

HERMIA



INSTRUCTIONS FOR USE

Hybrid Recon

Version 5.0.0



Document Name: P21-027 Instructions For Use Hybrid Recon 5.0.0 Rev.5_EN
Document revision date: 11/05/2026

This Instructions For Use (IFU) informs the user of the software's intended purpose, proper use, and any precautions that need to be taken and includes general product information and the information needed to identify the device and its manufacturer.

Any safety and performance information relevant to the user is stated in this IFU and residual risks are described. Study this manual carefully before using the software.

This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

This IFU contains WARNINGS concerning the safe use of the product. These must be followed.



This is the general warning sign.

NOTE: A note provides additional information to be aware of, for example, things to consider when performing a certain procedure.

The Instructions For Use and the medical device software itself are copyrighted and all rights are reserved by Hermes Medical Solutions. Neither the software nor the manual may be copied or in any other way reproduced without prior consent in writing from Hermes Medical Solutions who reserve the right to make changes and improvements to the software and the manual at any time.

Hermes Medical Solutions*, HERMIA*, the HERMIA logotype* and SUV SPECT* are trademarks of Hermes Medical Solutions AB.

Third-party trademarks as used herein are the property of their respective owners, who are not affiliated with Hermes Medical Solutions.

*Subject to registration in some markets

Table of contents

1	INTRODUCTION	3
1.1	GENERAL NOTES.....	3
1.2	REGULATORY INFORMATION	3
1.3	ASSOCIATED DOCUMENTATION	3
2	PRODUCT INFORMATION	4
2.1	INTENDED PURPOSE	4
2.2	INTENDED PATIENT POPULATION AND MEDICAL CONDITIONS	4
2.3	CONTRAINDICATIONS	4
2.4	PRODUCT LABEL.....	4
2.5	PRODUCT LIFETIME.....	5
2.6	COMPLAINTS AND SERIOUS INCIDENTS	5
2.7	HARDWARE AND OPERATION SYSTEMS	6
2.8	INSTALLATION.....	6
2.8.1	<i>Warnings.....</i>	<i>6</i>
3	SAFETY AND PERFORMANCE INFORMATION	7
3.1	LAUNCH	7
3.2	QUICK START	7
3.2.1	<i>Oncology Workflow</i>	<i>7</i>
3.2.2	<i>Neurology Workflow.....</i>	<i>15</i>
3.2.3	<i>Lung Workflow.....</i>	<i>24</i>
3.2.4	<i>Cardiology Workflow</i>	<i>33</i>
3.3	INTERFACE	43
3.4	SECURITY.....	44
3.5	WARNINGS	44
4	CONTACT INFORMATION.....	46
4.1	MANUFACTURER CONTACT INFORMATION.....	46
4.2	REGULATORY REPRESENTATIVES.....	46
4.3	SUBSIDIARIES.....	46
5	APPENDIX 1 - USER TRAINING REQUIRED CONTENT	47
6	APPENDIX 2 - WARNING MESSAGES IN THE APPLICATION.....	48

1 INTRODUCTION

1.1 General notes

Modification of the product is not allowed and may result in hazardous situations.

Only properly trained service personnel by an authorized dealer or by Hermes Medical Solutions shall perform installations, and service of this product.

All users need to be trained, by personnel from an authorized dealer or by Hermes Medical Solutions, in the basic functionalities of the software before use. See list of basic functionalities in *Appendix 1 - User Training Required Content*.

User provided protocols, scripts and programs are not validated nor warranted by Hermes Medical Solutions. The party using such programs is solely responsible for the results.

Hermes Medical Solutions takes no responsibility for loss of data.

The users of the software are solely responsible for its use and for the resulting diagnoses. Hermes Medical Solutions takes no responsibility for any results and diagnoses derived from using the program described or from information in this manual.

1.2 Regulatory information

Europe - This product complies with Medical Device Regulation (MDR) 2017/745. A copy of the corresponding Declaration of Conformity is available on request.

European SRN number

The single registration number (SRN) = SE-MF-000023032 has been issued to Hermes Medical Solutions, as required by the EU MDR – Regulation (EU) 2017/745.

Canada - the Device identifier, as defined with Health Canada, is the first two numbers in the release version number.

1.3 Associated documentation

- P21-050 Release Notes Hybrid Recon 5.0.0 Rev.5
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

A user guidance, intended to assist users in using the software, is available from the Help function in the software itself.

2 PRODUCT INFORMATION

2.1 Intended purpose

Intended Use

Hybrid Recon is a software application for nuclear medicine. Based on user input, Hybrid Recon reconstructs nuclear medicine imaging acquisition studies. The results can be stored for future analysis. The software application can be configured based on user needs. Hybrid Recon can also optionally be used to assess the quality of the acquired studies and perform motion correction when required, as well as produce quantitative SUV (Standardized Uptake Value) reconstructed studies.

Intended User

The intended users of Hybrid Recon are medical professionals trained in using the system.

2.2 Intended patient population and medical conditions

Patients of any age and gender undergoing molecular imaging investigations.

All medical conditions for which nuclear medicine SPECT imaging is performed.

Examples of indications for which the reconstructed studies generated by Hybrid Recon may be used to inform patient management include assessment of cardiac perfusion, function and viability, assessment of brain function in patients with Parkinson's' disease or dementia, assessment in patients with infection, rare tumours and bone disease, and assessment of lung perfusion and ventilation in order to provide a definitive diagnosis of pulmonary embolism or lobar lung function.

2.3 Contraindications

There are no contraindications.

2.4 Product label

The version number, the Unique Device Identification (UDI) and other product data of an installed Hybrid Recon 5.0 software can be found by clicking on the Hermes Medical Solutions logo at top left of the application.

The following information can be identified:

Product name = Hybrid Recon

Release version = 5.0.0

Marketing name = Hermia SPECT Reconstruction

Software build no = 193

Rx Only "Prescription only" - device restricted to use by or on the order of a physician



Date of Manufacture (YYYY-MM-DD)



Unique Device Identification number



Indicates that the product is a medical device


 CE mark and the Notified Body number

 Consult Instructions for Use (IFU)

 The support email addresses

 Manufacturer's contact information

 Swiss authorized representative

 About this application

×

Product name: Hybrid Recon


Release version: 5.0.0


Marketing name: Hermia SPECT Reconstruction

 CE 2862


Software build no: 193


 only

 Medical device

 2023-12-20

 (01)00859873006196(8012)005000000

 eIFU indicator
<https://www.hermesmedical.com/ifu>

 support@hermesmedical.com
Canada: support.ca@hermesmedical.com
USA: support.us@hermesmedical.com



HERMES Medical Solutions AB
Strandbergsgatan 16
112 51 Stockholm
SWEDEN



CMI-experts, Grellinger Str. 40,
4052 Basel, Switzerland

OK

2.5 Product Lifetime

The lifetime of Hybrid Recon 5.0 is 5 years.

The lifetime of 5 years starts running when Hybrid Recon 5.0.0 has been manufactured (5 years from Manufacturing date of 5.0.0). Possible patches on Hybrid Recon 5.0 will have new manufacturing dates, but the lifetime will not start over from manufacturing of a patch.

During the stated lifetime, Hermes Medical Solutions maintains the safety and performance of Hybrid Recon 5.0. Patches are provided if necessary to maintain the safety and performance of the product.

2.6 Complaints and serious incidents

Report incidents and errors to our support, see *Contact Information*.

Any serious incident that has occurred in relation to the device must be reported to the manufacturer.

Depending on applicable regulations, incidents may also need to be reported to national authorities. For the European Union, serious incidents must be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

Hermes Medical Solutions welcomes feedback from readers of this manual, please report any errors in content or typography and suggestions for improvements to our support, see *Contact Information*.

2.7 Hardware and Operation systems

For general requirements, see applicable *PC-007 System Environment Requirements*.

2.8 Installation

Installation must comply with applicable requirements such as, but not limited to, system requirements, configuration, and licensing.

2.8.1 Warnings



Modification of the product is not allowed and may result in hazardous situations.



Only properly trained service personnel by an authorized dealer or by Hermes Medical Solutions, shall perform installations, and service of this product.



User provided protocols, scripts and programs are not validated nor warranted by Hermes Medical Solutions. The party using such programs is solely responsible for the results.



No other, than Hermes Medical Solutions approved, applications shall be installed on the computer device for which Hermes Medical Solutions applications are intended to be used. Use of other applications may result in impaired performance and, in the worst case, incorrect output data.

3 SAFETY AND PERFORMANCE INFORMATION

3.1 Launch

Select your SPECT (or multi-bed SPECT) and launch a Hybrid Recon application.

If a CT scan is available. Select your CT scan, your SPECT scan (or multi-bed SPECT) and launch a Hybrid Recon application.

3.2 Quick start

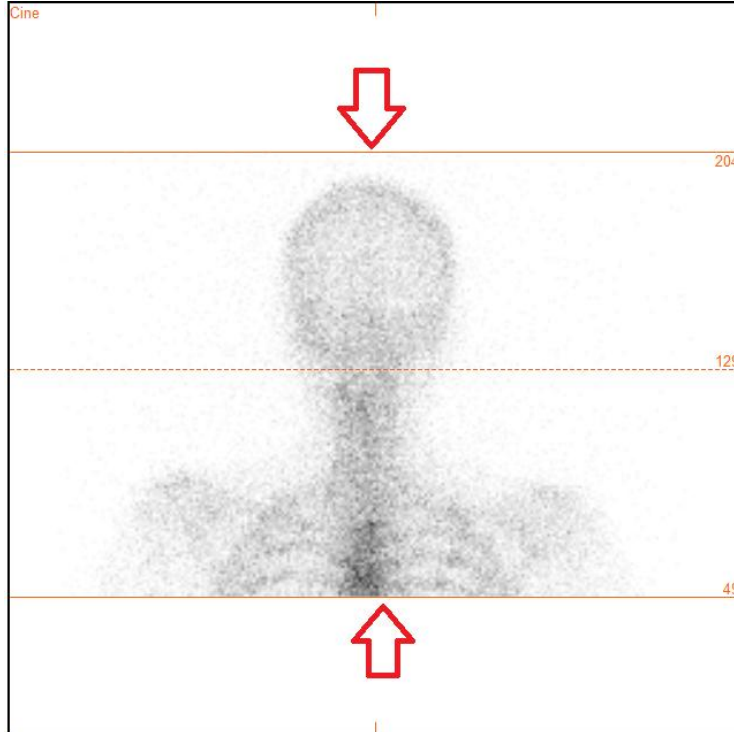
3.2.1 Oncology Workflow

3.2.1.1 Recon page

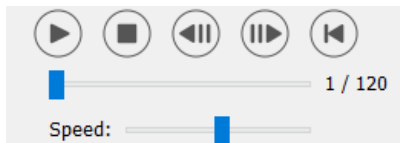
On the “Recon” tab, you may choose your reconstruction protocol by utilizing the dropdown box at the right side of the “Primary” recon protocol. It is possible to perform additional reconstructions of the same study, by turning on the “Secondary” and “Tertiary” radio buttons. You can choose the reconstruction protocol of the additional reconstruction by using the dropdown box next to the “secondary”, and “tertiary” reconstruction protocol.

The screenshot displays the 'Recon' tab of the Hybrid Recon application. At the top, there are three tabs: 'Recon', 'Moco', and 'Noise'. The 'Recon' tab is selected and highlighted with a red box. Below the tabs, the interface is organized into sections for 'Study 1' and 'Study 2'. For 'Study 1', there are three rows: 'Primary', 'Secondary', and 'Tertiary'. Each row contains a dropdown menu for selecting a reconstruction protocol and a 'Show' button. The 'Primary' dropdown is currently set to 'onco_rec_default' and is highlighted with a red box. Below these rows, there are two radio buttons: 'Secondary' and 'Tertiary', both of which are currently unselected. A red box highlights these radio buttons. For 'Study 2', there is a 'Primary' row with a dropdown menu set to 'onco_nac_rec_default' and a 'Show' button. Below this, there is a radio button labeled 'Link reconstruction limits with Study 1', which is currently unselected. At the bottom of the interface, there is a button labeled 'Perform reconstructions'.

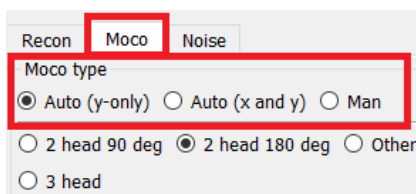
On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.



The cine of the SPECT projections can be started, stopped, moved forward, backward, or in reverse, using the media buttons "Play", "Stop", etc. You can evaluate any motion in the projection by referring to the "Sinogram" and "Linogram" pictures.



The "Moco" tab allows you to perform motion correction of the SPECT study. Three types of motion correction are available: "Auto (y-only)", "Auto (x and y)" and "Man". With the radio buttons, you can change the type of motion correction.



The "Auto" section will be available if an automatic motion correction type is selected. The "Start" button allows you to perform an automatic motion correction. The "Undo" button restores the original projections. The "Show" button allows you to display the "MoCo" window. When no motion correction have been applied, this button is grayed out.

