ComPACS

Review Station

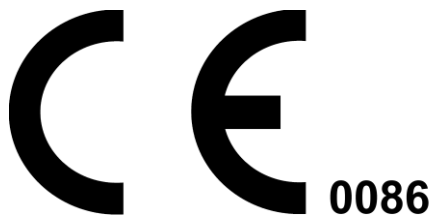## User's Guide

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MediMatic

CE 0086

Device: ComPACS

Manufacturer: MediMatic Srl
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USER'S GUIDE[1]

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SUMMARY

1. GENERAL INFORMATION

1.1. HOW TO USE THIS GUIDE

Use this guide for both training and reference, regardless whether you are a new user, or a user who is already familiar with the system.

Symbols, called icons, show up throughout the guide to assist you in quickly finding cautions, suggestions, urgent information, reminders, and custom settings. You will find an explanation of these icons in this chapter.

1.2. TEXT ICON

	Text written next to this caution sign indicates the most important information, safety precautions, or warnings.
	The stop sign indicates information that you should stop and read before continuing.
	This icon is a reminder to do something. It may be information you read about in a previous chapter. This icon may also indicate a suggestion or an idea, which may make it easier for you to use the software.

1.3. USING THE MOUSE

In this chapter are described the main functions of your mouse to quickly accomplish common functions and speed up your work. It teaches you mouse behavior, which is common to all Windows™ OS.

If you are used to working with Windows you can jump to the next section.

- **Left Mouse Button**

  This button is primarily used to select/deselect items on the desktop (for example an icon), to move items on the desktop and to open items or start applications.

  To select an item on the desktop

  1. Place the cursor over the item to be selected.

  2. Click once and quickly release the left mouse button (called left-click). The item is now selected.

  To deselect an item on the desktop

  1. Position the cursor away from the selected item.

  2. Click the left mouse button to deselect the item.

  To move an item on the desktop

  1. Point to the item.

  2. Click and hold down the left mouse button and drag the item to another location. Release the left mouse button at this point and this will release the item in the new location.

  To open an item on the desktop

  1.) Double-click on the item with the left mouse button.

  2.) If the item is connected to an application, e.g. ComPACS Report Manager, this application will be started. Other items like word processing files or spreadsheets will be opened with the tool they were created with.

- **Right Mouse Button**

    This button is primarily used to activate a context specific task menu associated with each item on the desktop.

    To complete common tasks on an item on the desktop

    1. Right-click on any item on the screen.

    2. A task menu appears, listing common tasks that you may want to carry out on this item. Click a task from this new menu to activate it. In this case, it is irrelevant which mouse button you click with.

- **Middle Mouse Button**

    This button (if available) provides application specific functionality. Refer to the manuals of the applications you use for detailed information.

2. INTRODUCTION

The present user's guide refers to the ComPACS Review Station software and integrated modules and components.

2.1. INDICATIONS FOR USE

The device is a software product intended to be used by qualified medical professionals, after proper installation on an appropriate hardware and middleware platform, for retrieving, archiving, transmitting, viewing, analyzing and, reporting medical image and loops.

The software is designed to be installed by qualified IT professionals on an adequate and compatible hardware platform.

 CAUTIONS AND WARNINGS

ComPACS can be used for diagnostic purposes only according to the European 93/42/EEC, 2007/47/EC Medical Device Directive, USA FDA 510k and Canadian SOR91/24 regulations. Diagnostic use under other regulations is expressly forbidden. **Restrictions under some regulations may also apply to specific product components.**

ComPACS and integrated modules and components may be subject to additional limitations. Please review the related certificates to determine which modules can be used for diagnostic purposes according to the above regulations.

ComPACS and integrated modules and components are under the license, terms and warranty in this document. Please review the license and warranty conditions carefully before using the device. Notice that the use of this device indicates your acceptance of this license agreement and warranty.

ComPACS and integrated modules and components system requirements are indicated in the following section. If the requirements are not met, the device may not function correctly.

The present document must be read carefully before using ComPACS and integrated modules and components. In particular it is important to note the following warnings and advices.

This software should not be used without prior training and a thorough understanding of the operating instructions.

No other software must be installed in the review station other than compliant software for the released components. Please contact ComPACS support if you want to install additional software. The manufacturer or its representative are not responsible for problems attributable to unauthorized changes, additions or deletions to the software or hardware device, or unauthorized installation of third party software.

The information contained in this guide is intended only for the operation of the device. It does not include information such as how to perform medical imaging procedures on the medical devices used to obtain the DICOM images, on any medical procedures or on other medical devices.

Do not remove or change disks from the disk drive during disk read and write operations. This may cause incomplete storage of data files, resulting in data loss.

If system power is lost during a patient study the content of the stored patient file may be incomplete.

Before saving or reviewing a patient study file, always double-check the patient name to be sure that it corresponds to the correct one.

When a patient study is deleted, the files are permanently lost. Be sure to copy the patient study to another storage media for archival before deleting it.

System administrators are responsible to ensure that the patient data is backed up daily to prevent the risk of permanent data loss. Furthermore a daily backup of the SQL Server database also needs to be scheduled.

When lossy compression is selected some information will be lost. The higher the compression ratio, then greater will be the data loss.

Workstation or viewer deployment and/or usage based on virtual desktop or remote desktop technologies is not supported. The usage of such technologies may alter image quality displayed and lead to incorrect diagnosis.

Only use accessories and replacements which are recommended by MediMatic.

2.2. SYSTEM REQUIREMENTS

ComPACS Workstation and ComPACS Web Workstation

- Intel/AMD Quad Core processor or higher
- 4GB RAM or higher (6 GB recommended)
- 80GB SATA disk or above
- 48X CD or CD/DVD combo writer
- Gigabit NIC
- (minimum) Graphics Card with 256MB and Dual DVI Dual 19" flat panel LCD color monitors Resolution: 1280*1024 @ 60Hz, Brightness: 250cd/m2, Dot Pitch: 0.27mm Response Time: 8 ms
- (recommended) Graphics Card with at least 1 GB dedicated memory, Dual DVI, Dual 23" flat panel LED color monitors Resolution: 1920*1080 @ 60Hz, Brightness: 300cd/ m2 , Dot Pitch: 0.27mm, Response Time: 8 ms, Contrast: 1.000:1 (typical), 2.000.000:1 (dynamic/max)
- Windows 7 Business/Ultimate, XP Professional, Internet Explorer 5.5 and above
- Keyboard, Mouse

Note. Windows Vista Business is also supported.

Note. Deployment based on Citrix® Virtual Desktops is not formally supported though it has been known to work. See further warnings below.

ComPACS Web Viewer

- Intel/AMD Dual Core equivalent processor or above
- 2 GB RAM or higher (6 GB recommended)
- 5GB disk or above
- 100Mbps or higher NIC
- (minimum) Graphics Card with 256MB and Single DVI Dual 19" flat panel LCD color monitors Resolution: 1024*768 @ 60Hz, Brightness: 250cd/m2, Response Time: 8 ms
- (recommended) Graphics Card with at least 1 GB dedicated memory, Single DVI, Dual 23" flat panel LED color monitors Resolution: 1920*1080 @ 60Hz, Brightness: 300cd/ m2 , Dot Pitch: 0.27mm, Response Time: 8 ms, Contrast: 1.000:1 (typical), 2.000.000:1 (dynamic/max)
- Windows 7, XP Professional, Internet Explorer 5.5 and above
- Keyboard, Mouse

Note. Windows Vista Business is also supported.

Note. Deployment based on Citrix® Virtual Desktops is not formally supported though it has been known to work. See further warnings below.

Third Party Components

When ComPACS is integrated with third party components (for example Philips QLAB) some additional requirements may apply. Please refer to the third party component documentation for additional requirements specifications.

> ⚠️ Application usage on system configurations different to those explicitly indicated is prohibited. Users shall be responsible for any and all consequences, including incorrect application behavior, performance, data loss, data corruption, and/or incorrect computations.
>
> ⚠️ No other software must be installed in the review station other than compliant software for the released components. Please contact ComPACS support if you want to install additional software. MediMatic or its representative are not responsible for problems attributable to unauthorized changes, additions or deletions to MediMatic software or hardware, or unauthorized installation of third party software.
>
> ⚠️ Workstation or viewer deployment and/or usage based on virtual desktop or remote desktop technologies is not supported. The usage of such technologies may alter image quality displayed and lead to incorrect diagnosis.

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ComPACS Review Station and integrated modules and components

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VP8 CODEC

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3. LAUNCHING THE APPLICATION

3.1. ACTIVATION AND LOGIN

To start the ComPACS Review Station simply double-click on the icon that is on your desktop.

The presence of the icon on the desktop depends on the options selected during installation. Usually the link refers to an executable that is also present on the installation path: generally *C:\Program Files\Medimatic\ComPACS\Workstation*.

The present operator's guide for ComPACS plugged-in modules documents their use integrated into the ComPACS Review Station. In case such components are integrated into a third party product please refer to such product operator's guide for specific and additional instructions.

ComPACS Report Manager operates together with the Reporting and Off-line analysis modules. If none of these modules are activated you will be prompted to activate at least one of them before proceeding.

At launch, the software needs some time to configure and to load the application and the installed modules correctly. A splash window will be displayed during this operation.
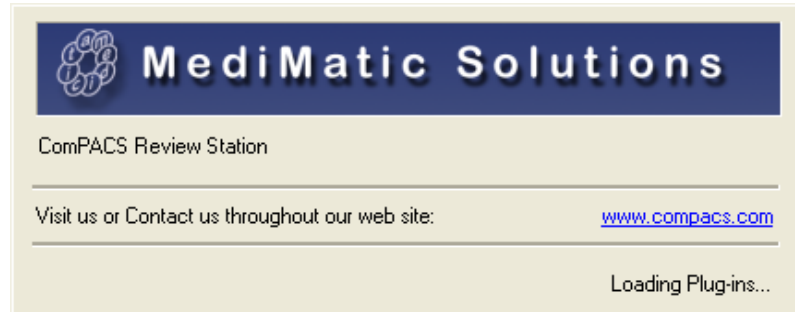
If the workstation is connected to a local archive or a remote server, a window will prompt you to login as follows.
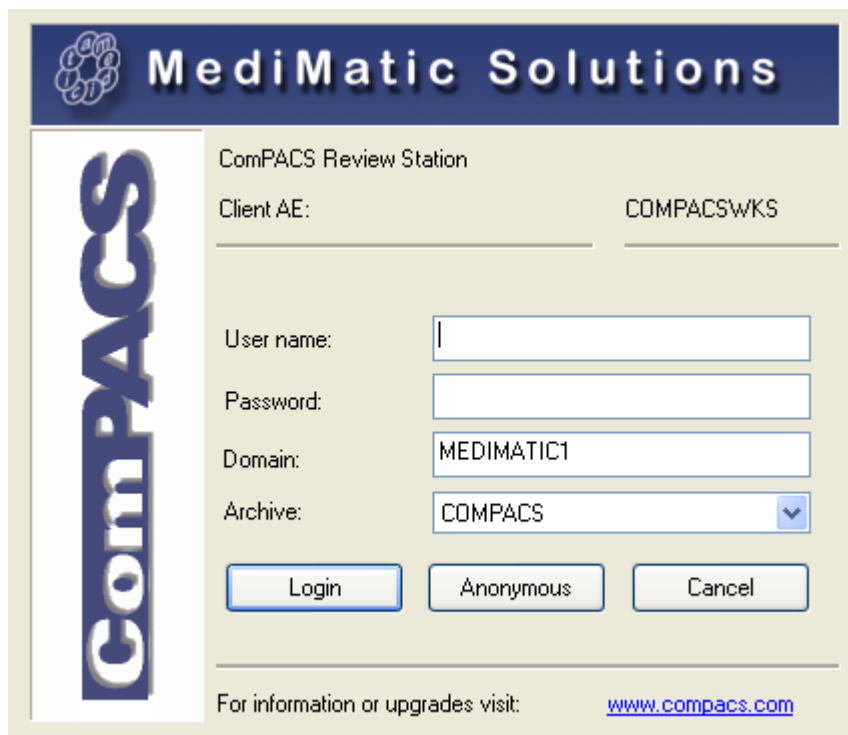
In this window you must enter your *User Name*, your *Password,* the *Microsoft® Active Directory* (Windows® OS login) to which your user name belongs and select which ComPACS archive to use. The last two parameters are generally set to default values upon set-up.

ComPACS does not force you to use an independent authentication mechanism but exploits the same user name and passwords used to log on the Windows® OS.

Generally there is only one _Archive Configuration_ (the drop down menu at the bottom) in the set-up. If there is more than one archive to which it is possible to connect, you need to make sure the one selected is the one in which you effectively want to log in.

If no archive configuration has been configured you will be automatically directed to the configuration window. Please refer to the chapter _Configuration_ for more details.

In some viewer only configurations, it is possible to be logged as Anonymous users; though you will have no access to the archive, all the functions of the stand-alone viewer will still work. This is the default behavior when the _Archive_ is not installed.

If Single Sign On is enabled for the default _Archive_ configuration, the system will automatically proceed to authentication on the basis of the current Windows logged on user. In order to inhibit such functionality, keep the _Shift_ key press while the application is launching.

3.2. CHANGING PASSWORD

In order to change the log-in password, you need to select the *Change Password* item from the *File* menu.
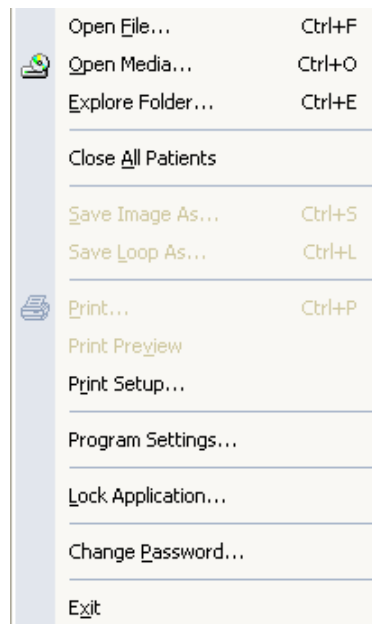
A dialog window will display the main log-in information of the Archive you are referring to (Archive Configuration, User Name and Domain) and prompt you to enter the current password (for safety purposes) and the new password. The new password also needs to be retyped for confirmation.
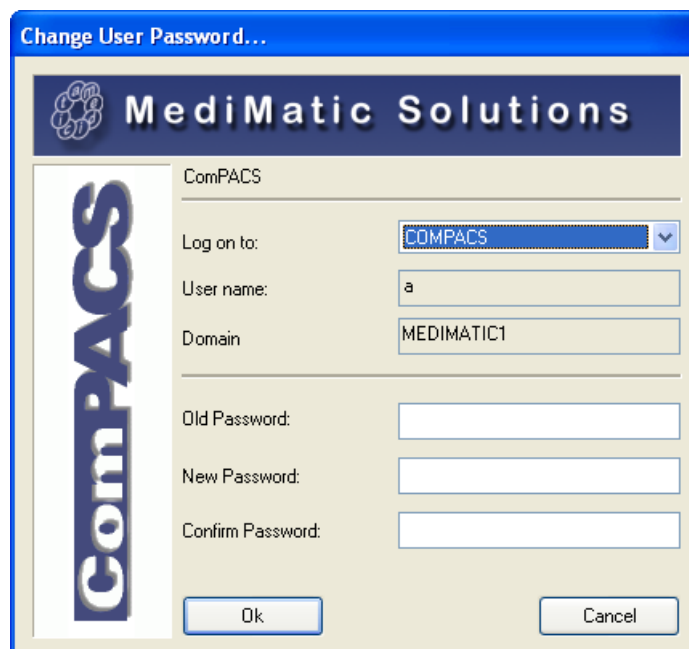
ComPACS exploits the same user name and passwords used to log on the Windows®
OS. This means that changing the password within ComPACS will also require changing the password
to access the Windows® system.

The new password must follow the rules and restrictions (minimum length, complexity,
etc..) defined by the related Windows® Domain.

3.3. IDLE TIME PROTECTION

In order to lock the application, you need to select the *Lock Application* item from the *File* menu. The
following dialog window will prompt you to enter the logged in user credentials before re-accessing the
application.

The application will also lock automatically after a period of user inactivity is reached on the
workstation. This period of time is defined by the system. A second timeout can also be defined to
automatically exit the application.

If an item such as a report is in edit mode the application will not exit, but will only lock.

4. APPLICATION LAYOUT

> ℹ️ The appearance of some objects within the viewer may vary. It depends on the installed modules.

Once you have started the program, the main window will appear.
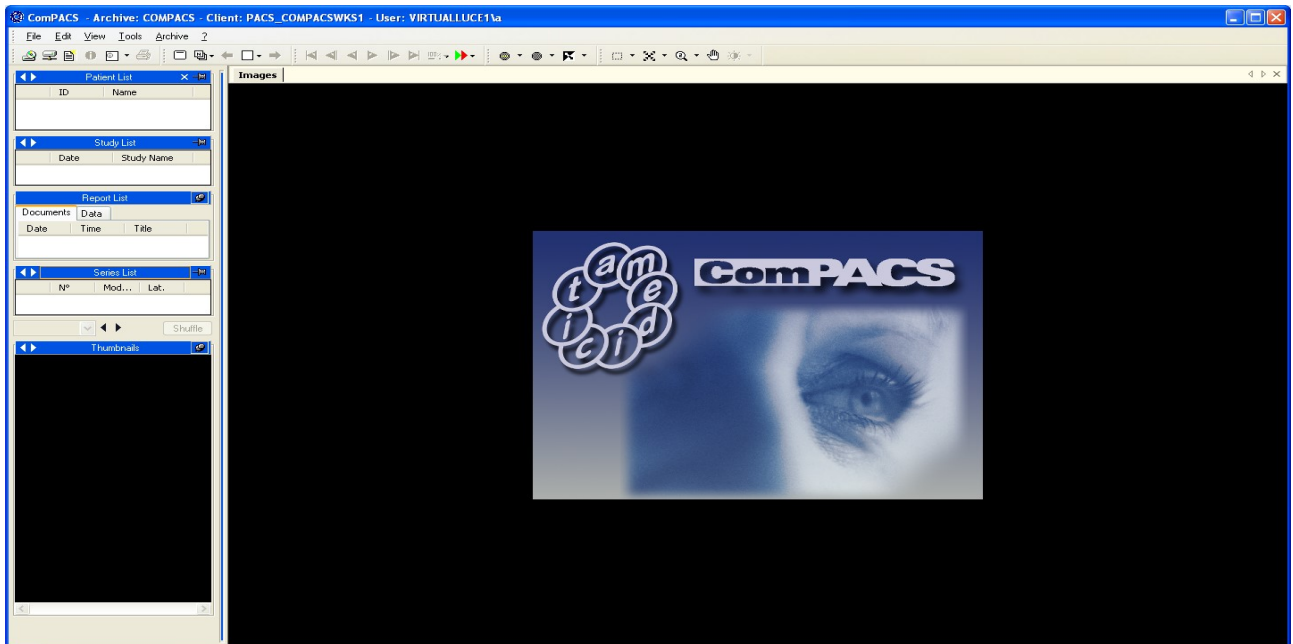
The following are the four key components to the main window.

1) The menu bar, on the top of the screen. On the menu bar you can open, save, print, edit, and close data. You can also retrieve information and set the general properties of the software;
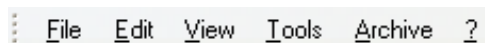
The menu bar can differ in relation to the optional modules installed. For example the *Archive* menu is only present if a local or remote archive is connected. Additional menus or submenu items may also be present.

2) The tools bar just under the menu bar. On this bar there are various icons that represent tools (i.e. filters, zoom, etc.) that you can apply to the selected image. In addition, there are play commands, and buttons to enter the archive (if installed) or to open a media. Additional buttons to create reports may also be present if the related modules are installed.

3) The controls window on the left allows you to have direct control on a patient, a study, a study documents and reports, a series and on the images (that are displayed as thumbnails). Here you can retrieve the information (on patient, studies, documents and reports, series, images). You can archive, you can attach files, and write a memo if the related modules are installed.
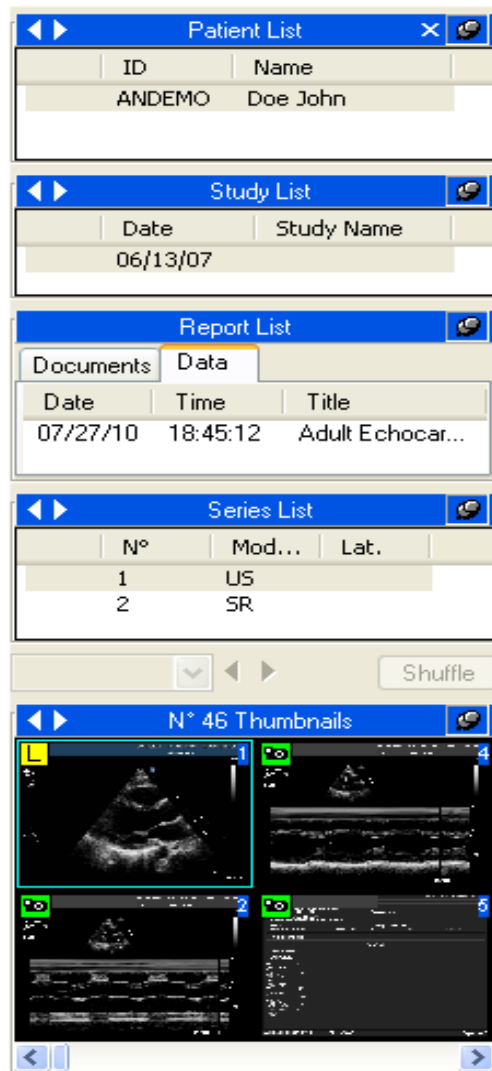
4) Finally, the tabs window is the main window of ComPACS Review Station, where the images and the loops are displayed. If you are searching for a media the explore window appears in the tabs window, indicated as an additional tab at the top; the attachments, the memos, and the reports (if the related modules are installed) are all displayed in the tabs window.
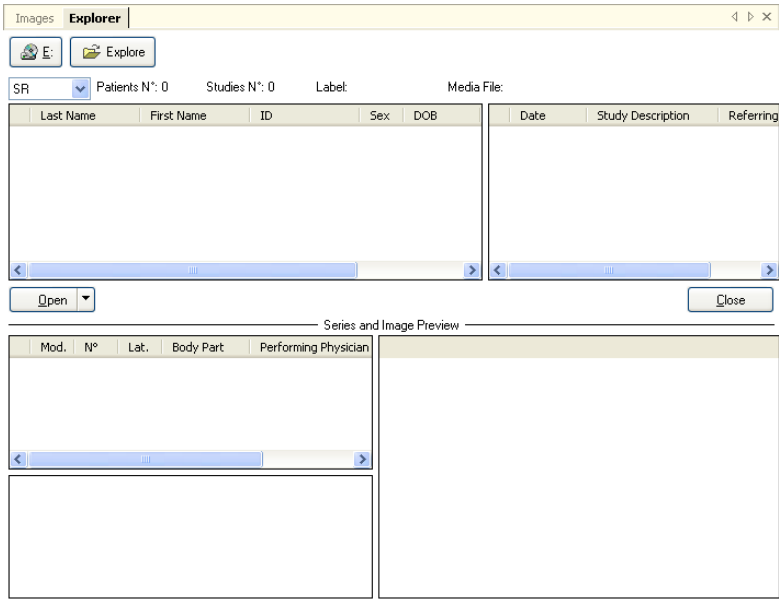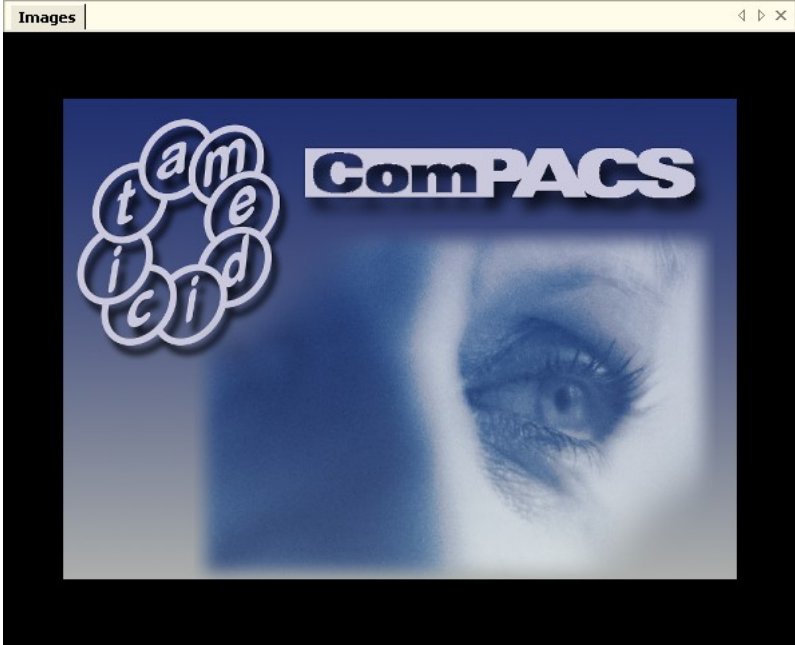
5. QUICK START

ComPACS Review Station automatically recognizes DICOM media. To view the content of a media simply put it in the applicable media reader (for example CD/DVD drive or Magneto-Optical drive) of your computer.

Once the content of the media is interpreted, ComPACS automatically opens an explorer interface.

> A *DICOMDIR* file has to be present in the root directory of the media otherwise the media is not recognizable by the software. The ComPACS review station can read some proprietary file formats as well, such as *DSR-TIFF* and *DEFF*.

> If the media is not automatically detected it is possible to access and explore the media content by clicking the *Open Media* button on the toolbar.

> A similar operation can be performed to access the central archive instead of the media content. To do so, click the *Search Archive* button on the toolbar. Please refer to *Archive* sections for more detailed instructions.

At this point the list of the studies is presented, displayed with some associated information and image thumbnails. To select a patient select it and click on open, or simply double-click on it. The same operation can also be performed at the study, series, or image level.

The selected items will be then opened for review. The service window on the left will display the information about the selected patient, the study, the series and the images' thumbnails. The *Images* tab window will display the first image or loop selected. The picture below shows a sample screenshot.

5.1. QUICK ACCESS TO MAIN FUNCTIONS

If the DICOM items are image loops, they can be played by using the play commands on the tool bar.

▶ Forward play / Stop if re-clicked

◀ Backward play / Stop if re- clicked

▶ and ◀ together Sweeping play

▷ Next frame

◁ Previous frame

▷| Last frame

|◁ First frame

Or by the smart keys on your keyboard.

↵   Play Forward / Stop

Pg↑ Previous Thumbnail

Pg↓ Next Thumbnail

←   Previous Frame

→   Next Frame

↑   First Frame

↓   Last Frame

F1   On-Line Help

F2   Toggle Normal/Full Screen view

By clicking the right mouse button when the cursor is in the tabs window, a quick access menu will appear to allow a rapid selection of some program function (i.e. zooming, display mode selection, information, etc.).

6

6. REVIEW STATION

6.1. OPENING FILES

6.1.1 FILE FORMATS

Opening and closing a file set through the *DICOMDIR*, (the file that according to the DICOM 3.0 standard contains all the information on the images present in the media support), is typically performed automatically by the program that detects respectively, media insertion and removal.

The *DICOMDIR* file has to be present in the root directory of the considered media. ComPACS viewer can read some proprietary file formats as well, such as *DSR-TIFF* and *DEFF*.

6.1.2 OPENING A FILE FROM REMOVABLE DRIVES

If your computer does not allow the detection of disk insertion and removal, or the *DICOMDIR* file is not in the root of the media, it is still possible to open a DICOM file set by clicking the explore icon

This can be done as well by clicking on the *File* menu then choosing *Open Media* (hotkey **Ctrl+O**)
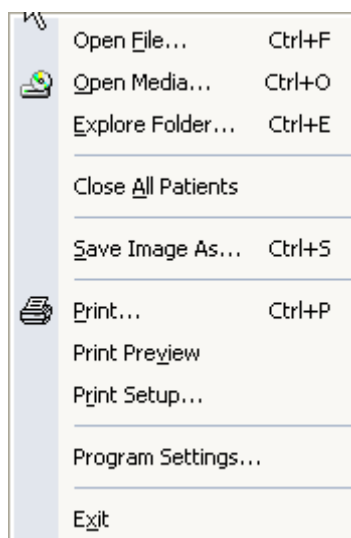
This operation opens in the tabs window, an explorer interface where you can explore the content of a removable drive, of the local hard drive, and of the Local Area Network.
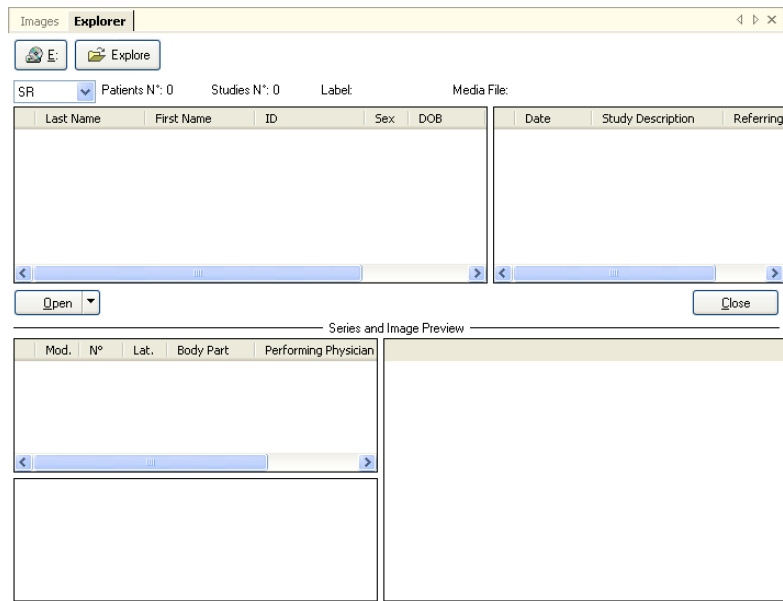
To explore the content of a removable media directly, click on one of the icons representing the removable media drives (CD, DVD, USB-keys etc.). For example:

 The letters on the icons depend on the settings on your computer.

The software searches for the *DICOMDIR* and if found, it will automatically open the related file set.
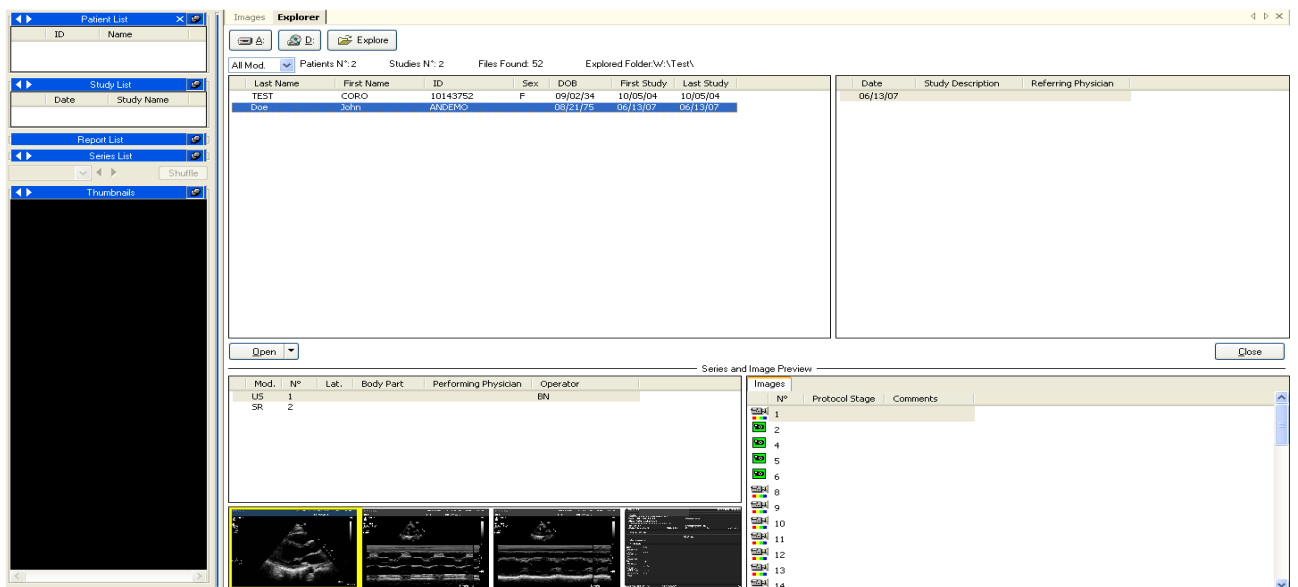
A list of studies in the fileset is presented with some related information. To select a patient (or a study) simply double-click on it. If you wish to open just one image or loop, double-click on the related thumbnail and similarly, for single studies or series. Please note; double clicking the patient name will open and load all studies of this patient that are in the media you are querying. If the patient has had numerous studies, this will take some time.

The fileset is closed automatically when the medium is extracted. The fileset can also be closed by the *Close All Patients* command in the *File* menu.
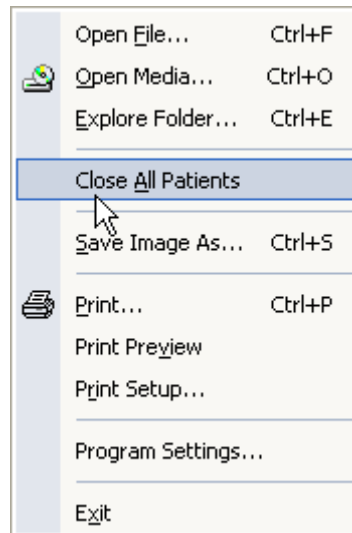
The same operation can also be performed from the patient list window by right-clicking and then selecting *Close Patient* or *Close all Patients*.

6.1.3 OPENING A FILE FROM LOCAL HARD DRIVES

To open a fileset present on a local Hard Disk, or on a network place, in the explore window, click the explore icon.

This can be done as well by choosing *File* menu, then *Explore Folder* (hotkey **Ctrl+E**).
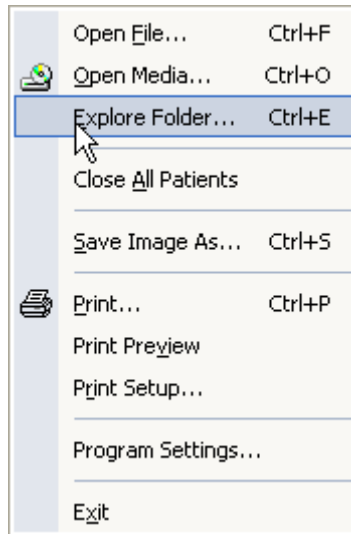
A dialog window appears that allows the selection of the desired folder present on a local disk, on a local device or on a network remote device
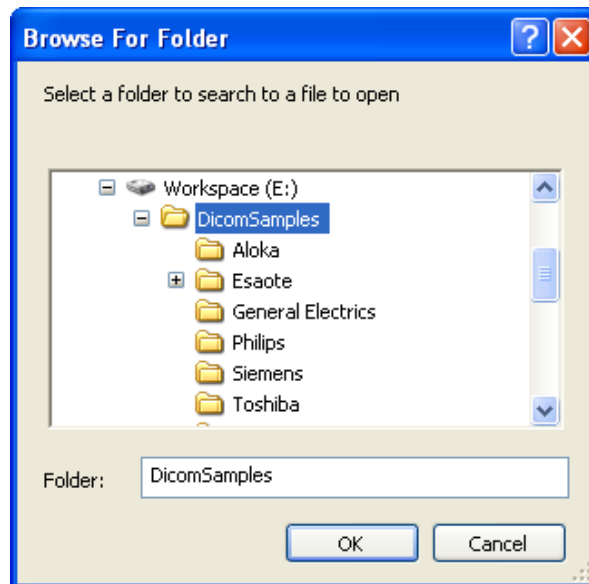
Another way to navigate through the folders is to select *Open File* (hotkey **Ctrl+F**) from the *File* menu and then select the specific file or *DICOMDIR* to open.
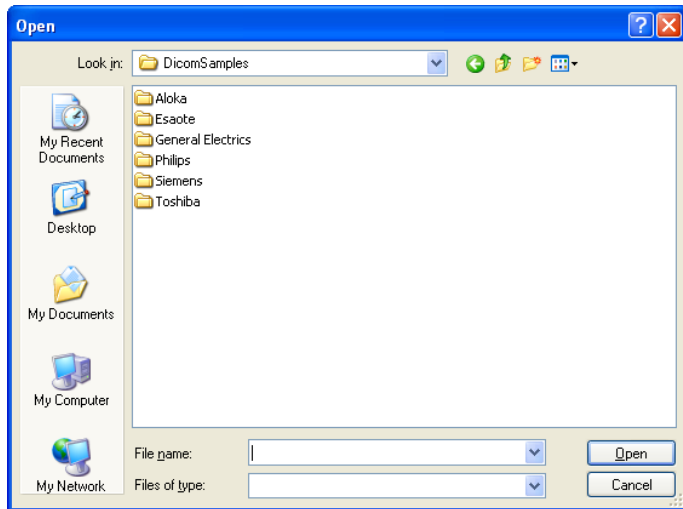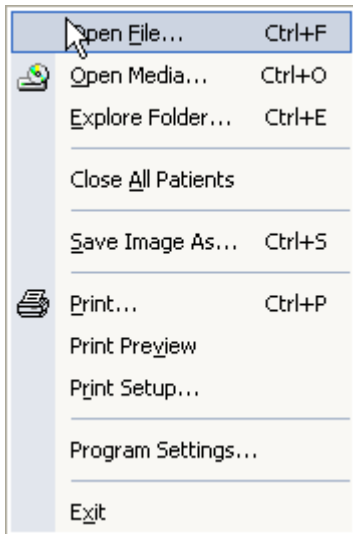
6.1.4 OPENING A PATIENT/STUDY FROM THE ARCHIVE

If a local or remote archive is connected it is possible to access the central archive instead of the media content. To do so, click the 🖥 *Search Archive* button on the toolbar. Please refer to the *Archive* sections for more detailed instructions.

6.2. VIEWING IMAGES AND REPORTS

6.2.1 THUMBNAILS

Once you have loaded the image set to be analyzed, you can see it on the service window as *thumbnails*.
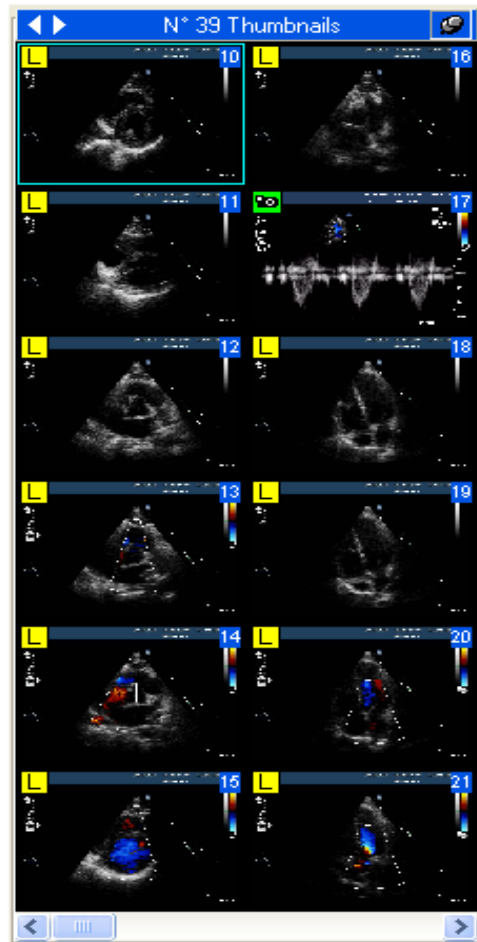
You can browse it with the mouse, or by using the Control keys, or by using the Numeric pad. Also you can use one of the two buttons created for this purpose.

➡ next thumbnail (hotkey **PgUp**) and ⬅ previous thumbnail (hotkey **PgDn**).

The thumbnails will display a small key image of the object they refer to if it represents an image or loop. Alternative, if it represents a different type of object such as a waveform or a report, it will display some key information such as the series modality, number and date/time.

Moreover, the thumbnails can be associated to different symbols to convey additional information about the object they refer to:

   L - for objects that contain data in a lossy format (for example a lossy DICOM transfer syntax).

- for objects that represent single frame images.

- for objects that are not supported by your software version.

- for objects that are still being downloaded from the central archive or prepared for display. This symbol will disappear once the download operation has completed and the object is accessible.

- for thumbnails that refer to a series of objects (and not just a single object, image or loop). This is typical for objects that often need to be stacked such as those of MR and CT modality.

6.2.2 IMAGE LAYOUT

ComPACS Review Station allows viewing one or more images at the same time. This can be done by clicking the *layout* icon and then selecting the desired splitting of the screen from the *layout* menu

	1 x 1
	2 x 1
	1 x 2
	2 x 2
	3 x 3
	4 x 4
	6 x 4
	6 x 6
	Custom …
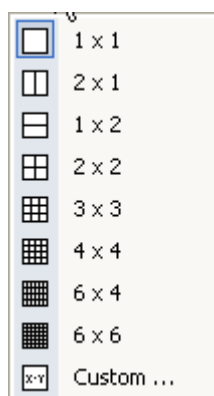
You can also do this by clicking the *View* menu and then selecting *View Layout*
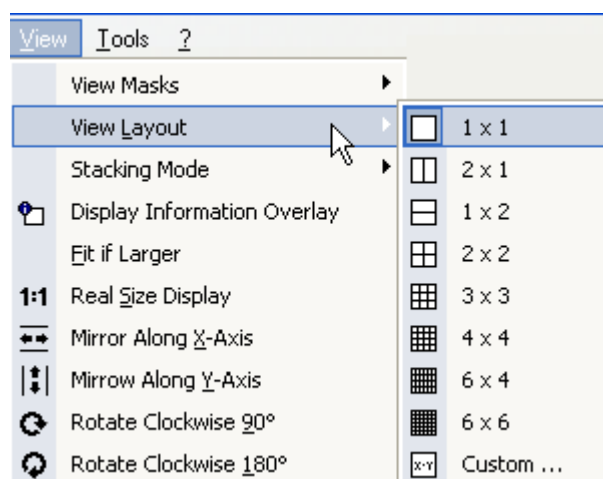
You can customize the division of the screen (the maximum allowed value is 10x10). By double-clicking on a thumbnail, you will see on the screen the image selected and the following images until the

screen is full. You can move as you prefer, the images in the tabs window by simply dragging-and-dropping them.

Please note that it is also possible to specify stacking information for a loop composed of a series of independent single image files (typically for MR and CT series). Additionally you can specify the unstacking of a DICOM loop into independent window views to observe the different frames in the loop side by side. This operation will be addressed in more details in another chapter.

