INSTRUCTIONS FOR USE

Hybrid Recon 5.1.0

Document revision date: 2026-02-05

www.hermesmedical.com

Table of content

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 partner or by Hermes Medical Solutions shall perform installations, and service of this product.

All users need to be trained by personnel from an authorized partner 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 information obtained from using the software shall, in conjunction with other patient related data, as appropriate, be used to inform clinical management. The users of the software are solely responsible for the clinical decisions, such as resulting diagnoses, radiation protection measures or treatments.

The IFU is translated into the local language for countries for which this is a market requirement.

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

- P21-120 Release Notes Hybrid Recon 5.1.0 Rev.1
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

A User Handbook, 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.

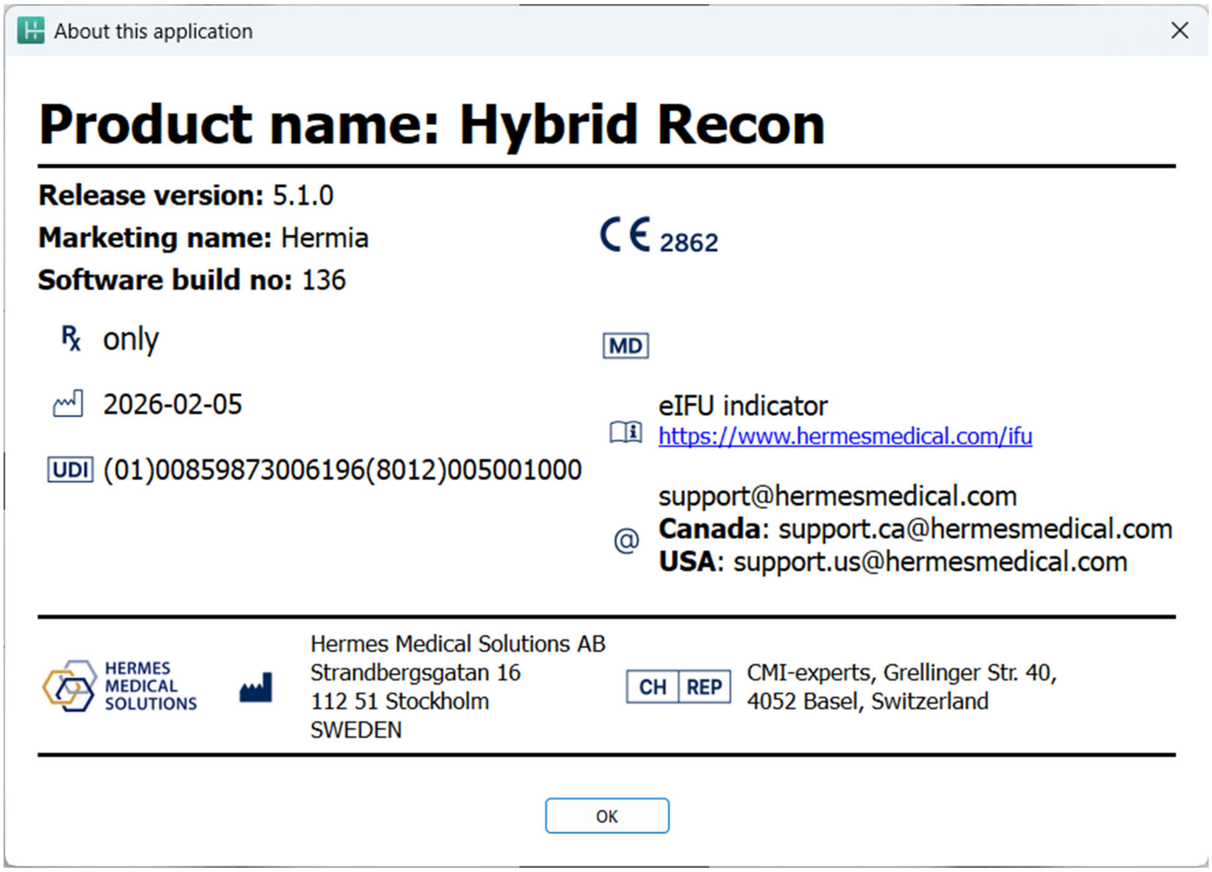
2.4 Product label

The version number, the Unique Device Identification (UDI) and other product data of an installed Hybrid Recon 5.1 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 = 5.1.0
Marketing name = Hermia
Software build no = 136

Rx Only	"Prescription only" - device restricted to use by or on the order of a physician
	Date of Manufacture (YYYY-MM-DD)
UDI	Unique Device Identification number
MD	Indicates that the product is a medical device
CE 2862	CE marking and the Notified Body number
	Consult Instructions for Use (IFU)
@	The support email addresses
	Manufacturer's contact information
CH REP	Swiss authorized representative



Product name: Hybrid Recon

Release version: 5.1.0
Marketing name: Hermia
Software build no: 136

CE 2862

Rx only

MD

2026-02-05

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

UDI (01)00859873006196(8012)005001000

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

HERMES MEDICAL SOLUTIONS

Hermes Medical Solutions AB
Strandbergsgatan 16
112 51 Stockholm
SWEDEN

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

2.5 Product Lifetime

The lifetime of Hybrid Recon 5.1 is 5 years.

The lifetime of 5 years starts running when Hybrid Recon 5.1.0 has been manufactured (5 years from Manufacturing date of 5.1.0). Possible patches on Hybrid Recon 5.1 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 5.1. 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 Operating systems

For general requirements, see *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 Modification of Product

NOTE: Adding radionuclides that have not been validated is a modification of the product. For validated radionuclides, see *Appendix 3 List of supported isotopes.*

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

2.8.2 Trained Service Personnel

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

2.8.3 User modfications not validated or warrantied

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.

2.8.4 Other applications

Using software other than that provided by Hermes Medical Solutions may lead to reduced performance and, in the worst cases, incorrect output data, if installed on the same system as Hermes Medical Solutions software.

2.8.5 Decimal and Digit grouping symbols

It is not allowed to configure the Decimal symbol and the Digit grouping symbol to the same symbol.

3 SAFETY, SECURITY AND PERFORMANCE INFORMATION

3.1 Supported data formats

The following lists provide a overview of the types of DICOM data that Hybrid Recon is capable of processing as both input and output. Each entry displays the official Information Object Definition (IOD) name, as referenced in the Innolitics DICOM browser (https://dicom.innolitics.com/ciods).

DICOM Input Data
- Nuclear Medicine Image (NM)
    - TOMO
    - GATED TOMO
- CT Image (CT)

DICOM Export Data
- Nuclear Medicine Image (NM)
    - TOMO
    - RECON TOMO
    - RECON GATED TOMO
- Secondary Capture (SC)

Other Input & Output Data Formats:
- Interfile

3.2 Launch

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

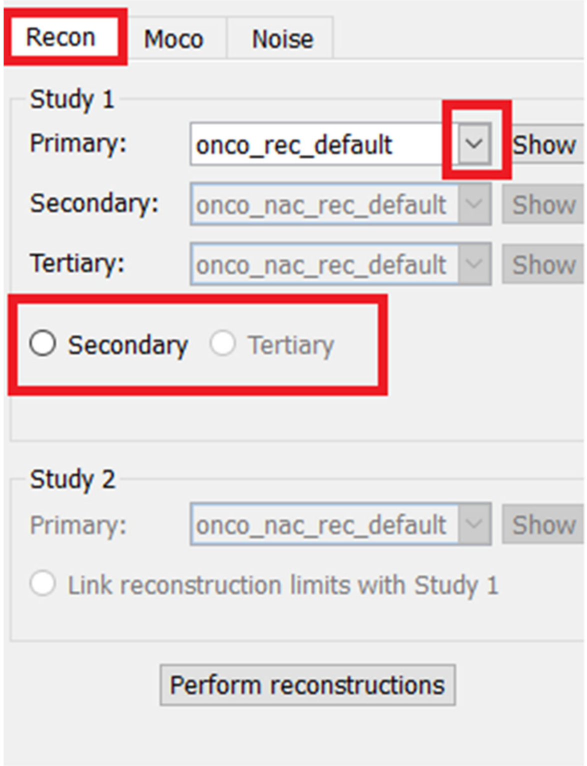
If a CT scan is available. Select your CT scan, your SPECT scan (or multi-bed SPECT) and launch a Hybrid Recon application.

3.3 Quick start

3.3.1 Oncology Workflow

3.3.1.1 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.



Primary: onco_rec_default

Secondary: onco_nac_rec_default

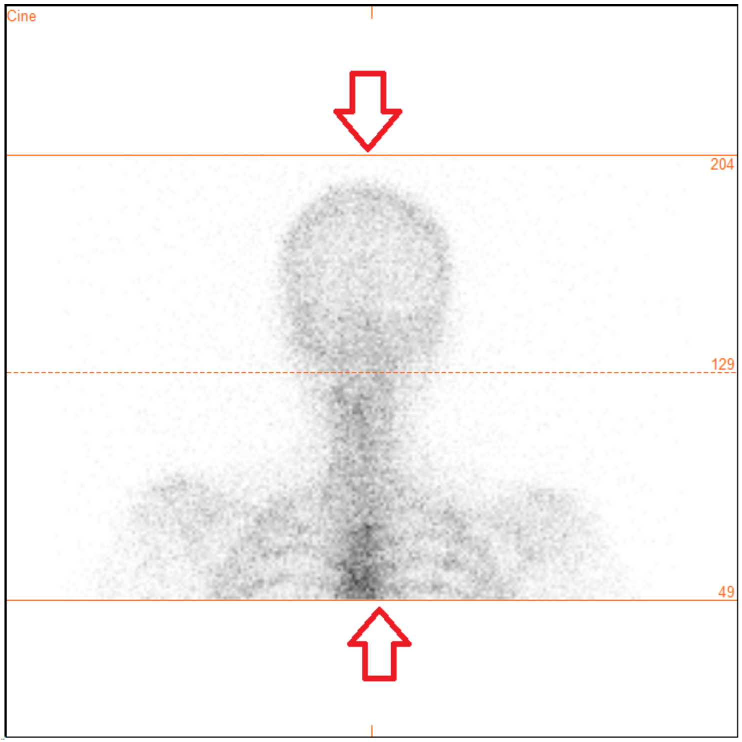
Tertiary: onco_nac_rec_default

○ Secondary ○ Tertiary

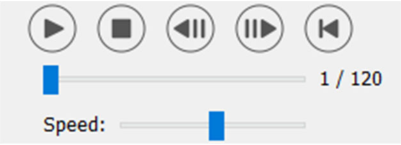
Primary: onco_nac_rec_default

○ Link reconstruction limits with Study 1

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

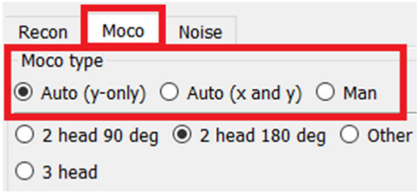


The cine of the SPECT projections can be started, stopped, moved forward, backward, or in reverse, using the media buttons "Play”, "Stop”, etc. You can evaluate any motion in the projection by referring to the "Sinogram" and "Linogram" pictures.



1 / 120

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.