Auto

Iterations:

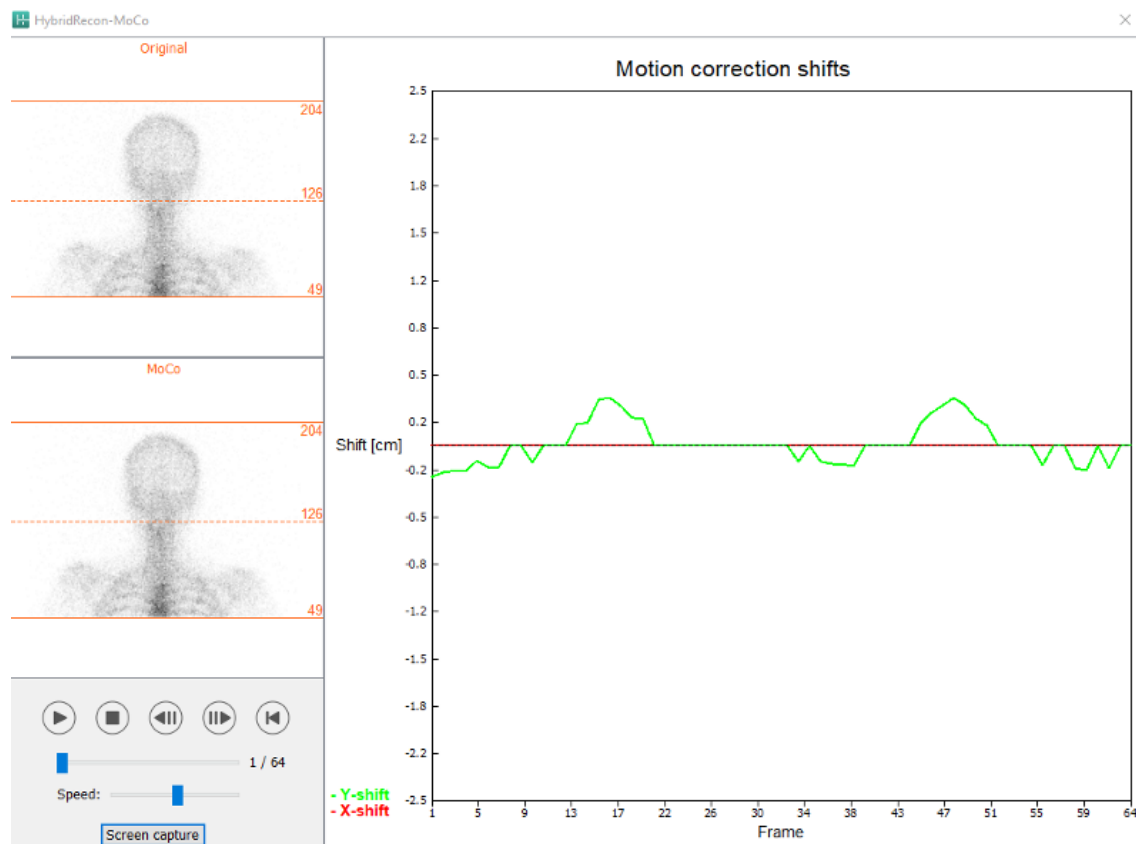
X-shift limit [cm]:

Y-shift limit [cm]:

Start **Undo** **Show**

Press "Start" to initiate automatic motion correction. A "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes made to your MoCo projection will be shown in this window. You may compare your original projections to your MoCo projections SPECT using the media buttons.

The "Screen Capture" button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo box.



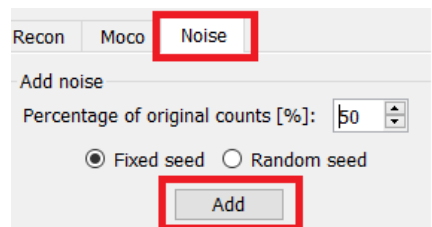
The "Man" section will be available if the "Moco type" is set to manual ("Man"). Your projection may be moved using the arrows. If the "One frame only" radio-button is toggled on, the change will be applied to only one frame. You may use the media buttons, the sliders or the mouse wheel (if your cursor is over the cine picture), to change the projection. You may select a range of projections to move manually by using the "From frame" and "To frame" fields.



You may save a copy of your motion-corrected projections by clicking the "Save" button. The "Screen Capture" button saves a screen capture of the cine, sinogram, and linogram pictures.

The "Moco" tool is grayed out if a multi-bed SPECT acquisition has been loaded.

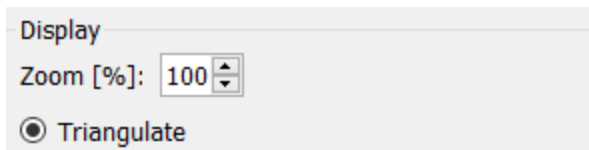
The "Noise" tab, allows you to add poisson noise to your projection.



3.2.1.2 SPECT-CT co-registration page

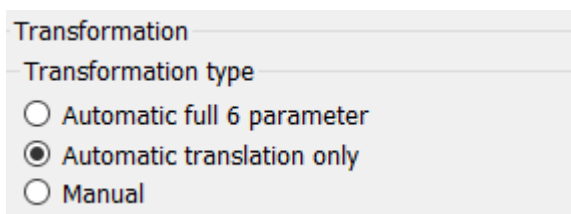
In the co-registration page, you will be able to perform a quality control check of your SPECT-CT alignment.

In the "Display" section, the "Zoom" field allows you to apply a specified zoom factor to your transverse, coronal and sagittal fusion views. When the "Triangulate" radio-button is active, you may triangulate in your TCS views by using a single left click on any view.



In the "Transformation" section, you can choose between three different alignment techniques:

- "Automatic full 6 parameter" allows you to perform an automatic co-registration of the X, Y, Z axis and rotations.
- "Automatic translation only" allows you to perform an automatic co-registration of the X, Y and Z axis.
- "Manual" allows you to perform a manual co-registration.

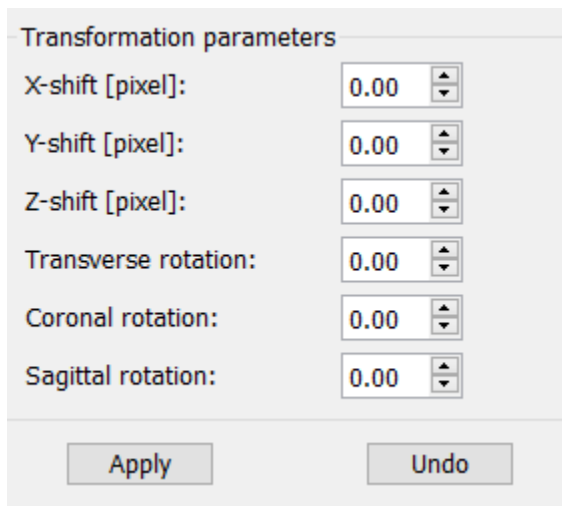


In the “Transformation parameters” section, the co-registration motion values will be displayed in the “X-shift”, “Y-shift”, “Z-shift”, “Transverse rotations”, “Coronal rotation” and “Sagittal rotation” fields.

The “Apply” button will perform the co-registration shifts. If an automatic transformation type is toggled, clicking on “Apply” will perform the automatic co-registration shifts.

If the “Manual” transformation type is toggled, values need to be entered manually into the “Transformation parameters” fields to allow shifts to be applied.

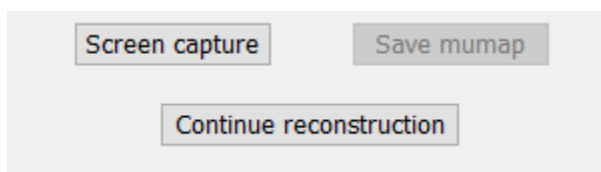
The co-registration shifts can be undone by using the “Undo” button.



The screenshot shows a panel titled "Transformation parameters" with six input fields, each containing the value "0.00" and a small up/down arrow icon. The fields are: X-shift [pixel], Y-shift [pixel], Z-shift [pixel], Transverse rotation, Coronal rotation, and Sagittal rotation. Below the fields are two buttons: "Apply" and "Undo".

When “Transformation type” is set to manual, you can drag the CT over the SPECT images by moving your mouse over the TCS views.

The “Screen capture” button allows you to save a screen capture of your co-registration shifts image. If the “Save mumap” option is enabled, the button will be active and will allow you to save a copy of the mumap. The “Continue reconstruction” button, allows you to continue the reconstruction process.



The screenshot shows three buttons: "Screen capture", "Save mumap", and "Continue reconstruction". The "Screen capture" and "Continue reconstruction" buttons are active (highlighted), while the "Save mumap" button is disabled (greyed out).

The "Color Table" dropdown menu in the "Emission study colors" section lets you change the SPECT color palette. The lower and upper threshold limits can be changed using the "LT" and "UT" sliders.

The "Level" and "Window" sliders in the "Transmission study colors" section, allows you to change the CT windowing. The “Alpha” slider allows to fade in between the SPECT on the left end and the CT on the right end.

The screenshot displays two sections of the software interface. The top section, titled "Emission study colors", includes a "Color Table" dropdown menu set to "Hot metal". Below it are two sliders: "LT:" with a blue marker at 0 and "UT:" with a blue marker at 100. The bottom section, titled "Transmission study colors", includes three sliders: "Level:" with a blue marker at 50, "Window:" with a blue marker at 500, and "Alpha:" with a blue marker at 25.

3.2.1.3 Filter page

There is an option to skip this page.

On the filter page, you may change the filter applied on your reconstructed SPECT.

You may select the dataset on which you want to apply the filter by using the "Dataset" dropdown menu in the "data" section.

In the "Display" section, the "Zoom" field allow you to choose the zoom applied on your right display splash view. The radio buttons labeled "Trans", "Coro", "Sag" and "TCS" let you choose which view(s) will be shown in the right splash area.

In the "Filter" section, you may change the filter type. Four types are available: Gaussian, Butterworth, Hanning and Hamming. The "FWHM [cm]", "Cutoff [1/cm]" and "Order" fields are available can be modified if needed. The available fields will be modified according to the filter type.

The "Apply" button will apply the custom filter changes to the SPECT dataset.

Recon **Filter** ReProj Results

Data
 Dataset: RR_ACSC Bone WB-tomo-Head - Be
 Show gate:

Display
 Zoom [%]: 100
 Trans Coro Sag TCS

Filter
 Filter type: Gaussian
 FWHM [cm]: 0.90
 Cutoff [1/cm]: 0.50
 Order: 10
 Apply

3.2.1.4 ReProj page

There is an option to skip this page.

This page is intended to generate reprojected statics/WB images from the AC SPECT.

In the “Protocol” section, the “Protocol” dropdown menu allow you to choose between different reprojection protocols. Clicking on the “Show Parameters” button will open a “Reprojection parameters” window allowing you to see which reprojection settings are configured for that protocol.

The reprojections will be generated when you click on the “Perform re-projection” button. The generated reprojections will be deleted by clicking the “Undo re-projection” button.

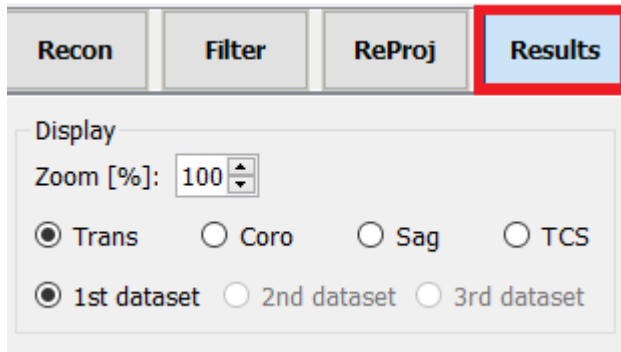
Recon **Filter** **ReProj** Results

Protocol
 Protocol: onco_reproj_default
 Show parameters
 Perform re-projection Undo re-projection

3.2.1.5 Results page

In the “Display” section, the “Zoom” field allows you to choose the magnification factor applied on your right display splash view. The “Trans”, “Coro”, “Sag” and “TCS” radio-buttons allow you to choose which view(s) will be displayed in the right splash section.

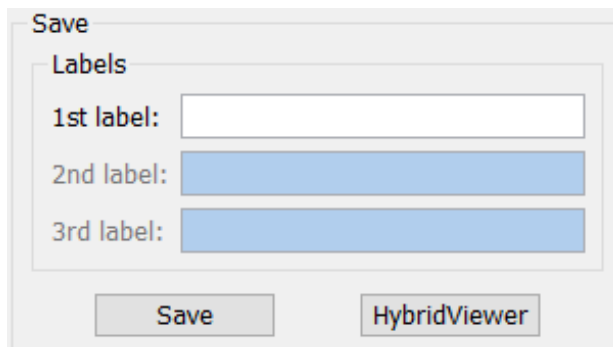
The “1st dataset”, “2nd dataset” and “3rd dataset” radio-buttons allow you to choose which series will be displayed in the right splash section.



The screenshot shows a control panel with four tabs: Recon, Filter, ReProj, and Results. The Results tab is highlighted with a red border. Below the tabs is a section titled "Display" containing a "Zoom [%]" field set to 100. Below the zoom field are two rows of radio buttons. The first row has radio buttons for "Trans", "Coro", "Sag", and "TCS", with "Trans" selected. The second row has radio buttons for "1st dataset", "2nd dataset", and "3rd dataset", with "1st dataset" selected.

