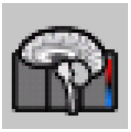
9 MR Longitudinal Brain Analysis

Introduction



Philips Medical Systems' MR Longitudinal Brain Analysis application is a post-processing software application intended to assist in the evaluation of serial brain imaging based on MR data.

The Longitudinal Brain application allows the user to view images, perform segmentation of lesions, along with segmentation editing tools and volumetric quantification of segmented volumes and quantitative comparison between time points. The Longitudinal Brain application provides automatic registration between studies from different time points, for longitudinal comparison.

The Longitudinal Brain application provides a supportive tool for the visualization of subtle differences in the brain images of the same individual across time, which can be used by clinicians for the assessment of disease progression.

The physician retains the ultimate responsibility for making the final diagnosis based on image visualization, as well as any segmentation and measurement results obtained from the application.

Key Features

The MR Longitudinal Brain Analysis application has the following key features:

- Longitudinal comparison between brain images in multiple studies.
- Support for multi-slice MR sequences (2D and 3D) and allows the user to use basic viewing operations such as: scroll, pan, zoom, windowing and annotation.
- Identifies pre-defined data types (presets) and user created hanging layouts.
- Automatic registration between studies (same patient, different time-points).
- Single mode - Allows reviewing each of the launched studies, showing multiple sequences of the same study, using the entire reading space.
- Tissue segmentation and editing tools allowing volumetric measurement of different lesion types.
- Lesion management tools allowing matching between lesions in different studies to facilitate the assessment of differences over time.
- CoBI feature (Comparative Brain Imaging) - A supportive tool for the visualization of subtle differences in lesions of the same individual across time for similar sequences. The CoBI feature provides mathematical subtraction of scans yielding, after bias-field correction and intensity scaling, a color-coded image of the differences in intensity between two registered scans.
- Results displayed in tabular and graphical formats.

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Indications for Use

The MR Longitudinal Brain Analysis application is a post-processing application to be used for viewing and evaluating neurological images provided by a magnetic resonance diagnostic device. The Longitudinal Brain application is intended for viewing, manipulation, 3D-visualization and comparison of medical imaging and/or multiple time-points. The Longitudinal Brain application enables visualization of information that would otherwise have to be visually compared disjointedly. The Longitudinal Brain application provides analysis tools to help the user assess, and document changes in diagnostic and follow-up examinations.

The Longitudinal Brain application is designed to support the workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.

The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

Intended Users

Advanced Visualization Workspace MR Longitudinal Brain Analysis application is intended to be used by adequately trained and qualified medical professionals, including but not limited to physicians and medical technicians. The main clinicians or medical and para-medical professionals who use the Philips Advanced Visualization Workspace Longitudinal Brain Imaging application are listed below:

- Radiologists in the radiology department/clinic
- 3D technologists in the radiology department

Other clinicians/roles using the Philips Advanced Visualization Workspace are listed below:

- Neurologists and neurology technologists
- Oncologists and oncology technologists
- Referring Physicians

Intended Patient Population

The Longitudinal Brain application is intended to be used for adults only.

Benefits

When used as specified in the Intended Use, under the circumstances and conditions as specified in the Indications for Use, the application assists the user with interpreting the clinical image data on par with the state of the art, thus realizing a positive impact on diagnosis or patient management.

More specifically the following patient and user benefits have been identified for the MR Longitudinal Brain Analysis application:

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- The subtraction functionality (CoBI) facilitates the detection of differences between scans, which may be difficult to discern solely with the naked eye. The Longitudinal Brain Analysis application includes tools which allow to delineate and volumetrically quantify changes between time points, yielding a more objective scan interpretation than current practices (eyeballing alone).
- If the device is used as specified in the Intended Use, under the circumstances and conditions as specified in the Indications for Use, the most important expected patient benefit is an accurate and faster comparison of the patients' MRI imaging studies, resulting in an accurate long-term monitoring of the disease evolution. A Philips' Ltd. study showed that automated co-registration and lesion detection of brain lesions using the Longitudinal Brain application reduced the required time to evaluate MRI follow-up exams and increased diagnostic accuracy in patients with Multiple Sclerosis in comparison to conventional radiological reading. Moreover, the results of a second study showed that the use of Longitudinal Brain Analysis for the interpretation of follow-up brain imaging was deemed beneficial in the majority of cases analyzed. The most cited benefits were “perceived faster interpretation of change”, followed by “perceived enhanced confidence” and “perceived easier comparison”.

Contraindications

None.

Limitations for Use

The Longitudinal Brain application should be used for adults only.

Main Longitudinal Brain Analysis User Workflow

The proposed Longitudinal Brain Analysis application consists of four main viewing modes:

- **Longitudinal mode**-Launched studies are displayed in timely ordered and automatically registered fashion and allows different hanging layouts.
- **Single mode**- A standard view that allows visualization and analysis of a single study to review multiple sequences of the same study.
- **Compare mode (CoBI)**- A tool that allows visualization of subtle differences in the brain over time between two selected images.
- **FLAIR* Method**- A tool that is intended to generate the FLAIR* series based on co-registered 3D FLAIR and 3D multi-shot EPI series. This could assist the user in visualization of the central vein sign of Multiple Sclerosis (MS) lesions.

