HERMIA

RELEASE NOTES

Hybrid Recon 5.1.0

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HERMES MEDICAL SOLUTIONS

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1 INTRODUCTION

These Release Notes inform users of news and improvements in Hybrid Recon, as well as any known issues to be aware of. Every user must be familiar with these known issues. Contact the manufacturer for any questions about the content.

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.

1.1 Associated documentation

- P21-112 Instructions For Use Hybrid Recon 5.1.0
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

The Instructions For Use contains the necessary basic information to configure the application at your own preferences.

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

Warning messages are now listed in both the Instructions For Use and the user guidance. The warning messages clearly describe intended users, limitations in the software and the risks of making changes to the software.

1.2 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.

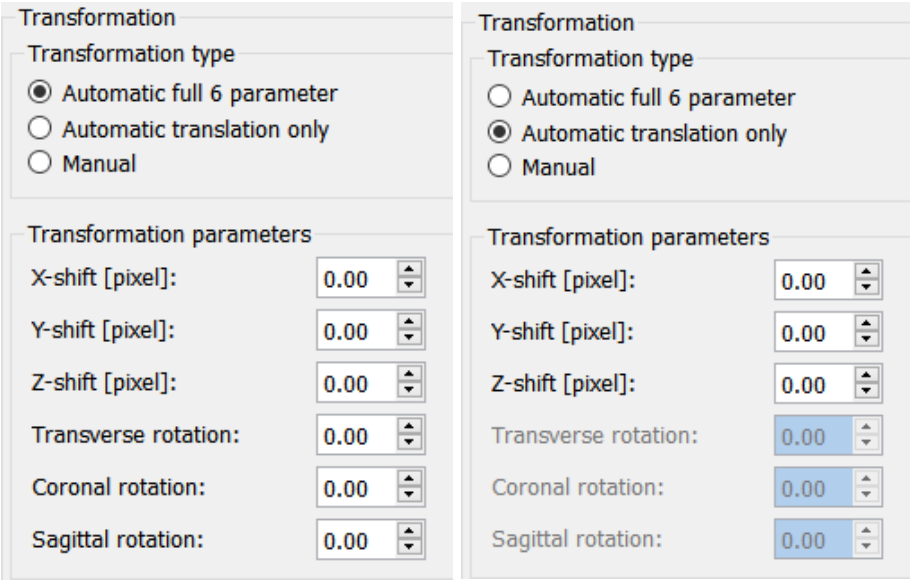
Hermes Medical Solutions welcomes feedback from readers of this manual, please report any errors in content or typography and suggestions for improvements to our support, see *Contact Information*.

2 NEWS AND IMPROVEMENTS

2.1 New features implemented in Hybrid Recon

New features implemented in Hybrid Recon 5.1.0

- Acquisition studies saved from Hybrid Recon, such as motion correction or noise, now have labels appended to their original label is order to distinguish from the original data. A message 'Acquisition studies saved from HybridRecon are intended only for viewing and QA purposes. Press OK to continue or Abort to abort' is now displayed when a study with "HR Acq" is in the series description. The user must acknowledge this message with either 'OK' or 'Abort' to continue.
- Increased speed with GPU based reconstructions is now available for all data corrections i.e., attenuation correction(AC), scatter correction(SC), and resolution recovery(RR). Allowed are:
  AC only
  AC & SC
  RR only
  AC & RR
  AC, SC, & RR
- Support for AC (CT), SC, and RR for Siemens pro.specta data.
- When CT conversion parameters are different between primary and secondary/tertiary protocols, a message will be displayed 'CT conversion parameters are different for primary and secondary reconstruction protocol. Attenuation map from primary reconstruction will be used despite the difference. Press OK to continue or Abort to Abort.'. The user can continue reconstruction by clicking OK and the parameters of the secondary/tertiary protocols will be modified to match those of the primary.
- When Butterworth post-filter is selected, only Butterworth settings shall be enabled. Similarly for Gaussian filter.
- Specific QC to calculate offset correction is no longer required for reconstructing SPECT/CT from Siemens camera. DICOM information is now used to calculate offsets.
- Transformation parameters for rotation shall only be enabled when using transformation type of automatic full 6 parameter (rigid) or Manual.

