INSTRUCTIONS FOR USE

Affinity

Version 4.0.2

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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

Table of contents

1 INTRODUCTION

1.1 General notes

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

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

All users need to be trained, by personnel 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 users of the software are solely responsible for its use and for the resulting diagnoses. Hermes Medical Solutions takes no responsibility for any results and diagnoses derived from using the program described or from information in this manual.

1.2 Regulatory information

Market specific information
- Europe - This product complies with Medical Device Regulation (MDR) 2017/745. A copy of the corresponding Declaration of Conformity is available on request.
- Canada - the Device identifier, as defined with Health Canada is the version number = 4.0.
- US – 510(k) clearance K202882.

European SRN number
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.

1.3 Associated documentation

- P60-142 Release Notes Affinity 4.0.2 Rev.1
- 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.

2 PRODUCT INFORMATION

2.1 About Affinity 4.0.2

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.

For specific DICOM Conformance statements for Affinity, see *Appendix 2 - DICOM Conformance statement for RT Structure Set.*

2.2 Intended purpose

Intended Use
Affinity is a software application for nuclear medicine and radiology. Based on user input, Affinity 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.
The software application can be configured based on user needs.
The investigation of physiological or pathological states using measurement and analysis functionality provided by Affinity 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 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.

Intended medical indication is any for which molecular imaging and radiology is performed. Examples include cancer diagnosis, cancer staging, diagnosis and monitoring of infection, diagnosis 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 4.0 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 = 4.0.2
Marketing name = Hermia Multimodality Viewer
Software build no = 111

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

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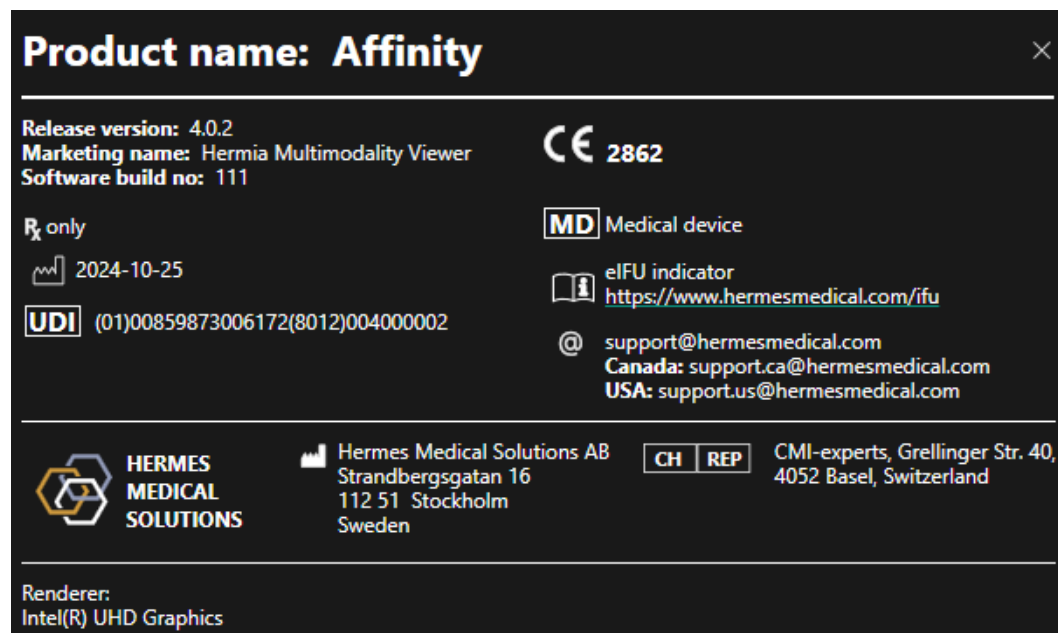
2.6 Product Lifetime

The lifetime of Affinity 4.0 is 5 years.

The lifetime of 5 years starts running when Affinity 4.0 has been manufactured (5 years from Manufacturing date of 4.0.0). Possible patches on Affinity 4.0 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 4.0. 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 6.0.9 (or later patch of 6.0)	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 6.0.9 can be downloaded from: https://dotnet.microsoft.com/en-us/download/dotnet/6.0
passwordTypes.xml	Includes all license options in accordance with the customer's order and managed by the Hermes license application ExplorerPWD.

