HERMIA

RELEASE NOTES

Affinity

Version 4.0.2

HERMES MEDICAL SOLUTIONS

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These Release Notes inform users of news and improvements in Release Notes Affinity 4.0.2, as well as any known issues to be aware of.

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.

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1 INTRODUCTION

This document contains the public Release Notes for Affinity 4.0.2. It provides a list of novel features, enhancements and bug fixes since last major release.

The document also includes known issues. Every user must be familiar with these known issues. Contact the manufacturer for any questions about the content.

1.1 Associated documentation

- P60-140 Instructions For Use Affinity 4.0.2 Rev.1
- PPC-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.

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

1.2 Complaints and serious incidents

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

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

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

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

2 NEWS AND IMPROVEMENTS

2.1 New Features implemented in Affinity 4.0

- A warning message will appear when data with different patient ID is loaded.
- The title bar contains the version of the application. When running the application as a non medical device, the title bar will clearly display that the used version is *not for clinical use.*
- It is possible to easily and comfortably reach and update your personal shortcuts. The shortcut list can be copied and pasted into your favourite editor or printed on a sheet of paper to have it next to you when working.

- Many new shortcut options have been added to simplify and speed up your work. You can now assign and/or personalize shortcut keys to:
    - take a full screen capture
    - perform a local registration
    - copy a secondary capture to the clipboard
    - toggle annotations on/off
    - toggle crosshair visibility on/off
    - toggle sphere/circle triangulation on/off
    - toggle fusion high (between 50% and 100%)
    - toggle fusion low (between 0% and 50%)
    - toggle VOI statistics on/off
    - toggle zoom/ruler visibility on/off
    - toggle cinematic slices on/off
    - toggle cinematic frames on/off
    - toggle patient banner on/off
    - go to the search box
    - create a new ruler
    - create a new text annotation
    - create new VOIs e.g. new ellipsoid, new box, new cylinder new paint brush and new threshold VOI
    - create a spherical VOI (when using the spherical triangulation)
    - activate blob splitter
    - activate new cross mode
    - change crosshair
    - switch to triangulate mouse mode
    - switch to manual coregistration mouse mode
    - activate scroll, zoom, pan and rotate mouse mode
    - activate window level mouse mode

- To easily restore a working configuration it is possible to have a copy of your latest working configuration.
- When you have several instances of the application running, you can now easily select the instance of choice. Hovering over the tab in the taskbar will show patient name and study date.
- It is possible to save and load regions that are stored as DICOM segmentation so that they can be loaded at a later occasion and be exported to PACS.
- To easily load data into Affinity you can now drag and drop zipped DICOM (with the exception of 7-zip) into a running session.
- It is now possible to create secondary captures AND MultiFrameSecondaryCaptures (MFSC) of the entire screen and/or a selected viewport.

- As a user you can limit the range for a MFSC so that only data from the relevant range is stored. The splash window is replaced by a slider to simplify selection.
- Prints (e.g. secondary captures (SC)) can be saved to the desired study. It is possible to drag and drop a non-saved SC from one study to another allowing you to associate a SC with another study.
- It is possible to load a previously stored session that includes regions, measurements and annotations.
- A patient banner has been introduced, the patient banner can be toggled on and of using a shortcut key and can be excluded from print (MFSC, SC).

- To efficiently work with the mouse, updates are made to configure mouse buttons and mouse wheel.
- New mouse wheel options are introduced:
    o mouse mode for changing triangulation sphere/circle size
    o mouse mode for changing triangulation sphere/circle presets
    o mouse mode for changing triangulation cross presets
    o fast scroll mode

- Double click to full screen can be enabled in the settings for any T C S 2D 3D or 3P viewport.
- You can now turn on cinematic for multi-frame datasets so that you can view the frames as a time-laps movie cycling through all frames. It is possible to set a default speed for this.
- As a user you can now interact with the statistics viewport table using a context menu. This makes it possible to access all functionality such as rename, color, triangulate to, etc.
- It is possible to export and copy regions statistics to further analyze it outside the application. For Dynamic PET Data: Frame reference time, Frame duration and Frame index, will be part of the output when visible.
- You can now plot time activity for dynamic images so you can see the biological uptake of the tracer over time in your region of interest.
- A customizable triangulation sphere and circle are introduced to easily scout images for relevant local statistics. It is possible to create a sphere/circle region based on this spherical/circle triangulation.
- Sphere/circular triangulation visibility can be turned on/off using "V" as a global shortcut (like in other Hermes products).
- It is possible to configure what statistics to show in the stat box so that only relevant information is shown.
- A MPR viewport slider is introduced to scroll through MPR images.
- A 2D viewport slider is introduced to scroll through 2D images.
- It is possible to make a selected region into a reference region.
- The windowing slider is updated. Windowing can be changed by dragging handles. A tooltip shows the actual windowing, set by the windowing slider.
- The color bar can be set up as floating and be displayed on top of a viewport (horizontal and vertical).
- Factory presets for: PET SUV(R), NM SUV(R), Counts, Bq/ml, Gy and other are configurable from the settings menu. Presets are accessible from the numeric keys 1-5.
- Regions interactions such as resize, reshape, change region color etc. are now well described in the user handbook.
- When using a preset to create a ROI/VOI, presets settings are visible in the preset combo box so you no longer have to select it to find out what the settings are.
- 2D Ellipse ROI is introduced. You can type the width and height of the ellipse using numerical input.
- It is possible to easily create and select presets for ellipse ROIs.

