INSTRUCTIONS FOR USE

Affinity 5.0.1

Document revision date: 11/03/2025

www.hermesmedical.com

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 by 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.

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

USA

⚠ Theranostic: Dose prediction functionality in the Theranostic tool is not authorized for clinical use in the United States.
This feature is intended for research or investigational purposes only.

⚠ SIRT: Use of radiopharmaceuticals not approved by the FDA, and/or off-label use of such by-product material is restricted to investigational use only

1.3 Associated documentation

- P60-098 Release Notes Affinity 5.0.1 Rev.3
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

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

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2 PRODUCT INFORMATION

2.1 About Affinity 5.0.1

Affinity provides 2D and 3D visualization, quantification and processing of medical images which have been loaded into the application in Digital Imaging and Communications in Medicine (DICOM) format.

2.2 Intended purpose

Intended Use
Affinity displays, processes and analyzes nuclear medicine and radiology imaging data for investigation of physiological or pathological states. The functionality in Affinity is not intended to replace visual assessment by the intended user.

Based on user input of injected activity, Affinity can calculate absorbed radiation dose and may guide the decision making for future selective internal radiation therapy (SIRT).

The information obtained from the images, including quantitative analysis, may be used, in conjunction with other patient-related data, to inform clinical management.

Intended User
The intended users of Affinity are medical professionals trained in using the system.

2.3 Intended patient population and medical conditions

Patients of any age and gender undergoing molecular imaging investigations or radionuclide therapy.

Intended medical indication is any for which molecular imaging and radiology is performed. Examples of indications for which Affinity is used to inform clinical management include, but are not limited to, cancer diagnosis, treatment and staging, diagnosis of neurological and cardiac conditions, and monitoring of inflammation.

2.4 Contraindications

There are no contraindications.

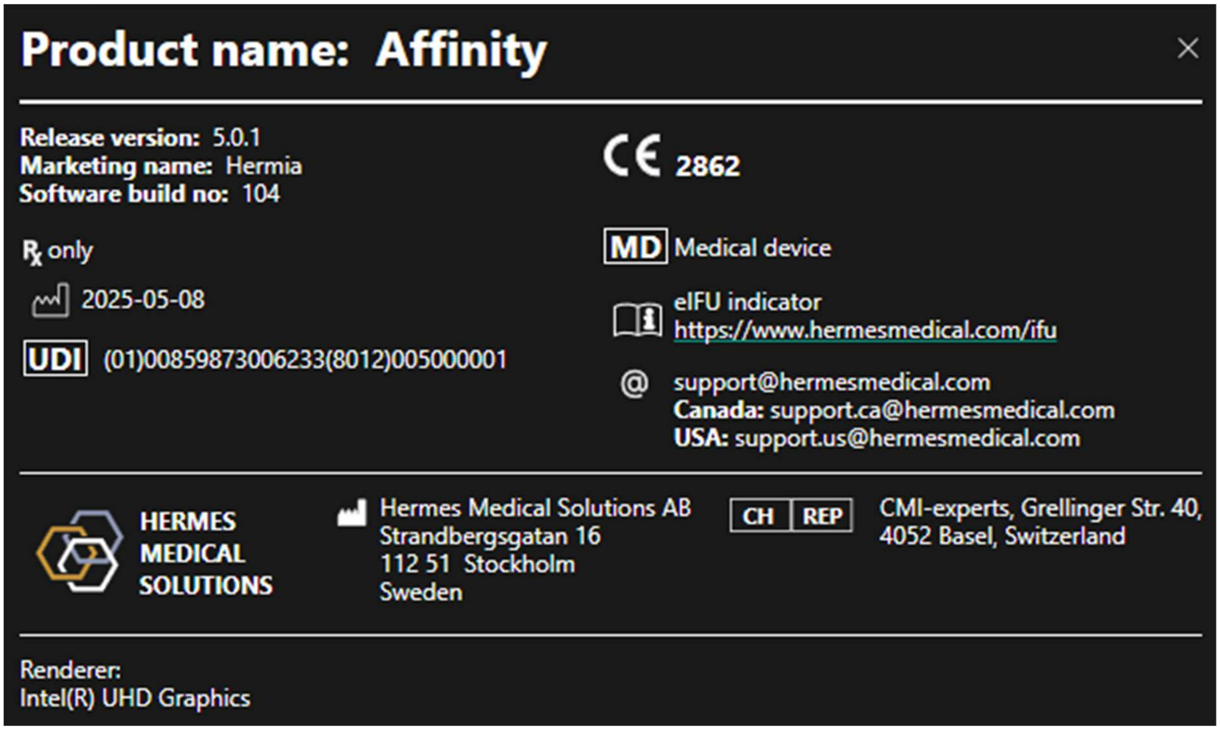
2.5 Product label

The version number, the Unique Device Identification (UDI) and other product data of an installed Affinity 5.0 software can be found by clicking on the information symbol at top right of the application window to open the ‘About Box’.

ⓘ

The following information can be identified:
Product name = Affinity
Release version = 5.0.1
Marketing name = Hermia
Software build no = 104

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
ℹ	Consult Instructions for Use (IFU)
@	The support email addresses
	Manufacturer's contact information
CH REP	Swiss authorized representative



Product name: Affinity

Release version: 5.0.1
Marketing name: Hermia
Software build no: 104

CE 2862

Rx only

2025-05-08

UDI (01)00859873006233(8012)005000001

MD Medical device

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

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

HERMES MEDICAL SOLUTIONS

Hermes Medical Solutions AB
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112 51 Stockholm
Sweden

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

Renderer:
Intel(R) UHD Graphics

Renderer = The Graphic Processing Unit (GPU) currently being used by the application.

2.6 Product Lifetime

The lifetime of Affinity 5.0 is 5 years.

The lifetime of 5 years starts running when Affinity 5.0 has been manufactured (5 years from Manufacturing date of 5.0.1). Possible patches on Affinity 5.0 will have new manufacturing dates, but the lifetime will not start over from manufacturing of a patch.

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

2.7 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*.

2.8 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.