In the “Save” section, you may enter a label into the “1st label”, “2nd label” and “3rd label” fields. After being saved, this text will be appended to the according SPECT series label.

You can save your reconstructions by clicking the “Save” button. You may display your reconstruction in an Hybrid Viewer application by clicking the “HybridViewer” button. This action may be done either before or after saving.



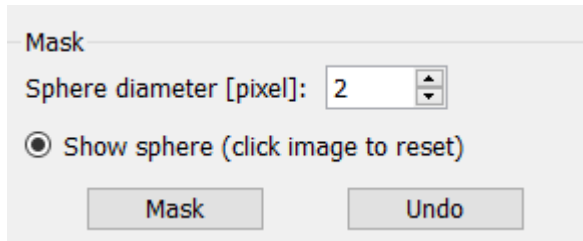
The screenshot shows a "Save" dialog box with a "Labels" section. It contains three text input fields labeled "1st label:", "2nd label:", and "3rd label:". The "2nd label:" and "3rd label:" fields are highlighted in blue. At the bottom of the dialog are two buttons: "Save" and "HybridViewer".

The “Mask” section allows you to mask a portion of your SPECT images using a spherical mask.

You may use the mask tool by clicking the “Show sphere” radio-button. Once the radio-button is active, a sphere will automatically be positioned at the position of the hottest pixel of your SPECT study.

The size of the mask sphere is controlled by the “Sphere diameter [pixel]” field.

The mask is applied to your SPECT by pressing the "Mask" button. The applied mask is removed using the "Undo" button.



Mask

Sphere diameter [pixel]:

Show sphere (click image to reset)

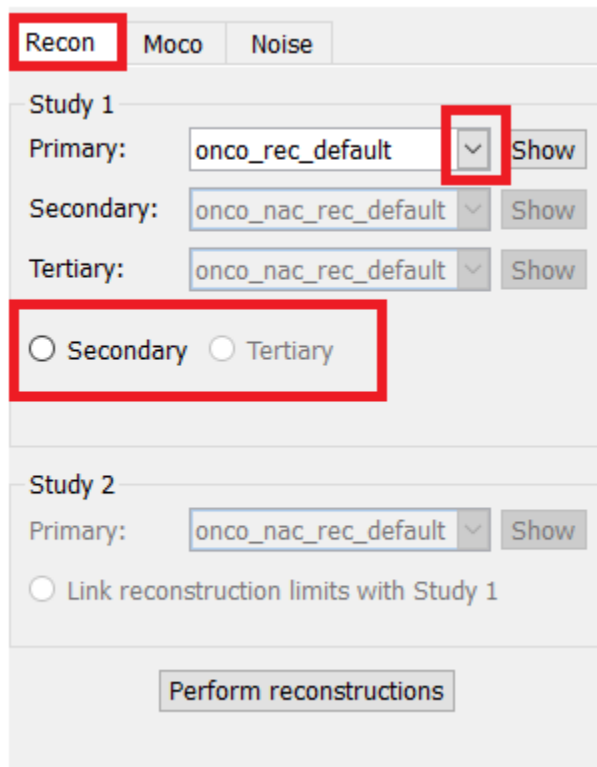
You may move the position of your spherical mask on your SPECT by doing a single click on your TCS views. By using your mouse wheel, you may scroll through your TCS single views.

3.2.2 Neurology Workflow

3.2.2.1 Recon Page

On the “Recon” tab, you may choose your reconstruction protocol, by utilizing the dropdown box at the right side of the “Primary” recon protocol.

It is possible to perform additional reconstructions of the same study. Turn on the “Secondary” and “Tertiary” radio-buttons. You can choose the reconstruction protocol of the additional reconstructions by using the dropdown box next to the secondary and tertiary reconstruction protocol.



Recon Moco Noise

Study 1

Primary:

Secondary:

Tertiary:

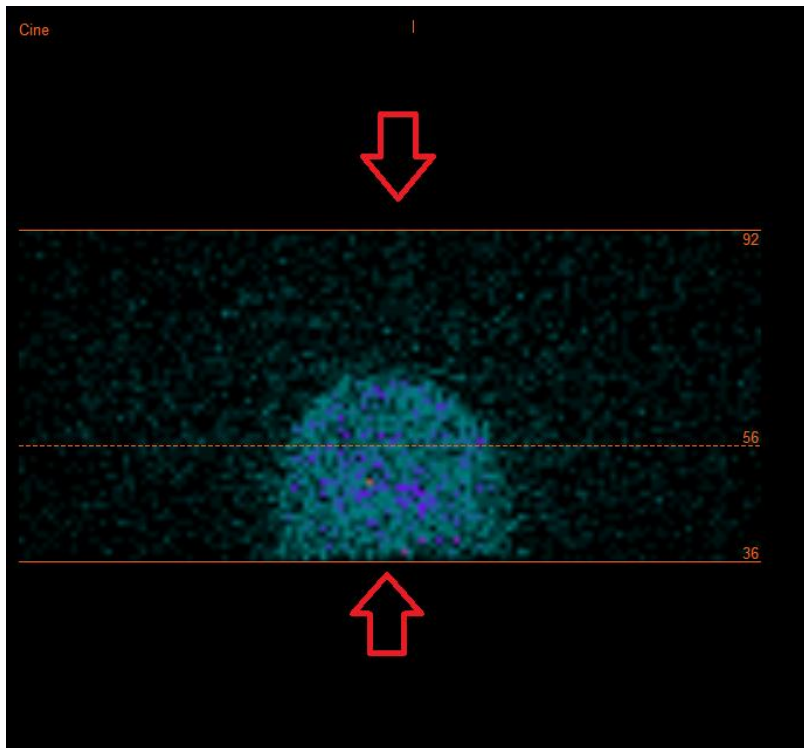
Secondary Tertiary

Study 2

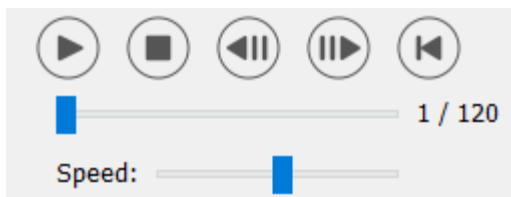
Primary:

Link reconstruction limits with Study 1

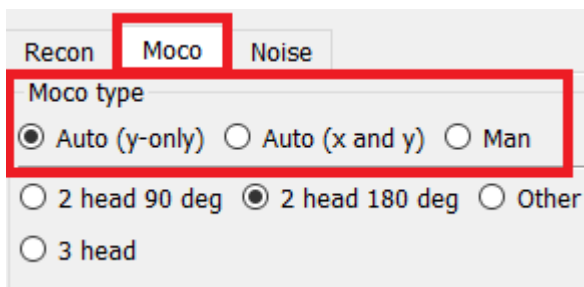
On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.



The cine of the SPECT projections can be started, stopped, moved forward, backward, or in reverse, using the media buttons "Play," "Stop," etc. You can evaluate any motion in the projection by referring to the "Sinogram" and "Linogram" pictures.



The "Moco" tab, allows you to perform a motion correction of the SPECT study. Three types of motion correction are available: "Auto (y-only)", "Auto (x and y)" and "Man". With the radio buttons, you may change the type of motion correction.



The "Auto" section will be available if an automatic motion correction type is selected. The "Start" button allows you to perform an automatic motion correction. The "Undo" button restores the original projections after applying the motion correction. The "Show" button allows you to display the "MoCo" window. When no motion correction have been applied, this button is grayed out.

Auto

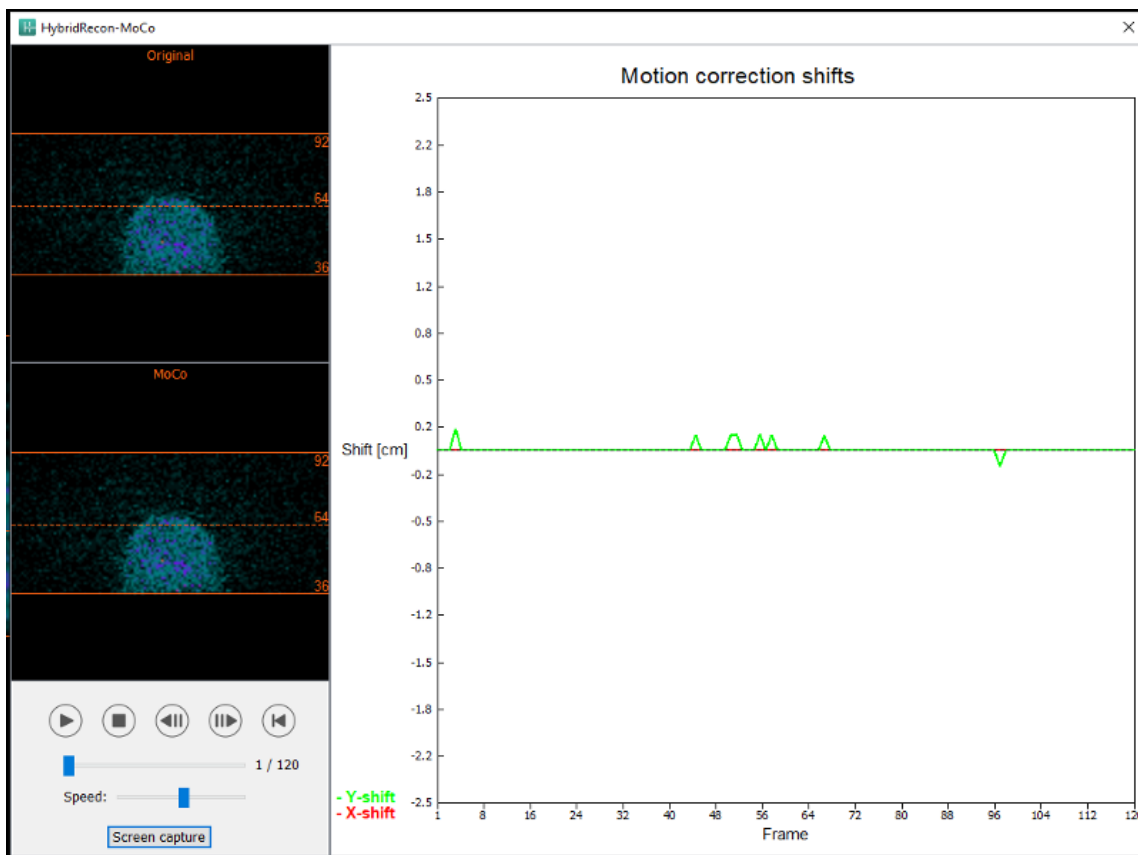
Iterations:

X-shift limit [cm]:

Y-shift limit [cm]:

Press "Start" to initiate an automated motion correction. A "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes, made to your MoCo projection, will be shown in this window. You may compare your original projections to your MoCo projections SPECT using the media buttons.

The "Screen Capture" button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo window.



The "Man" section will be available if the "Moco type" is set to manual ("Man"). Your projection may be moved using the arrows. If the "One frame only" radio-button is toggled on, the change will be applied to only one frame. You may use the media buttons, the sliders or the mouse wheel (if your cursor is over the cine picture), to change the projection.

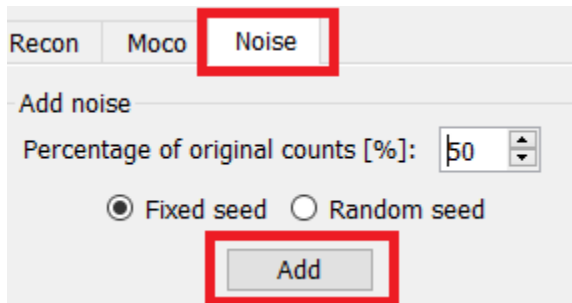
You may select a range of projections to manually move by using the "From frame" and "To frame" fields.



You may save a copy of your motion-corrected projections by clicking the "Save" button. The "Screen Capture" button saves a screen capture of the cine, sinogram, and linogram pictures.

The "Moco" tool is grayed out if a multi-bed SPECT acquisition has been loaded.

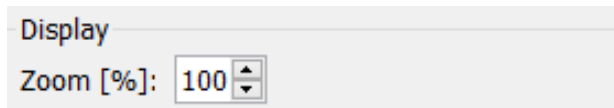
The "Noise" tab, allows you to add Poisson noise to your projection.



3.2.2.2 Uniform mu-map outline page

If a uniform attenuation map is used to performed the attenuation correction. A uniform mu-map page will be displayed.

In the "Display" section, the "Zoom" field allow you to modify the zoom factor of the displayed splash view.



In the "Outline" section, you may change the settings of the uniform map by using the "Outline threshold [%]" and "Outline filter FWHM [cm]" fields. The "Trace" button will set the contour of the uniform mumap, depending on the information provided in the above fields. The "Link outlines" radio-button allows you to move the uniform mu-map contour simultaneously on every slice.

The reconstruction process will continue once you click on the "Continue reconstruction" button. The "Screen capture" button will generate a screen capture of the uniform mu-map splash view.

Outline

Outline threshold [%]:

Outline filter FWHM [cm]:

Link outlines

3.2.2.3 SPECT-CT co-registration page

In the co-registration page, you will be able to perform a quality control check of your SPECT-CT alignment.

In the “Display” section, the “Zoom” field allows you to apply a specified zoom factor to your transverse, coronal and sagittal fusion views. When the “Triangulate” radio-button is active, you may triangulate in your TCS views by using a single left click on any view.