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.

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2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Advanced Visualization Workspace configuration, this application may not be available.

Patient Studies for Longitudinal Brain Analysis

NOTICE

Up to four MR studies can be selected for loading into the Longitudinal Brain Analysis application.

Make sure that all studies belong to the same patient before launching the Longitudinal Brain Analysis 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.

Longitudinal Brain Analysis 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 141 .

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 **MR Longitudinal Brain Analysis** application to load the data.

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Segmentation

1. Select a Preset from the list of predefined **Presets**. If necessary, select an alternate hanging layout from the Layout list. See section “Workspace Preparation” on page 143 and section “Configuring Presets” on page 144.
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 149.
3. When the application is loaded, Automatic Registration, between the studies, runs in the background and is automatically applied 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 150.
4. **Review the lesions** - Use the Viewing Tools to review the images and previous findings. See section “Viewing Tools” on page 147.
5. **Mark new finding** - Use the segmentation tools from the wheel Context menu. There are volumetric segmentation tools that allow segmentation to the lesion as a volume. See section “Mark New Finding” on page 162.

   Use the provided segmentation tools to mark the finding on the latest study and then:

   – Continue editing the lesion until satisfied. See section “Editing Tools” on page 158.
   – Match the new lesion to previously segmented lesions, if relevant. See section “Operations on Findings” on page 164.
   – Use the Properties dialog to label lesions, select the lesion type and mark changes. See section “Lesion Properties” on page 162.

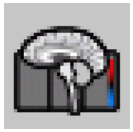
Results

1. View the **Results** tab by clicking on **Show Results**.
2. Review the tables and graphs.
3. Table reports can be exported to Microsoft Word® or CSV.
4. Save the results. (The segmentation and registration are saved for the next usage or follow-up study.)

Loading Patient Studies

1. Select appropriate studies from the Patient Directory.

   Up to 4 MR studies can be loaded and displayed.
2. Click the **Longitudinal Brain Analysis** icon to load the studies.



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NOTICE

Make sure that all studies belong to the same patient before launching the Longitudinal Brain Analysis application.

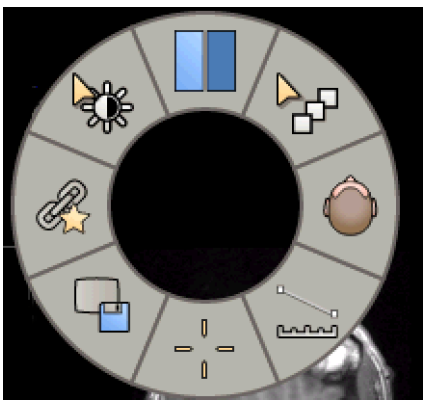
The application displays a warning message if you approve loading studies with different patient identification (may occur due to different spellings of patient name) to the application. The studies are treated as belonging to the same patient.

Segmentation

The Longitudinal Brain Analysis application opens with the default preset layout displayed.

The Longitudinal Brain Analysis screen displays the patient bar and workflow tools common to all Advanced Visualization Workspace applications. Below is a description of the Longitudinal Brain Analysis screen:

- **Upper toolbar** - Contains all the standard viewing tools that can be used during viewing
- **Control Panel** - Located on the left side of the screen. Contains application related selections on top (Presets/Layout selection and configuration), segmentation features, findings table in the middle, Comparison mode, fusion control panel when relevant and standard save buttons on the bottom (**Save Selected Image As**, **Save Display As** and **Save Results**.
- **Viewing area**: Has different organization depended on the mode:
  - **Multiple mode**: Longitudinal display of the launched time points, each time point uses a “Column”.
  - **Single mode**: Uses the whole viewing area for single studies, allowing the review of more series per study.
- **Context menu/Wheel** : The Context menu is represented as a wheel in Longitudinal Brain Analysis. The options that appear on the wheel are dependent on the location of the cursor when the right mouse button is clicked. The wheel contains the relevant tools for the current selection.



When lesions are selected, the content of the wheel changes to contain only the valid operations for the selected objects (similar to standard context menu).

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When opened on a general viewport without a selection, the default wheel appears, providing access to the main common viewing operations and to the segmentation tools.

In the Segmentation Work Stage you will:

- Select the Preset 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.

Workspace Preparation

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

- Select the relevant Preset from the drop down list (or select  **Configure Presets**)
- If necessary, use the Series List to change the series selection. See section “Series List” on page 149.

Manage Presets- The **Manage Presets** Protocol function allows you to create your own customized preset protocols, to handle exceptions. See section “Configuring Presets” on page 144.

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 a set of hanging layouts. Hanging layouts define the content of the viewports and which data type should be displayed. It is possible to define several hanging layouts per Preset.