Additional Software Requirements
The Affinity software is currently dependent on the following software:

Software	Description
7zip	Used to unzip the installation package. 7-Zip is free software with open source. Most of the code is under the GNU LGPL license. Some parts of the code are under the BSD 3-clause License. Also, there is unRAR license restriction for some parts of the code. Read 7-Zip License information. https://www.7-zip.org/license.txt 7-Zip can be downloaded from: https://www.7-zip.org/
.NET Desktop Runtime 8	Must be installed on the workstation, server, or environment where Affinity will run. .NET is open source and supported by Microsoft. There are no fees or licensing costs, including for commercial use. .NET Desktop Runtime 8 can be downloaded from: https://dotnet.microsoft.com/en-us/download/dotnet/8.0

2.9 Installation

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

2.9.1 Warnings

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

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3 SAFETY, SECURITY AND PERFORMANCE INFORMATION

3.1 Supported data formats

The following lists provide a overview of the types of DICOM data that Affinity 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 Import Data

- CT Image (CT)
- Encapsulated PDF
- MR Image (MR)
- Multi-frame True Color Secondary Capture Image (MFSC)
- Nuclear Medicine Image (NM)
- Positron Emission Tomography Image (PET)
- RT Structure Set (Contours)
- Secondary Capture Image (SC)
- Segmentation

DICOM Export Data

- CT Image (CT)
- Encapsulated PDF
- MR Image (MR)
- Multi-frame True Color Secondary Capture Image (MFSC)
- Nuclear Medicine Image (NM)
- Positron Emission Tomography Image (PET)
- RT Dose (Dose Map)
- RT Structure Set (Contours)
- Secondary Capture Image (SC)
- Segmentation

3.2 Launch

Studies can be loaded into Affinity in any of the following ways:

- By selecting the studies to be viewed from Hermes GOLD or other Patient Browser and selecting the Affinity application
- From a PACS or RIS list when PACS/RIS integration is in place
- By dragging and dropping the studies from a Windows folder onto the Hermes.exe file
- By dragging and dropping a Zipped DICOM file (not 7-Zip) onto the Hermes.exe file or in the Affinity application

It is also possible to load additional data into a running session by dragging and dropping file system paths containing DICOM datasets onto the running application.
When the application is running directly on a workstation without the use of Remote Desktop or Citrix, studies or study folders can be dragged and dropped from GOLD into the application.
In addition to studies, the following datasets can also be loaded:

- Regions stored as DICOM segmentation (Modality: SEG).
- DICOM RT Dose files (Modality: RTDOSE).
- JPEG images (Lossy and lossless JPEG 2000 compressed, lossy and lossless JPEG compressed, lossy and lossless JPEG-LS compressed) (Modality: OT).
- RT Structure Sets (Modality: RTSTRUCT).

- A previously stored session including regions, measurements, annotations, and co-registrations. The sessions are loaded automatically with the associated study.

The state of the current session in Affinity will automatically be saved. When restarting Affinity with the same datasets, it is possible to work from this state again. The rules for saving a session are defined in the settings.

When several instances of the application are running, it is possible to see the patient name and study date by hovering over the application icon in the taskbar.

3.3 Loading Studies

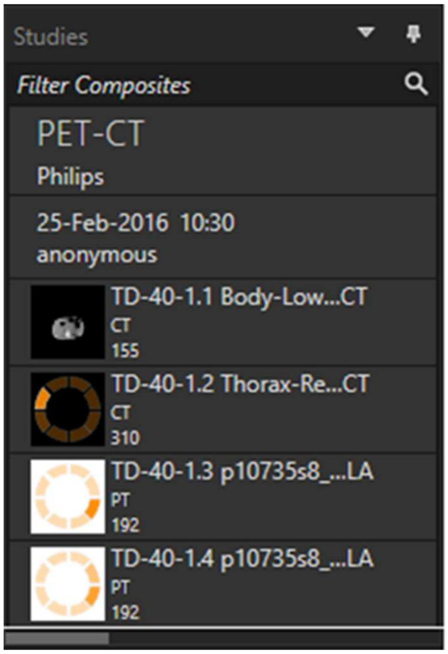
When the application is launched with the specified DICOM studies, they are listed in the **Studies window** grouped by Patient, Study Date and Study Time.

If studies from more than one Patient have been loaded, the Patients are listed in alphabetical order by Patient Name.

The studies for a specific Patient are ordered based on Study Date and Time, with the latest on top.

When two studies have been loaded for the same patient and with the same Study Date and Time, they are sorted based on Study ID.

Within a Study group, the data is sorted based on Series Date and Time, with the earliest series time displayed on top, except when there are two series with the same date and time, in which case they are sorted based on Modality.
Orange spinning wheels of all the series which are still being loaded are displayed to the left of the series description and a progress bar is displayed at the bottom of the **Studies window**.



PET-CT
Philips

25-Feb-2016 10:30
anonymous

TD-40-1.1 Body-Low...CT
CT
155

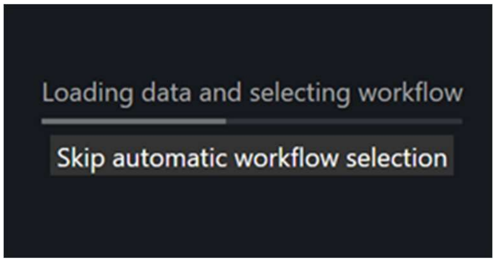
TD-40-1.2 Thorax-Re...CT
CT
310

TD-40-1.3 p10735s8_...LA
PT
192

TD-40-1.4 p10735s8_...LA
PT
192

DICOM loading progress bar

While the application is loading, the user can either wait for it to automatically open a predefined workflow which best fits the series which have been loaded, or abort by clicking "Skip automatic workflow selection". If the automatic workflow selection is aborted, the application will load the **Default workflow.**


Loading data and selecting workflow

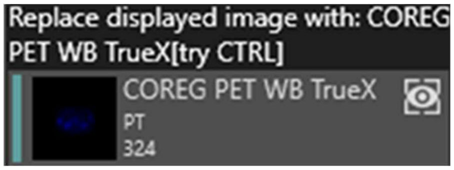
When the **Default workflow** is selected all default layouts are available, and any image series can be worked with as soon as it becomes visible in the **Studies window**.

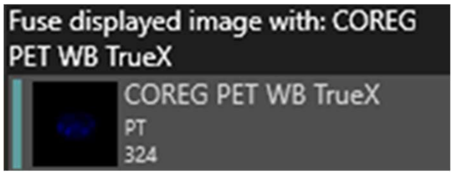
It is possible to preselect which workflow the application should startup with by using a (-p) command line option. For example, "*-p=Default*" will force the application to start with the **Default workflow**. See the Installation manual for more details.

Workflows are explained in the **Workflows and Layouts** section of this handbook.

