tool that allows the segmentation of a well defined CT finding with one click.

- Once the tool is selected, the application shows the preview of the potentially segmented volume according the location of the cursor. Hovering over the lesion until the red contour optimally "catches" the lesion. It is recommended to use reference images to get additional views of the lesion.
- The red contour represents the volume found in the selected viewport and on the reference images.
- The blue square defines the size of the segmented area. To change the maximal size of the automatically segmented volume, use the **Ctrl** key and the mouse wheel. In most cases, it is not necessary to change the size of the blue rectangle, only for very small or very large lesions.
- Every click adds another portion to the lesion.
- If a newly segmented lesion overlaps with an already existing lesion, a message appears, inquiring whether you want to create a new lesion or merge with an existing one.
- Once the lesion is segmented, a message appears in the message area of the screen. **New Lesion was segmented. Please verify correctness of segmentation**.

NOTICE

It is recommended to use the One Click Segmentation tool with reference images.

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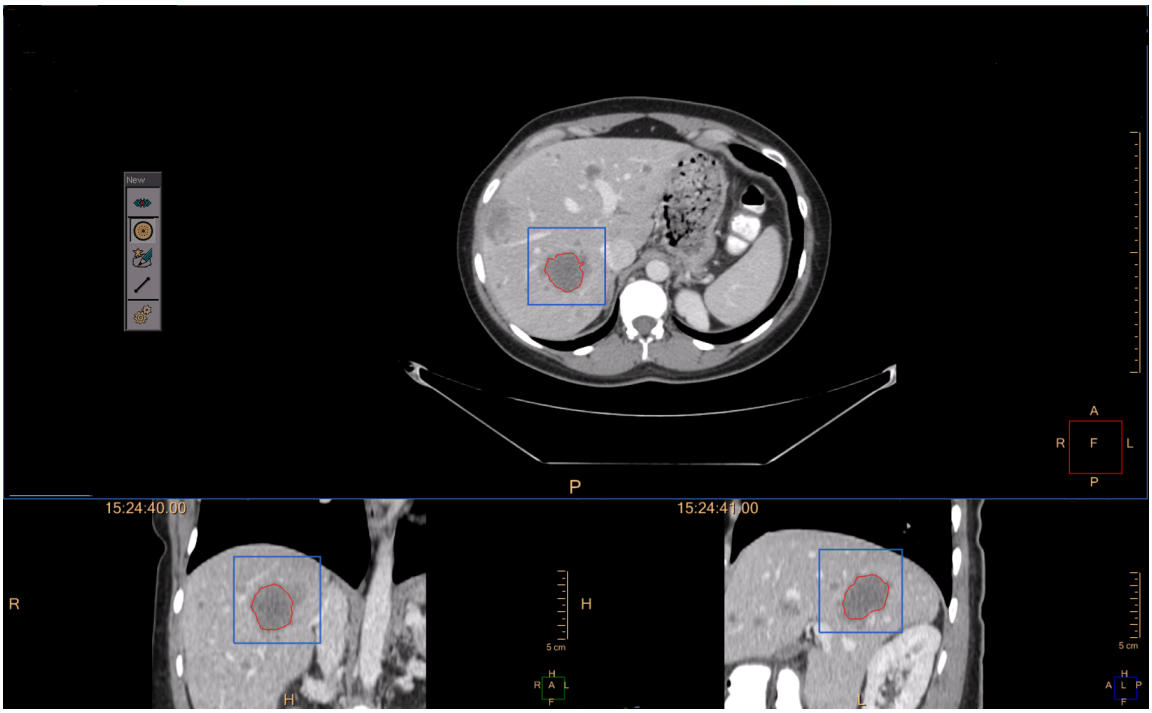
- Select the One Click Segmentation tool to activate the One Click preview mode.
- Drag the mouse over the lesion.
- Click on the lesion with the left mouse button. The volume is segmented and creates a new finding. Every click adds a portion to the lesion.
- The lesion is added to the Findings list.
- Use the Editing Tools to edit the lesion. See section “Lesion Editing Tools” on page 203.



Draw Smart ROI (except in NM studies)

Select the Draw Smart ROI tool.

- Click in the center of the lesion.
- Drag the left mouse to draw an ROI around the lesion. The tool attempts, in real-time, to track the boundary or contour of the lesion.
- As you drag the mouse, you can check the quality of segmentation in all the MPR views (if available).
- When you are satisfied with the boundary, release the mouse. The lesion is segmented.
- You can continue editing the lesion using the Smart ROI tool.

The lesion is assigned a number and placed in the Findings list.

Draw Smart ROI (when used in NM studies)

- Click in the center of lesion.
- Drag left mouse to define the search boundary for threshold segmentation (size the sphere as desired and center it over the lesion).

- When the correct size and position of the lesion are achieved, release the left mouse.

The lesion is added to the Findings list.

Draw diameter

This is a 2D tool for measuring the two dimensional diameters:

- the **Long Axis** (LA, the maximum 2D diameter)
- the **Short Axis** (SA, the perpendicular 2D diameter)

NOTICE

First draw the line to define the Long Axis, then draw the perpendicular Short Axis line.

NOTICE

Automatic propagation does not function with the Draw Diameter segmentation tool, even if it is turned ON.

Draw Single Diameter

This is a 2D tool for measuring single diameters.

The drawn single diameter is considered a Long Axis.

NOTICE

For RECIST1.1, mRECIST, CHOI the single diameter for lymph nodes is considered a short axis for calculation.

Mark finding (NM)

Click in the center of lesion to define the seed point to search outwards from the seed point, based on the threshold. Use this tool when the lesion is well-defined and separated from organs with high uptake.

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NOTICE

When performing segmentation on PET data, the threshold method is automatically selected by the application. When SUV is calculated, the segmentation is based on adaptive threshold calculation. When there is no SUV, the threshold is percentage based. As soon as the segmentation is completed, the user can change the threshold manually using the slider in the edit toolbox.

NOTICE

Once the finding is segmented using the segmentation tools described above, the Long Axis is displayed, and labeled, on the relevant slice in the segmented lesion.

MR Threshold

1. Select **MR Threshold** from the drop-down menu.

2. Click on the lesion. The ROI and contour appear. To change the ROI size, use 'ctrl' + mouse wheel.
   - The ROI represents the size of the volume the algorithm analyzed in order to define the threshold.
   - The contours represent the lesions boundaries.
3. Use the **slider bar** and the **Fill Holes** tool in the Edit menu to adjust.
   - **Slider.** The maximum and minimum are defined by the algorithm analysis. The position of the bar represents the threshold.
   - **Fill holes.** Use to fill holes in the lesions that are below the thresholds and surrounded by pixels above the threshold.