Display

Zoom [%]:

Triangulate

In the “Transformation” section, you can choose between three different alignment techniques:

- “Automatic full 6 parameters” allow to perform an automatic coregistration of the X, Y, Z axis and rotations.
- “Automatic translation only” allow to perform an automatic coregistration of the X, Y and Z axis.
- “Manual” allow to perform a manual coregistration.

Transformation

Transformation type

Automatic full 6 parameter

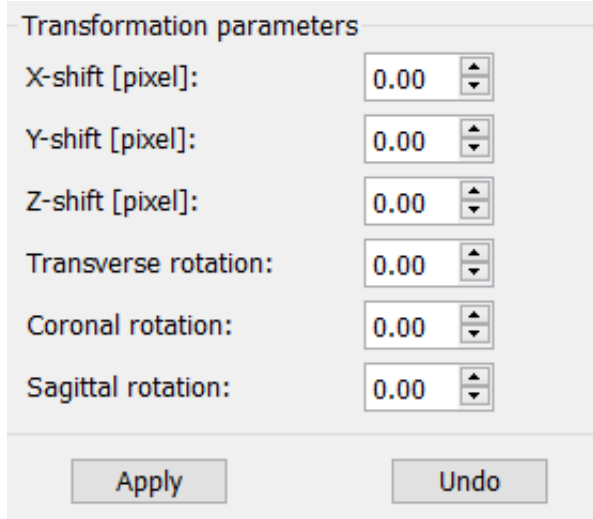
Automatic translation only

Manual

In the “Transformation parameters” section, the co-registration motion values will be displayed in the “X-shift”, “Y-shift”, “Z-shift”, “Transverse rotations”, “Coronal rotation” and “Sagittal rotation” fields.

The “Apply” button will perform the co-registration shifts. If an automatic transformation type is toggled, clicking on “Apply” will perform the automatic co-registration shifts. If the “Manual” transformation type is toggled, values need to be entered manually into the “Transformation parameters” fields to allow shifts to be applied.

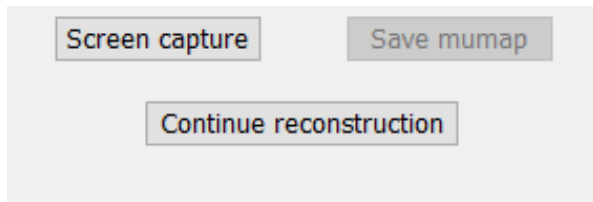
The co-registration shifts can be undone by using the “Undo” button.



The image shows a control panel titled "Transformation parameters". It contains six rows, each with a label and a numeric input field with up/down arrows. The labels and values are: X-shift [pixel]: 0.00, Y-shift [pixel]: 0.00, Z-shift [pixel]: 0.00, Transverse rotation: 0.00, Coronal rotation: 0.00, and Sagittal rotation: 0.00. Below these fields are two buttons: "Apply" and "Undo".

If “Transformation type” is set to manual. You may drag the CT over the SPECT images by using your mouse over the TCS views.

The “Screen capture” button allows you to save a screen capture of your co-registration shifts image. If the “Save mumap” option is enabled, the button will be active and will allow you to save a copy of your mumap. The “Continue reconstruction” button, allows you to continue the reconstruction process.



The image shows three buttons arranged in a control panel. The top row contains "Screen capture" and "Save mumap". The bottom row contains "Continue reconstruction".

The "Color Table" dropdown menu in the "Emission study colors" section lets you change the SPECT color palette. The lower and upper threshold limits can be changed using the "LT" and "UT" sliders.

The "Level" and "Window" sliders in the "Transmission study colors" section, allow you to change the CT windowing. The “Alpha” slider allows to fade in between the SPECT on the left end and the CT on the right end.

The screenshot displays two sections of the software interface. The top section, titled "Emission study colors", includes a "Color Table" dropdown menu set to "Hot metal". Below this are two sliders: "LT:" with a blue marker at the far left (0) and "UT:" with a blue marker at the far right (100). The bottom section, titled "Transmission study colors", includes three sliders: "Level:" with a blue marker at the center (50), "Window:" with a blue marker at the center (500), and "Alpha:" with a blue marker at approximately one-quarter of the range (25).

3.2.2.4 Filter page

There is an option to skip this page.

On the filter page, you may change the filter applied on your reconstructed SPECT.

You may select the dataset on which you want to apply the filter by using the "Dataset" dropdown menu in the "data" section.

In the "Display" section, the "Zoom" field allows you to choose the zoom applied on your right display splash view. The radio-buttons labeled "Trans", "Coro", "Sag" and "TCS" let you choose which view(s) will be shown in the right splash area.

In the "Filter" section, you may change the filter type. Four types are available: "Gaussian", "Butterworth", "Hanning" and "Hamming". The "FWHM [cm]", "Cutoff [1/cm]" and "Order" fields are available and can be modified if needed. The available fields will be modified according to the filter type.

The "Apply" button will apply the custom filter changes to the SPECT dataset.

Recon **Filter** **Align** **Results**

Data
 Dataset: MoCo_RR_ACSC TOMO DaT CT
 Show gate:

Display
 Zoom [%]: 100
 Trans Coro Sag TCS

Filter
 Filter type: Gaussian
 FWHM [cm]: 0.90
 Cutoff [1/cm]: 0.50
 Order: 10
 Apply

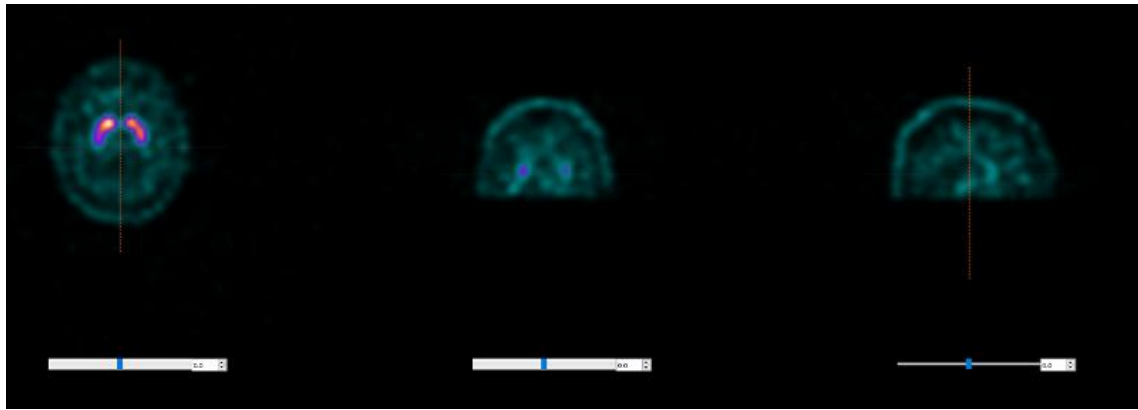
3.2.2.5 Align page

You may realign your SPECT TCS views in the align page.

In the “Mode” section, you can toggle between the “Align” and “Zoom” radio-buttons.

Mode
 Align Zoom
 Saved zoom [%]: 400
 Apply zoom Undo zoom

In the “Align” mode, dotted crosses will be displayed over your TCS views. You may move the cross over your SPECT by using your mouse. Each of your TCS views will automatically triangulate over the new cross location. Two options are available for rotating your views: slide the mouse to the required angle on the scale below your TCS views, or change the value in the right scale field. To alter a value, either type it in or use the up and down arrows.



3.2.2.6 Results page

In the “Display” section, the “Zoom” field allows you to choose the magnification factor applied on your right display splash view. The “Trans”, “Coro”, “Sag” and “TCS” radio-buttons allow you to choose which view(s) will be displayed in the right hand splash section.

The “1st dataset”, “2nd dataset” and “3rd dataset” radio-buttons allow you to choose which series will be displayed in the right hand splash section.

In the “Save” section, you may enter a label into the “1st label”, “2nd label” and “3rd label” fields. After being saved, this text will be appended to the according SPECT series label.

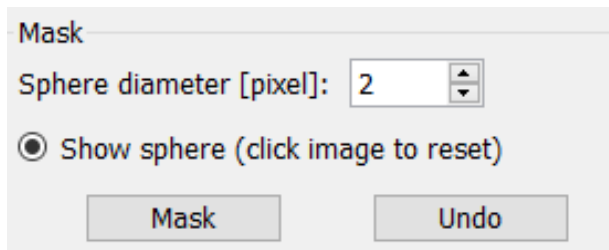
You can save your reconstructions by clicking the “Save” button. You may display your reconstruction in an Hybrid Viewer application by clicking the “HybridViewer” button. This action may be done either before or after saving.

The “Mask” section allows you to mask a portion of your SPECT images using a spherical mask.

You may use the mask tool by clicking the “Show sphere” radio-button. Once the radio-button is active, a sphere will automatically be positioned at the position of the hottest pixel of your SPECT study.

The size of the mask sphere is controlled by the “Sphere diameter [pixel]” field.

The mask is applied to your SPECT by pressing the "Mask" button. The applied mask is removed using the "Undo" button.



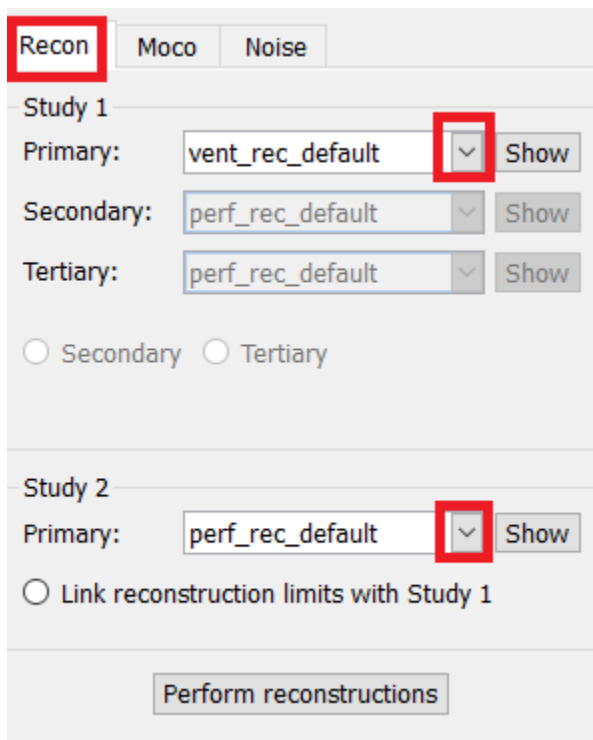
The screenshot shows a control panel titled "Mask". It contains a text input field for "Sphere diameter [pixel]" with the value "2" and a small up/down arrow icon. Below this is a radio button labeled "Show sphere (click image to reset)". At the bottom of the panel are two buttons: "Mask" and "Undo".

You may move the position of your spherical mask on your SPECT by doing a single click on your TCS views. By using your mouse wheel, you may scroll through your TCS single views.

3.2.3 Lung Workflow

3.2.3.1 Recon page

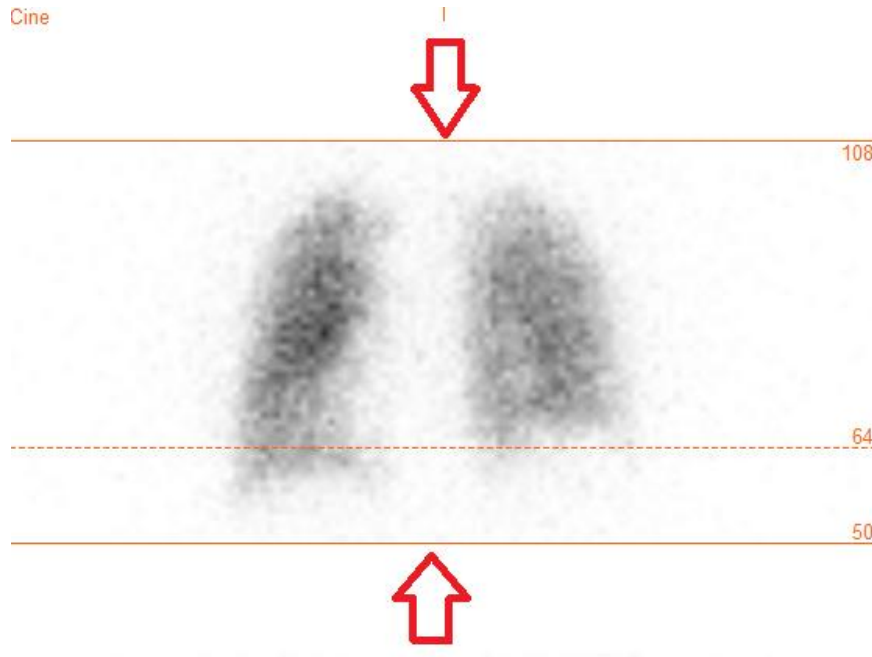
On the “Recon” tab, you may perform the reconstruction of up to two different studies. You may choose your reconstruction protocol, by utilizing the dropdown box at the right side of each “Primary” recon protocol box.



