INSTRUCTIONS FOR USE

Hybrid Viewer 7.2.0

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Table of content

1 INTRODUCTION

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

Any safety and performance information relevant to the user is stated in this IFU and residual risks are described. Study this manual carefully before using the software.
This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

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

 This is the general warning sign.

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

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*Subject to registration in some markets

1.1 General notes

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

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

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

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

Hermes Medical Solutions takes no responsibility for loss of data.

The 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.

United States - Hybrid Viewer 7.2.0 is not for sale in the USA.

1.3 Associated documentation

- P31-202 Release Notes Hybrid Viewer 7.2.0 Rev.1
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

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

2 PRODUCT INFORMATION

2.1 Intended purpose

Intended Use

Hybrid Viewer is a software application for nuclear medicine and radiology. Based on user input, Hybrid Viewer processes, displays and analyzes nuclear medicine and radiology imaging data and presents the results to the user. The results can be stored for future analysis.

Hybrid Viewer is equipped with dedicated workflows which have predefined settings and layouts optimized for specific nuclear medicine investigations.

The software application can be configured based on user needs.

The investigation of physiological or pathological states using measurement and analysis functionality provided by Hybrid Viewer is not intended to replace visual assessment. The information obtained from viewing and/or performing quantitative analysis on the images is used, in conjunction with other patient related data, to inform clinical management.

Intended User

The intended users of Hybrid Viewer 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.

Intended medical indication is any for which molecular imaging and radiology is performed. Examples of indications for which Hybrid Viewer may be used to inform patient management are assessment of cardiac blood flow using Tc99m in patients with cardiac disease, assessment of brain function in patients with Parkinson's' disease or dementia using Tc99m or amyloid tracers, and assessment of the difference between lung perfusion and ventilation using Tc99m tracers in order to provide a definitive diagnosis of pulmonary embolism.

2.3 Contraindications

There are no contraindications.

2.4 Product label

The version number, the Unique Device Identification (UDI) and other product data about installed Hybrid Viewer software can be found by clicking help from the toolbar and selecting "about".

The following information can be identified:
Product name = Hybrid Viewer
Release version = 7.2.0
Marketing name = Hermia
Software build no = 150

R͟x 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

CE 2862 CE marking and the Notified Body number

MD Indicates that the product is a medical device

Consult Instructions for Use (IFU)

@ The support email addresses

Manufacturer's contact information

CH | REP Swiss authorized representative

About this application　　　　　　　　　　　　　　　　? ✕

Product name: Hybrid Viewer

Release version: 7.2.0
Marketing name: Hermia
Software build no: 150

CE 2862

℞ only

MD Medical device

⚲ 2025-07-01

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

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Renderer:
NVIDIA RTX A2000 8GB Laptop GPU/PCIe/SSE2

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EXEMPLARY, OR
CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO,
PROCUREMENT OF

Licensed Modules

- ☑ Nuc Med Display
- ☑ Nuc Med Processing
- ☑ Macros
- ☑ Pre - Post
- ☑ Lung
- ☑ Dynamic Pet
- ☑ Radio Therapy Planning
- ☑ Cardiac
- ☑ Dosimetry
- ☐ Research
- ☐ **Brass**
  - ☐ Subtraction
  - ☐ Anatomy Registration
  - ☐ Spect Template
  - ☐ FDG Template
  - ☐ Earl Template
  - ☐ Amyloid Template
  - ☐ Receptors Template
  - ☐ Research

Renderer states the Graphic Processing Unit (GPU) currently being used by the application.
Licensed Modules lists all specific workflows. Checked workflow indicates active license.

2.5 Product Lifetime

 The lifetime of Hybrid Viewer 7.2 is 5 years.

The lifetime of 5 years starts running when Hybrid Viewer 7.2.0 has been manufactured (5 years from the Manufacturing date of 7.2.0). Possible patches for Hybrid Viewer 7.2 will have new manufacturing dates, but the lifetime will not restart from these dates.

During the stated lifetime, Hermes Medical Solutions will maintain the safety and performance of Hybrid Viewer 7.2. Patches will be provided when necessary to maintain the safety and performance of the product.

2.6 Complaints and serious incidents

Any serious incident that has occurred in relation to the device must be reported to our support, see *Contact Information*.

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 Instructions For Use. Please report any errors in content or typography and suggestions for improvements to our support, see *Contact Information*.

2.7 Hardware and Operation systems

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

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

2.8 Installation

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

NOTE: It is the customer's responsibility to install and maintain anti-virus software on the server and client computers, and apply the necessary protection against potential threats.

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

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

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

3 SAFETY, SECURITY AND PERFORMANCE INFORMATION

3.1 Supported data formats

DICOM Input & Output Data Formats:
- Nuclear Medicine Image (NM)
- Positron Emission Tomography Image (PT)
- CT Image
- MR Image
- RT Structure Set (RT Struct)
- RT Dose (Dose Map)
- Segmentation
- Secondary Capture Image (SC)
- Encapsulated PDF (Input only)

Other Input & Output Data Formats:
- Interfile
- PDF
- XML (Results)

3.2 Loading a study

A study can be loaded into Hybrid Viewer from different types of patient browsers:

- Hermia GOLD
- HERMES Fast Launch
- PACS (e.g. Agfa)
- RIS (e.g. Carestream)

The illustration shows 3 ways in which the Hybrid Viewer can be started from GOLD3, once the study or series within a study have been selected.

Both user and layout protocols can include string matching of the Series Description field. The consequence of this is that some studies which have been selected to load into the application may not load if the Series Description of the series does not match the strings defined in the protocol.
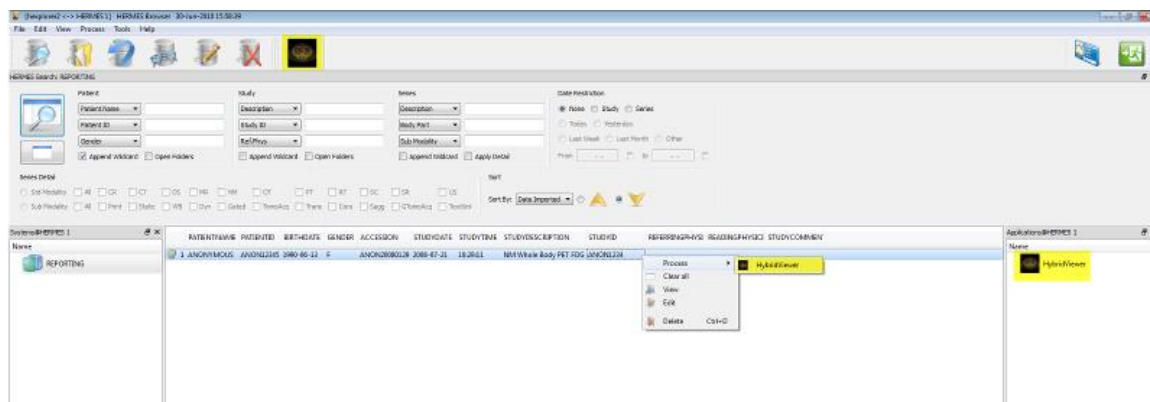
The order in which studies are selected in the patient browser does not matter. The layout protocol will ensure that series from different dates are grouped into the correct studies.