2.9 Installation

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

2.9.1 Warnings

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

3 SAFETY AND PERFORMANCE INFORMATION

3.1 Launch

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

- By selecting the studies to be viewed from Hermes GOLD 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 Zipped DICOM (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 images 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 current session state in Affinity will automatically be saved. When restarting Affinity with the same dataset, it is possible to work from this state again. The rules for saving the status 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 on the application icon in the taskbar.

3.2 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 study 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.
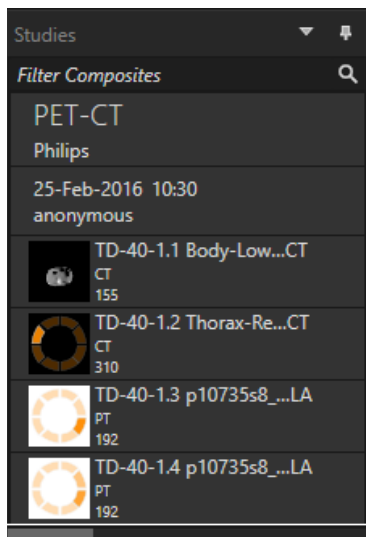
DICOM loading progress bar

While the application is loading, the user can either wait for the application 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.
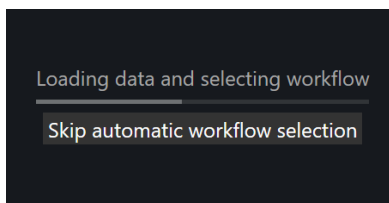

When the Default workflow is selected all layouts are available, and any image series can be worked with as soon as it becomes visible in the Studies window.
It is possible to preselect which workflow the application should startup with by using a -p flag.
For example *-p=Default* will force the application to start with the default workflow.
Workflows are explained in the section on *Workflows and Layouts*.

Single or multiple series of images are loaded into a selected viewport using one of the following methods:
- Automated population of a predefined workflow
- Left-click the series and drag-and-drop into a viewport
- Right-click, drag-and-drop into a viewport
- Left double-click
- Left-click the selected series and press Enter
- Left-click the eye at the top right corner of the series. The eye becomes visible when hovering over it.

Fuse displayed image with: COREG
PET WB TrueX

COREG PET WB TrueX
PT
324
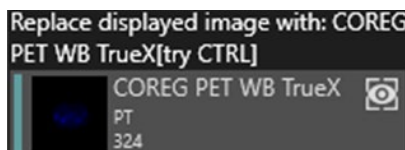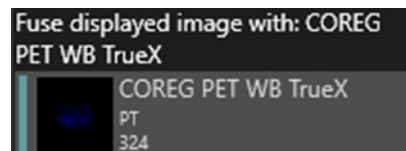
The series which is the active layer is shown by a box around the eye icon next tot the study in the data tree.