- Updates are made to the "show statistics" options. It is now possible to choose between:
    o show statistics for active layer
    o show statistics for maximum two visible layers
    o show statistics for all NM/PT layers
- You can now pin/unpin a region stat box directly in the stat box itself.

- When you draw a region using the region tool, the region is visible in the image where it was originally drawn. The region is then always visible no matter which viewport or layout the dataset is loaded into.
- If 2 datasets are fused, the ROI is also transferred to the fused dataset and is also visible for this dataset from the time when the fusion is cancelled.
- It is possible to display the *total number of counts* in an image as a viewport annotation for the NM modality. For dynamic images it will be the total counts for the currently displayed frame.

- A lot of changes are made to the layout builder, data rules settings and workflow.
  In the layout builder it is now possible to:
    o view the relative size of each viewport in the layout so that you can create layouts with more precise sizing than only visual assessment allow for
    o add/remove rows/columns to easily extend/reduce the layout
    o duplicate one screen to another screen in multi-screen layout
    o export and import layouts so they can be shared with colleagues
    o combine already created screens so that editing layouts become more efficient
- In the data rules settings it is now possible to:
    o create data rules to be used for populating viewports with data so that viewports can be automatically populated according to the defined rules
    o match a text string in a data element representing text so that you can specify data to use in your workflows
    o match text in a nested data element so that you can access DICOM header information in sequence tags
    o you can create nested rules so that you can create more complex rules for specific matching of data
    o (you can copy rules between admin setting files so that you can access rules made by a colleague)
    o export and import rules so they can be shared with colleagues
- In the workflow builder it is now possible to:
    o configure what to show in a specific layer in a selected viewport group
    o match a dataset based on study number followed by rule so that you can create workflows for multi time point studies
    o match studies based on rules so that you can define a dataset independent of which study the dataset belongs
    o setup a layer in a workflow stage to allow multiple matches so that you can load multi bed studies automatically
    o duplicate a stage in workflow builder
    o create workflows where each screen manage its own work flow stage independent from other screens so that you can toggle layouts independent for each screen
    o export and import workflows so they can be shared with colleagues

- You can now co-register images sharing the same native frame of reference so that you can adjust for patient movements between series.
- It is possible to pre-define the colors of a metabolic peak region using a preset with predefined color.

- Last but not least a brand new report tool is implemented. In the report tool it is possible to:
    - customize the report header to your needs
    - write comments
    - include secondary captures
- The report can be saved as DICOM encapsulated PDF so that it can be stored in a DICOM compatible storage.
- The PDF document can be opened directly from the data list in Affinity so that you have a complete overview of all patient information.

2.2 Problems fixed and minor enhancements in version 4.0.0

- 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
- Layout switching performance improved
- Dynamic SPECT from Spectrum Dynamics now generates a time activity curve
- When a label is reloaded from a saved session in previous version of Affinity, the arrow always came out of the top left corner rather than the nearest edge point, this has now been fixed

2.3 Problems fixed and minor enhancements in version 4.0.1

- Affinity crashes when reconnecting with RDP/Citrix
- For some layouts, the triangulation on fused images does not follow triangulation on MIP
- Pan/Zoom/Scroll/Region Stats shortcuts don't work with 2-screen layouts
- CT shown as 2D stack but expects a volume

2.4 Problems fixed and minor enhancements in version 4.0.2

- There is no handle to manage the upper threshold in the color bar
- MIPs do not rotate when two different fusion views are displayed in the same layout

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.

Other known issues:
- The Threshold cursor toggles between "pointy hand" and "pencil".
- It is not possible to set the Mean for the Thick Slab to 0mm if a study is dragged into the viewport rather than being autodetected by the Workflow.
- 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.

4 CONTACT INFORMATION

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

4.1 Manufacturer contact information

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