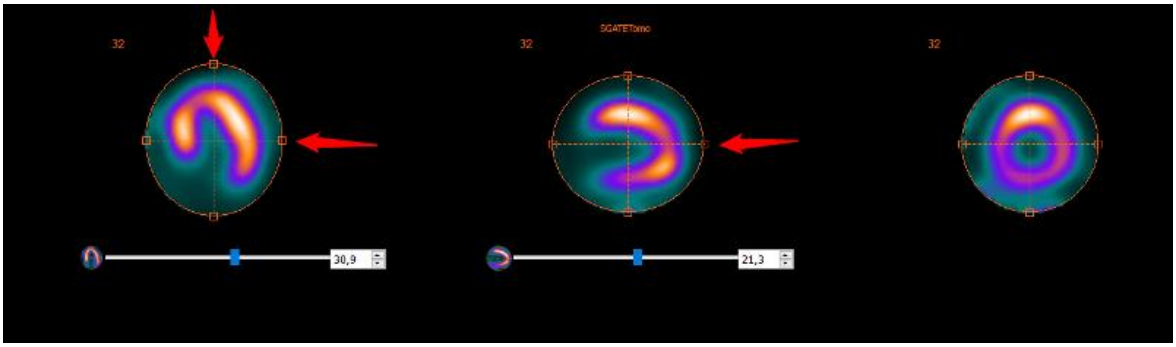


- Warning messages about Frame of Reference UID, subsets, number of CPU's, mumap truncation, and number of projection angles will now appear in the upper panel of the application. Tooltips providing additional detailed information will appear when hovering over the messages.
- Support for Swedish and French interface.
- Support for prone reconstruction of SPECT and CT from same or different scanners.
- Support for SPECT/CT reconstruction using 2 zipped CT's as a single CT.
- Implementation of deep-learning algorithm (Cardiology) to better guide realignment and cropping.
- Ability to reconstruct with 3 different reconstruction protocols. Quantitative secondary or tertiary reconstruction for Oncology and Neurology is only allowed if primary reconstruction is quantitative.
- Research options. A message 'Not For Clinical Use' will be displayed in the title bar of the application when feature is used.
    - Option to save mumap and noise reconstructions with the -research option.
    - The following isotopes are now supported for non-clinical use in the Oncology module when launching the application with the -research option. The following is a list of supported isotopes for their respective modules. Isotopes marked with * are only available in research mode.

Oncology	Cardiac	Neuro	Lung
Ga67 (300, 184, 93 keV)	I123 (159 keV)	I123 (159 keV)	Tc99m (140 keV)
Ga67_sum (164 keV)	Tc99m (140 keV)	Tc99m (140 keV)	Tl201 (72 keV)
I123 (159 keV)	Tl201 (72 keV)	Tl201 (72 keV)	
I131 (364 keV)			
In111 (245, 171 keV)			
In111_sum (207 keV)			
In111_lower (171 keV)			
In111_upper (245 keV)			
Kr81 (191 keV)			
Lu177 (208, 113 keV)			
Lu177_sum (173 keV)			
Lu177_lower (113 keV)			
Lu177_upper (208 keV)			
Tc99m (140 keV)			
Tl201 (72 keV)			
I123&Tc99m (159&140 keV)			
Ho166 (81 keV)			
Y90			
I131&Tc99m (364&140 keV)			
In111&Tc99m (245&171&140 keV)			
In111_sum&Tc99m (207&140 keV)			
*Ba133 (356 keV)			
*Pb203(279kev)			
*Pb203 (71keV & 279 keV)			
*Pb_sum(184kev)			
*Ac225 (218keV & 440 keV)			
*Ac225 (440,218,92kev)			

New Features implemented in Hybrid Recon 5.0.0

- Improvements to the heart detection, heart outline and automatic re-orientation have been made based on machine learning, improving the workflow efficiency for myocardial SPECT reconstructions.
- Dextrocardia studies are now handled better. There is now an option to 'flip' the short axis images to allow the data to be analysed in 3rd party software, such as Cedars QPS/QGS and Invia 4DM.
- 24 frame gated cardiac acquisition studies are now supported.
- Enhancement to the transverse saving options for myocardial SPECT recon. In addition to the standard cardiac re-oriented short axis slices, the entire FOV can be saved in standard anatomical orientation (i.e. not aligned to the heart axes), in order to more easily assess extra-cardiac uptake.
- A new keyboard shortcut key (letter 'c') will re-centre the heart when doing re-orientation and masking.