COREG CT_WB
CT
324

COREG PET WB TrueX
PT
324
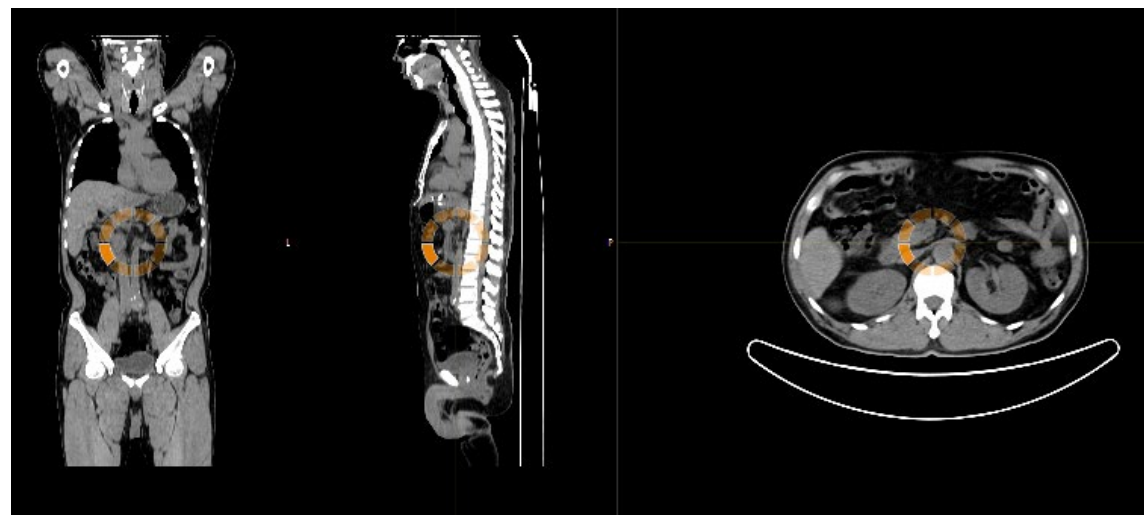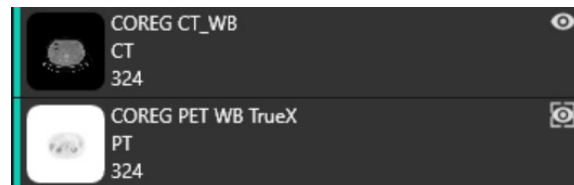
When loading a series into a viewport which is already displaying images, using Right-click, drag-and-drop a pop-up window will appear:

Fuse with displayed image

Replace displayed image

Replace active layer everywhere

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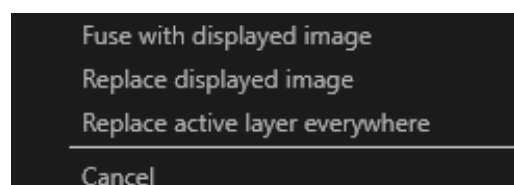
When dragging and dropping, the default action is to replace the existing series, but if **Ctrl** is pressed before dropping the series into the viewport, the series being dropped will be fused with the existing series.

In order to load a study consisting of more than one series, there are several possibilities:

- Left-click and drag and drop a Study date/Study ID item in the Studies window into the viewport
- Double-click + Ctrl over another series
- Left double-click over Study ID
- Right-click and drag-and-drop over another series. This shows the same context menu as when clicking on the eye icon

When a large number of studies and series have been loaded into the application, it may be helpful to click on Search to filter the contents of the Studies window.
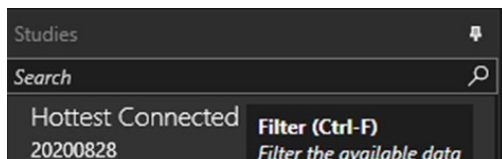
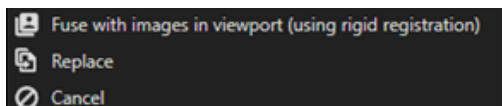When a series is loaded into a viewport which is displaying an existing series, and the Frames of Reference for the two series are not the same, a context menu appears asking if the user wants to Fuse with rigid registration, Replace or Cancel.

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 with each other. Series which have the same frame of reference are assumed to already be co-registered.

A co-registered study can be exported and will share the same frame of reference as the image to which it was co-registered. Prior to saving it is possible to assign the co-registered image a new series description.

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

NOTE: If loading CT Data with more than 2048 slices in one volume/frame, the set is split into two bed positions. First bed position will have 2048 slices go from head-to-feet.

3.2.1 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.