Lesion Properties

The lesion properties dialog allows you to assign the following properties to a lesion (finding):

- **Label** - Allows the user to type in a lesion name. It is recommended to use short names, as long names are cut off in the table display and may cause the user problems differentiating between lesions.
- **Type** - Allows the user to select either **Target** or **Non-target** and define whether it is a **Tumor** or **Lymph Node** or **Not Set**. If **Target** is selected, the user must define if it is a Tumor or Lymph Node.
- **Organ** - Allows the user to select from a list of relevant organs. This is especially relevant for RECIST users, that define a limit to the number of target tumors per organ. The organ list shows different options, depending on whether the lesion is marked as a tumor or a lymph node . First select the region and then select the relevant organ from the list.

- **Lesion Changes**- The following options are available:
  - **New Lesion** - Allows the user to define that a non-target lesion appeared on a specific date. The default date that is shown is always the first date that the lesion was segmented. A different date can be selected from the dropdown list.
  - **Lesion disappeared** - Allows the user to mark that a lesion disappeared and the date that the lesion disappeared. Only dates where the lesion is not segmented are displayed. The default date that is shown is always the first date that the lesion did not appear.
  - **Lesion major growth** - Allows the user to define that major lesion growth occurred on a specific date. This option is disabled when there is only a single study that contains the selected lesion.
  - **Comments** - Allows the user to type relevant comments.

NOTICE

All of these properties are reflected in the Findings List and in the Results Table.

Segmentation Settings

The Segmentation settings allow you to configure parameters for segmenting lesions.

NM Percentage

This method examines the input ROI on the PET/SPECT image and finds the maximum value within the ROI. Then it uses your percent setting as the threshold above which the lesion is segmented. The default percentage is 67%.

NM Values

Specify the number of points to average when calculating the maximum value.

NM Adaptive Threshold

This method uses the adaptive threshold technique to perform segmentation.

MR Percentage

This method examines the input ROI on the MR image and finds the maximum value within the ROI. Then it uses your percent setting as the threshold above which the lesion is segmented. The default percentage is 50%.

MR Values

The number of points to average for calculating the maximum value.

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CT Interactive, Smoothness

Use slider to control the level of smoothness of the contour shape.

CT Interactive, Adaptiveness

Use slider to control the contour level of the e topology of the region.

MR Interactive, Smoothness

Use slider to control the level of smoothness of the contour shape.

MR Interactive, Adaptiveness

Use slider to control the contour level of the e topology of the region.

MR Threshold Algorithm

Check the box to use Bright lesion feature. If Bright Lesion is checked, segmentation is looking for bright lesion on dark environment (default). If Bright lesion is unchecked, segmentation is looking for dark lesion on bright environment.

Lesion Diameter Calculation Method

The Long Axis calculation algorithm can be switched to work only inside the defined lesion by enabling the **Inside lesion diameter calculation** option. The action applies only to the currently selected lesion. The selection can be stored and reused as a part of results and bookmarks.

The default algorithm to calculate the diameter uses the **Inside lesion diameter calculation**.

To enable/disable the diameter calculation method:

1. Select the lesion (using either the left mouse or the Findings Management table).
2. On the viewport, right click on the selected lesion.
3. Click the **Inside lesion diameter calculation** option to enable/disable this option.

Lesion Editing Tools

The Lesion Editing tool box opens automatically on the viewport as soon as a lesion is selected.

The tool box opens on the viewport attached to the segmentation tool bar. You can drag the viewport to any location.

The editing tools that are included in the Lesion Editing tool box are dependent on the segmentation method that was used to create the original finding.

The available tools are described below:

Draw to Add

When needed, you can add to the current existing lesion:

Draw one or more ROI(s) around an area.

Click on a point (to “seed” new segmentation).

The segmentation is performed according to the HU values.

NOTICE

The tool to Add to segmentation is available only for CT and MR data.

Draw to Remove

When segmentation exceeds the lesion boundary, you can remove from an existing lesion as follows:

Draw one or more ROI(s) around area(s) to remove.

Click on a point (to “seed” segmentation removal).

The segmentation removal is performed according to the HU values.

NOTICE

The tool to Remove segmentation is available only for CT and MR data.

Edit contours, Edit contours (Volumetric) and Draw contour

Edit contours - Once the option is selected, you can edit the contour of an existing lesion by moving its control points. The contours should be added per slice.

Draw contour - Once the option is selected, you can add to an existing contour by drawing an adjacent contour. When you finish drawing the contours are joined into a single contour, as shown in the images below.

Edit contours (Volumetric) - Once the option is selected, you can edit the volumetric contour by holding the edges of the lesion, right clicking to select and then dragging.

NOTICE

Edit Contours only updates the contour in the slice that it is used on.

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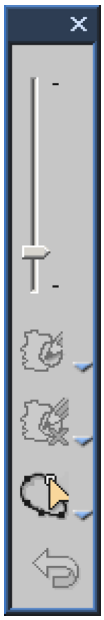

When editing a lesion in a PET study, you can use the slider tool to change the radius of the segmentation.

Undo/Redo

You can undo your last editing operation or redo an action that you undid.

Delete

To delete the contour from the current slice, point to the contour. It turns a red color. Right click on the contour and select **Delete.**

Working with the Findings List

Once lesions are segmented, they are identified in the Findings list under their respective studies, in columns and rows.

The Findings List displays all of the findings that were segmented for the selected patient.

The Findings List provides the following functionality:

- Provides an overview of the segmented lesion status, the number of Target and Non-target lesions and organ location.
- Allows the user to navigate between segmented lesions.
- Allows the user to select lesions in order to perform operations on them (Match, Unmatch, Join, Set Reference Region, Set Properties).

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The Findings List has two containers:

- Target lesions (upper container)
- Non target lesions (lower container)

Newly created lesions appear in the Non-target lesions container.

To move lesions from one container to another, drag and drop them to the other container.

Each Finding Lists includes the following columns:

- **Finding Icon** - represents the status of the finding, such as Tumor (Target and Non-target), Lymph Node (Target and Non-target), Disappeared tumor, Disappeared Lymph Node and Lymph Node.
- **Lesion Name** - Name defined by the user in the Properties dialog. If not defined, lesions are numbered and marked according to defined properties.
- **Organ** - Organ selected by the user in the Properties dialog.
- The number in parenthesis represents the number of times the lesion appeared during all follow-ups (based on loaded results or current segmentation).
- **Check Mark** - Indicates whether the finding is already marked in the latest study.