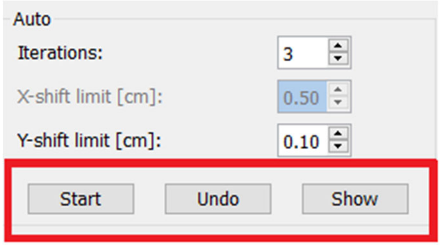
Moco type

● Auto (y-only) ○ Auto (x and y) ○ Man

○ 2 head 90 deg ● 2 head 180 deg ○ Other

○ 3 head

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

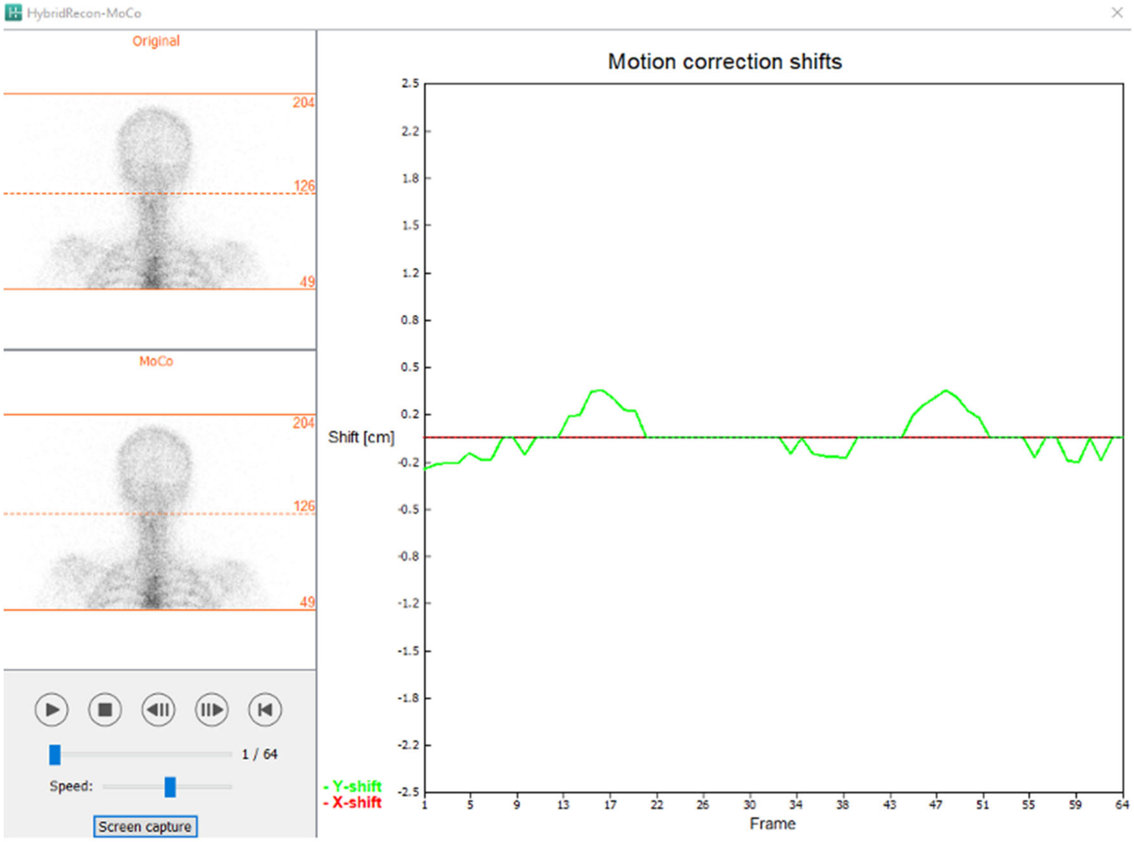
Iterations: 3

X-shift limit [cm]: 0.50

Y-shift limit [cm]: 0.10

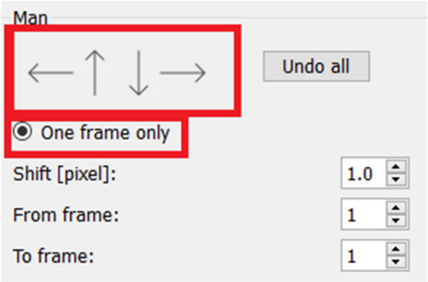
Press "Start" to initiate automatic motion correction. A "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes made to your MoCo projection will be shown in this window. You may compare your original projections to your 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.
If the "One frame only" radio-button is toggled off, you may select a range of projections to move manually by using the “From frame” and “To frame” fields.

The "One frame only" option applies synchronized X and Y shifts for dual-head 180-degree SPECT acquisitions. For all other camera orientations, the Y shift is applied to all simultaneously acquired projections, while the X shift affects only the selected projection. "Undo all-button" reverts all the shifts.



● One frame only

Shift [pixel]: 1.0

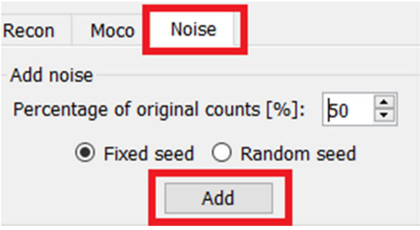
From frame: 1

To frame: 1

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. The use of this functionality requires a specific configuration and is for Research purposes.



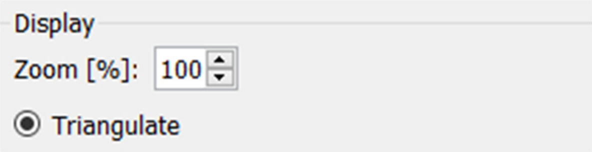
Percentage of original counts [%]: 50

● Fixed seed ○ Random seed

3.3.1.2 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.

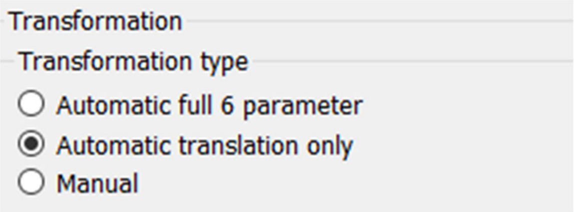


Zoom [%]: 100

● Triangulate

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.



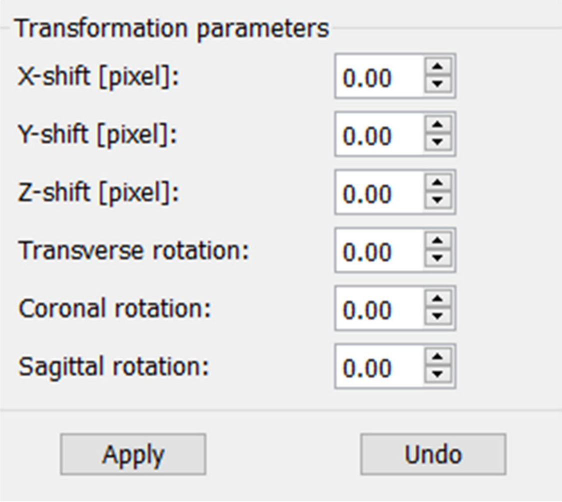
○ Automatic full 6 parameter
● Automatic translation only
○ Manual

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]: 0.00

Y-shift [pixel]: 0.00

Z-shift [pixel]: 0.00

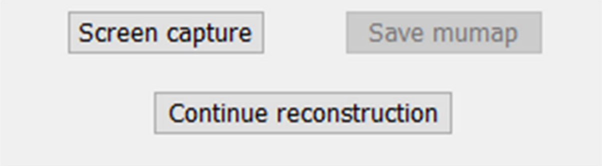
Transverse rotation: 0.00

Coronal rotation: 0.00

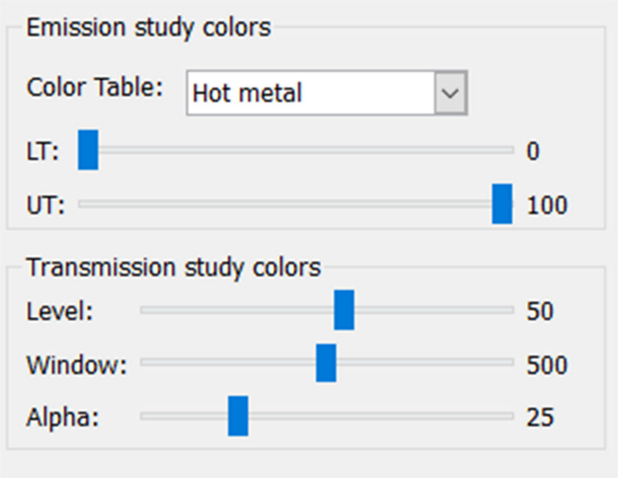
Sagittal rotation: 0.00

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 "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.



Color Table: Hot metal

LT: 0

UT: 100

Level: 50

Window: 500

Alpha: 25

3.3.1.3 Filter page

There is an option to skip this page on the Filter tab of the Program Parameters

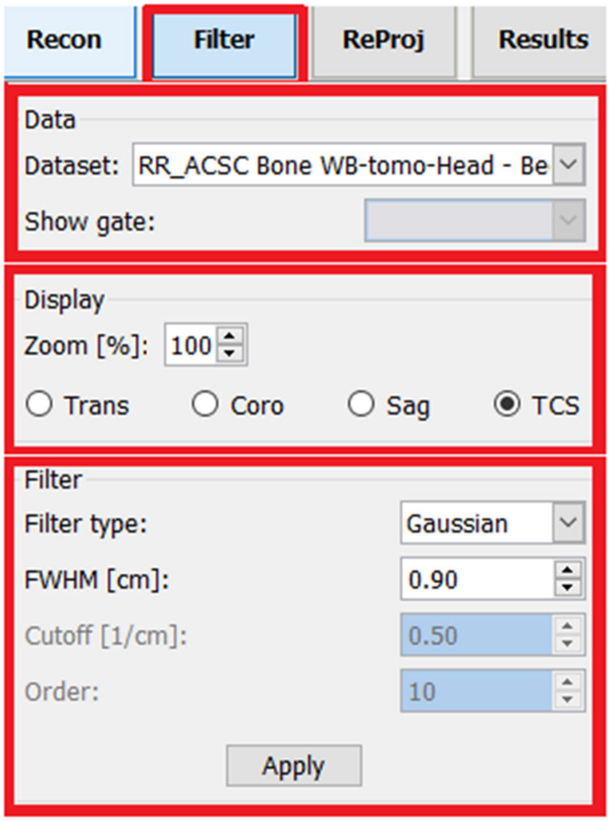
On the filter page, you may change the filter applied on your reconstructed SPECT.

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 display splash view. The radio buttons labeled “Trans”, “Coro”, “Sag” and “TCS” let you choose which view(s) will be shown in the 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.



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

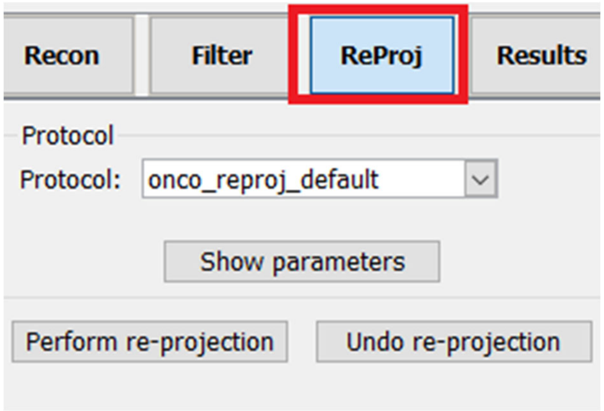
3.3.1.4 ReProj page

There is an option to skip this page on the ReProj tab of Program Parameters

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.



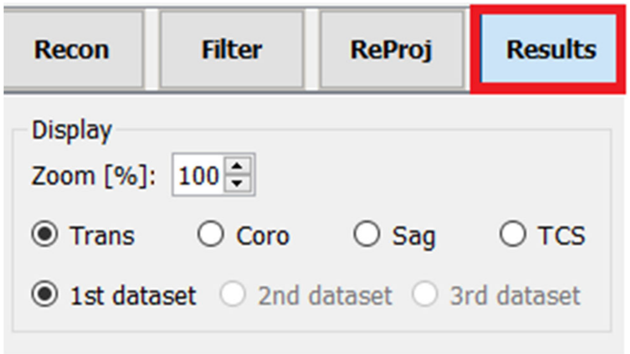
Protocol

Protocol: onco_reproj_default

3.3.1.5 Results page

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

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



Display

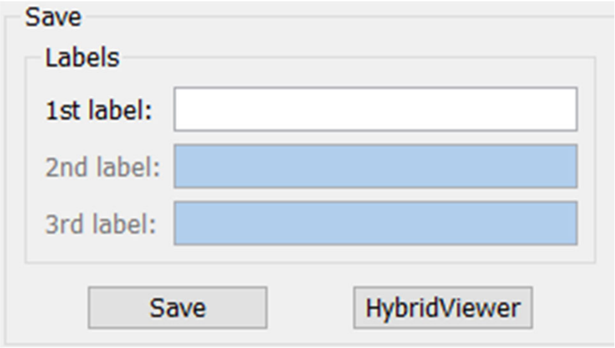
Zoom [%]: 100

● Trans ○ Coro ○ Sag ○ TCS

● 1st dataset ○ 2nd dataset ○ 3rd dataset

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.



Save

Labels

1st label:

2nd label:

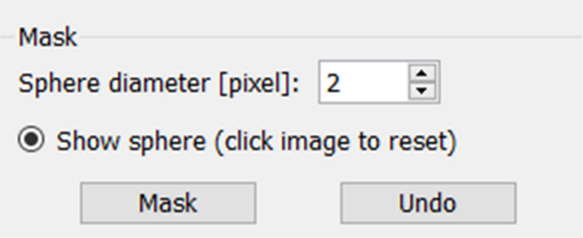
3rd label:

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.



