# RELEASE NOTES

# Affinity 5.0.1

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www.hermesmedical.com

## Table of content

# 1 INTRODUCTION

These Release Notes inform users of news and improvements in Affinity 5.0.1, as well as any known issues to be aware of. Every user must be familiar with these known issues. Contact the manufacturer for any questions about the content.

This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

## 1.1 Associated documentation

- P60-086 Instructions For Use Affinity 5.0.1 Rev.3
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

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

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

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

## 1.2 Complaints and serious incidents

Report incidents and errors to our support, see *Contact Information*.

Any serious incident that has occurred in relation to the device must be reported to the manufacturer.

Depending on applicable regulations, incidents may also need to be reported to national authorities. For the European Union, serious incidents must be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

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

# 2 NEWS AND IMPROVEMENTS

## 2.1 New Features, Clinical Workflows and Functions implemented in Affinity 5.0

**New Clinical Workflows:**

- The Lung Lobe Quantification workflow introduces an efficient and automated workflow solution to accurately compute 3D lobar anatomy from a CT (with or without contrast), with the aim of improving the assessment and planning of surgery for lung disorder patients. It can be an essential tool for lung transplant assessment, as it computes anatomically accurate lung volumes using a single click. The Lung Lobe Quantification workflow requires a dedicated license.
- 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. The SIRT workflow requires a dedicated license.
- The Theranostics Tool is designed to predict the maximum tolerated activity that can be injected into a patient. It achieves this by determining at what scale of an administered dose a patient will reach a dose limit, when multiple potential dose-limiting organs are involved. The Theranostics tool runs as an Affinity workflow. The Theranostic Tool requires a dedicated license.

**New Features:**

- Automatic organ segmentation is implemented for liver, kidneys, lungs and spleen regions. The segmentations must be carefully checked and edited if needed. Automatic organ segmentation is based on a CT, so a reference CT must be loaded in the viewport.
- Planar imaging support - load and view planar Dynamic NM, Gated NM, Static NM and Whole body NM.

**New Functions:**

- In Admin settings it is possible to add tutorials (e.g. hospital processing SOP, training videos, etc.). Tutorials will launch into the default Windows viewer for the specific file type.
- The Radial Menu is replaced by a Context Menu. From this Context menu it is possible to access all items that were included in the Radial menu in earlier versions plus some additional items:
    - Units
    - Color bar options for the active layer
    - Orientation options
    - LLQ workflow steps (only available when LLQ workflow is selected)
- The triangulation cross and crosshairs can be personalized. Triangulation cross: opacity. Crosshairs: size of aperture relative to viewport, central dot visualization, and colour.
- A record button is added to the toolbar to make it possible to create MFSCs of all viewports in the current layout. Using the slider bar handles allows you to set a limited slice range for movies.
- The active viewport is indicated with a blue box surrounding it.
- In the viewport annotations it is possible to add the following series information:
    - Uptake time
    - Administered activity
    - The series number from the DICOM header
- The statistics viewport can be selected at the bottom left corner of any image viewport

- All statistics can be personalized from the statistics viewport context menu. For each region it is possible to:
    - Change colour
    - Rename
    - Triangulate to SUVmax and SUVpeak values (PT) or to Max value (other modalities)
- SUVmax and SUVpeak markers can be set to Show or Hide in the Settings menu. SUVmax marker will be shown as a cross, SUVpeak will be shown with a circle which is the same size as the SUVpeak kernel. A user can triangulate to both SUVmax and SUVpeak markers from the region statistics box.
- Metabolic Peak presets can have a volume between 0.1ml and 100ml.
- The unit scaler as a pop-up window has been removed but all options are now available in the Properties window. For example, when clicking the orange annotation of the PET series "SUVBW" in a viewport, the unit information will be displayed in the Properties window.
- Arrow keys can be used for scrolling and are configurable in the Settings menu. Default arrow scroll settings are:
    - Up arrow key: +3 slices
    - Down arrow key: -3 slices
    - Right arrow key: +1 slice
    - Left arrow key: -1 slice
- +/- keyboard keys provide zoom up/down when hovering over a viewport.
- It is also possible to hover over measurements and VOIs in a viewport and delete them.
- In the Stage bar panel of the Settings menu, it is possible to personalize the look and feel of the stage bar.
    - Hidden or shown at top, right, bottom or middle.
    - Displayed as a title, icon or both.
    - Displayed horizontally or vertically.
    - Stage selector toolbar button set to shown or hidden.
- In the spherical triangulation settings, you can choose to disconnect the sphere or circle from the triangulation point to follow the cursor. A keyboard shortcut can be assigned to this function.
- 2D data: NM static, NM WB, NM dynamic and NM gated, can be loaded into the viewport by double clicking the dataset from the datatree.
- “Dmax” center to center distance measurement, allows users to measure the maximum distance between two or more lesions in a selected region. The distance is calculated from center to center, where the center of each lesion is defined as the center of mass (not based on intensity).

## 2.2 Problems fixed and minor enhancements in version 5.0.1

**Changes to and enhancements of existing functions:**

- Support for OpenApps licencing
- Possibility to scroll through 3D viewports using a slice slider.
- Possibility to limit the range of displayed slices in a 3D viewport using handles on slice slider to limit the number of slices included in a multi-frame secondary capture.
- Possibility to limit the range of displayed slices in a 2D viewport using handles on slice slider to limit the number of slices included in a multi-frame secondary capture.
- Possibility to limit the range of displayed slices in an MPR viewport using handles on slice slider to limit the number of slices included in a multi-frame secondary capture.
- Read and modify angle measurement properties from the property panel.
- Read and modify annotation properties from the property panel.
- Read and modify distance measurement properties from the property panel.