Finding Icon	Description
	Target Tumor
	Non-target Tumor
	Target Lymph Node
	Non-target Lymph Node
	Target/Non-target Tumor Disappeared
	Non-target Lymph Node Disappeared
	Segmented Study
	Unsegmented Study

Tab. 3: Findings List Icons

- **Column** - Red circles in a single vertical column identify all segmented lesions in that study.

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NOTICE

When you click a row to select a lesion in the Findings List, that lesion is displayed in all viewports that are displaying datasets. The lesion is displayed on the slice having the Long Axis.

To select multiple entries in the Findings List:

1. Select a row in the Findings List and drag the mouse button down. Release the mouse button.
2. Hold town the **Control** key and select another entry. The selected lesion in the Findings List will be colored red on the viewports.

Operations on Findings

There are several operations that can be done on Findings. The buttons are located below the Findings List. You can also access the Context menu by right clicking on a lesion. Only operations that are valid for the selected findings are enabled. The following operations can be done on a selected group of lesions:

Un-match - separates the selected lesion into individual lesions for each time point that was included in the original selection. This option is enabled only for a single entry selection which includes a lesion with more than one time point.

Match- Matches lesions between different studies to the same lesion. The lesion name (Label) of the matched lesion is the name of the oldest lesion. The lesion properties are merged. The “Match” option is enabled only when the selected entries include lesions from different time points that can be matched.

Join - Merges two (or more) parts of a lesion that are in the same dataset. This option is enabled only when multiple entries are selected and these contain a lesion at the same time point that can be joined. After the lesions are joined, they appear as one in the Findings List.

Mark as reference region - Defines a segmented area as a reference region. In NM studies, the reference region is used to label a “healthy region.” Use the reference region to “scale” or “normalize” results between studies. The display of the finding is changed to a blue square with an "R". This option is enabled only on a single selection of an entry which is not defined as a Target lesion. Once an entry is defined as a reference region, it is not possible to open the Properties dialog. The only option is to convert it to a “lesion” again by right-clicking on the reference region and defining it as a lesion again

Open Properties Dialog - Opens the Lesion Properties Dialog (see section “Lesion Properties” on page 201). This is enabled only for a single selection and only for lesions (not available for reference regions). In this dialog you can label a lesion and designate the type of lesion and its status.

Delete - deletes the selected lesion from all studies.

Show Segmented Series

The **Show Segmented Series** feature is available from the Context menu if a lesion is selected in the Findings List. When selected, the series on which the selected lesion was created is shown in the top viewport of the hanging layout, replacing the series in that viewport.

Based on the series description and data type, the relevant series is found and replaced on other time points, so that you are viewing the same data type across time points.

- The application does not replace series if the data type found is in a basic modality type (MR, CT, PT and SPECT).
- The application does not replace the viewport images in the case of NM fusion layouts and for CT Spectral image types.
- The application does not replace any view port if the lesion segmented series is already present in any other view port of the baseline study.

A **Show Segmented Series** preference option is available at the bottom of the Findings List. When selected, a dialog appears with the option to **Show segmented series on application launch**. Place a check mark in the check box and select **Save** to open the segmented series on application launch.

If the application does not find the same series on the follow-up studies on which the lesion was created, the following message appears:

Application could not find the same data type on follow-up study which was used for lesion segmentation in baseline. Please select the required series for segmentation from series tray.

Results Work Stage

In the Results stage, the user can review the calculated measurements based on the segmentation and matching that was done in the Segmentation stage. These results are presented in graphical and table format. For each parameter that the user requested for follow-up, there will be graph and a table. In addition, the user can receive a calculated conclusion for the treatment response of the disease, based on the selected criteria.

The Results stage is divided into a graph and table (measurements) section and a Conclusions section.

The content of the Results page is based on the Results parameters that were defined in the selected preset and can be controlled by the Control Panel, which allows you to:

- Decide whether images are displayed via the **Show Images** checkbox. When enabled, lesion images are displayed. The image that is displayed is the lesion that is currently selected in the Findings List. The image orientation and rendering mode can be modified. Right click on the displayed images to view the available options.
- In the main viewport, you can choose to view from among all spectral results. Pause the pointer on the name of the data type to see the options; and click to make your selection. In addition, you can adjust the MonoE keV level using the accompanying arrows. These actions adjust the associated viewports accordingly.
- Edit table contents.

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You can also review the Findings List.

Important: Always save results before exiting the application.

The table and graph sections are divided into three parts:

- Criterion Results
- Target Lesions measurements
- Non-target Lesions summary

Graphs and Tables

The Graphs display the change of selected parameters from study to study.

When the selected table is a Functional parameter (Mean, Max or Min) the user can toggle between graph and histogram of the distribution of the measured unit of the selected tumor instead of the graph. To view the histogram, click the **H** icon below the Target Lesions graph.

- Each measurement is represented by a dot in the graph, corresponding to a specific lesion in the loaded studies.
- You can choose which parameters to display (volume, diameter, RECIST, etc.) from the Table Contents Editor (see section “Table Operations” on page 212).

The indication of Baseline (B) and Nadir (N) appears in the table column title according to the relevant dates. The user can mark the date as Nadir or Baseline by right-clicking on the column title and selecting an option in the Context menu.

The columns of all tables are based on study dates, in the order of oldest (on the left) to the latest (on the right).

You may view and modify the Baseline and Nadir dates by selecting any of the time point dates from a drop down list on the left side of the screen.

Spectral Results

All the spectral result types are identified as functional data types and are available in the Results stage under **Edit table contents**.

Spectral results that are displayed in the Results stage can be selected from:

- All data types included in the selected preset in any of the layouts
- Additional data types that the user viewed in the segmentation stage

If a data type is not in presets or was not viewed, it is not available in **Edit table contents** in the Results stage.

Note: To see a result that is not available in the Results stage, return to the segmentation stage and view the needed datatype. After returning to the Results stage, the needed data will appear.

- Only the **Mean** functional parameter will show the histogram for the spectral functional data.
- The 2D spectral ROIs are also available in the histogram of each spectral functional parameter.

- An additional spectral functional parameter **Total Volume x Iodine Density (mg)** is calculated and is available for selection in **Edit table contents**.
- The Results stage displays the MonoE functional parameters of the last viewed energy level in the Segmentation stage.
- If monoE is changed in the Results stage to another energy level, the functional parameter is also dynamically updated.
- If there are different monoE energy levels selected for different studies, then they are shown separate in functional parameters. When changing the viewed energy level, the histogram, graph and table are updated according to the new energy level.
- If all studies display identical energy levels, it is possible to view lesions from all studies on the same histogram simultaneously by combining or having one MonoE functional parameter.
- When selecting a spectral result type from the Results stage viewport selector, the corresponding functional parameter is added to the target and non-target lesion display areas if they are not selected to view.
- The application supports only one CaSupp suppression level per time point, in the Segmentation and Results stages. The last viewed suppression level is displayed in the Results stage.