Sphere diameter [pixel]: 2

● Show sphere (click image to reset)

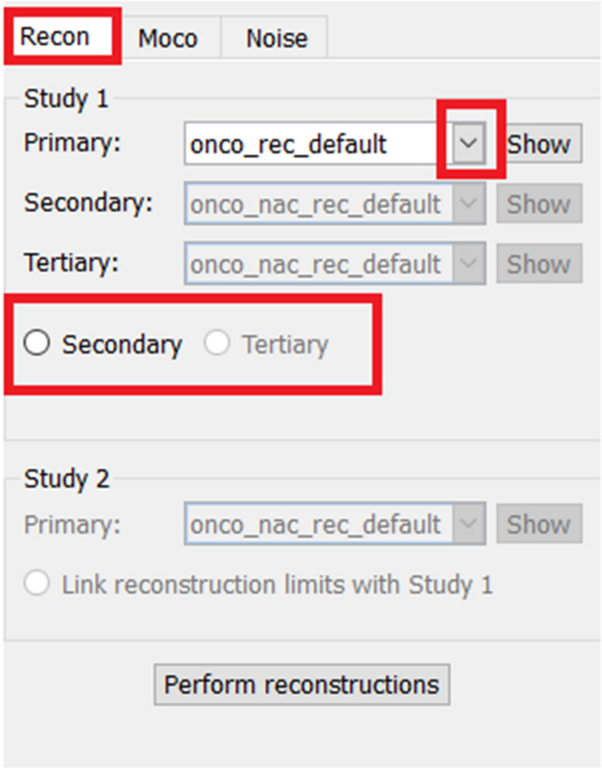
You may move the position of your spherical mask on your SPECT by doing a single click on your TCS views. By using your mouse wheel, you may scroll through your TCS single views.

3.3.2 Neurology Workflow

3.3.2.1 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.



Study 1

Primary: onco_rec_default

Secondary: onco_nac_rec_default

Tertiary: onco_nac_rec_default

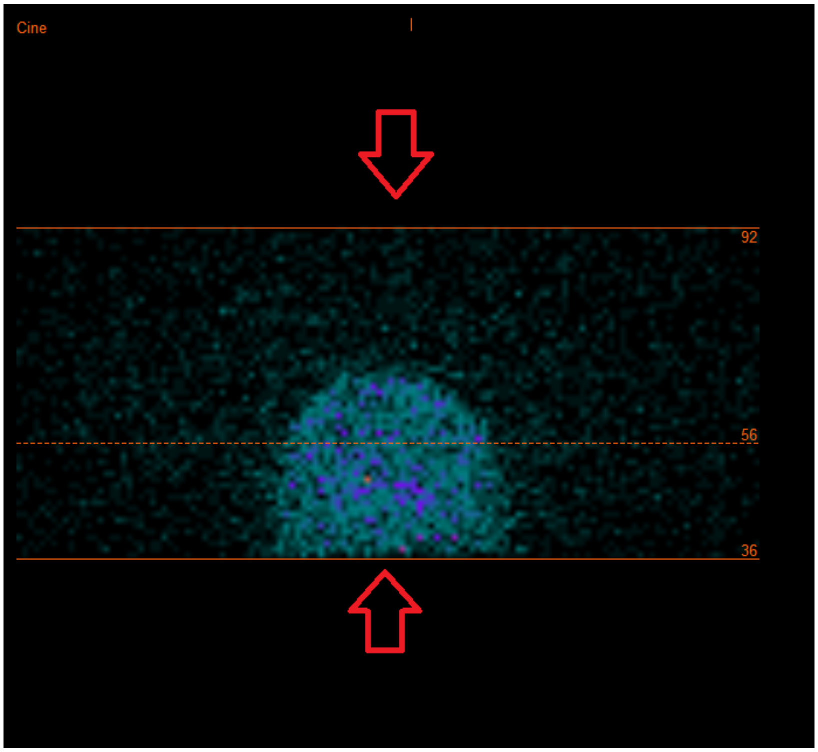
○ Secondary ○ Tertiary

Study 2

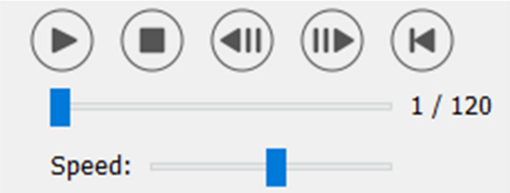
Primary: onco_nac_rec_default

○ Link reconstruction limits with Study 1

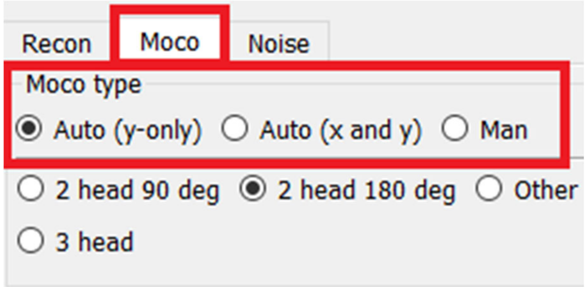
On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.



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.



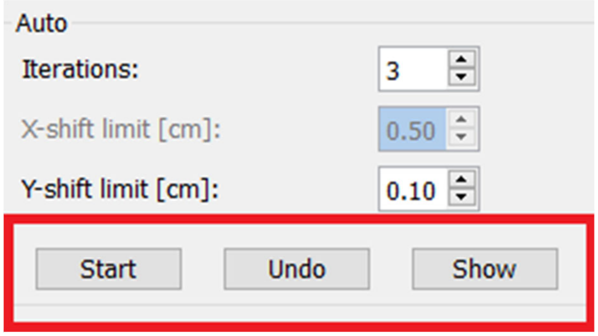
Moco type

● Auto (y-only) ○ Auto (x and y) ○ Man

○ 2 head 90 deg ● 2 head 180 deg ○ Other

○ 3 head

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

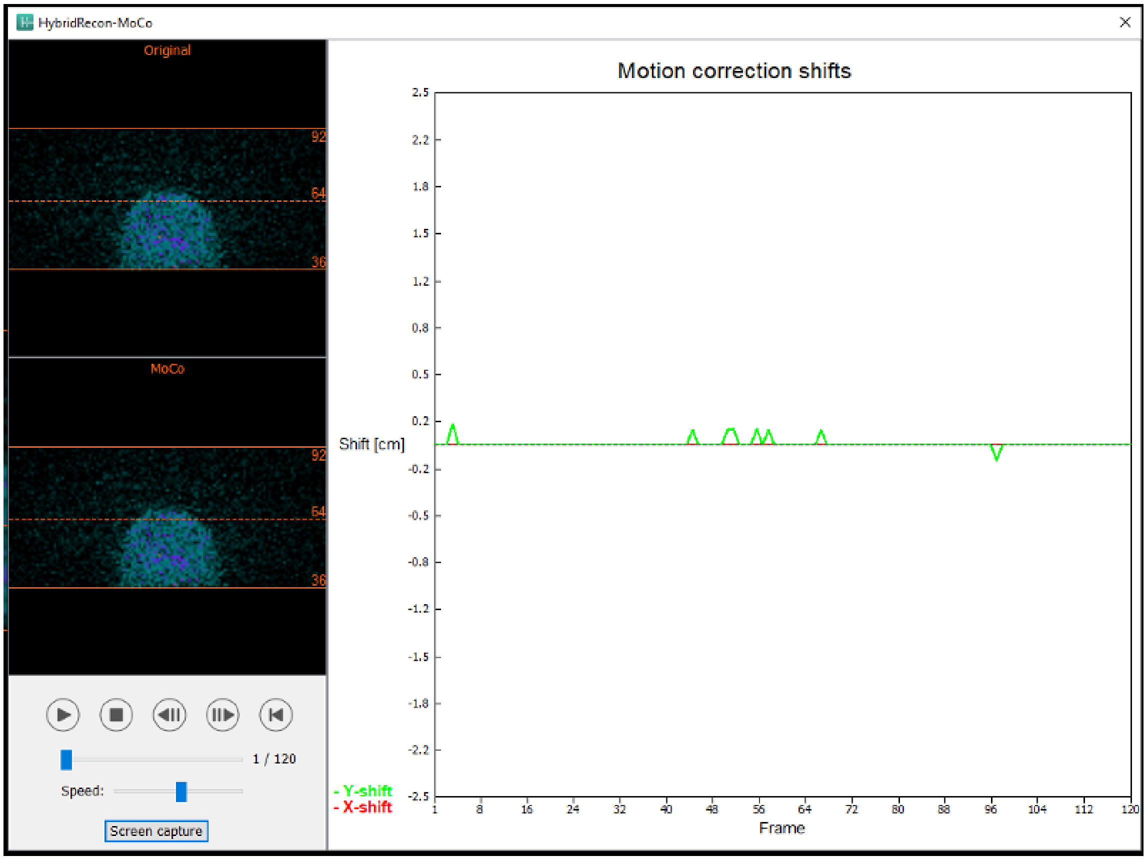
Iterations: 3

X-shift limit [cm]: 0.50

Y-shift limit [cm]: 0.10

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.

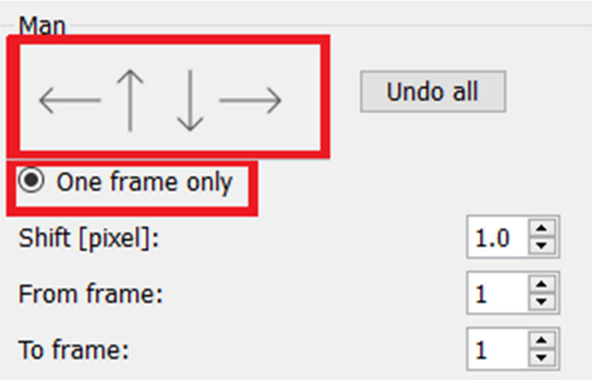
The “Screen Capture” button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo window.



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.

If the "One frame only" radio-button is toggled off, you may select a range of projections to manually move by using the “From frame” and “To frame” fields.

The "One frame only" option applies synchronized X and Y shifts for dual-head 180-degree SPECT acquisitions. For all other camera orientations, the Y shift is applied to all simultaneously acquired projections, while the X shift affects only the selected projection. "Undo all-button" reverts all the shifts.



● One frame only

Shift [pixel]: 1.0

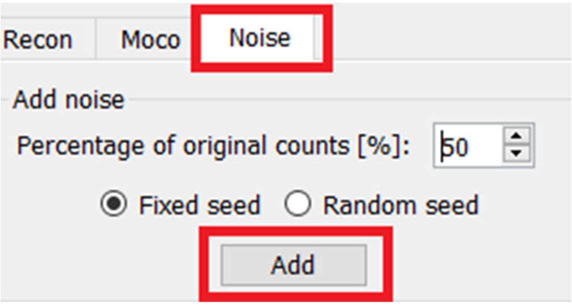
From frame: 1

To frame: 1

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. The use of this functionality requires a specific configuration and is for Research purposes.



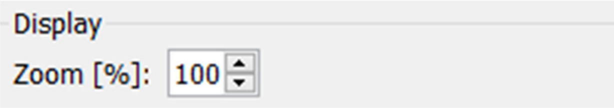
Percentage of original counts [%]: 50

● Fixed seed ○ Random seed

3.3.2.2 Uniform mumap outline page

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

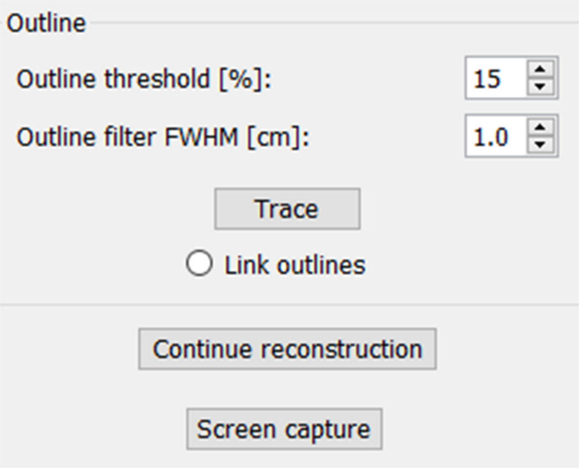
In the “Display” section, the “Zoom” field allow you to modify the zoom factor of the displayed splash view.



Zoom [%]: 100

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 mumap 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 mumap splash view.



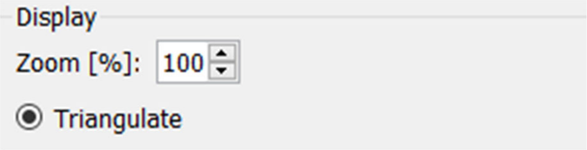
Outline threshold [%]: 15

Outline filter FWHM [cm]: 1.0

3.3.2.3 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.