Below as an example, a 3x3 grid is shown; please note that changing the layout does not affect other functions of the software.
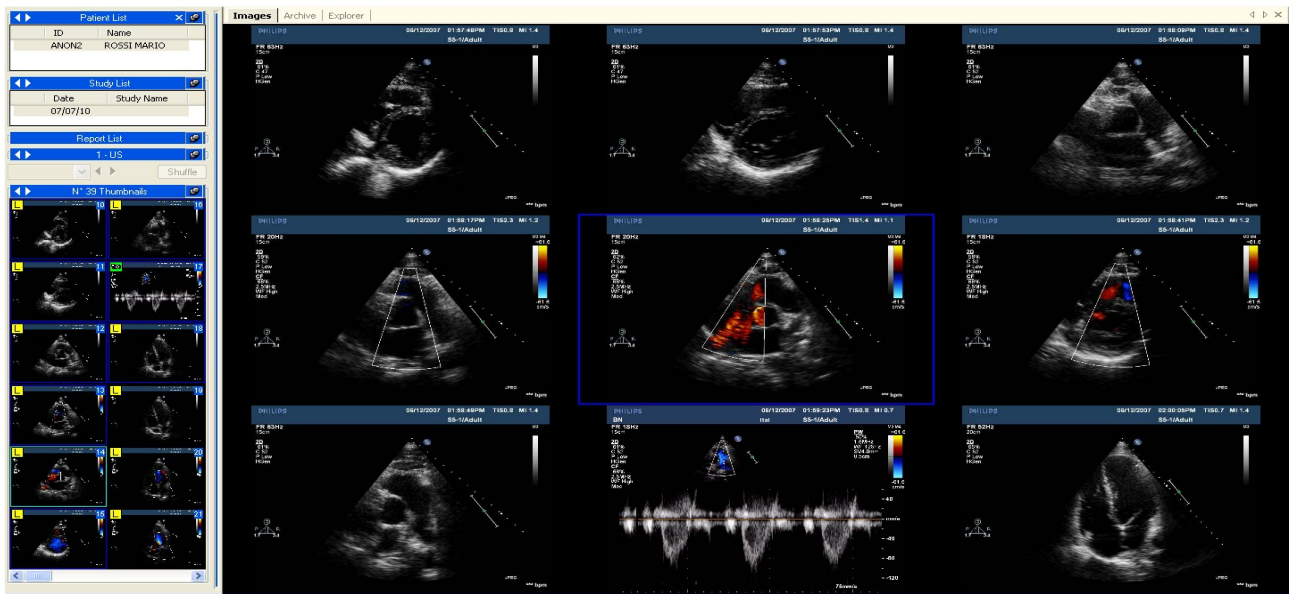

> ℹ️ The default stacking mode is *Image Number Order* 🔢▾. Please revert to this mode if you experience some anomalous behavior in the image or loop display.

6.2.3 FULL SCREEN

ComPACS Review Station allows the full screen mode. This option can be activated and deactivated using the button ▢ in the tool bar, or with the hotkey **F2**.

6.2.4 ADDITIONAL INFORMATION

On the service window, together with the thumbnails, you can see three other windows showing additional information about the active items. You have *Patient list, Study list, Report list* and *Series list*. In other words on the service window you can retrieve all the data about a patient, a study, a report or a series that is open for reviewing.
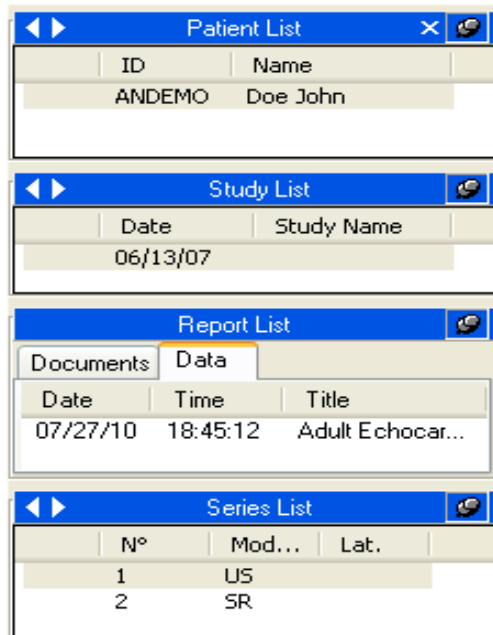
Additional information is available by right-clicking on an item. Then click on the selection, *DICOM Information*. By doing so, you will open a new window (*Information Properties* window) displaying different information about the item selected.
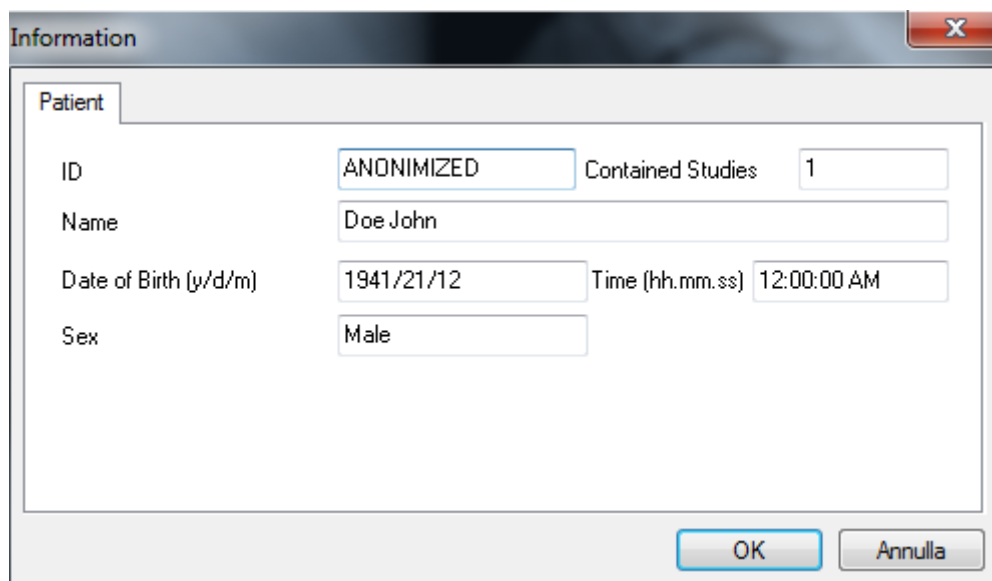

<u>Patient Information</u>
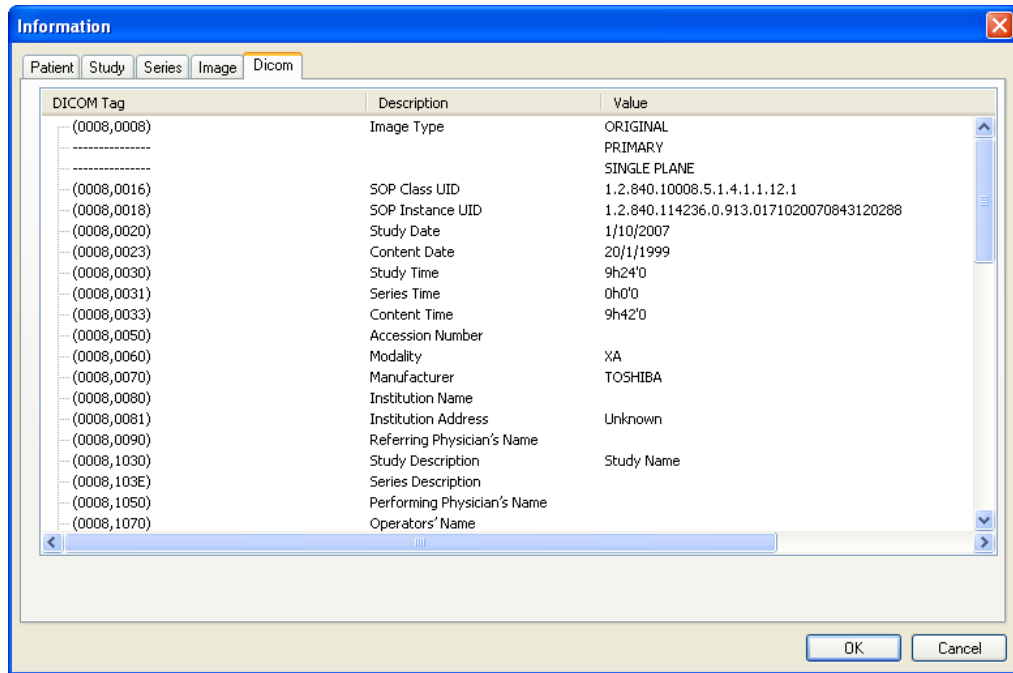
Extended DICOM Information

The tabs *Patient, Study, Series,* and *Image* have the same meaning of the service window menus. The *DICOM* tab contains all the information derived by the interpretation of the data contained in DICOM object itself.

Another way to display this window is to click on the *View* menu and then on *DICOM Information*, or directly by clicking on the *Information* icon on the tool bar.
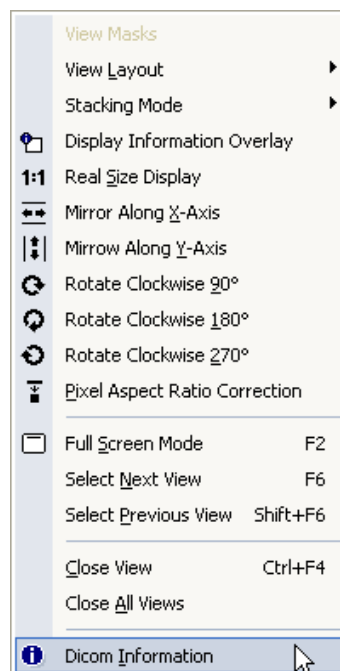
This procedure will open a similar new window with all the DICOM information and properties of each tab and subsequent field.
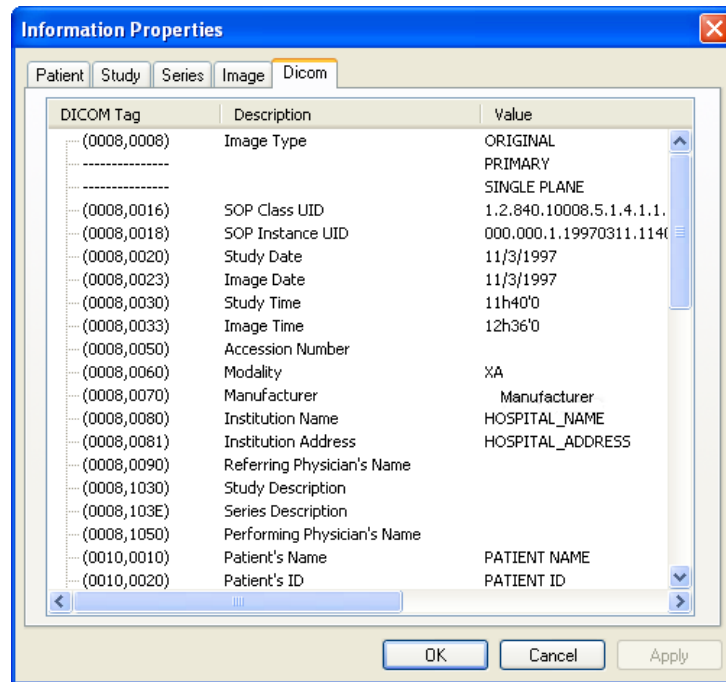

Alternatively, you may *Right Click* on the image in the tab window and select the *DICOM Information* item in the popup menu.
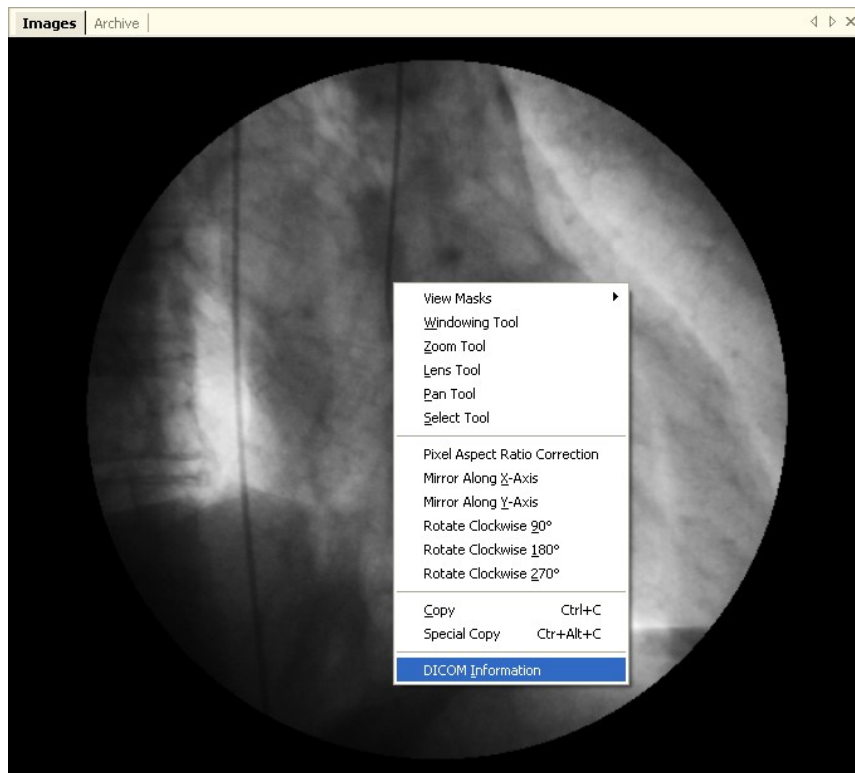
6.2.5 INFORMATION OVERLAY

It may be useful to hide or show the overlay information. That means showing information about the patient, study or image directly over the image itself. This can be done by clicking on the overlay icon or by clicking the *View* menu and then *Overlay Mode.*
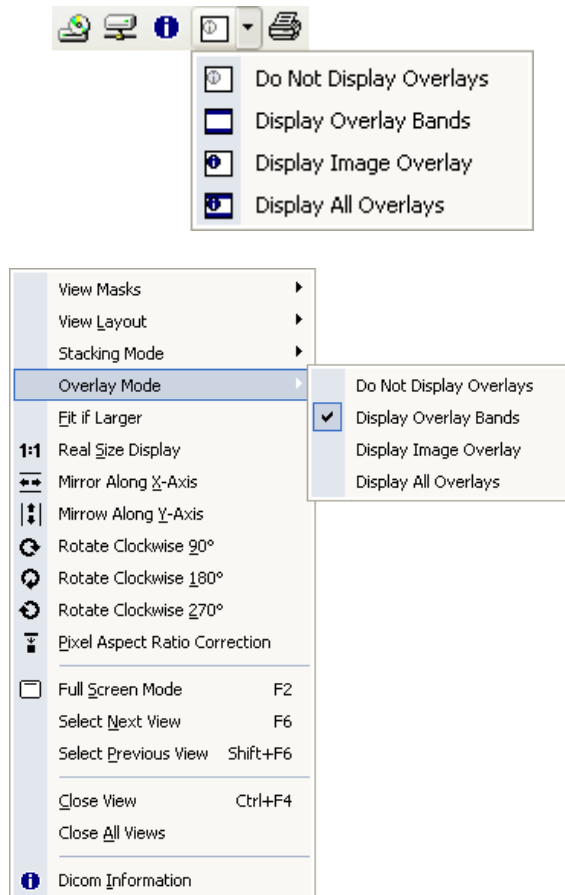

There are two main different types of overlays: a) image bands shown above and below the image to display main patient, study, and compression information, b) overlay on the image to show more detailed and configuration information (see the settings chapter for more information).

> ⚠️ If the Overlay Information is disabled, it will nevertheless remain on the screen for five seconds whenever different studies or different patients are open for review to warn the user of the change. Please be very careful when in this mode to avoid possible confusion between patients or studies.

6.2.6 VIEWING REPORTS

The "Report List" service window on the left will display the report documents and structured data respectively in the *Documents* and *Data* tabs.
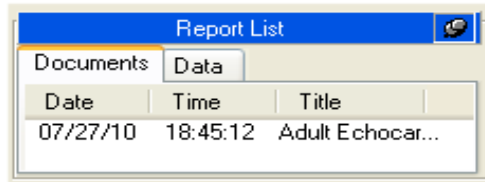
To display the report document simply click on the related item. A new tab will be opened on the right and it will display the selected document.


 In order to display the report document it is necessary to have Adobe® Acrobat Reader installed on your system.

 The structured data items in the *Data* tab can be analyzed only if the analysis or reporting modules are licensed and activated.

6.2.7 CLOSING ITEMS

To clear the main window while keeping the study open for review, click on *View* menu and then *Close View* (hotkey **Ctrl+F4**).
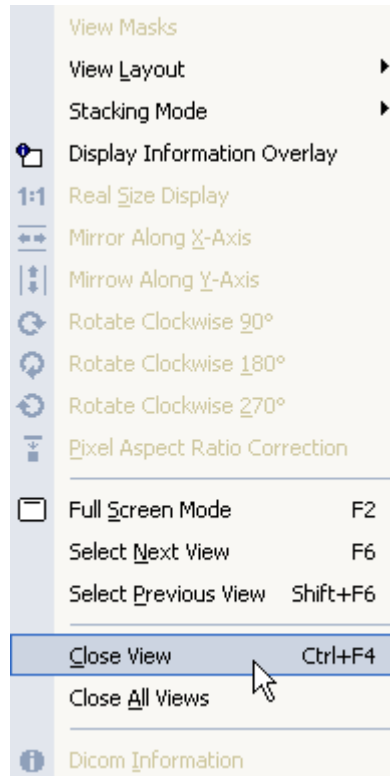

In case you have more than one image opened (i.e. layout modified) clicking on *Close View* will close only the selected image. To close all the images in the main window (without clearing the thumbnails) click on *Close All Views* or press the ✕ button on the tabs window.

Clicking the ✕ button on the *patient service window* will close all the opened patients for review and all the related studies. If only a single patient or study needs to be closed simply *right click* the appropriate service window and select the *Close xxx…* option.

6.2.8 MULTI-MONITOR

The ComPACS Review Station allows using a multi-monitor configuration (if the appropriate module is installed). To access the multi-monitor options click on the *File* menu, then on *Program Settings*.
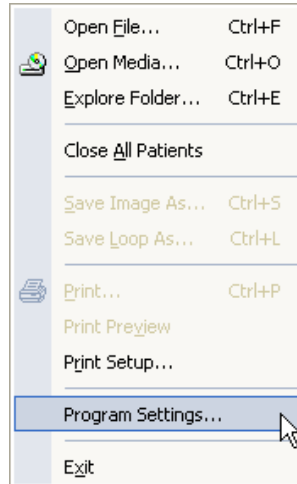
This opens a window with different tabs and subsequent fields. The tab *Multi-Monitor* allows the user to select the desired options for each monitor. The software settings can be modified to associate specific functions to each monitor.

- *Not used.*
- *Main Window*, i.e. Main software interface (containing the service windows).
- *Additional Window*, i.e. Additional image or report windows.
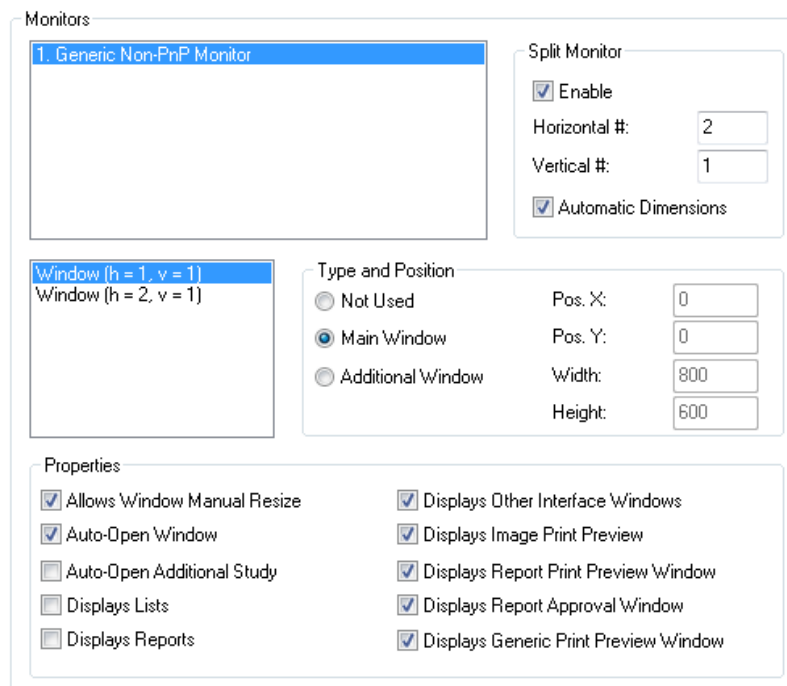
You can decide which roles are assigned to the additional monitors. Obviously one monitor must be the main window. The others can be selected as Additional Window. Once done, checking the desired options in the properties box assigns that function to that monitor. Remember that if a property is checked for a monitor, it should in general be not checked for the others.

The monitor primary properties are the following:

- Auto-Open Window. This property defines in which monitor the images and loops will be automatically displayed when a study is opened for review. If more than one monitor is selected, the images will be distributed across the selected monitors.
- Auto-Open Additional Study. This property defines in which monitor the images and loops will be automatically displayed when a second study is opened for comparison. If not set, all studies will be opened in the default monitors selected above. If more than one monitor is selected, the images for the studies to be compared will be distributed across the selected monitors.
- Display Lists. This property defines in which monitor the patient and study lists (for example the archive search windows) will be displayed.
- Display Reports. This property defines in which monitor the windows for creating and editing reports will be displayed.

All the remaining properties are self-explicatory.

Furthermore it is also possible to split monitors both horizontally and vertically, emulating a multi-monitor configuration and application behavior even in single monitor systems. The position and size of the windows within the monitor can also be defined.

These settings will become operational only after the application is restarted.

 Please note that multi-monitor options also depend on the video card installed on your computer. If no multi-monitor function is detected then the related settings will not be available.

6.3. PLAYING LOOPS

6.3.1 HOW TO PLAY

Once a DICOM file has been opened, ComPACS Review Station displays the image in the tabs window. If the tabs window is not large enough to host a full size DICOM image it will be automatically resized to fit in the window.

You have different ways to control the loop playing. You can use the play icon as follow

▶ Forward play / Stop if re-clicked

◀ Backward play / Stop if re-clicked
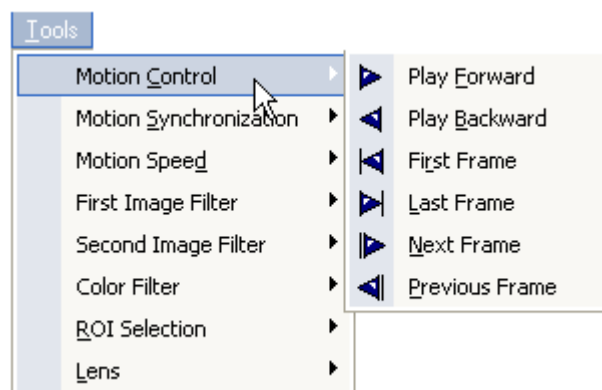
▶ and ◀ together Sweeping play

▶ Next frame

◀ Previous frame

▶| Last frame

|◀ First frame

All these commands are also included in the *Tools* menu, selecting *Motion Control*

There is another way to control the flow of images. You can use the Control keys

↵   Play Forward / Stop

Pg↑   Previous Thumbnail

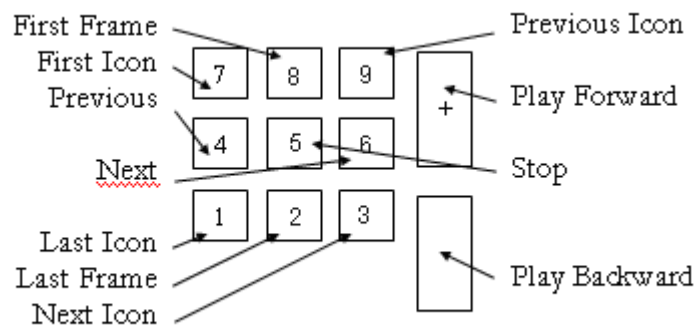**Pg↓**   Next Thumbnail

←   Previous Frame

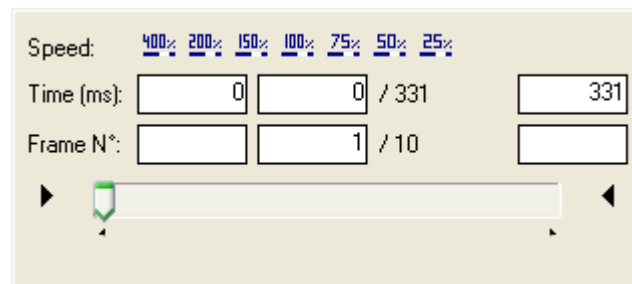→   Next Frame

↑   First Frame

↓   Last Frame

Finally the Numeric Pad may be used as follows:

6.3.2 SPEED CONTROL

Press the *Playback Settings* button to have access to a menu with which you can control the speed of playback and set different limits of the loop in terms of time or frame.

The speed can be changed between 400% and 25% of real time speed. The time and the frame limits can be modified and the progress bar shows the changes.

The requested speed can only be obtained if sufficient computational resources are available to accomplish the operation. Otherwise a reduced playback speed will occur.

The same window is accessible by *Tools* menu and then clicking on *Motion Speed*.
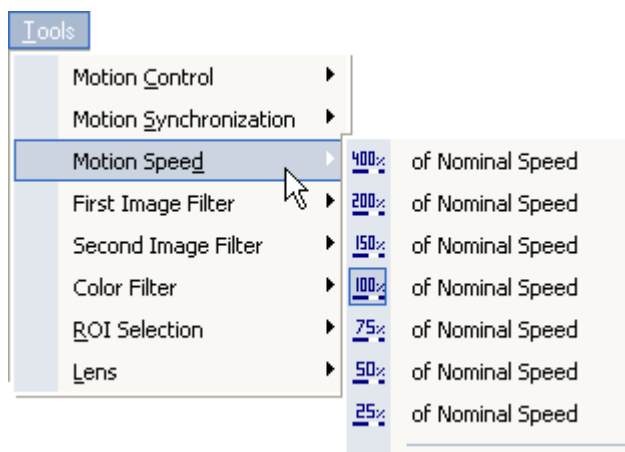
In this dialog, you may trim the loop to be displayed by selected the start and end portion and respectively clicking the ▶ and ◀ arrows. The markers in the bar will change accordingly.

These settings will become operational only after the application is restarted.

These settings are just temporary and will be lost the next time the loop is re-opened for display.

6.3.3 MULTI LOOP CONTROL

In case you are analyzing more than one loop (i.e. layout changed) you can easily control the synchronization of different loops. You can enter the *Synchronization* window by clicking the ▶▶ button. A drop down menu will be displayed.
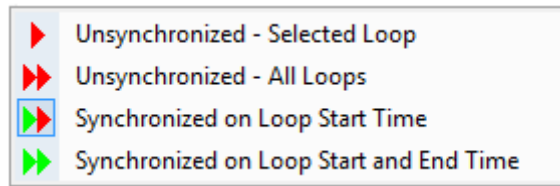
Most menu items have titles that are self-explanatory. This window allows, for example, to synchronize only on the start frame , or on the start and end frame etc. The same could be obtained by using the *Tools* menu and then choosing *Motion Synchronization*.
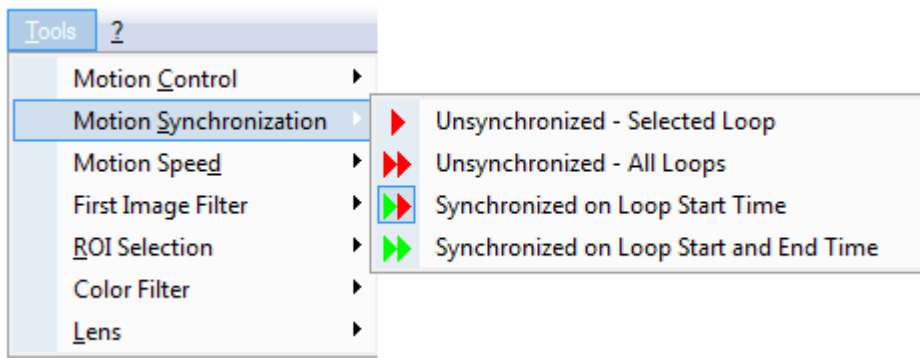
6.3.4 STACKING/UNSTACKING

Stacking means that you can build a loop with a series of single frames (for example a series of CT or MR images) or vice versa you can divide a loop in single images to analyze the video frame-by-frame. It is possible by accessing the stacking menu and using the button.
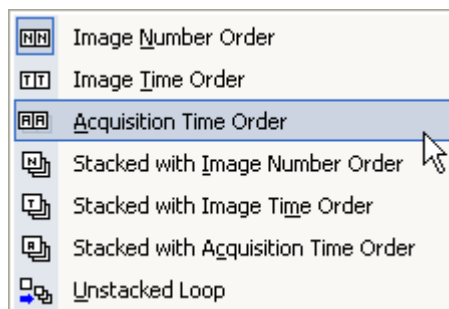
In this menu, you may decide what kind of sorting you need. The default behavior is to display images independently and sort by *Image Number Order*. This ordering information is generally generated by the modality device upon acquisition and conveys the order in which the images were effectively acquired. Other possible, but less often used, alternatives are to order using the *Image Time* (the time at which

pixel data creation started) or *Acquisition Time* (the time at which the acquisition of the data resulting in this image started).

For example the next screenshot displays an MR series in which the different slices are displayed in a grid. Clearly it is important to note that before doing any display operation, you should set the desired layout (in the following case the layout grid is 4x4).
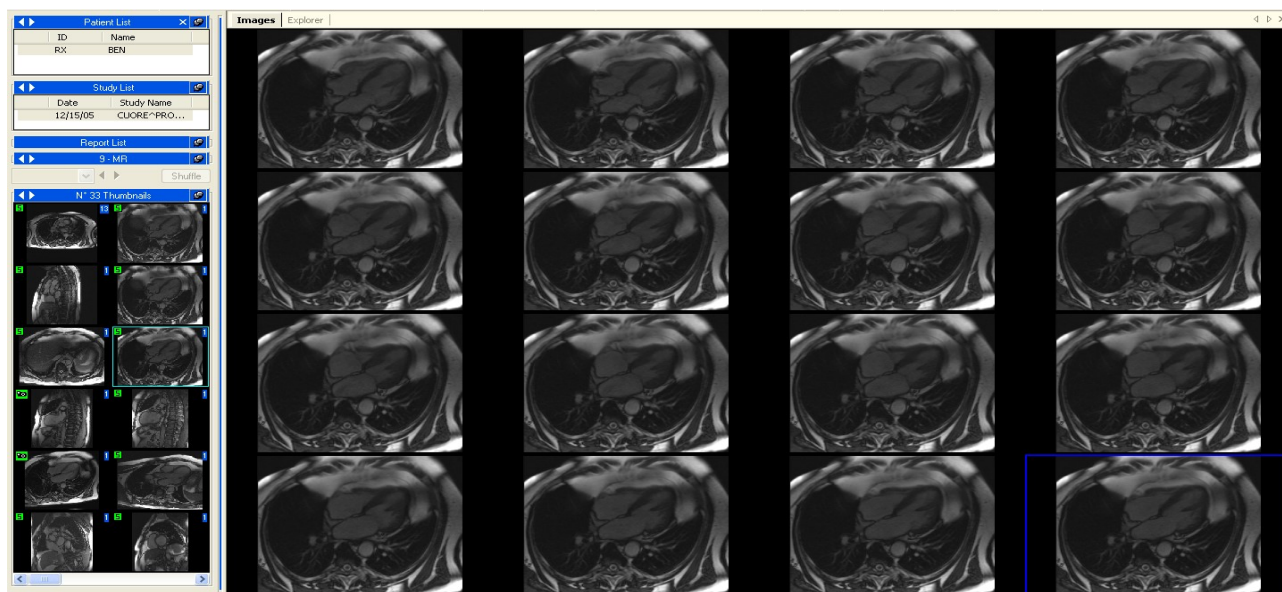
The system also allows a series of MR or CT images to be stacked to be displayed and processed as if it were a loop. In this case it is important to define how the images are going to be ordered in this loop, generally choosing the *Stacked with Image Number Order* option. Once this option is selected, all open operations that refer to a *series thumbnail* will be stacked into a loop.

In the opposite way the system also allows a loop to be unstacked into independent frames, shown side by side. To activate this option, select *Unstacked Loop* as the stacking mode. Once this option is selected, all open operations that refer to a loop will be unstacked into multiple image views.

> ℹ️ Most of the icons presented take the look of the last choice done by the user.

6.4. FILTERING IMAGES

There are two different filtering options: a *color filter* and a *dynamic filter*.

6.4.1 COLOR FILTER

To add a color filter to the images click on the Color Filter button ⬚ on the tool bar, and from the menu that appears, you can choose one of the following filters.
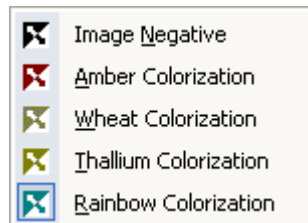
To access this window you can also click on the *Tools* menu and then *Color Filter*.

This filter works with each kind of analysis (single image, multi image, and loop). To remove the effects of the filter, just re-click the *Color Filter* button ⬚ .

6.4.2 DYNAMIC FILTER

Another set of filters available are the *Dynamic Filters* or *Image Filters*. These filters are characterized by buttons such as ⬚ or ⬚ (The list of possible buttons is displayed in the menu below). By clicking the *Image Filter* button you open a window where several kinds of filter are available to use.

As you can see in the following figure, by selecting a filter you impose the look of the related button. This menu is also available by clicking on *Tools* menu and then on *First/Second Image Filter*.
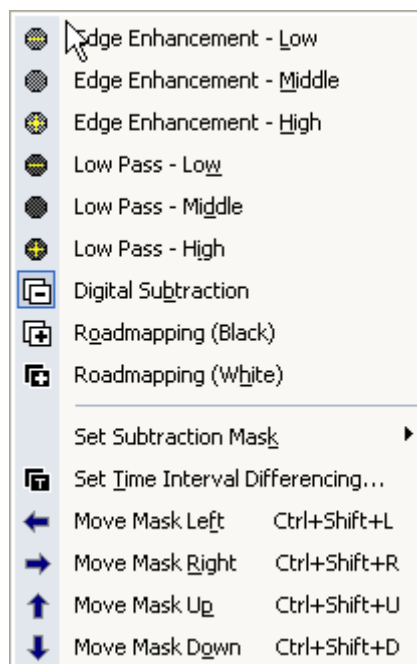
If the *Digital Subtraction* filter is chosen from the menu, the system automatically applies the subtraction masks as defined in the DICOM file. If no mask is defined, a set of additional operations is required. You then need to set a subtraction mask for a single frame with the hotkey **Ctrl+Shift+M** or choose one of the other options from *Set Subtraction Mask* menu, as shown below.

If the *Digital Subtraction* filter is chosen from the menu, a set of additional operations is required. You then need to set a subtraction mask for a single frame with the hotkey **Ctrl+Shift+M** or choose one of the other options from *Set Subtraction Mask* menu, as shown below.
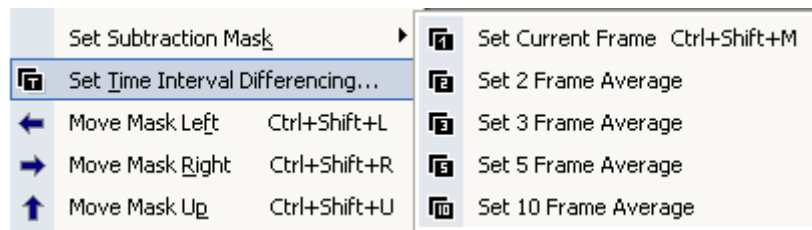
There is another mask control for the Digital Subtraction filter. You can decide to use a dynamic mask by clicking *Set Time Interval Differencing* on the previous menu. This operation opens a window where you can decide the offset of the mask in terms of frame or time interval.
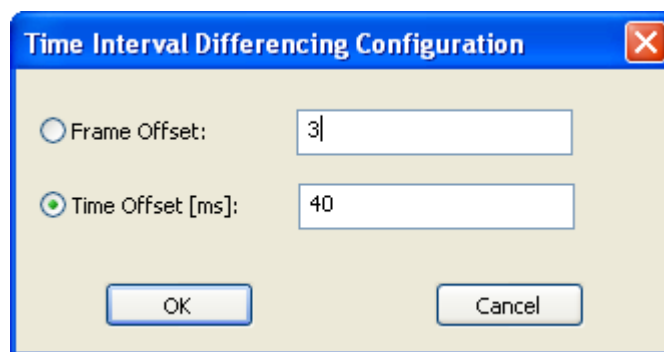
Once set, you can also move a mask along the image. This is useful in case where there are small movements which need to be adjusted. You can move a mask up (hotkey **Ctrl+Shift+U**), down (hotkey **Ctrl+Shift+D**), left (hotkey **Ctrl+Shift+L**) and right (hotkey **Ctrl+Shift+R**). The same options can be accessed from the *Image Filter* menu.

 It is important to underline that the filtering implies a computationally intensive operation that reduces playback efficiency. For this reason we suggest avoiding its use during cine loop viewing in slow system configurations.

6.5. TRANSFORMING IMAGES

6.5.1 MIRROR AND, ROTATION

ComPACS Review Station allows rotation, mirroring, and zooming on the images and loops. To do this, click on the *Zoom/Transforms* button [X ▾] and obtain access to the following menu.

1:1	Real <u>S</u>ize Display
	<u>F</u>it if Larger
↔	Mirror Along <u>X</u>-Axis
↕	Mirrow Along <u>Y</u>-Axis
↻	Rotate Clockwise <u>9</u>0°
↻	Rotate Clockwise <u>1</u>80°
↺	Rotate Clockwise <u>2</u>70°
↧	Pixel Aspect Ratio Correction
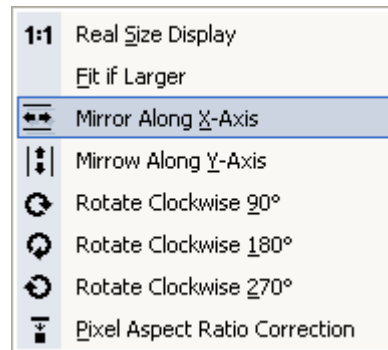
Here you have several options concerning rotation and mirroring. Please note that there's the possibility to correct the size of the displayed image to fit it to the screen, display it in real size or correct the pixel aspect ratio (square pixel transform). The same menu is available by *right clicking* on the tabs window.

6.5.2 INTERPOLATED ZOOM

For *Zooming,* click once on the [X ▾] button. The mouse pointer will now resemble the button itself. In this situation, keep the *left mouse button* pressed, and then move the mouse along the view window. You will obtain a zoom in/out effect. To return to the default settings, simply *double-click* on the view window.

The *Zoom* tool is also available by right-clicking on the image and then choosing the *Zoom* tool.

⚠️ The quality of the display and speed of the zoom depends on the hardware installed. It is important to note that zooming on some platforms is a computationally intensive operation that reduces playback efficiency.

6.5.3 PAN

When the zoom is activated and the dimension of the image is bigger than the screen, you can move the screen along the image by selecting the *Pan* 🖑 button, and then keeping the *left mouse button* pressed and moving the mouse on the view window. This function is available also by *right-clicking* on the image and then selecting *Pan Tool.*

6.5.4 LENS

Another way to zoom the image is the *Lens* tool. This tool is identified by this button ⊕ ▾ that gives access to a *Lens* menu.
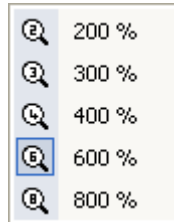
The same menu can be opened by clicking on *Tools* menu and then on *Lens*.

The appearance of the mouse pointer will be similar to a lens. Keeping the *left mouse button* pressed and then moving the mouse along the image creates a lens effect. Refer to the following page for an example.
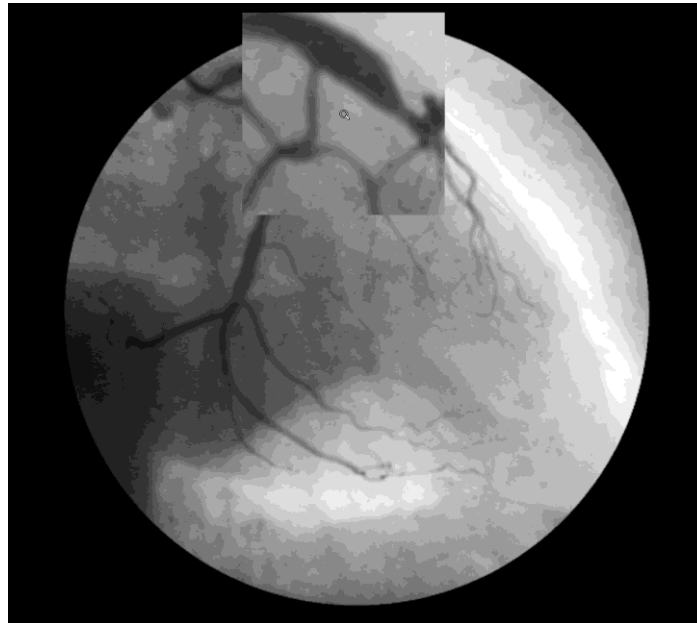
6.5.5 BRIGHTNESS AND CONTRAST

To change the brightness and contrast levels, use the *Brightness* ☀ ▾ button. It will open a window where you can change the brightness and contrast values for one image or for all the images.
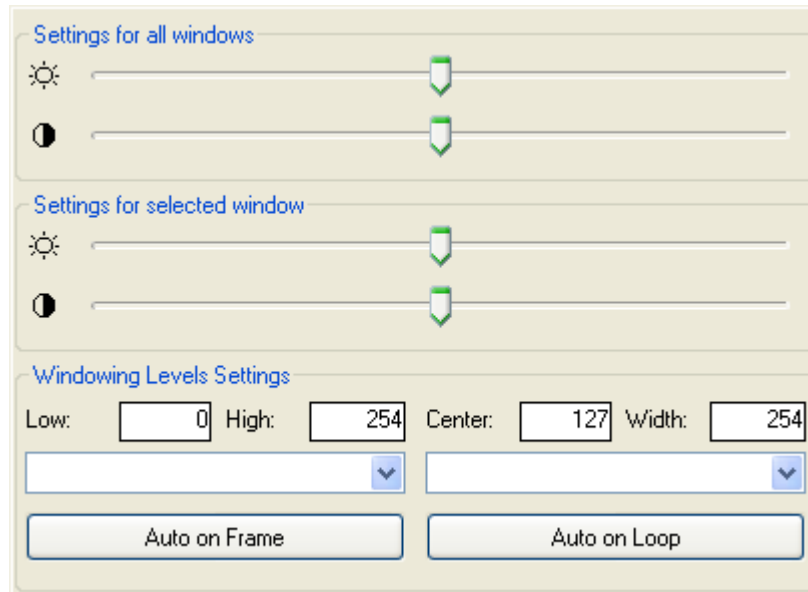
Another way is to click on the button and then keep the left button pressed while over the image. Scrolling the mouse up and down will change the level of contrast; scrolling the mouse right-left will change the brightness level. To reset the original value, double-click on the image.

Another tool present on the above window is the *windowing* tool. A monitor is not capable of displaying more than 256 gray levels therefore if the selected image contains a greater number of gray levels, it is necessary to establish the value range that must be displayed and rescale it to a 256 levels range.