Criterion Section

The Criterion section displays the criterion measured values over the time points presented as numeric and graphical values.

A vertical indicator on the graph shows the baseline location. The default value of the baseline is the earliest study date.

If a low point exists in the graph, it is marked as the Nadir point.

A green horizontal line on the graph indicates the threshold for Partial response according the selected criterion. For example - 30% below the baseline for RECIST.

A red horizontal line on the graph indicates the threshold for progressive disease according the selected criterion. For example - 20% above the NADIR for RECIST.

Table Values:

- **Criterion Value** - The value in the first row of the table displays the criterion measurement value for each of the dates.
- **Relative to Baseline** - The value in the second row of the table displays the delta between the measured value to the baseline.
- **Relative to Nadir** - The value in the third row of the table displays the delta between the measured value to the previous time point.
- **Relative to Previous** - The value in the fourth row of the table displays the delta between the measured value to the NADIR. The row appears only when the Nadir is defined. Only values after the Nadir time point are presented as the delta.

If a delta indicates reduction in size, it is colored green. A size increase is reflected in red.

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The Target Lesion and Non-target Lesion sections display the graph and table for all of the measurements that were selected.

The following options are available to select how to display the measurements in the columns that follow the baseline:

- Absolute value (Same units as baseline)
- Relative to Baseline (%)
- Relative to Previous (%)
- Relative to Nadir (%) - When this setting is selected, the Baseline and Nadir values appear as absolute numbers. The time point until Nadir shows the delta from the baseline and the values after the Nadir show the delta to the Nadir.

The title of the Target Lesion and Non-target Lesion row contains the lesion name and the organ.

If the number of rows in the table exceeds the viewport limit, the table opens on the most recent data. Scroll to view data that is not currently displayed.

The bottom row of the table is the Total value of each of the columns. If the table content is longer than the viewport length, scroll down.

The last column of the Target Lesions table displays the comments entered by the user in the **Properties** dialog for the finding.

Navigate between the tabs above the graph to view the various parameters.

The Baseline column always contains the absolute value of the measured parameter.

NOTICE

If a Reference region was defined, it will be used for calculations. New columns will be added to the table, with a column head labeled “Scaled… parameter.”

Non-target Lesion Section

The Non-target Lesion table also displays the status of each of the Non-target lesions with dates and a summary.

The content of the cells displays the status of the lesion with the following options:

- **New** - When the lesion was defined as **New lesion** + when lesion was marked that it exists without any special indication. Colored red to indicate a progression.
- **Disappeared** - When the lesion was marked as **Lesion disappeared**. Colored green to indicate a response.
- **Major Growth** - When the lesion was marked as **Lesion major growth**. Colored red to indicate a progression.
- **Present** - When the delta does not indicate progressive or responding disease.

The last row of the table contains a summary of the time point regarding the number of new lesions, major growths and disappeared lesions.

Table Operations

Table Contents Editor

Selecting this function displays the **Table Contents Editor** dialog. (This page is part of the Protocol Editor, which is available in the Setup stage.)

This dialog allows you to define various settings, including:

- **Generic Parameters** - The generic results to be displayed in the table
- **Criterion Parameters** - Treatment response criteria calculated results (RECIST and WHO) to be displayed in the Target Lesions Summary Table.
- **Functional Parameters** -The Functional parameters to be displayed in the table (Mean, Min and Max of the voxels in the segmented volume, according to the specific data type).

The table provides the series number where the lesion was finalized and the slice number of the center of the lesion, where the long and short axis are found in the table results.

Please refer to the **Define Results View** description earlier in this chapter for more information (described in section “Preset Editor” on page 183).

NOTICE

Make sure that relevant parameters are selected.

Exporting Table Results

To export table results:

1. Click on the icon in the upper right corner of the table.

   It is possible to select the **Copy Table** icon or **Copy All Tables** icon.
2. Open either Microsoft Word® or Excel® and paste the contents from your clipboard into the application.

Histogram

The Histogram displays the distribution of the measured units on the lesion images. The Histogram displays only one matched lesion at a time (the lesion that is selected in the Findings List).

When the selected table is a Functional parameter (Mean, Max or Min), the user can see the histogram of the distribution of the measured unit of the selected tumor instead of the graph.

The Histogram displays the lesion that is selected in the Findings List, in conjunction with the drawn spectral ROI. These results are indicated by the "Findings and 2D ROIs" naming convention.

Histograms can be selected and saved using the **Save Selected Image(s) as** option, in DICOM or non-DICOM formats.

For spectral results:

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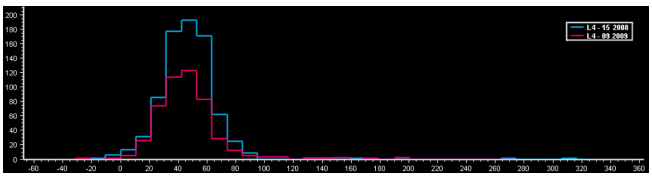
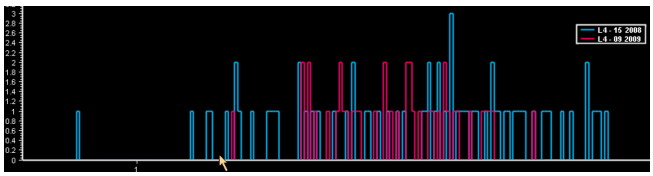
- Only the Mean functional parameter has the capability to show the histogram for the spectral functional data.
- By default, each functional parameter is shown with a time graph and table.
- Select the histogram button in the upper right corner of the table to show the histogram.

NOTICE

To view histograms of all lesions, navigate between findings in the Findings List.

CAUTION

Histograms for CT datasets are valid only with “contrast free” studies.

HU Histogram	SUV Histogram
	

Save results before exiting the application.

Conclusions

The **Conclusion** panel includes the following fields:

- **Physician Decision** - Options are **Complete Response**, **Partial Response**, **Stable Disease**, **Progressive Disease** and **Unable to Evaluate**.
- **Comments** - Field to type in physician's comments.
- **Automatic Suggestion** - Calculates a conclusion using the measurements based on the criterion selected.

  When the **Calculate** button is pressed, the suggestion dialog pops up, with the suggested decisions and rationale based on the selected criterion.

  The user may approve or reject the suggestion. Upon approval, the suggested decision and rationale are copied into the **Physician Decision** and **Comments** fields.
- The user can manually override the decision and comment fields.
- The application report will indicate whether the physician-approved decision was calculated by the application or selected manually.