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In order to create meaningful hanging layout, it is important to first define the “Data types” that should be included. The basic data types (T1, T2, Flair) are defined by the application.

1. Select a preset from the Preset list. This is a drop-down list of predefined (factory) application presets.
2. If required, select a different hanging layout from the dropdown list.

To create a new Preset, see section “Configuring Presets” on page 144.

To manage Data Types, see section “Managing Data Types” on page 145

Configuring Presets

Presets in Longitudinal Brain Analysis provide an easy way to customize the application to your needs. The **Configure Presets** function allows you to create preset behavior of the application, that changes according to the loaded data.

Shared Presets

Users can create a new preset, which is defined as a **Site** preset.

Site presets are seen by all Advanced Visualization Workspace users.

NOTICE

Factory presets cannot be edited or deleted.

The Configuring Presets includes the following steps:

1. Creation of a new preset
2. Association with a hanging layout and specific data type

The Preset Editor page is divided into three sections.

- **Preset Information/Definition** - The left section displays the existing Preset Names, Modalities and Sharing Status (Factory or Site). It is possible, create a new preset, rename an existing preset or remove a preset.
- **Layout/Properties Information/Definition** - The middle section displays the hanging layouts that belong to the selected preset. It is possible to add a new hanging layout, rename a layout or remove a layout.
- **Datatype/Viewport Information/Definition** - The right section displays the viewports and what data type appears in which viewport and which combination of data appears as part of the preset.

Creating a New Preset

To create a new Preset:

1. Click on the **Configure Presets**  button.

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2. Click **New preset**.
3. Type a Preset Name for the new preset.
4. For Access Level, select **Site** in the drop down list. This preset is can be used by all Advanced Visualization Workspace users.
5. Click **OK**.
6. Select the default hanging layout. **To create a new hanging layout**:.
   - Select **New Hanging**.
   - Type a Hanging Name and click **OK**.
7. Select the Datatype(s) that you want to appear in the viewports.
8. Click **Save**.

Modifying a Preset Layout

To modify a Preset:

1. In the **Preset Editor**, select the Preset that you want to modify.
2. Select a different Hanging Layout in the middle column.
3. For each viewport define the underlay data type in the right column.
4. Click **Save**.

Deleting a Preset

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

Philips installed factory protocols cannot be removed or edited.

Renaming Presets

To rename a Preset:

1. In the **Preset Editor**, select the Preset that you want to modify.
2. Select **Rename**..
3. Type a new name.
4. Click **OK**.
5. Click **Save**.

Selecting the **Manage Data Types** button opens the Data Type Editor table.

Managing Data Types

Managing Data Types allows the association of a series to a specific data type.

The Data Type Editor displays a table showing 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, FLAIR, T1, T2, ADC, DWI etc.

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The user can change the associated data type for a series to another existing and valid data type, using the drop down list in the table, or create a new data type which would be associated to the selected series.

The data type association table includes the following columns:

- **Series Number** - Series number
- **Study Date**
- **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.

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. 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.

Creating a New Data Type

1. Click on the  **Manage Data Types** button. The editor opens to the **Data Type Editor** page with the Data Type Association table.
2. Click the **Create New Data Type** button.

   The **Create New Data Type** dialog appears.
3. Type a **Data Type** name.
4. Choose the **Access Level** from the drop-down list (User or Site).
5. Press **OK**.

   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. Click on the  **Manage Data Types** button. The editor opens to the **Data Type Editor** page with the Data Type Association table.
2. In the Data Type Editor page, select a series and press the **Manage Data Types** button.
3. To delete a Data Type, in the **Manage Data Types** window, click **Delete Data Type**.
4. Click **OK**.
5. To delete a Description, select the Description in the **Manage Data Types** window and click **Delete Description**
6. Click **OK**.
7. Click **Save** to save your changes. The changes are reflected in the Data Type Editor.

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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.

Supported Data Types

- Flair
- T1
- T2
- ADC
- DWI
- SWI
- MR

Viewing Tools

Icon	Description
	Axial Viewing Orientation
	Coronal Viewing Orientation
	Sagittal Viewing Orientation
	Reset Original Viewing Orientation - Returns to the original acquired orientation. This is helpful in single mode.
	**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.
	**Previous time point** (available only in the Single time point mode) moves to the previous time point in time.
	**Next time point** (available only in the Single time point mode) moves to the next time point in time.
	**Enable/Disable Links** - When **Link** is clicked, viewport navigation is linked between all displayed data, according to the registration method used.
	**Show Series List** toggles between show and hide the series list. For additional information see section “Series List” on page 149.
	**Show/Hide Reference** adds the reference images to each displayed view port, with no dependence on the hanging layout or the time-point layout.