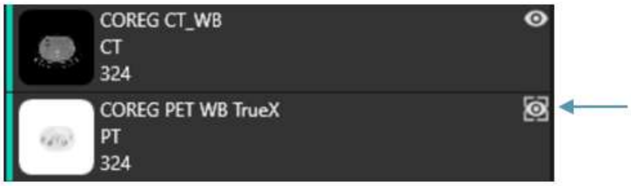
Single or multiple series are loaded into a selected viewport using one of the following methods:

- Automated population of a predefined workflow.
- Click, drag-and-drop into a viewport.
- Right-click, drag-and-drop into a viewport.
- Double-click.
- Click the selected series and press Enter.
- Click the eye at the top right corner of the series. The eye becomes visible when hovering over it.

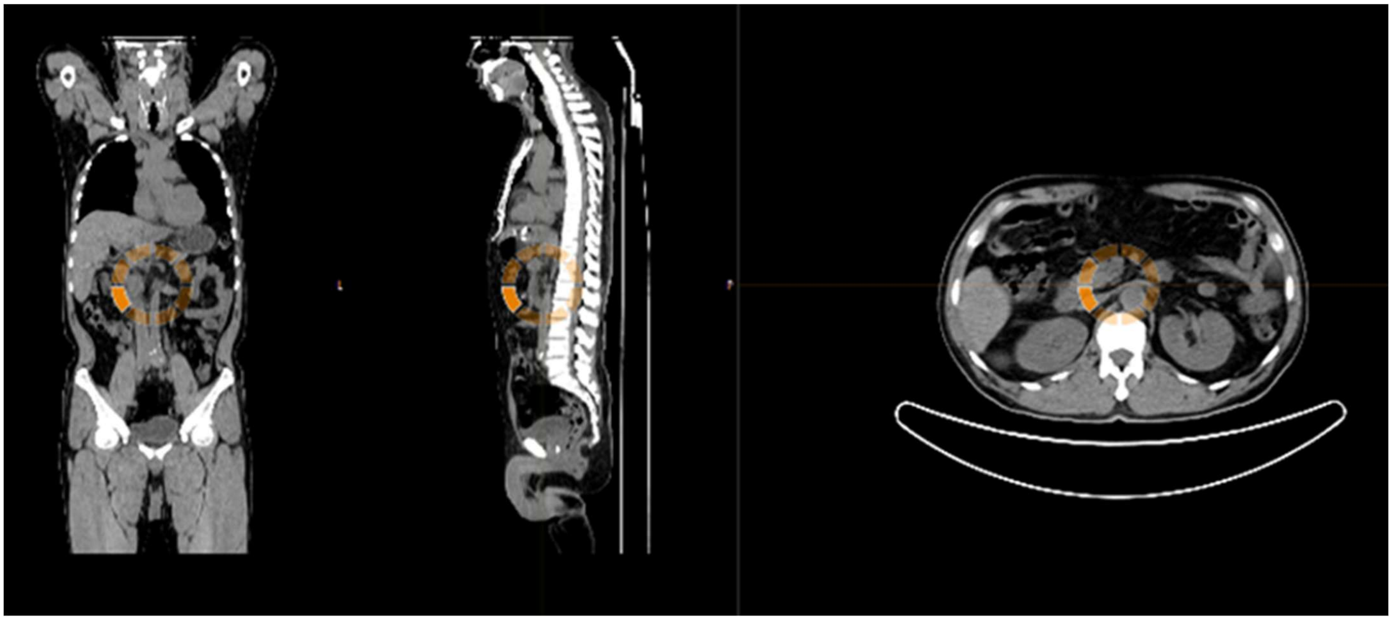

Replace displayed image with: COREG PET WB TrueX[try CTRL]


Fuse displayed image with: COREG PET WB TrueX

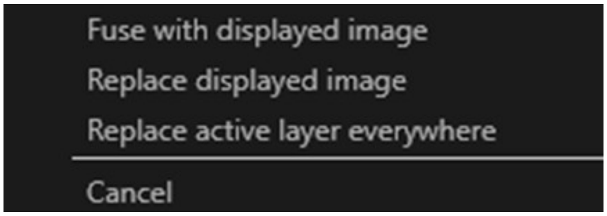
The series which is the active layer is displayed with a box around the eye.



Box around the eye



When loading a series into a viewport which is already displaying images, using **Right-click**, **drag-and-drop**, a popup window will appear:



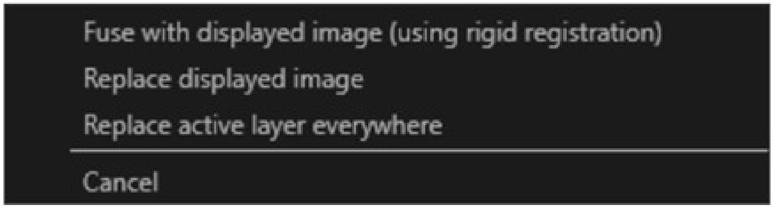
When dragging and dropping, the default action is to replace the existing series, but if CTRL is pressed before dropping the series into the viewport, the series being dropped will be fused with the existing series.

To load a study consisting of more than one series into a viewport, there are several possibilities:

- Click and drag and drop a Study Date/Description item in the **Studies window** into the viewport.
- **Double-click** over Study Date/Description item.
- ‘**CTRL**’+ **double-click** one series over another series.
- Right-click and drag-and-drop one series over another series. This shows the same context menu as when clicking on the eye icon.

When many studies have been loaded into the application, it may be helpful to enter text in the “*Search*” box in the **Studies window** to filter the contents.

When a series is loaded into a viewport which is displaying an existing series, and the Frames of Reference for the two series are not the same, a context menu appears:



Co-registration can be performed automatically, manually and locally around a defined region of interest.

The goal with image registration is to align the images from one or more studies with each other. It is assumed that series which have the same frame of reference are already co-registered.
A co-registered study can be exported, in which case it will share the same frame of reference as the study to which it was co-registered. Prior to saving, it is possible to assign the co-registered study a new series description.

NOTE: When comparing multiple SPECT reconstructed studies from the same patient, ensure that the GPU is enabled or disabled for all reconstructions, as the results using GPU and CPU may differ slightly.

3.3.1 Warning

Always ensure that the DICOM information, shown in the **Properties window** when a study is selected in the **Studies window**, is correct.