3.3 Interface

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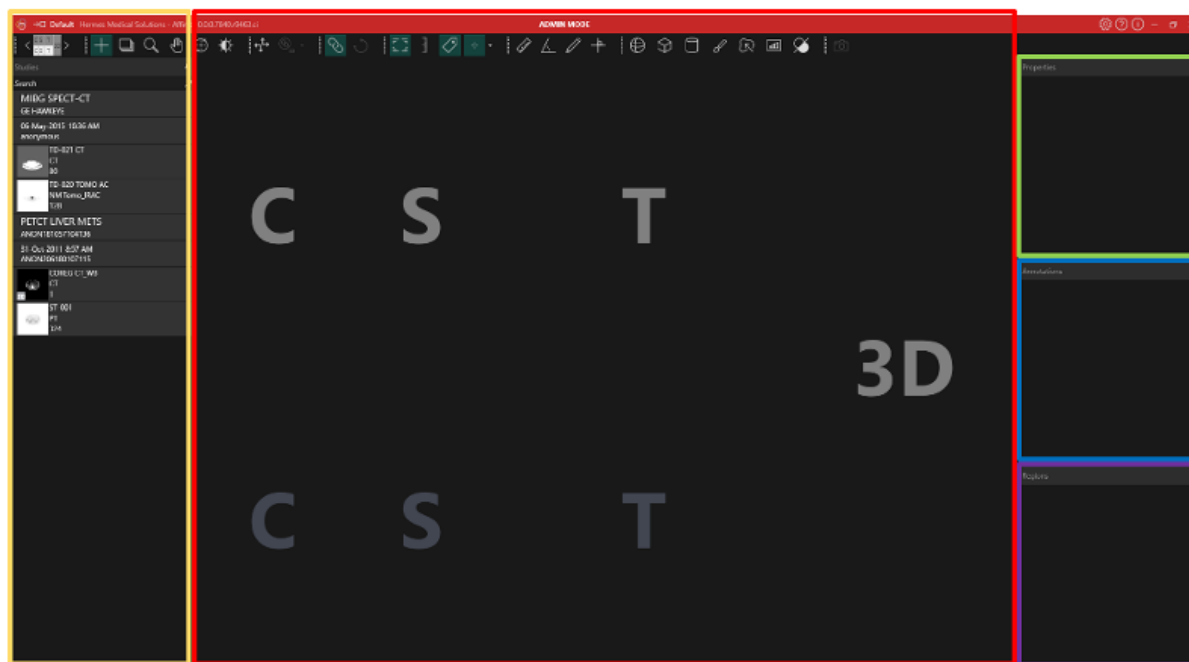

The *red* highlighted area is the *Image window*, within which tomographic slices, 3D rendered images, annotations, volumes of interest etc. are displayed. In the picture above, C (coronal), S (sagittal) and T (transverse) slices and a 3D image are each displayed in their own Viewport. Together, the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

The *yellow* highlighted area is the *Studies window (datatree)* , 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 Patient data tree 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 User Settings.
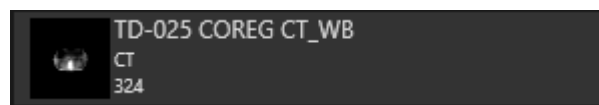
The *blue* highlighted area is the *Annotations window*. The annotations window contains a list of created annotations and measurements.

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

Objects such as Regions, Measurement and Annotations can be added and removed from the active image window by clicking the eye icon next to the object name.
The *green* highlighted area is the *Properties window,* which can display information about regions or the DICOM header information for selected patient studies.
Regions:
When a region icon is clicked, all settings for the currently selected region are displayed. It is also possible in this window to set the geometry of a region before placing it on a study.
Study DICOM header:
When one or more datasets from the Studies window are selected, the properties window displays the DICOM header information for each of the datasets, one column per dataset.
Yellow, green, blue, and purple windows highlighted are all floatable, dockable and hideable. They can be hidden by clicking on the pin needle icon (Auto Hide).

In hidden state the windows will be 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.