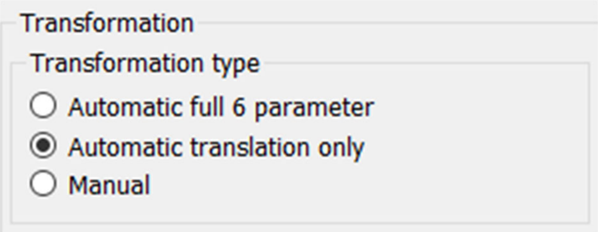


Zoom [%]: 100

● 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

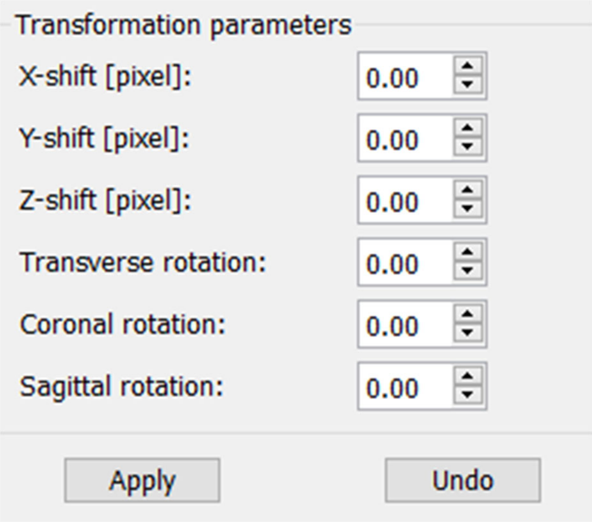
Transformation type

○ 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.

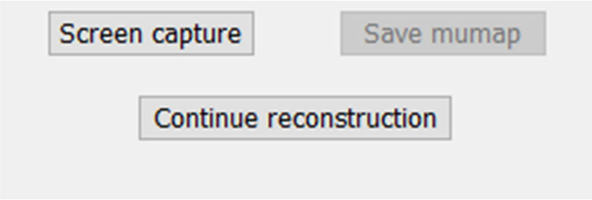


Transformation parameters

X-shift [pixel]: 0.00
Y-shift [pixel]: 0.00
Z-shift [pixel]: 0.00
Transverse rotation: 0.00
Coronal rotation: 0.00
Sagittal rotation: 0.00

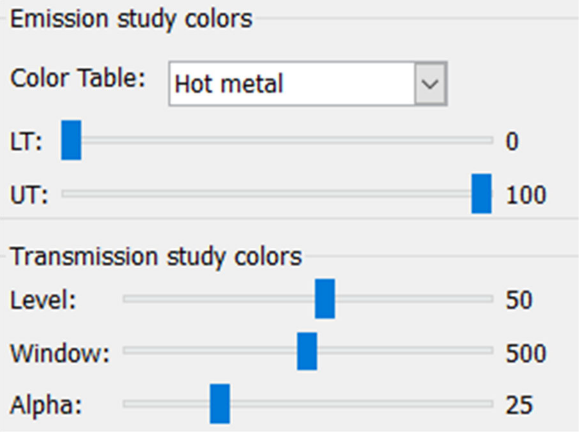
If “Transformation type” is set to manual. You may drag the CT over the SPECT images by using your mouse over the TCS views.

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 "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.



Emission study colors

Color Table: Hot metal

LT: 0

UT: 100

Transmission study colors

Level: 50

Window: 500

Alpha: 25

3.3.2.4 Filter page

There is an option to skip this page on the Filter tab of the Program Parameters

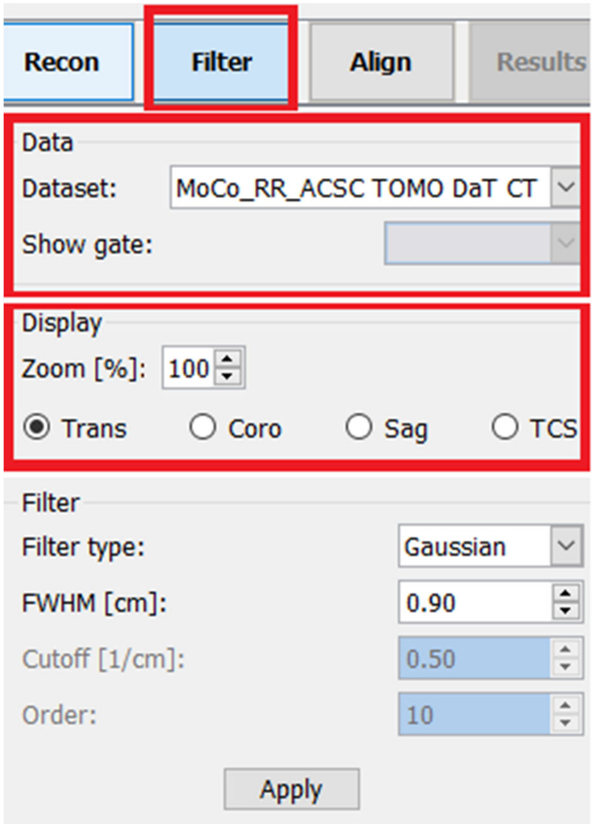
On the filter page, you may change the filter applied on your reconstructed SPECT.

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.



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

3.3.2.5 Align page

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

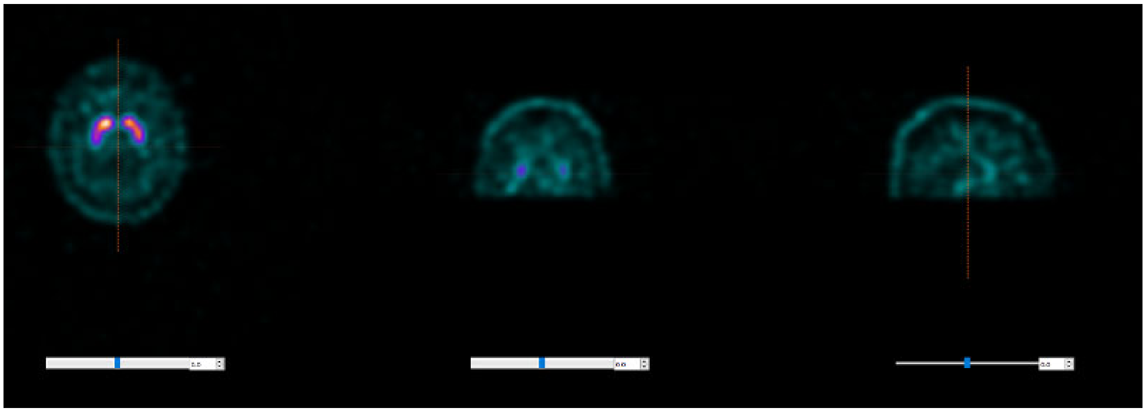
In the “Mode” section, you can toggle between the “Align” and “Zoom” radio-buttons.

Mode

● Align ○ Zoom

Saved zoom [%]: 400

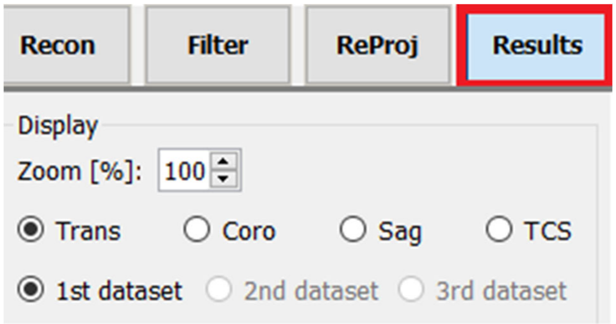
In the “Align” mode, dotted crosses will be displayed over your TCS views. You may move the cross over your SPECT by using your mouse. Each of your TCS views will automatically triangulate over the new cross location. Two options are available for rotating your views: slide the mouse to the required 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.



3.3.2.6 Results page

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

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



Display

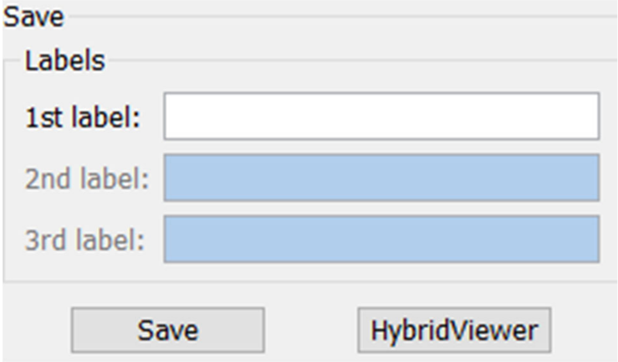
Zoom [%]: 100

● Trans ○ Coro ○ Sag ○ TCS

● 1st dataset ○ 2nd dataset ○ 3rd dataset

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.



1st label:

2nd label:

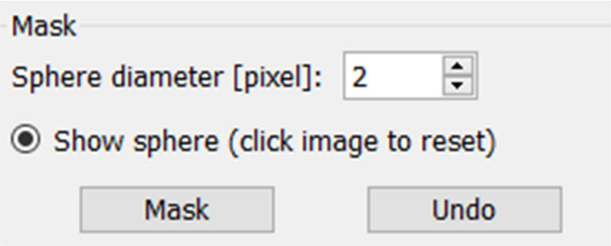
3rd label:

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.



Sphere diameter [pixel]: 2

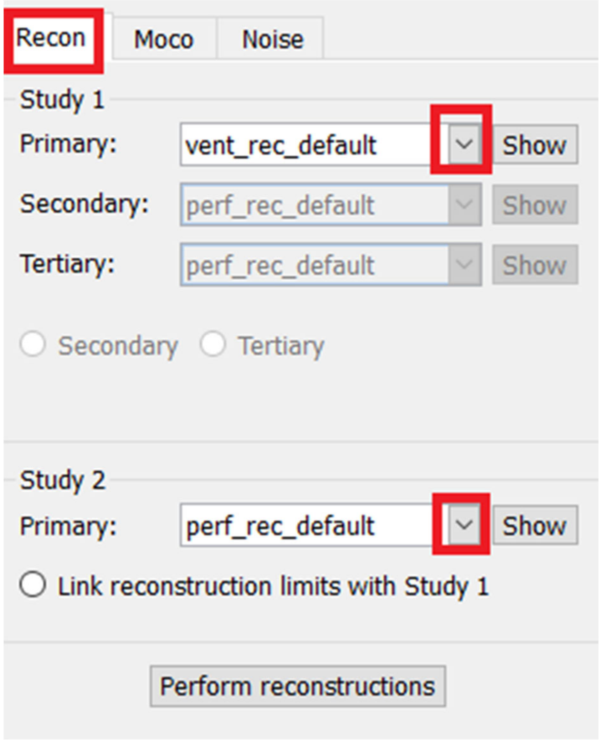
● Show sphere (click image to reset)

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.

3.3.3 Lung Workflow

3.3.3.1 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.



Study 1

Primary: vent_rec_default

Secondary: perf_rec_default

Tertiary: perf_rec_default

○ Secondary ○ Tertiary

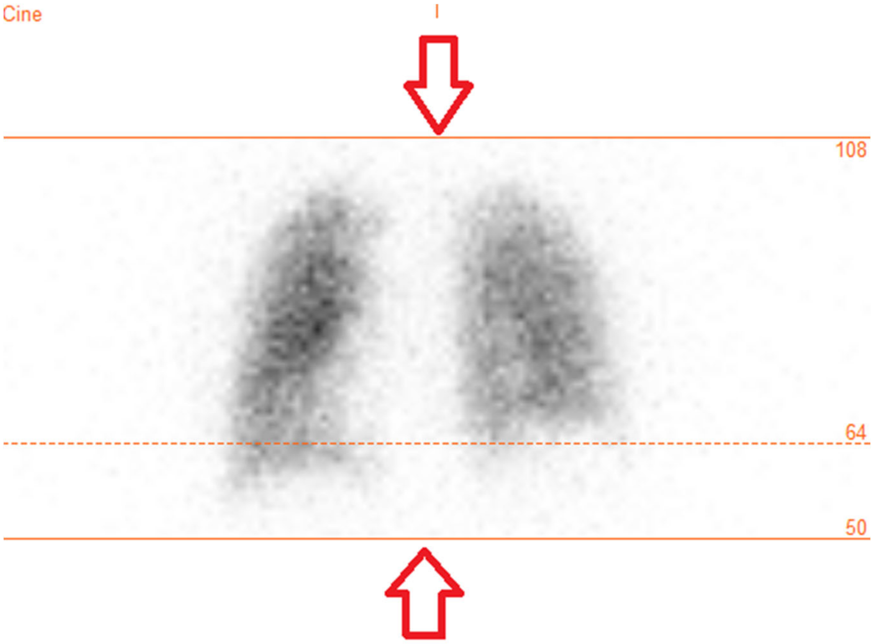
Study 2

Primary: perf_rec_default

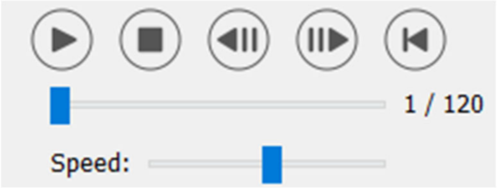
○ Link reconstruction limits with Study 1

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

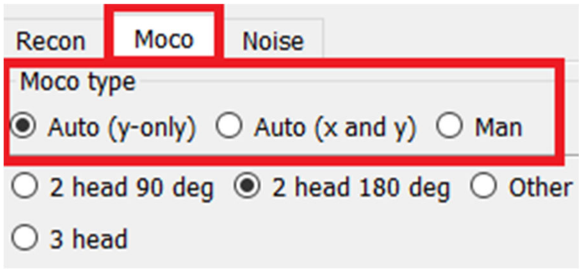
On the cine picture, dragging the horizontal lines up and down will change the reconstruction field size.