The layout protocol also determines whether the older or newer study is displayed on the top or bottom of the screen for a single screen protocol or on the left or right screen for a dual screen protocol.
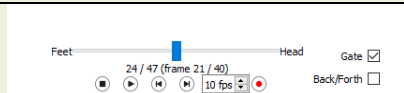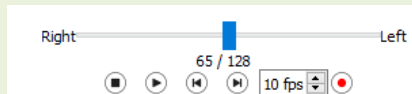
3.3 Quick start
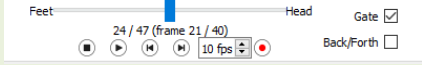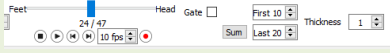
User operations described in the manual have been color coded as follows:
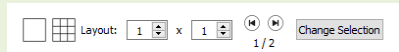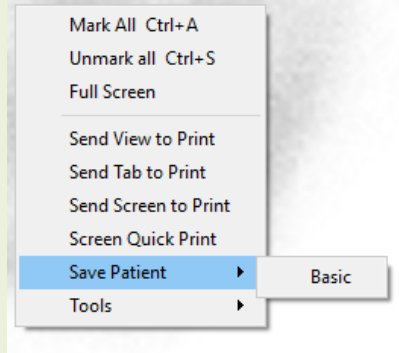
- **BLUE**   **LEFT MOUSE BUTTON**
- **RED**   **RIGHT MOUSE BUTTON**
- **GREEN**   **KEYBOARD**

Change display	**CLICK** on tab **on right hand side** *or* Type **.** to step forward **,** to step backward through tabs *or* Type **1, 2, 3 etc to change tab**	Full TCS 4View Splash
Change CT window/level	**F1-F12 on** keyboard	

Change color table	**RIGHT CLICK** on color bar and select color table	
		Hermes
		Thermal
		Thermal Low
		Finn Table
		Hot Iron
		Inverse Hot Iron
		Kidney
		Cardiac1
		Cardiac2
		Cardiac3
		BW Linear
		BW Log8
		BW Log4
		BW Log2 (24bit)
		BW Real Log (24bit)
		✔ Inverse Linear
		Inv Log8
		Inv Log4
		Inv Log2 (24bit)
		Inv Real Log (24bit)
		Thermal White
		Centre Pink
		Thermal 2 Contours
		Inverse Red Ramp
		Split Linear Hotmetal
		Split Linear Pink
		20 Point
		16 point
		Blue Black Red
		Rainbow
		Canterbury
		Thermal Red
		Hot metal
		Cequal
		Bronson
		Red Max
		Yellow Ramp

Change thresholds	**CLICK** on lines on color bar and drag to new position	8.6 0
Play movie	**CLICK** on "Play"	
Play time movie of tomographic gated or dynamic study	**CLICK** on "Gate option" **CLICK** on "Play"	Feet ——— Head　Gate ☑ 24 / 47 (frame 21 / 40) 10 fps　Back/Forth ☐
Scroll through slices	**Mouse wheel** *or* **Scroll mode** *or* **Move sliders below images** *or* **Use double arrows** *or* **Use Keyboard** **Left/Right arrows - move one slice at a time** **Up/Down arrows - move 3 slices at a time**	Right ——— Left 65 / 128 10 fps
Triangulate	**CLICK** on images	
Display/remove text overlay	**O on keyboard**	
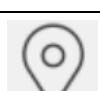
Zoom an image full screen	**DOUBLE CLICK over an image or RIGHT CLICK over image** **and select "Full Screen"**	
Quick Print (no need to use Print window)	**CLICK on "QuickPrint" icon (creates a print for each screen)** ***or*** **RIGHT CLICK over image** • **"Screen Quick Print" (prints current screen)**	
Print (manual)	**CLICK on "Print icon"** ***or*** **P on keyboard** **RIGHT CLICK over image** • **"Send View to print"** • **"Send Tab to print"** • **"Send Screen to print"**	
	Drag an individual image into print window by CLICKING over the image and DRAGGING into the Print Window	
	Drag the whole screen display into print window by CLICKING anywhere in the grey space below the tabs and DRAGGING the small box into the Print Window	
Annotate	**CLICK on "annotate" icon**	
Scroll through time frames of tomographic gated or dynamic study	**CLICK on "Gate" option** **Mouse wheel** ***or*** **Use double arrows** **Note: Scroll mode, slider and keyboard all scroll through slices not through time when Gate option is set**	
Sum frames of tomographic gated or dynamic study	**CLICK "Gate" option Off** **Set First and Last Frame to be summed** **CLICK on "Sum"**	

Display single or multiple prints or images	**CLICK** on this button to display a single image or print **CLICK** on the arrows to move through the images **CLICK** on this button to display multiple images or prints	Layout: 1 x 1 ⏮ ⏭ Change Selection 1 / 2
Save a study after masking, manually moving etc	**RIGHT CLICK** over any image in the study and choose "Save Patient" → "Basic"	Mark All Ctrl+A Unmark all Ctrl+S Full Screen Send View to Print Send Tab to Print Send Screen to Print Screen Quick Print Save Patient　　▶　　Basic Tools　　　　　▶
Save a clipped study	With ROI tool open, **RIGHT CLICK** over a clipping ROI and choose "Export" → "Clip and Save Patient"	

3.4 Tools summary

The main toolbar is displayed at the top of the application window.
The tools in the application can be selected by clicking on an icon along the top of the application, using a keyboard shortcut or right clicking over an image and choosing an option in the Tools menu.

OPERATION	ICON	KEYBOARD SHORTCUT	OPERATION	ICON	KEYBOARD SHORTCUT
TRIANGULATION		T	SYNCHRONIZATION		
SCROLL		S	FILTER		
ZOOM		Z	PROFILE		
PAN		N	MATH TOOL	f(x)	
LOOK UP TABLE		L	REPORT		
MEASURE		M	PRINT		P
ANGLE		K	QUICK PRINT		
ANNOTATE		W	PATIENT INFORMATION (PET)		
ARROW		D	BOOKMARKS		
ROI/VOI			SHORTCUTS		
QUICK ROI		Q	MANUAL		
			QUIT		

3.5　Protocols

The application uses two types of protocol - layout protocols and user protocols.

Layout Protocols

These protocols are designed by Hermes Medical Solutions staff and include the following:

- The layout of each of the pages displayed by clicking on the tabs on the right hand side of the screen
- The number of pages you can display
- The number of screens used

User Protocols

These protocols can be configured by the user within the Tools menu and the specific investigation menus of the application. Details of the choices for these protocols are described in the relevant handbooks.

The user protocol *userDefault* is loaded automatically. If you would like to use a different user protocol there are 2 possibilities:

- Load the protocol automatically from the patient browser. This is the preferred method. Hermes staff can configure this for you.
- Load the protocol using the Tool/Load Properties menu item in the application after the application has started.

3.6　Hybrid Viewer Workflows for specific investigations

There are workflows in Hybrid Viewer with calculations specifically designed for different clinical investigations. The following chapters give a short summary of the respective workflows.
More detailed information on how to run each workflow is included in the compulsory user training, see *Appendix 1 - User Training Required Content*, and in the respective user guidance in the software.

3.6.1　BRASS

BRASS™ provides tools to improve the analysis of brain images.

The original program BRASS™ was developed at London Health Science Centre (LHSC), Canada by Perry Radau and Piotr Slomka. BRASS™ is a program for the automatic fitting of brain scans, and quantification and localization of abnormal regions. The methods are based on the papers listed in the bibliography.