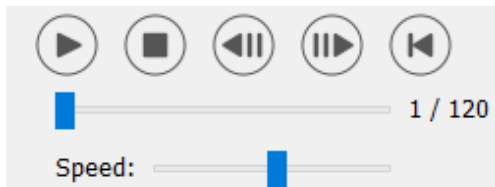
The screenshot shows the "Recon" page with three tabs: "Recon", "Moco", and "Noise". The "Recon" tab is selected and highlighted with a red box. Below the tabs, there are two study sections: "Study 1" and "Study 2". Each study has a "Primary" protocol dropdown menu, a "Secondary" protocol dropdown menu, and a "Tertiary" protocol dropdown menu. The "Primary" dropdown menus are highlighted with red boxes. Each dropdown menu has a "Show" button next to it. Below the dropdown menus, there are radio buttons for "Secondary" and "Tertiary". At the bottom of the page is a button labeled "Perform reconstructions".

To force the reconstruction fields to be linked between studies, click the “Link reconstruction limits with Study 1” radio-button.

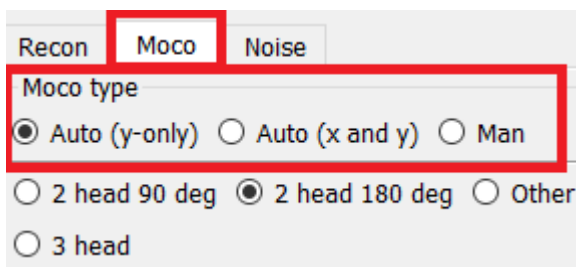
On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.



The cine of the SPECT projections can be started, stopped, moved forward, backward, or in reverse, using the media buttons "Play," "Stop," etc. You can evaluate any motion in the projection by referring to the "Sinogram" and "Linogram" pictures.



The “Moco” tab, allows you to perform motion correction of the SPECT study. Three types of motion correction are available: “Auto (y-only)”, “Auto (x and y)” and “Man”. With the radio-buttons, you may change the type of motion correction.



The “Auto” section will be available if an automatic motion correction type is selected. The “Start” button allows you to perform an automatic motion correction. The “Undo” button restores the

original projections. The “Show” button allows you to display the “MoCo” window. When no motion correction have been applied, this button is greyed out.

Auto

Iterations:

X-shift limit [cm]:

Y-shift limit [cm]:

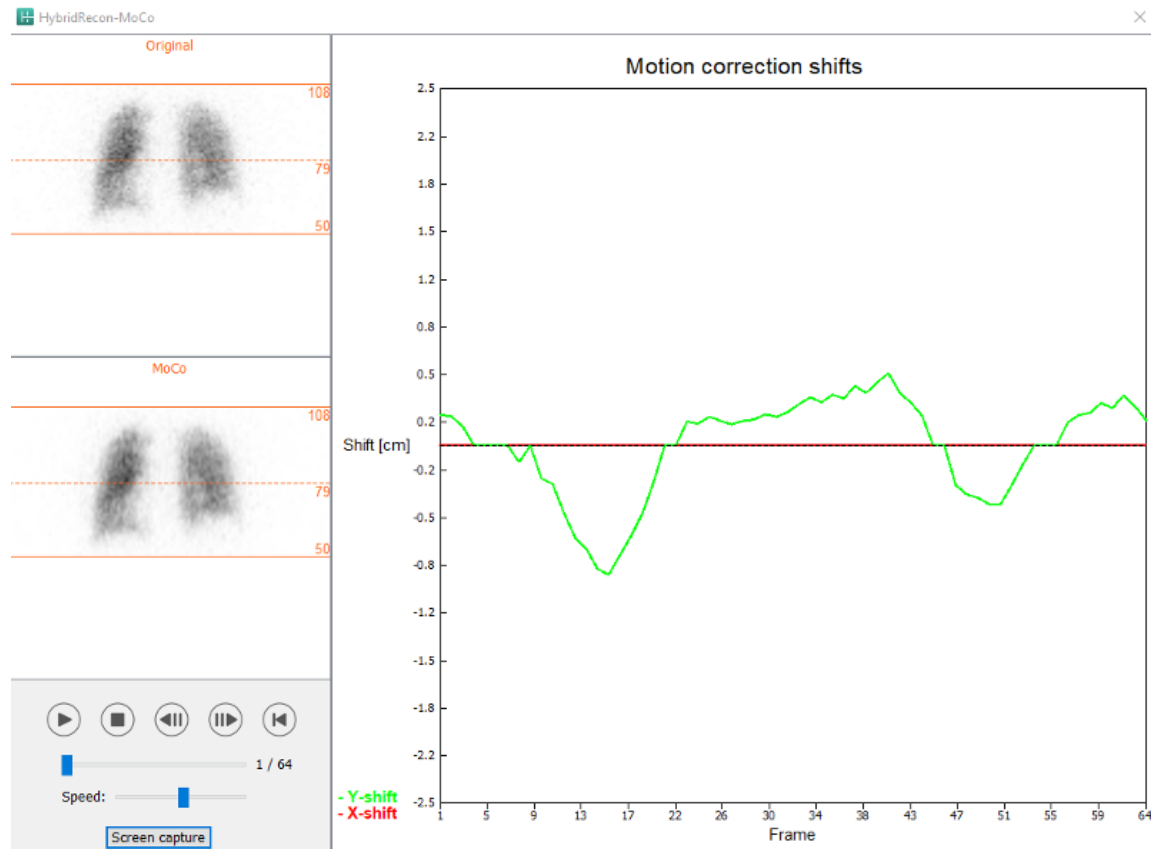
Motion correction may be performed to only one study at a time. The study that has his series label colored in orange is the active one.



A single click over the second study will change the selected study.

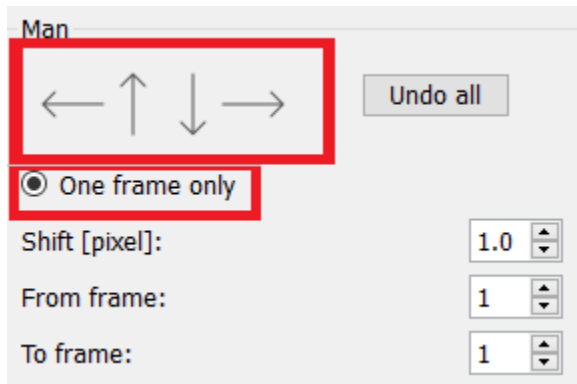
Press "Start" to initiate an automated motion correction. An "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes, made to your MoCo projection, will be shown in this window. You may compare your original projections to your MoCo projections SPECT using the media buttons.

The "Screen Capture" button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo window.



The "Man" section will be available if the "Moco type" is set to manual ("Man"). Your projection may be moved using the arrows. If the "One frame only" radio-button is toggled on, the motion will be applied to only one frame. You may use the media buttons, the sliders or the mouse wheel (if your cursor is over the cine picture) to change the projection.

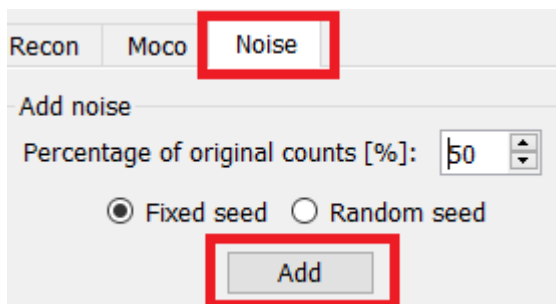
You may select a range of projections to manually move by using the "From frame" and "To frame" fields.



You may save a copy of your motion-corrected projection by clicking the "Save" button. The "Screen Capture" button saves a screen capture of the cine, sinogram, and linogram pictures.

The "Moco" tool is greyed out if a multi-bed SPECT acquisition has been loaded.

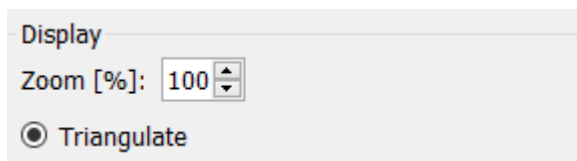
The "Noise" tab, allows you to add poisson noise to your projection.



In the co-registration page, you will be able to perform a quality control check over your SPECT-CT or synthetic mumap alignment.

3.2.3.2 SPECT-CT or synthetic mumap co-registration page

In the "Display" section, the "Zoom" field allows you to apply a specified zoom factor to your transverse, coronal and sagittal fusion views. When the "Triangulate" radio-button is active, you may triangulate in your TCS views by using a single left click on any view.



In the "Transformation" section, you can choose between three different alignment techniques:

- "Automatic full 6 parameters" allows you to perform an automatic co-registration of the X, Y, Z axis and rotations.
- "Automatic translation only" allows you to perform an automatic co-registration of the X, Y and Z axis.
- "Manual" allows you to perform a manual co-registration.

Transformation

Transformation type

Automatic full 6 parameter

Automatic translation only

Manual

In the “Transformation parameters” section, the co-registration motion values will be displayed in the “X-shift”, “Y-shift”, “Z-shift”, “Transverse rotations”, “Coronal rotation” and “Sagittal rotation” fields.

The “Apply” button will perform the co-registration shifts. If an automatic transformation type is toggled, clicking on “Apply” will perform the automatic co-registration shifts. If the “Manual” transformation type is toggled, values need to be entered manually into the “Transformation parameters” fields to allow shifts to be applied.

The co-registration shifts can be undone by using the “Undo” button.

Transformation parameters

X-shift [pixel]:

Y-shift [pixel]:

Z-shift [pixel]:

Transverse rotation:

Coronal rotation:

Sagittal rotation:

If “Transformation type” is set to manual, you can drag the CT over the SPECT images by moving your mouse over the TCS views.

The “Screen capture” button allows you to save a screen capture of your co-registration shifts image. If the “Save mumap” option is enabled, the button will be active and will allow you to save a copy of the mumap. The “Continue reconstruction” button, allows you to continue the reconstruction process.

The "Color Table" dropdown menu in the "Emission study colors" section lets you change the SPECT color palette. The lower and upper threshold limits can be changed using the "LT" and "UT" sliders.

The "Level" and "Window" sliders in the "Transmission study colors" section, allow you to change the CT windowing. The "Alpha" slider allows to fade in between the SPECT on the left end and the CT on the right end.

The screenshot displays two sections of the software interface. The top section, titled "Emission study colors", features a dropdown menu for "Color Table" set to "Hot metal". Below it are two sliders: "LT:" with a blue marker at 0 and "UT:" with a blue marker at 100. The bottom section, titled "Transmission study colors", contains three sliders: "Level:" with a blue marker at 50, "Window:" with a blue marker at 500, and "Alpha:" with a blue marker at 25.

3.2.3.3 Filter Page

On the filter page, you may change the filter applied on your reconstructed SPECT.

You may select the dataset on which you want to apply the filter by using the "Dataset" dropdown menu in the "data" section.

In the "Display" section, the "Zoom" field allows you to choose the zoom applied on your right display splash view. The radio-buttons labeled "Trans", "Coro", "Sag" and "TCS" let you choose which view(s) will be shown in the right splash area.

In the "Filter" section, you may change the filter type. Four types are available: "Gaussian", "Butterworth", "Hanning" and "Hamming". The "FWHM [cm]", "Cutoff [1/cm]" and "Order" fields are available can be modified if needed. The available fields will be modified according to the filter type.

The "Apply" button will apply the custom filter changes to the SPECT dataset.

Recon **Filter** ReProj Results

Data
 Dataset: VENT_RR_NC TOMO VENTILATION
 Show gate:

Display
 Zoom [%]: 100
 Trans Coro Sag TCS

Filter
 Filter type: Gaussian
 FWHM [cm]: 1.25
 Cutoff [1/cm]: 0.40
 Order: 10
 Apply

3.2.3.4 ReProj page

This page is intended to generate reprojected statics images from the AC SPECT.

In the “Protocol” section, the “Protocol” dropdown menu allows you to choose between different reprojection protocols. Clicking on the “Show Parameters” button will open a “Reprojection parameters” window, allowing you to see which reprojection settings are configured for that protocol.

The reprojections will be generated when you click on the “Perform re-projection” button. The generated reprojections will be deleted by clicking the “Undo re-projection” button.

Recon **Filter** **ReProj** Results

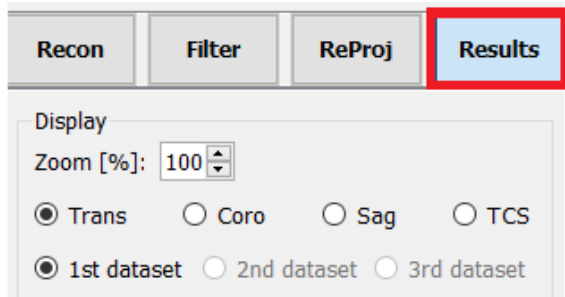
Protocol
 Protocol: lung_reproj_default
 Show parameters

Perform re-projection Undo re-projection

3.2.3.5 Results page

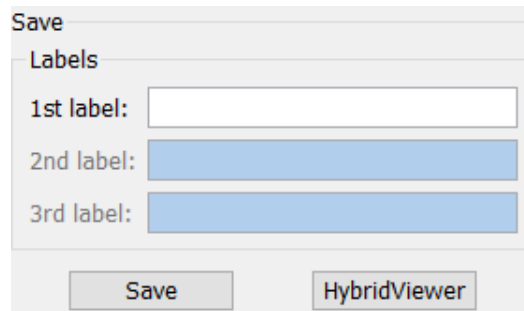
In the “Display” section, the “Zoom” field allows you to choose the magnification factor applied on your right display splash view. The “Trans”, “Coro”, “Sag” and “TCS” radio-buttons allow you to choose which view(s) will be displayed in the right hand splash section.