Normally, if the image requires a windowing operation, the possible window(s) are stored with the image in the DICOM file. These automatic settings, if present, are available in the combo box. By selecting an item in the drop down menu the related windowing levels will be applied.
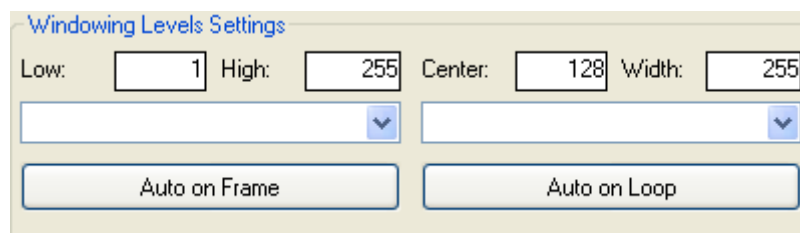
 If these settings are not present, it is possible to calculate them automatically by use of the *Auto* buttons or to set them manually in the edit boxes at the bottom of the control window. The boxes indicate the *Center* level of the window and the window *Width*.

6.5.6 ROI SELECTION

It is possible to select a ROI (Region of Interest) on the view window by using the [⬚ ▼] button. A drop down menu will list all the possible choices.
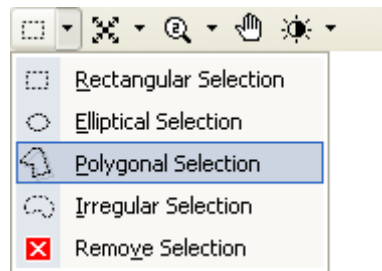
Once the option is activated, you may draw the ROI by using the mouse buttons. The left click adds a point and the right click removes it. The geometry of the ROI will depend on the option chosen.

These ROIs can then be used for all operations that can support them, for example printing or exporting to AVI or to Multi-Media image formats.

6.5.7 MASKING

You may hide or replace portions of the image or loop by applying a mask which will be overlaid onto the image. The opaque portion of the mask will replace the image content whereas the transparent ones will keep the underlying region visible.
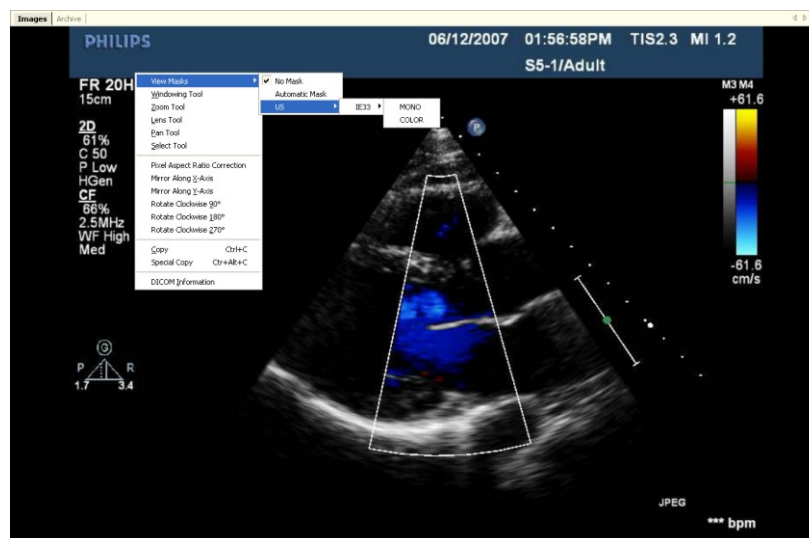
Simply right click on the image and access the View Masks menu to manually select a mask or let the system automatically pick the best one out of the available choices. These masks can then be used for

all operations that can support them, for example printing or exporting to AVI or to Multi-Media image formats.

> [i] The available need to configured in application properties for each User Profile before they can be used in the application.

6.6. STRESS ECHO

In cases where ComPACS Lite Viewer recognizes a Stress Echo examination in the DICOM fields, it creates a new menu on the service window (above the thumbnails window).

In this menu, all the different stages and views of the examination are available so it is very easy to choose a particular stage by clicking on the *Stress Echo* menu. You can also change stage or view by clicking the small arrows on the right of the menu.
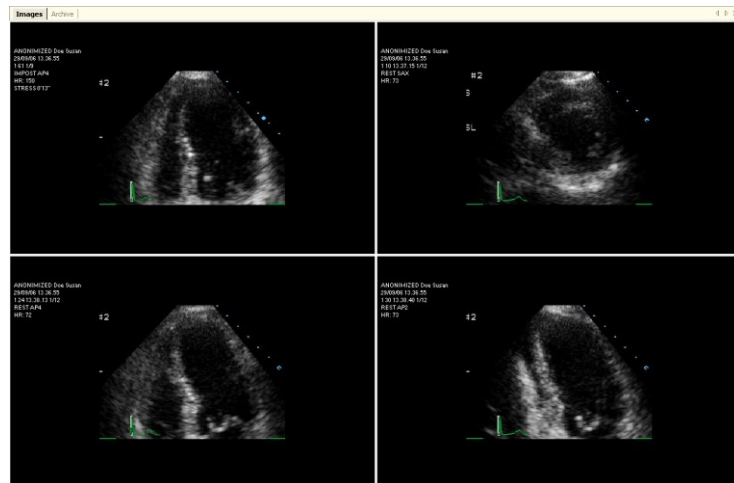
Depending on user settings, ComPACS will automatically open the first view or the first stage. Furthermore the playback speed can be set to 50% and the synchronization to the start-end of the loops. The information about the view, stage and heart rate will be displayed as image overlays.

When the study is closed, the viewing preferences will return to their original value.

Clicking the *File* menu, then on *Settings* and selecting the *Stress Echo* tab, the user settings can be viewed and modified if necessary.
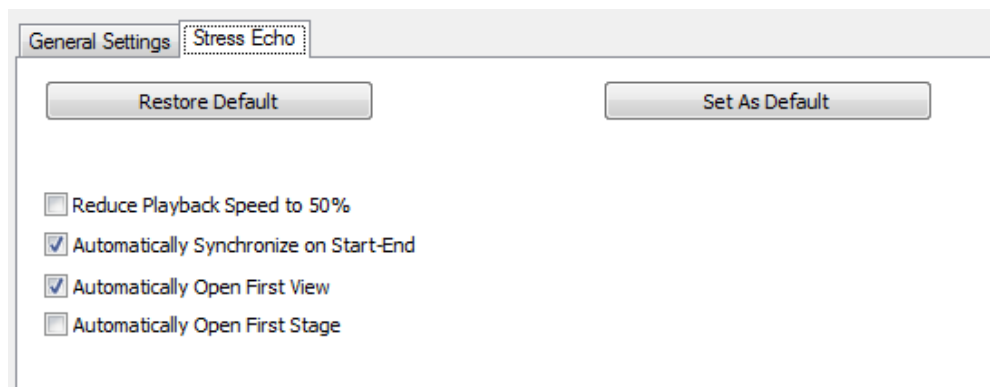
ComPACS Lite Viewer allows shuffling between a stage and a view by clicking the *shuffle* button.

 This shuffling is possible with all views and stages recognized by the viewer in the DICOM header of the file. If such information is not stored in the DICOM file, the stress echo protocol will not be automatically detected.

If more than one acquisition has been performed for the same stage and view, a rectangle, containing the number of such acquisitions, will be displayed as an overlay to inform the user.
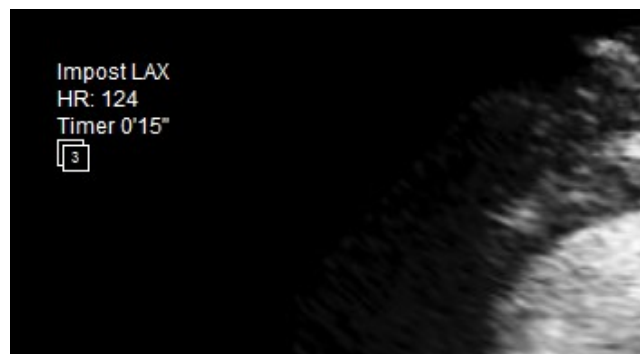
Clicking the left mouse button within the rectangle will display a menu with the list of such different acquisitions. Selecting an item in the list will update the display accordingly. The selection will persist until the study is closed.
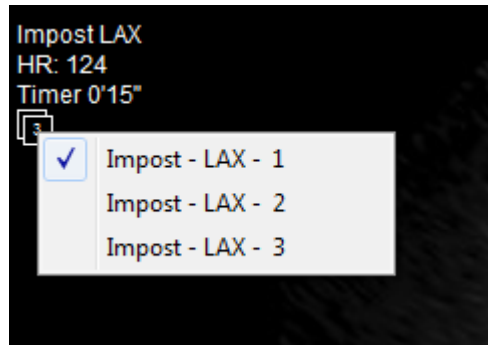
6.7. PRINTING OR EXPORTING TO MULTI-MEDIA FORMATS

6.7.1 AVI EXPORT

The ComPACS Review Station allows saving loops in AVI format to embed them in *Microsoft®* *PowerPoint* presentations. To save a loop in AVI format, click on *File* menu and then on *Save Loop As* (hotkey **Ctrl+L**)
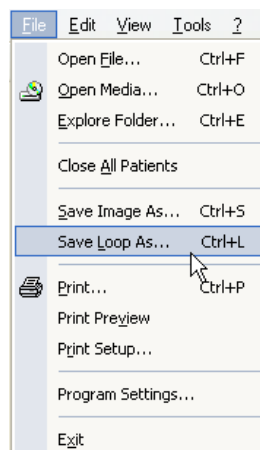
This operation opens a new window where you can set some of the properties of the AVI file:

- Trimming, i.e. setting the start and end frames.
- Cropping, i.e. *Entire View, Selected Image,* or *Selected ROI.* (Please note that a ROI needs to be first selected in the view window for the *Selected ROI* option to be available.)
- Masking. For this option to be available it is necessary to first select and activate the mask in the view window. The mask will remain valid for all export operations.
- Zoom, expressed as a percentage of the original view.
- FPS – Frames per Second.
- Compressor. This exploits the list of AVI CODECS installed on your Windows® OS.

Please make sure the CODEC used to generate the AVI file is also available on the system that is intended to open/review the file.
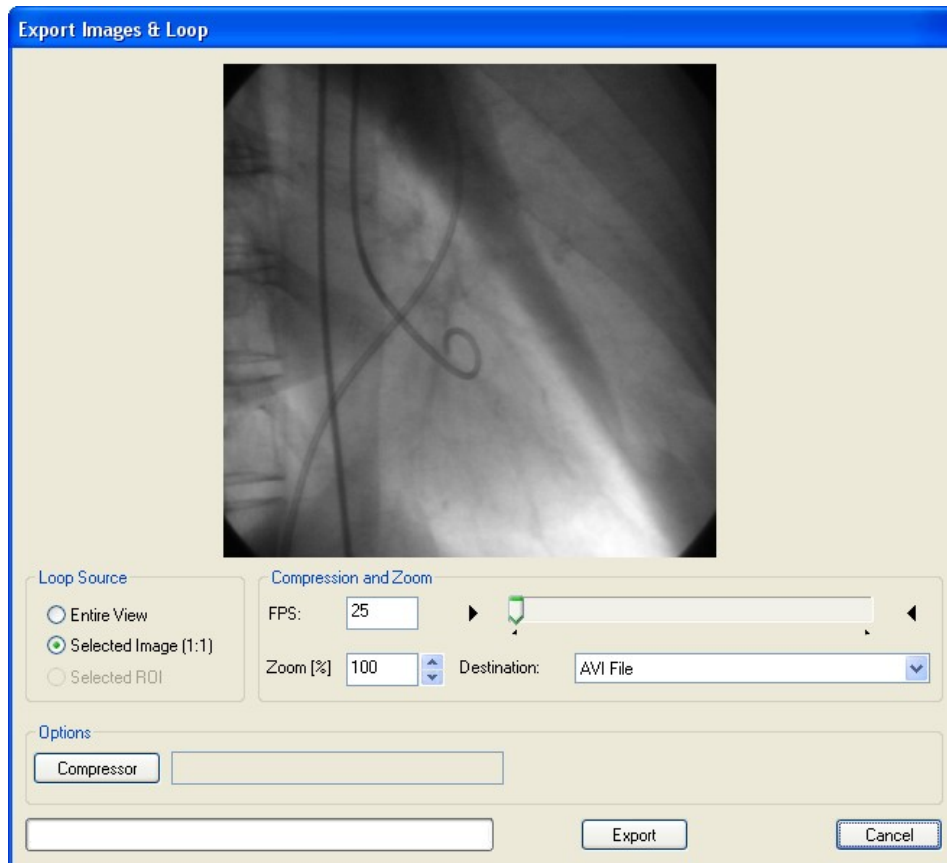
6.7.2 FRAME EXPORT

With the software it is also possible to export a single frame to a multi-media file. To do so, click the *File* menu, and then on *Save Image As* (hotkey **Ctrl+S**).
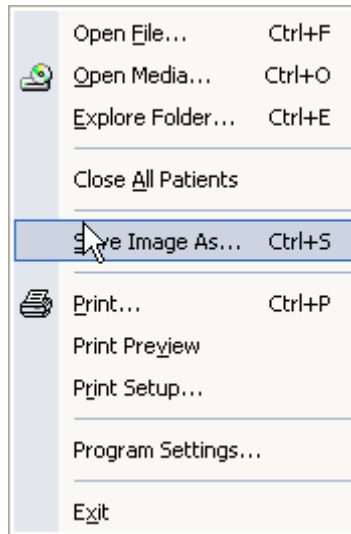
This operation opens a new window where you can set some of the properties of the output file:

- Cropping, i.e. *Entire View*, *Selected Image* or *Selected ROI*. Please note that a ROI needs to be first selected in the view window for the *Selected ROI* option to be available.
- Masking. For this option to be available it is necessary to first select and activate the mask in the view window. The mask will remain valid for all export operations.
- Zoom, expressed as a percentage of the original view.
- Output format (for example *TIFF*, *JPEG* or *BMP*).
- Compression Quality, where applicable.

6.7.3 PRINTING IMAGES

Another way to export images is printing.

ComPACS Review Station allows printing images by clicking the *Print* button or by clicking on *File* menu and then *Print* (hotkey **Ctrl+P**).
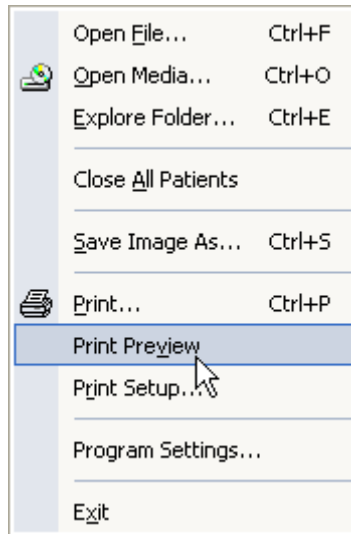
In that window you can hide, show or edit the details of a patient.
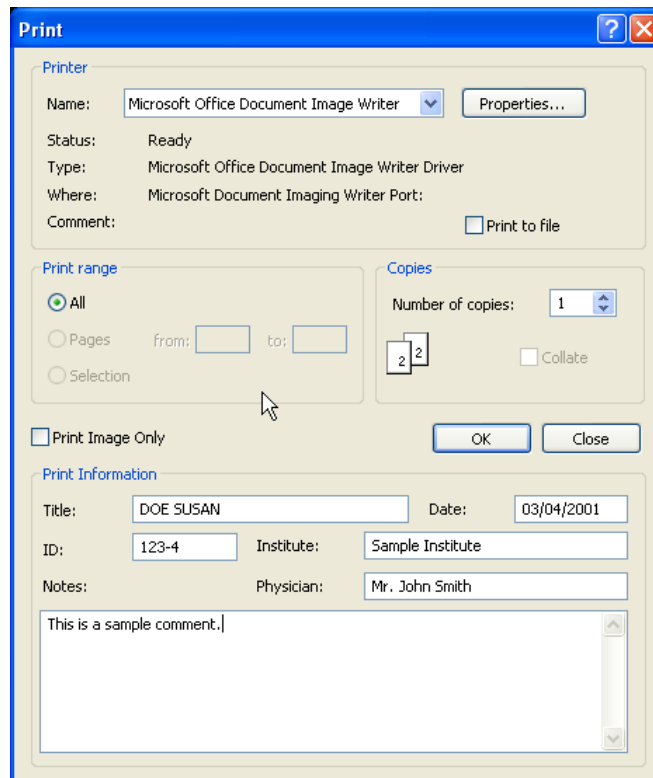
The software also allows setting some printer properties such as page type and margins by clicking on *File* menu and then on *Print Setup*.

Also, before printing it may be useful to have a preview. This is possible with ComPACS Review Station by clicking on *File* menu and then on *Print Preview*.
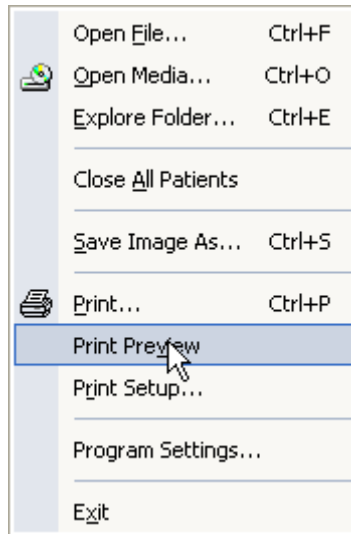
By doing this a new tab is opened displaying the page to be printed.
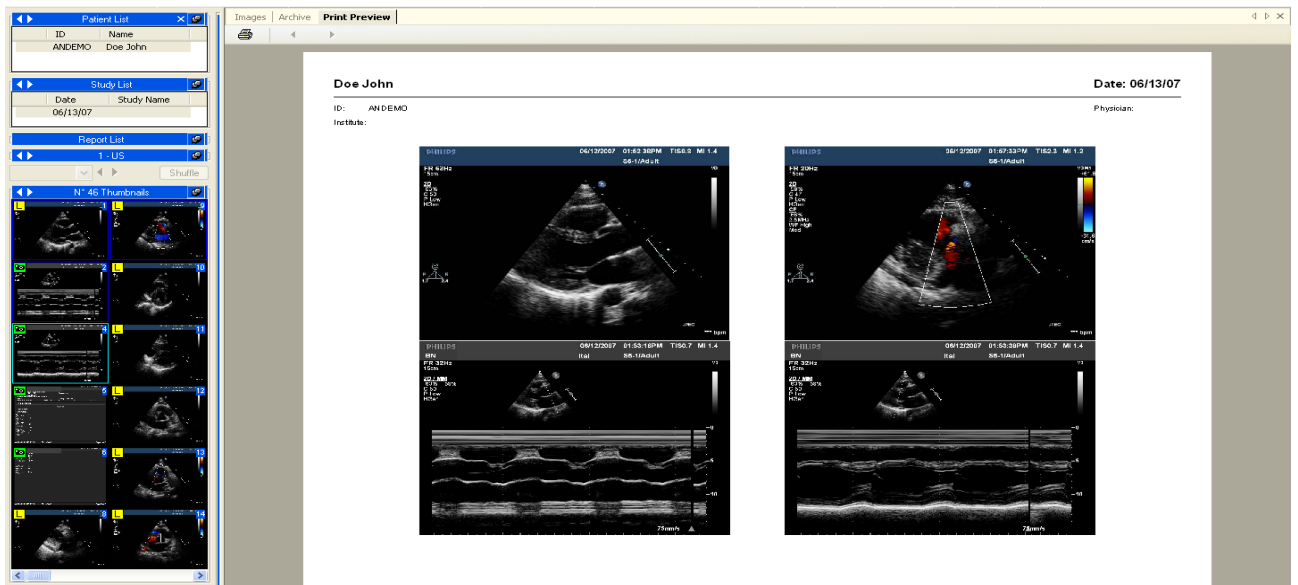
6.8. EXPORTING TO DICOM FOLDERS OR MEDIA

To export selected items to a folder or to removable media you can simply right-click on the image thumbnail, series, study or patient in the *service window* displays and select the *Export* function from the pop-up menu.
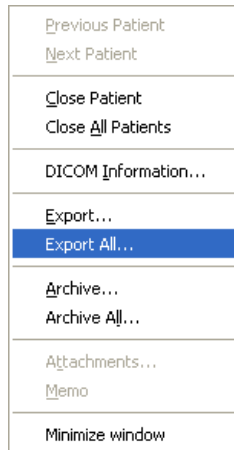
The process is practically identical to the archive process. Please refer to the section of this guide that addresses the archive process for a more detailed description. Here you need to click the *Export* button instead of the *Archive* button to activate the function. At this point an additional dialog is displayed, as shown below.
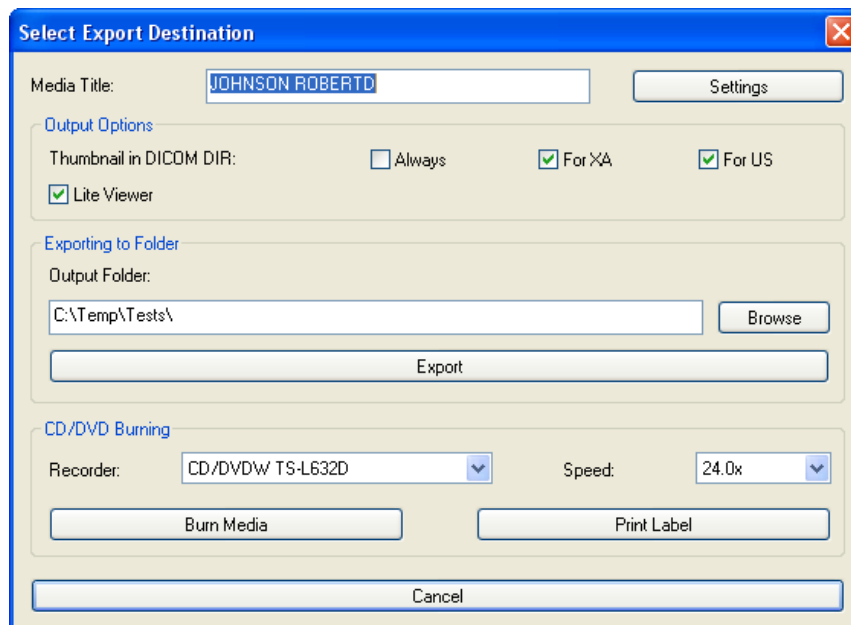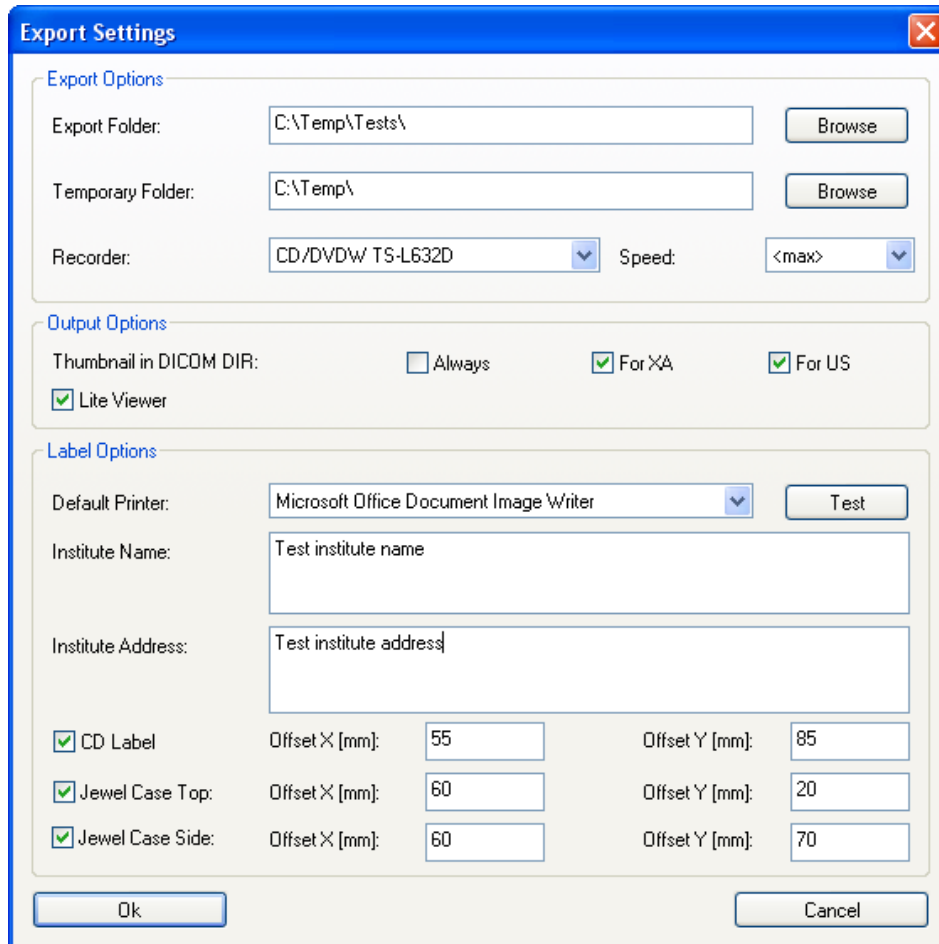
In this window you need to indicate the desired destination, such as a folder or a removable media, as well as some indications on the output format:

- If pre-built thumbnails need to be placed in the DICOMDIR (some viewers are not capable of managing DICOMDIRs with such information).

- If a lite viewer needs to be burnt together with the image set.

These settings can be defined as well as some additional information for label printing by clicking on the *Settings* button.

7

7. PROPERTIES SETTINGS

It is possible to set several general properties of the software by clicking on *File* menu and then on *Program Settings*.
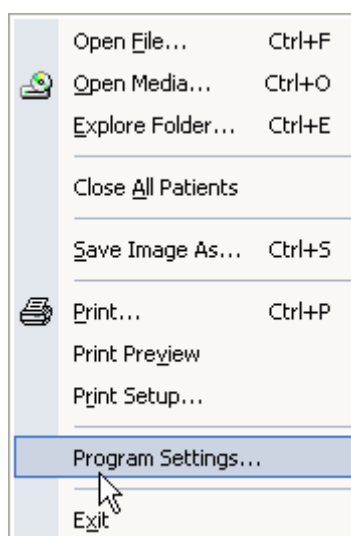
A new dialog window appears.
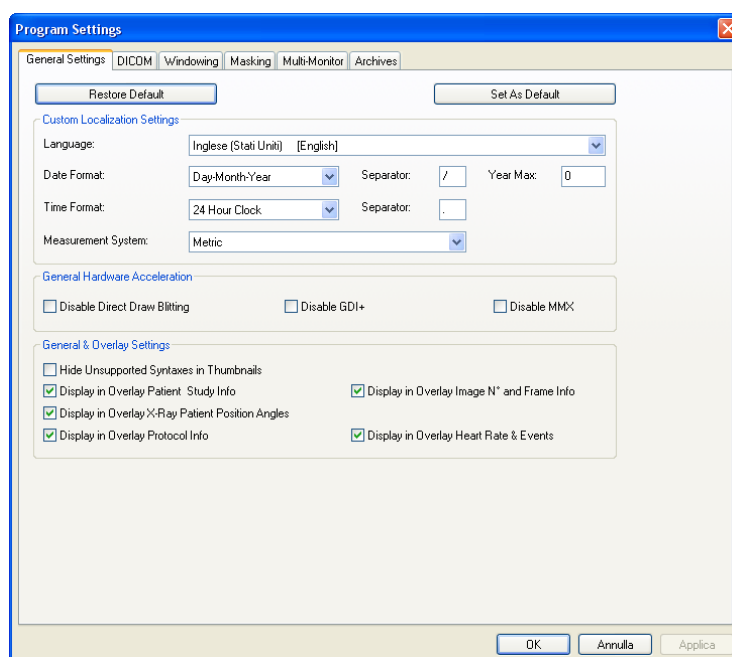
Here you can set the general parameters to optimize the performance of ComPACS Review Station and to customize some functions. In particular you will notice the following tabs:

General Settings – On this tab you can select the localization preferences (language, measurement system, date & time displays), the hw/sw acceleration features, and the image overlay settings.

DICOM – On this tab you can select specific DICOM conversion/interpretation options as well as checking if any specific proprietary plugins are installed.

Windowing – On this tab you can select the pre-defined windowing levels to be later selected. For easier access and management, these levels can be arranged in groups and indicated either as *center/width* levels or *low/high* levels depending on your preferences.

Masking – On this tab you can select the pre-defined masks to be applied to automatically anonymize images and loops. For easier access and management, these masks can be arranged in modalities and groups. Different DICOM values can be specified for each mask in order to allow the system to automatically select the best mask for a particular DICOM file.

Multi-Monitor – Addressed in the multi-monitor chapter.

Stress Echo – In this window it is possible to select the specific settings for the Stress Echo Module. Please refer to the Stress Echo chapter for further information.

Changing these properties requires in-depth knowledge of ComPACS Review Station and with the applications of your computer.

Additional tabs may be present in relation to the optional modules installed.

8. THE ARCHIVE

8.1. QUERY & RETRIEVE

8.1.1 NORMAL QUERY

To query the local or remote archive to retrieve data, click on the *Search Archive* button [image] or select *Search Archive* from *Archive* menu.
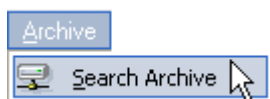
The *Archive* interface is opened in the tabs window. In this interface, you can decide the querying option.
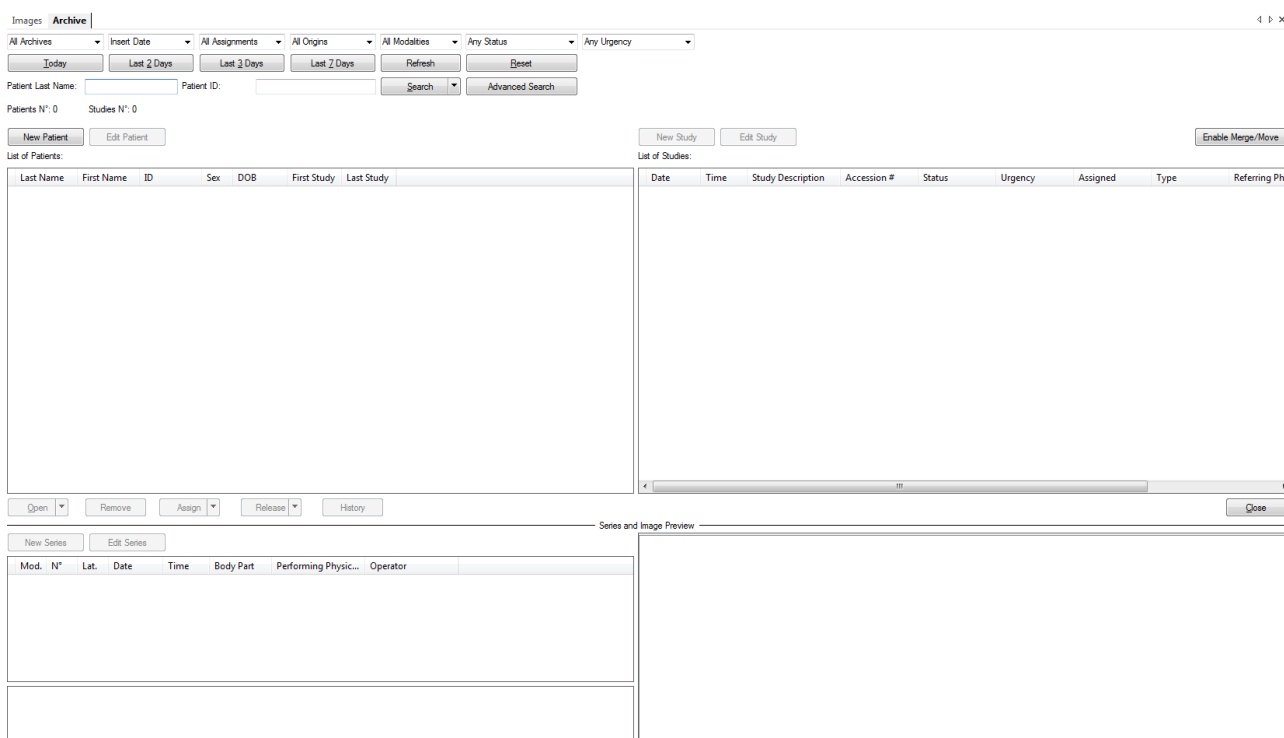
In the top portion of the window set the query parameters; the results are displayed in the window in a similar way to the one used to retrieve studies from media.

At the top of the window, by clicking the drop down menus, you can choose different search options and some result filtering information:

- Choosing which Archive to search or if all archives are to be searched simultaneously.
- Choosing the search date criteria. This determines if the queries based on study dates are to be interpreted as the date in which the study was performed, the date in which the study was stored into the archive or the date of the study last assignment.
- Filtering on the assignments (if a study is assigned to a user or a group).
- Filtering on the origins (the Application Entities that stored the object as defined and grouped using the *Web Tool*).
- Filtering on the modalities to query for.
- Filtering on the status of the study (created, in progress, etc.).
- Filtering on the urgency of the study.

⚠ Some filters or query options may depend on Server Side functionality and may not function correctly for all archives.

The top buttons allow the operator to process the query (*Search* button filtered on the *Patient Last Name* or *Patient ID* or predefined date queries such as *Today*, *Last 2 Days*, *Last 3 Days* or *Last 7 Days*).

The default behavior of the search buttons is to clear the result list and execute the query. Alternatively, by clicking the arrow to the right of the *Search* button, it is possible to search without resetting the results. In this case the new results will be added to the already listed ones.

Search ▼
Search
Search without Resetting Results
Advanced Search ...
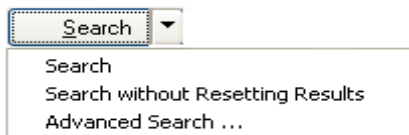
8.1.2 QUERY RESULTS, COLORS AND INFORMATION ICONS

The results are shown in the lists below.

The layout is arranged as follows:

- On the top left hand side are the patients matching the query.
- On the top right are the available studies for the selected patient.
- On the lower left are the available series for the selected study.
- On the lower right are the available object items for the selected series. These objects are organized in tabs according to the different types.
- On the bottom left, if available, a thumbnail display for the identified objects.
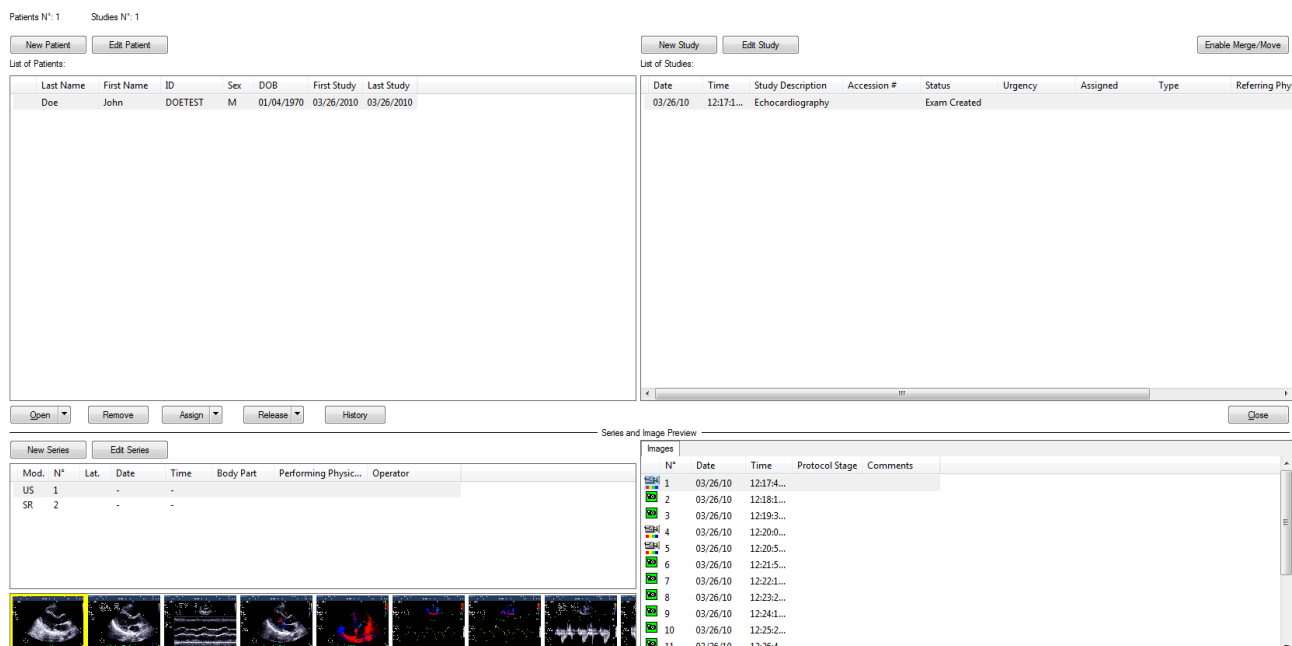
To the left of each item (patient, study, series or object) a number of different icons may be present, providing additional information on the status of the corresponding item:

- 📎   - *Attachments*. This means that the item has attached one or more external documents such as, Microsoft Word files, Excel sheets, or PDF files.

- 🗒️   - *Notes*. This means that the item has an associated note to inform users of important information.

- 🔵   - *Media*. This means that the item has been backed up on media. If the icon is only partially present it means that only a portion of the item (for example a subset of the images within a study) has been backed up on media.

- 🟡   - *Deep Archive*. This means that the item has been backed up to a deep archive. If the icon is only partially present it means that only a portion of the item (for example a subset of the images within a study) has been backed up to a deep archive.

- 🗄️   - *Near Line Data*. This means that the item is not entirely present in the on-line archive and needs to be retrieved from a deep archive before being displayed. The retrieve and display time will consequently take a longer time.

At the patient level additional icons will also inform on:

- the urgency status for the studies of the patient the icons refers to. These icons ⬦, 🟢, 🟡, 🔴 are explained in more detail in the PATIENT AND STUDY URGENCY STATUS section.
- the report status for the studies of the patient the icons refers to. These icons ▯, 📄, 🔳, 🟩 are explained in more detail in the PATIENT, STUDY AND REPORT STATUS section.

Furthermore the color of text for the query results may change to underline the status of the related item in the archive as follows:

- ONLINE.   This means that the item is on line. The text color is standard black text.

- NEARLINE.   This means that the item is present only in a deep archive and it needs to be retrieved before being displayed with a consequent longer display time. The text color is green.

- OFFLINE.   This means that the item is present only in backup media and can only be retrieved by physically locating the media and inserting it into the review station. The text color is brown.

- UNAVAILABLE. This means that the item files are either corrupt or have been removed from the system before backup. These items can no longer be retrieved. The text color is red.

8.1.3 ADVANCED QUERY

This module allows performing complex queries by posing constraints on patient, study, and series data.

In the *Archive* screen, by clicking on the *Advanced Search* button, you can further specify the parameters for the query.

As you can see in the following figure there are many parameters that allow you to make a more organized and optimized query.
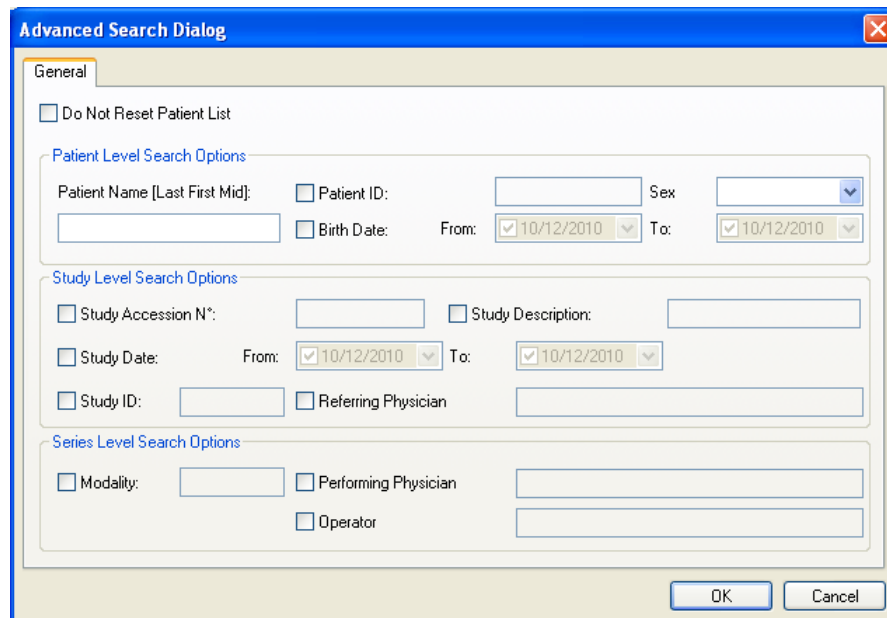
Please note that the information inserted in the fields may be incomplete; it is enough to enter just the first characters. Wildcard characters (* ?) are allowed.

The availability of simple or advanced queries depends on the features of the server. Whereas it is fully functional with the *ComPACS Server* you may experience some limitations with third party DICOM servers.

8.1.4 RETRIEVAL AND DISPLAY

To retrieve a selected item from the archive, click the *Open* button. The images will be automatically displayed when retrieved. The software automatically detects if the information is already present in the local archive or if it is necessary to open a communication channel with the remote server to retrieve the necessary information

The system behavior when opening a patient has changed. Instead of opening all studies belonging to the patient, only the most recent study is opened. If you would like to open one or more studies, please first select the patient, then select the studies to be opened and finally click the *Open* button.

If you want to compare different studies or patient you can click on small arrow to the side of the *Open* button and select the related function.
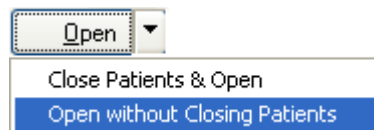
8.1.5 WEB COMPRESSION

When retrieving images from a ComPACS Web Server it is possible to adjust the compression to optimize the download time in relation to the available bandwidth and requested image quality. A drop down menu allows the selection of the compression level applied.
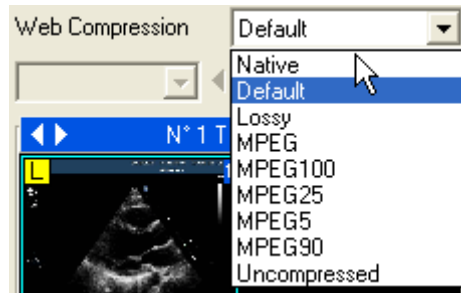
The items in the list are those pre-configured by the system administrator. The *Native* value corresponds to the files as they were stored to the server, whereas *Default* corresponds to a default compression also pre-configured by the system administrator.

STOP The selected compression level in the drop down list must be chosen before the images are retrieved from the archive window. To change the compression level of an already opened study you must first close it, change the compression level, and then re-open it.

8.2. STUDY TYPES

It is possible to associate a type to a study by double-clicking on the *Type* field in the study panel list. A dialog window will prompt you with the list of types based on the configuration settings within the *Web Tool*.