Icon	Description
	**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. Relate between studies is functional only when the studies are registered.
	**Show Crosshair** - Shows/hides crosshairs on all reference images. When Links are enabled, all crosshairs move as one. When Link is disabled, they can be moved independently.
	**Compare Images/Select for Comparison** - Used to select images for comparison and to activate image comparison operation. See section “Compare Mode” on page 151.
	**Show/Hide Segmentation** - This is used to show/hide lesions and their contours on all images.
	**Same Anatomy Size** - Makes the images from two different studies the same anatomy size.
	**Registration Alignment** - Transforms images in the follow-up studies to be aligned with the baseline according to registration. **Note**: Transformation may cause blurring (reduced image quality), resulting in a in low resolution image, since slices are “reformed”.
	**Enable/Disable Registration** - Toggles Automatic Registration on and off.
	**Re-apply registration** – Applies automatic registration on the displayed images. This can be used when the user changes the default layout.

General Viewing

WARNING

When scrolling using Scroll (the left mouse button or Ctrl + left mouse button), some slices may be skipped. The extent of skipping depends on the quality of the network connection. For continuous scrolling use the scroll wheel.

Icon	Description
	Scroll (see above warning)
	Pan
	Zoom
	Zoom to Point

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Icon	Description
	Change Window Level
	Invert Gray Level

Annotations

Icon	Description
	Straight Line
	Angle
	Ellipse
	Pixel Value
	Arrow and Text
	Text

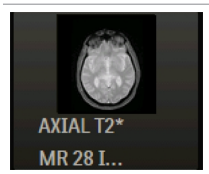
Series List

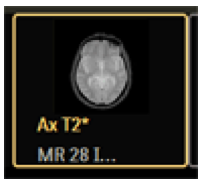
The Series List provides tools to choose the studies and series to be displayed in the viewing area.

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		
	No frame	This series is not displayed

	Gray title and frame	This series is displayed
	Orange 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.

Register Examinations

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

Automatic Registration

Automatic registration occurs between the series of each time point based on rigid MR registration with optimized parameters for brain MR.

NOTICE

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

If you deselect the Automatic Registration button, there will be no link between the exams.

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.

1. The **Enable/Disable Registration** button is applied automatically as soon as registration succeeds.

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2. Turn off Automatic Registration by clicking the **Enable/Disable Registration** button.

If studies are not linked, **Enable/Disable Registration** is disabled.

Registration Alignment

Registration Alignment transforms images in the follow-up studies to be aligned with the baseline according to registration.

Re-apply Registration

Re-apply registration – Applies automatic registration on the displayed images. This can be used when the user changes the default layout.

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.

NOTICE

When a 2D image is transformed, a reduction in resolution may occur.

Compare Mode

The Longitudinal Brain Analysis application allows the user to view images and perform segmentation of lesions, using segmentation editing tools and volumetric quantification of segmented volumes and quantitative comparison between time points.

The Longitudinal Brain Analysis application includes a supportive tool (CoBI) for the visualization of differences in MRI images by highlighting intensity differences.

The Longitudinal Brain Analysis application, using the CoBI feature, takes two MR images, performs the Bias Field correction, Registration and Intensity Normalization and finally subtracts them, creating the color overlay image. The algorithm is mathematical and deterministic: it will produce exactly the same results when repeated for the same two images.

The Longitudinal Brain Analysis application does not provide any interpretation of the highlighted intensity differences between the two images. Interpretation is performed only by the physician.

CoBI provides the user further assistance in visualization of the images. The user retains the ultimate responsibility for making the decision whether the images presents a clinically meaningful change.

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WARNING

The Longitudinal Brain Analysis application provides a supportive tool (CoBI) for visualization of differences in the MRI images by highlighting intensity differences. The CoBI feature highlights the intensity differences between two images and does *not* distinguish or interpret between noise/artifact/real anatomical changes. The CoBI functionality does not distinguish between intensity differences coming from real anatomical change and intensity differences coming from MR artifacts or other noise sources such as patient positioning. It is the user's responsibility to analyze and interpret the highlighted differences and to decide if it is a clinically meaningful change or not.

CoBI allows the comparison and viewing (side-by-side) of two selected series, with the subtracted volume appearing as a subtraction overlay.

The Compare functionality offers a mathematical subtraction of scans taken at different time points yielding, after bias-field correction and intensity scaling, a color-coded signal for the difference in intensity between two registered scans.

The resulting volume is displayed with different color map options as an overlay on the baseline image which is used as an underlay below the result volume (in fusion mode). The result volume and original volumes are linked and you can navigate in the volumes in a synchronized manner.

It is possible to manually refine the registration between the two originals and to re-apply the mathematical operation.

The subtracted volume is displayed in colors based on the selected color map (either **Red Blue [Linear]** or **Heat Color Map**). Color maps can be selected from a drop down list located to the right of the  icon.

The colored area indicates regions of difference between the series. This technique allows the physician easy and quick detection of subtle differences between the images, facilitating easier estimation of differences.

The colored image displays the subtraction results between the two images after they are normalized and registered. The values, which are positive or negative, are shown in colors and possibly indicate the differences between the images.

Different acquisition parameters, resolution, orientation may lead to artifacts in the subtracted results.