- Option to apply the same manual shift corrections to the opposing camera head for dual head studies.
- GPU operations now implemented in CUDA (Compute Unified Device Architecture) instead of OpenCL.
- Full Collimator Modelling (FCM) Resolution Recovery option is now available with GPU acceleration. This substantially reduces the reconstruction time for FCM reconstructions.
- A new anatomically guided SPECT reconstruction method, based on the KEM (Kernelized Expectation Maximization) algorithm, and intended for Bone SPECT/CT reconstructions, is now available. This new algorithm complements the already available Bayesian Anatomically Guided reconstructions that have been available since version 4.0. Full details of this algorithm can be found in: Vuohijoki HE, Constable CJ, Sohlberg AO. Anatomically guided reconstruction improves lesion quantitation and detectability in bone SPECT/CT. Nuclear Medicine Communications 2023; Apr 1;44(4):330-337.
- The user handbook has also been updated with detailed information about all reconstruction algorithms used in Hybrid Recon v5.0.
- Support has been added for the Mediso Anyscan model triple head gamma camera.
- It is now possible to make 3 concurrent reconstructions in the Oncology module. This is intended to allow a standard OSEM reconstruction, a non-AC reconstruction and a third advanced (e.g. Bayesian anatomically guided) reconstruction to be performed concurrently.
- Enhancement to dual energy Kr-81m/Tc-99m lung studies: it is now possible to perform motion correction on either study and apply the correction to both studies simultaneously.
- The DICOM element for Slice Thickness (0018,0050) is now saved in the DICOM header of all reconstructed studies.
- Reprojected planar studies which are non-square are now saved as "Whole Body" type so that they can be displayed using whole body display protocols.

- The current date and time can optionally be appended to the series description of reconstructed studies.
- Patient name, study series description and study date are automatically embedded in the screen captures of fused studies.

2.2 Problems fixed and minor enhancements

Problems fixed and minor enhancements in 5.1.0

- For Millenium MG data, the number of frames are correctly read from the DICOM header resulting in the images being properly displayed.
- In HybridRecon Neurology, the ellipse on uniform mumap is correctly placed under various screen resolutions (e.g.,1920x1080, 1280x720, 1366x768, 1600x900 and 1680x1050).
- In prone reconstructions, ellipses are properly positioned on lateral view.
- DICOM tags SeriesDate and SeriesTime are populated correctly when AcquisitionDate/AcquisitionTime DICOM tags are not populated.
- Patient demographics mismatch warning is no longer truncated.
- SPECT MUGA reconstruction no longer fails to start and now proceeds as intended.
- Outline and zoom of image on mumap page now correlate as expected.
- Loading a tomo series without a CT no longer results in premature exit of application.
- CUDA error no longer appears when performing reconstruction with attenuation correction (AC), scatter correction (SC), but not collimator correction (RR).
- Hybrid Recon can now load DICOM studies that have Interfile-like suffixes e.g., .A00.
- GE850 prone SPECT-CT now display, register, and reconstruct as expected.
- Ability to simultaneously reconstruct cardiac SPECT acquisitions when they are of a different matrix.
- Ability to use 'Automatic parameter override' in conjunction with the use of scatter window to generate a synthetic mumap.
- Mediso AnyScan data can now be reconstructed without error.
- Philips multi-bed SPECT-CT with uneven number of slices will now load and reconstruct as expected.

Problems fixed and minor enhancements in 5.0.0

- Additional camera and collimator models added to the parameter auto-override function.
- In batch file mode (noGUI), the same Frame of Reference UID is now saved for AC and NAC studies.
- A quantitative reconstruction bug for multi-bed SPECT/CT reconstruction has been fixed.
- Rotated cardiac and neurology studies are now saved so that the SPECT and CT are aligned when displayed fused.
- Improvements to some warnings and error messages.
- The third label fields in the Results page are now enabled for Neurology and Oncology.

3 KNOWN ISSUES

There are no known issues related to patient safety in this version of Hybrid Recon.

Other known issues:

- Scatter correction is not producing identical results when using GPU. Repeating reconstructions using GPU, including scatter correction, produces different total counts and different max count values (difference is less than 1%). The difference goes away when switching off scatter correction or if using CPU reconstruction.
- Minor issues related to specific camera models.

4 CONTACT INFORMATION

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

4.1 Manufacturer contact information

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