8.3. ASSIGNING STUDIES

It is possible to *Assign* or *Release* a study by using the respective buttons after having selected a specific study.
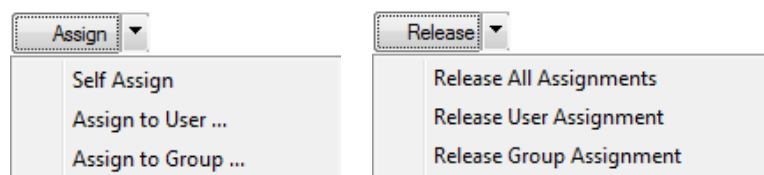
If you assign it to a different user or group, a dialog will prompt you for user selection. The assignment information will be immediately updated in the study panel.
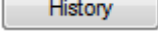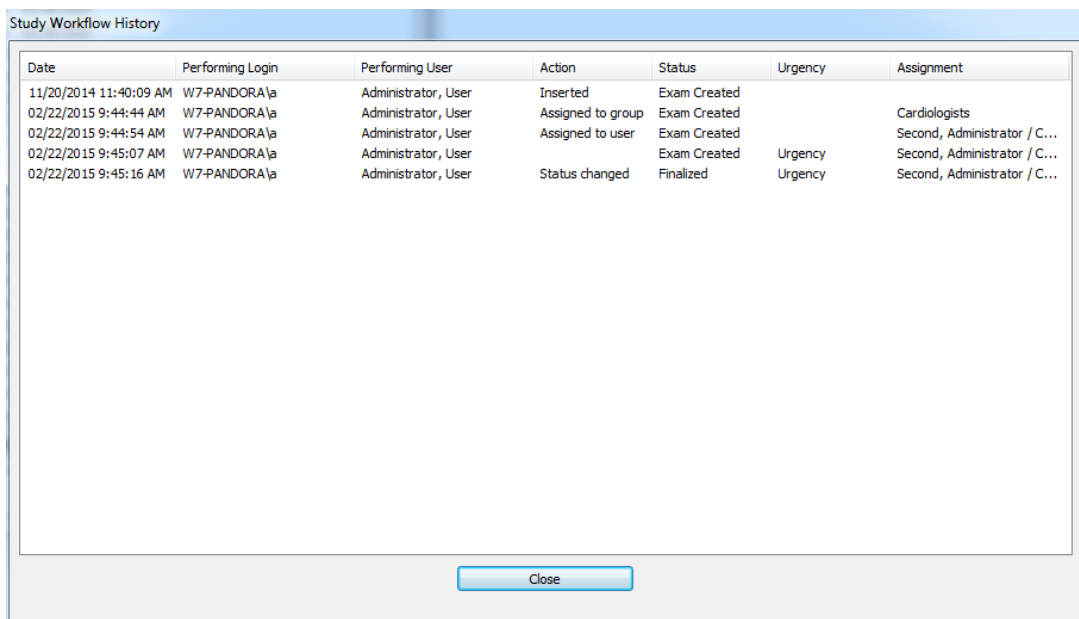
> [i] Additionally when a study is assigned to a user identified as belonging to a *Technician* or *Physician* type, the report status will automatically progress during the different reporting phases.
>
> [i] The user and group assignments are independent. A study may be assigned both to a group and to a user who belongs to a different group.
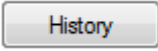
Clicking the **History** button will display a window with the history of the study assignment and status changes. The window also displays the date and time in which the change occurred and the user performing the operation.

Date	Performing Login	Performing User	Action	Status	Urgency	Assignment
11/20/2014 11:40:09 AM	W7-PANDORA\a	Administrator, User	Inserted	Exam Created		
02/22/2015 9:44:44 AM	W7-PANDORA\a	Administrator, User	Assigned to group	Exam Created		Cardiologists
02/22/2015 9:44:54 AM	W7-PANDORA\a	Administrator, User	Assigned to user	Exam Created		Second, Administrator / C…
02/22/2015 9:45:07 AM	W7-PANDORA\a	Administrator, User		Exam Created	Urgency	Second, Administrator / C…
02/22/2015 9:45:16 AM	W7-PANDORA\a	Administrator, User	Status changed	Finalized	Urgency	Second, Administrator / C…

8.4. PATIENT, STUDY AND REPORT STATUS

You can modify the status of a study by clicking on the status field in the list. A dialog window will allow the new status selection.
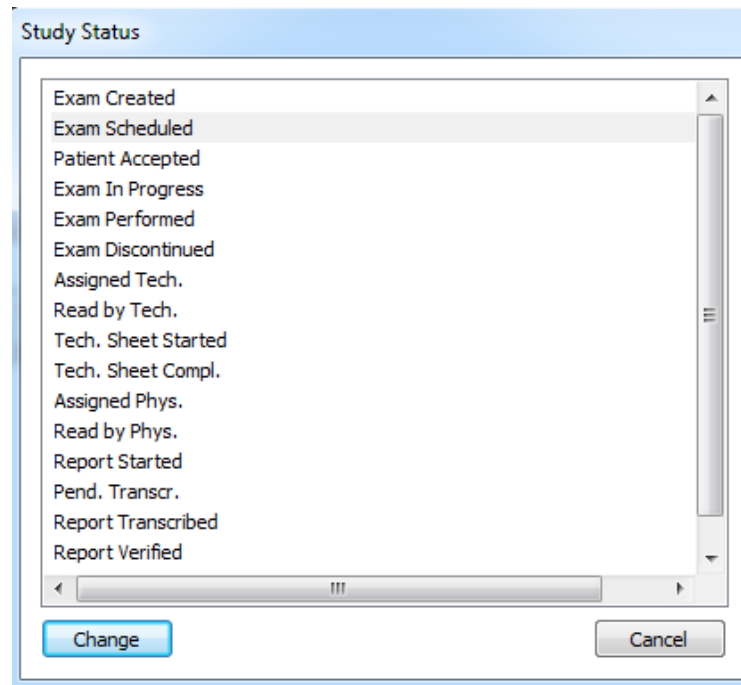
Unless your user account belongs to a profile with "Admin Management" rights, you may be subject to certain restrictions on the basis of the system configuration. It is possible that some states can be set only automatically by the system (for example using DICOM MPPS) and not manually by the user. Also it is possible that some states, once reached, cannot be manually modified. The "Change" button will be grayed out in such circumstances to prevent the change.

The above status change is also performed automatically by the ComPACS Worklist and/or HL7 Server when such components are installed.

Additionally when a study is assigned to a user identified belonging to a *Technician* or *Physician* type the report status will automatically progress during the different reporting phases.

The status information will be displayed in the study panel list. Moreover at the patient level a set of symbols to the left of the patient name will warn the user if some reports are pending activity for the specified patient.

The possible icons with descending priority are the following:

- *No icon*. This means that at least one study for the patient is still *Not Read*.

- *Tech Sheet Started*. This means that at least one study for the patient is in the preliminary tech sheet reporting phase.

- *Tech Sheet Completed*. This means that at least one study for the patient has a completed technician sheet which is pending reporting or report verification.

- *Report Verified*. This means that at least one study for the patient has a verified report which is pending finalization.

- *Report Finalized*. This means that all reports for the study have been reported and finalized.

8.5. PATIENT AND STUDY URGENCY STATUS

You can modify the urgency status of a study by clicking on the urgency field in the list. A dialog window will allow the new urgency status selection.
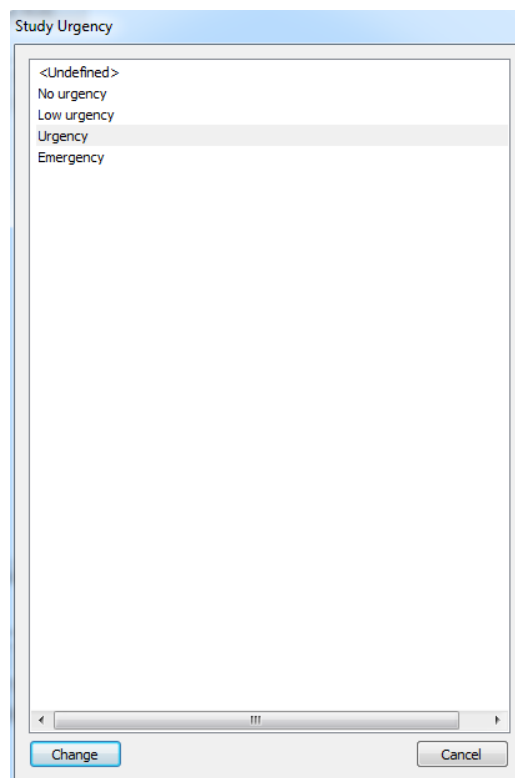
 Unless your user account belongs to a profile with "Admin Management" rights, you may be subject to certain restrictions on the basis of the system configuration. It is possible that some states can be set only automatically by the system (for example using HL7) and not manually by the user. Also it is possible that some states, once reached, cannot be manually modified. The "Change" button will be grayed out in such circumstances to prevent the change.
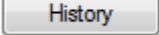
 The above status change can be performed automatically by the HL7 Server when such components are installed.

The status information will be displayed in the study panel list. Moreover at the patient level a set of symbols to the left of the patient name will warn the user about the urgency of its related studies.

The possible icons with descending priority are the following:

- 🔴 - *Emergency*. This means that at least one study for the patient has an emergency status.

- 🟡 - *Urgency*. This means that at least one study for the patient has an urgency status.

- 🟢 - *Low Urgency*. This means that at least one study for the patient has a low urgency status.

- ⚪ - *No Urgency*. This means that at least one study for the patient has a no urgency status.

- *No icon*. This means that the urgency for all the patient studies has not been defined.

Clicking the [History] button will display a window with the history of the study urgency status changes. The window also displays the date and time in which the change occurred and the user performing the operation.

| Date	Performing Login	Performing User	Action	Status	Urgency	Assignment
11/20/2014 11:40:09 AM	W7-PANDORA\a	Administrator, User	Inserted	Exam Created		
02/22/2015 9:44:44 AM	W7-PANDORA\a	Administrator, User	Assigned to group	Exam Created		Cardiologists
02/22/2015 9:44:54 AM	W7-PANDORA\a	Administrator, User	Assigned to user	Exam Created		Second, Administrator / C…
02/22/2015 9:45:07 AM	W7-PANDORA\a	Administrator, User		Exam Created	Urgency	Second, Administrator / C…
02/22/2015 9:45:16 AM	W7-PANDORA\a	Administrator, User	Status changed	Finalized	Urgency	Second, Administrator / C…

8.6. ADDING OR EDITING NEW ITEMS

To add a new item it is sufficient to click the *New Patient*, *New Study* or *New Series* buttons and enter the content in the displayed dialog windows:

New Patient   New Study   New Series
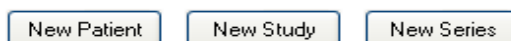
Alternatively a selected item can be edited by clicking the corresponding buttons:

Edit Patient   Edit Study   Edit Series
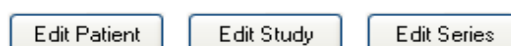
8.6.1 ADDING OR EDITING PATIENTS

The information about the patient to be added is displayed in the following page:

In the top portion of the dialog window it is possible to import the patient from the available databases. By default the system will search all the available information sources but a specific one can also be selected using the drop down menu. The "Default Demographics Provider" is always present and it searches the ComPACS patient database. Other external sources may also be present.

The *Search Patients* button searches the database patient demographics and the *Search Studies* button search the study worklist.

The bottom portion of the dialog window displays the selected patient information. Such information may also be manually inserted if the patient cannot be found in the information sources.

The *Select & Update* button confirms the selection of the identified patient and updates the ComPACS database information in case it differs from the selected information source. The *New* button instead adds a new patient to the ComPACS database. Both buttons will complete the operations and the dialog will close.

If a study search has been performed, a new dialog to add a study to the patient will be opened. This dialog will be populated with the data imported from the information source.

The window displayed for editing is very similar. In place of the *Select & Update* and *New* buttons, the *Reset*, *Update* and *Merge* buttons can be found.

These buttons respectively reset the patient information to the original values, update the database with the new inserted information or merge the patient with the patient selected from the list.

8.6.2 ADDING OR EDITING STUDIES

The information about the study to be added is displayed in the following page:

In the panel on the right, a pre-built list of study descriptions can be found for rapid selection. These descriptions are system wide settings to be configured by your system administrator.

Below the study descriptions you can find information about the study *Status* and the procedure steps related to the selected study. For each procedure step it is possible to define the *Modality* and the group of Application Entities (*AE Group*) associated to the procedure.

Click the *New* button to confirm the operation. The new study will be added.

The window displayed for editing is very similar. In place of the *New* button an *Update* button is present to confirm the new information. The confirmed changes will immediately affect the study and all its contained items (series, objects).

8.6.3 ADDING OR EDITING SERIES

The information about the series to be added is displayed in the following page:

In the panel on the right, a pre-built list of series descriptions for each modality can be found for rapid selection. These descriptions are system wide settings to be configured by your system administrator.

Click the *New* button to confirm the operation. The new series will be added.

The window displayed for editing is very similar. In place of the *New* button an *Update* button is present to confirm the new information. The confirmed changes will immediately affect the series and all its contained objects.

8.7. MERGING AND MOVING ITEMS

Merging and moving Objects, Series, Studies, or Patients can be easily and intuitively performed using mouse based drag and drop actions.

These operations carry out critical changes to the information in the ComPACS database and they are not reversible. To avoid their inadvertent activation, they must be first enabled by clicking the following button:

8.7.1 MERGING ITEMS

To merge patients, studies or series, simply select one or more such items in their related result window, drag them over the item in the same window to which they should be merged and them drop the selection. A dialog box will warn you about the importance and non-reversibility of the operation which you will need to accept in order to proceed.

> At the end of the requested operations the user is advised to de-select the *Enable Merge/Move* button to inhibit other operations.

8.7.2 MOVING ITEMS

To move studies, series, or objects simply select one or more such items in their related result window, drag them over the parent item to which they should be moved and them drop the selection. A dialog box will warn you about the importance and non-reversibility of the operation which you will need to accept in order to proceed.

For parent items, only the direct parent is intended. An object has a series as its parent, a series has a study, and a study has a patient.

> At the end of the requested operations the user is advised to de-select the *Enable Merge/Move* button to inhibit other operations.

8.7.3 SPLITTING ITEMS

The splitting of the content of an item can be performed with new and move operations. For example to split the content of a study you would proceed as follows:

- Create a new study.
- Create new series of the same type of the ones already contained in the study to be split. For example if a study contains a US series, create a new additional US series.
- Select the objects that need to be separated into a different study and first move them to the new created series within the same study.
- Now complete the operation by moving the new series to the new study.

8.8. ARCHIVING PATIENT IMAGES AND LOOPS

To archive the images displayed or opened for review you can simply right-click on the image thumbnail, series, study, or patient in the *service window* displays and select the archive function from the pop-up menu.
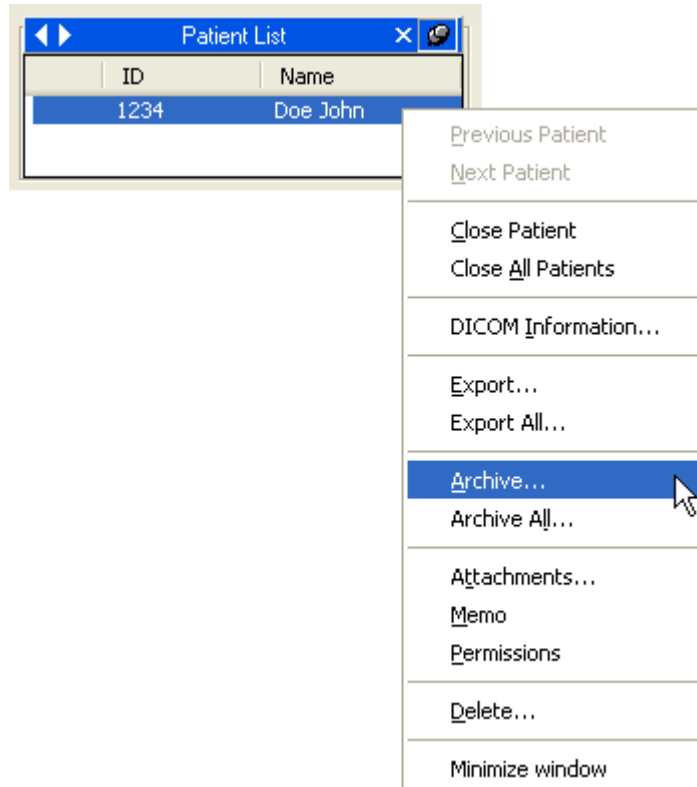
A dialog window with the list of selected image objects will be displayed. On top of the window you can choose the destination archive and see a brief summary on the items selected.

It is now possible to refine the selection by clicking on each check box to select/deselect the image or loop. You can also select/deselect a patient, a study, a series and an image.

While navigating in this object hierarchy, it is possible to examine the related DICOM information in the panels on the right hand side of the window.
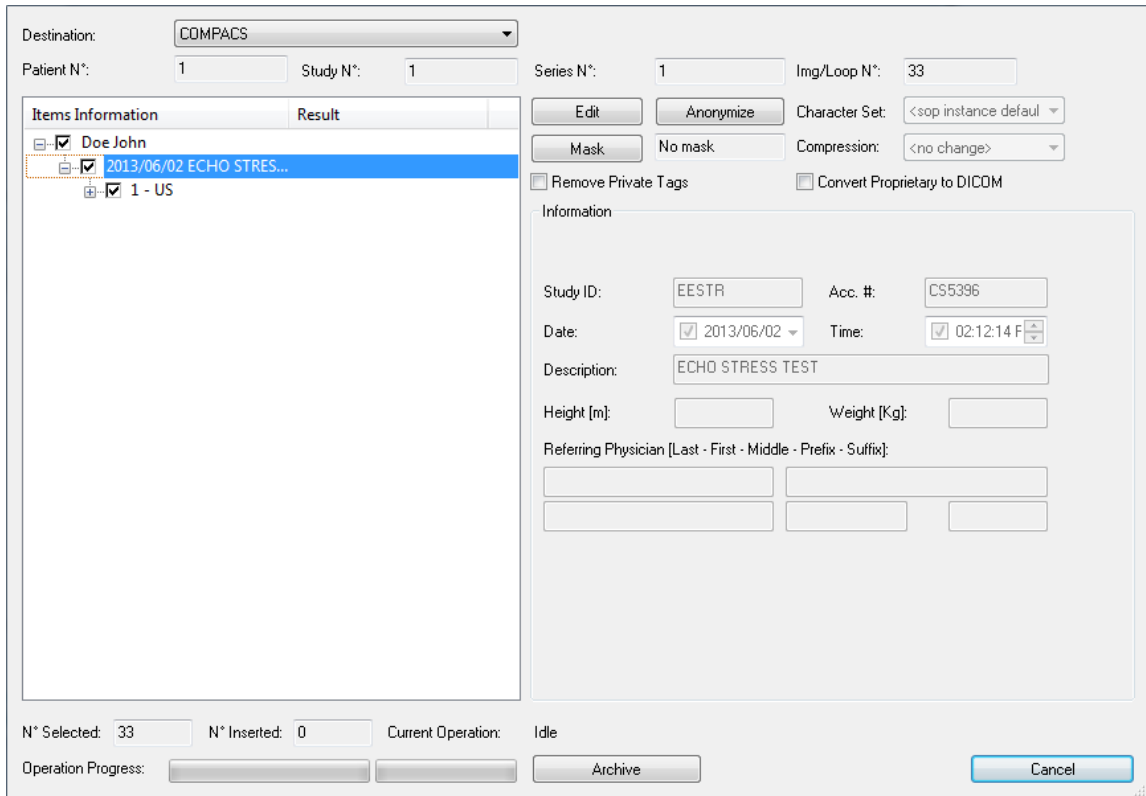
If you click the *Archive* button the selected images will be transferred to the archive. If a network archive has been selected the transfer will take longer. The slider bars indicate the progress of the transfer to the archive.

When the transfer is completed successfully a green icon will be displayed. A yellow icon indicates a warning, whereas a red icon indicates a failure. Please look at the result section at all levels for more information. In the example below to the left the archive was successful whereas on the one to the right a warning is returned because the patient was already present in the archive.
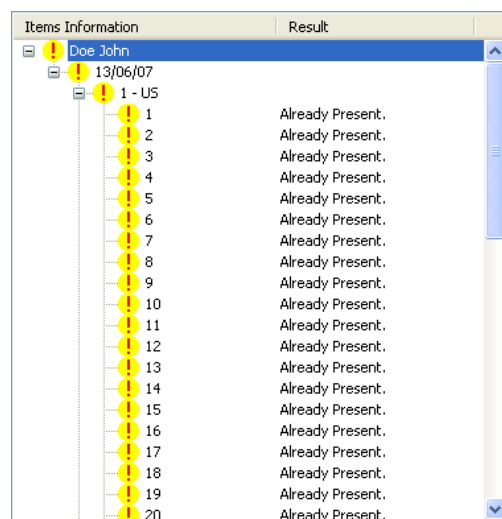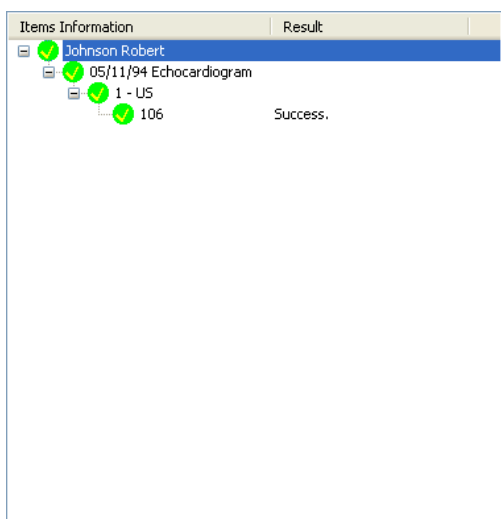
You can also archive all the data present in the control window. To do this, right-click on the *Patient List* of the control window and then select *Archive All.*

8.8.1 EDITING INFORMATION

During the archive process it is also possible to edit some of the DICOM information or even anonymize the items selected. To perform this operation, select an item and click the *Edit* or *Anonymize* button. The information panels will now be editable for you to set to the desired values.
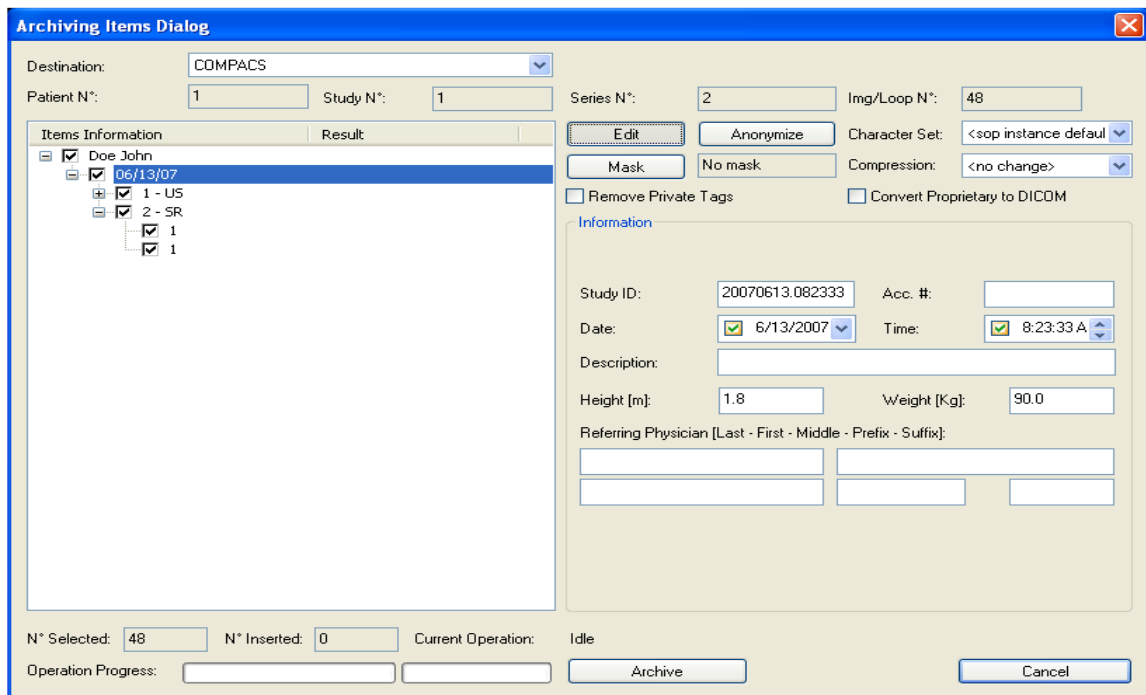
During this operation it is possible to change the character set used or change the object/image compression. Changing the character set can be performed for the entire patient set (including all sub-series) whereas changes in compression can be performed for different individual images.

It is also possible to remove any DICOM private tag from the selected objects or convert them to a standard DICOM format (for example Aloka Line Data).

By clicking again on the *Edit* button you can revert back to the original data values.

8.8.2 ANONYMIZING IMAGES

In addition to data, ComPACS also allows for the anonymization of DICOM images and loops. The technique is identical to the one described in this guide for what concerns *Masks* usage. You can allow the system to automatically detect the masks or manually select it for each image or loop.

8.8.3 TRIMMING IMAGES

The archive dialog can be resized (by dragging the bottom right corner with the mouse). This causes the resize of the image and loop information page to better display the preview of the selected item. If the item is a loop, it will be displayed as playing at a fixed frame rate of 25 frames per second. This display is not intended for diagnostic review but only for item identification purposes.
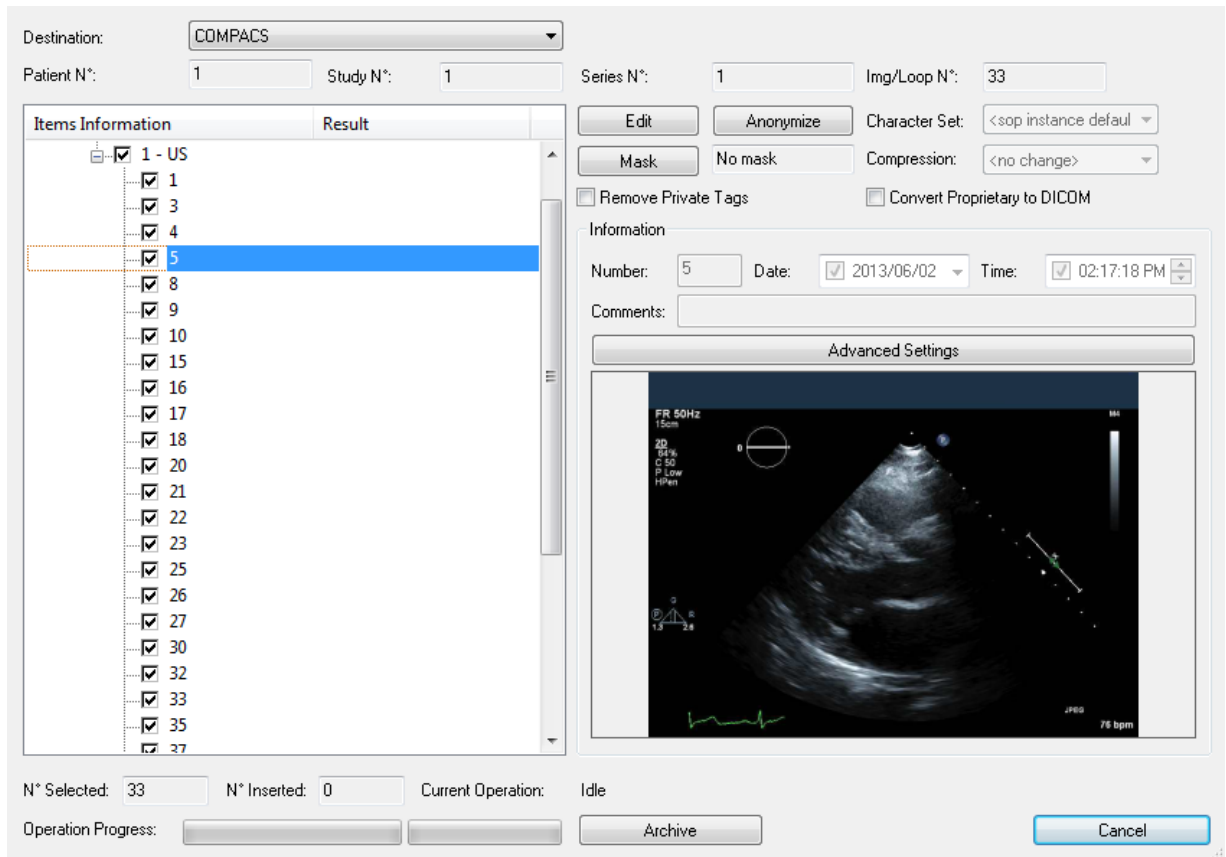
ComPACS also allows you to trim the image loops during storage. To perform this operation you need to select a specific loop and then click the *Advanced Settings* button.

A new window will appear in which it is possible to review the loop and select the trimming points.
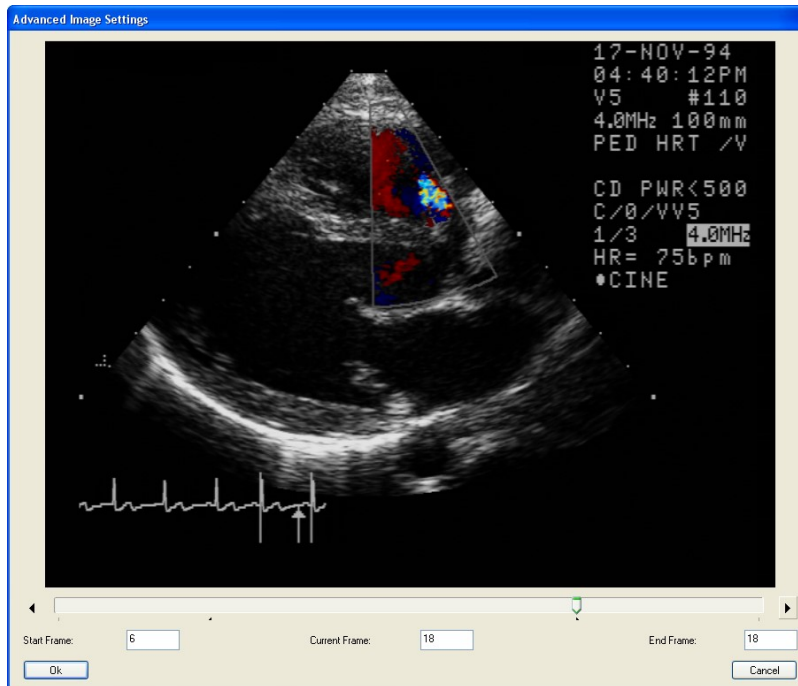
8.9. ATTACHMENTS

ComPACS Review Station, in addition to DICOM data, allows the management of non-DICOM information such as Adobe® PDF and Microsoft® Word documents as attachments.
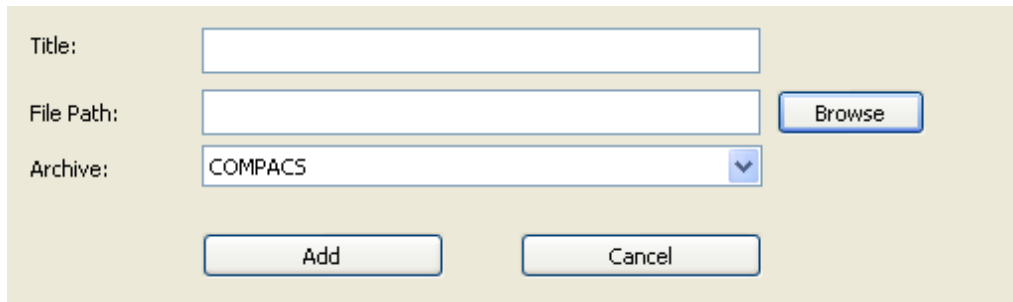
Attachments can be related to each level of the Patient/Study/Series/Object hierarchy. To attach, display or remove an attachment you simply need to *right-click* on an image thumbnail, a series, a study, or a patient name and then click on *Attachments*.
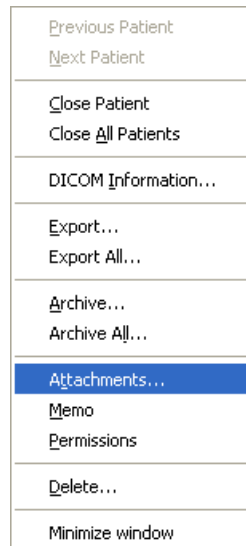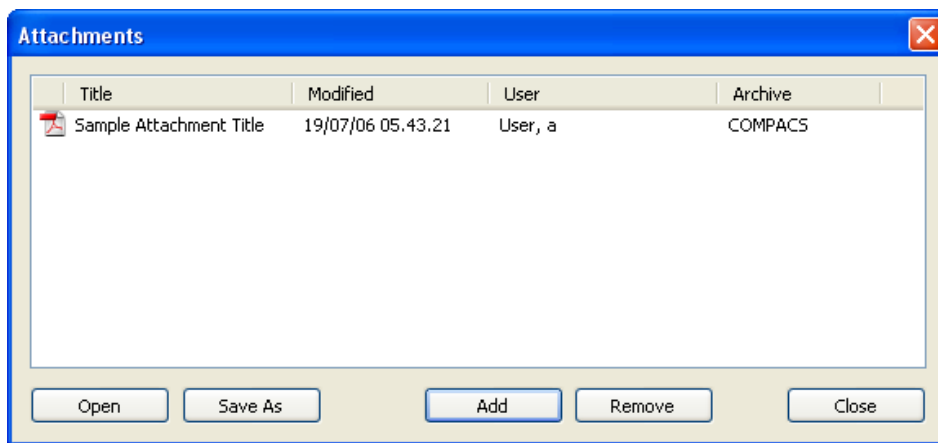
A new window is displayed in which all attachments for the selected item are listed.
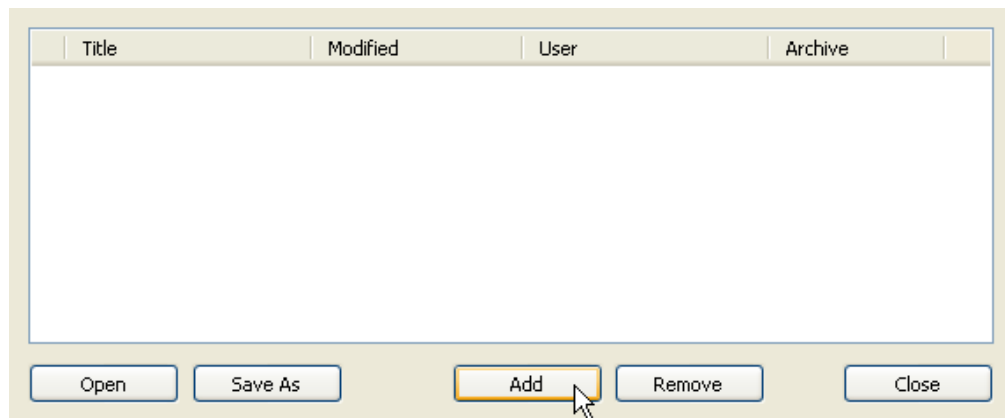
Clicking the *Add* button allows you to add a new attachment.

After you have given the attachment a title (and selected the appropriate archive if more than one is configured) you can browse your computer and then attach any kind of file. Clicking on *Add* will effectively attach the selected file. If the file is associated to an icon, the related icon will be displayed to the left of the selected title as shown below.

The attachment list also identifies the user that stored the attachment, the archive in which it has been stored and the last modification date.

It is also possible to manage the attachments by selecting them and then clicking on the button related to the requested operation: *Open* – to open the attachment within ComPACS, *Save As* – to save it to an external file, *Remove* – to delete the attachment.

Please note that the operations allowed on attachments depend on your privileges to the selected item (Patient, Study, Series, or level). Therefore some or all of the operations may be grayed out because they may not be accessible.

If the attachment is opened within ComPACS, it will be displayed as a new tab window.
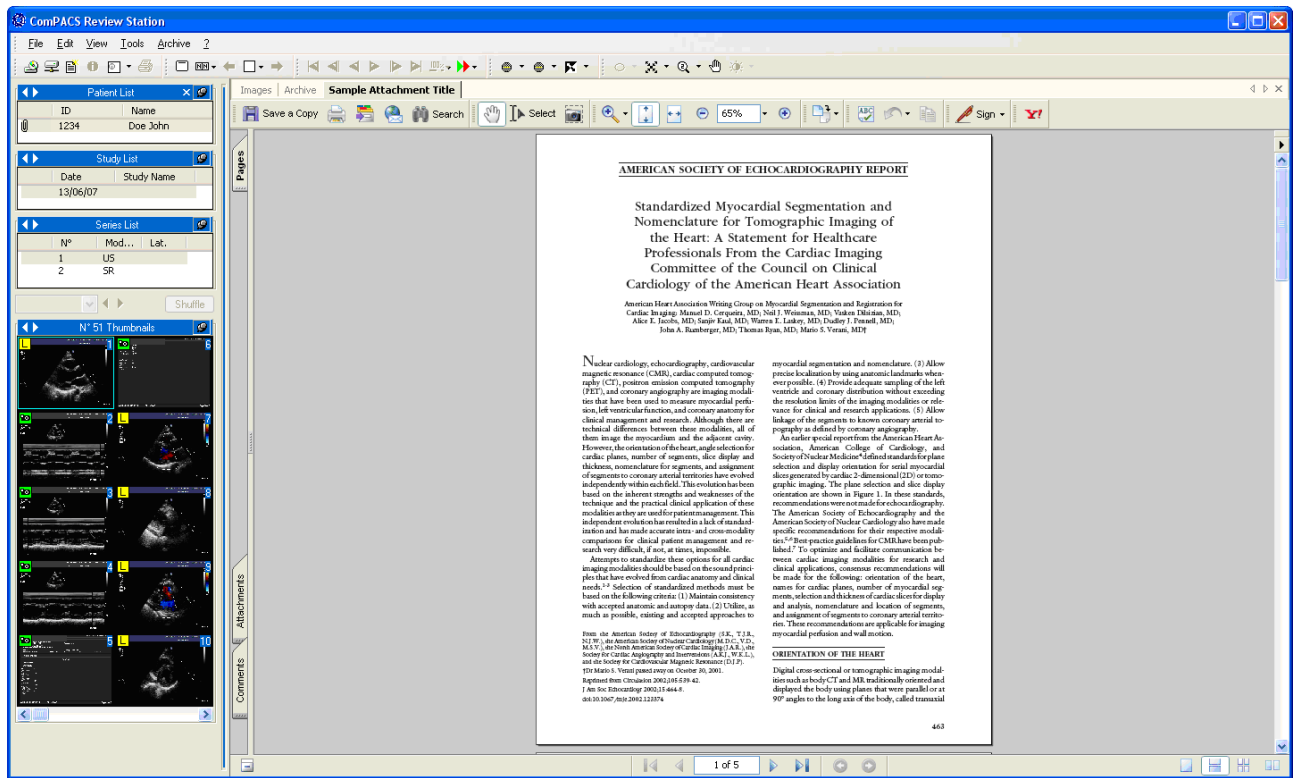
 For the document embedding function to work, it is necessary that the selected document and related viewing application comply with ActiveX and Active Document technology. Examples are Adobe® PDF and Microsoft® Office files.

If an item contains one or more attachments, the user will be warned by a *paper clip* symbol that will be visible to the left of the related item as shown in the picture below. The same information is also displayed in the query window.

8.10. MEMO

A memo is a way to attach an important note to an item in the Patient/Study/Series/Object hierarchy.

To access the memo options, right-click on an image thumbnail, a series list, a study or on a patient and then select *Memo*.
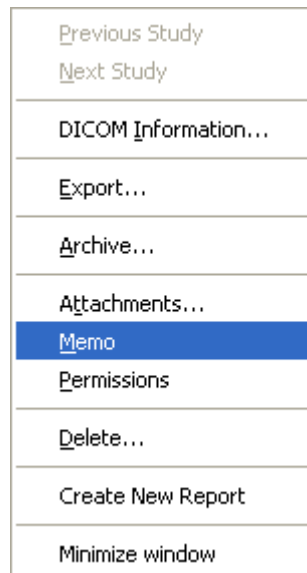
The operation will open a *memo* window.
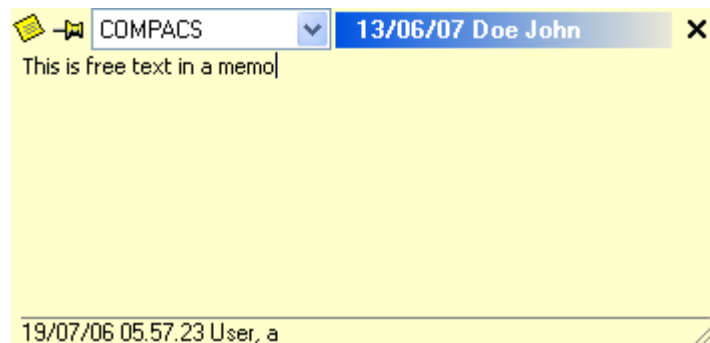
The window, in addition to the main memo text, will also show the *Archive* and the item's main information (for example patient name or study date) to which the *Memo* belongs, the user that created or last modified the memo and the modification date.

To edit the memo text simply type directly into the memo box. By clicking the X in the upper right corner you will confirm your selection and close the window.

To *Remove* the memo you can clear the text and close the window. Alternatively, this and other functions are available by clicking on the small *memo* icon on the top-left of the window accesses.

> Please note that the operations allowed on memos depends on your privileges on the selected item (Patient, Study, Series or level). Therefore some or all of the operations may be grayed out because they are not accessible.

If an item contains a *Memo,* the user will be warned by a special symbol visible to the left of the related item as shown in the picture below. The same information is also displayed in the query window.
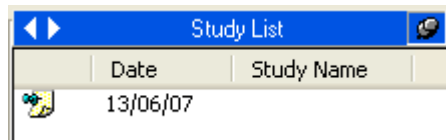
8.11. PERMISSIONS

ComPACS allows advanced and granular permissions to be associated to each item (Patients, Studies, Series, Objects, or even Attachments and Memos). To open the permission menu, right-click on an image thumbnail, series, study, or on patient name and then select *Permissions*.
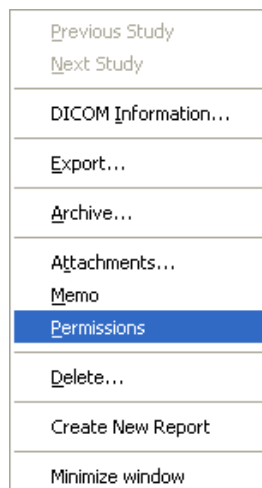
Below is an example of the (ACL) *Access Control List Editor* window that will be displayed.
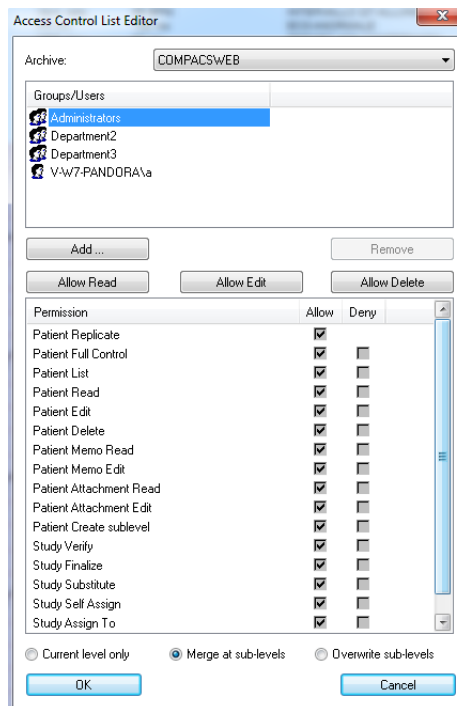
In the window you can select a user (or a group of users) and allow or deny operations such as reading, editing, deleting, etc. Three quick settings buttons (*Allow Read*, *Allow Edit* and *Allow Delete*) assist you in the most frequently modified security settings.