CoBI can highlight an intensity difference for an area with a minimum size of 1 mm assuming:

- The resolution of the images is greater than or equal to 1 mm.
- Comparable data is used and normal performance of motion and intensity correction.
- There is actual visible differences in the images.
- The intensity difference of that area is above the threshold, set by default to 10% of the maximum difference range after the 2 percentile outlier removal.

Based on the above assumptions, the lower limit for the minimum lesion size that can be detected and monitored is in the range of the normal scan resolution of approximately 1 mm.

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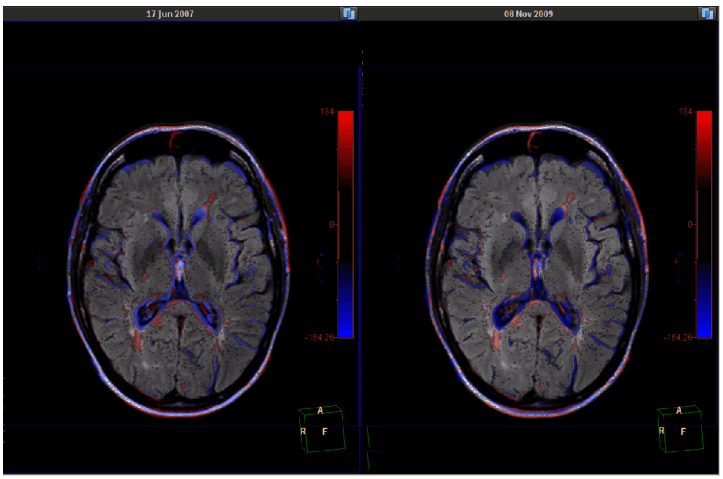
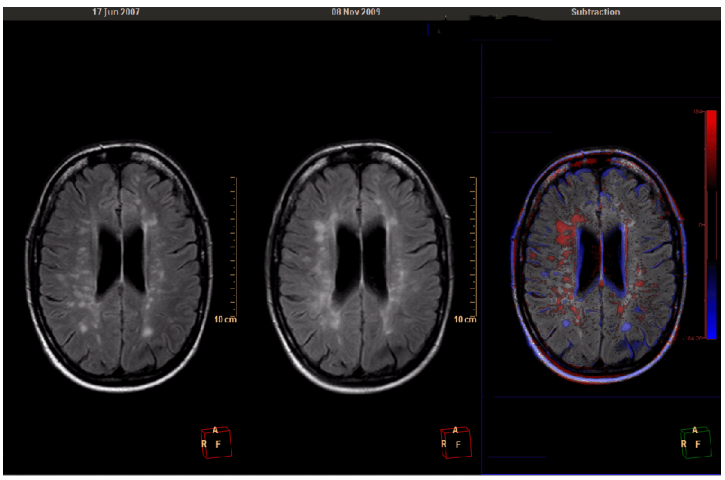
Compare Mode Layouts

There are two layouts available in Compare mode:

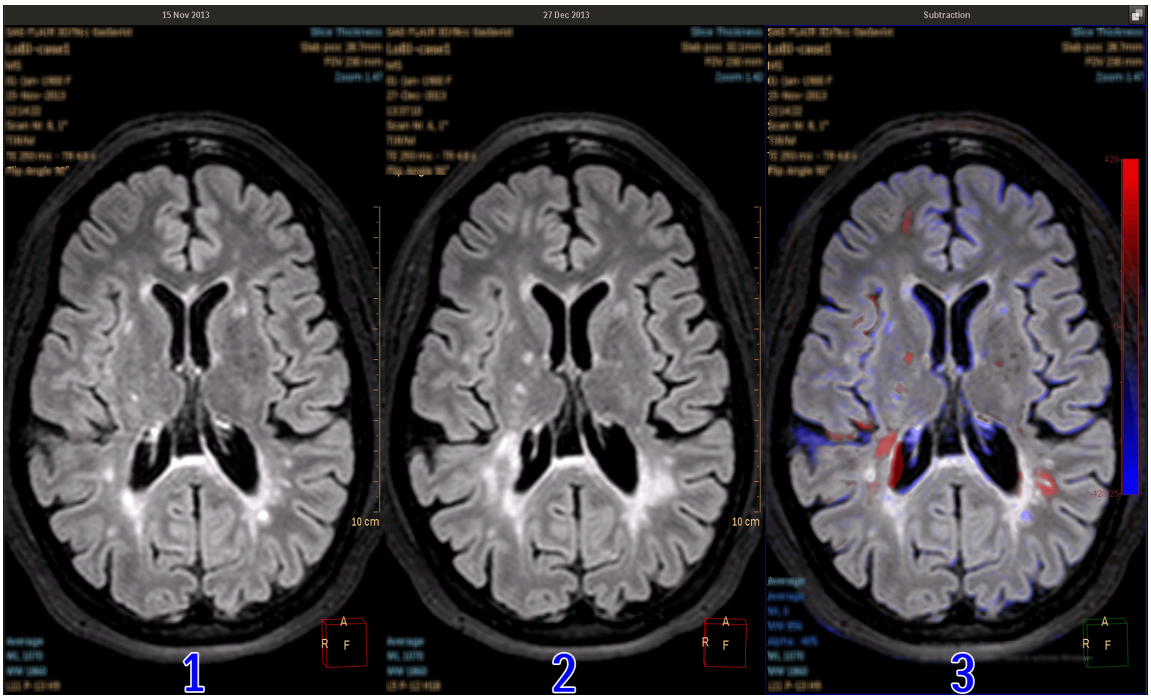
- **Compare** - Displays the baseline and the follow-up positioned side by side with the subtracted image as an overlay (or vertical). Toggle the overlay on/off on each of the images using the  **Show/Hide Subtraction Overlay** icon appearing to the right of the date. When user clicks on the  icon, the subtracted image is displayed as an overlay above the image (in fusion mode) . When the subtracted image is shown , the user is able to control the opacity (alpha blending) of the overlay image.