The “1st dataset” and “2nd dataset” radio-buttons allow you to choose which series will be displayed in the right hand splash section.



In the “Save” section, you may enter a label into the “1st label” and “2nd label” fields. After being saved, this text will be appended to the corresponding SPECT series label.

You can save your reconstructions by clicking the “Save” button. You may display your reconstruction in a Hybrid Viewer application by clicking the “HybridViewer”. This action may be performed either before or after saving.

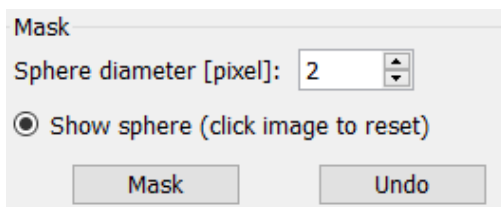


The “Mask” section allows you to mask a portion of your SPECT images using a spherical mask.

You can use the mask tool by clicking the “Show sphere” radio-button. Once the radio-button is active, a sphere will automatically be positioned at the position of the hottest pixel of your SPECT study.

The size of the mask sphere is controlled by the “Sphere diameter [pixel]” field.

The mask is applied to your SPECT by pressing the “Mask” button. The applied mask is removed using the “Undo” button.



You may move the position of the spherical mask on your SPECT using a single click on your TCS views. By using your mouse wheel, you may scroll through the TCS single views.

3.2.4 Cardiology Workflow

3.2.4.1 Recon Page

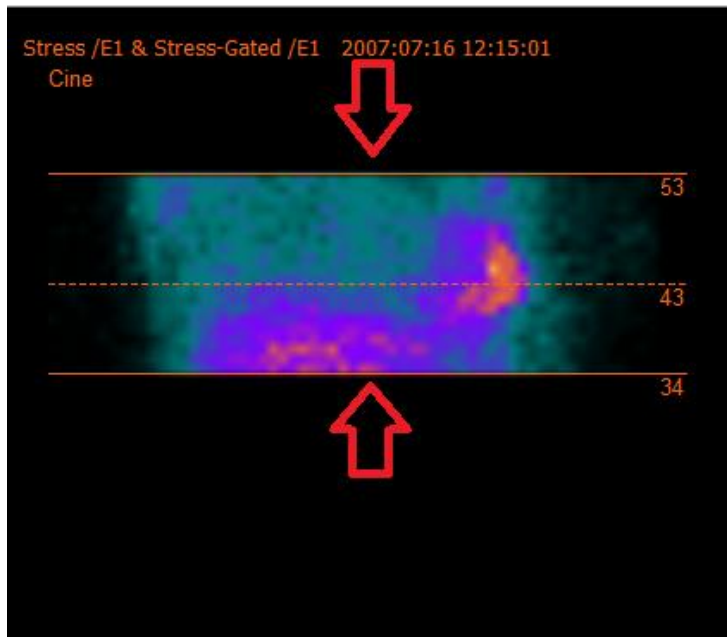
On the “Recon” tab, you may perform the reconstruction of up to three different studies. You may choose your reconstruction protocol utilizing the dropdown box at the right hand side of each of the “Non-gated” and “Gated” recon protocol boxes. If no gated SPECT studies have been loaded in the application, the “Gated” boxes are greyed out.

If the “2nd NG” radio-button is active, the “2nd Non-gated” boxes will be available. You may choose your reconstruction protocol by using the dropdown menu at the right side of these boxes.

The use of attenuation correction is available only for the first “Non-gated” boxes.

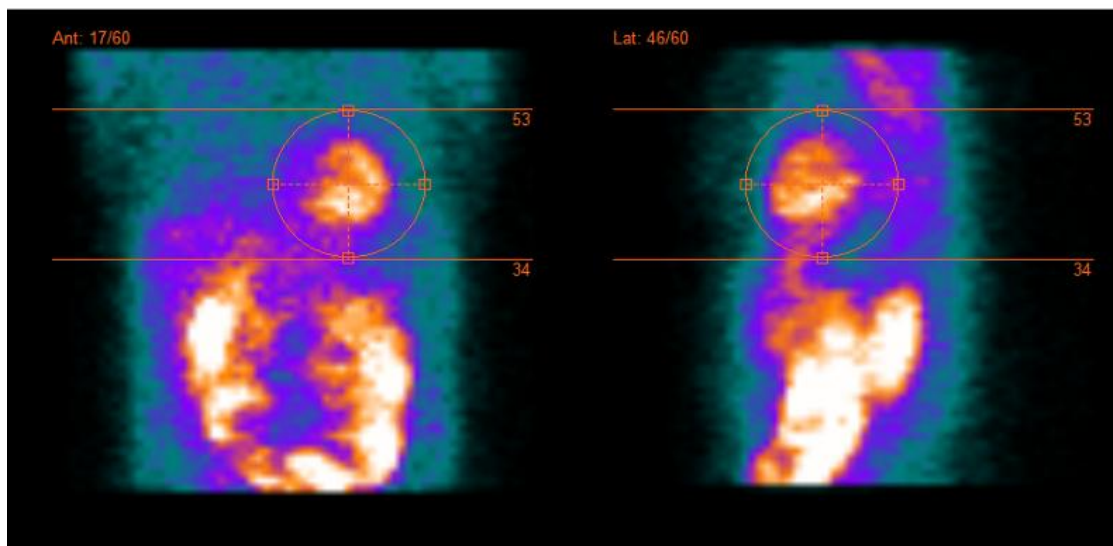
The screenshot shows the 'Recon' tab selected. The interface is organized into three study sections: 'First study', 'Second study', and 'Third study'. Each section has a '2nd NG' radio button. For each study, there are three rows: 'Non-gated', '2nd Non-gated', and 'Gated'. Each row contains a text input field with a dropdown arrow on the right and a 'Show' button. The dropdown menus are highlighted with red boxes. At the bottom, there is a 'Perform reconstructions' button.

On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.

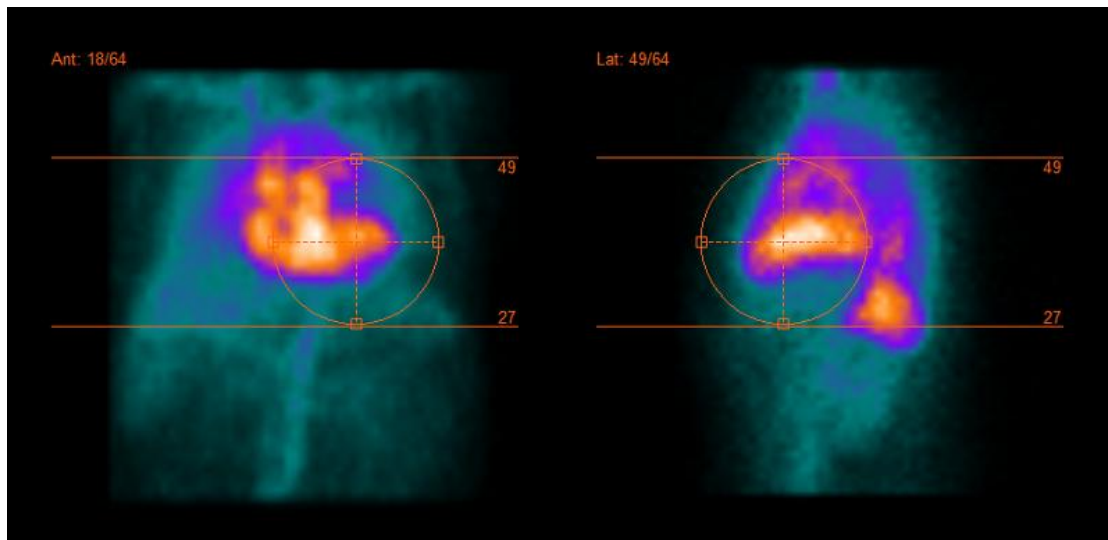


The circle-cross should be centered in the middle of the myocardium on the anterior and lateral views for stress/rest cardiac studies and centered in the left ventricle position for bloodpool SPECT studies.

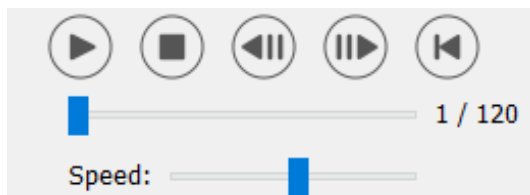
Stress and rest cardiac study



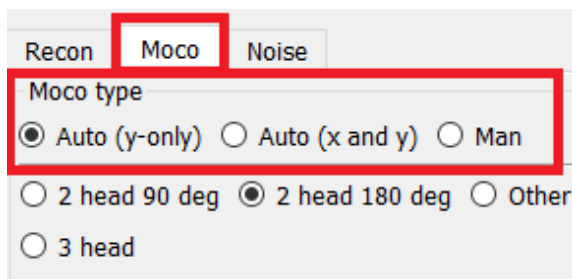
Bloodpool study



The cine of the SPECT projections can be started, stopped, moved forward, backward, or in reverse, using the media buttons "Play," "Stop," etc. You can evaluate any motion in the projection by referring to the "Sinogram" and "Linogram" pictures.



The "Moco" tab, allows you to perform a motion correction of the SPECT study. Three types of motion correction are available: "Auto (y-only)", "Auto (x and y)" and "Man". With the radio buttons, you may change the type of motion correction.



The "Auto" section will be available if an automatic motion correction type is selected. The "Start" button allows you to perform an automatic motion correction. The "Undo" button restores the original projections. The "Show" button allows you to display the "MoCo" box. When no motion correction has been applied, this button is greyed out.

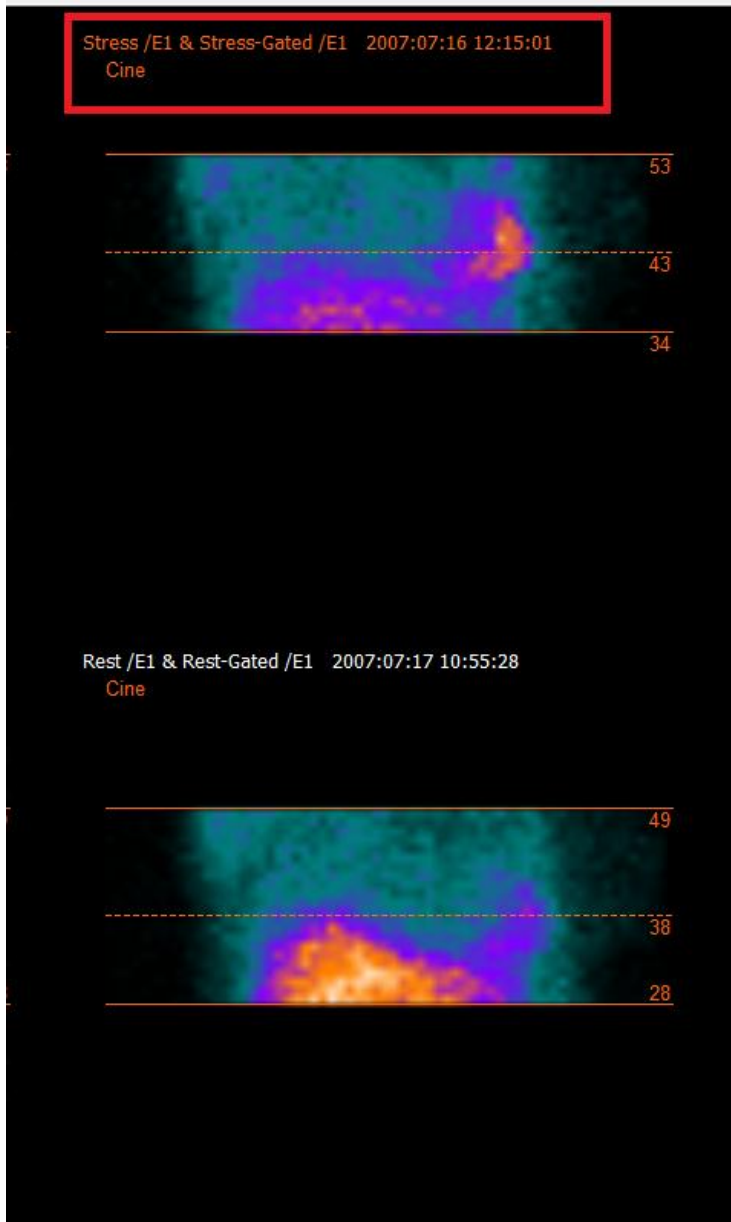
Auto

Iterations:

X-shift limit [cm]:

Y-shift limit [cm]:

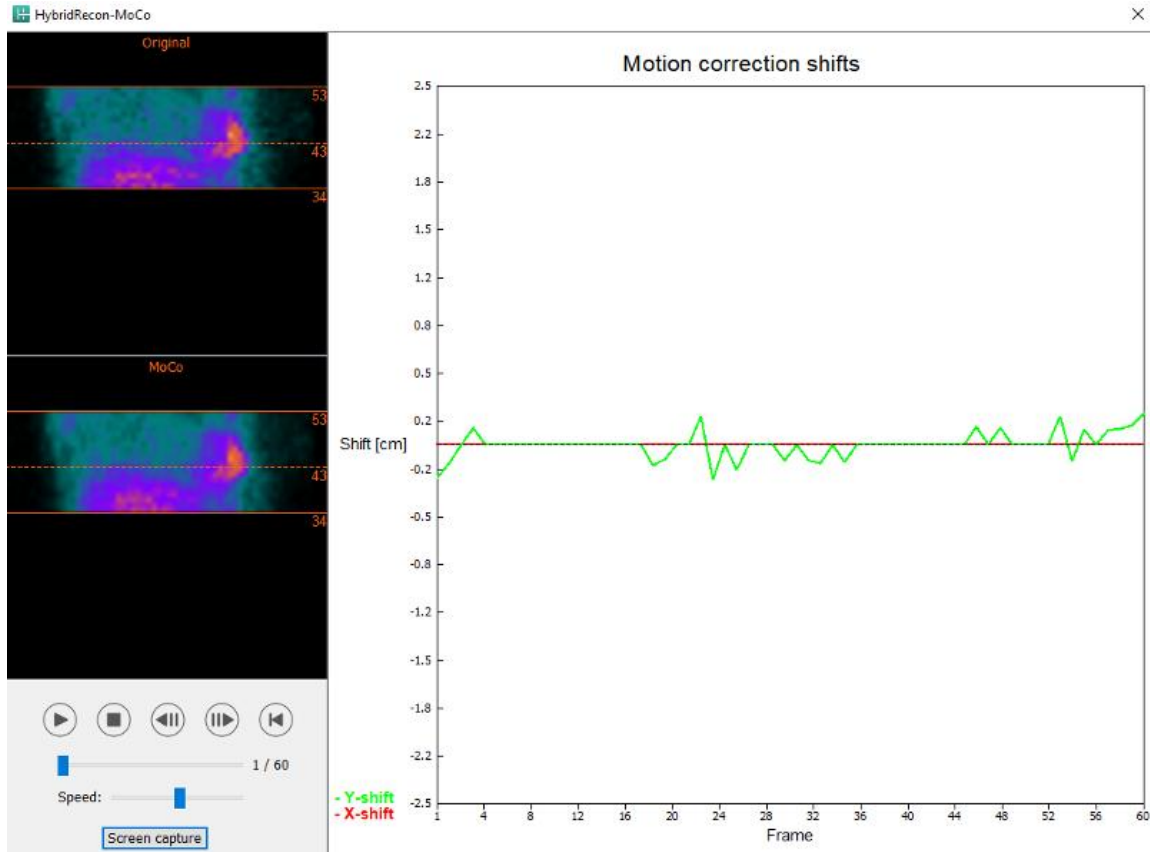
Motion correction may be performed to only one study at a time. The study that has his series label colored in orange is the active one.



A single click over another study will change the selected study.

Press "Start" to initiate an automated motion correction. An "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes, made to your MoCo projections, will be shown in this window. You may compare your original projections to your MoCo projections SPECT using the media buttons.

The "Screen Capture" button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo window.



The "Man" section will be available if the "Moco type" is set to manual (Man). The projection may be moved using the arrows. If the "One frame only" radio-button is toggled on, the motion will be applied to only one frame. You may use the media buttons, the sliders or the mouse wheel (if your cursor is over the cine picture), to change of projection.

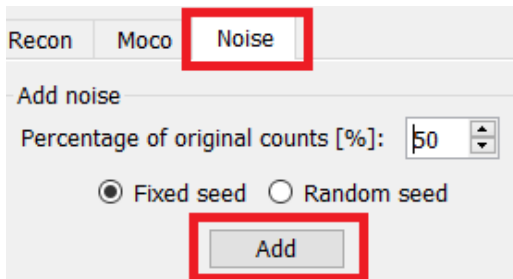
You may select a range of projections to manually move by using the "From frame" and "To frame" fields.



You may save a copy of your motion-corrected projections by clicking the "Save" button. The "Screen Capture" button saves a screen capture of the cine, sinogram, and linogram pictures.

The "Moco" tool is greyed out if a multi-bed SPECT acquisition has been loaded.

The "Noise" tab, allows you to add Poisson noise to your projection.

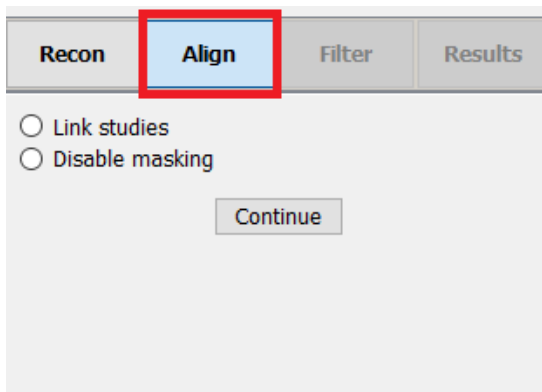


3.2.4.2 Align Page

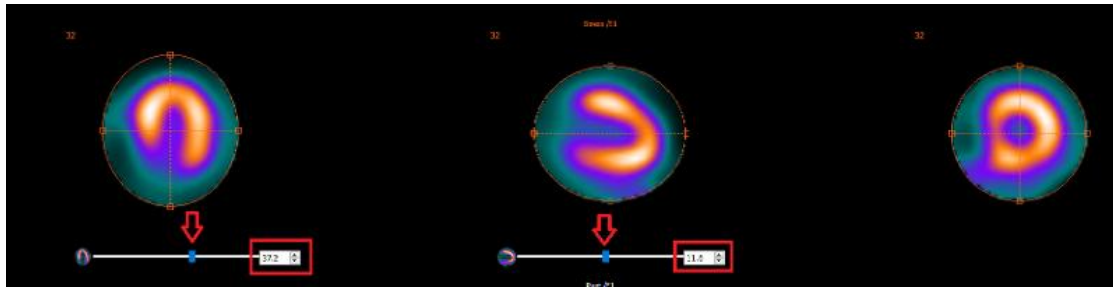
In the align page you may change the orientation of your studies.

The "Link studies" radio-buttons will link the orientation of your studies. You may disable masking by activating the "Disable masking" radio-button.

You may continue the reconstruction process by clicking on the "Continue" button.



To rotate the VLA and HLA views, you may either drag the cursor on the horizontal scale below the views or modify the value in the angulation box with your keyboard or the up/down arrows.

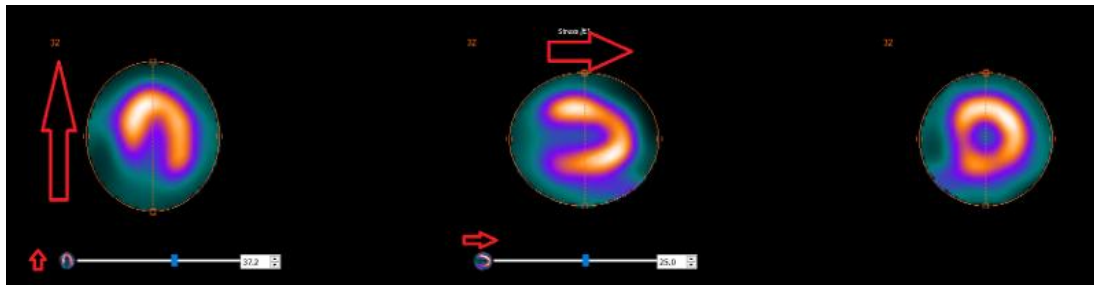


When a view has your pointer over it, you may scroll through the slices with the mouse wheel.

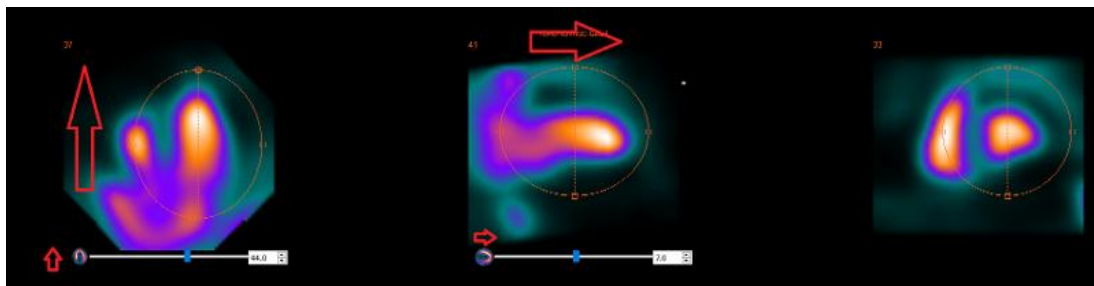
You may change the triangulation of your views by dragging the circle-cross center. We do recommend to locate the middle of your circle-cross in the middle of your myocardial or, for bloodpool studies, in the center of the left ventricle.

To help you visually orient your VLA and HLA views, a small cardiac symbol is displayed underneath each view. For bloodpool studies, you may refer to the apex position of the cardiac symbol to find the most suitable orientation for your views.

Stress/Rest study



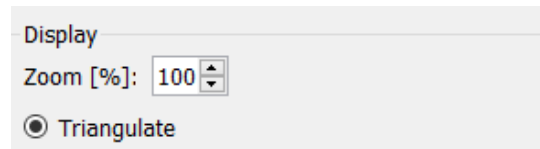
Bloodpool study



3.2.4.3 SPECT-CT or synthetic mumap co-registration page

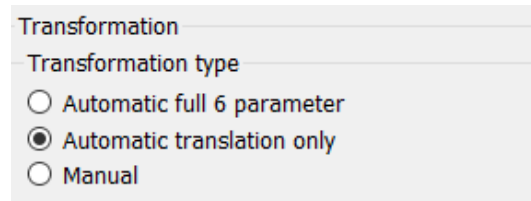
In the co-registration page, you will be able to perform a quality control check over your SPECT-CT or synthetic mumap alignment.

In the “Display” section, the “Zoom” field allows you to apply a specified zoom factor to your transverse, coronal and sagittal fusion views. You may triangulate in your TCS views when the “Triangulate” radio-button is active, by using a single left click on any view.



In the “Transformation” section, you can choose between three different alignment techniques:

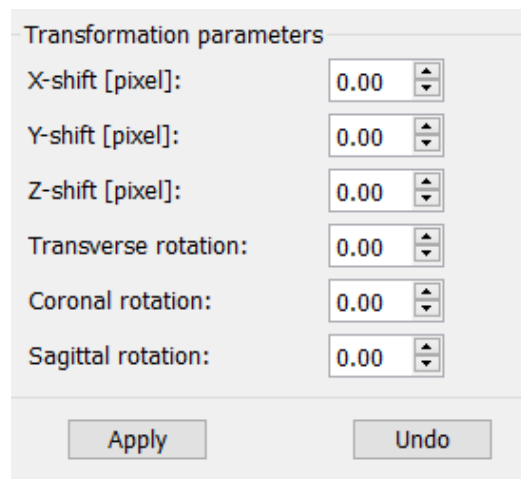
- “Automatic full 6 parameters” allows you to perform an automatic co-registration of the X, Y, Z axis and rotations.
- “Automatic translation only” allows you to perform an automatic co-registration of the X, Y and Z axis.
- “Manual” allows you to perform a manual co-registration.



In the “Transformation parameters” section, the co-registration motion values will be displayed in the “X-shift”, “Y-shift”, “Z-shift”, “Transverse rotations”, “Coronal rotation” and “Sagittal rotation” fields.

The “Apply” button will perform the co-registration shifts. If an automatic transformation type is toggled, clicking on “Apply” will perform the automatic coregistration shifts. If the “Manual” transformation type is toggled, values need to be entered manually into the “Transformation parameters” fields to allow shifts to be done.

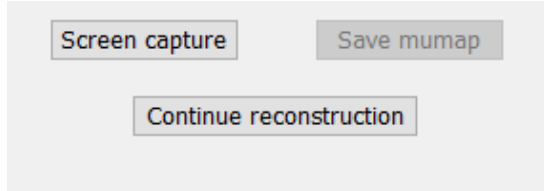
The co-registration shifts can be undone by using the “Undo” button.



If “Transformation type” is set to manual, you can drag the CT over the SPECT images by moving the mouse over the TCS views.

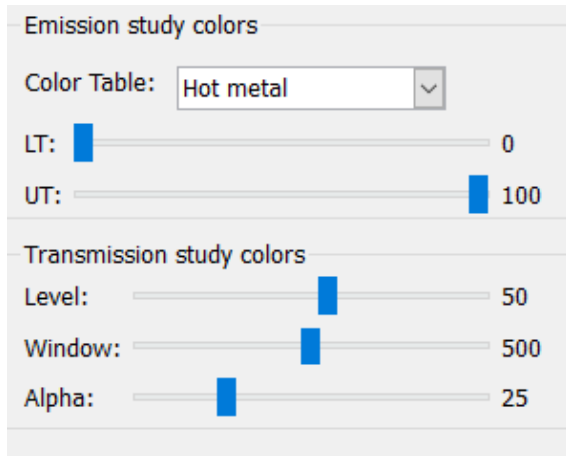
The “Screen capture” button allows you to save a screen capture of your co-registration shifts image. If the “Save mumap” option is enabled, the button will be active and will allow you to save

a copy of the mumap. The “Continue reconstruction” button, allows you to continue the reconstruction process.