 The names of such operations refer to the item selected and directly convey the types of permission being managed. However please refer to your system administrator for more details.

It is also possible to add or remove users and groups from the list by clicking the *Add* or *Remove* buttons. When the *Add* button is selected, a related window will appear to allow the user or group selection.
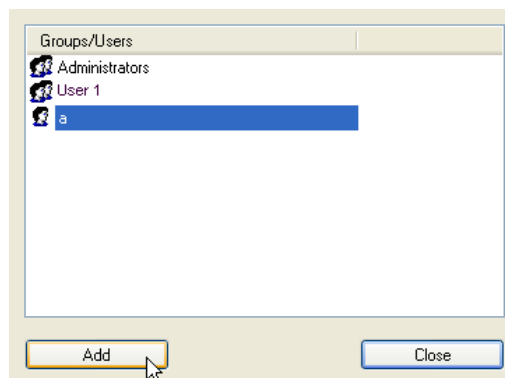
Please note that the users and groups that can be added are only those registered for the ComPACS application. Please refer to your system administrator to modify this list.

Upon confirmation, it is also necessary to specify how the changes will be applied to the ComPACS database. Three different options are available:

Current Level Only — Modifies the permissions only for the selected level.

Merge at Sub-Levels — Modifies the permissions for the selected level and then merges the changes to all the sublevels (for example the sublevels of a study are its series and objects). The merge operation will preserve any additional and specific permission settings at the lower levels if not affected by the changes made (for example if it refers to different users or groups).

Overwrite Sub-Levels — Modifies the permissions for the selected level and then applies it to all the sublevels (for example the sublevels of a study are its series and objects), overwriting and prior permission settings that may have been set for such levels.

It is important to note that to set the permissions parameters, you must have *Full Control Permission* on the related object.

These permissions will refer to the item level (Patient, Study, Series or Object) you have selected but will necessarily be propagated to the upper levels to maintain consistency in the permission settings. For example setting a *Read* permission at the *Study* level requires at minimum a *List* permission at the *Patient* level.

Changing the permission settings will affect the possibility users will have to list, read, modify and delete the different objects in the ComPACS database. Please ensure to use this feature with great care.

9

9. MANAGING EVIDENCE AND REPORTS
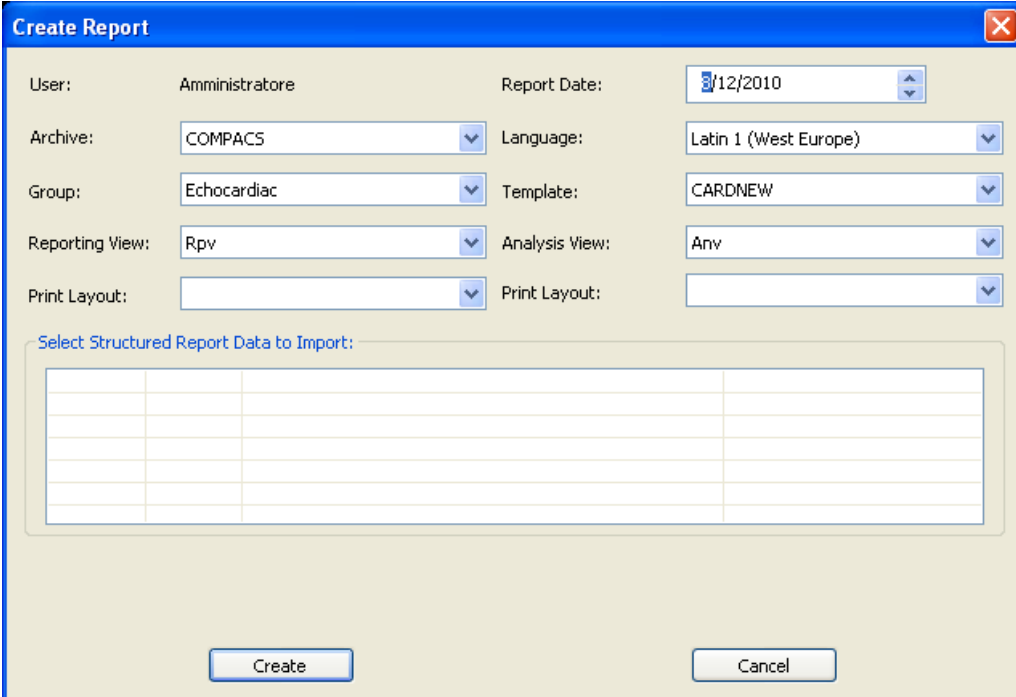
9.1. CREATING A NEW REPORT

STOP To be able to create or open a report, you must first adequately configure your system. Please refer to your system administrator and to the *System Administrator's manuals* for more details.

In order to create a new report, a study first needs to be opened for review.

Then click the open/create report button 📄 on the toolbar. A dialog window will prompt you to enter a number of parameters.

Let us examine these parameters in detail:

Report Date — this is the date for the new report. It defaults to the current system date.

Archive — this is the archive in which the created report will be stored.

Language — this is the language used in the report. It defaults to the configured language for the client application entity to which your review station corresponds.

> ⚠ It is important to choose the correct language. Otherwise some special characters may not be stored correctly into the report.

Group — report types are grouped to allow you to better identify and select the type required. This field allows you to select the group of report types you are interested in, for example *Echo Vascular* reports.

Template — this field identifies the report type (or template) that you effectively need to create. For example a *Vascular Report*.

Reporting View — the information stored in a report of a certain type (identified by its template) can be displayed in different ways (Views), if present, depending and optimized for reporting purposes based on the body part, user preferences, patient pathology, trial protocol, etc. A possible example is the *Carotid View* for a *Vascular Report*.

This field allows the selection of the default view for each report. Please note that this is just an initial selection that can then be changed dynamically during the processing of the report.

Print Layout — under the *Reporting View* field it is possible to select the *Print* Layout. With this parameter you can define the final print layout of the information stored in a report of a certain type (identified by its template and reporting view).

This field allows the selection of the default print layout for each report. Please note that this is just an initial selection that can then be changed dynamically during the reporting process.

Analysis View — the information stored in a report of a certain type (identified by its template) can be displayed in different ways (Views), if present, depending and optimized for image analysis purposes based on the body part, user preferences, patient pathology, trial protocol, etc. A possible example is the *Carotid View* for a *Vascular Report*.

This field allows the selection of the default view for each report. Please note that this is just an initial selection that can then be changed dynamically during the analysis process.

Print Layout — under the *Analysis View* field it is possible to select the *Print* Layout. With this parameter you can define the final print layout of the information stored in an analysis report of a certain type (identified by its template and analysis view).

This field allows the selection of the default print layout for each analysis report. Please note that this is just an initial selection that can then be changed dynamically during the analysis process.

Once you have selected the right parameters you can create the report by clicking the *Create* button. Please note that this operation may take some time depending on the size and type of report being created.

The system stores the last settings used by each user in report creation. Therefore if you always create the same type of report it will be sufficient to directly click *Create*.

9.2. IMPORTING EXISTING REPORTS

If existing reports that have not yet been associated are detected, such reports will be listed in the dialog window. If checked, the content of these reports will be included and merged in the newly created report.

This is the typical scenario when a preliminary report has been generated from the modality and stored to the system. In this case the report window parameters will be automatically selected on the basis of the detected preliminary report type and configuration.

 If only a single report is present and if ComPACS is capable of automatically and univocally assigning the necessary parameters, the report window dialog may not be displayed and the report object may be automatically opened for editing.

 Such dialogs will always be displayed if more than one report needs to be merged to warn the user about such a condition. This operation should be performed with great care to make sure the data in the different reports does not conflict.

9.3. EDITING A REPORT

In order to open an existing report for editing, the report object needs to be opened and visible in the *Report List* control window, on the *Data* tab.
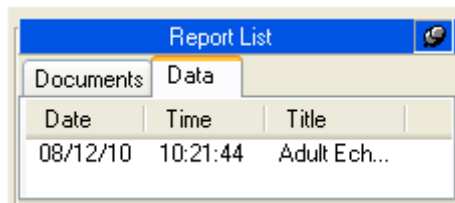
The operation is identical to the one performed to create a new report. Click the open/create report button on the toolbar .

If only a single, non-obsolete, report is present then the object will be automatically opened for editing.

If additional, non-obsolete, structured report objects have been stored to the system, the report window dialog described in the previous sections will be displayed. This will both warn the user about the existence of such additional reports, and it will also allow such reports to be imported and merged with the current report.

This typically occurs if the report is initialized prior to image and measurement acquisition. In this situation the measurements structured data will have to be imported when the initialized report is completed.

⚠ Importing and merging reports should be performed with great care to make sure the data in the different reports does not conflict.

9.4. OPENING REPORT DOCUMENTS

🛑 To be able to create or open a report it is first necessary to adequately configure your system. Please refer to your system administrator and to the *System Administrator's manuals* for more details.

In order to open a specific report document, a study containing a report needs to be opened for review. The available reports for the selected study are listed in the *Report List* control window, on the *Documents* tab:

Finalized reports and generally documents are stored as PDF files in DICOM Encapsulated PDF format. Such items are visible in the *Documents* tab and can be opened by a simple mouse click.

ℹ A *DICOM Encapsulated PDF Report* object may also be present if created by a third party system and then stored in the ComPACS Database.

🛑 To display the PDF report it is necessary for the *Encapsulated Report Module* to be installed and licensed. Furthermore, Adobe® Acrobat PDF Reader needs also to be installed.

The report structured information is generally stored in a DICOM SR object and visible in the *Data tab*. These items can be opened by a simple mouse click and reviewed in depth with the specific analysis or reporting modules licensed. This is equivalent to right clicking on the report item and selecting *Open Report Data*.

> **If the report was not generated by a *ComPACS Review Station* or *ComPACS measurement import plugin,* but was received directly from a third party template, then upon clicking the report object, you will be prompted with a dialog window that will require the user to select the template and view information.**
>
> **This operation is similar to report creation shown in the previous section but it does not lead to the generation of a new report, only to the association of the correct template and views.**

It is also possible to manually associate a report to a different template. This can be performed by right clicking on the report item and selecting *Assign Reporting Template to Structured Report Data.*
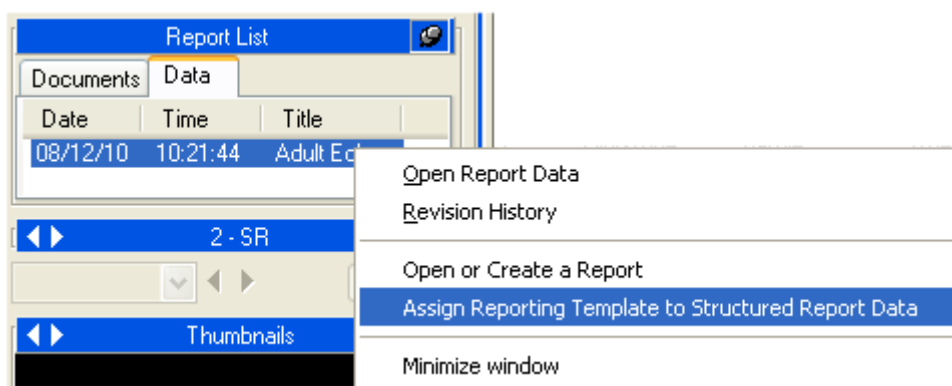
9.5. REPORT REVISION HISTORY

ComPACS keep track of report revisions. The *Report List* tabs will show only the most current revision of the documents and structured data opened for review. To examine any previous documents, right click the item and select *Revision History.*
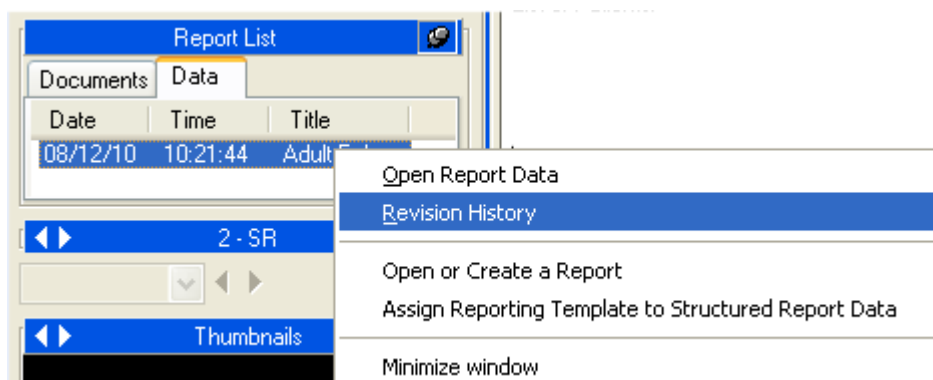
A window will display in a hierarchical tree the revision history for the selected item. The report date, time, type and status is reported for each revision.
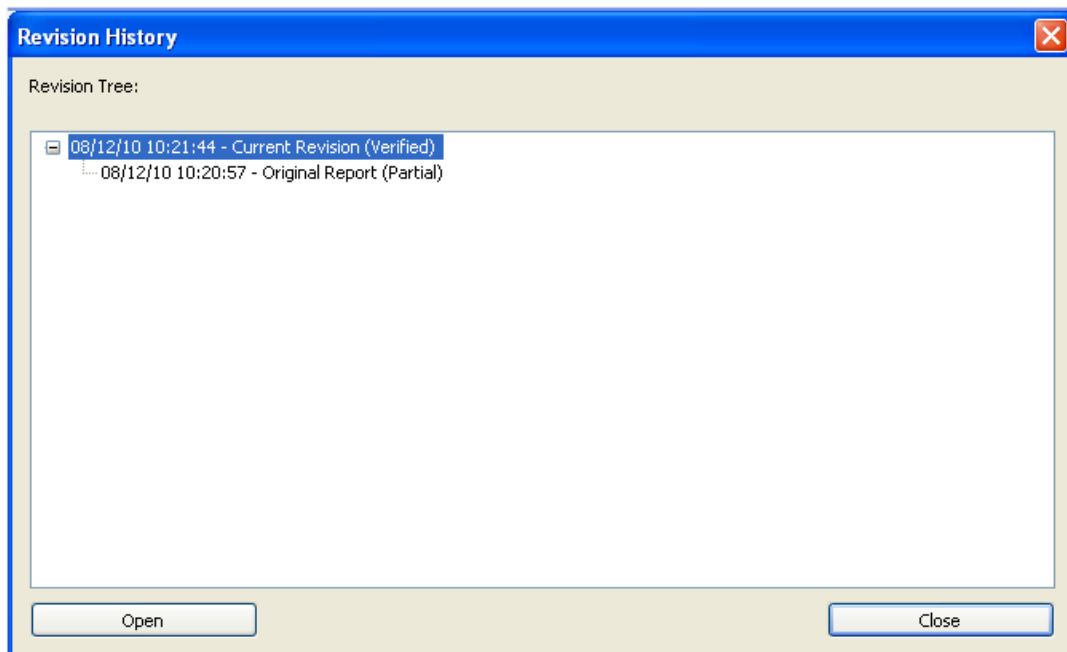
It is possible to open an obsolete document revision by selecting it and clicking on the *Open* button. These documents will be available for review but cannot be edited.

⚠ The revision history is limited to the object opened for review from the ComPACS archive. If only a limited set of objects is opened on the workstation, the items in the revision history shall be incomplete and may lead to an incorrect interpretation of the current report status.

⚠ Please ensure that all documents are always opened or that at least the most current report revision is always present in the opened list.

10. ECHO ANALYSIS

10.1. ACTIVATING OFF-LINE ECHO ANALYSIS

If ComPACS ECHO is enabled on your system, the following button will be visible in the toolbar, on the right hand side:

If the button is pressed down then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation, the module will request a runtime license from the ComPACS Server. If the license cannot be received, then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active, a window named "Echo Analysis" is added and visible in the control window. It can be opened or minimized with a single mouse left button click on the blue bar.
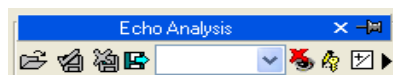
10.2. OFF-LINE MEASUREMENTS

The ECHO module provides the possibility of performing measurements on every type of echo image.

Simple measurements are always available in the *Generic* tab of the echo analysis window:
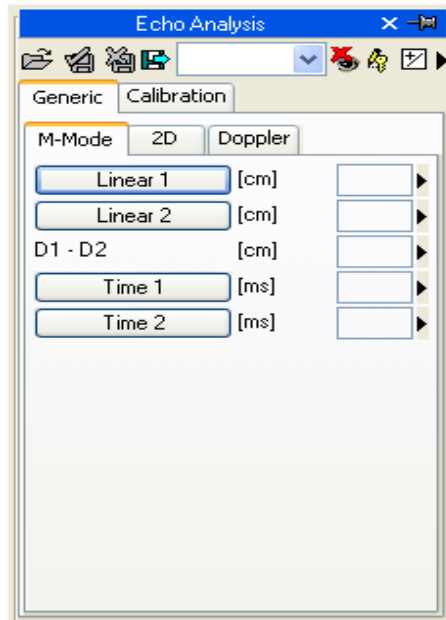
These are basic and generic M-Mode, 2D, and Doppler measurements for rapid verification purposes.

> ⚠️ Generic measurements are only temporary. They are not stored to the ComPACS database and cannot be retained.

To access a more advanced measurement panel, open either an already existing report or create a new one. This operation can be performed by clicking on the toolbar icon 📄 as described in the "*Managing Evidence and Report*" chapter.

The analysis window will be extended with an additional *Structured* tab containing all the structured measurements. The appearance and content of the tab will depend on the reporting templates and analysis views configured by the system administrator for the specific workstation or user.

> ℹ️ Structured measurements are stored in the DICOM SR object they refer to.

In this interface, only the windows corresponding to the data present in the open object will be filled (with numbers). To edit the opened report click the *Editing* icon:

To close and save the changes made click on the *Close and Save changes* icon:

To close without saving any changes click on the *Close discarding changes* icon:

To export the data it is necessary to click the *Export the report data to file* icon:

An interface will be opened where you may select the data format and the file destination.

In the drop-down list, it is also possible to select an export template based on the installed configurations.

 This functionality has been extended to export not only numerical values but also other field types (text, findings, dates, etc.). Furthermore the export also includes nested and repeated record structures (for example each phase of a echo stress study).

The template is a simple text file which lists, in separate lines, the fields which need to be exported. Each line has the following format:

FieldID; *Label - Optional*; *Unit - Optional*

If the label or the unit are not specified, the default values shall be used.

For repeated records, the list of fields need to be enclosed in the following statement:

BEGINGROUP(*Record Field ID*); *Label – Optional; Index – Optional*
… *list of fields* ..
ENDGROUP(*Record Field ID*)

The index is optional and, if omitted, all records shall be exported.

Finally some special fields consist in DICOM fields. They are identified as follows:

$(Group,Element) ; *Label - Optional*;

 Editing operations will be described in the next chapters.

10.3. IMPORTED MEASUREMENTS

The ECHO module allows importing measurements taken from the ultrasound devices through DICOM SR. Therefore, the product offers the possibility to view the data measured on the platform as well as to insert new measurements, or correct the existing ones.

For the most common ultrasound platforms that do not comply to the DICOM SR standard, some ad hoc techniques are also available to import the measurements. The ComPACS architecture allows importing such measurements and transforming them into the DICOM SR format to assure maximum portability.

When a study is opened for review and a DICOM SR object is present, the *Report List* will display such element on the *Data* tab.

The *Data* tab initially represents the measurements performed on the modality, if any. However please note that the data object will also be revised to include off-line measurements or other reporting activities.

In the *Series List*, an item line with SR as the modality will also appear. This is the DICOM series containing the DICOM SR object elements.
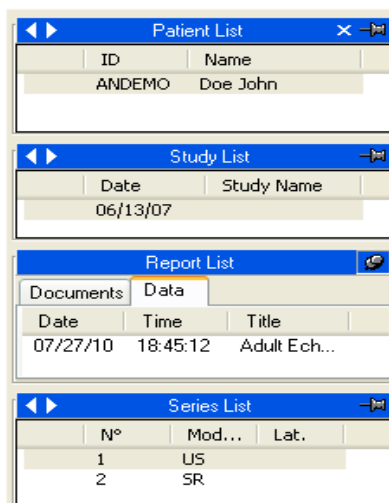
By clicking on the toolbar icon as described in the "*Managing Evidence and Report*" chapter, you can open existing reports for review and further analysis. This includes imported modality data.

Alternatively it is possible to specifically open an DICOM SR document and access the contained data by clicking on the selected SR item on the *Data* tab.

10.3.1 IMAGE CALIBRATION

The calibration information is usually contained in the DICOM file. The product exploits it to avoid a manual calibration and ensure greater accuracy. Therefore calibrating images in order to perform measurements is generally not necessary nor is it recommended.

By simply moving the mouse over the image, the calibration information will appear in the *Calibration* tab. This way it is possible to quickly verify if the image calibration is present or not.
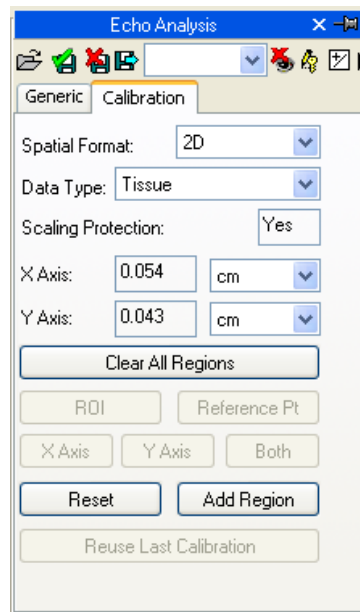
If no information is displayed when moving the mouse, the image needs to be calibrated.

Ultrasound images can contain multiple regions of calibration. Therefore it is possible that the calibration information differs in relation to the position of the mouse on the image. Also some regions may be calibrated whereas in others the calibration information may be absent.

If the calibration information is absent, it is possible to manually calibrate the entire image or a region.

The first thing to do to calibrate an image is to choose the Spatial Format (2D, Doppler, M-Mode, etc…) and the type of data (Tissue, PW, CW, etc…). Using the two drop down menus in the *Calibration* tab:

Next, establish (using the X axis and the Y axis) the calibration values to be assigned to the image. For instance, in case of a Doppler image, assign a time value on the X axis and a speed value on the Y axis. For 2D images, which have the same unit of measurement for both axis, it is also possible to calibrate both axis at once with a single diagonal segment using the *Both* button.

On the image, the mouse pointer will change into a pen and allow you to trace a segment. Click the left button once at the start point and then a second time at the end point. When finished, a dialogue window will prompt you to enter the dimension of the traced segment in the suitable unit of measurement.

It is also possible for the Doppler images to indicate the zero point position (the baseline) by the reference point button and then clicking it with the mouse.

Once the operation is performed on both axes you may decide if the calibration applies to the entire image (by clicking on *Add Region*) or only to a ROI (Region Of Interest). In the second case, select the ROI button and after tracing on the image the interest area, calibrate by clicking on the *Add Region* button.

When moving the mouse pointer on the calibrated region, you will see all the calibration information on the *Calibration* tab.

⚠ In the absence of a correct calibration all measurements on the images are invalid.

⚠ The program does not perform any control on the consistency of the calibration factor. It is <u>always</u> necessary to check the calculated calibration factor to verify whether it is admissible.

⚠ The accuracy of the calibration factor depends on the accuracy with which the segment is traced and it is inversely proportional to the pixel dimensions of the known structure. In the appendix, the reference accuracy and precision values of this approach are reported.

10.3.2 PERFORMING MEASUREMENTS

Now we are ready to perform some offline measurements on the images. ComPACS ECHO allows measuring 2D images, Doppler tracings, M-Mode images, and TDI images. For every data format there are specific measurements. For instance, in 2D the software allows measuring the length, area, perimeters, and calculates volumes. In Doppler, it allows measuring time, and speed, calculating flows, and other derived values.

Once the image is chosen, select the value to be measured on the measurement panel. In particular there are two panels: the *Generic* panel, which is always available, and the *Structured* panel which depends on the configuration set up and requires the opening of a report (intended as DICOM SR object).

> ⚠️ The generic measurements are only temporary and will not be stored to a DICOM SR Object.

By clicking on the item, the mouse pointer becomes a pen. With a few mouse button clicks on the image, the software traces the measurement (in yellow) and saves it to the ComPACS Database in the DICOM SR format. The following picture shows an example of linear measurement on a 2D image:
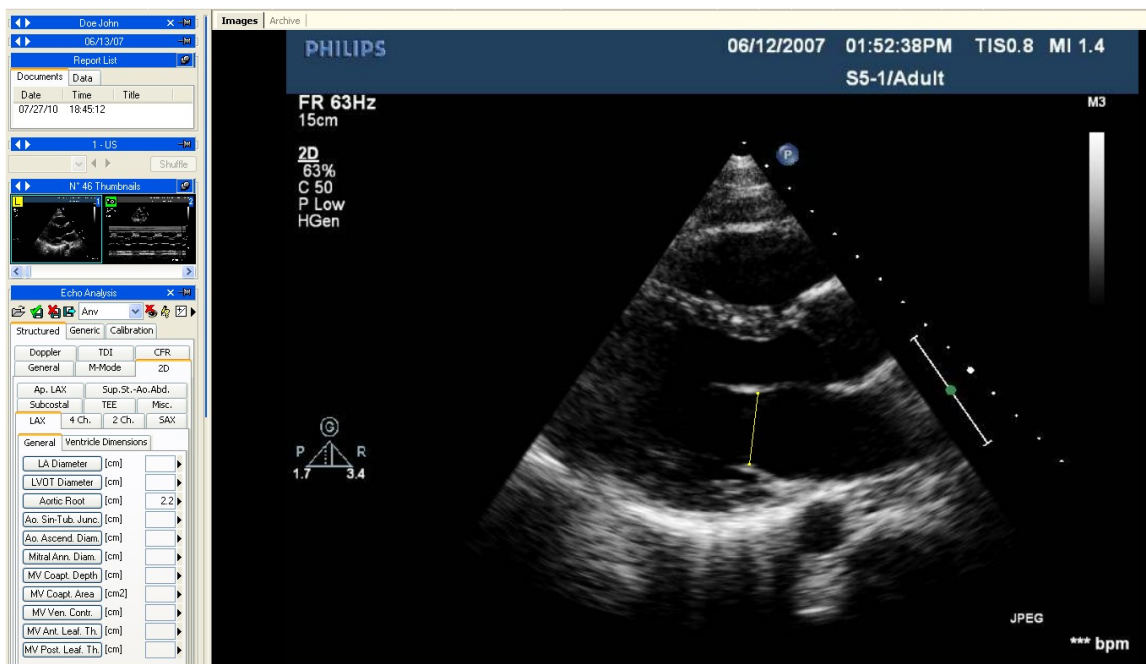
To proceed, first select the desired measurement by clicking the chosen button in the control panel. Move the cursor to the starting point of the desired measurement and left-click once, the cursor will become a pen. Move the cursor to the end point of the measurement and left clicking once will terminate the measurement and populate the result in the chosen location. For measurements that are commonly performed in sequence, such as IVSD, LVID, LVPWD, each left mouse click will continue the sequence until the sequence is complete.

In more complex measurement case (i.e.: an area), an area point is fixed at every mouse left button click and the software creates a soft line passing through such points – "*Spline*" - to give it the harmonized shape. A double click terminates the measurement. In case of a tracing error, click the right mouse button to delete points and double right click to entirely cancel the measurement.

In the following example we have measured the left ventricle End Diastolic area in a 4 Chamber projection. ComPACS ECHO also automatically calculates the long axis and the Volume.
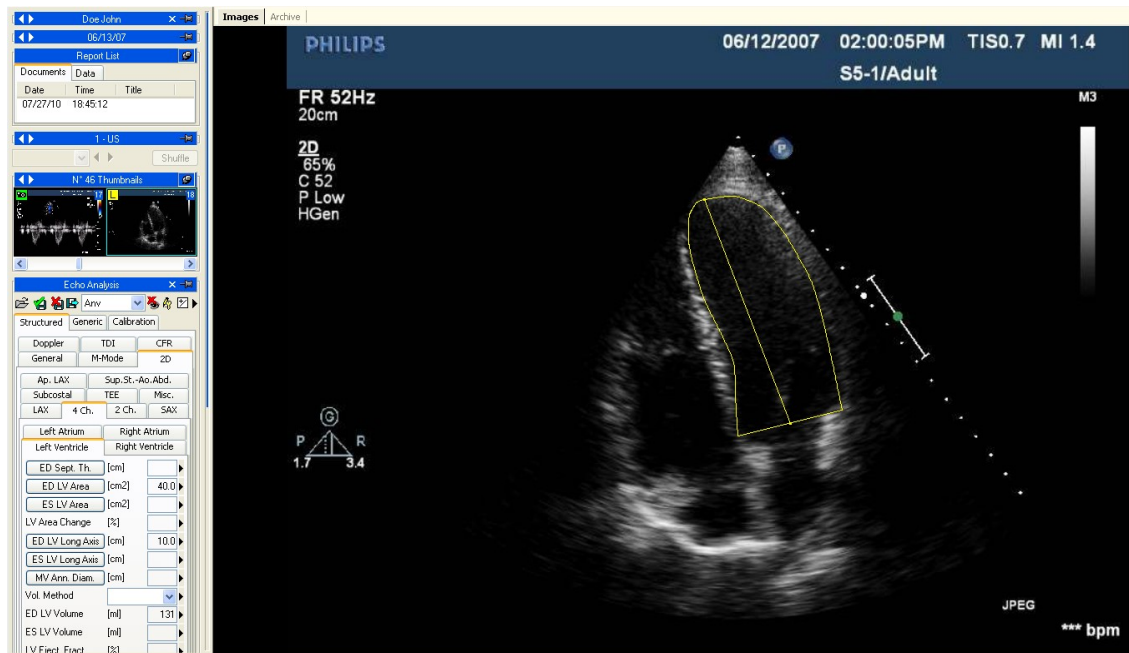
For velocity measurements as in the case of Doppler images, the software automatically identifies the baseline and in the case of a Doppler measurement where time is a factor, it creates a horizontal line.

The following is an example of a velocity measurement on a Doppler image:
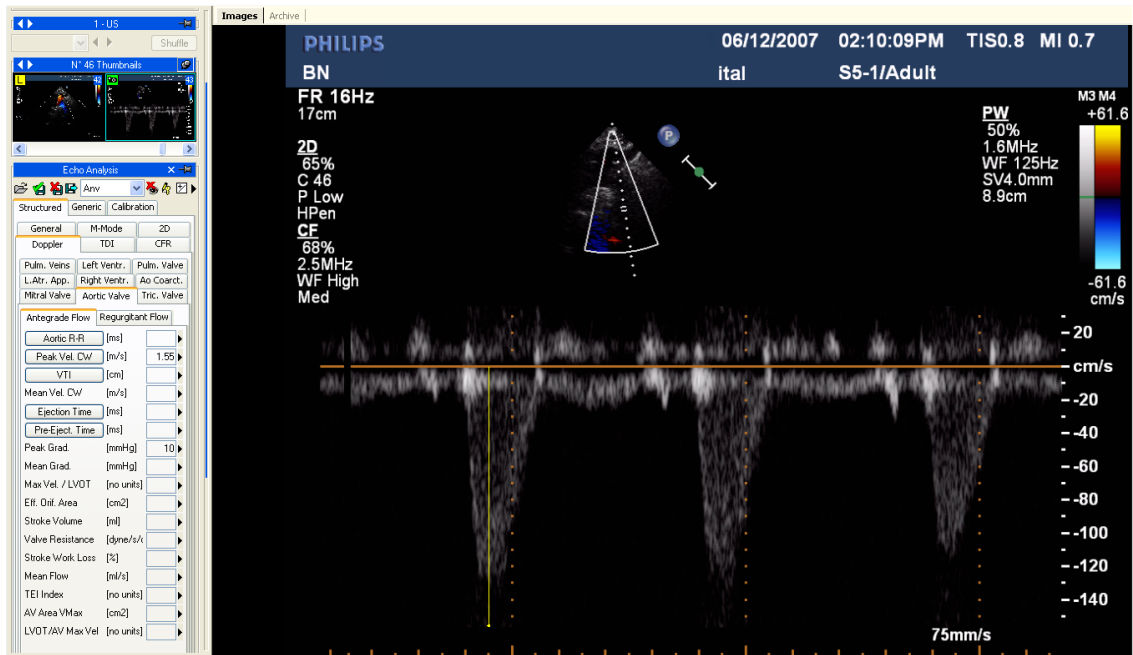
The next example is of a time measurement showing that even if the measurement is traced in diagonal way, the software takes the projection on the x axis.
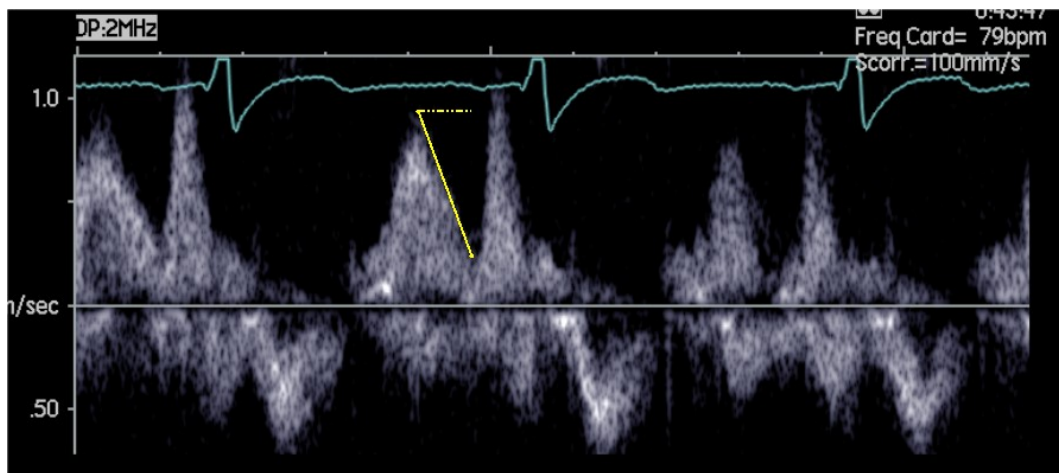
M-Mode images have their own set of dedicated measurements. In the next example we see the intra-ventricular dimension measurements.
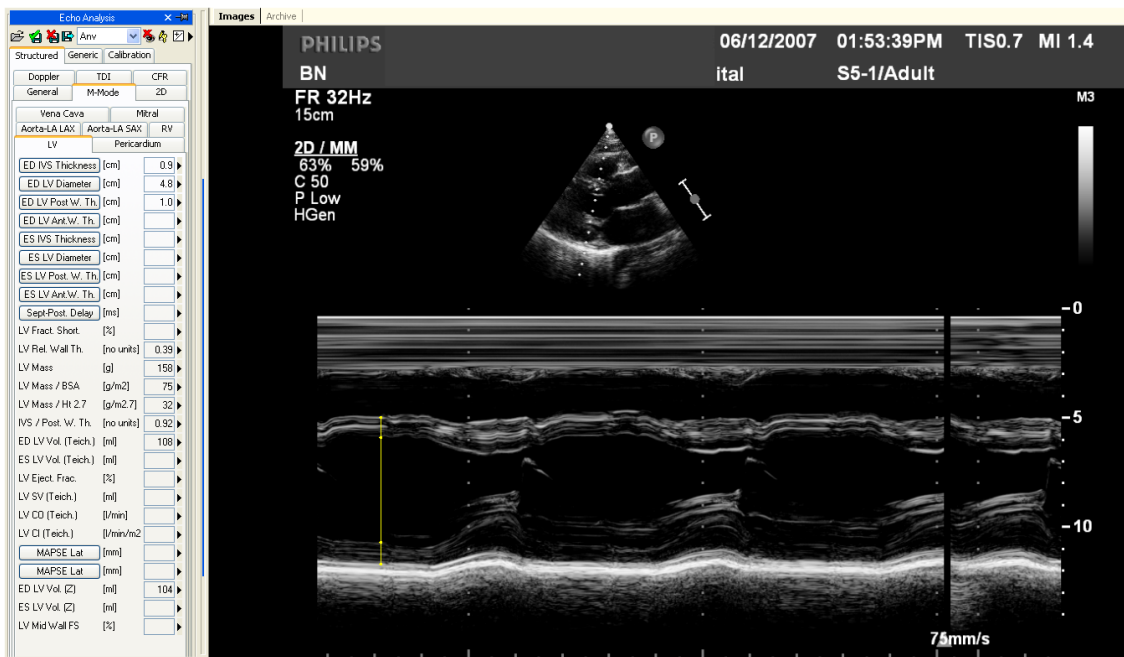
Not all the measurements are available on all types of images. For instance trying to perform a 2D area measurement on a Doppler image produces an error; in fact Doppler is not calibrated to make 2D area or length measurements. Or vice versa, if you try to measure a velocity on a 2D image, the software will again display an error message.

10.3.3 CALCULATIONS AND FORMULAS

The software not only allows performing direct measurements, but it is also capable of computing derived parameters by use of different mathematical formulas. For example, consider the left ventricle in the 4 chamber view. Once the area is measured in systole and diastole, the software computes the volumes with different methods (Area-length, Simpson) and then calculates the ejection fraction.

⚠️ In the absence of a correct calibration all measurements on the images are invalid.

⚠️ The program does not perform any control on the consistency of the calibration factor. It is <u>always</u> necessary to check the calculated calibration factor to verify whether it is admissible.

⚠️ The program does not perform any control on the clinical validity of the measurement. The operator must visually verify the validity of any measurements taken.

10.4. MEASUREMENTS MANAGEMENT

The product allows for detailed management of the measurements taken.

It is possible to select the baseline and the axes during the measurement process. In fact, not all of the Doppler images have a baseline (the line of 0) set up correctly and a few 2D images have the X and Y axes reversed. In these situations, click the arrow on the right of the measurement panel and select the requested behavior with respect to such problems.

When a measurement is already present and re-executed, the software, by default, replaces the old value with the new one.

However more than one measurement on the same sample (or on various samples) can be performed and stored, calculating the mean value and the standard deviation. To perform multiple measurements and display the mean value click the button shown below. If this mode is active the button will turn yellow.

In the case of repeated measurements, the value shown nearby the item text is that of the mathematical average. However it is still possible to see all the measured samples. Alongside of every measurement is an arrow which allows accessing a management menu for the item.

By clicking on the little arrow and then on *Show Details*, a window will be displayed in which all the samples taken for that item are shown together with the average and the standard deviation.

It is possible to delete a measured value if it seems incorrect. Simply select it and click on the *Remove* button. Use the buttons *Show* and *Hide* to show or hide the measurements on the image.

If echo analysis has been performed on the same patient in previous studies stored in the ComPACS database, you may view how a specific measurement field has varied over time.

This operation can be performed by clicking on the *Show Trend* item in the menu. A window will be displayed in which the different values over time for the identified measurement are displayed both numerically and in a graphical format.

Another useful function is the ability to immediately display the image frame from which the measurement was taken. From the measurement menu, when clicking on the *Go to measurement time* option, the software automatically selects the image and the specific frame on which the measurement was performed.

> The feature *Go to measurement time* is available only for off-line measurements taken with ComPACS ECHO.

Also by clicking on the *Edit Manually* button it is possible to manually insert the value instead of measuring it or calculating it. This value will be underlined in yellow to indicate it is a manually inserted measurement.
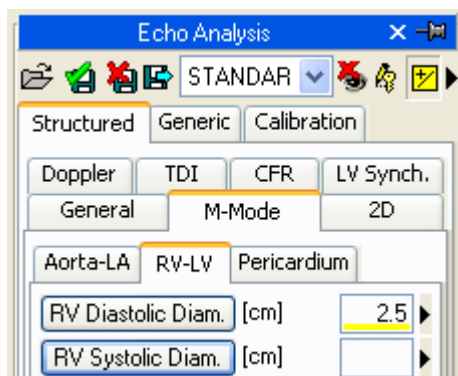
To show/hide the measurements on the images click on this icon:

To show the measurement graphics on all frames of the loop (and not just on the frame on which the measurement was taken) click on this icon:

To close and save the changes click on the *Close and Save* icon:

To close without saving the changes click on the *Close Discarding changes* icon:

10.5. CUSTOM SETTINGS

This component provides different user configurable settings, located in the *Program Settings* window, under the *Echo Analysis* tab.

"Enable measurement average at startup" automatically enables the average function when the component is activated.

"Multiple measurements (if average is enabled)" allows the user to measure a specific field multiple times, without having to press again the corresponding button. The measurement sequence can be interrupted by pressing the right mouse button.

"Invert X and Y axis" is used if the X and Y axis are to be interpreted differently in relation to the measurement structured menu. This option can be automatically enabled when the component is activated.

"Automatically detect Doppler baseline" is used automatically detect the Doppler baseline and allow for faster, one-click, velocity measurements. This feature can be disabled if the DICOM image does not contain a correct encoding of the Doppler baseline correctly.

"Use original pen cursor" uses the pen cursor of previous software revisions. Starting from 10.8.6 the pen cursor has been replaced with a sight view cursor.

11. ANGIOGRAPHIC ANALYSIS

11.1. ACTIVATING QCA II

If ComPACS QCA II is enabled on your system, the following button will be available on the toolbar, on the right hand side:

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server. If the license cannot be received then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses, it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active a window named "Angiographic Analysis" and containing a QCA tab is added and visible in the control window. It can be opened or minimized with a single left click on the blue bar.
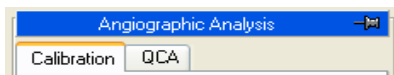
11.2. ACTIVATING LVA

If ComPACS LVA is enabled on your system the following button will be available on the toolbar, on the right hand side:

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server. If the license cannot be received then the module will fail to activate and an error message will be displayed.

 In case of concurrent licenses, it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active a window named "Angiographic Analysis" and containing an LVA tab is added and visible in the control window. It can be opened or minimized with a single left click of the mouse on the blue bar.
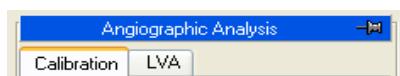
11.3. CALIBRATION

The calibration is an essential operation that must be carried out before any measurement or analysis on the images. This procedure leads to the computation of the zoom factor of the image by relating the measure in *pixels* of a known structure to its real measure in millimeters.