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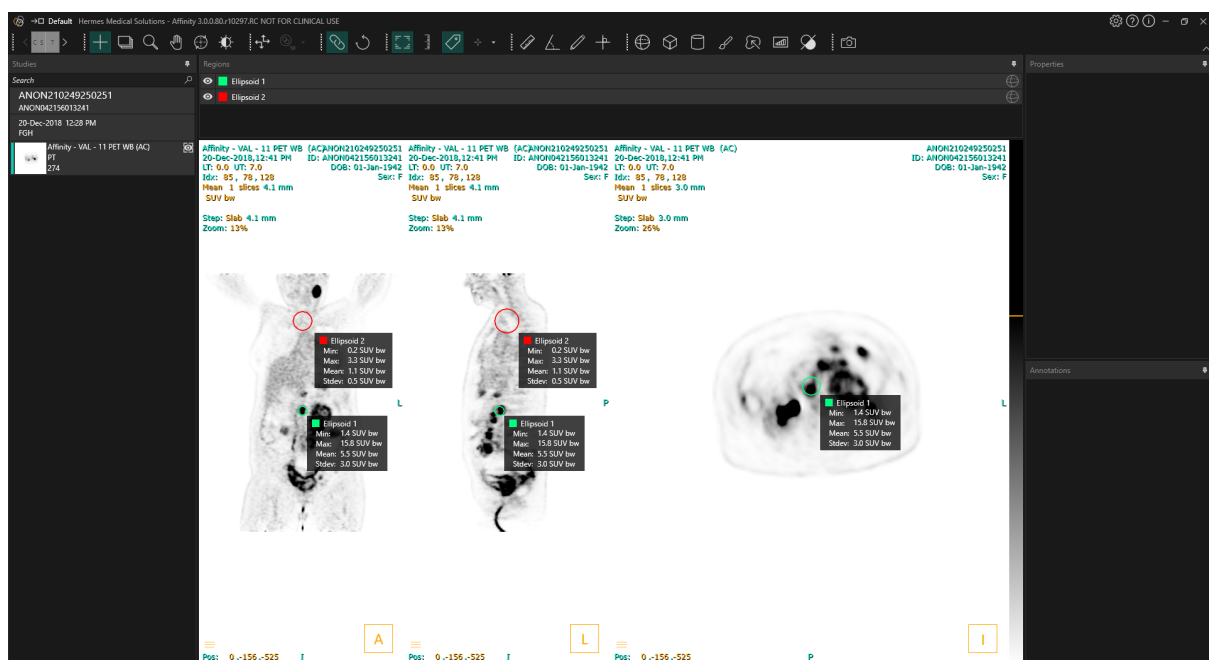
The position of all dockable panels is persistent. Hence closing the application and starting a new session will allow a user to start working in the same environment as they were working in before closing the application. See the Settings section for a description of how to reset windows to their original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

The Unit window is 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.
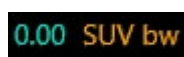
Depending on which modality is being displayed, the Unit window will automatically be displayed and will allow selection of different options such as:

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

To edit fields in this window, tick the '*Allow edit*' option. 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 window.

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.

3.4 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 not in triangulation mode it is possible to grab and drag the haircross to change the triangulation point without changing the mouse mode.

Main toolbar operations		
Operation	**Icon**	**Description**
Layout/Stages		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 selected, and the text overlay 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
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 sharing the same modality. To change this: right-click the color table and untick: "Use window for all Hounsfield (respectively PET SUV) images.
Manual coregistration		Click to manually translate and rotate series relative to each other. Only available for series which do not share the same initial frame of reference.
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. Only available for series which do not share the same initial frame of reference.
		The shortcut for this function is the 'R' key
Viewport linked/unlinked		Click to link/unlink viewports
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 small or large 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 dialog in the *crosshair* tab.
Triangulation Sphere/Circle		Toggle visibility of triangulation sphere/circle ON and OFF. The available spherical/circular triangulation presets (if created): Sphere (50 mm) Circle (50 mm) Spherical/circular triangulation presets can be created in the Settings dialog in the *Crosshair* tab
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 so that they cross each other

Hover near the center of the cross until both lines are highlighted to move the cross by dragging. Hover over only 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.

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 missing slice/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 on icon 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 on icon and the mouse cursor will change to a knife symbol. Click with the knife on a region to be split into its 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. To do so: select the knife symbol, left click on the part of the threshold that you want to delete and **immediately** press the "delete" key!
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 selected viewports (orange border) as a DICOM Multi Frame Secondary Capture. The MFSC 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. |

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.

For Ellipse, Ellipsoids, Boxes and Cylinders, the Lock Aspect Ratio option must be unticked in the Properties window to enable independent scaling.
The following region types support translation in any direction: Ellipse, Ellipsoid, Box, Cylinder and Brush.