- **CoBI** - Displays the two originals and the fusion between the baseline and the subtracted results, side-by-side.



CoBI is designed to highlight intensity differences by drawing attention to them. This is done via a mapping color scale, representing the range of intensity differences in the subtracted image. The color map range is suggested by the application. The user can modify the color map by increasing or decreasing the range. The figure below provides an example of a CoBI baseline image (#1), follow up image (#2) and an overlay image of the subtraction result (#3 -CoBI output). The underlay is the baseline image.



The overlay on the right image (#3) is a colored image of the subtraction result between the follow up and base line (#1 on left side)

The opacity is changing gradually from the edges towards the center. The color scale has a color opaque where the intensity differences are greater (closer to the edges), while the color scale turns transparent where the intensity differences are smaller. Color is stronger where the intensity differences are greater. The user should interpret the presented differences and make the decision based on the presented three images, baseline image, follow up image and the overlay image.

Entering Compare Mode

To enter Compare Mode:

1. Select two images from different time points (same image types) by pressing **<Ctrl>** + clicking on the view port.

   The selected viewports are marked with an orange square  .

   Once two viewports are selected, the **Compare Images** button is enabled.

2. Select either  in the Context wheel or the **Compare Images** button to start the Compare operation.

   The two selected images are displayed in the two view ports (side by side or one above the other).

3. The resulting volume is displayed with different color map options. The results volume and original volumes are linked and you can navigate in the volumes in a synchronized manner.

The following operations can be performed in Compare mode:

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- Control the window level of the overlay and the range of the transparent part in th overlay color map
- Select the preferred color map between a given list of color maps (which fits the subtraction functionality)
- Simultaneously scrolling compared images.
- Simultaneously Pan/Zoom the compared images.
- Use the relate option to locate lesions exposed by the subtraction.
- Measure the differences in volume by segmenting lesions on the images and reviewing the differences.
- Choose between the compare mode layouts, 1x2 (for a vertical monitor) or 2x1 (for a horizontal monitor).
- Show three reference images: Axial, Coronal and Sagital without fusion

NOTICE

Please note in the Subtraction viewport, if the compared images are not similar (different resolution, orientation, etc) a yellow  or red warning traffic light appear at the top of the viewport. Please click on the light and review the information provided. Note that a warning traffic light will not appear in all instances of sub-optimal subtraction.

WARNING

When using Compare mode, the Subtraction viewport provides assistance and should *not* be used as the sole basis for diagnosis.

Edit Registration

If the user is not satisfied with automatic registration, select **Edit Registration** button in the Control Panel which leads him to the Edit Registration mode. In this mode – the user can refine the registration using pan and rotate tools on each of the orientation

The **Edit Registration** button in the Control Panel is disabled (near the **Compare Images** button) and is only enabled when two images are selected in Compare mode.

Edit Registration is enabled only when in Compare mode.

All changes performed in this mode, impact Compare mode.

Pressing the  Reset button, at any stage, re-applies automatic registration between the selected images.

To return to Compare mode, press **Edit Registration**.

When user presses the **Edit Registration** button, the application enters the **Refine Registration** mode on the two selected images.

When in refine registration mode the two selected images are displayed fused on the main viewport, while the three reference images (axial coronal sagital) are displayed near the main image in fusion mode as well.

Refine registration manually by moving the overlay image on relatively to the underlay image.

The following operation are available in this mode:

- Pan
- Rotate
- Fine tuning operation operators
- Undo/Redo
- reset the registration back to the original calculated registration

When leaving the **Edit Registration** mode, all actions that were performed to refine registration are saved by the application and applied.

When exiting **Edit Registration**, the application uses the updated registration value to subtract again the images based on the refined registration

When exiting the **Edit Registration** mode, the refined registration values shall be preserved and used by the application for these two images

Segmentation Tools

The application provides two tools for volumetric segmentation. Both tools are based on image processing techniques and can be used according to the nature of the image.