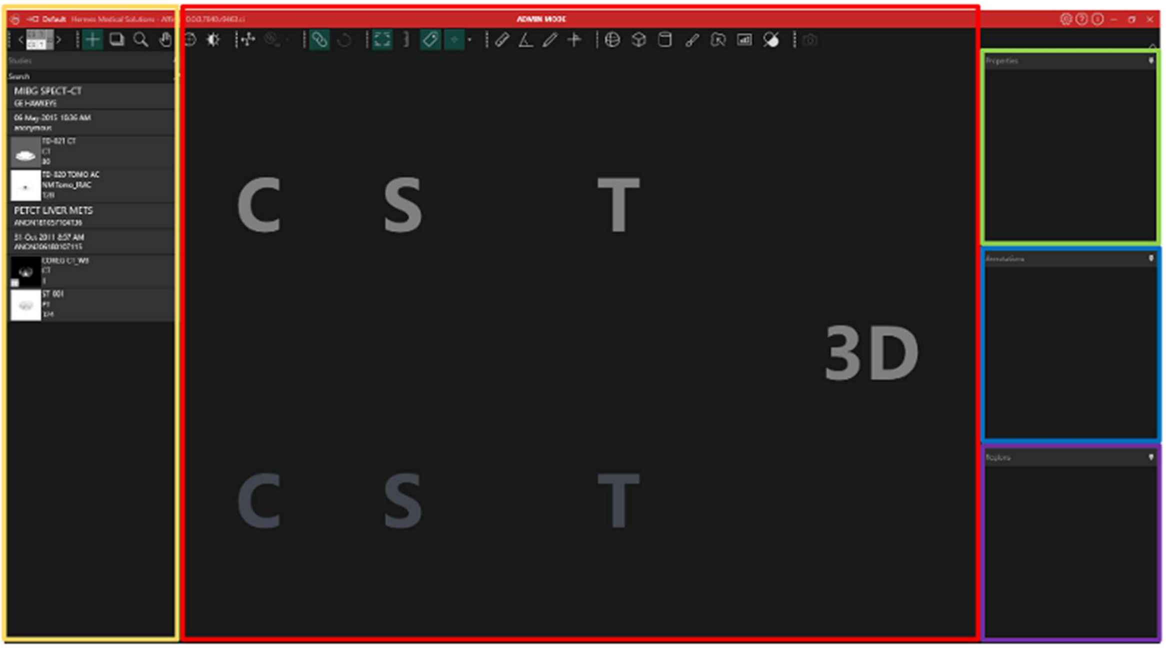
Always ensure that the input data, such as patient weight and administered activity, which may influence quantitative output, is correct.

If the series date or time is missing a warning triangle is displayed in the viewport annotation beside the series date with a tooltip to state that study date and time are being used.

If studies from more than one patient have been loaded, the patients are listed in alphabetical order by patient name and a warning message 'Patient ID does not match' will be displayed at top left of the viewport.

3.4 User Interface

The Affinity application has a User Interface with key components, referred to throughout this manual.



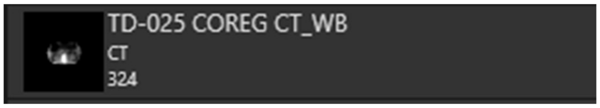
The red highlighted area is the **Image window**, within which tomographic slices, 3D rendered images, annotations, volumes of interest etc. are displayed. In the picture above, C (coronal), S (sagittal) and T (transverse) slices and a 3D image are each displayed in their own **Viewport**. Together, the viewports are called a **Viewport Group**. The active viewport will be surrounded by a blue box.

The **yellow** highlighted area is the **Studies window,** which displays items of available data in groups within a tree structure. The series that have been loaded are grouped based on Patient Name and ID -> Study Date and ID -> Series -> Composite images.

Each item at the composite image level in the **Studies window** contains the following information:

- icon representing the composite image
- series description
- modality
- number of images that make up the composite image

The icon is sometimes referred to as a thumbnail and is, by default, presented with the modality specific color map, which can be configured in the **Settings window**.



TD-025 COREG CT_WB
CT
324

The **blue** highlighted area is the **Annotations window**. The annotations window contains a list of created annotations and measurements.

The **purple** highlighted area is the **Regions window.** The regions window contains a list of created Regions.

Annotations and Regions can be added and removed from the active image window by clicking the eye icon next to the object name in the respective window. When a region is displayed in the image window a **Stats box** will be displayed, with values which depend on the **Region settings.** When an annotation is displayed in the image window, a measurement is also displayed.

The **green** highlighted area is the **Properties** or **Slab/Step window**.

The **Properties window** displays one of the following:

- DICOM header information: When one or more datasets from the **Studies window** are selected, the window displays the DICOM header information for each of the datasets, one column per dataset.
- Annotation and Region information: When a region or annotation is selected in the **Regions** or **Annotations window**, all settings for the selected object are displayed in the window. It is possible to set the geometry of a region in this window before placing it on a study.
- Unit information: When clicking the orange value in the overlay text of a series which has units, such as SUV, the unit properties will be shown in the window. Series description, series date and series time for the displayed series are also displayed in the window. The fields which can be edited depend on the modality of the study and units in which the study is displayed. For PT studies, the unit options are:
- Counts - CNTS
- Bq/ml
- Relative to Reference SUVR
- Different types of SUV

Depending on which unit has been selected, other fields may be displayed and be editable.

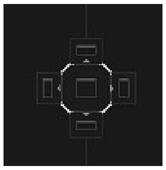
The **Slab/Step window** displays information when the orange value of Slab or Step in the overlay text is clicked. Properties of both can be changed by selecting **Custom** in the window.
The yellow, green, blue, and purple windows highlighted are all floatable, dockable and hideable. They can be hidden by clicking on the **Auto Hide** pin.

In the hidden state, the windows are represented as tabs on the right-hand side of the main application window. Click once on the tab name to unhide the window and display the contents.


ANON210249250251
ID: ANON042156013241
DOB: 01-Jan-1942
Sex: F

Clicking the pin icon again will bring the selected window back to the position it was in before being hidden.

Any of the windows can be moved anywhere on the screen or screens in a floating state. To float a window, double-click on the grey title bar of a docked window. Double-click on the grey title bar once more to move it back to its previous docked position.
When in floating state, the windows can be docked to different positions in the image window. The image below illustrates where the areas are dockable.



Once a floating window is dragged and dropped onto a dockable area, it will be docked to that position. In the following example the **Regions window** is docked on top of the image window.