BRASS™ fits and compares patient images to three-dimensional reference templates created from images of normal subjects. If two studies are loaded, then both will either be aligned to each other and the template or just to each other. Clusters are quantified against a database of images from neurologically healthy subjects on a voxel-by-voxel basis and therefore the marked voxels can be assessed statistically, using the standard deviation criterion. Abnormalities may also be determined by analysis within a 3-dimensional region-of-interest (ROI) map. Advanced score like the Centiloid for Amyloid tracer may be calculated in the module.
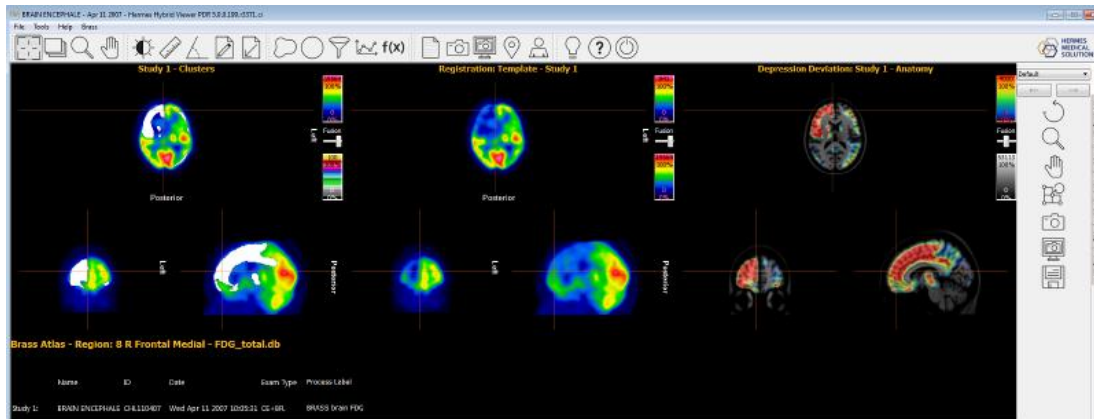
BRASS™ accepts one or two studies reconstructed in the transverse (horizontal) plane.

Additionally, an MR or CT study of patient can be loaded. This then replaces the standard MR provided with the template, provided the Brass license includes the 'Patient Anatomy Registration' option. If this option is not included in the license a warning message will be provided and the patient's MR or CT will not be displayed.

3.6.2 First Pass Shunt and Ejection Fraction Analysis

This is designed to calculate left and right ventricular ejection fractions and provide a pulmonary to systemic flow ratio (QP/QS) for first pass radionuclide ventriculograms.

For calculation of systemic flow ratio, regions of interest are drawn over the superior vena cava (SVC), and the right lung and optionally over the right and left ventricles (1). Curves are calculated and gamma variate fits are made to the lung curve for both the initial and the recirculation phases. The areas under the curve are used to calculate the QP/QS ratio. Deconvolution of the lung curve can be optionally performed and the QP/QS ratio calculated for both the raw curves and the deconvolved curves (2).
For ventricular ejection fraction, calculations are performed over a selected number of good beats.

3.6.3 FUGA

FUGA™ (Functional Gated Analysis) is designed to analyse data from planar gated blood pool studies of the heart.

FUGA™ uses cycle-dependent background correction to correct the counts within the end diastolic region for non-ventricular counts. Although the program calculates a ventricular region of interest for each frame in the study, these ROIs are only used in the movie display. For calculation of ejection fraction, regional ejection fraction, filling and emptying rates and the final volume curve, the counts within the end diastolic region, corrected for cycle-dependent background, are used. This method has been shown to generate time activity curves with a minimum of processor related noise and therefore to be accurate for calculating ventricular function parameters.

The left ventricular edge detection is performed automatically using a variation on a second differential method, which was developed at Yale University.

3.6.4 Heart to Mediastinum Ratio

Heart to Mediastinum Ratio is designed to calculate and display the ratio between 2 regions of interest on a single static or wholebody image.

Heart to Mediastinum Ratio accepts one static or whole body image as input.
A multiplanar study can be loaded and the required image selected using the String Matching in the user properties.
This application can be used for any calculation of Heart to Mediastinum ratio using any method, but specific options have been included which provide processing according to the imaging guidelines published by GE Healthcare for quantifying AdreView™ cardiac uptake.
These guidelines contain the following section related to study acquisition.
Begin anterior planar imaging of the chest at 4 hours (± 10 minutes) following administration of AdreView™. Single photon emission computed tomography (SPECT) can then be performed. The recommended collimator for all imaging is a low-energy high-resolution. The recommended matrix for planar images is 128x128. The camera should be positioned to include the entire heart and as much of the upper chest as possible within the field of view.

Heart to Mediastinum Ratio is intended to estimate the Heart/Mediastinum Ratio in patients with congestive heart failure. The measurement is made on anterior planar images of the chest.
The application can be configured to be used according to the guidelines published by GE Healthcare for quantifying AdreView™ cardiac uptake, but options are also available to run the application using other methods.

3.6.5 Right-Left Shunt Analysis

A Right-Left Shunt can be diagnosed by administrating MAA particles intravenously and acquiring a whole body planar image. The MAA particles have the property of being trapped in both pulmonary and systemic capillary beds. The ratio of extrapulmonary to total body should reflect the fraction of blood entering the right atrium which is shunted from the right heart to the systemic circulation.

Right-Left Shunt Analysis quantifies the ratio between the activity in the total body and the activity in the lungs.

3.6.6 Gastric Emptying

Gastric Emptying calculates the emptying rate of the stomach after eating a solid or liquid meal. The application can calculate these values from anterior images only, or from anterior and posterior images using a geometric mean calculation.

The main features are:
- ROI drawing tool to delineate the stomach and if necessary the region for the background correction. ROIs are drawn on one of the anterior images and copied and pasted automatically onto the other images. If posterior images are available, the ROIs are mirrored to match these images. For each image frame, the user can manually adjust the position of the ROIs in order to fully cover the stomach.
- Background correction if requested
- Tc99m Decay correction
- Geometric mean calculation for curves and results
- Graphical display with curves, input data and calculated results.

3.6.7 Colonic Transit

Colonic Transit measures whole gut and regional colonic transit in patients with suspected colonic motility disorder or more diffuse disorders involving the stomach and small intestine. The application can calculate these values from anterior images only, or from anterior and posterior images using a geometric mean calculation.

The main features are:
- ROI drawing tool to delineate the gut regions and if necessary, the region for the background correction. ROIs are drawn on one of the anterior images and copied and pasted automatically onto the other images. If posterior images are available, the ROIs are mirrored to match these images. For each image frame, the user can manually adjust the position of the ROIs in order to fully cover the stomach.
- Background correction if requested.
- Decay correction for In111 and Ga67.
- Geometric mean calculation for curves and results.
- Graphical display with curves, input data and calculated results.

Static images acquired at intervals from 6h after administration up to 7days, normally once or twice a day following ingestion of a single isotope liquid meal labelled with In111-DTPA. The anterior and posterior images can be acquired simultaneously on a dual head gamma camera or consecutively on a single head camera system.

If the patient excretes anything before the first acquisition the morning after administration (which is unusual), the patient is asked to collect the faeces, which must be imaged either just before or just after the first patient acquisition.

The study may be performed as a continuation of standard Colonic Transit.

Radioactive markers may be placed at the right costal margin to help with relative positioning when drawing ROIs, in which case care should be taken to exclude them in any drawn ROIs.

3.6.8 Oesophageal Transit Reflux

Oesophageal Transit Reflux is used to evaluate transit motility and transit time along the oesophagus. The application also allows the evaluation of gastro-oesophageal reflux.

In the evaluation of transit motility a time activity curve is generated for different segments of the oesophagus and for the total oesophagus.

Oesophageal Transit Reflux accepts dynamic studies, with single or dual phase acquisition.
It will accept simultaneously one or more transit acquisitions and/or one or more reflux acquisitions.
Transit and reflux can be acquired sequentially in the same series, but in that case, they must have different frame times so that the 2 groups can be separated for processing.
Often the evaluation of reflux is performed in combination with the transit evaluation.
All types of data can be loaded for review.
String matching can be used to select the correct studies for processing.
The string matching is used to distinguish between transit and reflux studies. If the studies have been acquired in a single series, string matching is not required.