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.



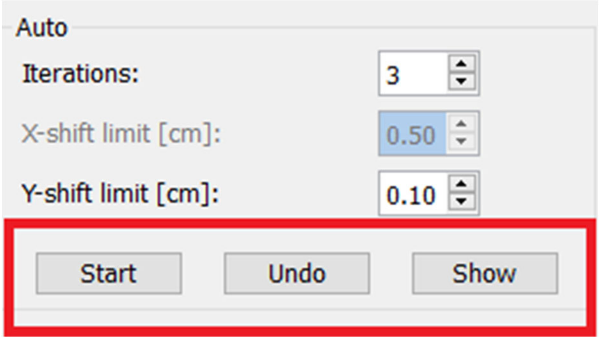
Moco type

● Auto (y-only) ○ Auto (x and y) ○ Man

○ 2 head 90 deg ● 2 head 180 deg ○ Other

○ 3 head

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.



Iterations: 3

X-shift limit [cm]: 0.50

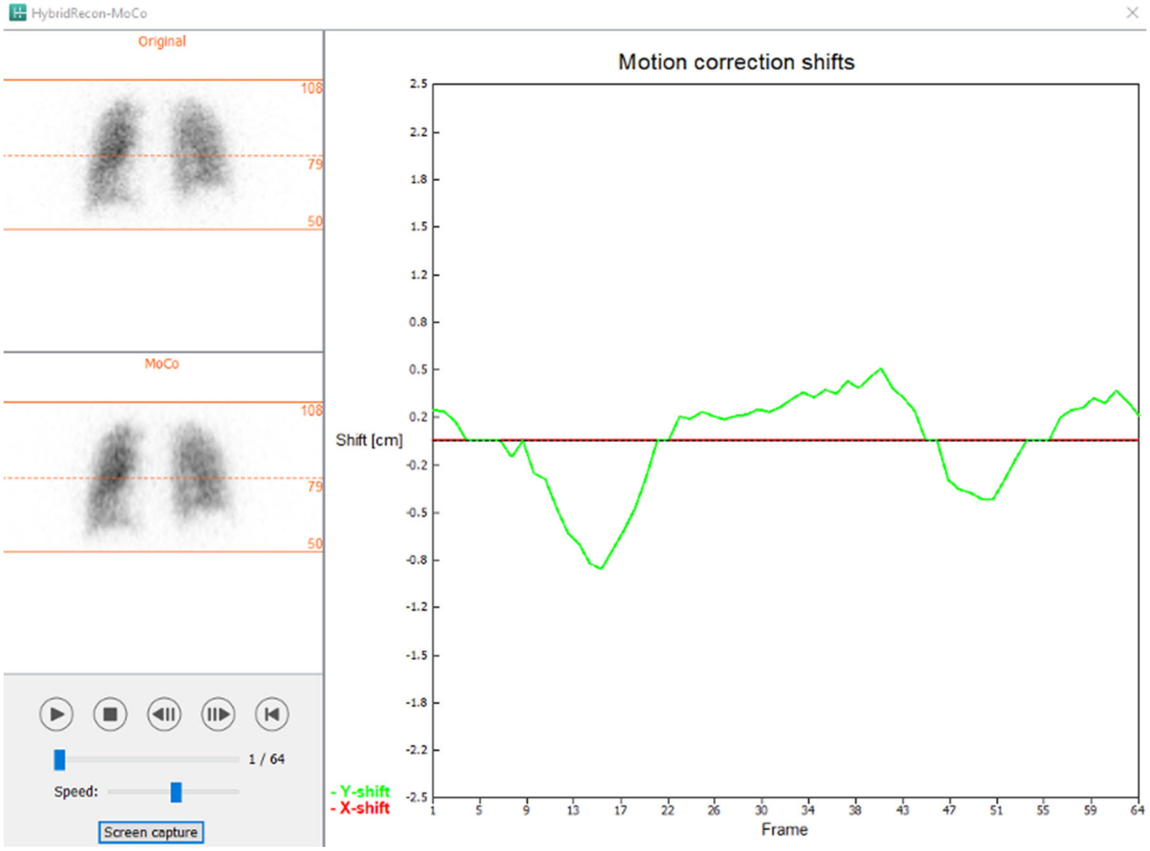
Y-shift limit [cm]: 0.10

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.

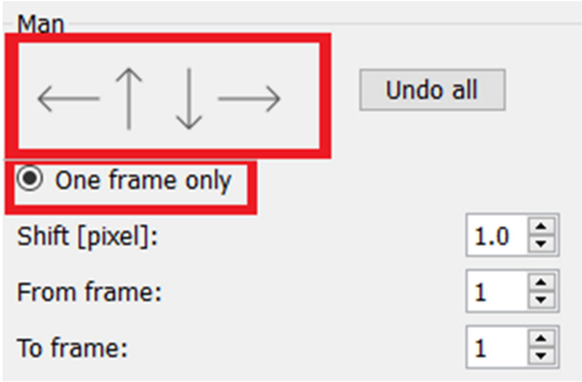
Press "Start" to initiate an automated motion correction. An "HybridRecon-MoCo" window will appear when the motion correction is finished. A visual representation of the motion correction changes, made to your MoCo projection, will be shown in this window. You may compare your original projections to 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.
If the "One frame only" radio-button is toggled off, you may select a range of projections to move manually by using the “From frame” and “To frame” fields.

The "One frame only" option applies synchronized X and Y shifts for dual-head 180-degree SPECT acquisitions. For all other camera orientations, the Y shift is applied to all simultaneously acquired projections, while the X shift affects only the selected projection. "Undo all-button" reverts all the shifts.



● One frame only

Shift [pixel]: 1.0

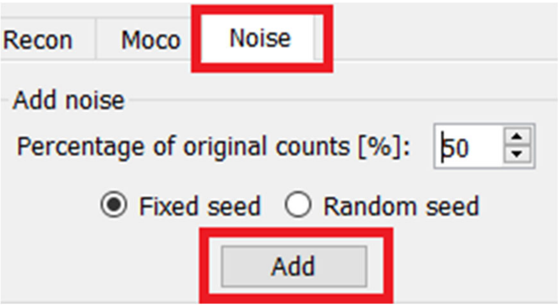
From frame: 1

To frame: 1

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. The use of this functionality requires a specific configuration and is for Research purposes.



Percentage of original counts [%]: 50

● Fixed seed ○ Random seed

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

3.3.3.2 SPECT-CT or synthetic mumap co-registration page

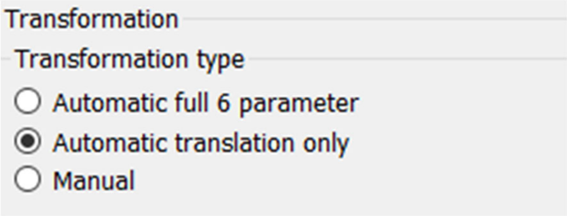
In the “Display” section, the “Zoom” field allows you to apply a specified zoom factor to your transverse, coronal and sagittal fusion views. When the “Triangulate” radio-button is active, you may triangulate in your TCS views by using a single left click on any view.

Zoom [%]: 100

● Triangulate

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

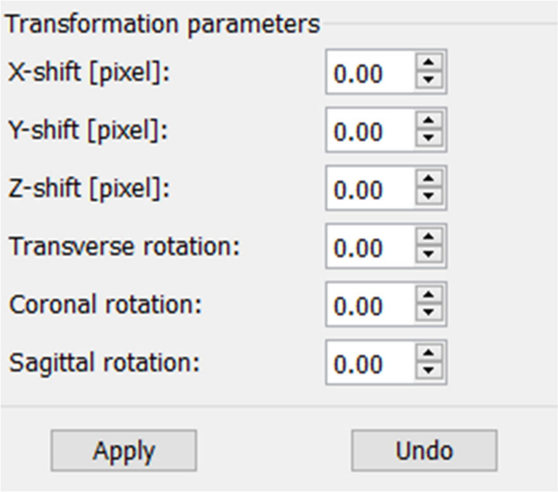
Transformation type

○ 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.

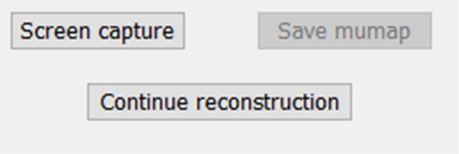


Transformation parameters

X-shift [pixel]: 0.00
Y-shift [pixel]: 0.00
Z-shift [pixel]: 0.00
Transverse rotation: 0.00
Coronal rotation: 0.00
Sagittal rotation: 0.00

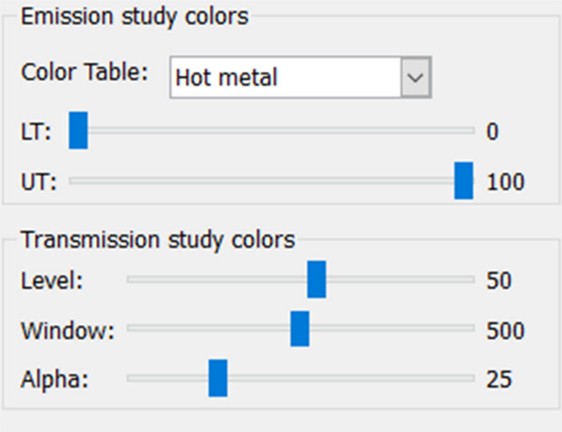
If “Transformation type” is set to manual, you can drag the CT over the SPECT images by moving your mouse over the TCS views.

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.



Emission study colors

Color Table: Hot metal

LT: 0

UT: 100

Transmission study colors

Level: 50

Window: 500

Alpha: 25

3.3.3.3 Filter Page

There is an option to skip this tab on the Filter tab of the Program Parameters.

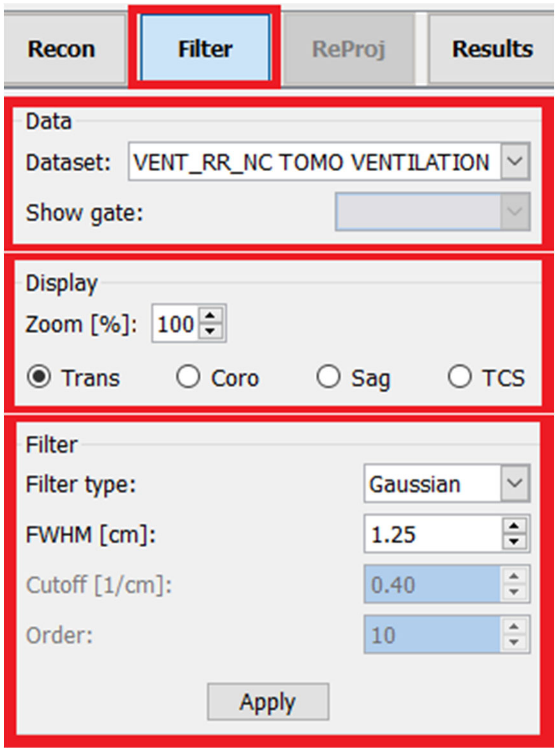
On the filter page, you may change the filter applied on your reconstructed SPECT.

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.



Data
Dataset: VENT_RR_NC TOMO VENTILATION
Show gate:

Display
Zoom [%]: 100
● Trans ○ Coro ○ Sag ○ TCS

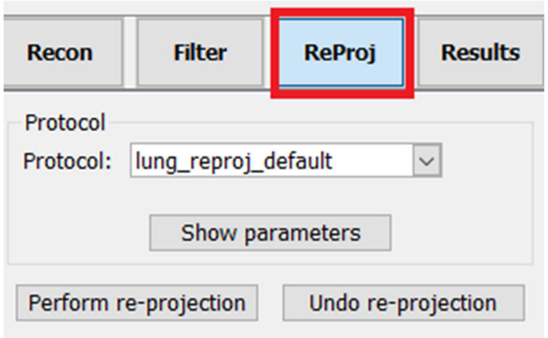
Filter
Filter type: Gaussian
FWHM [cm]: 1.25
Cutoff [1/cm]: 0.40
Order: 10

3.3.3.4 ReProj page

There is an option to skip this page on the ReProj tab of Program Parameters

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.