ANON210249250251
ANON042156013241
20-Dec-2018 12:28 PM
FGH
Affinity - VAL - 11 PET WB (AC)
PT
274

Affinity - VAL - 11 PET WB (AC) ANON210249250251
20-Dec-2018,12:41 PM ID: ANON042156013241
LT: 0.0 UT: 7.0 DOB: 01-Jan-1942
Idx: 85, 78, 128 Sex: F
Mean 1 slices 4.1 mm
SUV bw
Step: Slab 4.1 mm
Zoom: 15%

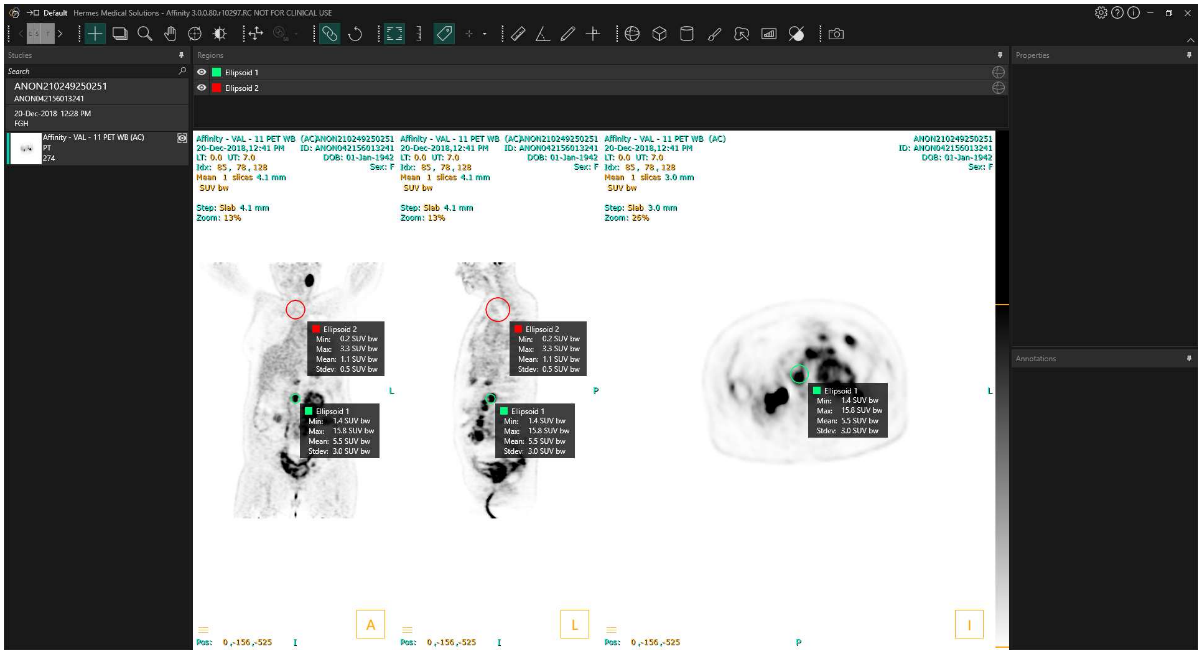
Affinity - VAL - 11 PET WB (AC) ANON210249250251
20-Dec-2018,12:41 PM ID: ANON042156013241
LT: 0.0 UT: 7.0 DOB: 01-Jan-1942
Idx: 85, 78, 128 Sex: F
Mean 1 slices 4.1 mm
SUV bw
Step: Slab 4.1 mm
Zoom: 15%

Affinity - VAL - 11 PET WB (AC) ANON210249250251
20-Dec-2018,12:41 PM ID: ANON042156013241
LT: 0.0 UT: 7.0 DOB: 01-Jan-1942
Idx: 85, 78, 128 Sex: F
Mean 1 slices 3.0 mm
SUV bw
Step: Slab 3.0 mm
Zoom: 30%

🟥 Ellipsoid 2
Min: 0.2 SUV bw
Max: 3.3 SUV bw
Mean: 1.1 SUV bw
Stdev: 0.5 SUV bw

🟩 Ellipsoid 1
Min: 1.4 SUV bw
Max: 15.8 SUV bw
Mean: 5.5 SUV bw
Stdev: 3.0 SUV bw

Regions
🟩 Ellipsoid 1
🟥 Ellipsoid 2



The position of all dockable panels is persistent. Hence closing the application and starting a new session will allow a user to start working in the same environment as they were working in before closing the application. See the Settings section for a description of how to reset windows to their original positions.

The Unit properties are presented in the same manner as for all windows described above.

Click on the orange text in the Unit overlay to select the available units for a series.


0.00 SUV bw

Depending on which modality is being displayed, the Unit information will automatically be displayed in the properties panel and will allow selection of different options such as:

- Counts-CNTS
- Bq/ml
- Relative to Reference SUVR
- Different versions of SUV

The fields which can be edited depend on the modality of the study and units in which the study is displayed.

Series description, series date and series time for the displayed dataset is presented in the unit information in the properties panel.

The "*Reset*" button is only active if anything has been changed, in which case clicking the button will revert the information back to the original values.

3.5 Toolbar

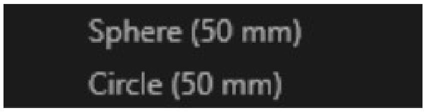
The main toolbar is displayed at the top of the application window.

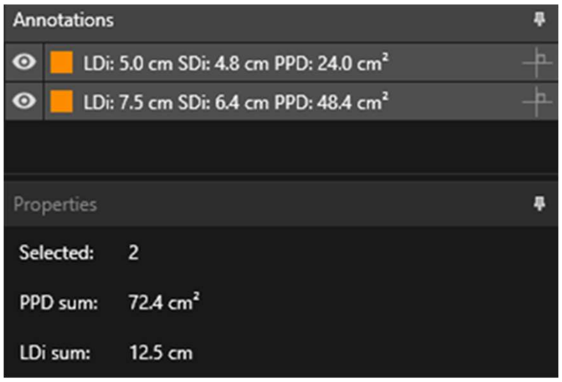
Information about the function and the shortcut of each icon can be displayed in a tooltip by hovering over it.

Deselecting a previously selected icon - like Scroll, Zoom, Pan, Rotate, Window level, New Ruler, New Angle, New Ellipsoid etc. - will reset the mode to Triangulation, which is the default mode. When triangulation mode is not activated, it is still possible to adjust the triangulation point by simply dragging the crosshairs. This allows users to reposition the point without altering the current mouse mode, providing a seamless and intuitive way to adjust while maintaining control of the tool's functionality.

Main Toolbar operations		
Operation	Icon	Description
Layout/Stages	< C S T >	This icon allows the user to select from the available stages. Should the default workflow be selected, all stages will be made available here. A Viewport group is temporarily highlighted when the mouse hovers over the viewport group. It is possible to switch stage using the following short cut keys: ‘**PgDn**’ for next and ‘**PgUp**’ for previous.
Triangulation / Spherical Triangulation	+	Toggle visibility of the triangulation cursor ON and OFF.
Scroll	↕	Click and drag over images in a viewport to scroll.
Zoom	🔍	Click and drag over images in a viewport to zoom.
Pan	✋	Click and drag over images in a viewport to pan.
Rotate	⊕	Click and drag on the circle or triangulation lines to rotate an image around the triangulation center. Click and drag on the triangulation cursor in the middle of the circle to triangulate.
Window Level	☀	Click and drag to change window level. Only affects the active layer and all studies of the same modality. To change this, right-click the color table and untick: "Use window for all Hounsfield/PET SUV images”.