The main features are:
- Customizable options for display, review and results

- Automatic ROI copy onto the other images and studies.
- Graphical display with curves, input data and calculated results.
- Transit and Reflux specific displays
- Linogram

3.6.9 SeHCAT

SeHCAT is used in the diagnosis of bile acid malabsorption in the gut.

SeHCAT accepts anterior and posterior patient, background and optional standard images acquired on Day 0 and (normally) Day 7 post capsule administration. These images can be from single series dual head static or whole body studies or from multiplanar studies. Images acquired on Day 8, Day 9, and Day 10 rather than Day 7 can also be processed by the SeHCAT application.

The images can be acquired with or without a collimator, or with dummy collimators.

SeHCAT (GE Healthcare) is a radiopharmaceutical licensed for measuring bile acid pool loss and investigating bile acid malabsorption.

The SeHCAT test involves two scans acquired a week apart. The percentage of activity retained at the second scan is expressed as a percentage of the activity at the first scan.

An optional feature is the use of a standard for each scanning session, which is usually an intact SeHCAT capsule. This is used to evaluate and compensate for drift in the sensitivity of the scanning equipment. Decay correction is applied in the application according to the difference between the scanning date and time from the DICOM header information.

Normal ranges can be displayed, using either the default normal ranges supplied with the application or custom normal ranges which can be entered by the user. The appropriate normal ranges are displayed automatically, depending on the delay between capsule administration and the second image.

3.6.10   Salivary Gland Analysis

Salivary Gland Analysis studies the salivary glands by calculating various quantitative values for the parotid and submandibular glans and the oral cavity.

Salivary Gland accepts 1 or 2 dynamic studies as input.
String matching can be used to select the correct studies for processing.

3.6.11   Gallbladder EF

Gallbladder Ejection Fraction Analysis evaluates the contractility of the gallbladder by determining the ejection fraction and ejection rate. This procedure is often done to study the response of the Gallbladder to injection or infusion of cholecystokinin (CCK). The acquisition is usually acquired over a period of 20 to 45 minutes, normally at a frame rate of 1 frame/minute. The ejection fraction and ejection rate are then calculated from the ROIs and values on the time activity curves. Gallbladder EF accepts 1 anterior dynamic study when **Dynamic** study type is selected in the user protocol, or up to 2 anterior static images when **Static Studies** study type is selected. When both Dynamic and Static study types are selected, any number of static images can be loaded for review.
String matching can be used to select the correct studies for processing.

3.6.12 Hepatobiliary Analysis (HIDA)

Hepatobiliary Analysis studies the biliary system by tracing the production and flow of bile from the formative phase in the liver, and its passage through the biliary system into the small intestine. The application uses a dynamic acquisition of the liver and biliary ducts area to generate time activity curves and emptying results from different ROIs.

Hepatobiliary Analysis accepts 1 anterior dynamic study.
If **Dynamic and Static Studies** is selected in the user protocol, the dynamic study is used for processing and any number of additional static studies can be loaded for review.
String matching can be used to select the correct studies for processing.

3.6.13 Remnant liver Analysis

Preoperative evaluation of future remnant liver (FRL) function is crucial in the determination of whether a patient can safely undergo liver resection. Although dynamic 99mTc-mebrofenin hepatobiliary scintigraphy (HBS) is used to measure FRL function, 2-dimensional planar images lack the ability to assess segmental liver function. Modern SPECT/CT cameras combine dynamic 99mTc-mebrofenin HBS with additional SPECT and the anatomic information of the CT scan. 99mTc-mebrofenin SPECT is used for the measurement of segmental liver function and liver functional volume.

3.6.14 Lung/Liver Shunt

Lung/Liver Shunt is designed to calculate and display the percentage of Y90 which is shunted to the lungs, using a dual head wholebody image.

Lung/Liver Shunt will accept the following:
- Multiplanar or single planar static studies with anterior and posterior liver and lungs in the field of view
- Dual head whole body study

Lung/Liver Shunt is used to estimate lung shunts for Y90 microsphere treatment planning.

3.6.15 Lung quantification

Lung Quant quantifies differential pulmonary function from planar images. The application accepts ventilation and/or perfusion images, posterior only images or anterior and posterior. For the latter it performs geometric mean calculations. The application segments each lung into 3 regions and quantifies each segment.

Lung Quant accepts 1-4 static planar images as input – anterior and/or posterior perfusion and/or anterior and/or posterior perfusion.
String matching can be used to select the correct studies for processing.

3.6.16 Lung V/Q Ratio

Lung V/Q Ratio requires reconstructed ventilation and perfusion scans and optional planar and CT studies. The studies can be acquired as dual isotope (Kr81m-Tc99m) or as separate Tc99m studies, with the perfusion scan acquired after the ventilation scan. If a CT study is loaded, the protocol **Lung VQ Ratio with CT** should be used.

Lung V/Q Ratio can also optionally display reprojected or acquired static images.

3.6.17   Thyroid

Thyroid calculates percentage uptake in the thyroid, size and weight of the thyroid and suggested therapy dose.
Thyroid Analysis accepts static planar images as input.
String matching must be used to select the correct studies for processing.

3.6.18   Parathyroid

Parathyroid performs subtraction of a radionuclide thyroid image from a corresponding 'parathyroid' image (typically from 99mTc-sestamibi).

Parathyroid accepts as input either planar static, planar dynamic or reconstructed SPECT transverse image series. In the case of dynamic series input, motion correction and summing of the dynamic frames is first performed. The program will then (optionally) co-register the Thyroid and Sestamibi Parathyroid image series. Next, the program will normalize the count levels between the Thyroid and Parathyroid image series using one of several user-selectable methods. Finally, the program will subtract the Thyroid image from the Parathyroid image and display the subtraction image result.

User interactive scaling of the subtraction weighting factor is also provided at display time.

3.6.19   Bone 3Phase Analysis

Bone 3Phase allows for quantification and analysis of different phases of a blood pool study. Time activity curves are generated, quantitative values for the different phases of the flow study and ratio between 2 regions of interests on blood pool and late static images are also calculated.

Bone 3Phase accepts one dynamic series and up to 2 static series as input for processing. All types of data can be loaded for reviewing.
String matching can be used to select the correct studies for processing.

3.6.20   SI Joint Analysis

SI Joint Analysis is designed to quantify sacroiliac bone images using two methods — profile analysis and region of interest analysis. In each case the counts in the sacroiliac joints are quantified relative to the sacrum counts. Background subtraction is undertaken for the region of interest analysis only.
SI Joint Analysis accepts a Static or Whole body study as input. The data must contain at least a posterior projection view which includes the sacrum and pelvis.
String matching can be used to select the correct studies for processing.

The main features are:
- Customizable options (for display-review-results).
- ROI and Profile calculations.
- Background correction if necessary.
- Graphical display with profile, input data and calculated results.

3.6.21   DMSA quantification

DMSA™ calculates differential uptake results for right and left kidney from ANT and POST or POST only static studies, ANT and POST or POST only dynamic studies and reconstructed SPECT studies. When ANT and POST views are present, it will also optionally calculate the differential uptake using geometric mean calculations. The application can also calculate relative uptake values for duplex kidneys.

DMSA™ accepts 1 or 2 static planar images, 1 or 2 dynamic planar images, reconstructed SPECT or SPECT/CT as input for analysis. It can also accept additional static planar images which can be displayed with the results by configuring a suitable layout.
String matching is mandatory in this application as it is essential to distinguish between opposing views.

3.6.22   Classic DMSA

Classic DMSA is the HERMIA Classic "DMSA" application modified to run in the Hybrid Viewer Suite.
It was primarily designed to help detect the onset of pyelonephritis in young children and to monitor the effect of treatment on infected patients. The program compares the function of each kidney with the function for a database of reference cases in order to assist detection of abnormal function. It is important that the studies are acquired in the same way as the studies stored in the reference database.
If comparison with references is not required, the program can be used to calculate kidney size and divided function only.
The program can be used to calculate divided function from a single posterior image or from both anterior and posterior images using a geometric mean calculation.