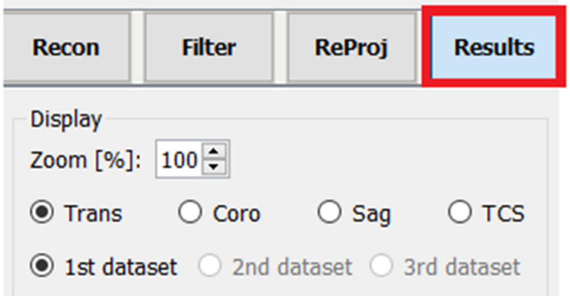


Protocol
Protocol: lung_reproj_default

3.3.3.5 Results page

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

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



Display

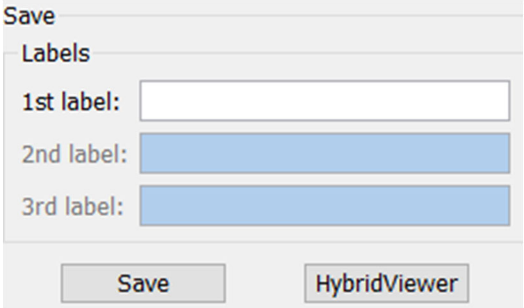
Zoom [%]: 100

● Trans ○ Coro ○ Sag ○ TCS

● 1st dataset ○ 2nd dataset ○ 3rd dataset

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.

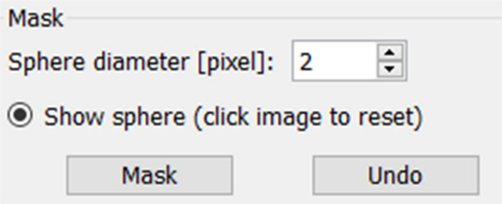


The “Mask” section allows you to mask a portion of your SPECT images using a spherical mask.

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.



Sphere diameter [pixel]: 2

● Show sphere (click image to reset)

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.

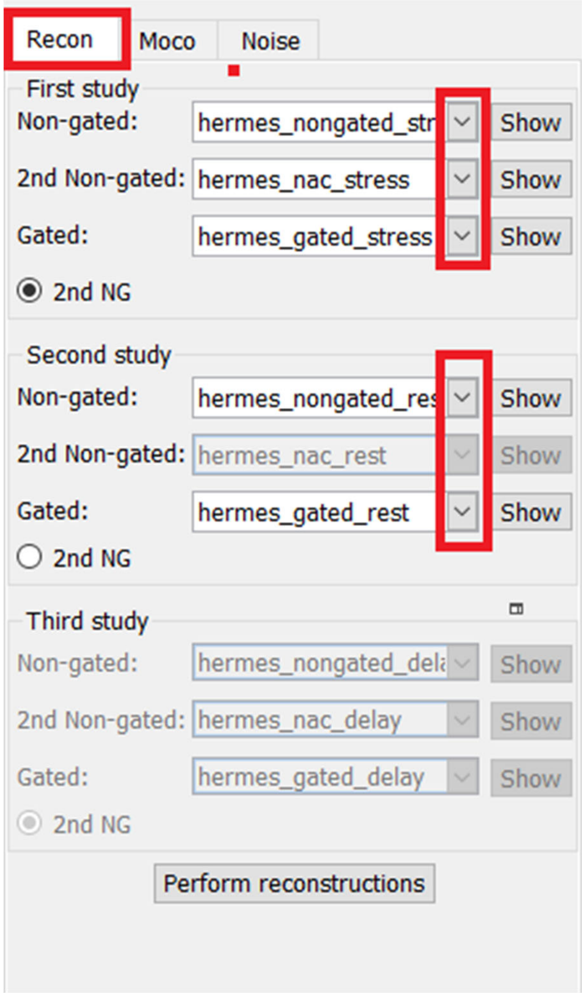
3.3.4 Cardiology Workflow

3.3.4.1 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.

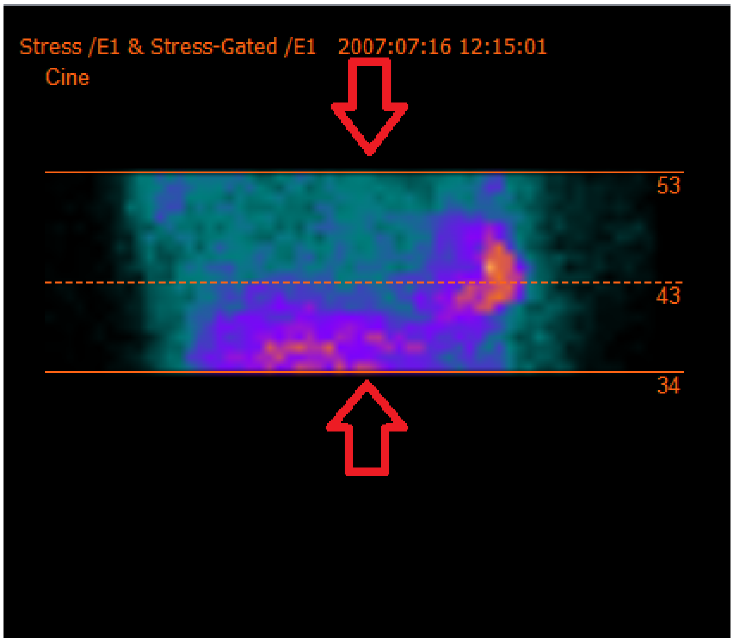


First study
Non-gated: hermes_nongated_str
2nd Non-gated: hermes_nac_stress
Gated: hermes_gated_stress
● 2nd NG

Second study
Non-gated: hermes_nongated_res
2nd Non-gated: hermes_nac_rest
Gated: hermes_gated_rest
○ 2nd NG

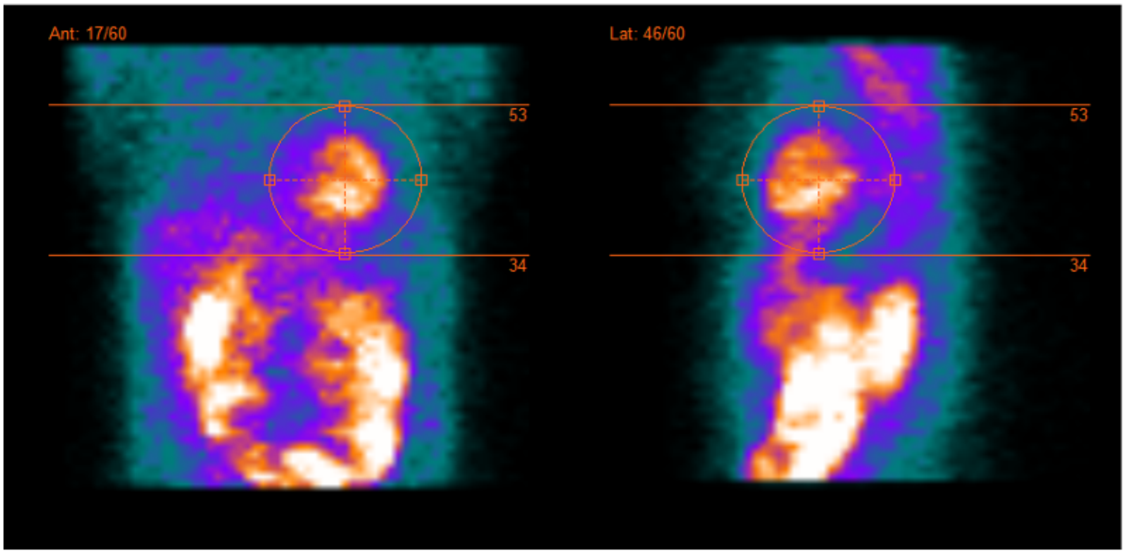
Third study
Non-gated: hermes_nongated_del
2nd Non-gated: hermes_nac_delay
Gated: hermes_gated_delay
○ 2nd NG

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

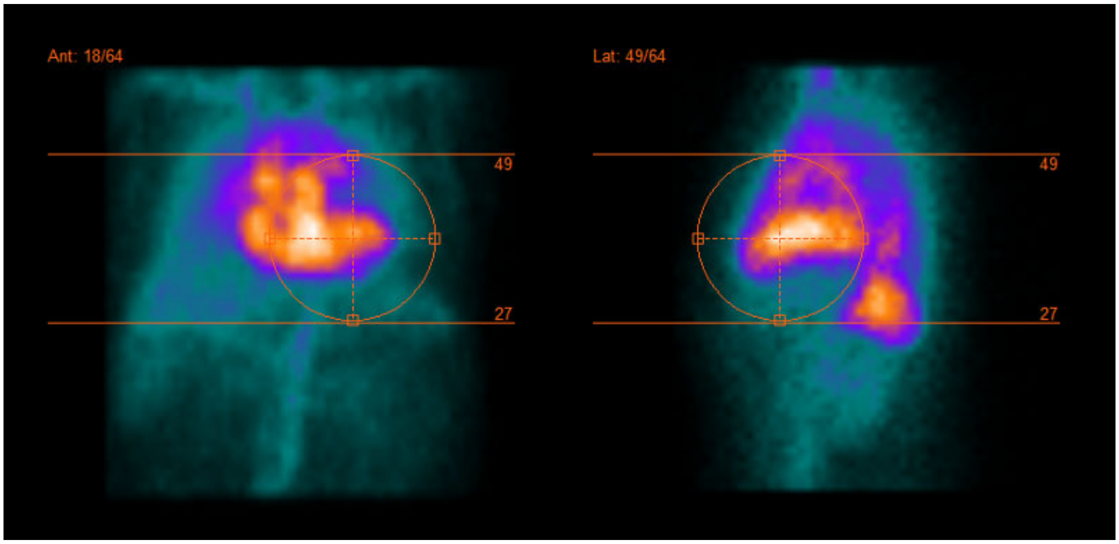


The circle-cross should be centered in the middle of the myocardium on the anterior and lateral views for stress/rest cardiac studies and centered in the left ventricle position for bloodpool SPECT studies.

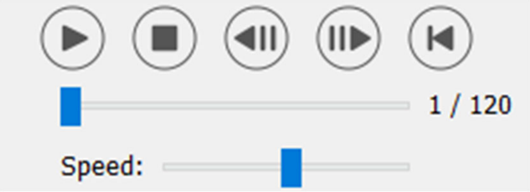
Stress and rest cardiac study



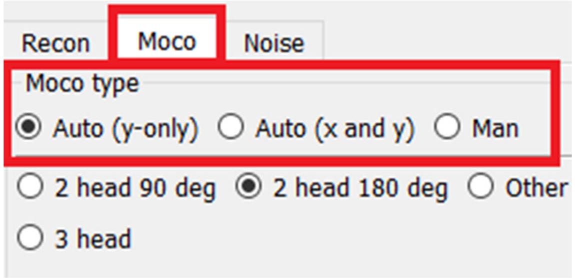
Bloodpool study



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.



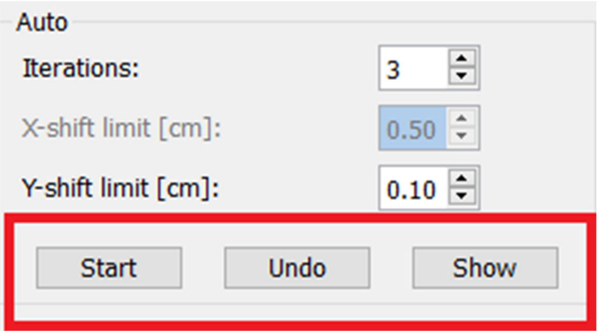
Moco type

● Auto (y-only) ○ Auto (x and y) ○ Man

○ 2 head 90 deg ● 2 head 180 deg ○ Other

○ 3 head

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.