3.5 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.
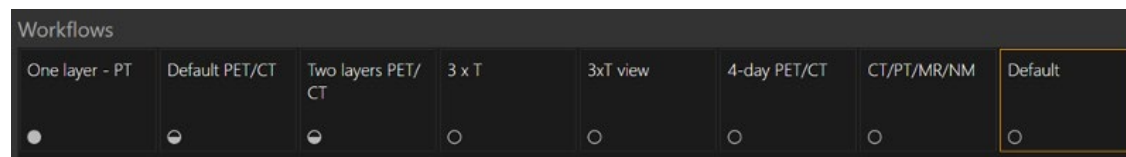
Each workflow has a circular symbol indicating how well the currently loaded studies match the workflow. Three different symbols are used:

- 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.

3.5.1 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.

3.6 Settings

In Admin mode, the factory settings can be overridden, and the settings will be applied to all users being run under the same Admin system. Pressing '*Reset*' in any tab under settings will reset them to the factory settings.
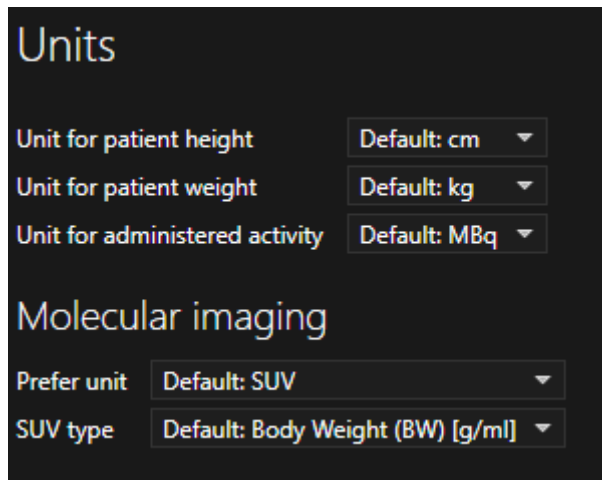
In User mode, Admin settings can be overwritten, and the settings will only be applied for the user who has made the changes. Pressing '*Reset*' in any tab under settings will reset them to the Admin settings.

To access the settings, click on the settings icon up in the right corner, ⚙.

Color maps
Crosshair
Keyboard Shortcuts
Mouse
Name presets
Patient banner
Regions
Report
Secondary capture
Session
SIRT
Units
Viewport
Window presets
Windows layout
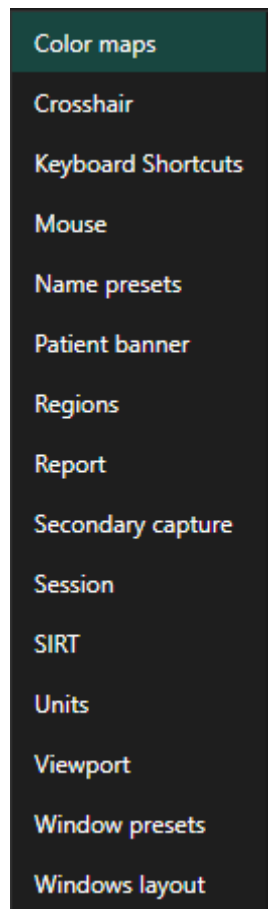
3.6.1 Units

It is possible to choose between SI or Imperial units.

3.7 Security

Affinity process Personal Identifiable Information (PII) and Hermes Medical Solutions actively work with cyber security during manufacturing to ensure highest level of security. To increase security further, the software support customers security measurements, such as, but not limited to, access control and authorization, antivirus, Operating system patching, and disk encryption. For more information, please refer to *PC-009 System Environment Guidelines*.

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

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

3.8 Additional Information

3.8.1 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.

3.8.2 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.

3.9 Warning Messages in the Application

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

⚠️ 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.

⚠️ 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.

⚠️ 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.

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

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

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

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

⚠️ At top of viewport: Patient ID does not match.