Manual coregistration		Click to manually translate and rotate series relative to each other. Available for series which do not share the same initial frame of reference (Study) and for images which share the same initial frame of reference (Image). The shortcut for this function can be assigned manually.
Local registration		Click to perform a local image registration around a defined region of interest. The size of the region of interest can be set from the dropdown menu beside the icon. The shortcut for this function is the '**R**' key.
Reset View		Reset the geometry of the image/images displayed. Also reset Window/Level and LT/UT in all visible viewports to the default preset set in the User settings. The shortcut for this function is the '**Esc**' key.
Annotation ON/OFF		Toggle visibility of patient and study overlay text. The shortcut for this function is the '**O**' key.
Zoom Ruler ON/OFF		Toggle visibility of a ruler displayed to the right of each viewport.
Region statistics		Toggle visibility of region statistics for all regions. The shortcut for this function is the '**L**' key.
Patient banner		Toggle visibility of patient banner.
Report		Toggle visibility of Report panel ON and OFF.

Crosshair ON/OFF	⌖ ▾	Toggle visibility of crosshair ON and OFF. Left-click the menu on the right of the crosshair icon to display the available triangulation mode options. Spherical triangulation presets can be created in the **Settings window** in the **crosshair tab**.
Triangulation Sphere/Circle	🌐 ○	Toggle visibility of triangulation sphere/circle ON and OFF. The available spherical/circular triangulation presets (if created) are:  Sphere (50 mm) Circle (50 mm) Spherical/circular triangulation presets can be created in the **Triangulation** panel of the **Settings window**. Spherical/circular triangulation can follow the triangulation point or cursor. A keyboard shortcut key to toggle this can be assigned in the **Keyboard Shortcuts** panel of the **Settings window**.
New Ruler	📏	Create a distance measurement between 2 points.
New Angle	∠	Create an angular measurement between 3 points.
New Annotation	✎	Create an arrow with text label. Text is edited either in the Measurement/Annotation window or in the box associated with the created arrow.

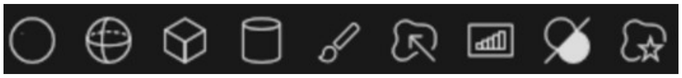
New Cross		Create a set of 2 orthogonal axes by drawing 2 straight lines that cross each other. Hover near the center of the cross until both lines are highlighted to drag the cross to a new position. Hover over one line, which will be highlighted, to move, rotate or change the length of the line. This tool can be used to evaluate tumor progression, either according to the WHO or the RECIST criteria (based on the CT). The following statistics will be shown in the annotation box next to the long-axis/short-axis measurements as well as in the Annotations list: • Longest transverse diameter (LDi) which shows the length of the longest intersecting perpendicular measurement • Shortest axis perpendicular to LDi (SDi) • Product of the perpendicular diameters (PPD). Note: The PPD is calculated from the unrounded values of LDi and SDi and is then rounded to the first decimal place. The value may therefore differ from the product of the LDi and SDi values which are displayed. If several crosses are drawn and selected within the **Annotations window**, the **Properties window** will show the summed PPD and LDi values.  Annotations LDi: 5.0 cm SDi: 4.8 cm PPD: 24.0 cm^2 LDi: 7.5 cm SDi: 6.4 cm PPD: 48.4 cm^2 Properties Selected: 2 PPD sum: 72.4 cm^2 LDi sum: 12.5 cm Ref: Wahl RL, Jacene H, Kasamon Y, Lodge MA. From RECIST to PERCIST: Evolving Considerations for PET Response Criteria in Solid Tumors. J Nucl Med. 2009;50(Suppl_1):122S-150S. doi:10.2967/jnumed.108.057307 Miller A.B., Hoogstraten B., Staquet M., Winkler A. Reporting Results of Cancer Treatment. Cancer 47:207-214, 1981 Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). Eur J Cancer. 2009;45(2):228-247. doi:10.1016/j.ejca.2008.10.026
New Ellipse		Click to create an ellipse region (2D).
New Ellipsoid		Click to create an ellipsoid region.

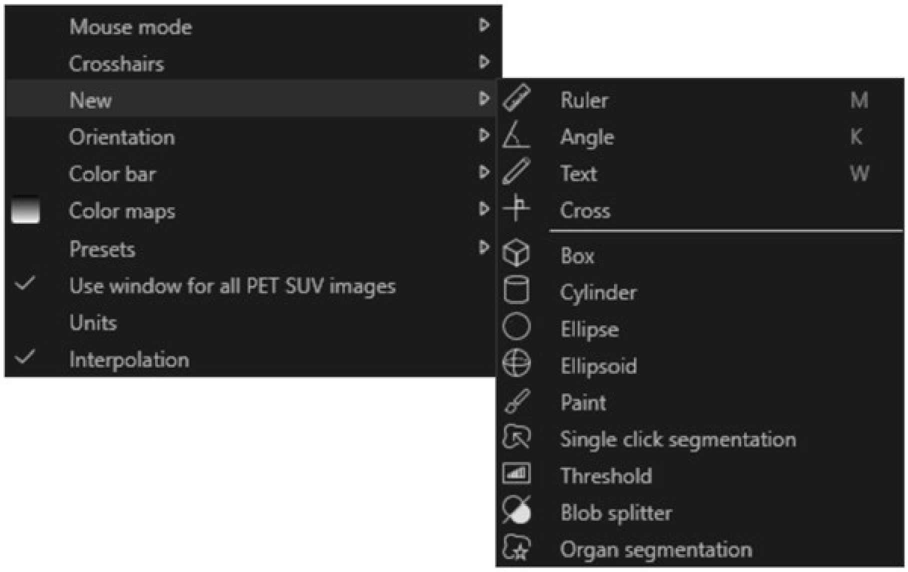
New Box		Click to create a box region.
New Cylinder		Click to create a cylindrical region.
New paint brush region		Click to paint a region. Draw on multiple slices within the same orientation to create a region consisting of several slices. It is not necessary to draw on every slice, as a missing slice or slices will be interpolated.
Single Click Segmentation		Click to segment an object using a threshold criterion on the active layer. All connected voxels satisfying the criterion will be included in the region.
New Threshold		Click to create a threshold region on the active layer. All voxels in the image satisfying the threshold criterion will be included in the region.
Blob Splitter		Click and the mouse cursor will change to a knife symbol. Click with the knife on a region to split it into the most natural two portions using a combination of region shape and functional information from the image data. Multiple splits can be performed until the desired region is obtained. The knife symbol can also be used to delete a specific part of a threshold. Select the knife symbol, click on the part of the threshold that you want to delete and **immediately** press the keyboard Delete key.
Organ segmentation		Click to start automatic organ segmentation for Liver, Kidneys, Lungs and Spleen regions. Automatic organ segmentation is based on a CT, so a reference CT must be loaded in the viewport.
Secondary capture of the whole screen		Click to create a screen capture of the view as a DICOM Secondary Capture. The screen capture will appear in the **Studies window** with modality SC, from where it can be copied, saved, renamed, or deleted. Note: To enable secondary capture a spooler directory must be defined. This is described in the Installation manual. The shortcut for this function is the '**P**' key