- Read and modify orthogonal axis measurement properties from the property panel.
- Set inverse transverse slice numbering.
- Review the display options for all layouts and batch edit.
- Drag regions from region list to a viewport.
- View statistics for all the visible regions in a viewport showing images in fullscreen mode.
- Delete a region, measurement or annotation by pressing the delete key when hover over it.
- Load RT-Dose files with Gy/s units.
- RT Structure set - support for MR images.
- The method to copy and duplicate regions from one study to another has been updated to make it easier and faster. It also mimics the behaviour in Hybrid Viewer:
  - Left click + drag/drop a region from the regions list from one study to another will copy the region and create a duplicate.
  - Left click + ctrl + drag/drop will copy the region without creating a duplicate.
  - Right click + drag/drop will active a dropdown menu from which you can chose to make the region visible or cancel your action.
- To efficiently work with the mouse, updates have been made to mouse buttons and mouse wheel settings.
  - New mouse button options:
    - Spherical triangulation sphere size
    - Sphere selection for spherical triangulation
  - New mouse wheel options:
    - + and – zoom on hovered viewport
- Many changes have made to the layout builder, data rules settings and workflow:
  - Layout builder:
    - It is possible to use the new “Advanced edit” option. Here you can edit display options (annotations) on a summary page of all layouts, e.g. select all T viewports and update annotations for all of them at once or you can make a random selection of multiple viewports to update simultaneously.
    - Each viewport starts with default annotations for the selected viewport type.
    - Four new viewport types have been added: SIRT Planning (SP), SIRT Verification (SV), Lung Lobar Quantification (LLQ), Theranostics viewport (TN)
  - Workflow builder:
    - Default workflows have been added based on Hybrid Viewer (e.g. 1Fusion, 2Fusion, 1Fusion PET/CT +NAC, PET only etc. These workflows can be adjusted as needed to fit local requirements (special workflow config file).
    - It is possible to set “Match series number, counting from earliest to latest", then “Match by rule”, and to set “Match series number, counting from latest to earliest, then “Match by rule”.
    - There is an option to match based on “Series time”, making it easier to differentiate between series which have the same name and are part of the same study
    - Automatic co-registration can be set on or off
  - Data rules settings:
    - A rule can be duplicated
    - NM Planar frame label (HmsPlanarFrameLabel) and energy window (HmsPlanarEnergyWindowName) are accessible to the rule editor for string matching.

**Problems fixed:**

- Viewport for creation of SEG-file is now active while exporting SEG.
- Red overlay is displayed with Single Click Segmentation.

- When a layout is composed of non fused MIPs and Fused TCS views (2 PET and 1 CT) and more than one triangulation are done on the same MIPs, the triangulation is now automatically updated on the fused TCS views.
- MR Dataset from GE SIGNA PET/MR is now loaded correctly.
- MR with 6x76 slices are no longer shown as one volume.

# 3 KNOWN ISSUES

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

For information:
Drag and drop into Affinity from Gold does not work when running with RDP or Citrix.
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.
RTSS saving for large datasets can cause the application to freeze.

Other known issues:

- MFSCs cannot be annotated.
- Lag when scrolling and triangulating when using remote access (RDP or Citrix).
- Unable to load RTDOSE file from Varina Eclipse.
- Triangulation point is used as center of rotation in 3D. Workaround: Press ESC to Reset. Scroll 3D viewport. The body rotates around its center as expected.
- Time activity curve generation does not work for Dynamic SPECT from MIM.
- Triangulation in 3D viewport not updated when selected the first time.
- OpenApps hides the title bar and our additional buttons.
- The ellipse drawn by the user might disappear under certain circumstances.
- The VOI is not selected when clicked in the plot (stat viewport).
- In global mode: Panning C and S views in sync fails when another stage shows a 3D viewport.
- Copy from statistics viewport doesn't work the very first time. Workaround: If the Copy button and Ctrl-C shortcut has no effect in the statistics viewport, then reload the dataset in the viewports of the current stage, or select another stage, or reselect the desired workflow.

# 4 CONTACT INFORMATION

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

## 4.1 Manufacturer contact information

**Head office**
**Hermes Medical Solutions AB**
Strandbergsgatan 16
112 51 Stockholm
SWEDEN
Tel: +46 (0) 819 03 25
www.hermesmedical.com

**General e-mail address:**
info@hermesmedical.com

**Support e-mail addresses:**
support@hermesmedical.com
support.ca@hermesmedical.com
support.us@hermesmedical.com

## 4.2 Regulatory Representatives

**UK Responsible Person**
Hermes Medical Solutions Ltd
Cardinal House
46 St. Nicholas Street
Ipswich, IP1 1TT
England, United Kingdom

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

CH REP

**CH Authorized Representative**
CMI-experts
Grellinger Str. 40
4052 Basel
Switzerland

## 4.3 Subsidiaries

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

**Hermes Medical Solutions Canada, Inc**
1155, René-Lévesque O., Suite 2500
Montréal (QC) H3B 2K4
Canada
Tel: +1 (877) 666-5675
Fax: +1 (514) 288-1430

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

**Hermes Medical Solutions Germany GmbH**
Robertstraße 4
48282 Emsdetten
Deutschland
Tel: +46 (0)819 03 25