Classic DMSA accepts static planar images as input, string matching must be used to select Anterior and Posterior images correctly. The input data may contain other static views which can also be displayed.

3.6.23   Renogram Analysis

Renogram Analysis is designed to calculate a number of renal function parameters, including relative perfusion, renal uptake function, renal transit times and renal outflow efficiency. The relative perfusion is calculated by integrating under the background subtracted curves over the early perfusion phase, and the relative function calculated from Patlak plots, from the uptake slope of the renogram curves, or from the integral of the renogram curves over a defined time period.

Renogram Analysis can display the retention function curves of the two kidneys and the parenchymal regions and calculate the relative function from the retention curves as well as the minimum, mean and maximum transit times.

Renogram Analysis can display the outflow curves for both kidneys and the value of the outflow at any selected time.

3.6.24   Organ based Dosimetry

HERMIA Hybrid Viewer Dosimetry together with OLINDA/EXM® is used to determine organ, lesion and wholebody doses using the Medical Internal Radiation Dosimetry (MIRD) system. The

application allows the user to perform all steps required within a convenient workflow:

- Registration of multiple time point datasets for planar wholebody (WB) and SPECT/CT scans
- Comprehensive tools for definition of ROI/VOI on planar WB and SPECT/CT scans
- Conversion of counts to activity using calibration factor based on total activity in patient or predetermined value (including SUV·SPECT® compatibility)
- Selection of radionuclide and anthropomorphic phantom from extensive OLINDA/EXM® library
- Generation of time activity curves with option for user to choose type of fit
- Calculation of integral under these curves to determine residence time
- Dose calculation in OLINDA/EXM®
- Creation of report pages

Hybrid Viewer Dosimetry and OLINDA/EXM® applications are designed to provide a seamless workflow for the user. When the Report icon is selected:
- The required anthropomorphic phantom, radionuclide and residence times generated by Hybrid Viewer Dosimetry are saved in a 'Case' file which contains the necessary information for OLINDA/EXM® to calculate organ, lesion, and WB doses
- The 'Case' file is saved to GOLD and automatically passed to OLINDA/EXM®
- The absorbed and effective doses are then calculated, and the results saved in a CSV file which is saved to GOLD and automatically passed to HybridViewer Dosimetry
- The dose results are then shown in a print window, together with the Time·Activity curves, and images with ROI/VOIs delineated. The prints can be saved as Screen Captures and sent to PACS.

Hybrid Viewer Dosimetry accepts the following combinations of datatype:
- 3 or more serial anterior/posterior WB studies
- 3 or more serial anterior/posterior WB studies and one SPECT or SPECT·CT study
- 3 or more serial SPECT or SPECT·CT studies (SPECT·CT with HERMIA SUV·SPECT® reconstruction recommended)
- 1 diagnostic CT with more than 1 serial SPECT
- 1 anterior/posterior WB study or SPECT study with WB dose rate measurements from an external probe (please refer to appendix 3)
- 1 anterior/posterior WB studies or SPECT study, assuming physical decay

Imaging time points should preferably be selected such that they adequately show the behavior of the therapeutic radiopharmaceutical with time for each organ. This should include the uptake phase (including pre·excretion) and both short- and long·term clearance.

Addition of a volume dataset (e.g. SPECT·CT) allows a potentially more accurate dose calculation to be made due to better assessment of distribution of radiopharmaceutical in the body (organ overlap is not a problem for volume datasets) and more accurate conversion of counts to activity (quantitative SPECT reconstruction).

String matching can be configured for parsing the series descriptions of incoming images in the 'Dosimetry' menu 'Properties' option. It is possible to load 1 CT for anatomical definition with multiple SPECT scans in fusion views, in which case ensure that the option 'Diagnostic CT: fusion with multi·SPECT' is checked as in the screenshot below.

Physical decay from one imaging time point is assumed if data from only one imaging time point is loaded and no external dose rate measurements are specified. The warning message is displayed on load as in the screenshot below to inform the user of this.
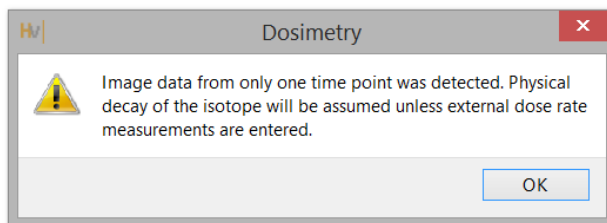
3.6.25   *Quality Control Analysis*

UNIF™ analyses a flood, acquired with a Gamma Camera, as specified in the NEMA standard. All the calculated data is displayed and can be saved in a history database which can be exported to a csv file, in order to perform trend analysis over time.

COR™ analyses a SPECT acquisition study of a line source, acquired with a Gamma Camera, as specified in the NEMA standard.

Options also exist for measuring Full Width Half Maximum (FWHM) and Sensitivity and for CT Quality Control.

3.6.26   *ROI Ratio*

ROI Ratio is designed to calculate and display the ratio between 2 regions of interest on either one or two static or wholebody images.
ROI Ratio will take one or two static or whole body studies as input.
A multiplanar study can be loaded and the required image or images selected using the String Matching in the user properties.

The main features of ROI Ratio are:
- Calculation and display of the ratio between the Total or Mean counts of 2 regions of interest (ROIs).
- ROIs can be drawn on one or two static or whole body images.
- The first ROI can be automatically copied and mirrored to create a second ROI.

3.7 Settings

General settings for Hybrid Viewer can be selected and saved using the Tools menu described in section 3.3 of this document.

Each workflow designed for a specific investigation, as described in the previous section, has additional settings which can be selected and saved from the menu with the name of the workflow.

3.8 Security

Hybrid Viewer 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 Viewer 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.

3.8.1 Interfaces

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

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

Network Interface
The Hybrid Viewer 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 Viewer 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.

<u>User Interface (UI)</u>

Graphical User Interface (GUI)
The User Interface (UI) for Hybrid Viewer is its Graphical User Interface (GUI).

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

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

<u>File System Interface</u>
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 Viewer 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.

<u>Database Interface</u>
Hybrid Viewer does not utilize data storage in a database. Instead, all information is managed locally within the application itself.

3.9 Warnings

<u>Security</u>
If the network is unavailable it may not be possible to maintain the Intended Use of the device.

<u>Generic</u>
Changing patient or study information can lead to changes in quantitative results

<u>Generic</u>
The intended user should not rely solely on the output identified by Hybrid Viewer NM Processing™ but should perform a full systematic review and interpretation of the entire patient dataset.

<u>Generic</u>
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.

<u>Generic</u>
If the CT has a larger slice thickness than the PET, some PET slices are skipped when scrolling on the fused images or when using Quick ROI. The workaround is to either set the PET as the master volume, or scroll in the PET only view.

Generic
Due to the fact that there is no Radiopharmaceutical vector in the Dicom header, as there is for EnergyWindow, we cannot guarantee which pharmaceutical applies to which image for multi-isotope studies. Therefore the Acquisition Info option for overlay of Radiopharmaceutical for Planar studies should not be used for multi-isotope studies.

Generic for all NM Processing
The quantitative results generated should be used only as an aid to diagnosis and under no circumstances should they be used without interpreting and analyzing the original images.

Generic for all NM Processing
To minimize the risk of errors in processing, it is recommended to always use one of the predefined protocols distributed with the Hermia software, or one configured on site with Hermes Medical Solutions.

Generic for all NM Processing
If an NM Processing application is used to follow up a patient, and earlier studies for this patient have been processed in an older version or another application, these studies should be reanalyzed in the current version of the application before any comparison between previous and current studies is performed. Comparison of studies processed with different applications or versions, can result in inaccurate quantification and may lead to misdiagnosis.