Multi frame Secondary capture of the whole screen		Click to create a screen capture of all viewports in the current layout as a DICOM Multi Frame Secondary Capture. Set a limited slice range for movies using slide bar handles. Note: To enable secondary capture a spooler directory must be defined. This is described in the Installation manual.

3.6 Regions

Regions can be generated on non-fused or fused views of the study selected as the current study. A region can be created by selecting any of the following options: New Ellipse, New Ellipsoid, New Box, New Cylinder, New paint brush, Single click segmentation, New Threshold, Blob splitter and Organ segmentation (semi-automatic segmentation) of the right and left kidneys, right and left lungs, liver and spleen. All regions created using these tools shall be inspected by the user, by scrolling through all image slices, and shall be edited as considered needed. These options are available in the **Toolbar** or by right-clicking in the viewport and selecting “New” to see the following dropdown-menu.





On selecting a region type, the **Properties window** will show all adjustable settings for a new region of this type, i.e. label, color, presets.

Once a region has been created it is displayed in the viewport in which it was created and in the Region list panel. Each region type displays a specific icon in the **Regions window**.

Binary bit map regions, such as those created with single click segmentation, region splitting and Metabolic Peak (MP) regions, share the same icon.

If multiple regions have been generated, it is possible to quickly triangulate to a required region by using up/down arrows followed by Enter in the Region panel.

Region visibility can be toggled by clicking the eye-icon for a specific region
Regions can be rotated and scaled by clicking and dragging the border of the created region. Holding '**Ctrl**' or '**Shift**' will enable rotation or scaling only respectively.

3.6.1 Region values

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.

3.6.2 Warning

⚠ **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.

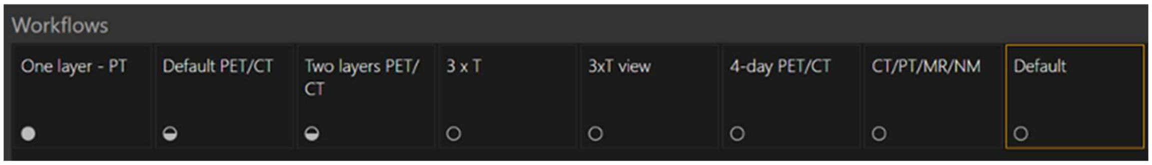
⚠ All region segmentations must be carefully checked by scrolling through all image slices.

3.7 Workflows and Layouts

Clicking the **Workflows** icon in the title bar will open the Workflows view, see below.

→☐

The view contains all workflows already configured for the user.



Each workflow has a circular symbol indicating how well the currently loaded studies match the workflow. Three different symbols are used:

- Filled circle. All the predefined layers of the workflow will be filled.
- Half-full circle. Some of the predefined layers of the workflow will be filled.
- Empty circle. No layer of the workflow will be filled.

The current workflow is highlighted with a contrasting border.
Clicking a workflow will load the workflow and make it the current workflow. The first stage in the workflow is set as the current stage and series which match the layers of the stage will populate the viewports.

Each workflow consists of one or more layouts, which in turn are constructed from viewport types.

The following viewport types are available:

- 2D

- Transverse (T)
- Coronal (C)
- Sagittal (S)
- 3D/MIP/Volume rendering
- Statistics (STAT)
- SIRT Planning (SP)
- SIRT Verification (SV)
- Lung Lobar Quantification (LLQ)
- TN (Theranostics viewport)

3.7.1 Warning

⚠ User provided workflows, layouts and rules are not validated nor warranted by Hermes Medical Solutions. The party using such workflows, layouts or rules is solely responsible for the results.

3.7.2 SIRT

The SIRT workflow is used in the evaluation of pre- and post-treatment absorbed dose calculations in Y-90 and Ho-166 microsphere liver radioembolization.

3.7.3 LLQ

LLQ provides the percentage function in each lobe by combining semi-automated CT segmentation of lung, airway, and lobar anatomy with functional image data.

3.7.4 Theranostics

The Theranostics software utilizes diagnostic imaging to quantify dose values within user-defined volumes. It presents key metrics to the end user, including maximum dose, mean dose, dose planning volume (i.e. D90%, D95%).
The software can apply dose scaling to define the maximum dose based on user-specified limits per volume.

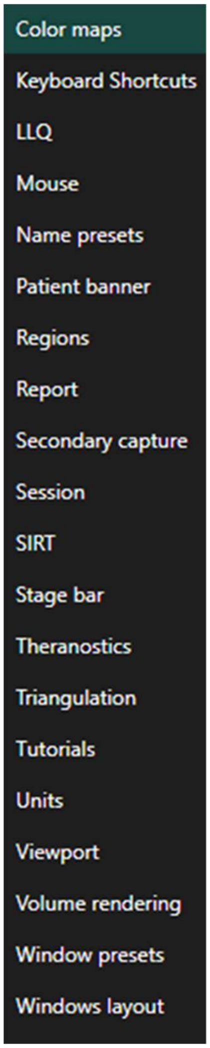
3.8 Settings

Factory settings can be overridden in Admin mode; the new settings will be applied to all users being run under the same Admin system.

A Reset icon is displayed at the bottom of each panel in the **Settings window**. This is active when a change has been made to the default settings for that tab. Clicking on this icon will reset all options in that panel to the factory settings.

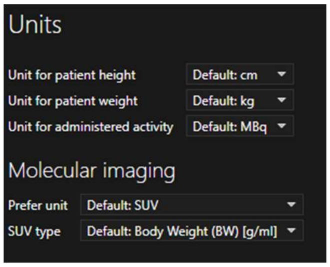
In User mode, Admin settings can be overwritten, but the settings will only be applied for the user who has made the changes. Clicking on **Reset** in any panel of the **Settings window** will reset all options in that panel to the Admin settings.