The "Color Table" dropdown menu in the "Emission study colors" section lets you change the SPECT color palette. The lower and upper threshold limits can be changed using the "LT" and "UT" sliders.

The "Level" and "Window" sliders in the "Transmission study colors" section, allow you to change the CT windowing. The “Alpha” slider allows to fade in between the SPECT on the left end and the CT on the right end.



3.2.4.4 Filter Page

There is an option to skip this page.

On the filter page, you may change the filter applied to the reconstructed SPECT.

You may select the dataset on which you want to apply the filter by using the "Dataset" dropdown menu in the "data" section.

In the “Display” section, the “Zoom” field allows you to choose the zoom applied on the displayed splash view. The radio-buttons labeled “Trans”, “Coro”, “Sag” and “TCS” let you choose which view(s) will be shown in the right hand splash area.

In the “Filter” section, you may change the filter type. Four types are available: “Gaussian”, “Butterworth”, “Hanning” and “Hamming”. The “FWHM [cm]”, “Cutoff [1/cm]” and “Order” fields are available and can be modified if needed. The available fields will be modified according to the filter type.

The “Apply” button will apply the custom filter changes to the SPECT dataset.

Recon Align **Filter** Results

Data
 Dataset: RST_RR_AC Rest /E1
 Show gate:

Display
 Zoom [%]: 100
 Trans Coro Sag TCS

Filter
 Filter type: Gaussian
 FWHM [cm]: 0.90
 Cutoff [1/cm]: 0.00
 Order: 10
 Apply

3.2.4.5 Results page

In the “Display” section, The “HLA”, “SA” and “VLA” radio-buttons allow you to choose which view(s) will be displayed in the splash section.

The “1st study gate”, “2nd study gate” and “3rd study gate” dropdowns, allow you to choose which frame of your gated SPECT will be displayed in the splash section.

Recon Align Filter **Results**

Display
 HLA SA VLA
 1st study gate: 1
 2nd study gate: 1
 3rd study gate:

In the “Labels” section, you may enter a label into the “1st label”, “2nd label” and “3rd label” fields. After being saved, this text will be appended to the corresponding SPECT series label.

In the “Coronal” section, the “Save coronal” toggle button will activate saving of the coronal views. If your study is a situs inversus or Dextrocardia study, the “Dextrocardia” toggle button will flip the heart views.

You may apply a zoom factor to your saved coronal views by clicking the “Save with zoom” radio-button in the “Zoom” section. “Save without zoom” will deactivate the zoom factor. You may

adjust the zoom factor, by modifying the “Saved zoom [%]” box value. To change that value, use your keyboard or the up/down arrows.

The “Gated only” section allows you to only save the gated series. This option is available if a bloodpool study is loaded. In other cases, the option will be grayed out.

You may save your transverse views by toggling on/off the “Non-gated” and “Gated” radio-buttons in the “Transverse” section.

The “Save” button allows you to save the views specified in the above “Coronal” and “Transverse” sections. You may display your reconstruction in a Hybrid Viewer application by clicking the “HybridViewer” button. This action may be performed either before or after saving.

Save

Labels

1st label:

2nd label:

3rd label:

Coronal

Save coronal Dextrocardia

Zoom

Saved zoom [%]:

Save without zoom Save with zoom

Gated only

Save gated only

Transverse

Non-gated Gated

3.3 Interface

You can open the advance parameters of the application by clicking on the “Program Parameters” list icon on the upper right of the application window.



A “program parameters” window will open giving you access to the configured parameters. The handbooks of each specific workflow provide further details on the advance settings and their effect.

Clicking on the “question mark” symbol will launch the specific Hybrid Recon handbook for that specific workflow.



The “i” icon will launch the application Aboutbox.



In that section, you will find information about the product name, the release version, marketing name, software build, manufacturing date, email addresses, etc.

3.4 Security

Hybrid Recon 5.0 processes Personal Identifiable Information (PII) and Hermes Medical Solutions actively works with cybersecurity during manufacturing to ensure the highest level of security. To increase security further, the software supports customers' own security measures, such as, but not limited to, access control and authorization, antivirus, operating system patching, and disk encryption. For more information, please contact support@hermesmedical.com.

It is the customers responsibility to install and maintain anti-virus software on the server and client computers and apply the necessary protection against threats.

Backup routines:

- A backup copy of the latest config file is created once per session when in user or admin mode
- A backup copy of the latest config is made the first time the user makes any changes to the settings (including workflow/layout/rules etc.)
- A backup copy of factory defaults is never created
- A maximum of 10 copies shall be stored, and if the maximum number of copies is exceeded, the oldest backup will be deleted.

3.5 Warnings



All studies to be used in this application (SPECT and CT) should be sent to the Hermes Medical Solution software directly from the originating scanners.



When performing quantitative reconstruction (SUV SPECT), the patient information, such as weight and height, and the study activity should be checked carefully.



Motion correction should be performed only in cases where it is truly needed. It is recommended to compare reconstructed studies produced from the original acquisition study and the motion corrected acquisition study. Consideration should be given to repeating the scan in cases of severe patient motion.



The accuracy of quantification is dependent on several factors such as, but not limited to, camera resolution, type of collimator, the energy of the isotope, partial volume effect and size of the imaged target. The quantitative accuracy is higher with larger targets compared with smaller targets. It is important that the accuracy is evaluated based on conducted phantom measurements, to ensure the reliability of the quantified values.



Decay correct projections:

- This option is only available when string matching is enabled

- This option should be enabled when reconstructing quantitative SPECT reconstruction
- The option to save Motion corrected studies is only available when this is enabled



When comparing multiple studies from the same patient, it is recommended to use either GPU or CPU reconstruction for all studies. Quantitative results using GPU and CPU may differ slightly.

When using reconstructed studies in applications which compare to a database, such as Cedars and 4DM for Cardiology and BRASS for Neurology, it is recommended to use reconstruction parameters which are as close as possible to those used for reconstructing the studies included in the databases. In most cases the databases have been created from studies reconstructed with CPU.



Hybrid Recon 5.0 - Neurology

In order to obtain the most accurate and reproducible results when reconstructing studies which will be evaluated using the HybridViewer BRASS application for DATScan with the EARL database, the following guidance should be followed.

- The ENCDAT reconstruction protocol provided by Hermes Medical Solutions should be used. The uniform attenuation outlines should not be adjusted, as the slice range reconstructed is set automatically based on these outlines. This will ensure the results from BRASS are reproducible. The user defined slice limits are not used.
- The Uniform attenuation outlines should not be adjusted.
- The reconstructed images should not be aligned manually.
- The reconstructed images should not be zoomed.
- If a different reconstruction protocol is used and uniform attenuation correction is selected, the 'Automatic Reconstruction Limits' option should be ticked in the AC page of Reconstruction Parameters.



Hybrid Recon 5.0 - Neurology

Rotations and zooming require interpolation, which reduces resolution. Thus rotations and zooming should be performed only when needed.

4 CONTACT INFORMATION

Contact any of the addresses below for service, support or if you have any other questions.

4.1 Manufacturer contact information



Head office
Hermes Medical Solutions AB
 Strandbergsgatan 16
 112 51 Stockholm
 SWEDEN
 Tel: +46 (0) 819 03 25
 www.hermesmedical.com

General e-mail address:
 info@hermesmedical.com

Support e-mail addresses:
 support@hermesmedical.com
 support.ca@hermesmedical.com
 support.us@hermesmedical.com

4.2 Regulatory Representatives

UK Responsible Person
 Hermes Medical Solutions Ltd
 Cardinal House
 46 St. Nicholas Street
 Ipswich, IP1 1TT
 England, United Kingdom

CH Authorized Representative
 CMI-experts
 Grellinger Str. 40
 4052 Basel
 Switzerland

CH REP

Australian Sponsor
 Cyclomedica Australia Pty Ltd
 4/1 The Crescent,
 Kingsgrove,
 Sydney 2208
 Australia

4.3 Subsidiaries

Hermes Medical Solutions Ltd
 York Suite, 7-8 Henrietta Street
 Covent Garden
 London WC2E 8PS
 UK
 Tel: +44 (0) 20 7839 2513

Hermes Medical Solutions, Inc
 710 Cromwell Drive, Suite A
 Greenville, NC27858
 USA
 Tel: +1 (866) 437-6372
 Fax: +1 (252) 355-4381

Hermes Medical Solutions Canada, Inc
 1155, René-Lévesque O., Suite 2500
 Montréal (QC) H3B 2K4
 Canada
 Tel: +1 (877) 666-5675
 Fax: +1 (514) 288-1430

Hermes Medical Solutions Germany GmbH
 Robertstraße 4
 48282 Emsdetten
 Deutschland
 Tel: +46 (0)819 03 25

5 APPENDIX 1 - USER TRAINING REQUIRED CONTENT

Launch

- Aboutbox and link to IFU's
- User Handbooks

User interface

- Heart position is automatically selected using deep learning and an ellipse displayed on the images. User should check and can adjust position and size of the ellipse if required.
- Motion correction
- Slices are automatically oriented along the heart axis using deep learning. User should check and can adjust orientation if required.
- Attenuation correction (CT, Chang or synthetic mumap). An outline of the heart is automatically overlaid on the fused SPECT-CT images using deep learning. User should check and can adjust registration if required.
- Realign study – when applicable
- Attenuation correction (CT, Chang or synthetic mumap)
- Apply filter
- Reprojection – when applicable
- Save results
- Launch viewer

Settings

- Protocol parameters
- Advanced parameters
- SUV SPECT – Calibration

Toolbar

- Basics (Triangulate, scroll, rotate, windowing)
- Screen captures

Reconstruction variation

- Multi-energy window study
- Dual isotope study
- With and without attenuation correction
- CT – INTERNAL v. EXTERNAL
- Multi-bed study
- Prone study
- SUV SPECT

6 APPENDIX 2 - WARNING MESSAGES IN THE APPLICATION

May be warnings only or a message box with option for OK or Abort

- Anatomical prior requires 256x256 acquisition matrix size for best possible performance.
- Anatomical prior requires collimator modelling for best possible performance.
- Attenuation correction is not enabled or attenuation map is not available.
- Attenuation map is not available.
- Cannot normalize camera model name.
- Cannot open collimator and ct parameter file.
- Cannot open isotope parameter file.
- Cannot organise Interfiles according to time.
- Down-scatter simulation does not support fan-beam collimation.
- Dual isotopes with two half-lives require two or three energy windows.
- Energy window info is not available or wrong.
- Error in 128x128 to 256x256 resampling.
- Error in allocating activity table.
- Error in anterior projection determination.
- Error in determining projection angle in multi-bed study.
- Error in lateral projection determination.
- Error in PSF energy settings.
- Error in reading image file.
- Error in the starting angle.
- FBP is not allowed with GPU. Modify your reconstruction protocol.
- Fold-factor could not be found in MULTI_RES_FOLD_FACTOR.
- Full collimator modelling is not supported.
- Gated multi-isotope reconstruction is not allowed.
- GPU reconstruction is not allowed with fan-beam collimator.
- Header and PSF energy window settings do not match.
- Image position info is needed for knitting acquisition studies.
- Image position information is missing.
- Isotope does not match acquisition energy window settings.
- Isotope does not match with number of acquisition energy windows.
- Mismatch in rotation directions in whole body SPECT.
- Necessary field missing in psf-header.
- Noisy study was created and saved to database.
- Number of projection angles has to be divisible with the number of subsets.
- Number of projections is not divisible by the number of detector heads.
- Only 1-64 subsets are allowed.
- Radionuclide transmission scanning based mumap is no longer supported.
- Radius of rotation info is not available.
- Reconstruction with full collimator model supports only 1 or 2 energy windows.
- Reconstruction with full collimator model with 2 energy windows is allowed only for dual I123/Tc99m reconstruction.
- Scatter correction is not supported for acquisitions where energy windows have been summed.
- Selected isotope and PSF isotope do not match.
- SPECT and CT frame of reference does not match.
- Uniform attenuation map is not supported.

- Unknown isotope-setting.
- Unknown reconstruction method.
- Unknown slice orientation flag.
- Unknown study type.
- Unknown transformation type in 2D registration.
- With byte-reverse sequence only 1, 2, 4, 8, 16, 32 or 64 subsets are allowed.
- Acquisition with 720 degree extension of rotation is converted into a study with 360 degree extension. Dual head system is assumed.
- Cannot do multi-bed dual isotope decay correction.
- Decay correction is not supported for this camera.
- Projections have not been decay corrected. To enable decay correction tick 1) Isotope string matching and 2) Decay correct projections buttons in the program parameters dialog.
- Empty projection(s) detected. This might lead to reconstruction failure.
- Isotope was not correctly detected.
- Patient names or ids do not match in all studies.
- Projection maximum count is very low. This might lead to reconstruction failure.
- Several SPECT acquisition studies have been loaded. If you want to sum these and continue press OK otherwise press Abort to abort.
- Ventilation/perfusion string matching failed.

Cardiology

- Decay correction is not supported for this camera.
- Patient names or ids do not match in all studies.
- Projection maximum count is very low. This might lead to reconstruction failure.
- Stress/rest/delay string matching failed.
- Stress/rest/delay/bloodpool string matching failed.