Notes

- The calculation of the decision is based on the selected criterion.
- It should be clear that this calculation is not Philips' proprietary logic.

Automatic Suggestion

To receive an automatic suggestion:

1. Press **Calculate.**

   The **Automatic Suggestion** dialog opens, displaying the Criterion, Suggested decision and Rationale for the decision.
2. Review the suggestion.
3. Press **Approve** if you agree with the suggestion or press **Reject** if you disagree.

   If you select **Approve**, the Physician Decision and Comments are automatically filled with the information that appeared in the Suggestion dialog.

Sending Findings to Report

When sending findings to report, the Patient History and Findings dialog box opens. Fill in the patient information.

Criterion Guidelines

RECIST 1.0

Baseline

1. **Target Lesions** - Segment up to ten Target Lesions per body and no more than five per organ.
2. **Non-target lesions** - Mark locations of all Non-target lesions.

Follow-up

1. **Target lesions** - Use the Findings List to navigate between previous target lesions. For each lesion, inspect the latest study:
   - Find matched lesions segmented on the latest study and match them.
   - If a target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.
2. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions, mark on the latest study and match them.

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- If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the **Lesion major growth** attribute.
- If a Non-target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.

3. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.

RECIST 1.0 Calculation

The RECIST 1.0 value is calculated as the sum of the longest axial diameters of all the target lesions.

RECIST = ∑ (long diameter of target lesions)

RECIST 1.1

Baseline

Non-target Lesions - Mark the locations of all Non-target lesions.

Follow-up

1. **Target lesions** - Use the Findings List to navigate between previous target lesions. For each lesion, inspect the latest study:
   - Find matched lesions segmented on the latest study and match them.
   - If a target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.
2. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions, mark on the latest study and match them.
   - If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the **Lesion major growth** attribute.
   - If a Non-target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.
3. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.

RECIST 1.1 Calculation

The RECIST 1.1 value is calculated as the sum of the longest axial diameter of the target tumors and the (longest) short axial diameter of the target lymph nodes.

RECIST = ∑ (longest diameter of target tumors, (longest) short diameter of target lymph nodes)

WHO

Baseline

Segment Target Lesions - Segment all Target Lesions.

Follow-up

1. **Find Matched Lesions & Segment** - Use the Findings List to navigate between previous findings. For each finding, inspect the latest study. Find matched lesions segmented on the latest study and match them.
2. **Mark Disappeared Lesion** - If a target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**. Include the relevant date.
3. **Mark New Findings** - Check if there are new findings in the latest study. Segment the new findings. Open the **Lesion Properties** dialog and indicate that there is a new finding.

WHO Calculation

The WHO value is calculated as the sum of the product between the two longest diameters in the perpendicular dimensions in the axial orientation.

WHO = ∑ (long diameter * short diameters) of target lesions

PERCIST

Baseline

1. **Reference Region** (Optional) - Mark a reference VOI (recommended on the right lobe of the liver or the descending aorta) and compute the PERCIST threshold.
2. **Target Lesions** - Use PET segmentation tools to segment up to five Target Lesions per body and no more than two per organ.
3. **Non-target lesions** - Mark locations of all Non-target lesions.

Follow-up

1. **Reference Region** (Optional):
   - **Mark a reference VOI** - Mark a reference VOI in the same location.
   - **Check the delta** - Check if the delta between the reference region's SUV mean is less than 20%.

     If it is greater than 20%, then studies are not comparable.
2. **Target Lesions** - Use the Findings List to navigate between previous target lesions. For each lesion Inspect the latest study:
   - Find matched lesions segmented on the latest study and match them.
   - If a target lesion disappeared, - open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.

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3. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions - Mark lesions on the latest study and match them.
   - If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the lesion as **Lesion major growth**.
   - If a Non-target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**. Include the relevant date.
4. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.

PERCIST Calculation

PERCIST is based on the SUL Peak which is the largest possible mean value of a 1 cm 3 spherical VOI positioned within a tumor or hotspot, using SUL (or SUVlbm) as the reported unit.

The application uses the sum of the SUL Peak of the target tumors for the decision calculation.

Tumor SUL Peak = (largest mean value of a 1 cm 3 spherical VOI in a tumor)

Total PERCIST = Sigma (SUL Peak of the target tumors)

CHOI

Baseline

1. **Target Lesions** - Segment up to five Target Lesions per body and no more than two per organ.
2. **Non-target Lesions** - Mark the locations of all Non-target lesions.

Follow-up

1. **Target lesions** - Use the Findings List to navigate between previous target lesions. For each lesion, inspect the latest study:
   - Find matched lesions segmented on the latest study and match them.
   - If a target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.
2. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions, mark on the latest study and match them.
   - If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the **Lesion major growth** attribute.
   - If a Non-target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**.
3. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.

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CHOI Calculation

- For CHOI the RECIST value is calculated based on RECIST 1.1 (the sum of the longest axial diameters of all the target tumors and the (longest) short diameter of the target lymph node).
- Tumor density is calculated as the mean density of all target tumors.
- The mean density is calculated as the average of segmented tumors.

RECIST 1.1 = ∑ (long diameter of target tumors, (longest) short diameter of target lymph nodes)

Tumor Density = Mean HU of the tumor

Total Density = Mean (Target tumors density)

mRecist

Baseline

1. **Target Lesions** - Segment the target lesion in the baseline on the post injection series. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.
2. **Non-target lesions** - Mark locations of all Non-target lesions.
3. Use the reference region tool to allocate the reference region on the baseline in a valid location according to guidelines.
4. Create the qEASL map using the qEASL map creation button.
5. The enhanced long axis and short axis are calculated on the enhanced part of the lesion.

Follow-up

1. **Target lesions** - Use the Findings List to navigate between previous target lesions. For each lesion, inspect the latest study:
   - Find matched lesions segmented on the latest study, segment the enhanced and necrotic parts of the lesion and match them.
   - **If a target lesion disappeared** - Open the **Lesion Properties** dialog and mark the lesion as **Disappeared**.
2. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions, mark on the latest study and match them.
   - If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the **Lesion major growth** attribute.
   - If a Non-target lesion disappeared, open the **Lesion Properties** dialog and mark the lesion as **Disappeared**.
3. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.
4. Use the reference region tool to allocate the reference region in the baseline in a valid location according to guidelines.

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5. Create the qEASL map using the qEASL map creation button.