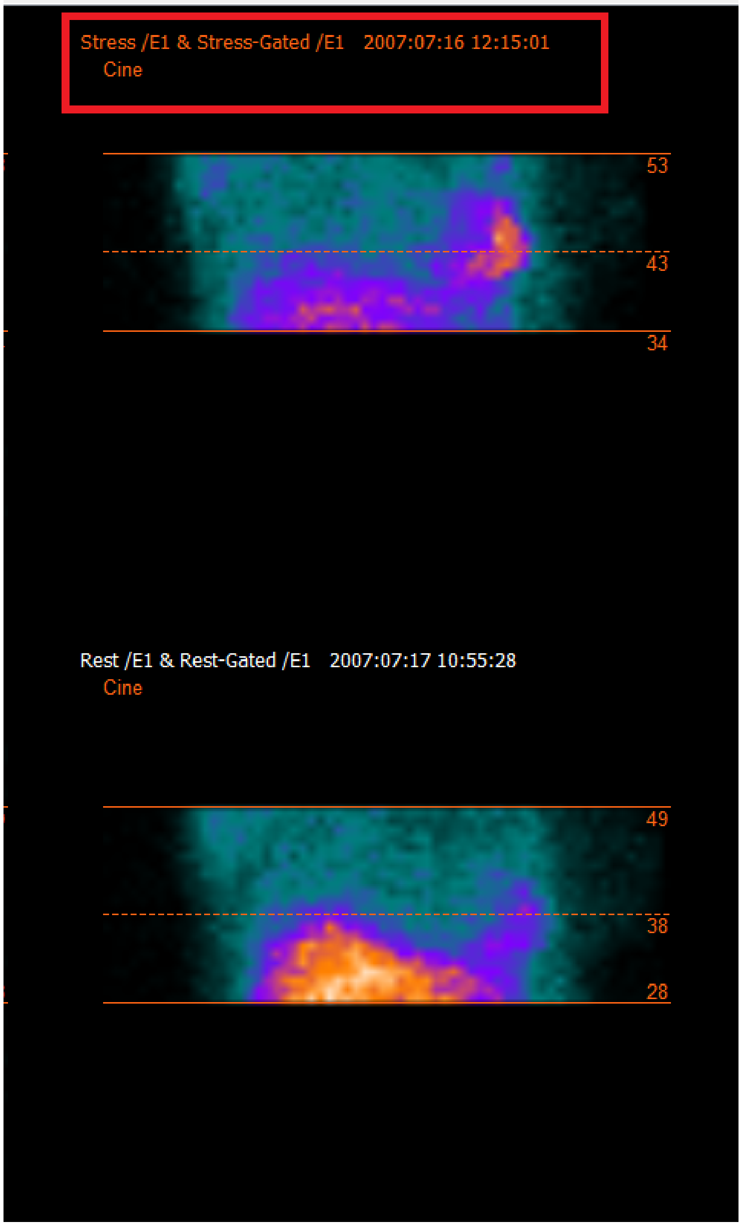
Auto

Iterations: 3

X-shift limit [cm]: 0.50

Y-shift limit [cm]: 0.10

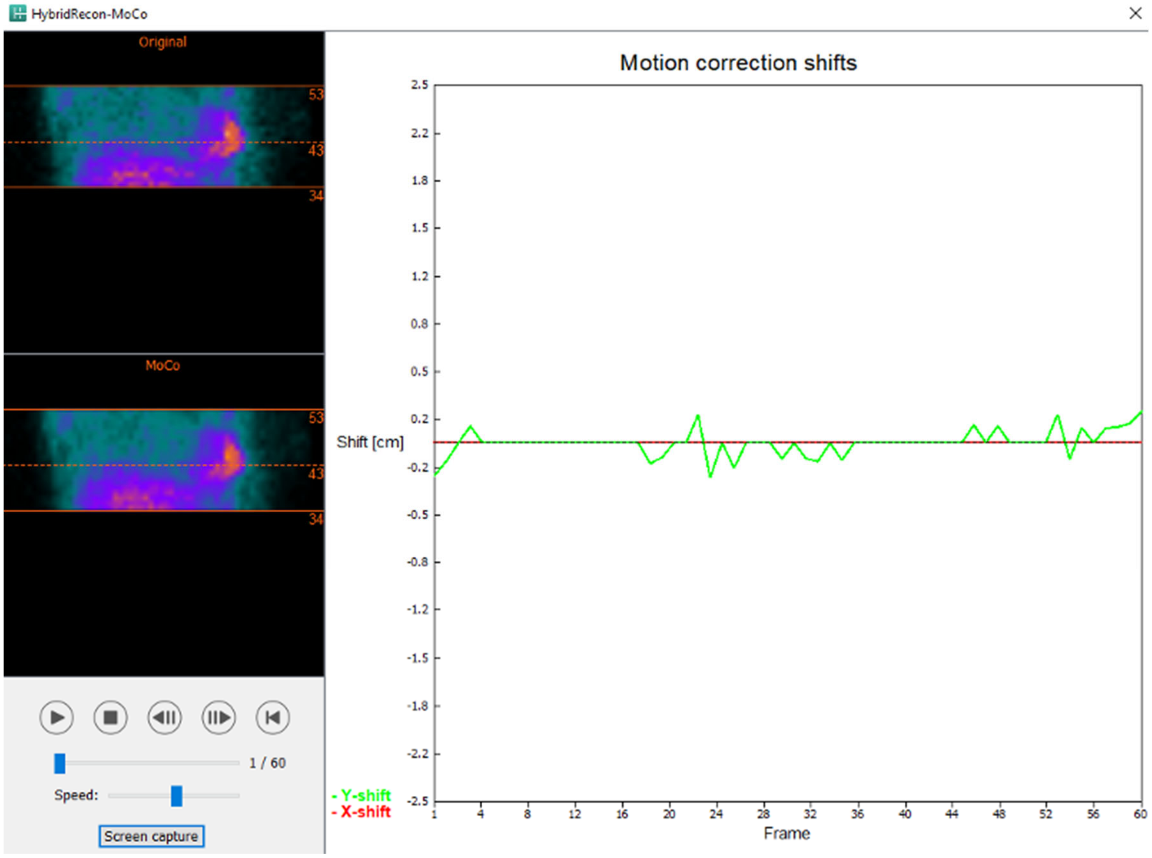
Motion correction may be performed to only one study at a time. The study that has his series label colored in orange is the active one.



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.

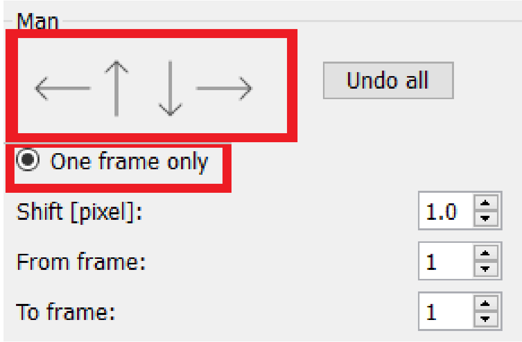
The “Screen Capture” button allows you to save a screen capture of the MoCo window. Hit the cross at the upper right of that window to close the MoCo window.



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.

If the "One frame only" radio-button is toggled off, you may select a range of projections to move manually by using the “From frame” and “To frame” fields.

The "One frame only" option applies synchronized X and Y shifts for dual-head 180-degree SPECT acquisitions. For all other camera orientations, the Y shift is applied to all simultaneously acquired projections, while the X shift affects only the selected projection. "Undo all-button" reverts all the shifts.



● One frame only

Shift [pixel]: 1.0

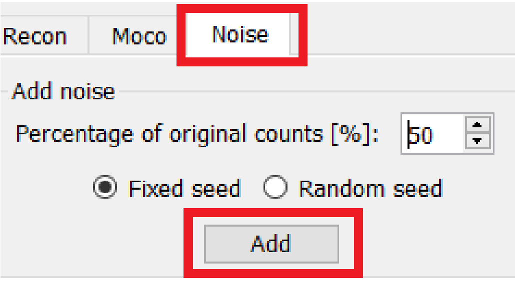
From frame: 1

To frame: 1

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. The use of this functionality requires a specific configuration and is for Research purposes.



Percentage of original counts [%]: 50

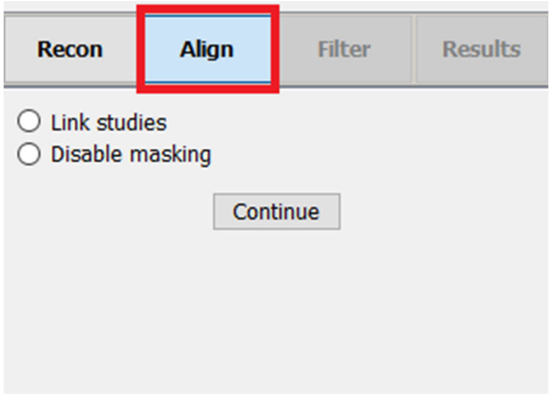
● Fixed seed ○ Random seed

3.3.4.2 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.

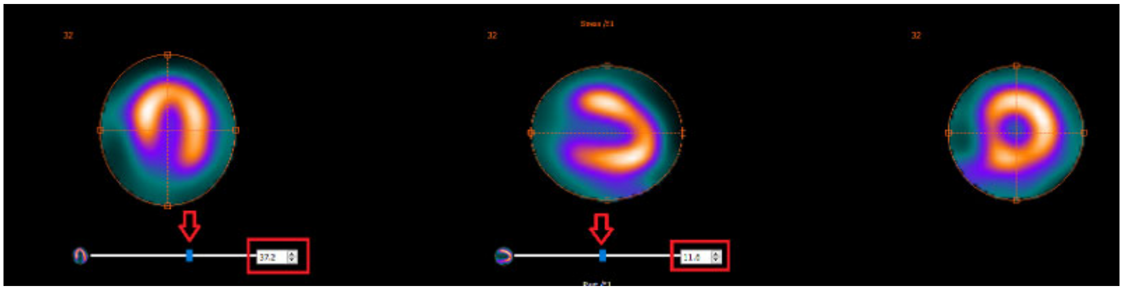
You may continue the reconstruction process by clicking on the “Continue” button.



○ Link studies

○ Disable masking

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.

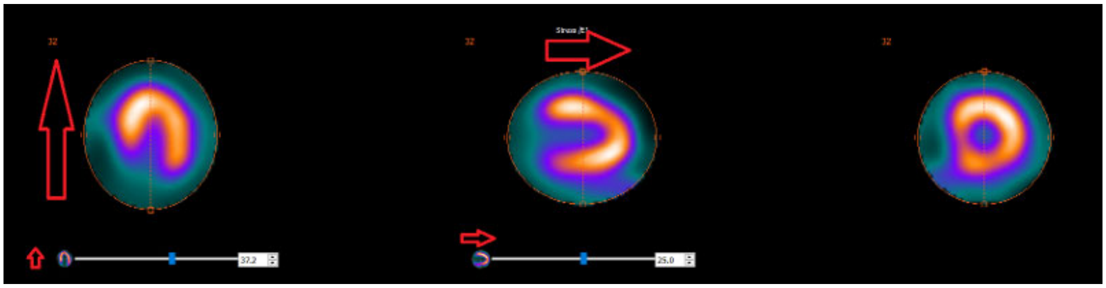


When a view has your pointer over it, you may scroll through the slices with the mouse wheel.

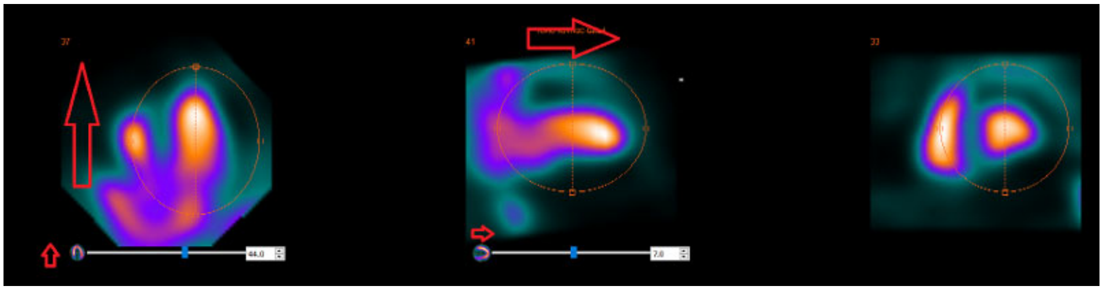
You may change the triangulation of your views by dragging the circle-cross center. We do recommend to locate the middle of your circle-cross in the middle of your myocardial or, for bloodpool studies, in the center of the left ventricle.

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



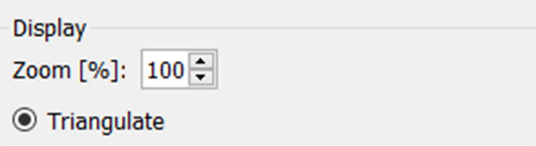
Bloodpool study



3.3.4.3 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.



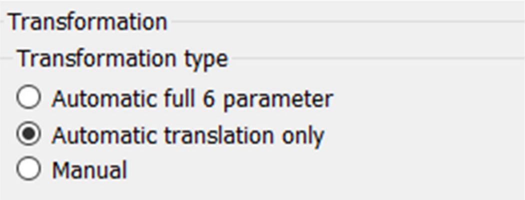
Display

Zoom [%]: 100

● Triangulate

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

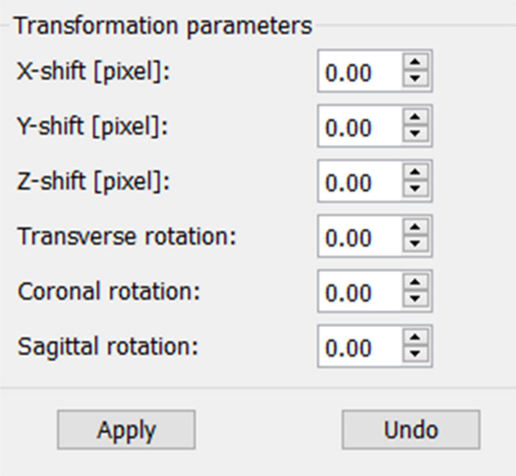
● Automatic translation only

○ 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 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.