-  **Seed Point Segmentation**
  - Works on both bright and dark lesions.
  - Using an algorithm based on calculating an adaptive threshold based on the cursor location, it tries to automatically find the edges of the lesion.
  - To set the lesion threshold for Seed Point Segmentation on a dark or bright lesion, hold down the **<Shift> key** + **Mouse wheel**.
  - There is a limiting sphere (user can change its size) that limits the range of the lesion. The lesion boundaries will be found only inside the sphere. The sphere size can be increased or decreased using the **<Control> key** + **Mouse wheel**.

    When reference images are displayed, the preview is displayed on all of the images.

    When you click on the lesion, it is actually segmented.
-  **Smart ROI Segmentation**
  - The standard smart ROI tool
  - Works on all tissues (dark or bright)
  - Click and drag the mouse. An interactive "balloon" tracks the tissue limits.

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Once the user selects a segmentation tool, he can continue to use it. The application automatically decides if the new finding should be joined to an existing finding (based on amount of overlapping) or to create a new finding. A message appears inquiring whether you wan to match the lesions.

Use the Escape key to exit segmentation.

When lesions are selected, the content of the Context wheel changes to contain only the valid operations for the selected objects. See section “Editing Tools” on page 158.

Once a lesion is segmented, the tissue of the segmented lesion appears as a blue colored overlay on the image.

When a lesion is selected, hovering over the contour activates the contour editing tool.

Use **Hide Segmentation**  to hide the entire lesion, along with its contour.

To change the transparency (opacity) of the tissue, use the slider in the left panel.

Automatic Propagation

The automatic propagation option allows you to automatically propagate a finding to the following time points based on the registration and the segmentation tools used. This works only on Seed Point segmentation and provides a preview of propagation.

- When a preview of a lesion is shown, pressing **<Shift>** displays a preview of the propagated lesions.
- Automatic propagation is applied only when a lesion is segmented using **<Shift>** + click.
- If the preview of the propagated lesion is not acceptable, using simple segmentation (without using the **<Shift>** key) segments the lesion on the viewport.

Automatic propagation is only available when automatic registration is enabled and registration is selected.

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 in all studies.

Editing Tools

The user can edit an existing lesion by selecting a lesion on the image and using the wheel context menu to access the editing tools.

The following editing tools are available:

	Add to Smart ROI
	Remove from Smart ROI
	Undo
	Redo

Flair-star Method for Multiple Sclerosis (MS) Differential Diagnosis

The Central Vein Sign (FLAIR-star) is a post processing method to ascertain Multiple Sclerosis (MS) lesions from Non-MS lesions in the brain. Multiple Sclerosis is defined as an inflammatory autoimmune neuro-degenerative disease of the central nervous system, characterized by inflammation, demyelination, gliosis, and neuro-axonal loss in lesions.

The FLAIR-star method is intended for viewing and comparing one plane with two orthogonal planes to confirm the presence of vein sign in the suspected lesions.

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Typically, MS Lesions exhibit the following characteristics:

- Lesions appear with a thin hypo-intense dot/line inside.
- Lesions can be visualized on at least two perpendicular planes.
- The lesion has a small apparent diameter of >3mm.
- The hypo-intense line runs partially or fully through the lesion.
- The hypo-intense line is positioned centrally in the lesion, meaning equidistance from the edges.

NOTICE

For optimal multiplication results, it is recommended to scan 3D Flair and 3D SWI-EPI sequences one after another, without any patient motion between the two scans.

NOTICE

For smooth registration and window normalization, it is recommended that:

- The SWI image has a thickness of ≤1.5mm
- The Flair image has a thickness of ≤ 1.5mm

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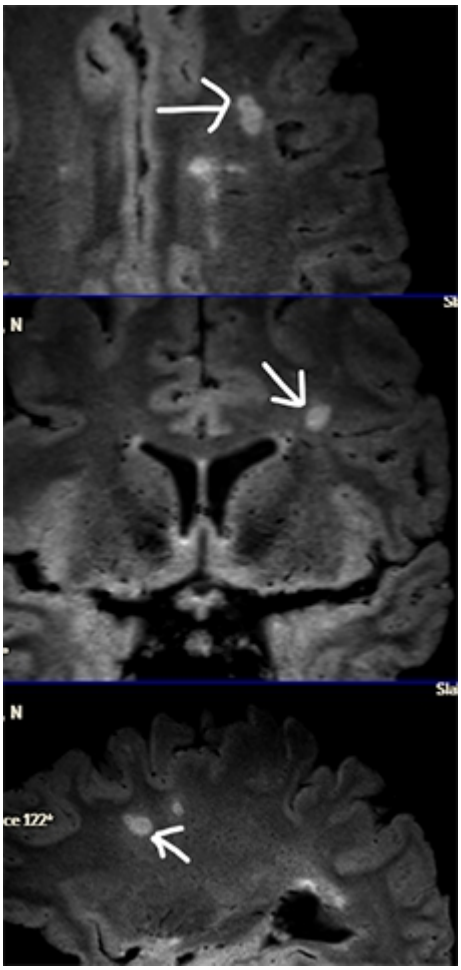
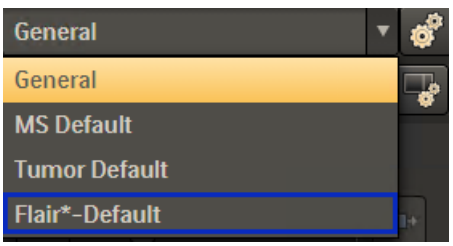


Fig. 42: Example of Typical MS Lesions

Launching the Flair-star Method

Registration is launched by selecting a new hanging protocol (HP): **Flair-star-Default** inside the list of default HP.