   The enhanced long axis and short axis are calculated on the enhanced part of the lesion.

mRECIST Calculation

mRECIST value is calculated as the sum of the enhanced longest axial diameter of the target tumors and the enhanced (longest) short axial diameter of the target lymph nodes.

mRECIST value equals the sum of the longest axial diameters of all the enhanced part of the target tumors This is the same as RECIST 1.0.

mRECIST = ∑ (enhanced longest diameter of target tumors, enhanced (longest) short diameter of target lymph nodes)

irRC

Baseline

NOTICE

Index lesions are the measurable lesions that are defined at the baseline.

1. **Segment Target Lesions** - Segment the **Index** lesions and mark them as Target Lesions (up to **five** lesions per organ, up to **ten** in total).
2. **Non-target lesions** - Mark locations of all Non-target lesions.

NOTICE

According to irRC, a measurable lesion is a lesion which is >= 5*5 mm.

Follow-up

1. **Find Matched Lesions & Segment** - Use the Findings List to navigate between previous findings. For each finding, inspect the latest study. Find matched lesions segmented on the latest study and match them.
2. **Mark Disappeared Lesion** - If a target lesion disappears, open the **Lesion Properties** dialog and mark the lesion as **Lesion disappeared**. Include the relevant date.
3. **Mark New Findings** - Check if there are new findings in the latest study. Inspect the latest study. If there are new lesions, segment them and mark the measurable lesions as additional target lesions. As a result, they will be included in the calculation of the total tumor burden.

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NOTICE

According to the criterion, the number of new measurable lesions should be up to five per organ and up to ten in total.

irRC Calculation

The SPD value equals the SPD (sum of perpendicular diameters).

EASL

Baseline

1. **Target Lesions** - Segment the target lesion in the baseline on the post injection series. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.
2. **Non-target lesions** - Mark locations of all Non-target lesions.
3. Use the reference region tool to allocate the reference region on the baseline in a valid location according to guidelines.
4. Create the qEASL map using the qEASL map creation button.
5. The enhanced long axis and short axis are calculated on the enhanced part of the lesion.

Follow-up

1. **Target lesions** - Use the Findings List to navigate between previous target lesions. For each lesion, inspect the latest study:
   - Find matched lesions segmented on the latest study, segment the enhanced and necrotic parts of the lesion and match them.
   - **If a target lesion disappeared** - Open the **Lesion Properties** dialog and mark the lesion as **Disappeared**.
2. **Non-target Lesion** - Use the Findings List to navigate between previous non-target lesions. For each lesion, inspect the latest study:
   - Find matched lesions, mark on the latest study and match them.
   - If a Non-target lesion shows major growth, open the **Lesion Properties** dialog and mark the **Lesion major growth** attribute.
   - If a Non-target lesion disappeared, open the **Lesion Properties** dialog and mark the lesion as **Disappeared**.
3. **New Findings** - Check if there are new findings in the latest study. Mark the new findings. Open the **Lesion Properties** dialog. Choose the **Non-target** label and select **New Lesion**.
4. Use the reference region tool to allocate the reference region in the baseline in a valid location according to guidelines.
5. Create the qEASL map using the qEASL map creation button.

   The enhanced long axis and short axis are calculated on the enhanced part of the lesion.

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EASL Calculation

The EASL value is calculated as the sum of the product between the two enhanced longest diameters in the perpendicular dimensions in axial orientation obtained from qEASL map.

qEASL cm³

Baseline

1. Segment the Target Lesion in the baseline on the post injection series. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.
2. Use the reference region tool to allocate the reference region in the baseline in a valid location according to the guidelines.
3. Create the qEASL map using the qEASL map creation button.

Follow-up

1. Use the Findings List to navigate between previous Target Lesions.
2. Segment the target lesion in the follow up exam. Use the same post injection series as used in the baseline. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.
3. Use the reference region tool to allocate the reference region in a similar location in the follow up study.
4. Create the qEASL map using the qEASL map creation button.

qEASL cm³ Calculation

The qEASL value is calculated as sum of volume of the enhancing tumor obtained from the qEASL map.

The following rules are used for response criteria:

- If there was a complete disappearance of all enhancing tissues in all target lesions (sum of all enhanced volume = 0), then it is a Complete Response.
- If the sum of enhancing tissue volume increased compared to NADIR by more than 73%, then it is a Progressive Disease.
- If the sum of enhancing tissue volume decreased compared to the baseline by more than 65%, then it is a Partial Response.
- If there is insufficient shrinkage to qualify as a Partial Response and insufficient growth to quality as a Progressive Disease, then it is a Stable Disease.

qEASL%

qEASL% Baseline

1. Segment the Target Lesion in the baseline on the post injection series. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.

2. Use the reference region tool to allocate the reference region in the baseline in a valid location according to the guidelines.
3. Create the qEASL map using the qEASL map creation button.

qEASL% Follow-up

1. Use the Findings List to navigate between previous Target Lesions.
2. Segment the target lesion in the follow up exam. Use the same post injection series as used in the baseline. Be sure to include the enhanced and necrotic parts of the lesion in the segmented lesion.
3. Use the reference region tool to allocate the reference region in a similar location in the follow up study.
4. Create the qEASL map using the qEASL map creation button.

qEASL% Calculation

The qEASL% is calculated as the sum of the percentage in the volume of the enhancing part of the tumor compared to the total volume of tumor obtained from the qEASL map.

The following rules are applied for response criteria:

- If there was a complete disappearance of all enhancing tissues in all target lesions (sum of percentage of the enhancing tissue volume = 0) then it is a Complete Response.
- If the sum of percentages of the enhancing tissue volume increased compared to NADIR is more than 73%, then it is a Progressive Disease.
- It the sum of percentages of the enhancing tissue volume decreased compared to baseline by more than 65%, then it is Partial Response.
- If there is insufficient shrinkage to qualify as a Partial Response and insufficient growth to quality as a Progressive Disease, then it is a Stable Disease.

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qEASL Appendix

The qEASL (quantitative European Association for the Study of the Liver) group created tumor response criteria optimized for liver cancer (EASL) based on comparing non-contrast to contrast enhanced scans. Philips has further enhanced this approach to include 3D (volumetric) measurements and provide quantitative results of the tumor enhancing volume in cc. (cubic centimeters) and as percentage of total tumor volume.

This value is calculated as the quantitative measure of tumor enhancement as a % of enhancing tumor volume compared to the total tumor volume over timepoints. In addition, a color map is over-layer on the scans to show volumetric and regional tumor enhancement heterogeneity. The color regions of the segmented lesions display greater enhancement than the pre-defined reference region.

qEASL requires a license and it does not appear in the Tumor Tracking application if a license is not available.

Philips

For accurate qEASL calculation, it is important to remove the motion artifacts between the series by performing inter-series registration.