There are different ways to calibrate an image:

- **default** - By selecting a pre-calculated (default) zoom factor because there are no known structures in the image, or the structure is significantly distorted (for example close to the image borders);

- **distance** - By manually tracing a segment indicating the length of a structure of known size with the mouse (for example the distance between the markers in a catheter);

- **catheter** - Automatically, based on a catheter (empty or contrast filled) of known diameter (for example 7 French).

Calibration can be carried out in all three ways by using the buttons in the *Calibration* tab on the *Angiographic Analysis* panel on the Control Window on the left.

> ⚠️ In the absence of a correct calibration, all measurements on the images are invalid.
>
> ⚠️ The program does not carry out any control on the consistency of the calibration factor. You must <u>always</u> check the calculated calibration factor to verify whether it is admissible.
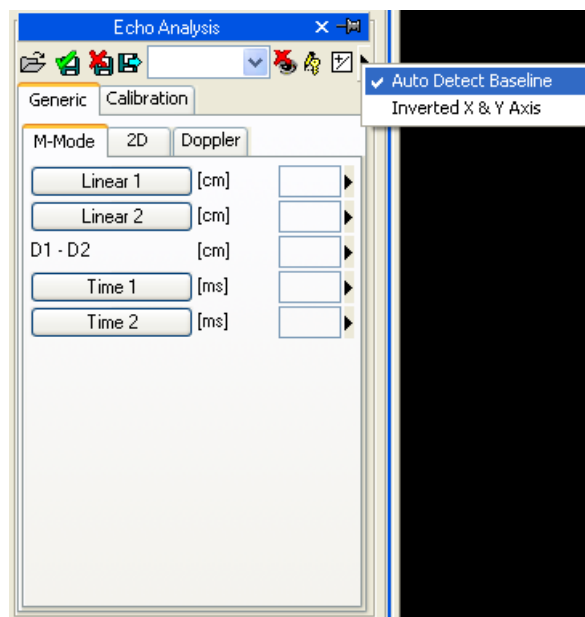
11.3.1 DEFAULT CALIBRATION
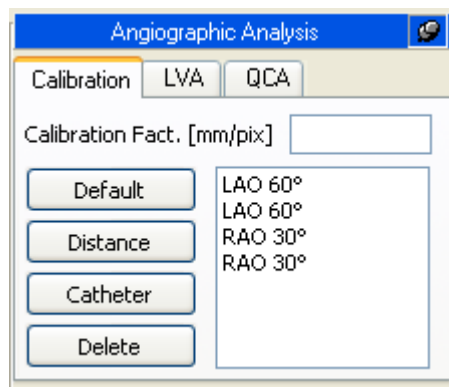
Default calibration can be carried out by clicking the *Default* button in the *Calibration* frame on the control window. In the white frame a list of names corresponding to the pre-set default calibration values are shown. Click with the left mouse button to select one. The corresponding calibration value will be displayed in the dedicated edit box above.

Alternatively, it is possible to directly set the calibration factor by selecting the related edit box with the mouse and by typing in the desired value.

> ⚠️ The program does not carry out any control on the consistency of the calibration factor. The operator is entirely responsible for its value.

11.3.2 CALIBRATION BASED ON A KNOWN DISTANCE
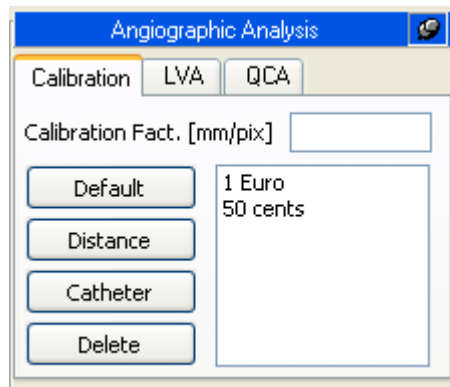
The calibration based on a known distance can be carried out by clicking the *Distance* button in the *Calibration* frame in the control. A list of names corresponding to the pre-set known distance values are shown in the white frame. Click with the left mouse button to select one.
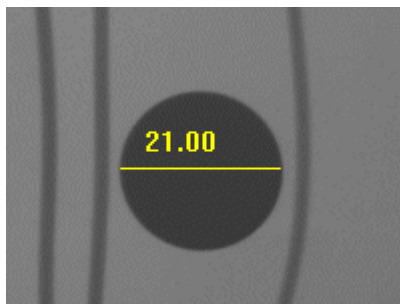
On the image, click the left mouse button at one end of the segment to be measured and then release it. By moving the mouse it is possible to trace the desired segment. Click the left mouse button once again, the segment can be fixed. The related calibration factor will be automatically calculated and displayed in the suitable edit control. Alternatively, by right clicking the mouse button during segment tracing, the operation can be cancelled.

If a known distance has not been selected, a dialog box requesting the insertion of the length of the traced segment in millimeters will be displayed. In this case the calibration factor will be then automatically calculated and displayed.
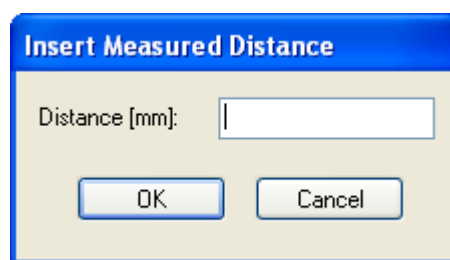
⚠️ The program does not carry out any control on the consistency of the calibration factor. The operator is entirely responsible for its value.

⚠️ It is necessary to calibrate on a known structure on the same plane as the ventricle to be measured.

⚠️ The accuracy of the calibration factor depends on the accuracy with which the segment is traced and it is inversely proportional to the pixel dimensions of the known structure. In the appendix the reference accuracy and precision values of this approach are reported.

11.3.3 CATHETER BASED CALIBRATION
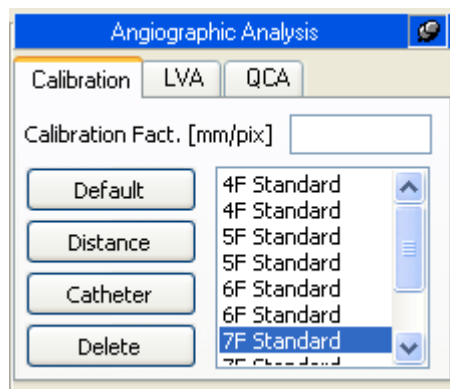
The calibration on a known catheter size can be carried out by clicking the *Catheter* button in the *Calibration* tab. In the white frame, a list of names corresponding to the pre-set known catheters are shown. By default, the catheter most recently used is selected and emphasized in blue If needed, select a different one with the left mouse button.

Now select two points along the catheter (preferably in the portion that is closest to the coronary lesion) by clicking the left mouse button on the image. The points are indicated by a yellow cross.
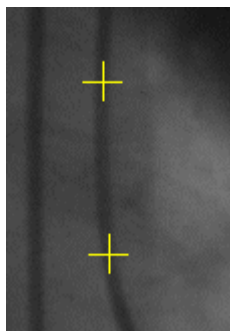
Around these points the program generates a region of interest in which the catheter skeleton and borders are automatically detected.

If the program does not detect the catheter skeleton or if the selected points are too close, an error is displayed by a message box. The operator will then have to select two different points or another image to perform the calibration.

When the analysis is completed, a results window will be shown in which the measured catheter borders are displayed in overlay. The image and the borders are zoomed to facilitate the verification of correctness of the measure. On the left, the calculated calibration factor and known diameter used are shown.

⚠ You must calibrate a catheter on the same plane as the ventricle to be measured. Also you calibrate a structure on the same plane as the ventricle to be measured.

⚠ The program does not carry out any control on the consistency of the calibration factor. The operator is entirely responsible of its value. For this reason you must always verify if the analysis is correct by comparing the measured profiles with those directly visible from the image.

⚠ The accuracy of the calibration factor depends on the image quality and varies if carried out on empty or contrast filled catheters. In the appendix, the reference accuracy and precision of this approach are discussed. Moreover the accuracy and precision depend on the overall correct system calibration to the images to be analyzed.

11.3.4 CALIBRATION SETTINGS

The calibration procedures require the presence of some reference information (default calibrations, known distances, known catheter dimensions). To avoid typing in these values for every computation, you may store this information and retrieve it when necessary.

To set these values, select the *Program Settings...* menu item from the *File menu*. These settings remain valid for all following activations of the program until they are modified again.

A dialog window will appear. Selecting the *Angiographic Analysis* tab*,* to set the required data using the following frames: *Default Calibrations*, *Reference Distances* and *Catheter Lists*. The procedure is similar for all frames (excepting, of course, the meaning of the values) and is as follows:

- The frame displays a list of names attributed to the values currently set.

- When a name in the window is selected, the name and the corresponding value are displayed on the right where they can be modified.

- To accept the modifications, click the *Modify* button.

- To remove some value from the list, click the *Delete* button.

- To set a new value and assign the name typed on the right, click the *New* button.
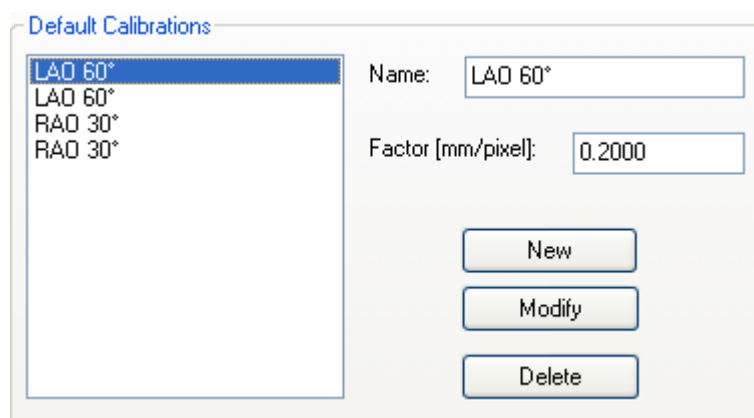
All changes will be applied when the *OK* button or the *Apply* button is pressed. Clicking the *Cancel* button will discard the changes.

11.4. CORONARY ANALYSIS

Having calculated the image calibration factor, it is possible to carry out the coronary analysis. Coronary stenosis measurements are carried out by selecting with the left mouse button, two points above and below the stenosis to be analyzed after having pressed the *2 Points* button in the *QCA* tab in the control window.

The selected points are indicated by yellow crosses. Around these points, the program generates a region of interest in which the centerline and the coronary borders are automatically determined. The program calculates the vessel diameter starting from the nearest points to the ones selected by the operator.
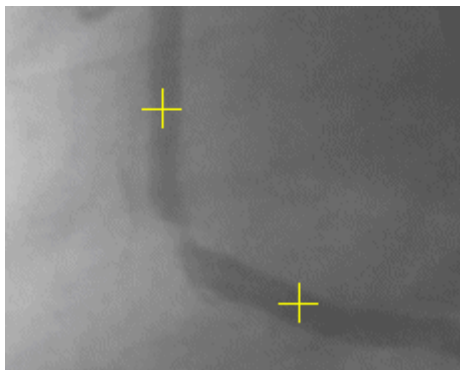
If the program cannot detect the coronary skeleton or if the selected points are too close, an error is reported. The operator will then have to select two further points or select a different image to analyze.

It is worth noting that the program finds the closest coronary path (in red) that connects the selected points. In some cases this may not be the desired path that needs to be analyzed. The problem can be overcome by indicating a third point in the path by activating the analysis with the *3 Points* button. In this case the intermediate point typically corresponds to the stenotic region or to a relevant way-point.

Finally you may carry out the analysis of a coronary vessel in which a stent has been inserted. In this case you need to click the *Stent* button and select four points on the vessel that will be indicated by yellow crosses. The first one corresponds to the start of the vessel we need to measure. The two intermediate points are needed to identify the beginning and the end of the region within the vessel in which the stent is present. The last one represents the end of the vessel.

The system will exclude the area in which the stent is present from the calculation to consider the profile as normal and will estimate three stenosis values: a proximal one within 5 mm from stent, an internal to stent itself, and one a distal one (within 5 mm from stent).

11.4.1 THE RESULTS WINDOW

When the analysis is concluded, a result window will appear displaying the detected borders in overlay on the analyzed image.
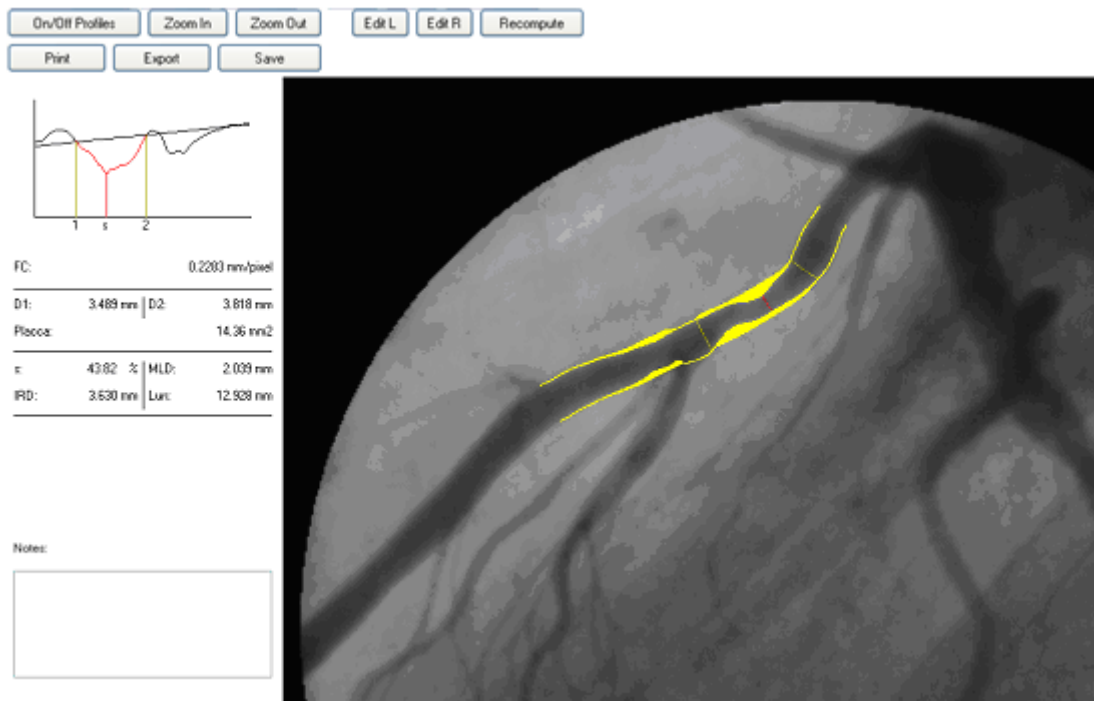
The image and the borders are zoomed to better visually verify the correctness of the measure. The coronary borders are displayed in yellow on the original image. The program also identifies the stenotic point of the vessel and the estimated normal profile. The former is indicated by a red segment perpendicular to the centerline whereas the latter is indicated in yellow. The region between the measured coronary borders and the normal profile is also filled with a yellow color.

On the left, the geometric analysis results are shown:

1) The calibration factor   (CF)

2) The proximal normal diameter   (D1)

3) The distal normal diameter   (D2)

4) The percentage of stenosis   (s)

5) The minimum luminal diameter   (MLD)

6) The interpolated reference diameter   (IRD)

7) The length of the stenosis   (LEN)

In the same window, a graph shows the diameter function of the analyzed vessel. The normal segments are identified by vertical segments labeled 1 and 2. The MLD is also identified by a vertical segment labeled s. Moreover an interpolated line indicates the estimated normal profile used in the computation of the percentage of stenosis.

The operator can modify the position of the segments 1, 2, and s by dragging them with the mouse on the graph window. The corresponding positions of such segments on the image are thus updated. When the mouse button is released, all measured parameters are recomputed on the basis of the new segment position.
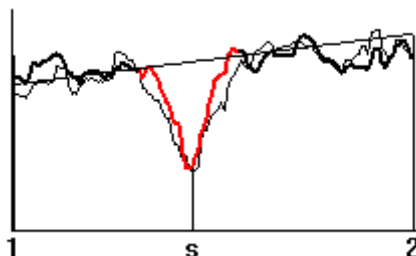
Moreover, with a double click on the graph, the program will display the densitometric analysis results. The previous geometric analysis is reported in underlay for a direct comparison. A further mouse double click will return to the previous results display.

The software also allows you to manually modify the profiles in the situation where an error in the automatic estimate is discovered. This operation is performed by the buttons *Edit L* and *Edit R* according to what profile part you wish to modify. The area subject to modification will turn of green.
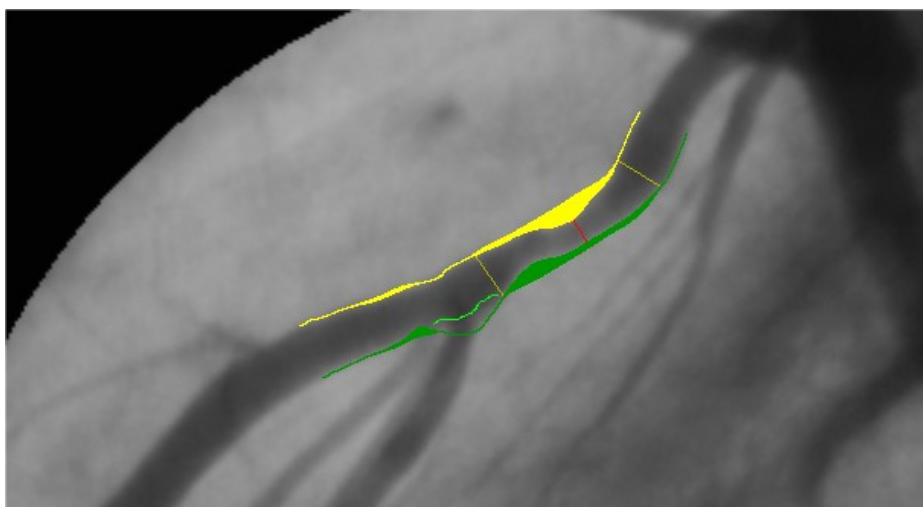
At this point the user must use the mouse to trace the part of the profile that was incorrect and click the *Recompute* button. The software will re-execute an estimate of the coronary profile on the basis of the provided information.

The window contains a set of further buttons with the following functions:

🔵 **On/Off Profiles**   It allows the activation/deactivation of the measured coronary borders overlay. It is thus possible to verify the automatic analysis by toggling the display on and off.

Zoom In	It magnifies the image using interpolated zooming.
Zoom Out	It reduces the image zoom factor using interpolated zooming.
Print	It prints a report of the results of the analysis complete of patient name and study and image references.
Export	Exports the analysis results.
Save	Generates a DICOM image containing the analysis results which can be archived by the operator on the ComPACS Archive.

In particular the *Export* button allows you, depending on the installed export modalities, to export the analysis results to an external database, an Excel worksheet (if Microsoft Excel® is installed on the same PC), or event in proprietary or user defined formats.
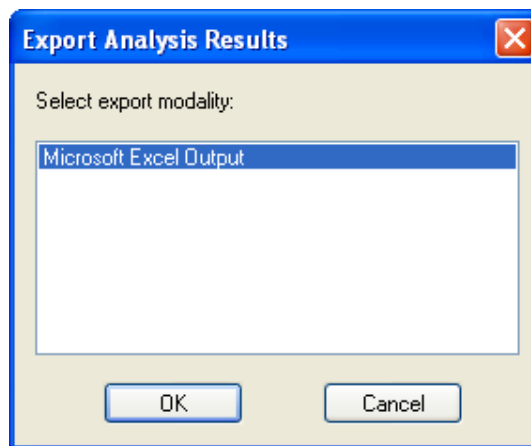
On returning to the program interface, you may view the analysis results again by clicking the *Report* button. To remove the results, click the *Delete* button. The selection of a new image will also and automatically remove the results.

⚠ In the absence of a correct calibration, the measurements carried out on the images are invalid. It is always necessary to control the calculated calibration factor, the obtained measure and the borders traced to verify their admissibility.

⚠ In the appendix the accuracy and precision of the method are reported.

11.4.2 ANALYSIS AND STENT

To carry out the analysis of a coronary vessel in which a stent has been inserted, the same procedure for coronary analysis must be followed but clicking the *Stent* button instead of *2 Points* or *3 Points*.
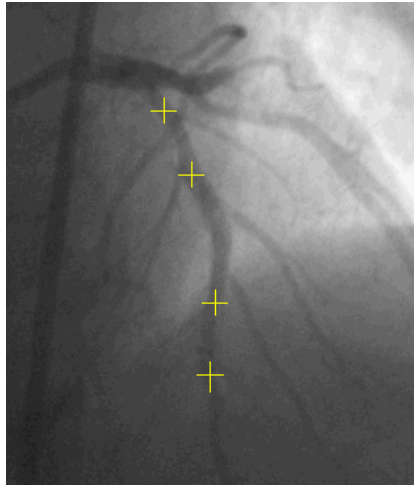
To do so, select four points on the vessel that will be indicated by yellow crosses. The two intermediate points are needed to identify the beginning and the end of the region within the vessel in which the stent is present.

If the program cannot detect the coronary skeleton or if the selected points are too close, an error is reported in a message window. The operator will then have to select two further points or select a different image to analyze.

It is worth noting that the program finds the closest coronary path that connects the selected points (in red). In some cases this may not be the desired path that needs to be analyzed.

The stent position is used to remove the corresponding part of the vessel from the computation of the normal vessel borders. Moreover the program will calculate three stenosis values:

1) The stenosis within the stent   (s)

2) The stenosis before the stent   (p)

3) The stenosis after the stent   (d)

For each stenosis, the percentage value, the absolute measured diameter, and the interpolated reference diameter are displayed. The stent position is indicated in a magenta color.

> ⚠️ In the absence of a correct calibration, the measurements carried out on the images are invalid. It is always necessary to control the calculated calibration factor, the obtained measurement and the borders traced to verify their admissibility.
>
> ⚠️ In the appendix the accuracy and precision of the method are reported.

11.5. VENTRICLE ANALYSIS

After having calculated the image calibration factor, it is possible to perform the left ventricle analysis with the following procedure.

- Select a diastolic image in the image window. Click the *Trace Diastolic* button in the *LVA* tab in the control window.

- Click the left mouse button on the image window and to trace the ventricle profile. When the button is released you may continue to trace the profile by clicking the left mouse button again or alternatively you may progressively delete the traced profile backwards by keeping the right mouse button pressed. Finally by double clicking, the traced profile will be fixed.

- Repeat the same procedure with the systolic image. Click the *Trace Systolic* button in the *LVA* tab in the control window. It is now possible to manually trace the systolic profile with the same procedure above.

- Click the *Analysis* button. In the main window, a tab called *LVA* with the results of the analysis (ventricular volumes, ejection fraction, etc…) will be displayed.

The ventricle profile tracing is not allowed if the calibration factor is null. You must calibrate the image before proceeding with the ventricle analysis.

The program does not perform any control on the consistency of the profiles traced by the operator. For this reason you must <u>always</u> verify if the traced profiles are correct by comparing the graphic trace in overlay.

An example of the result is shown below.
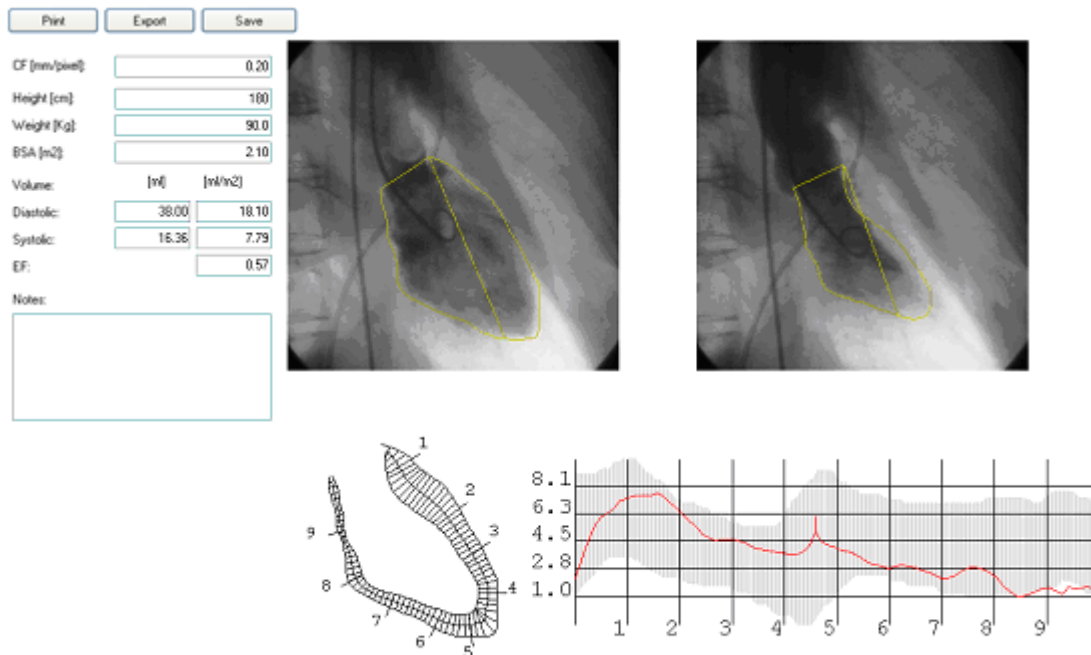
The window displays the ventricular volumes and ejection fraction calculated with the *Area-Length* method and the regional shortenings calculated with the *Centerline* method.

The volumes are expressed in ml and can be normalized with the body surface calculated from the patient height and weight. These values are taken from the main application and/or can be inserted/modified in this dialog window.

Regional shortenings are expressed as percentage values referred to the ventricle diastolic perimeter. In the background, in gray, is the normality region. It corresponds to the mean shortenings value +/- 2 units of standard deviation.

In this window it is also possible to insert annotations on the analysis and/or print a report. The latter is automatically set up and it reports patient information, study information, image information, the selected ventricle images, the results obtained and the possible annotations.

Using the *Save* button, the report will be generated as a DICOM image to allow the operator to archive it with the study images.

It is also possible, depending on the installed import and export modalities, to import patient weight and height information from an external database and/or to export the analysis results to the same database, an Excel worksheet (if Microsoft Excel® is installed on the same PC) or even in proprietary or user defined formats.

The import and export operations can be manually activated by clicking respectively the *Import* (not present if no import modalities are available) and *Export* buttons. The same operations can be

automatically activated when the dialog window is opened or closed. In this last case the user will be asked to confirm their activation.
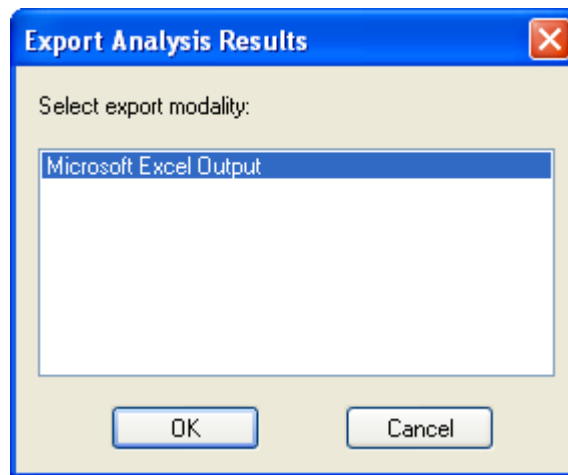
Finally you may also perform the following operations:

- The profiles can be removed by clicking the *Delete* button.

- It is possible to display the previously selected systolic image by clicking the *Go to Systolic* button or by selecting the *Go to Diastolic* button to display the Diastolic image.

⚠️ In the absence of a correct calibration and of a correct ventricle profile tracing, the measurements carried out on the images are invalid. It is necessary to control the calculated calibration factor, the obtained measure, and the profile traced to verify their admissibility.

⚠️ In the appendix, the accuracy and precision of the method are discussed.

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12. IVUS ANALYSIS

12.1. ACTIVATING IVUS ANALYSIS

If ComPACS IVUS is enabled on your system the following button will be available on the toolbar, on the right hand side:

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server. If the license cannot be received then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active, a window named "IVUS Analysis" is added and visible in the control window. It can be opened or minimized with a single left button click on the blue bar.
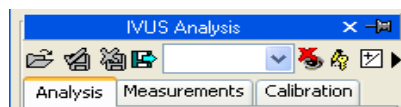
12.2. LONGITUDINAL RECONSTRUCTION (ILD)
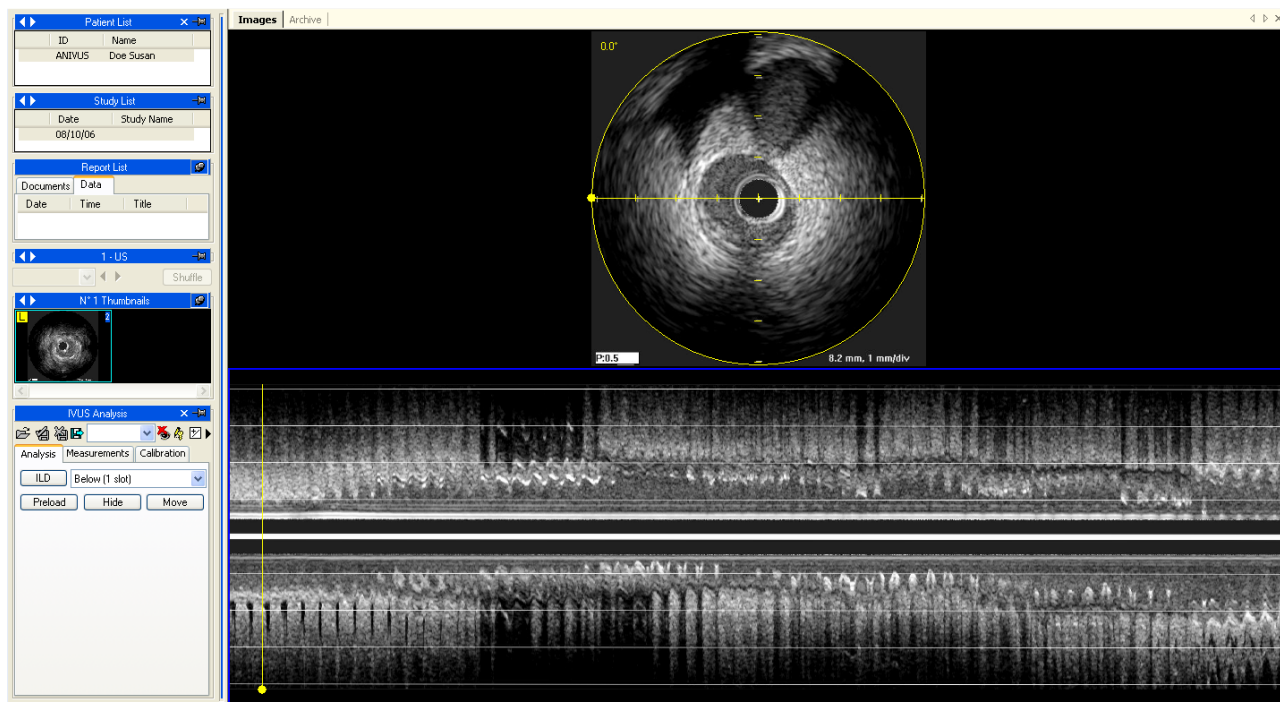
If the DICOM object is an IVUS sequence, you may perform a longitudinal reconstruction in real time during loop playback by clicking the *ILD* button. The position and the image dimension depend on the drop-down window near the *ILD* button.

On the image, a yellow circle and a line show the undergoing reconstruction area and the sampling axis orientation. On the reconstructed image (ILD) a yellow line which shows the correspondence with the frame of the original sequence is shown. Such graphic information can be hidden with the *Hide* button.

The reconstruction is automatically performed during the clip sequence reproduction. It is possible to have it available all at once by clicking the *Preload* button.

By clicking the *Move* button in the control window, the module allows a direct and intuitive modification of the sampling axis direction using the mouse. The reconstruction is then automatically updated, provided enough RAM is installed. Otherwise the file will have to be played back again for the 2D reconstruction update.

Similarly, by moving the yellow line along the image, it will be possible to move to the frame corresponding to the original image.

12.3. OFF-LINE MEASUREMENTS

The IVUS module offers the ability to perform measurements on IVUS images and the longitudinal reconstruction. The calibration information is usually contained in the DICOM file and the software uses it to avoid a manual calibration while at the same time ensure greater data accuracy. If the calibration information is absent, it is still possible to manually calibrate the image.

Simple generic measurements are always available in the *Measurements* tab of the IVUS Analysis window:
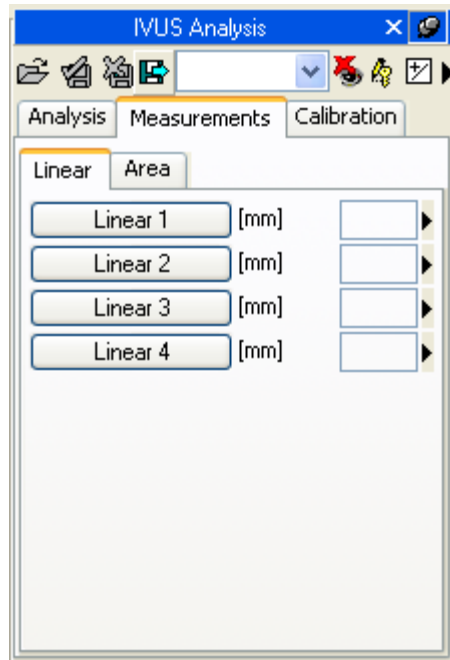
These are basic linear and area measurements for rapid verification purposes.

⚠️ Generic measurements are only temporary. They are not stored to the ComPACS database and cannot be retained.

To access a more advanced measurement panel, open either an already existing report or create a new one. This operation can be performed by clicking on the toolbar icon 📄 as described in the "*Managing Evidence and Report*" chapter.

ℹ️ Structured measurement and reporting functionality is not available in the core IVUS module. IVUS II license or above is required.

The analysis window will be extended with an additional *Structured* tab containing all the structured measurements. The appearance and content of the tab will depend on the reporting templates and analysis views configured by the system administrator for the specific workstation or user.

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i   Structured measurements are stored in the DICOM SR object they refer to.

In this interface, only the windows corresponding to the data present in the open object will be filled (with numbers). To edit the opened report click the *Editing* icon:

To close and save the changes made click on the *Close and Save changes* icon:

To close without saving any changes click on the *Close discarding changes* icon:

To export the data it is necessary to click the *Export the report data to file* icon:

An interface will be opened where you may select the data format and the file destination.

In the drop-down list, it is also possible to select an export template based on the installed configurations.

This functionality has been extended to export not only numerical values but also other field types (text, findings, dates, etc.). Furthermore the export also includes nested and repeated record structures.

The template is a simple text file which lists, in separate lines, the fields which need to be exported. Each line has the following format:

> *FieldID*; *Label - Optional*; *Unit - Optional*

If the label or the unit are not specified, the default values shall be used.

For repeated records, the list of fields need to be enclosed in the following statement:

> BEGINGROUP(*Record Field ID*); *Label – Optional*; *Index – Optional*
> … *list of fields* ..
> ENDGROUP(*Record Field ID*)

The index is optional and, if omitted, all records shall be exported.

Finally some special fields consist in DICOM fields. They are identified as follows:

> $(Group,Element) ; *Label - Optional*;

12.3.1 IMAGE CALIBRATION

To see if the image calibration is automatically imported or if it is absent, simply move the mouse cursor over the image. If present, the calibration information will be displayed in the *Calibration* tab.
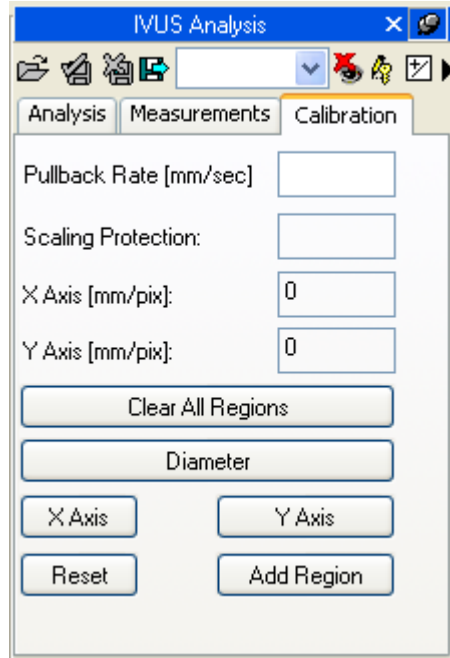
If no information appears then the image needs a calibration. This operation must be executed very carefully because all subsequent measurements strictly depend on the calibration procedure.

To manually calibrate the image you have to determine the image axis values, using the *X Axis* and *Y Axis* buttons. The mouse pointer will change into a pen and it will allow you to trace a segment by clicking the mouse button in the center of the IVUS image and then a second time in the chosen axis end point. At the end, a dialog window will prompt you to type in the distance traced indicated in millimeters to perform calibration.
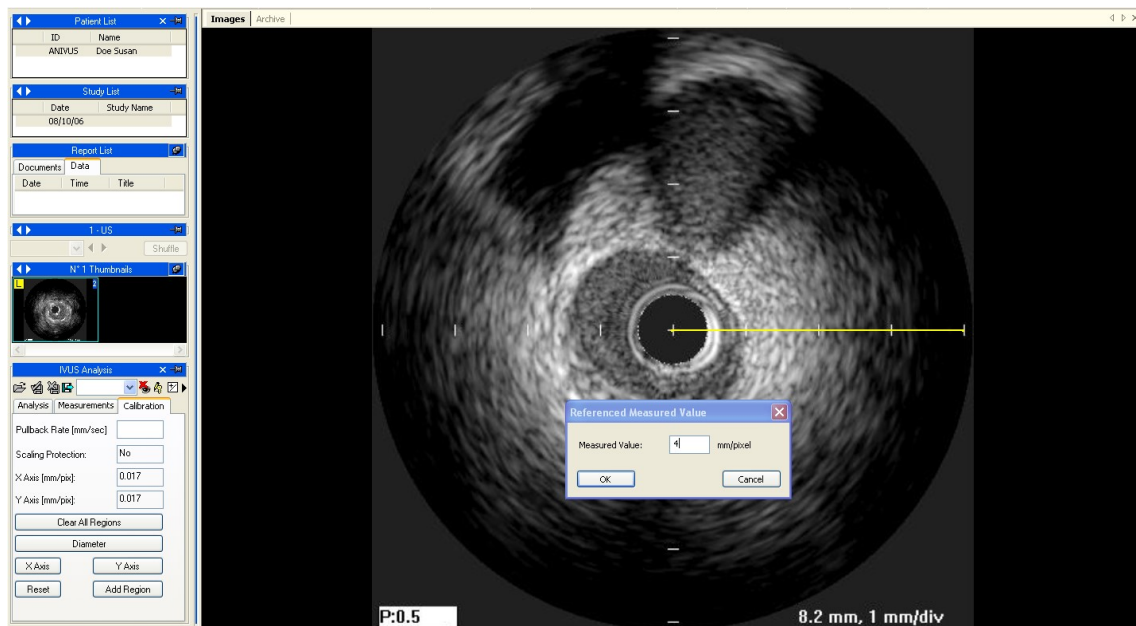
It is also possible to set the IVUS image diameter by clicking separately on the *Diameter* button. If such operation is not executed, the diameter is the greater value between the one identified by the X and the Y calibration.

Once this operation has been performed for both axes, the calibration can be accepted by clicking on the *Add Region* button. Now, when moving the mouse pointer over the calibrated area, you will see the calibration information displayed in the calibration tab.

⚠ In the absence of a correct calibration or pullback velocity, all measurements are invalid.

⚠ The program does not perform any control on the consistency of the calibration factor. The operator is therefore entirely responsible of its value. For this reason you must <u>always</u> verify if the analysis is correct by comparing the measured profiles with those directly visible from the image.

⚠ The accuracy of the calibration factor depends on accuracy of the operator and it depends on the image size in pixels

12.3.2 LONGITUDINAL RECONSTRUCTION CALIBRATION

The longitudinal reconstruction calibration factor is not directly set up but is imported by the images' reconstruction when performed. Therefore the IVUS images will have to be calibrated before performing the longitudinal reconstruction.

However, for the reconstruction to be fully calibrated, an additional parameter - the Pullback Speed – is required. Without this information it is not possible to perform measurements on the reconstructed image.

This parameter also is imported from DICOM (if present) but it can be manually set up in the *Calibration* tab after (and not before) the reconstruction has been created.
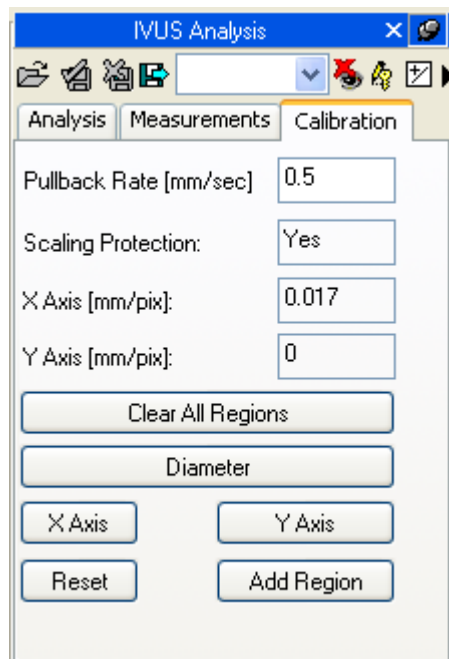
⚠ In the absence of a correct calibration or pullback velocity all measurements are invalid.

⚠ The program does not perform any control on the consistency of the calibration factor. The operator is therefore entirely responsible of its value. For this reason you must <u>always</u> verify if the analysis is correct by comparing the measured profiles with those directly visible from the image.

12.3.3 PERFORMING MEASUREMENTS

Now we are ready to perform some off-line measurements on the images. ComPACS IVUS allows measuring both the original IVUS image and the longitudinal reconstruction (ILD).

Once the image is chosen, select the value to be measured on the measurement panel. In particular there are two panels: the generic *Measurements* panel, which is always available, and the *Structured* panel which depends on the configuration set up and requires the opening of a report (intended as DICOM SR object).

> ⚠️ The generic measurements are only temporary and will not be stored to a DICOM SR Object.