Registration can be performed for both single and multiple studies but only between scans of the same time point.

Prerequisite: Data Labeling

Before starting registration, it is necessary to check data labeling for correctness and mark the relevant series as Flair or SWI.

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This activity is done once. The application automatically marks similar scans in the future via semantic labeling.

The labeling window is accessed via the  **Manage Data Types** icon in the left panel. See section “Managing Data Types” on page 145

Workflow

Once the data is correctly labeled, perform the following (similar to Longitudinal Brain Analysis Comparison mode).

1. Select the first viewport with relevant image.
2. Open the context menu and select **select SWI image for FlairStar**.
3. Select the second view port and select **select Flair for FlairStar**.

NOTICE

It is also possible to select a viewport and use **< Ctrl><+>** to select a second viewport. Then select the **FlairStar Mode** option from the context menu to launch the multiplication feature.

Comparison Mode

- Once registration and multiplication are completed, the resulting image and two other images are displayed side by side with their descriptions at the top of each viewport.
- Scroll through the images and adjust windowing and alpha to modify image contrast if necessary.
- The application can display all three planes of each image type in this layout or you can switch to a 3x3 layout.
  - In this layout compare all images across all planes.
  - Pan and Zoom functionality is linked across rows.
  - Windowing is linked across columns.

Saving Images

The resultant series can be saved as:

- **Save FlairStar Series**: Batch with new series number (original series)

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- **Save Selected image as**: DICOM or non-DICOM
- **Save Display as**: DICOM and non-DICOM

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.

An indication of in the Finding List displays how many follow ups are matched to a specific finding.

Mark New Finding

Use the tools described in section “Segmentation Tools” on page 156 to mark new findings.

Once a lesion is segmented, it is assigned a number and is placed in the Findings list.

When marking new lesions, if a lesion 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.

Lesion Properties

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

- **Name** - 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.
- **Lesion Type** - Allows the user to select a lesion type. Options include: **Lesion** or **MS Lesion** , **Tumor**, **Cavernoma**, **Bleeding** and **Edema**.
- **Lesion Location** - Allows the user to select from a list of relevant locations.
- **Lesion Changes**- Display a graph with the history of the lesion and allows you to mark lesions as: **LesionAppeared, Increased, Significant, Increased, Decreased, Significant Decrease, Stable, Disappeared**
- You can change the **Lesion Change** value. If the lesion disappeared in a study, you can mark it as **Disappeared**. The application uses a volume of **0** for this date.
- **Comments** - Allows the user to type relevant comments.

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NOTICE

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

Select **Save** once entering all of the information.

Working with the Findings List

Once lesions are segmented, they are identified in the Control Panel 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.
- 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 Properties).

Each Finding Lists includes the following columns:

- Finding Icon - represents the status of the finding, such as Tumor .
- **Lesion Name** - Name defined by the user in the Properties dialog. If not defined, lesion are numbered and marked according to defined properties. up to five characters can be displayed.
- The number in parenthesis represents the number of times the finding appeared during all follow-ups (based on loaded results or current segmentation).
-  **Check Mark** - Indicates whether the finding is already defined in the latest study, whether segmented or disappeared.

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 down 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.

Open Properties Dialog - Opens the Lesion Properties Dialog (see section “Lesion Properties” on page 162). This is enabled only for a single selection and only for lesions 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.

Review Results Work Stage

Results are viewed by selecting **Show Result...** in the left panel.

The application displays the measured results over time in a graphic (Volume and Total) and table format.

Each lesion appears in a separate line in the table, with the first column of the table displaying the name of the lesion.

Addition columns display lesion measurements per date.

Graphs and Tables

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

- Each measurement is represented by a dot in the graph, corresponding to a specific lesion in the loaded studies.

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

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.

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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.

Table Operations

Exporting Table Results

To export table results:

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

   Select the **Copy to Clipboard**.

2. Open either Microsoft Word® or Excel® and paste the contents from your clipboard into the application.

Saving Images and Results

Save Selected Images - Saves the selected images as either:

- **DICOM** secondary captures in the original location of the study.
- **NON_DICOM** images (JPEG, TIFF or BMP formats) in the original location of the study.

Save Display As - Save the Display as a secondary screen capture in the latest study.

Save Results As - Saves Results (with default name and location). Launching a study with a saved results series loads the segmented lesions and allows follow up,

Save Batch - Saves batches as defined by the user. Opens a dialog that allows the user to select the following:

- Type
- Adjust Range including Number of Image, Increments and Thickness.