Generic for all NM Processing
The intended user should not rely solely on the output identified by Hybrid Viewer NM Processing ™, but should perform a full systematic review and interpretation of the entire patient dataset.

First Pass
It is important to note whether the SVC curve represents a good bolus i.e. is a short curve with a sharp peak, as this will affect the accuracy of the results. If the curve has several peaks, the application should not be used. If it has a prolonged peak (> 3seconds wide at 10% of the peak2), it may be possible to use SVC deconvolution).

Renogram
Patlak Analysis should not be used if the acquisition was started late.

Renogram
A good quality bolus and resultant input curve is imperative when using Patlak methodology.

Renogram
If Renogram Analysis is used for following up a patient, and earlier studies for this patient have been processed in an older version or another application, these studies should be reanalyzed in the current version of Renogram Analysis before any comparison between previous and current studies is performed. Comparison of studies processed with different applications or versions can result in inaccurate quantification and may lead to misdiagnosis.

Renogram
Normalize perfusion To Max: Scale renogram perfusion curve to the max value: This option should not be used when processing transplant studies with a protocol which calculates Perfusion index. The index would not be affected but the iliac and transplant curves would not be correct.

Renogram
Relative Function (Retention): Values for the relative function are calculated as the ratio of the amplitudes of the retention plateau during the uptake phase. It is not recommended to use this method as the results may be unreliable.

Renogram
GFR Gates and ERPF Arroyo methods are not valid for transplant kidneys, as the depth correction used in the calculations is not accurate for anterior acquisitions. ERPF Bubeck can be used for transplant kidneys as this method does not require depth correction.

BRASS
If the current version of BRASS™ is used for following up a patient, and EARL/ENC-DAT studies for this patient have been processed in an older version of BRASS™, these studies shall be reanalyzed in the current version of BRASS™ before any comparison between previous and current studies is performed. Comparison of studies processed with different versions of BRASS™ or with different databases, can result in inaccurate quantification and may lead to misdiagnosis.

BRASS
Important to read System Environment Requirements. Only the computer devices and application specified shall be used. Use of other applications and computer devices may result in impaired performance and, in the worst case, incorrect diagnosis of patients.

BRASS
A study which has been processed with a previous version of BRASS should processed with the updated version, to make sure the same quantitative values are being produced. This should be done for studies of each type used in BRASS (HMPAO,FDG etc).

⚠️ **Thyroid**
If Thyroid Analysis is used for following up a patient, and earlier studies for this patient have been processed in an older version or another application, these studies should be reanalyzed in the current version of Thyroid before any comparison between previous and current studies is performed. Comparison of studies processed with different applications or versions can result in inaccurate quantification and may lead to misdiagnosis.

⚠️ **Dosimetry**
This application should not be used with versions of OLINDA/EXM earlier than version 2.1.

⚠️ **Dosimetry**
It is important that the scan lengths and speed be the same between time points to avoid quantification errors.

⚠️ **Dosimetry**
The wholebody scans must always be acquired with the same speed and length when using a planar calibration factor.

⚠️ **Dosimetry**
Calibration technique: First WB:In cases where this method is used and no quantitative SPECT is available, it is important that the scan lengths and speed be the same between time points to avoid quantification errors.

⚠️ **Dosimetry**
If a single Background ROI is drawn, (second in the ROI list underneath the Standard ROI), this ROI will be used to subtract background from all ROIs except the Standard. Care should be taken to draw it in a place which is suitable as a generic background. The results are very sensitive and if the ROI is not correctly positioned the curve fitting will be incorrect.

⚠️ **Lung V/Q**
The image subtraction and ratio calculations made by this program assume that the ventilation and perfusion SPECT images are reconstructed with the same algorithm and settings. Large differences in settings between ventilation and perfusion reconstructions, such as different matrix size, different corrections applied or large differences in iterations and subsets or different post-filtering parameters might cause unintended effects in the ratio and Q-Corrected images. The Q-Corrected images and the VQ Ratio images should always be interpreted in conjunction with the original unprocessed ventilation and perfusion images.

DICOM SEG
Volumes of regions viewed in Hybrid Viewer may not perfectly match those displayed in external DICOM viewing applications for the same region. This is due to differences in the voxel grid used to define segmentations in different applications, and quantitation methods for voxels on region boundaries. This may affect dose map region statistics which use all region voxels, for example mean dose, especially for smaller regions.

3.10 List of acceptable symbols

Hybrid Viewer uses Windows local settings for thousand and decimal separator. The following separators are accepted:

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

3.11 Additional Information

3.11.1   Regions

Region Values
The format of the region values depends on the local settings of the operating systems (including Integral and decimal digits, group separators, and a decimal separator with optional negative sign).
Be aware of your local settings.

Rasterization
Rasterization is the process by which regions of interest formed of shapes and curves are converted into voxels.
Whenever region rasterization occurs the quantitation may be affected.
Differences in quantification may arise for all region types.
Some metrics, such as Volume, are more likely to be affected than others.
Rasterization of regions happens during the following operations: region split; blob split; single-click segmentation; Metabolically active Tumor Volume (MTV) Definition; region merge; region extract; region constraint; saving DICOM SEG files; saving RTSS files.
Shape regions, such as Ellipsoid, Box and Cylinder, and Paintbrush regions are rasterized in the resolution of the active layer before the contours are traced.
Threshold and Single Click regions are originally rasterized in the resolution of the active layer.
In groups or constrained regions, all contributions are considered to obtain a good resolution.
For small shape regions, there is a mechanism to ensure a minimum resolution.
For large regions, there is a mechanism to avoid overly high resolutions that may use unnecessary amounts of computational resources.

Saving DICOM segmentation regions (SEG)
When DICOM segmentation regions (SEG) are saved, they are rasterized in the resolution of the current active layer.
When saving SEG files, a box containing the series description of the currently active layer will pop up.

Loading DICOM segmentation regions (SEG)
When SEG files of shape regions, such as Ellipsoid, Box, Cylinder, and Paintbrush regions are reloaded, the quantitation of the regions may be affected.

Loaded regions should always be checked with the images to ensure that the positions, size and shape are appropriate.
Threshold and Single Click regions are originally rasterized so will be unaffected.

Saving Radiotherapy Structure Set Files (RTSS)
Radiotherapy Structure Set Files (RTSS) are saved as contour traced regions with higher resolution than the rasterized region and with interpolation applied.
When saving RTSS files, a box, containing the series descriptions of the currently active layer will pop up.

Loading Radiotherapy Structure Set Files (RTSS)
RTSS contours are rasterized when reloaded.
Loaded RTSS regions should always be checked with the images to ensure that the positions, size and shape are appropriate.