Once the user has selected the image, it is necessary to select the parameter requested in the measurement panel on the left. Possible measurements include: distances, areas, angles and computing derived calculations.
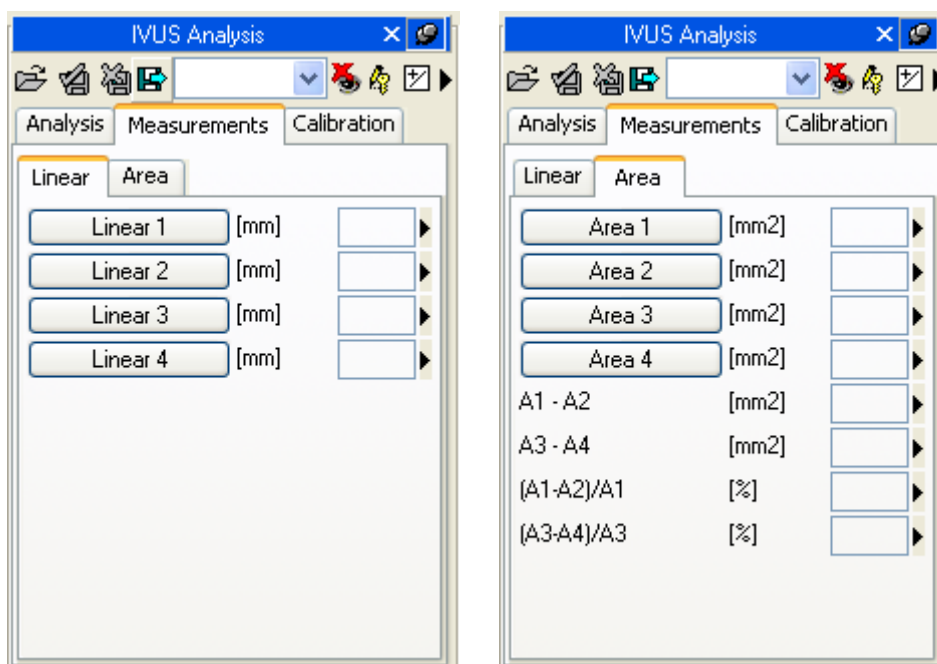
By clicking on the chosen button, the mouse pointer becomes a pen and with some simple clicks on the image, ComPACS traces the requested measurement.

The following is an example of linear measurement on an IVUS image.
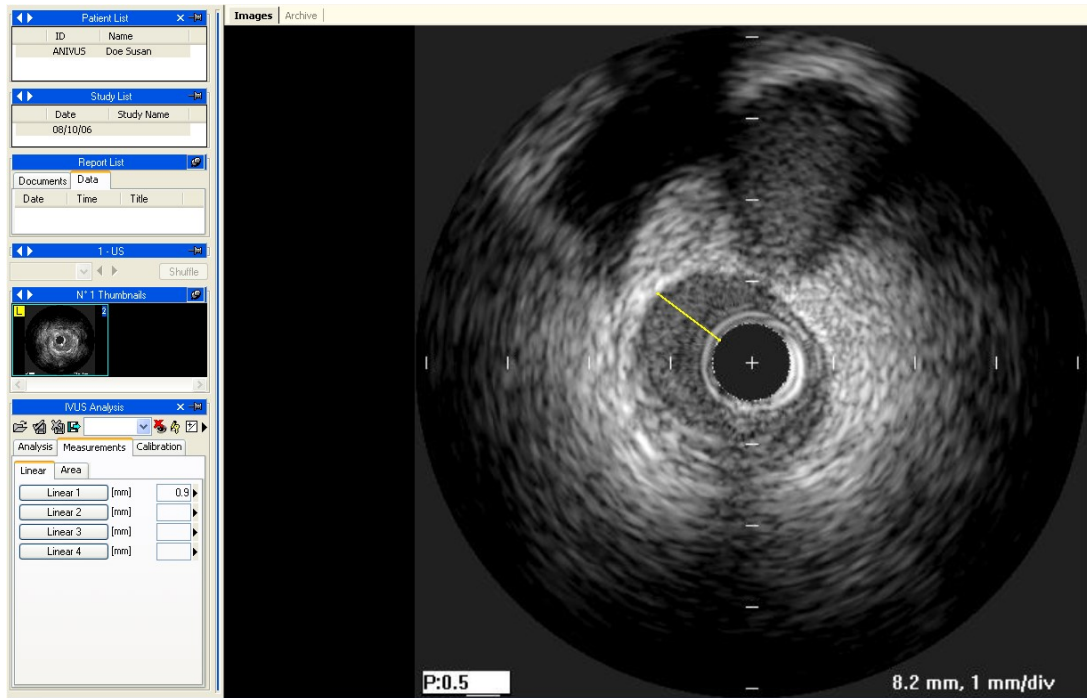
In case of area tracings, for each mouse click, a point of the area is fixed and the software creates a smooth line passing over these points – "spline". A double click sets the end of the measurement. In case of errors, you may delete points using the right mouse button or, with a double click, entirely cancel the measurement.
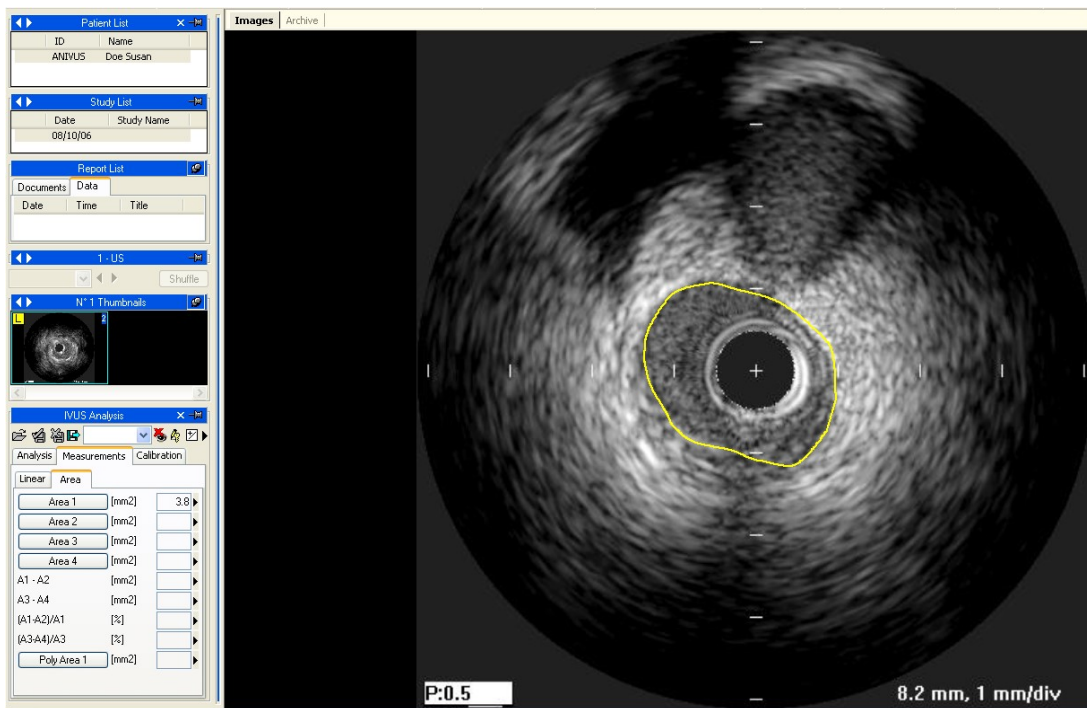
In case of angle measurements, the system automatically uses the center of the image as a reference point. It is therefore sufficient to click two points, moving clockwise, to measure an angle. In case of errors, you may delete a point using the right mouse button or, with a double click, entirely cancel the measurement.
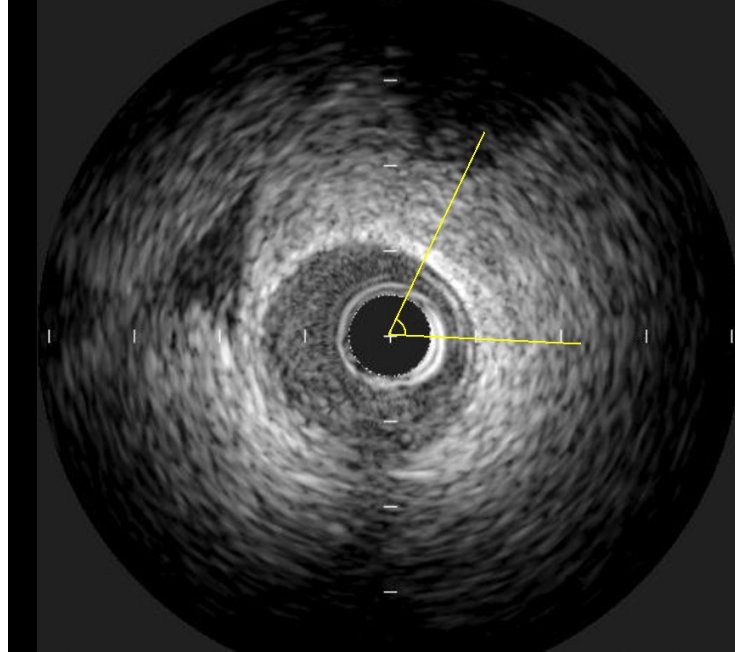
12.3.4 CALCULATIONS AND FORMULAS

The software not only allows performing direct measurements, but it is also capable of computing derived parameters by use of different mathematical formulas. For example, if multiple area measurements are performed in different cross-sectional images over a manually inserted distance, it is possible to estimate the volume.

> ⚠ In the absence of a correct calibration or pullback velocity all measurements are invalid.
>
> ⚠ The program does not perform any control on the consistency of the calibration factor. The operator is entirely responsible of its value. For this reason you must always verify if the analysis is correct by comparing the measured profiles with those directly visible from the image.
>
> ⚠ The program does not perform any clinical validation of the measurement. The operator is therefore entirely responsible and must visually verify the accuracy of what has been measured.

12.4. MEASUREMENTS MANAGEMENT

The software allows a detailed management of the measurements that have been taken.

When a measurement is already present and re-executed, the software, by default, replaces the old value with the new one.

However, more than one measurement on the same sample (or on various samples) can be performed and stored, calculating the mean value and the standard deviation. To perform multiple measurements and display the mean value it is necessary to click the button shown below. If this mode is active, the button will turn yellow.

In cases of repeated measurements, the value shown near the item text is that of the mathematical average. However it is still possible to see all the measured samples. Alongside every measurement is an arrow that allows accessing a menu for that item.
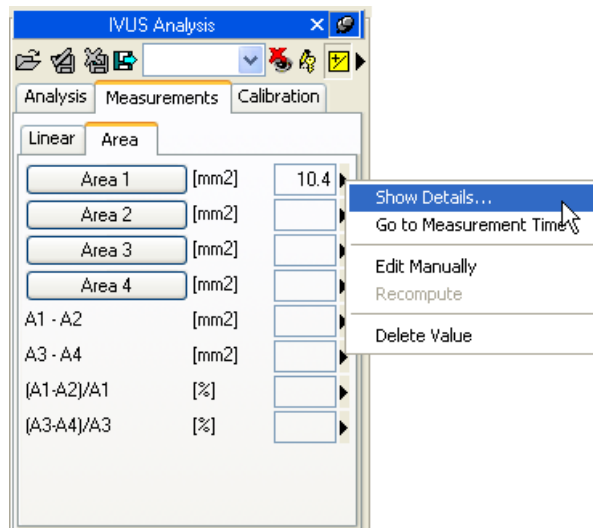
By clicking on the little arrow and then on *Show Details,* a window will be displayed in which all the samples taken for that item are shown together with the average and the standard deviation.
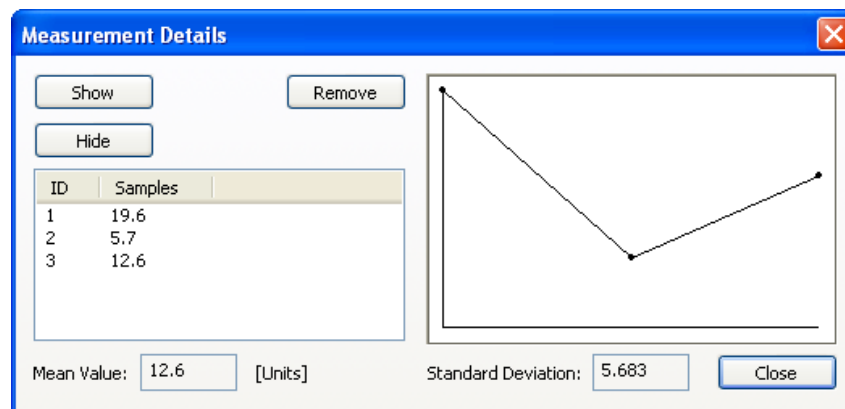
You may delete a measured value if it seems incorrect by simply selecting it and clicking the *Remove* button. Use the *Show* and *Hide* buttons to show or hide the measurements on the image.

If IVUS analysis has been performed on the same patient in previous studies stored in the ComPACS database, you may view how a specific measurement field has varied over time.

This operation can be performed by clicking on the *Show Trend* item in the menu. A window will be displayed in which the different values over time for the identified measurement are displayed both numerically and in a graphical format.
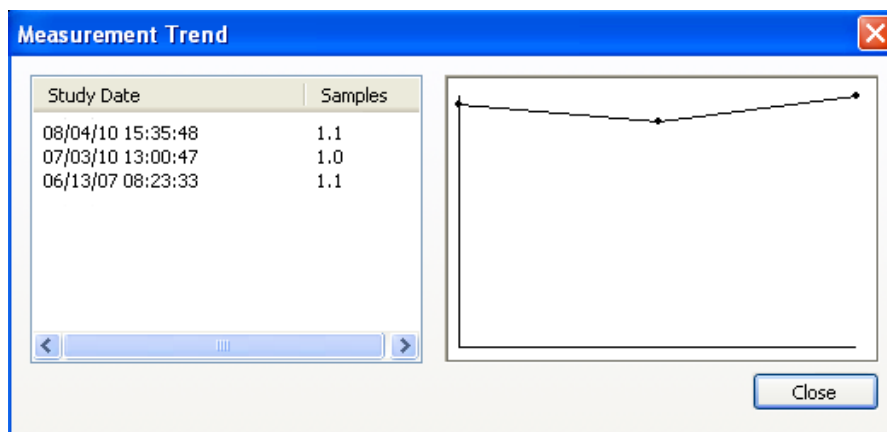
Another useful function is the ability to display the image frame from which the measurement was taken. Again on the *Measurement* menu, when clicking on the *Go to measurement time* option, the software automatically selects the image and the specific frame on which the measurement was performed.

> [i] The feature *Go to measurement time* is available only for off-line measurements taken with ComPACS IVUS.

Also by clicking on the *Edit Manually* button it is possible to manually insert the value instead of measuring it or calculating it. This value will be underlined in yellow to highlight it as an operator manually inserted measurement.
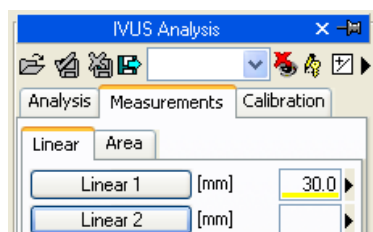
To show/hide the measurements on the images click on the icon:

To show the measurement on all frames of the loop (and not only on the frame on which the measurement was taken) click on the icon:

To close and save the changes click on the *Close and Save* icon:

To close without saving the changes click on the *Close Discarding changes* icon:

12.5. CUSTOM SETTINGS

This component provides different user configurable settings, located in the *Program Settings* window, under the *IVUS Analysis* tab.

☐ Enable measurement average at startup
☐ Multiple measurements (if average is enabled)
☐ Invert X and Y axis
☐ Use original pen cursor

"Enable measurement average at startup" automatically enables the average function when the component is activated.

"Multiple measurements (if average is enabled)" allows the user to measure a specific field multiple times, without having to press again the corresponding button. The measurement sequence can be interrupted by pressing the right mouse button.

"Invert X and Y axis" is used if the X and Y axis are to be interpreted differently in relation to the measurement structured menu. This option can be automatically enabled when the component is activated.

"Use original pen cursor" uses the pen cursor of previous software revisions. Starting from 10.8.6 the pen cursor has been replaced with a sight view cursor.

13. GENERIC MEASUREMENTS

13.1. ACTIVATING OFF-LINE GENERIC MEASUREMENTS

If ComPACS Generic Measurements module is enabled on your system, the following button will be visible in the toolbar, on the right hand side:

If the button is pressed down then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation, the module will request a runtime license from the ComPACS Server. If the license cannot be received, then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active, a window named "Generic Measurements" is added and visible in the control window. It can be opened or minimized with a single mouse left button click on the blue bar.
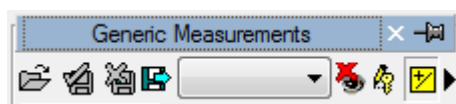
13.2. OFF-LINE MEASUREMENTS

The module provides the possibility of performing measurements on different types of images. Such simple measurements are always available in the *Measurements* tab of the analysis window:
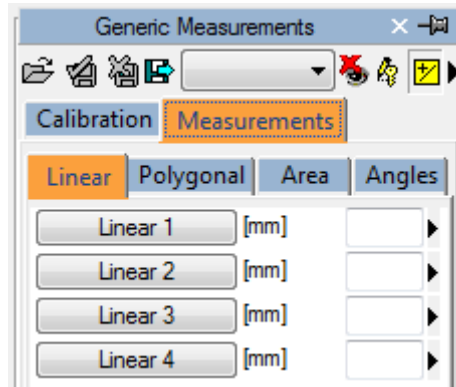
Linear, polygonal, area and angle measurements are available for rapid verification purposes.

⚠ Generic measurements are only temporary. They are not stored to the ComPACS database and cannot be retained.

To export the data it is necessary to click the *Export the report data to file* icon:

An interface will be opened where you may select the data format and the file destination.

In the drop-down list, it is also possible to select an export template based on the installed configurations.

> **STOP** This functionality has been extended to export not only numerical values but also other field types (text, findings, dates, etc.). Furthermore the export also includes nested and repeated record structures (for example each phase of a echo stress study).

The template is a simple text file which lists, in separate lines, the fields which need to be exported. Each line has the following format:

> *FieldID*; *Label - Optional*; *Unit - Optional*

If the label or the unit are not specified, the default values shall be used.

For repeated records, the list of fields need to be enclosed in the following statement:

> BEGINGROUP(*Record Field ID*); *Label – Optional; Index – Optional*
> *… list of fields ..*
> ENDGROUP(*Record Field ID*)

The index is optional and, if omitted, all records shall be exported.

Finally some special fields consist in DICOM fields. They are identified as follows:

> $(Group,Element) ; *Label - Optional*;

13.2.1 IMAGE CALIBRATION

The calibration information is usually contained in the DICOM file. The product exploits it to avoid a manual calibration and ensure greater accuracy. Therefore calibrating images in order to perform measurements is generally not necessary nor is it recommended.

By simply moving the mouse over the image, the calibration information will appear in the *Calibration* tab. This way it is possible to quickly verify if the image calibration is present or not.
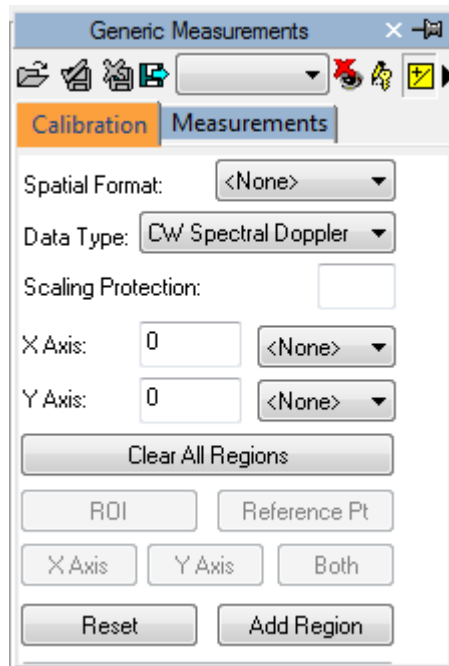
If no information is displayed when moving the mouse, the image needs to be calibrated.

⚠️ Calibration for radiology images (DICOM Pixel Spacing) is supported. It is however important that this calibration is done on the receiving surface which is not necessarily in the same plane and orientation as the structure that is measured. This may lead to inaccurate results. Verifying the calibration (or manually recalibrating) using a structure of known size in the same plane and orientation is recommended.

ℹ️ Ultrasound images can contain multiple regions of calibration. Therefore it is possible that the calibration information differs in relation to the position of the mouse on the image. Also some regions may be calibrated whereas in others the calibration information may be absent.

If the calibration information is absent, it is possible to manually calibrate the entire image or a region.

The first thing to do to calibrate an image is to choose the Spatial Format (2D, Doppler, M-Mode, etc…) and the type of data (Tissue, PW, CW, etc…). Using the two drop down menus in the *Calibration* tab:

Next, establish (using the X axis and the Y axis) the calibration values to be assigned to the image. For instance, in case of a Doppler image, assign a time value on the X axis and a speed value on the Y axis. For 2D images, which have the same unit of measurement for both axis, it is also possible to calibrate both axis at once with a single diagonal segment using the *Both* button.

On the image, the mouse pointer will change into a pen and allow you to trace a segment. Click the left button once at the start point and then a second time at the end point. When finished, a dialogue window will prompt you to enter the dimension of the traced segment in the suitable unit of measurement.

It is also possible for the Doppler images to indicate the zero point position (the baseline) by the reference point button and then clicking it with the mouse.

Once the operation is performed on both axes you may decide if the calibration applies to the entire image (by clicking on *Add Region*) or only to a ROI (Region Of Interest). In the second case, select the ROI button and after tracing on the image the interest area, calibrate by clicking on the *Add Region* button.

When moving the mouse pointer on the calibrated region, you will see all the calibration information on the *Calibration* tab.

> ⚠ In the absence of a correct calibration all measurements on the images are invalid.
>
> ⚠ The program does not perform any control on the consistency of the calibration factor. It is <u>always</u> necessary to check the calculated calibration factor to verify whether it is admissible.
>
> ⚠ The accuracy of the calibration factor depends on the accuracy with which the segment is traced and it is inversely proportional to the pixel dimensions of the known structure. In the appendix, the reference accuracy and precision values of this approach are reported.

Now we are ready to perform some offline measurements on the images. Once the image is chosen, select the value to be measured on the measurement panel.

> ⚠️ The generic measurements are only temporary and will not be stored to a DICOM SR Object.

By clicking on the item, the mouse pointer becomes a pen. With a few mouse button clicks on the image, the software traces the measurement (in yellow).

To proceed, first select the desired measurement by clicking the chosen button in the control panel. Move the cursor to the starting point of the desired measurement and left-click once, the cursor will become a pen. Move the cursor to the end point of the measurement and left clicking once will terminate the measurement and populate the result in the chosen location.

In more complex measurement case (i.e.: an area), an area point is fixed at every mouse left button click and the software creates a soft line passing through such points – "*Spline*" - to give it the harmonized shape. A double click terminates the measurement. In case of a tracing error, click the right mouse button to delete points and double right click to entirely cancel the measurement.

Not all the measurements are available on all types of images. For instance trying to perform a 2D area measurement on a Doppler image produces an error; in fact Doppler is not calibrated to make 2D area or length measurements.

13.2.3 CALCULATIONS AND FORMULAS

The software not only allows performing direct measurements, but it is also capable of computing derived parameters by use of different mathematical formulas.

> ⚠️ In the absence of a correct calibration all measurements on the images are invalid.
>
> ⚠️ The program does not perform any control on the consistency of the calibration factor. It is <u>always</u> necessary to check the calculated calibration factor to verify whether it is admissible.
>
> ⚠️ The program does not perform any control on the clinical validity of the measurement. The operator must visually verify the validity of any measurements taken.

13.3. MEASUREMENTS MANAGEMENT

The product allows for detailed management of the measurements taken.

When a measurement is already present and re-executed, the software, by default, replaces the old value with the new one.

However more than one measurement on the same sample (or on various samples) can be performed and stored, calculating the mean value and the standard deviation. To perform multiple measurements and display the mean value click the button shown below. If this mode is active the button will turn yellow.

In the case of repeated measurements, the value shown nearby the item text is that of the mathematical average. However it is still possible to see all the measured samples. Alongside of every measurement is an arrow which allows accessing a management menu for the item.

By clicking on the little arrow and then on *Show Details*, a window will be displayed in which all the samples taken for that item are shown together with the average and the standard deviation.

It is possible to delete a measured value if it seems incorrect. Simply select it and click on the *Remove* button. Use the buttons *Show* and *Hide* to show or hide the measurements on the image.

Another useful function is the ability to immediately display the image frame from which the measurement was taken. From the measurement menu, when clicking on the *Go to measurement time* option, the software automatically selects the image and the specific frame on which the measurement was performed.

The feature *Go to measurement time* is available only for off-line measurements taken with ComPACS.

13.4. CUSTOM SETTINGS

This component provides different user configurable settings, located in the *Program Settings* window, under the *Generic Measurements* tab.

"Enable measurement average at startup" automatically enables the average function when the component is activated.

"Multiple measurements (if average is enabled)" allows the user to measure a specific field multiple times, without having to press again the corresponding button. The measurement sequence can be interrupted by pressing the right mouse button.

"Invert X and Y axis" is used if the X and Y axis are to be interpreted differently in relation to the measurement structured menu. This option can be automatically enabled when the component is activated.

"Automatically detect Doppler baseline" is used automatically detect the Doppler baseline and allow for faster, one-click, velocity measurements. This feature can be disabled if the DICOM image does not contain a correct encoding of the Doppler baseline correctly.

"Use original pen cursor" uses the pen cursor of previous software revisions. Starting from 10.8.6 the pen cursor has been replaced with a sight view cursor.

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14. PHILIPS QLAB

14.1. ACTIVATING PHILIPS QLAB

If Philips QLAB integrated in ComPACS Workstation is enabled on your system, the following button will be available on the toolbar, on the right hand side:

QLAB ▾

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server. If the license cannot be received then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

Philips QLAB, in addition to the core viewer, comprises of different analysis modules that can be separately licensed. The specific modules licensed for your workstation can be viewed by clicking on the arrow to the right hand side of the activation button. A drop down window will be displayed, listing the available modules.

In this window you may to select or de-select the modules that you wish to activate. When clicking on the QLAB button only the license for the selected modules will be requested.

14.2. LAUNCHING PHILIPS QLAB

The Philips QLAB plug-in can be activated simply by right clicking in the thumbnail window on the item to be analyzed. The following menu will be displayed:
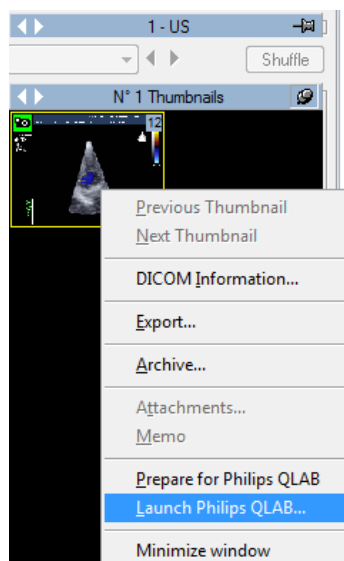
By selecting *Launch Philips QLAB* the plugin will be immediately opened on such selected image.
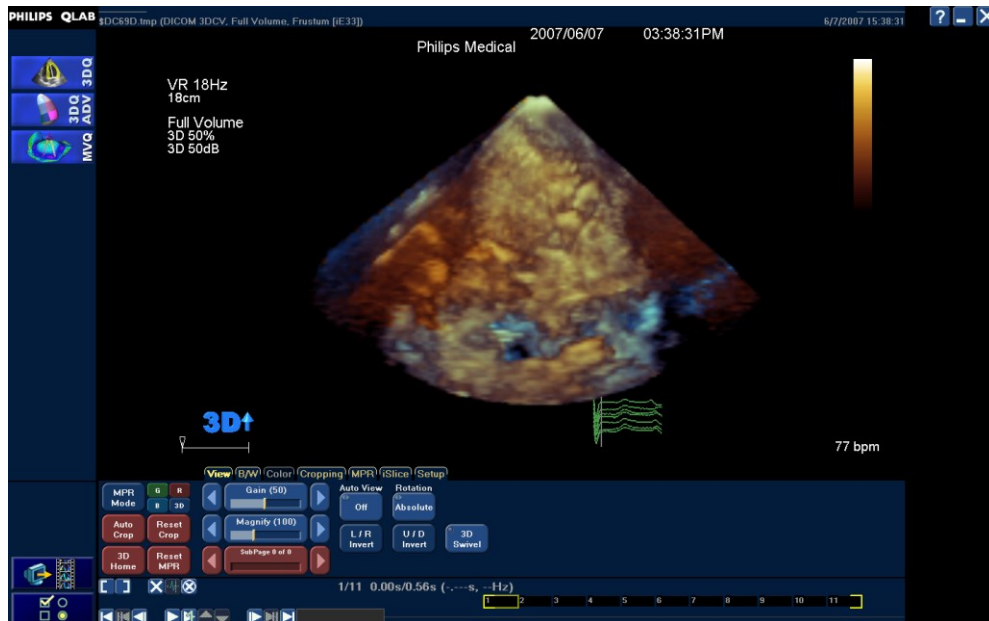
Alternatively, you may add the selected image to the analysis queue. This can be used if more than one item needs to be passed to the QLAB application.

Furthermore, by right clicking on the series window, you may directly analyze an entire series. The following menu will be used:
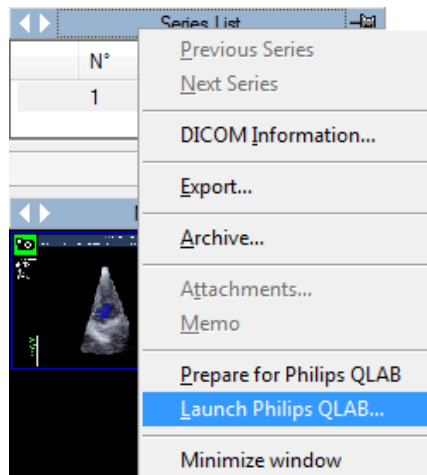
When working within the QLAB application, the content of the screen can be saved, either as an image or as a loop, using the following button:

The saved object will be automatically stored to the archive together with the original image analyzed.

Similarly it is also possible to export DICOM Structured Report data using the following button:

The report data will also be automatically imported in the opened report, if there is one open for editing at the time the data is exported.

> ⚠ This guide describes only how the Philips QLAB application can be launched. For usage information, cautions and warnings, and any other instruction please refer to the QLAB user guides and documentation.

15. GE ECHOPAC PLUGIN

15.1. ACTIVATING GE ECHOPAC PLUGIN

If General Electric EchoPAC Plugin integrated in ComPACS Workstation is enabled on your system, the following button will be available on the toolbar, on the right hand side:

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server in addition to the local workstation license provided by General Electric. If the license cannot be received then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

15.2. LAUNCHING GE ECHOPAC PLUGIN

The EchoPAC plug-in can be activated simply by right clicking in either the patient window, the study window, the series window or even the thumbnail window on the item to be analyzed. Typically this operation is performed at the study level.

The following menu will be displayed:
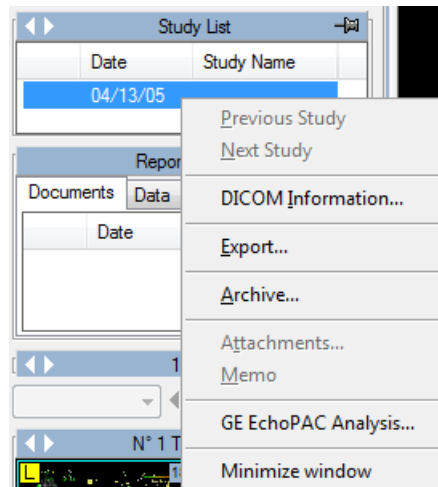
By selecting GE EchoPAC Analysis... the plugin will be immediately opened on such selected item.

When working within the EchoPAC application, the content of the screen can be saved, either as an image or as a loop, using the following button:

The saved object will be automatically stored to the archive together with the original image analyzed.

If any measurement is performed in the application, automatically a DICOM Structured Report will be saved once the user exits the application. This will allow the results of the measurements to be imported into the report.

> ⚠ This guide describes only how the GE EchoPAC Plugin application can be launched. For usage information, cautions and warnings, and any other instruction please refer to the EchoPAC Plugin user guides and documentation.

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16. TOMTEC ANALYSIS

16.1. ACTIVATING TOMTEC ANALYSIS

If TomTec Analysis modules integrated in ComPACS Workstation are enabled on your system, the following button will be available on the toolbar, on the right hand side:

If the button is pressed down, then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation the module will request a runtime license from the ComPACS Server in addition to the license provided by the TomTec licensing server. If the license cannot be received then the module will fail to activate and an error message will be displayed.

In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

TomTec, in addition to the core Image-Com viewer, comprises of different analysis modules that can be separately licensed. The specific modules licensed for your workstation can be viewed within the TomTec application once the TomTec viewer is launched.

16.2. LAUNCHING TOMTEC ANALYSIS

The TomTec Analysis plug-in can be activated simply by right clicking in either the patient window, the study window, the series window or even the thumbnail window on the item to be analyzed. Typically this operation is performed at the study level.
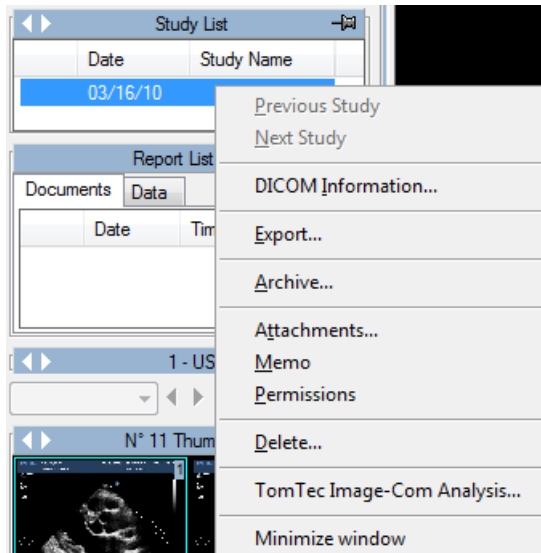
By selecting TomTec Image-Com Analysis… the plugin will be immediately opened on such selected item.

When working within the TomTec application, the content of the screen can be saved, either as an image or as a loop, using the following button:
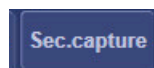

The saved object will be automatically stored to the archive together with the original image analyzed.

If any measurement is performed in the application, automatically a DICOM Structured Report will be saved once the user exits the application. This will allow the results of the measurements to be imported into the report.

 This guide describes only how the TomTec Image-Com application can be launched. For usage information, cautions and warnings, and any other instruction please refer to the TomTec user guides and documentation.

17. ECG MANAGEMENT

17.1. REVIEW OF DICOM ECG

> **ℹ** In order to review DICOM ECG in ComPACS, the ECG Viewer module needs to be licensed. The ECG viewer does not require any user manual activation: the license is automatically activated at login.

If a DICOM ECG object is present for the selected study, a thumbnail similar to the one shown below will be visible in the *Thumbnails* window.
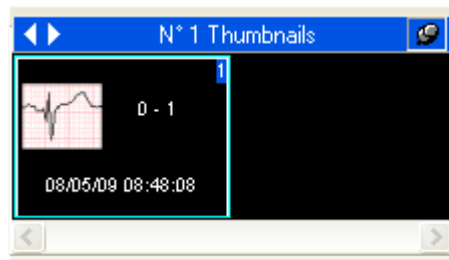
Clicking the thumbnail will open the ECG DICOM object for review. At the top of the ECG display window, a set of controls are visible:
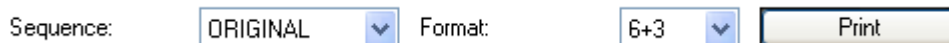
The *Sequence* drop down control lists all the ECG sequences available. The *Format* drop down control allows you to choose the preferred display format. The *Print* button allows you to print the selected ECG sequence in real scale units.

Immediately below the user controls, information about the patient, study and ECG object is displayed in different columns. The first column contains patient information (ID, Name, Date of Birth, Age, Height, Weight, Systolic and Diastolic Pressure), the second column contains study information (Date, Time, Accession Number) and ECG reference measurements (Heart Rate, PR interval, etc.). On the right hand side, the ECG report is displayed. Please note that some information may not be visible if not present in the DICOM file.

Patient ID: ANONIMIZED.CPS000000   Study Date: 08/05/09   SAMPLE REPORT
Last Name: Doe   Study Time: 08:48:08
First Name: John   Vent. rate: 69 BPM   NORMAL ECG.
Patient Sex: Male   PR int.:   183 ms
DOB: 03/18/47   QRS dur.:   92 ms
Age: 62 years   QT/QTc: 364 / 382 ms   Electronically signed by Amministratore on 11/14/10 at 11:36:14
Height: 1.80 m   P-R-T axes: 62 57 52
Weight: 90.0 Kg
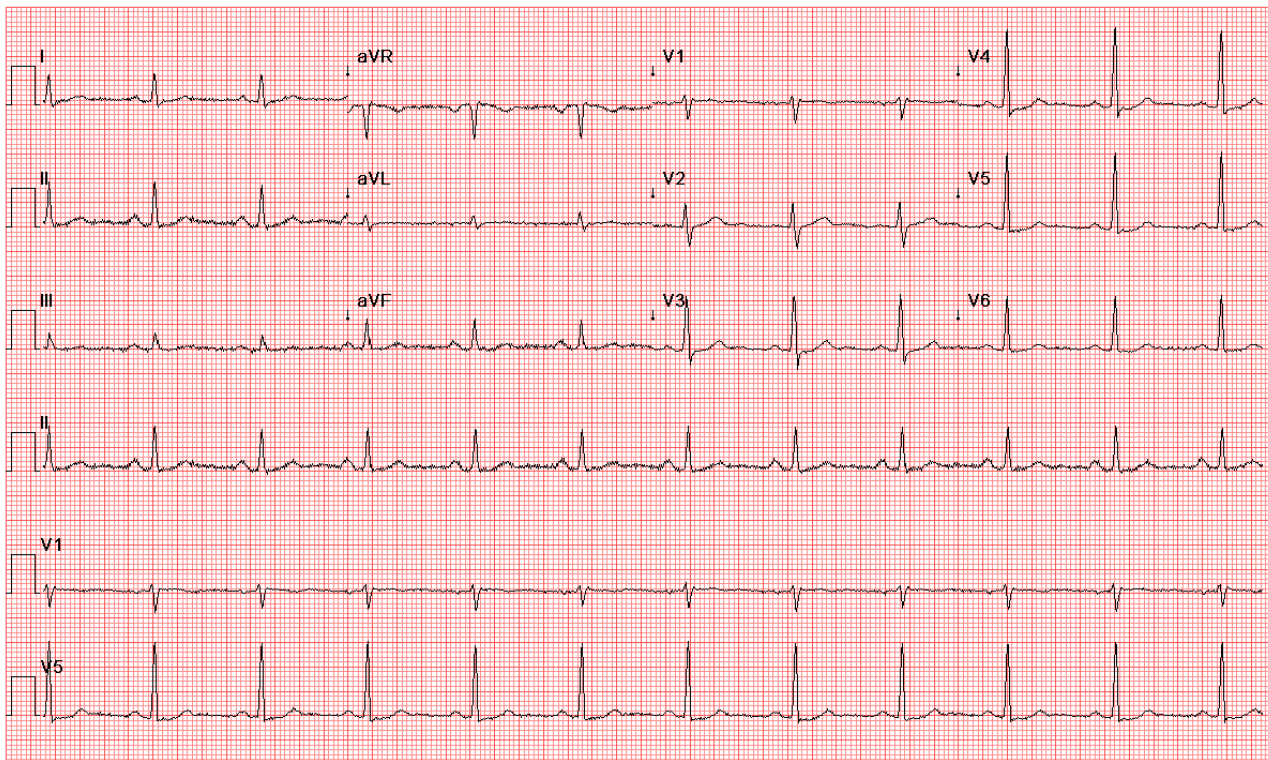
i ECG objects can also be processed with the same tools described in this manual for image objects. For example the features related to multi-study comparison, zooming, exporting and storing are all available.

17.2. ACTIVATING ECG ANALYSIS AND REPORTING

If the ECG analysis and reporting module is enabled on your system, the following button will be visible in the toolbar, on the right hand side:

If the button is pressed down then the module is already active. Otherwise it can be activated by clicking the button with the mouse.

Upon activation, the module will request a runtime license from the ComPACS Server. If the license cannot be received, then the module will fail to activate and an error message will be displayed.

 In case of concurrent licenses it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.

Activation failure can also occur if the network connection to the server is no longer available.

Please ensure that the module is released, by releasing the above button, after you have finished using the product so that the license is available for use by other users.

When the module is active, a window named "ECG Analysis" is added and visible in the control window. It can be opened or minimized with a single mouse left button click on the blue bar.

17.3. REPORTING

The ECG preliminary report, imported from the ECG device, is displayed on the right hand side, above the ECG traces as shown below.

Depending on the ECG system used, this portion can either be empty or contain automated diagnosis performed by the software on board of the device.

Double clicking on the report text area, a new report will be created or, if a report already exists, such report will be opened in editing mode.

Please refer to the "Reporting" Chapter for more information.

17.4. OFF-LINE MEASUREMENTS

The ECG module provides the possibility of performing measurements on DICOM ECG objects.

Measurements are available in the *Generic* tab of the ECG Analysis window.

> ⚠ Generic measurements are only temporary. They are not stored to the ComPACS database and cannot be retained.
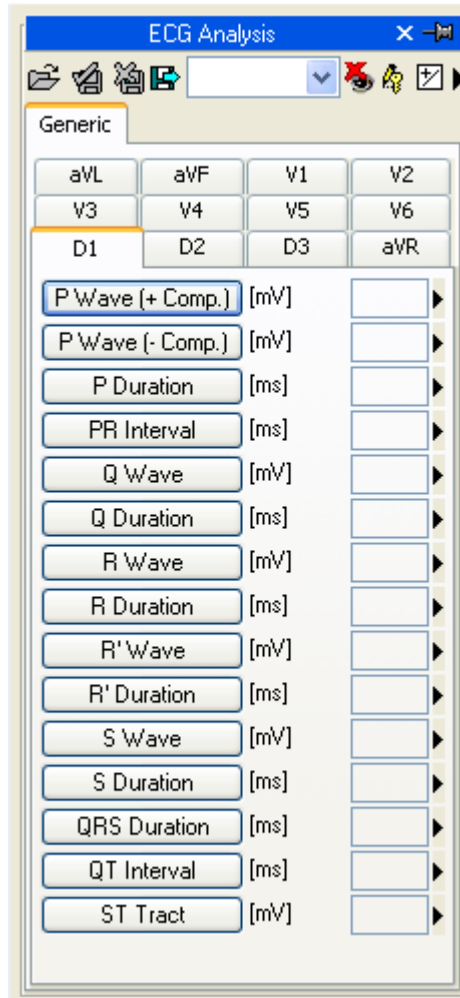
To access a more advanced or customized measurement panel, open either an already existing DICOM SR ECG report or create a new one. This operation can be performed by clicking on the toolbar icon ▤ as described in the "*Managing Evidence and Report*" chapter.

The analysis window will be extended with an additional *Structured* tab containing all the structured measurements. The appearance and content of the tab will depend on the reporting templates and analysis views configured by the system administrator for the specific workstation or user.

> ℹ️ Structured measurements are stored in the DICOM SR object they refer to.

In this interface, only the windows corresponding to the data present in the open object will be filled (with numbers). To edit the opened report click the *Editing* icon:

To close and save the changes made click on the *Close and Save changes* icon:

To close without saving any changes click on the *Close discarding changes* icon:

To export the data it is necessary to click the *Export the report data to file* icon:

An interface will be opened where you may select the data format and the file destination.

In the drop-down list, it is also possible to select an export template based on the installed configurations.

This functionality has been extended to export not only numerical values but also other field types (text, findings, dates, etc.). Furthermore the export also includes nested and repeated record structures.