There are different default background algorithms depending on the modality.

- **CT/CT Registration** – Elastic registration algorithm for dynamic series (i.e pre injection, arterial phase and late phase acquisitions - inter series) and automatic rigid registration between time points (pre-treatment and post treatment) .
- **MR/MR Registration**- Rigid registration between dynamic (intra or inter series) and MR studies (pre-treatment and post treatment).

To activate intra series registration for MR dynamic data:

1. Select the series from the **Patient Directory** and right click to display the context menu.
2. Select **Run Processing** > **MR Registration**.

   On successful completion of MR Dynamic registration processing, a new Derived series is added to the study with the **Reg** indication before the original series description .

qEASL Presets

The selected preset defines the hanging layouts, the selected criterion and the results. See section “Workspace Preparation” on page 182 and section “Preset Editor” on page 183.

Preparing qEASL presets simplifies and optimizes the workflow of the application.

Data Type Association

The pre-contrast and post contrast series of each study should be associated with the Pre-Injection and Post-Injection data types respectively.

Pre-defined default Presets:

- CTQEASL Multiphase – For CT multiphase data
- MRQEASL Multiphase– For MR multiphase data
- MRQEASL– For MR Dynamic data

It is also possible to create a user defined Preset for qEASL. It is important to create a preset with only one series using the **Data Type** defined as **Pre-injection** and one series using **Post-injection**.

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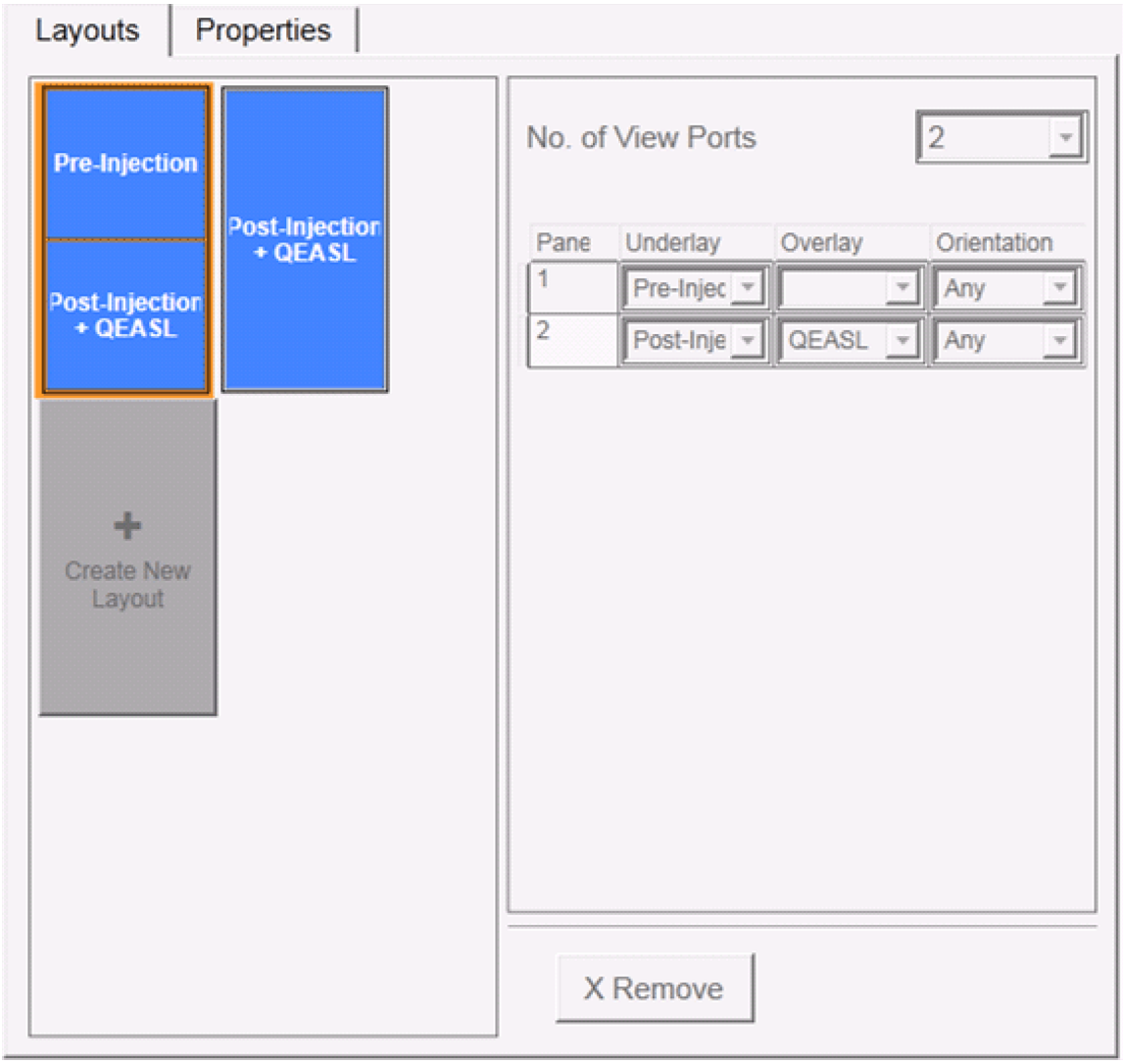

Properties Tab (in Presets)

- For qEASL Segmentation Tools, select both **2D Tools** and **3D Tools**.
- Four new Results View **Generic parameters** were added for qEASL:
  - Enhanced percentage
  - Enhanced volume (cm^3)
  - Enhanced Mean
  - Enhanced SD

Select the relevant parameters.

qEASL Workflow

1. Select the latest study and any prior studies of the same patient that are relevant for the follow-up session.

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Multiple studies of the same patient can be selected for loading into the application.

2. Select a Preset from the list of predefined Presets.

   Each of the loaded studies should contain Pre-injection and Post-injection scans or the complete dynamic MR scan. The user can create presets with the association of pre-injection and post injection data types. The qEASL data type can then be used as an overlay to the post-injection underlay. See section “qEASL Presets” on page 223.

   Based on the selected preset the application displays the series in the view ports.

3. For each timepoint, check the  **Inter-series registration** icon, which appears on top of each time point. If the icon is enabled, automatic inter- series registration was run when the application was loaded and the series in that study are registered.

4. Use the  Relate button to verify that registration results are acceptable.

NOTICE

If registration results are not acceptable, do *not* continue with the qEASL measurement.

5. After approving registration, it is recommended to move to the next hanging layout (post injection + fused qEASL) by selecting the  **Layout** icon.