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

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
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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 Representatives

Authorized representatives

UK Responsible Person
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46 St. Nicholas Street
Ipswich, IP1 1TT
England, United Kingdom

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

4.3 Subsidiaries

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1155, René-Lévesque O., Suite 2500
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Tel: +1 (877) 666-5675
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48282 Emsdetten
Deutschland
Tel: +46 (0)819 03 25

5 APPENDIX

5.1 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)
- Radial menu
- Load data into viewport (single and fused)
- Workflow stages

Settings
- Colormaps, crosshair
- Keyboard shortcuts, mouse
- Name and window presets
- Patient banner, report
- Regions
- Secondary capture, session
- SIRT, units
- Viewport, windows layout
- Settings hierarchy

Toolbar
- Basics (triangulate, scroll, zoom, Pan, rotate, windowing)
- Co-registration (manual, automatic, local refinement)
- Linking, reset, annotations, regions stat. patient banner, report
- Crosshair, triangulation (sphere, circle)
- Measurements, annotations
- Quantification tools (sphere, box, cylinder, paintbrush, SCG, threshold, blobsplitter, 2 D Ellipse)
- Screen capture, multi-frame secondary capture

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

SC + MFSC
- Saving + Display + Import + Export

5.2 Appendix 2 - DICOM Conformance statement for RT Structure Set

This statement provides an unambiguous specification for how Affinity implement the DICOM standard for loading and saving RT Structure Set (NEMA, 2021, *www.dicomstandard.org*). Included are the module definitions, which define all data elements used by the application for loading and saving RT Structure Set.

Definitions:

RT	Radiotherapy
DICOM	Digital Imaging and Communications in Medicine
IE	Information Entity
CT	Computed Tomography
PET	Positron Emission Tomography
UID	Unique Identifier

5.2.1 RT Structure Set IOD Module Table

The Mandatory modules (M) and User defined modules (U) that are implemented have links in the Section column.

IE	Module	Reference	Usage	Section
Patient	Patient	C.7.1.1	M	5.2
	Clinical Trial Subject	C.7.1.3	U	
Study	General Study	C.7.2.1	M	5.3
	Patient Study	C.7.2.2	U	5.4
	Clinical Trial Study	C.7.2.3	U	
Series	RT Series	C.8.8.1	M	5.5
	Clinical Trial Series	C.7.3.2	U	
Equipment	General Equipment	C.7.5.1	M	5.6
Frame of Reference	Frame of Reference	C.7.4.1	U	5.7
Structure Set	Structure Set	C.8.8.5	M	5.8
	ROI Contour	C.8.8.6	M	5.9
	RT ROI Observations	C.8.8.8	M	5.10
	Approval	C.8.8.16	U	
	General Reference	C.12.4	U	
	SOP Common	C.12.1	M	5.11
	Common Instance Reference	C.12.2	U	

When saving an RTSTRUCT file, certain attributes are copied from the CT or PET series that is currently active and where regions are shown, while other attributes depend on the regions, or they have hardcoded values or user-defined values.
Copy = copy from an associated CT or PET.
Set = set value, hardcoded, user-defined, unique generated UID, empty string, etc.

5.2.1.1 Meta Header

Attribute Name	Tag	Type	Attribute Description
File Preamble		1	Set (128 bytes zero)
DICOM Prefix		1	Set (DICM)
File Meta Information Group Length	(0002,0000)	1	Set
File Meta Information Version	(0002,0001)	1	Set (byte 0, 1)
Media Storage SOP Class UID	(0002,0002)	1	Set
Media Storage SOP Instance UID	(0002,0003)	1	Set
Transfer Syntax UID	(0002,0010)	1	Set Explicit Little Endian
Implementation Class UID	(0002,0012	1	Set 1.2.752.37.60. + version
Implementation Version Name	(0002,0013)	3	Set HMSAFF_version

5.2.1.2 Patient Module Attributes

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010,0010)	2	Copy
Patient ID	(0010,0020)	2	Copy
Patient's Birth Date	(0010,0030)	2	Copy
Patient's Sex	(0010,0040)	2	Copy

5.2.1.3 General Study Module Attributes

Attribute Name	Tag	Type	Attribute Description
Study Instance UID	(0020,000D)	1	Copy
Study Date	(0008,0020)	2	Copy
Study Time	(0008,0030)	2	Copy
Referring Physician's Name	(0008,0090)	2	Copy
Study ID	(0020,0010)	2	Copy
Accession Number	(0008,0050)	2	Copy
Study Description	(0008,1030)	3	Copy