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　　　　　　　　　　　　　　**General e-mail address:**
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112 51 Stockholm　　　　　　　　　　　**Support e-mail addresses:**
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Tel: +46 (0) 819 03 25　　　　　　　　　support.ca@hermesmedical.com
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4.2 Regulatory Representatives

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4.3 Subsidiaries

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5 APPENDIX 1 - USER TRAINING REQUIRED CONTENT

Launch
- About box and link to IFU's
- User Handbooks

General Tools and Standard Workflow
- Loading studies
- Toolbar processing operations
- Saving DICOM prints
- Saving Results

Specific Investigations

Neurology
- BRASS

Cardiology
- First Pass Shunt and Ejection Fraction Analysis
- FUGA
- Heart Mediastinum
- Cardiac Splash

Gastroenterology
- Gastric Emptying
- Colonic Transit
- Oesophageal Transit/Reflux
- SeHCAT
- Salivary Glands

Hepatology
- Gall Bladder Ejection Fraction
- HIDA
- Remnant Liver Analysis
- Lung Liver Shunt

Pneumology
- Lung Quantification
- Lung V/Q

Endocrinology
- Thyroid
- Parathryoid

Osteology
- Bone 3 Phase
- Sacro Iliac Joint

Nephrology
- DMSA Kidney Analysis
- Classic DMSA Kidney Analysis
- Renogram Analysis

Organ based Dosimetry

Settings
- Tools settings
- User settings for specific workflows

6 APPENDIX 2 - WARNING MESSAGES IN THE APPLICATION

GENERAL APPLICATION MESSAGES
CRITICAL:
- vdconf.xml file was not found. Application could not start.
- User protocol doesn't exist. Application could not start.
- Protocol doesn't exist. Application could not start.
- OpenGL version 2.0 or higher is required to use shaders.
- No data loaded.
- Problem exporting statistics
- Problem exporting table results to cvs file.
- Export directory doesn't exist. Saving study is not possible.
- Dynamic/Gated data is not supported.
- Need power of 2 color table size.
- Program will not launch due to insufficient memory. Please quit some other applications and try again.
- Studies or SC were not loaded successfully. The file format is not supported or the data is corrupted.

WARNING:
- Print spool doesn't exist. Printing and Saving will not be possible.
- Spool directory doesn't exist. Saving Result File is not possible.
- Spool directory doesn't exist. Saving Movie is not possible.
- Prints are not saved correctly.
- Dynamic Splash Zoom value had been defined in common protocol. This value is not the same that value defined in properties. We recommend to save your properties with this value.
- There are defined movie groups that are not created and saved. Do you want to save them before closing?
- Coregistration parameters will be saved in the result file. It is not necessary to save registered studies. You have to reload original data with the application and result file.
- xx doesn't exist. Saving CSV statistics is not possible.
- Spool directory doesn't exist. Saving Screen Capture is not possible.
- Data too large to perform filtering on this system.
- A number in the image order cannot be duplicated. The label images order will not be applied.
- The image order number cannot be larger than the number of images loaded. The label image order will not be applied.
- All transformations applied, like masking values, rotation, flipping, duplicate an image or adding an empty image, will be lost.
- PNG files are not saved correctly.
- Missing or invalid information.
- Studies or SC were not loaded successfully. Time step is not the same, although Data will be displayed. Computed values may be affected.
- You should update your Lung Reprojection layout protocol to the latest version.

SYNC MESSAGES
WARNING:
- Semi-automatic alignment cannot be applied to the images from the opposing view because one or more ANT and POST images do not have identical date and time.
- Data have not been registered due to different frame of reference.

- Fusion may not be appropriate.
- Fusion may not work properly!
- Frames of reference are different, fusion may not be appropriate.

MOTION CORRECTION MESSAGES
WARNING:
- The two series don't have same acquisition date and time. Do you still want to apply motion correction to this series?

REPORT TOOL MESSAGES
WARNING:
- The report has been modified.\n" "Do you want to save your changes?

ROI/VOI MESSAGES
WARNING:
- You are not drawing on the right study.
- Refresh display prior to copy rois/vois.
- Non-transverse VOIs exist for this dataset. Only transverse VOIs can be saved as RT Structure Sets.
- RTP Export", "Unable to save to RT Structure set - Not available for Interfile Data.
- Non-transverse VOIs exist for this dataset. Only transverse VOIs can be saved as DICOM SEG.
- Unable to save to DICOM SEGMENTATION - Not available for Interfile Data.

ROI RATIO MESSAGES
CRITICAL:
- You should have one first static image.
- You should have one second static image.

SAVE AVI MESSAGES
WARNING:
- Unable to Create Compatible DC.
- SetErrorMessage(_T("Unable to Create Heap")).
- Unable to Allocate Memory on Heap.
- Unable to Create the Movie File.
- Unable to Create Video Stream in the Movie File.
- Unable to Create Compressed Stream: Check your CODEC options.
- Unable to Set Video Stream Format.
- Unable to Write Video Stream to the output Movie File.

SPECIFIC APPLICATION MESSAGES

LUNG VQ
WARNING:
- Lung VQ calculations not performed as Perfusion and Ventilation series cannot be identified. Check string matching in user protocol.
- Lung Ratio can not be performed. Ventilation and Perfusion series are not selected correctly in the layout protocol.
- The total counts of the ventilation study are greater than the total counts of the perfusion study so this application is probably unsuitable for these studies.
- No energy information in %1, perfusion correction will be applied.

BRASS

CRITICAL:
- No valid license for template.
- Database missing for template.
- Database signature invalid for template.
- BRASS will not work with a dynamic PET.
- At least one SPECT or PET study must be loaded.
- No Template Loaded or Missing Dataset for Difference.
- Missing Dataset for Difference.

WARNING:
- Anatomy patient will not be registered/displayed.
- BrassRegistration folder is not present. Registration can't be applied.
- Problem exporting brass region map counts.

CLASSIC DMSA

CRITICAL:
- No "POST" image found. Cannot run.

WARNING:
- Large difference in Left/Right kidney uptake or kidneys too close. Please check kidney and background positions.
- If only one kidney drag the missing kidney cross out of the image.
- Same string matching has been detected for ANT and POST Studies. The protocol will be saved anyway.
- ANT Labels and POST Labels must be defined for string matching.
- No Static Dataset Found with String Matching.

DMSA

CRITICAL:
- You can't load different modalities (Planars/Dynamics/Volumes) at the same time.
- ANT Labels and POST Labels must be defined for string matching.
- No Static Dataset Found with String Matching.
- No Dynamic Dataset Found with String Matching.
- No POST image found.
- No Volume Dataset Found with String Matching.
- No strings matched, loading default view.

WARNING:
- ANT Study and POST Study were detected as the same Study using string matching. Only POST study will be used.
- It is not possible to remove all frames.
- Motion Correction can not be applied to Ant Study as Post and Ant series don't have same acquisition date and time.
- Dynamic acquisition loaded, you need to enable saving summed dynamic in properties.
- Same string matching has been detected for ANT and POST Studies. The protocol will be saved anyway.

DOSIMETRY

CRITICAL:
- Error reading isotopes or phantoms files.
- The Dicom fields ActualFrameDuration (0018,1242) and/or NumberOfFramesInRotation (0054,0053), required for SPECT calibration, are missing in at least one SPECT study. Application will exit.
- Unable to locate Olinda.exe.

- An Olinda version prior to V2.1 has been detected and should not be used with this application. Update Olinda to V2.1 or later.
- No Whole Body dosimetry patient found with string matching defined in protocol. And no SPECT/Quantitative SPECT were loaded.

WARNING:

- Residence time bigger that whole body residence time. It could lead to incorrect dose calculation.
- Be sure the calibration factor is set correctly and the studies correctly aligned.
- Effective half-life is greater that physical half-life, so physical half-life will be used.
- Image data from only one time point was detected. Physical decay of the isotope will be assumed unless external dose rate measurements are entered.
- ANT/POST mismatch in string matching.
- Calculated values may be incorrect if the series date/time has been changed.
- External dose-rate option has been selected and more than one study has been loaded.
- Triple Energy Window Scatter Correction will be applied.
- Photopeak only will be used.
- ROIs have not been copied. Copy them using 'Copy Rois/Vois' in the ROI/VOI window.
- Probe values have not been set.
- A pre-determined residence time for Red Marrow has been entered in the user properties. Red marrow ROIs/VOIs will be ignored.
- Some lesions have been drawn, but no masses are associated with those lesions. Enter masses in 'Target Organ Masses.
- As no vois are drawn, SPECT will not be used.
- Moved/Edited/Rotated local ROIs will be reset to their original position/form.