To access the settings, click on the **Settings** icon at the right corner ⚙.



3.8.1 Units

It is possible to choose between SI or Imperial units.



Units

Unit for patient height	Default: cm
Unit for patient weight	Default: kg
Unit for administered activity	Default: MBq

Molecular imaging

Prefer unit	Default: SUV
SUV type	Default: Body Weight (BW) [g/ml]

3.9 Security

Affinity 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 Affinity 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.

Backup routines:

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

3.9.1 Interfaces

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

Hardware Interface
Affinity functions exclusively as software without any hardware interfaces.

Network Interface
The Affinity 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 Affinity 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 Affinity is its Graphical User Interface (GUI) which is described in detail above in the *User Interface* section above.

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

Data Exchange Interface

Affinity interfaces with the file system to read and write medical imaging data. The application supports DICOM and Nifti-1 file format (https://nifti.nimh.nih.gov/nifti-1/) for data exchange.

File System Interface

To enable DICOM file handling, this system utilizes a proprietary DICOM parser to read and write files directly from the file system, supporting specific DICOM IODs detailed in the *Supported data formats* section above.

Default configuration of workflows, layouts, and rules are automatically retrieved from an configuration file which is modified from within the application.

Database Interface

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

3.9.2 Warning

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

3.10 Additional Information

3.10.1 Standard Uptake Value (SUV)

The SUVmax of small structures could be higher by up to 60% when reconstructed with algorithms which use Ultra High Definition or any Resolution Recovery or PSF modelling, when compared to reconstruction with algorithms which do not.
Kuhnert G, Boellaard R, Sterzer S, Kahraman D, Scheffler M, Wolf J, Dietlein M, Drzezga A, Kobe C. Impact of PET/CT image reconstruction methods and liver uptake normalization strategies on quantitative image analysis. Eur J Nucl Med Mol Imaging. 2016 Feb;43(2):249-258

Calculated SUVs e.g. SUVpeak should not be compared with that calculated from studies acquired on other PET cameras or from other programs, due to the fact that the SUV and volume definitions and the voxel size may vary.

3.10.2 Warning

This section describe warning to safely use the application.

3.10.2.1 Patient Info Edits Impact SUV Values

Modification of patient information affects SUV values (displayed after patient or study info is edited in Units window).

3.10.2.2 SUV Accuracy Warning: DICOM Data Issues

Beside SUV value: Accuracy is uncertain due to the following problems with your DICOM dataset: Missing decay factor Cannot double check the time to which images are decay corrected MMDDYYYY HHMMSS AM/PM.

3.10.2.3 SUV Accuracy Warning: Implausible Decay Factor

Beside SUV value: Accuracy is uncertain due to the following problems with your DICOM dataset. Decay Factor value is less than or equal to 1, suggesting that the administered activity at the scan time is greater than or equal to that at the administration time.

3.10.2.4 SUV Accuracy Warning: Inconsistent Decay Time

Beside SUV value: Accuracy is uncertain due to the following problems with your DICOM dataset: Poor consistency in the time of decay correction. Possible values are MMDDYYYY HHMMSS AM/PM. Using MMDDYYYY HHMMSS AM/PM.

3.10.2.5 Missing or Invalid Height Value

Tooltip over warning symbol in unit scaler window: Missing or invalid information. Missing height.

3.10.2.6 Missing or Invalid Weight Value

Tooltip over warning symbol in unit scaler window: Missing or invalid information. Missing weight.

3.10.2.7 Dose Value Missing or Incorrect

Tooltip over warning symbol in unit scaler window: Missing or invalid information. Invalid dose.

3.10.2.8 Missing Series Date/Time – Using Study Info

Tooltip over warning symbol displayed beside series date: Missing series date and/or series time. Using study date and study time.

3.10.2.9 At top of viewport: Patient ID does not match

⚠ At top of viewport: Patient ID does not match

3.10.2.10 Using Study Date and Time

⚠ Beside the series date. Tooltip: The study date and time are being used.

3.10.2.11 Isotope Mismatch Between Planning and DICOM

⚠ SIRT - If you, for example, do a Planning for y-90 and then verify with Ho-166, the Ho-166 is read from DICOM header but y90 is read from planning report, then a warning message will appear saying: “Isotope in DICOM header is X but planning was for X".

3.10.2.12 Warning: SIRT Parameters Modified Since Planning

⚠ SIRT - If the SIRT settings affecting the dose calculations have changed since the planning stage, a warning triangle shall be displayed in the SIRT Verification viewport. When hovering over the triangle, a message indicating which settings have changed shall be displayed.

3.10.2.13 Lung Dose Warning – Based on Planar Shunt

⚠ SIRT - If the partition model values are displayed and a lung region is selected a warning triangle will be displayed next to the partition model lung dose value together with a text "Partition model lung dose is always calculated using planar lung shunt". This is because the partition model limiting lung dose is defined from planar lung shunt calculations, not SPECT lung regions.

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
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England, United Kingdom

Australian Sponsor
Cyclomedica Australia Pty Ltd
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Kingsgrove,
Sydney 2208
Australia

CH Authorized Representative CH REP
CMI-experts
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4052 Basel
Switzerland

4.3 Subsidiaries

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48282 Emsdetten
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5 APPENDIX 1 - USER TRAINING REQUIRED CONTENT

Launch

- Aboutbox and link to IFU's
- User Handbook

User interface

- Datatree (structure and search), Viewport, Properties panel, Annotations panel and Regions panel
- Overlay options (interactive features)
- Colorbar features
- Hidden menu viewport (Grid, SC, MFSC, Full screen, more, cinematic, statistics)
- Load data into viewport (single and fused)
- Workflow stages

Settings

- Color maps
- Keyboard shortcuts
- LLQ
- Mouse
- Name presets
- Patient banner
- Regions
- Report
- Secondary Capture
- Session
- SIRT
- Stage bar
- Theranostics
- Triangulation
- Tutorials
- Units
- Viewport
- Volume rendering
- Windows preset
- Windows layout
- Settings hierarchy

Toolbar

- Basics (triangulate, scroll, zoom, pan, rotate, windowing)
- Co-registration (manual, automatic, local refinement)
- Reset, annotations, zoom ruler, region statistics, patient banner, report
- Crosshair, sphere
- Measurements, annotations
- Quantification tools (ellipsoid, box, cylinder, paintbrush, SCG, threshold, blobsplitter, 2 D Ellipse, organ segmentation)
- Screen capture, multi-frame secondary capture

Regions

- All features
- Save + Export + Import (Dicom seg and RT Structure set)

SC + MFSC

- Saving + Display + Import + Export