5.2.1.4 Patient Study Module Attributes

Attribute Name	Tag	Type	Attribute Description
Patient's Size	(0010,1020)	3	Copy
Patient's Weight	(0010,1030)	3	Copy

5.2.1.5 RT Series Module Attributes

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	Set RTSTRUCT
Series Instance UID	(0020,000E)	1	Set
Series Number	(0020,0011)	2	Set empty
Series Date	(0008,0021)	3	Copy
Series Time	(0008,0031)	3	Copy
Series Description	(0008,103E)	3	Set (by user)

5.2.1.6 General Equipment Module Attributes

Attribute Name	Tag	Type	Attribute Description
Manufacturer	(0008,0070)	2	Set "Hermes Medical Solutions"
Manufacturer's Model Name	(0008,1090)	3	Set "Affinity"
Device Serial Number	(0018,1000)	3	Set
Software Versions	(0018,1020)	3	Set

5.2.1.7 Frame of Reference Module Attributes

Attribute Name	Tag	Type	Attribute Description
Frame of Reference UID	(0020,0052)	1	Set
Position Reference Indicator	(0020,1040)	2	Set empty

5.2.1.8 Structure Set Module Attributes

Attribute Name	Tag	Type	Attribute Description
Structure Set Label	(3006,0002)	1	Set "Affinity RTSS"
Structure Set Date	(3006,0008)	2	Set
Structure Set Time	(3006,0009)	2	Set
Referenced Frame of Reference Sequence	(3006,0010)	3	Set (refers to PET or CT)
>Frame of Reference UID	(0020,0052)	1	Set
>RT Referenced Study Sequence	(3006,0012)	3	Set
>>Referenced SOP Class UID	(0008,1150)	1	Set
>>Referenced SOP Instance UID	(0008,1155)	1	Set (Study Instance UID)
>>RT Referenced Series Sequence	(3006,0014)	1	Set
>>>Series Instance UID	(0020,000E)	1	Set
>>>Contour Image Sequence	(3006,0016)	1	Set
>>>>Referenced SOP Class UID	(0008,1150)	1	Set
>>>>Referenced SOP Instance UID	(0008,1155)	1	Set
Structure Set ROI Sequence	(3006,0020)	1	Set
>ROI Number	(3006,0022)	1	Set
>Referenced Frame of Reference UID	(3006,0024)	1	Set
>ROI Name	(3006,0026)	2	Set (region name)
>ROI Generation Algorithm	(3006,0036)	2	Set SEMIAUTOMATIC

5.2.1.9 ROI Contour Module Attributes

Attribute Name	Tag	Type	Attribute Description
ROI Contour Sequence	(3006,0039)	1	Set
>Referenced ROI Number	(3006,0084)	1	Set
>ROI Display Color	(3006,002A)	3	Set
>Contour Sequence	(3006,0040)	3	Set
>>Contour Number	(3006,0048)	3	Set
>>Contour Image Sequence	(3006,0016)	3	Set

Attribute Name	Tag	Type	Attribute Description
>>>Referenced SOP Class UID	(0008,1150)	1	Set
>>>Referenced SOP Instance UID	(0008,1155)	1	Set
>>Contour Geometric Type	(3006,0042)	1	Set CLOSED_PLANAR
>>Contour Offset Vector	(3006,0045)	3	Set (0,0,0)
>>Number of Contour Points	(3006,0046)	1	Set
>>Contour Data	(3006,0050)	1	Set

5.2.1.10 RT ROI Observation Module Attributes

Attribute Name	Tag	Type	Attribute Description
RT ROI Observations Sequence	(3006,0080)	1	Set
>Observation Number	(3006,0082)	1	Set
>Referenced ROI Number	(3006,0084)	1	Set
>RT ROI Interpreted Type	(3006,00A4)	2	Set empty
>ROI Interpreter	(3006,00A6)	2	Set empty

5.2.1.11 SOP Common Module Attributes

Attribute Name	Tag	Type	Attribute Description
SOP Class UID	(0008,0016)	1	1.2.840.10008.5.1.4.1.1.481.3
SOP Instance UID	(0008,0018)	1	Set
Specific Character Set	(0008,0005)	1C	Set