GALBLADDER

CRITICAL:

- Loaded patients do not have same image size, they can not be combined. First patient will be displayed.
- No Dynamic Dataset Found with String Matching.
- No Static Dataset Found with String Matching.
- No Static/Dynamic Dataset Found with String Matching.
- It is not possible to load 2 series from the same time point together.
- Two static studies required for processing.
- A dynamic study label is assigned to a static study.
- A static study label is assigned to a dynamic study.

GASTRIC EMPTYING

CRITICAL:

- A dynamic study label is assigned to a static study.
- A static study label is assigned to a dynamic study.
- ANT Labels and POST Labels must be defined for string matching.
- No Static Dataset Found with String Matching.
- Conflict in String Matching. It has not been possible to differentiate POST and ANT.
- No Dynamic Dataset Found with String Matching.
- Number of Static Images Mismatch for ANT/POST.
- Number of Dynamic Acquisitions Mismatch for ANT/POST.

WARNING:

- Calculated values may be incorrect if the series date/time has been changed.
- Motion Correction can not be applied to POST Study as ANT and POST series don't have same acquisition date and time.

- Same string matching has been detected for ANT and POST Studies. The protocol will be saved anyway.

LUNG QUANTIFICATION

CRITICAL:
- ANT Labels and POST Labels must be defined for string matching.
- No Static Dataset Found with String Matching.

WARNING:
- All transformations applied, like masking values, rotation, flipping, duplicate an image or adding an empty image, will be lost.
- Same string matching has been detected for ANT and POST Studies. The protocol will be saved anyway.

PARATHYROID

CRITICAL:
- Application will not run if parathyroid string matching is not defined .
- Application will not run if thyroid string matching is not defined.
- No parathyroid patient found with string matching .
- No thyroid patient found with string matching .

WARNING:
- Dynamic study loaded. Enable 'Save summed dynamic study' in Results section user protocol.
- Motion Correction can not be applied to Parathyroid Study as Thyroid and Parathyroid series don't have same acquisition date and time.
- Motion Correction can not be applied to Thyroid Study as Thyroid and Parathyroid series don't have same acquisition date and time.
- Same string matching has been detected for parathyroid and thyroid studies. The protocol will be saved anyway.

REMNANT LIVER

CRITICAL:
- ANT Labels and POST Labels must be defined for string matching.
- No Dynamic Dataset Found with String Matching.

WARNING:
- No Post Dynamic Dataset Found with String Matching.
- No Ant Dynamic Dataset Found with String Matching.
- Same string matching has been detected for ANT and POST Studies. The protocol will be saved anyway.

RENOGRAM

CRITICAL:
- No Geometric Mean study was detected using string matching. Renogram will be applied on Post series.
- It is possible to load 2 series from the same time point together only if the option to create Geometric Mean is selected or if the 2 series are Geometric Mean and Post.
- It is not possible to load 2 series from the same study at the same time unless the Geometric Mean option is selected.
- An incorrect label has been matched against a study.
- You should have geometric mean study for flow/renogram/orthostase and diuretic.
- No Dynamic Dataset Found with String Matching, application could not start.
- Post/Ant patients have not been detected correctly using string matching for %1. No Geometric Mean patients can be computed.

- No Post patients were detected using string matching. %1 cannot run with only Ant Views.
- No Post/Ant patients were detected using string matching for %1. No Geometric Mean patients can be computed.

WARNING:

- Motion correction seems to be applied and study not saved. If you want to reload result file with saved motion correction study, you need to save the study before. Click Ignore to continue and to save result file.
- Kidney depth is missing in Patient Information Widget.
- Injected Activity information is missing in Patient Information Widget.
- Loaded patients do not have same image size, they can not be combined. First patient will be displayed.
- Patlak/OutFlow/Retention graphs will not be displayed on Compare Tab.
- Pharmaceutical found in study header is not the same as the one defined in properties. Study header will be used.
- Result will be saved in more than one xml file.
- All calculations will be made from Geometric Mean study. Depth Correction and GFR/ERPF will be disabled.
- Calculated values may be incorrect if the series date/time has been changed.
- A maximum frame time of 20 seconds (throughout the study) is required to calculate Patlak/Outflow and Retention.
- An acquisition of at least %1 seconds with a maximum frame time of 20 seconds (throughout the study) is required to calculate Patlak/Outflow.
- An acquisition of at least %1 seconds with a maximum frame time of 20 seconds (throughout the study) is required to calculate Retention.
- A maximum frame time of 20 seconds (throughout the study) is required to calculate Retention. Lasix part will not be used.
- An acquisition of at least 20 minutes with a maximum frame time of 20 seconds (throughout the study) is required to calculate Retention.
- All studies don't have same pixel size. Combined study can't be computed.
- Please select a new range, intercept value must be > 0. Background subtraction and values related to patlak will not be computed.
- There are prints in the Print Window that are not saved/printed.\n" "Do you want to save/print them?

SALIVARY

CRITICAL:

- No Static Dataset Found with String Matching.

WARNING:

- Same string matching has been detected for Pre/Post Lemon studies. The protocol will be saved anyway.

SeHCAT

CRITICAL:

- You should have two ANT standard images.
- You should have two POST standard images.
- You should have four standard images.
- You should have two ant or post images.
- You should have two ANT Background images.
- You should have two POST Background images.
- You should have four Background images.
- You should have two ant or post images.

- You should have four Patient images.
- No strings are defined for the study.
- Duplicate strings are chosen. Please select again.
- No strings are selected. Would you like to continue?
- You should have two ant or post images.

WARNING:

- If you want to save the new string matching, you need to open the properties and set the new string matching/detector numbers.

THYROID

CRITICAL:

- Application will not run if thyroid string matching is not defined
- No thyroid patient found with string matching.
- Date/Time is missing from one study. Application could not start and will exit.

WARNING:

- Reference image not detected from string matching. Camera efficiency value stored in user protocol will be used instead.
- Full and empty images not detected from string matching. Syringe activity measured from external counter.
- Isotope was not detected in study header. Please select the correct isotope from the drop down menu..
- The Reference activity dose was not detected in the study. Please enter the value manually.
- The Thyroid activity dose was not detected in the study. Please enter the value manually.
- Full and empty images not detected from string matching. Syringe activity measured from external counter.

OESOPHAGEAL TRANSIT REFLUX

WARNING:

- Same string matching has been detected for transit and reflux studies. The protocol will be saved anyway.

QUALITY CONTROL

CRITICAL:

- Problem exporting uniformity history.
- No Acquisition Dataset Found with String Matching.
- Phantoms have not been detected correctly.
- Phantom has not been detected correctly.

WARNING:

- Source/Collimator distance illegal. Setting it to a default value. Check Manual.

BONE 3 PHASE

CRITICAL:

- No Dynamic Dataset Found with String Matching, application could not start.
- No Static Dataset Found with String Matching.
- A dynamic study label is assigned to a static study.
- A static study label is assigned to a dynamic study.

COLONIC TRANSIT

CRITICAL:

- ANT Labels and POST Labels must be defined for string matching.
- Number of Images Mismatch for ANT/POST.

- You have loaded only one study, you don't have enough data.

FIRST PASS
CRITICAL:
- No Dynamic Dataset Found with String Matching.

FUGA
CRITICAL:
- No Planar Gated Dataset Found with String Matching.

HEART MEDIASTINUM
CRITICAL:
- You should have one static image.

HIDA
CRITICAL:
- No Dynamic Dataset Found with String Matching.
- No Static Dataset Found with String Matching.

LUNG LIVER SHUNT
CRITICAL:
- Lung Liver Ratio calculations are disabled as Lung and Liver series cannot be identified. Suggest setting the 'Use string matcher'.

SI JOINT
CRITICAL:
- No Static Dataset Found with String Matching.