6. Segment the target lesion on the enhanced series (post injection) using any of the available segmentation tools. See section “Mark New Finding” on page 197.

7. Set a Reference region on the enhanced series.

   The Reference region should be carefully selected to avoid any adjacent main branch blood vessels, the gallbladder, liver periphery and motion artifacts that may affect qEASL results and reliability.

   – Select  , which represents the reference region predefined square (1).
   – When a green square appears (2), select the best location for the reference region, representing healthy tissue behavior.

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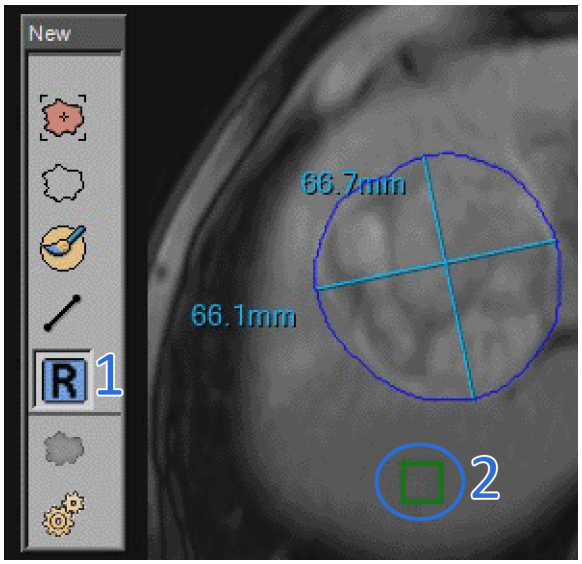
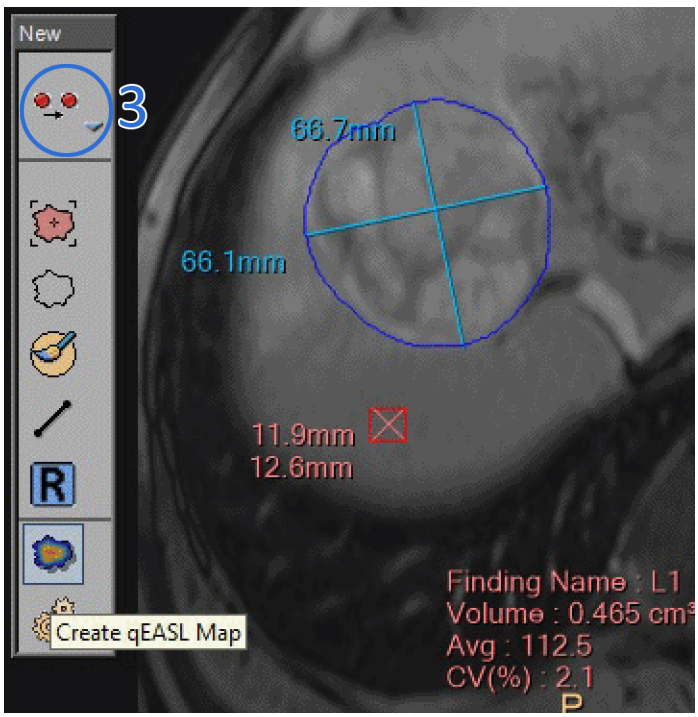


– For studies with follow-up, press the  propagate icon (3).



The creation of a qEASL map occurs across all studies automatically for studies with both lesions and reference.

– For CT data, scroll to verify that the reference is not part of a blood vessel, or any other enhanced artifact. For MR data, if the CV shown for the segmented reference region is more than five, then the reference region can be deleted or re-segmented.

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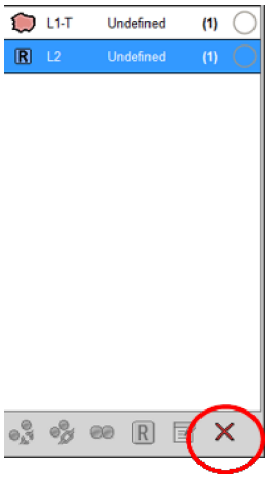

– Once a reference region is placed, the qEASL becomes active.

NOTICE

It is possible to change the qEASL threshold, by selecting the Standard Deviation Factor before applying qEASL. The default parameter set to **2SD**. To change the default value, select the  **Segmentation Settings** icon and adjust the **Standard Deviation Factor** as necessary.

8. Apply qEASL by selecting the  **Create qEASL volume** icon.

   The qEASL map is generated and is available in the series tray. Only lesions get overlaid with the qEASL map on the post-injection series as per the selected preset. The user can use the **F12** key to hide the map overlay to view the underlying anatomy.
9. Continue to the Results stage.
10. To save the qEASL map, select **Save qEASL Map**. Generate a new imaging DICOM series containing the qEASL map.

CAUTION

Spectral Do not use qEASL in combination with Spectral CT data for clinical reporting. The combination is available for research purposes only.

QEASL References

qEASL is currently a research based response criterion. The relevant resources are shown below:

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1. MingDe Lin, PhD, Olivier Pellerin, MD, MSc, Nikhil Bhagat, MD,Pramod P. Rao, MD, Romaric Loffroy, MD, PhD, Roberto Ardon, PhD, Benoit Mory, PhD, Diane K. Reyes, BS, and Jean-Francois Geschwind, MD; "Quantitative and Volumetric European Association for the Study of the Liver and Response Evaluation Criteria in Solid Tumors Measurements Feasibility of a Semiautomated Software Method to Assess Tumor Response after Transcatheter Arterial Chemoembolization"; Journal of Vascular and Interventional Radiology, 23 + (2012) 1629-1637. doi:10.1016/j.jvir.2012.08.028.
2. Julius Chapiro, MingDe Lin, Rafael Duran, Rüdiger E Schernthaner, Jean-François Geschwind; "Assessing tumor response after loco-regional liver cancer therapies: the role of 3D MRI, Expert Review of Anticancer Therapy"; Early Online 0.0:1-7 (2014).
3. Julius Chapiro, MD Laura D. Wood, MD, PhD MingDe Lin, PhD, Rafael Duran, MD, Toby Cornish, MD, PhD, David Lesage, PhD, Vivek Charu, BS, Rüdiger Schernthaner, MD, Zhijun Wang, MD, PhD, Vania Tacher, MD, Lynn Jeanette Savic, BS, Ihab R. Kamel, MD, Jean-François Geschwind, MD; "Radiologic-Pathologic Analysis of Contrast-enhanced and Diffusion-weighted MR Imaging in Patients with HCC after TACE: Diagnostic Accuracy of 3D Quantitative Image Analysis"; Radiology: Volume 273: Number 3—December 2014;

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