Transformation parameters

X-shift [pixel]: 0.00

Y-shift [pixel]: 0.00

Z-shift [pixel]: 0.00

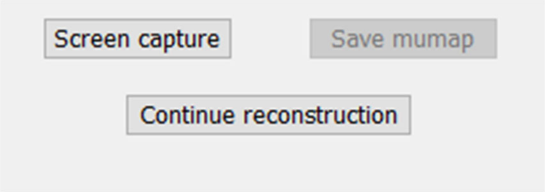
Transverse rotation: 0.00

Coronal rotation: 0.00

Sagittal rotation: 0.00

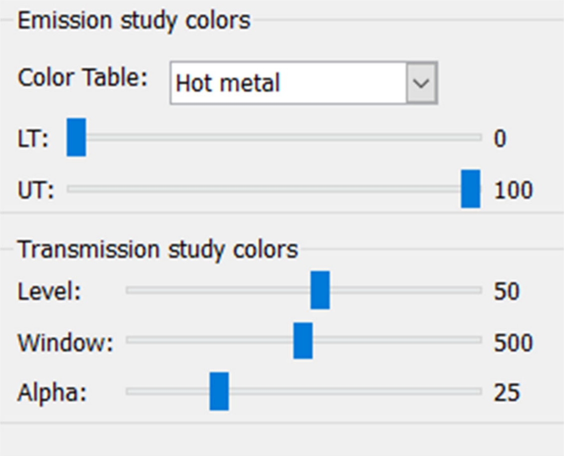
If “Transformation type” is set to manual, you can drag the CT over the SPECT images by moving the mouse over the TCS views.

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.



Color Table: Hot metal

LT: 0

UT: 100

Level: 50

Window: 500

Alpha: 25

3.3.4.4 Filter Page

There is an option to skip this page on the Filter tab of the Program Parameters.

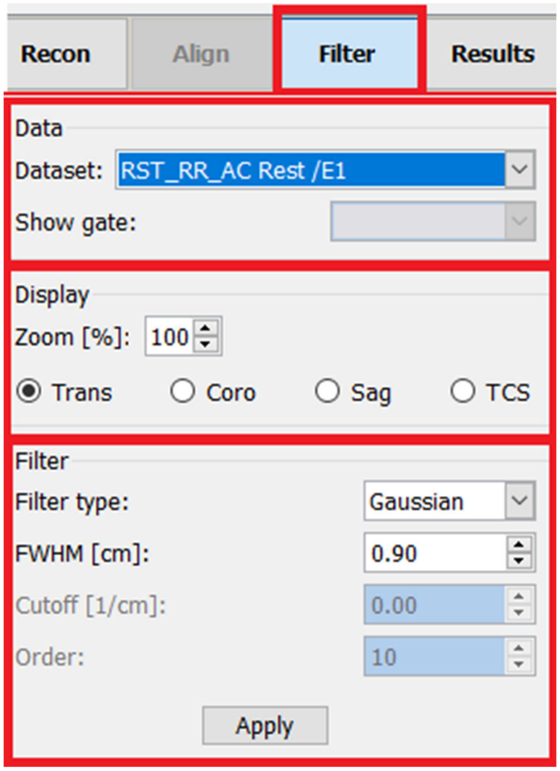
On the filter page, you may change the filter applied to the reconstructed SPECT.

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 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.



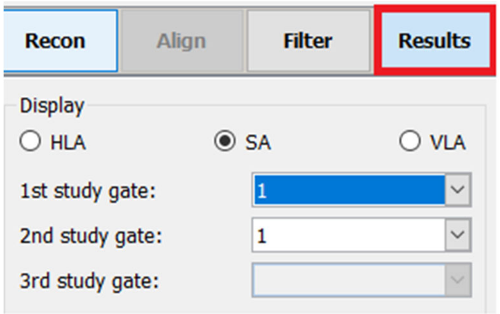
Data
Dataset: RST_RR_AC Rest /E1
Show gate:

Display
Zoom [%]: 100
● Trans ○ Coro ○ Sag ○ TCS

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

3.3.4.5 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.



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.

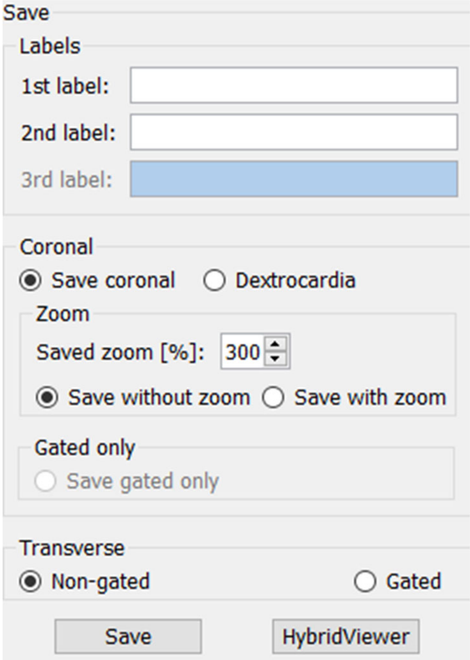
In the “Coronal” section, the “Save coronal” toggle button will activate saving of the coronal views. If your study is a situs inversus or Dextrocardia study, the “Dextrocardia” toggle button will flip the heart views.

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 [%]: 300

● Save without zoom ○ Save with zoom

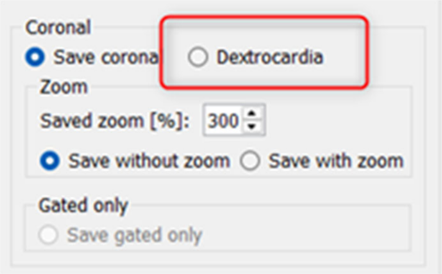
Gated only

○ Save gated only

Transverse

● Non-gated ○ Gated

When saving cardiac reconstructed slices, there is an option to apply a "dextrocardia flip" to the saved images. Applying this setting will flip the saved images left-to-right and will allow the images to be processed more easily in 3rd party myocardial analysis software such as Cedars QPS/QGS or INVIA Corridor 4DM. Dextrocardia flip should only be applied if the patient's heart is oriented in the opposite direction to usual, i.e. the heart apex is pointing to the right side of the body instead of the left. The saved series will have the text "dextrocardia flip" appended to the series description. In these cases, it is also recommended to include both ventricles in the masked short axis slices in order to facilitate identifying the septal and lateral walls in the final images. Contact Hermes Medical Solutions support if you have any questions.



Coronal
● Save corona ○ Dextrocardia
Zoom
Saved zoom [%]: 300
● Save without zoom ○ Save with zoom
Gated only
○ Save gated only

3.4 User 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.

3.5 Security

Hybrid Recon processes Personal Identifiable Information (PII), so 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 responsibility of the customer to install and maintain anti-virus software on the server and client computers and apply the necessary protection against threats.

Backup copies of all user and layout protocols supplied with Hybrid Recon are stored separately at installation so that the user can revert if required.

Any detected, or suspected, cyber security incident that has occurred with the product must be reported to our support, see Contact Information.

In case Hermes Medical Solutions identify a security issue in our product, Field Security Notices will be issued to all potentially affected customers. The notice will contain detailed instructions on how the users should respond and act to recover from any issue taken place and minimize the risk of being affected by the identified issue.

Depending on applicable regulations, incidents may also need to be reported to national authorities.

The product executable is signed with *Hermes Medical Solutions Aktiebolag*'s Digital Signature to ensure the authenticity and integrity.

In case of network unavailability, starting the product or loading/saving data may fail.
In case the network fails during use of the product, the user should re-load and verify that the saved data is complete. If not, the data should be processed again.

3.5.1 Interfaces

This section lists all interfaces available in Hybrid Recon. To be noted, the Hybrid Recon application is fully reliant on the security features of the Hosting Environment.

Hardware Interface
Hybrid Recon functions exclusively as software without any hardware interfaces.

Network Interface
The Hybrid Recon application interfaces with the Local Area Network (LAN) of its Hosting Environment and can import and export data from and to file systems across the network.

Service Interface
In order to run the Hybrid Recon application, a license is needed. The license key can be read from local disk, network disk or Windows Registry. Licenses can also be read over the network (TCP/IP) from a license server.

User Interface (UI)

Graphical User Interface (GUI)
The User Interface (UI) for Hybrid Recon is its Graphical User Interface (GUI) which is described in detail above in Section *User Interface*.

Command Line Interface (CLI)
Hybrid Recon includes a Command-Line Interface (CLI) which supports arguments at launch.

Data Exchange Interface
Hybrid Recon interfaces with the file system to read and write medical imaging data. The application supports DICOM and Interfile file formats for data exchange.

File System Interface
In order to read/write DICOM input/output (I/O) files from the filesystem, an open-source implementation of the DICOM standard called Grassroots DICOM (GDCM) is utilized. This implementation has been further modified by HMS.

Additionally, Hybrid Recon retrieves default parameters for various image protocols from an XML configuration file. These parameters can also be modified within the application itself and in aforementioned configuration file.

Database Interface
Hybrid Recon does not utilize data storage in a database. Instead, all information is managed locally within the application itself.

3.6 Warning

This section describe warning to safely use the application.

3.6.1 Network Unavailable

⚠ If the network is unavailable it may not be possible to maintain the Intended Use of the device

3.6.2 Data transmission

⚠ 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.

3.6.3 Manual Verification Recommended

⚠ The intended user should not rely solely on the automatic procedures undertaken by Hybrid Recon but should verify the results and process manually if required.

3.6.4 Verify Patient Data for SUV SPECT

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

3.6.5 Motion Correction: Use with Caution

⚠ 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.

3.6.6 Factors Affecting Quantitative Accuracy

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. No dead-time correction is applied during reconstruction, so quantitative accuracy might be reduced at very high count rates- in particular for SPECT scans acquired very soon after some high-dose radionuclide therapy procedures. It is important that the accuracy is evaluated based on conducted phantom measurements, to ensure the reliability of the quantified values.

3.6.7 Decay Correction Requirements

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

3.6.8 Consistent Reconstruction for Study Comparison

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.

3.6.9 Neurology Reconstruction, BRASS

Hybrid Recon - 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.

3.6.10 Minimize Rotations and Zooming

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

3.6.11 Use Correct Decimal Separator

Decimal numbers should be entered using a point or comma depending on the Windows Locale setting. If an inappropriate separator is entered it will be removed automatically, so care should be taken to use this correctly.

3.7 List of acceptable symbols

Hybrid Recon uses Windows Regional format settings for the decimal separator. The thousand (group) separator is not displayed in the User Interface and it is recommended not to use it.
The following decimal separators are accepted:

- "." (full stop)
- "," comma

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 CH REP
CMI-experts
Grellinger Str. 40
4052 Basel
Switzerland

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

4.3 Subsidiaries

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

Hermes Medical Solutions, Inc
2120 E. Fire Tower Rd, #107-197
Greenville, NC27858
USA
Tel: +1 (866) 437-6372

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.
- 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 - MESSAGES FROM 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.
- Decay correction is not supported for this camera
- 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 divisible with the number of subsets and at least 4 projections per subset are required.
- Number of projections is not divisible by the number of detector heads.
- Only 1-64 subsets are allowed.
- Patient names or ids do not match in all studies
- 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.
- Acquisition studies saved from HybridRecon are intended only for viewing and QA purposes. Press OK to continue or Abort to abort.
- CT conversion parameters are different for primary and secondary reconstruction protocol. Attenuation map from primary reconstruction will be used desptie the difference. Press OK to continue or Abort to Abort.

Warnings in top panel of main application window displayed in red

* Pre-recon X: FoR warning!!!
Tootip: Frame of referenceUID's are different for SPECT and attenuation map. If Mu-map source was set to internal DICOM coordinates will be used in registration. Check attenuation map alignment carefully

* Recon X: Subset warning!!!
Tooltip: Number of projection angles has to divisible with the number of subsets and at least 4 projections per subset are required. Number of subsets was automatically modified

* Recon X: Number of CPUs warnings!!!
Tooltip: Number of CPUs has to be equal or smaller than number of angles per subset. Number of CPUs was automatically modified.

* Mumap X: Truncation warning!!!
Tooltip: Attenuation map has been truncated when it was converted to SPECT size. Attenuation correction artifacts might occur.

* !!Patient demographics mismatch

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.