The template is a simple text file which lists, in separate lines, the fields which need to be exported. Each line has the following format:

FieldID; *Label - Optional*; *Unit - Optional*

If the label or the unit are not specified, the default values shall be used.

For repeated records, the list of fields need to be enclosed in the following statement:

BEGINGROUP(*Record Field ID*); *Label – Optional; Index – Optional*
… list of fields ..
ENDGROUP(*Record Field ID*)

The index is optional and, if omitted, all records shall be exported.

Finally some special fields consist in DICOM fields. They are identified as follows:

   $(Group,Element) ; *Label - Optional*;

17.4.1 ECG TRACE CALIBRATION

The calibration information is contained in the DICOM ECG file. The product exploits it to avoid a manual calibration and ensure greater accuracy. Therefore calibrating ECG files in order to perform measurements is not required.

17.4.2 PERFORMING MEASUREMENTS

Now we are ready to perform some offline measurements on the ECG traces.

Once the ECG object is chosen, select the value to be measured on the measurement panel. In particular there are two panels: the *Generic* panel, which is always available, and the *Structured* panel which depends on the configuration set up and requires the opening of a report (intended as DICOM SR object).

⚠ The generic measurements are only temporary and will not be stored to a DICOM SR Object.

By clicking on the item, the mouse pointer becomes a pen. With a few mouse button clicks on the ECG trace, the software traces the measurement (in blue) and saves it to the ComPACS Database in the DICOM SR format. The following picture shows an example of time measurement:
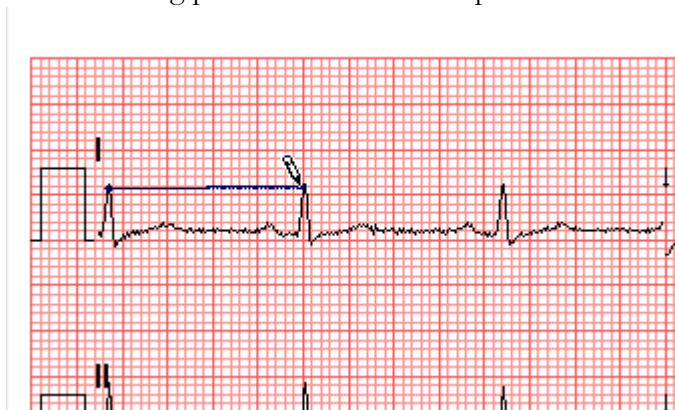
To proceed, first select the desired measurement by clicking the chosen button in the control panel. Move the cursor to the starting point of the desired measurement and left-click once, the cursor will become a pen. Move the cursor to the end point of the measurement and left clicking once will terminate the measurement and populate the result in the chosen location.

17.4.3 CALCULATIONS AND FORMULAS

The software not only allows performing direct measurements, but it is also capable of computing derived parameters by use of different mathematical formulas.

> ⚠ In the absence of a correct calibration all measurements on the images are invalid.
>
> ⚠ The program does not perform any control on the consistency of the calibration factor. It is <u>always</u> necessary to check the calculated calibration factor to verify whether it is admissible.
>
> ⚠ The program does not perform any control on the clinical validity of the measurement. The operator must visually verify the validity of any measurements taken.

The product allows for detailed management of the measurements taken.

When a measurement is already present and re-executed, the software, by default, replaces the old value with the new one.

However more than one measurement on the same sample (or on various samples) can be performed and stored, calculating the mean value and the standard deviation. To perform multiple measurements and display the mean value click the button shown below. If this mode is active the button will turn yellow.

In the case of repeated measurements, the value shown nearby the item text is that of the mathematical average. However it is still possible to see all the measured samples. Alongside of every measurement is an arrow which allows accessing a management menu for the item.

By clicking on the little arrow and then on *Show Details*, a window will be displayed in which all the samples taken for that item are shown together with the average and the standard deviation.

It is possible to delete a measured value if it seems incorrect. Simply select it and click on the *Remove* button. Use the buttons *Show* and *Hide* to show or hide the measurements on the image.

If ECG analysis has been performed on the same patient in previous studies stored in the ComPACS database, you may view how a specific measurement field has varied over time.

This operation can be performed by clicking on the *Show Trend* item in the menu. A window will be displayed in which the different values over time for the identified measurement are displayed both numerically and in a graphical format.
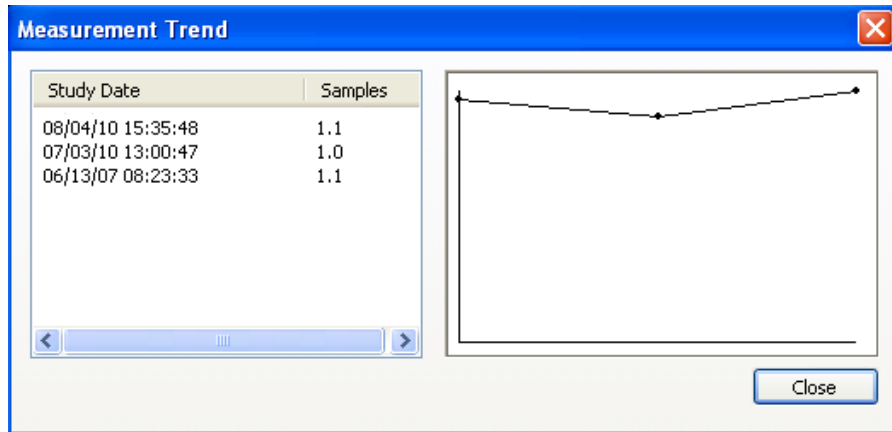
Another useful function is the ability to immediately display the ECG trace from which the measurement was taken. From the measurement menu, when clicking on the *Go to measurement time* option, the software automatically selects the trace on which the measurement was performed.

 The feature *Go to measurement time* is available only for off-line measurements taken with ComPACS ECG.

Also by clicking on the *Edit Manually* button it is possible to manually insert the value instead of measuring it or calculating it. This value will be underlined in yellow to indicate it is a manually inserted measurement.
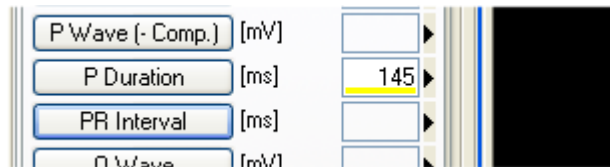
To show/hide the measurements on the images click on this icon:

To fix the measurement graphics on the display:

To close and save the changes click on the *Close and Save* icon:
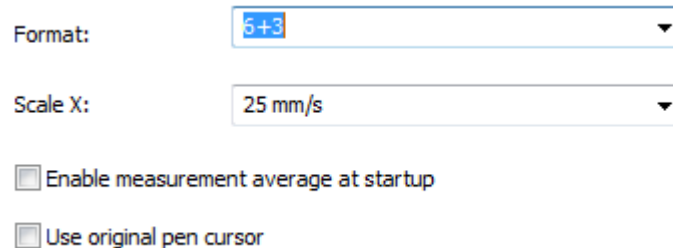
To close without saving the changes click on the *Close Discarding changes* icon*:*

17.6. CUSTOM SETTINGS

This component provides different user configurable settings, located in the *Program Settings* window, under the *ECG* tab.

| Format: | 5+3 ▼ |
| Scale X: | 25 mm/s ▼ |

☐ Enable measurement average at startup

☐ Use original pen cursor

The default format and time scale to use for review can be indicated.

"Enable measurement average at startup" automatically enables the average function when the component is activated.

"Use original pen cursor" uses the pen cursor of previous software revisions. Starting from 10.8.6 the pen cursor has been replaced with a sight view cursor.

18

18. REPORTING

18.1. ACTIVATING COMPACS REPORTING

> **STOP** To be able to create or open a report, it is first necessary to adequately configure your system. Please refer to your system administrator and to the *System Administrator's manuals* for more details.

If ComPACS Reporting is enabled on your system, the following button will be visible in the toolbar, on the right hand side:

If the button is pressed then the module is already active. Otherwise it can be activated by pressing the button with the mouse.

Upon activation, the module will request a runtime license from the ComPACS Server. If the license cannot be received, then the module will fail to activate and an error message will be displayed.

> **i** In case of concurrent licenses, it is possible that all available licenses have already been requested and assigned to other users that are using the module at that time and that no licenses are left for activation. This is a likely cause for failure.
>
> Activation failure can also occur if the network connection to the server is no longer available.
>
> Please ensure that the module is released by releasing the button above, after you have finished using the product so that the license is also released for use by other users.

When the module is active each time a report is opened or created a reporting window will be displayed.

18.2. CREATING OR OPENING A REPORT

In order to create or open a report, a study first needs to be opened for review.

Then, press the report button on the toolbar . There can be different situations:

a) There are no reports for the selected study. A new report is created. A dialog window will allow you to select all the necessary parameters.

b) Only one report exists for the selected study and the report type is automatically identified. The report is opened for editing. Please note that obsolete reports (i.e. reports that are marked as predecessor of other reports) are not included in the report count.

c) Only one report exists for the selected study but the report type cannot be automatically identified. A dialog window will ask the user to associate the report to one of the configured templates.

d) More reports exist for the selected study. A dialog window will be displayed, asking the user to confirm the creation of a new report and the importing of the previous reports.

Please refer to the "Managing Evidence and Reports" chapter for more detailed information.
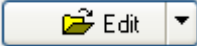
Once the report is opened, a new *Report* tab window will be opened in the monitor identified for this operation. At the top of the window, a brief report summary will be presented.

The summary will present the patient ID, name, study date, report date, report status (if modified, verified, finalized, etc.), language (character set used) and the *Reporting Views* and *Print Templates* currently selected.

 The *Reporting Views* and *Print Templates* can also be changed dynamically, similarly to the character set used, simply by selecting from the drop down menus displayed above. The other fields are read only and managed directly by the software.

Newly generated reports will be opened directly in *Edit* mode. Existing reports are instead opened by default in *Viewing Only* mode. To edit them, you simply need to press the button and have sufficient privileges to perform this operation on the selected report.

If a report has already been approved and signed, it is no longer possible to edit its content. A new cancellation report or replacement reports needs to be created, by clicking the arrow to the left of the button and selecting the appropriate item from the drop down menu:

Open the Report for Editing
Create a Replacement report
Create a Cancellation report
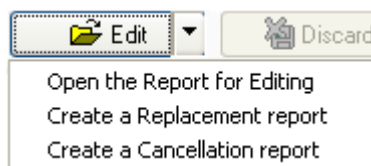
Below you will see a number of sub-windows, also arranged by tabs. The first tab is always present and conveys the *Revision History* information about the report. The layout of the remaining tabs varies depending on the specific template and view selected. A possible example is depicted in the following picture.
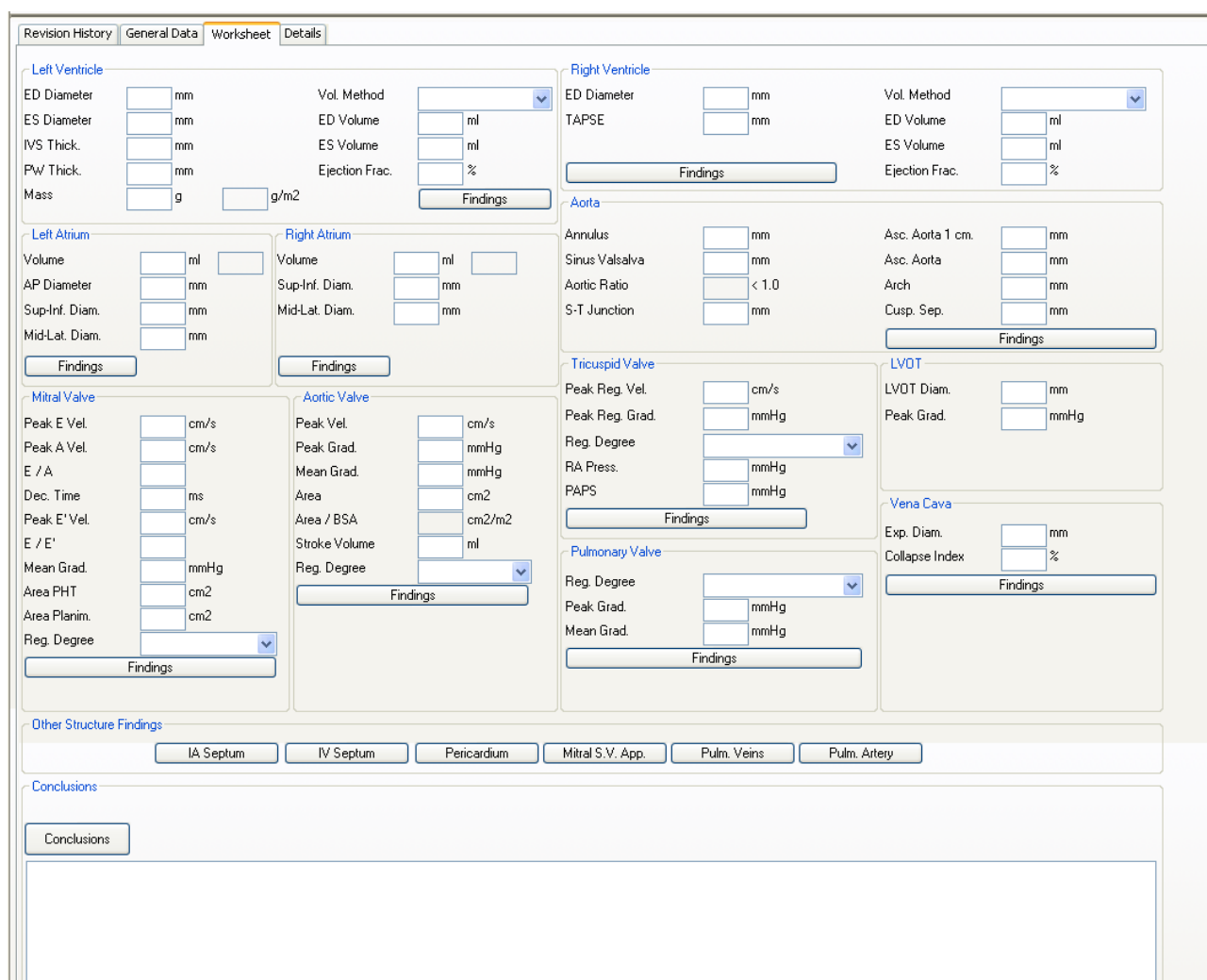
In the example, you can see a worksheet with different measurement fields and with buttons named after anatomical structures. By pressing these buttons, pop-up windows will be displayed to allow structured reporting selections.
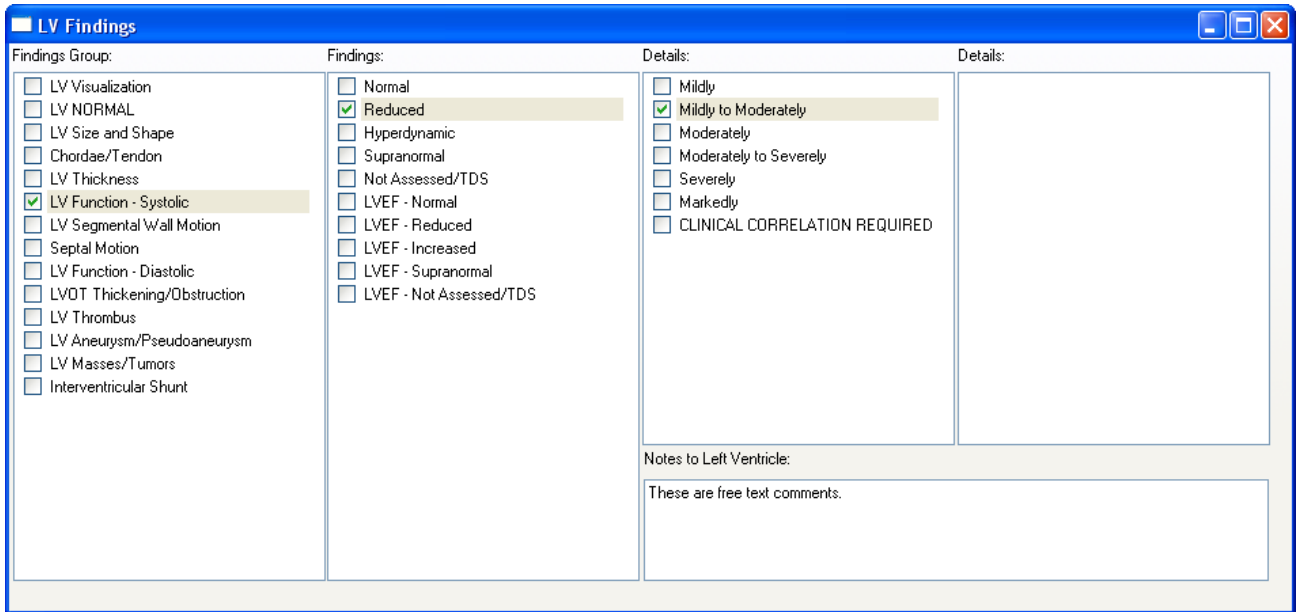
Some boxes for free text or graphical items can also be present.
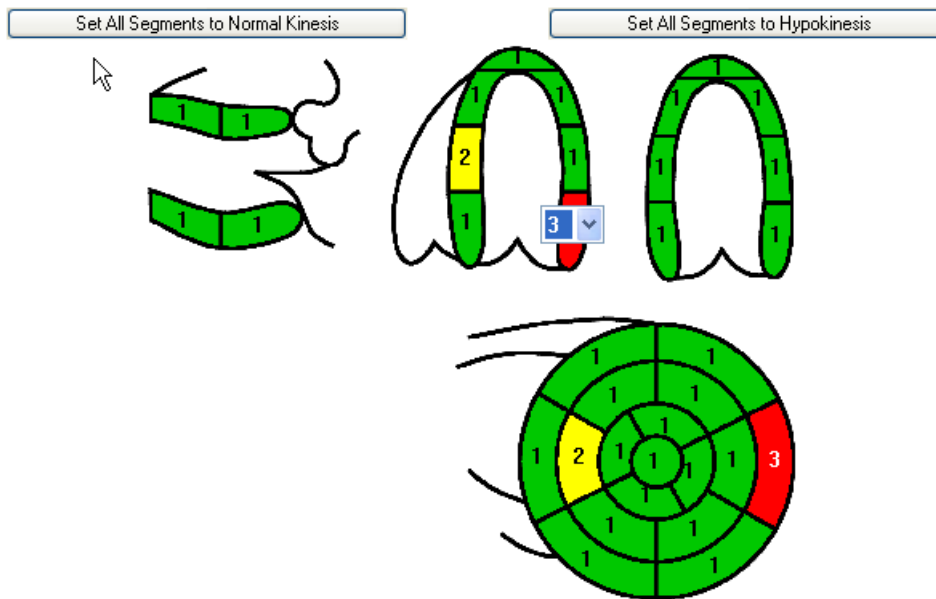
The structure of the report menus depends entirely on the template and the related *Context Groups* and *Reporting Views* selected. What is presented in this guide is just a possible example.

18.3. PREVIEWING AND PRINTING THE REPORT

It is possible to display a preview of the report by pressing the *Preview* button. An additional tab will be displayed with the requested preview.
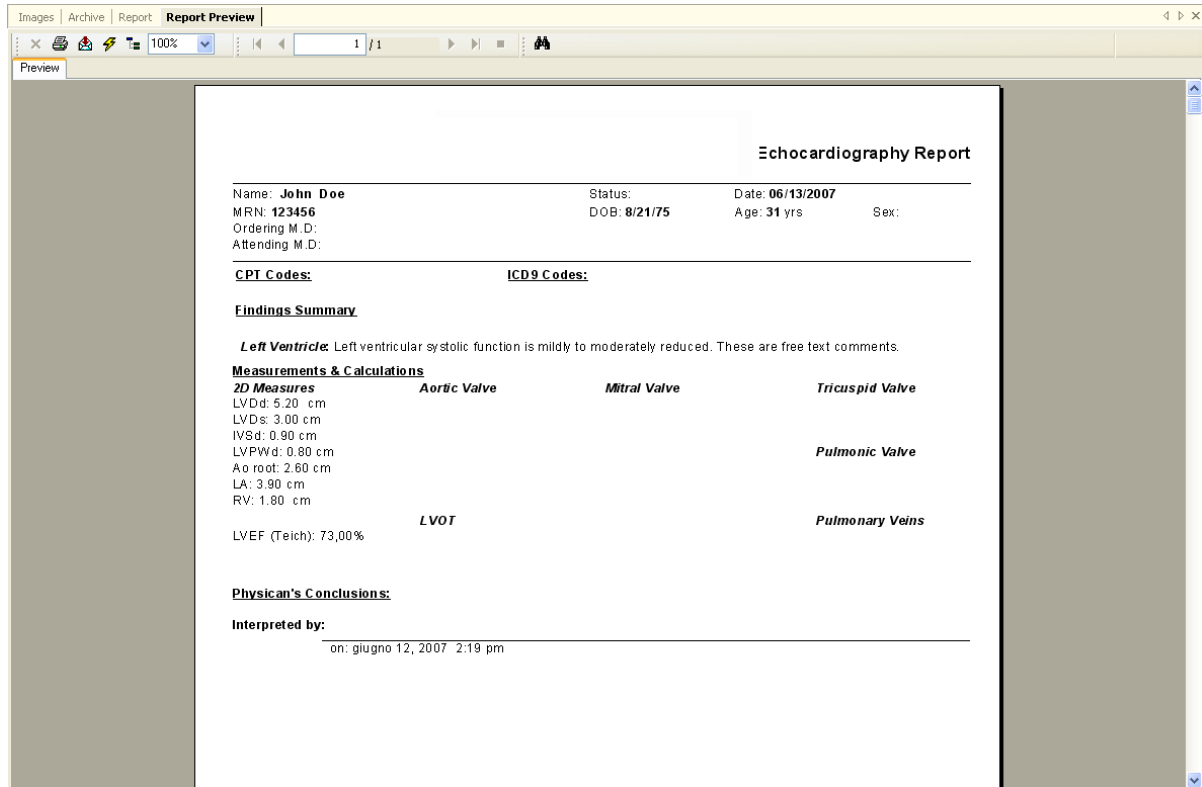
If the report is being created or edited, this preview will be dynamically updated every time some changes are made to the structured reporting selections or in the measurements.
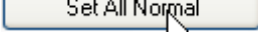
 In a multi-monitor setting, this preview could be shown side by side to the structured reporting view.

The *Print* button allows you print the report to a system printer and the *Export* button to export it to common electronic formats such as *PDF, RTF, HTML, Excel,* etc.

18.4. ADVANCED OPERATIONS

18.4.1 ALL NORMAL STATEMENTS

Reports for normal patients can be created quickly using the button [Set All Normal] which sets the default normal values for the report being edited.

It is also possible to remove such selection by using the "*Other Tasks*" drop down menu and selecting "Remove All Normal" item.
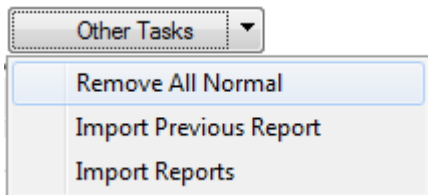
18.4.2 IMPORTING PREVIOUS REPORTS

Using the "*Other Tasks*" drop down menu and selecting "Import Previous Reports" or "Import Reports" items it is possible to import a report a previous study of the same patient in order to avoid entering a similar diagnosis.
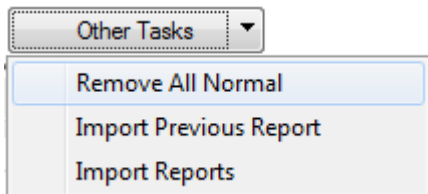
If the "Import Previous Report" item is selected, the system will automatically import the most recent compatible (of the same type) report.

If the "Import Reports" item is selected a dialog will be displayed to allow the manual selection of the report to import.

The specific fields to be imported are to be configured by an application specialist.

18.4.3 RECOMPUTING VALUES

[Recompute]

The Recompute button is activated when the mouse cursor is positioned on a measurement field with an associated formula. By clicking the button, the formula will be executed and, if applicable, the selected field value updated.

18.4.4 MEASUREMENT DETAILS

[Details]

The Details button is activated when the mouse cursor is positioned on a measurement field. By clicking the button, a window will display all the different measured or imported samples for the selected field, their mean value and the standard deviation.
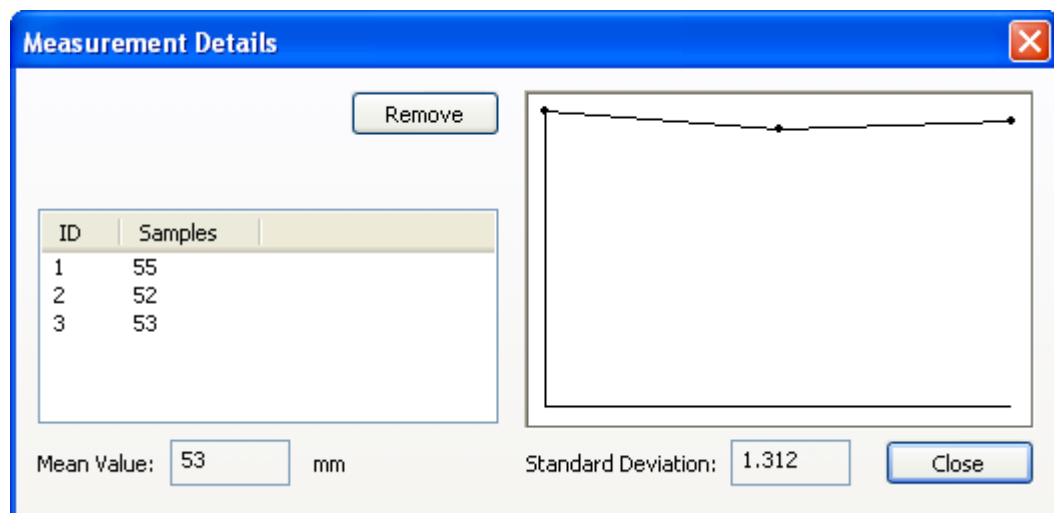
18.4.5 MEASUREMENT TRENDS

[Trends]

The Trends button is activated when the mouse cursor is positioned on a measurement field. By clicking the button, a window will display the trend over time for the selected field, considering all previous reports for the selected patient.
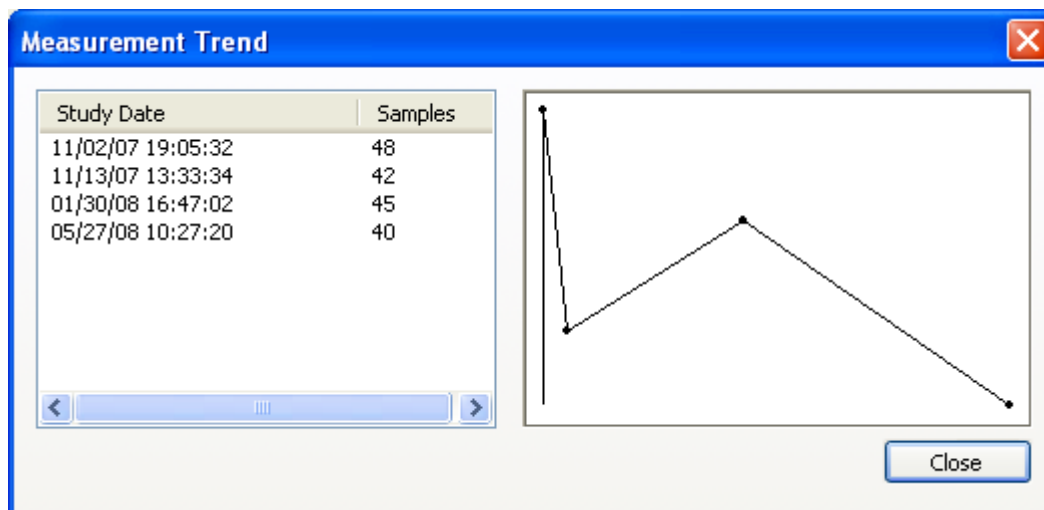
18.5. CONFIRMING OR DISCARDING CHANGES
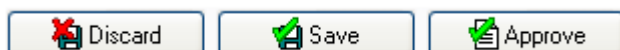
If in Edit mode, you need to decide what to do with the changes applied before closing the report. If you want to discard the changes made since the last edit operation or just discard a new report, simply press the Discard button. If instead you want to save the changes but leave the report open for editing, press the Save button; a dialog will prompt you for additional information.

Please press the button to confirm your choice.

To Be Completed – This is used if you need to temporarily stop the reporting process in the middle of a non complete report.

To Be Verified – This is used if the report is complete but you do not have the authority to verify/validate its content from a medical standpoint.

Verified – This is used if the report is complete and is to be verified from a medical standpoint. The report can still be edited pending final approval by an authorized user.

Finally, if you want approve and sign the report, press the *Approve* button. A window will display the final, signed, report in PDF format for your review and final confirmation.

Information about the user currently logged on, his or her name and the type of report (Original, Replacement or Cancellation) is also provided.

 Depending on your privileges, it is possible that only a subset of these options is available to you.

 After *Approval* no further changes are allowed on the report which is definitively archived.

 Upon approval, the system generates a PDF version of the report with the print template in use at the time of finalization. This PDF file, encapsulated in a DICOM object, is stored for future reference in the exact content and layout.

⚠️ If the print templates are modified, the report content and layout in preview may change even after finalization. It is important to always reference the PDF version for the content and layout of the report issued.

18.6. REVISION HISTORY

The revision history tab is common to all templates and shows the current status of the report as well as the history of the changes that occurred, the user responsible for such changes and the date/time at which they took place.

If a digital signature has been applied to the report document, the details about the signature process as well as possible additional information, is also listed.

19. APPENDIX A

19.1. POST MARKETING SURVEILLANCE

⚠️

This software is subject to post marketing surveillance in order to detect or become aware of, as rapidly as possible, real or potential hazards for the patient and/or operator due to incorrect functioning of the software and consequently resolving such problems in the fastest and most efficient way.

For this reason, if the operator notices any incorrect functioning of the software, reduction or limitation in its performance, inaccuracy or inadequacy of the labeling or operator's manuals, that may lead to a real or potential hazard for the patient and/or operator, we kindly request to be immediately informed directly or through our representatives by filling in the following form or sending a communication conveying the same information. All the information related to the software (name, version, license code) are available in the *about window* of the program and in the installation CD. In this way, we can undertake all adequate preventive and corrective actions with the greatest efficiency and speed.

19.2. Hazard Notification Form

Send to: MEDIMATIC S.R.L.

              Quality Assurance Function

              Viale Cembrano 4C

              I-16148 Genova ITALY

Fax :   + 39 - 010 - 3074548

Software Name: …………………...……………..

Integrated Module(s) Name(s):   ………………...……………

…………………………………………………………………………………………………….

License Code(S/N):   …………………...…………….

Description of the real/potential hazards: ………………….........................………….

        …………...……………

        …………...……………

Notes and suggestions: …………………...………….

        …………...……………

        …………...…………….

Person/Department to Contact: …………………...…………

        …………...……………

Address: ……………………...…………….

        …………...……………

Phone: .... Fax: ………………….........................…………

E-Mail: ...…………………………...……………………………………..

Date: ……………….. Signature: …………………….......................................…………………..

B

20. APPENDIX B

20.1. CONFIGURATION

20.1.1 WEB & SERVER TOOLS

Before using ComPACS Review Station your site must first make sure each server-side component is installed and correctly configured. Please refer to the *System Administrator's Manuals* to configure each server component.

> **STOP** The configuration parameters of the *ComPACS Server* determine the parameters to be used in configuration of the *ComPACS Review Station* to access the archive/server.

20.1.2 FIRST LAUNCH

Once the software is installed, by clicking the start icon of ComPACS Review Station (as described in chapter 3) the software will be launched.

At the first launch, a configuration window will appear. This is the *Archive Configuration* window.

The first choice is to determine if this configuration is valid only for the current workstation (identified by its *Workstation AE* Title) or to *All others*, meaning all the workstations for which no dedicated configuration has been defined. The *Add Workstation* and *Delete Workstation* respectively allow the creation or removal of dedicated workstation settings.

Then in this window you need to initially assign the following parameters:

Configuration Name   - A name identifying this specific archive configuration

Archive Type   - The type of archive you are connecting to.

Default Domain   - The default domain the users logging into this archive belong to.

Default Archive   - If this is the default configuration to be prompted upon startup.

There currently two different sets of *Archive Types* available: a) archives which represent ComPACS systems (ComPACS Server – Protocol 2) and, b) Third party archives accessible via DICOM network protocol (DICOM).

To connect to a ComPACS archive you need to specify the following additional information:

Host Name/IP - dns name or IP of the server on which the *ComPACS Archive Service* is running.

AE Title - The AE Title of the Server

Description - A free text description (does not need to match the server side description).

SQL Server - The name of the Microsoft® SQL Server instance on which the ComPACS database is installed.

<table>
<tr><td>SQL Catalog</td><td>- The name of the catalog within the above SQL server in which the database is installed.</td></tr>
<tr><td>COM Auth. Level</td><td>- The type of COM/DCOM authentication the client uses to access the archive service.</td></tr>
<tr><td>Port</td><td>- The default value automatically prompted is recommended.</td></tr>
<tr><td>Timeout</td><td>- The default value automatically prompted is recommended.</td></tr>
</table>

and for the *Client*:

<table>
<tr><td>AE Title</td><td>- The AE title of the workstation. This needs to have been already configured with the Web & Server Tools.</td></tr>
<tr><td>Request Single Sign On</td><td>- This parameter can be checked if the workstation is to automatically authenticate the user on the basis of the current Windows logged on user.</td></tr>
</table>

To connect to a ComPACS Web Server archive using HTTP/HTTPS you need to specify the same information and, in addition, the following items:

<table>
<tr><td>Server URL</td><td>- This is the URL of the Web Server. Typically http://<machinename>/webserver.</td></tr>
<tr><td>Proxy Type</td><td>- The type of proxy used. Generally "Default Internet Explorer". Custom proxy settings (Address, User and Password) may also be configured.</td></tr>
</table>

To connect to a DICOM archive you need to specify the following additional information:

<table>
<tr><td>Host Name/IP</td><td>- dns name or IP of the server on which the DICOM Server is running.</td></tr>
<tr><td>AE Title</td><td>- The AE Title of the DICOM Server</td></tr>
<tr><td>Description</td><td>- A free text description.</td></tr>
<tr><td>Port</td><td>- The port on which the server is listening for incoming connections.</td></tr>
<tr><td>Timeout</td><td>- The association timeout that the server allows for a connection (expressed in seconds).</td></tr>
</table>

Max PDU	- The maximum PDU size that the server expects. The value is expressed in Kb.
<DICOM Prop.>	- Check boxes for the different DICOM services that the server provides.
<Advanced>	- Advanced DICOM settings, recompression formats for C-STORE operations and logging functions.

And for the *Client*:

AE Title	- The AE Title of the DICOM Server
Port	- The port on which the server is listening for incoming connections.
Timeout	- The association timeout in attempting a connection (expressed in seconds).
Max PDU	- The maximum PDU size to propose in DICOM associations. The value is expressed in Kb.

The *Verify* button allows you to perform a C-ECHO to see if the parameters are correctly set.

Once set, apply the parameters by clicking the *New* button. The software will put the registered archive in the field labeled *Archive List*. This method allows you to add several archives or to edit already defined ones.

It is worth noting that the main archive should be set as the default by clicking on *Set As Default*. This way it will automatically be available to all Windows® users and it will also always be possible to retrieve the default settings (in case of mistakes) by clicking on *Restore Default*.

Once all the necessary parameters have been set, each successive start will bring up the *log in* dialog window and ask the user for a *user name* and the *password* needed for the logon. You can also logon as Anonymous, but this logon does not allow the access to the archive. The allowed logins are only those previously configured with the *Web Tool*.

20.1.3 ADDITIONAL ARCHIVES

The login configuration defines the main archive. In addition secondary archives per each configuration can be configured in a similar way using the *Program Settings* item of the *File* menu and going to the *Archive* tab. This way, ComPACS can perform simultaneous queries on multiple archives instead of a single one.

20.1.4 OTHER OPTIONS

The *Other Options* button allows the configuration of the default archive settings.

It is possible to indicate whether wildcard characters are to be automatically added to search fields. Please note that this feature does not apply to ID fields such as Patient ID or Accession Number.

It is also possible to indicate the default filtering values for the Archive Search window, the Information Source provider to use and the default status for new created studies. For most fields the system can also retain the last settings used for each user.

21. APPENDIX C

21.1. ECHO ANALYSIS ACCURACY AND PRECISION

In this appendix the terms *accuracy* and *precision* have the following meaning:

Accuracy - the absolute value of the difference between the real measure and the mean of the estimated measurements;

Precision - the standard deviation of the estimated measurements.

The following table reports the mean values and precision of an experiment in which repeated measurements of geometrical artificial structures in an ultrasound DICOM image.

Measurement	Accuracy	Precision
Linear measurements	0.3 pixel	1.2 pixel
Areas	0.1 pixel^2	0.4 pixel^2
Perimeters	0.3 pixel	1.3 pixel

Values are expressed in pixel units since the real measurement uses various units of measurement for each ultrasound image type (meters, second, m/sec). To obtain the accuracy and the precision in the specific unit of measurement for the given image type, it is simply sufficient to compute the derived value on the basis of the horizontal and vertical calibration image factor.

Generally for the measurements we suggest to apply a zoom factor on the image to reduce the effect of the introduced mistake from the manual indication of the distance to be measured.

⚠ In the absence of a correct calibration, the measurements carried out on the images are invalid. It is always necessary to control the calculated calibration factor, the obtained measure and the borders traced to verify their admissibility.

⚠ In the appendix the accuracy and precision of the method are reported.

22. APPENDIX D

22.1. ANGIOGRAPHIC ANALYSIS ACCURACY AND PRECISION

In this appendix the terms *accuracy* and *precision* have the following meaning:

Accuracy - the absolute value of the difference between the real measure and the mean of the estimated measurements;

Precision - the standard deviation of the estimated measurements.

22.2. KNOWN DISTANCE BASED CALIBRATION

The following table reports the mean values and precision of an experiment in which repeated measurements of known distances of different dimensions have been carried out on the same image. The table underlines a relation between the size of the measured structure in the image and the precision of the measurement; when the size in pixels increases (in the experiment this also corresponds to an increase in the real dimension) the measurement precision increases.

Square Side Length	Accuracy	Precision
4 mm	0.0013 mm/pixel	0.0070 mm/pixel
8 mm	0.0016 mm/pixel	0.0032 mm/pixel
12 mm	0.0010 mm/pixel	0.0016 mm/pixel
16 mm	0.0000 mm/pixel	0.0019 mm/pixel
20 mm	0.0004 mm/pixel	0.0017 mm/pixel
40 mm	0.0001 mm/pixel	0.0003 mm/pixel

For this reason it is better to carry out calibration on structures with sufficiently large pixel dimensions (dimensions in the image to be analyzed). Alternatively it is possible to apply a zoom factor to the image to reduce the error introduced by the manual selection of the distance to be measured.

22.3. CATHETER BASED CALIBRATION

The following table reports the results of a calibration experiment on a set of empty and contrast filled catheters of different size and vendor.

Contrast filled	
Accuracy	**Precision**
0.008 mm	0.009

22.4. CORONARY ANALYSIS

The following table reports the results of an in vitro analysis of a set of phantoms of different diameters:

Dimensions	**X-ray Images**	
Size	**Accuracy** **mm**	**Precision** **mm**
5.0 mm	0.00143	0.01349
4.5 mm	0.00684	0.02083
4.0 mm	0.00245	0.01854
3.5 mm	0.00274	0.02282
3.0 mm	0.00391	0.02812
2.5 mm	0.00001	0.02370
2.0 mm	0.00066	0.02994
1.5 mm	0.00336	0.03547
Mean Value	**0.002681**	**0.02411**

22.5. VENTRICULAR VOLUME

The following table reports the results obtained by using the program to measure an elliptic synthetic image in order to estimate the error due to the manual profile tracing:

	Accuracy	**Precision**
Diastolic Volume	0.34 ml	1.858 ml
Systolic Volume	0.47 ml	0.254 ml

It is clear that the errors are negligible not only with respect to the measure carried out, but also with respect to the intrinsic errors in the applied *Area-Length* method for volume calculation.

22.6. BODY SURFACE

The formula used to compute the body surface is:

$$BSA = 71.84 \cdot W^{0.425} \cdot H^{0.725}$$

where *W* corresponds to the *weight* in *Kg*, *H* corresponds to the *Height* in *cm* and the calculated body surface is *cm²*.

22.7. REGIONAL SHORTENING

The following table shows the error in the detection of the regional shortenings on a synthetic image:

	Accuracy	Precision
Regional Shortening	0.0193 %	0.0266 %

23. APPENDIX E

23.1. IVUS ANALYSIS ACCURACY AND PRECISION

In this appendix the terms *accuracy* and *precision* have the following meaning:

Accuracy - the absolute value of the difference between the real measure and the mean of the estimated measures;

Precision - the standard deviation of the estimated measures.

The following table reports the mean values and precisions of an experiment in which repeated measures of known distances of different dimensions have been carried out on the DICOM file.

Measurement	Accuracy	Precision
Horizontal segment	0.002 mm	0.028 mm
Vertical segment	0.002 mm	0.044 mm
Diagonal segment	0.006 mm	0.032 mm
Areas	0.001 mm^2	0.020 mm^2

For these measurements it is suggested to apply a zoom factor to the image to reduce the error introduced by the manual selection of the distance to be measured.

The following table reports the mean values and precisions of an experiment in which repeated measures of known distances and areas into the image longitudinal reconstructed.

Measurement	Accuracy	Precision
Horizontal segment	0.001 mm	0.022 mm
Vertical segment	0.020 mm	0.050 mm
Diagonal segment	0.026 mm	0.032 mm
Areas	0.058 mm^2	0.060 mm^2

24. APPENDIX F

24.1. GENERIC MEASUREMENTS ACCURACY AND PRECISION

In this appendix the terms *accuracy* and *precision* have the following meaning:

Accuracy - the absolute value of the difference between the real measure and the mean of the estimated measurements;

Precision - the standard deviation of the estimated measurements.

The following table reports the mean values and precision of an experiment in which repeated measurements of geometrical artificial structures in an ultrasound DICOM image.

Measurement	Accuracy	Precision
Linear	0.1 pixel	0.050 pixel
Polygonal Area	0.1 pixel^2	0.793 pixel^2
Angle	0.1 °	0.589 °

Values are expressed in pixel units since the real measurement uses various units of measurement for each ultrasound image type (meters, second, m/sec). To obtain the accuracy and the precision in the specific unit of measurement for the given image type, it is simply sufficient to compute the derived value on the basis of the horizontal and vertical calibration image factor.

Generally for the measurements we suggest to apply a zoom factor on the image to reduce the effect of the introduced mistake from the manual indication of the distance to be measured.

⚠ In the absence of a correct calibration, the measurements carried out on the images are invalid. It is always necessary to control the calculated calibration factor, the obtained measure and the borders traced to verify their admissibility.

⚠ In the appendix the accuracy and precision of the method are reported.