

Three Palm Software



WorkstationOne™ User Manual

Three Palm Software
16 Yankee Point Dr.
Carmel, CA 93923
+1-408-356-3240
support@threepalmsoft.com



Contents

SOFTWARE END USER LICENSE AGREEMENT	5
1. WorkstationOne™ system.....	7
1.1. Device description	7
1.2. Indication for use	8
1.3. Contraindications	9
1.4. Warnings and Precautions	9
1.5. Residual risks	10
1.6. Device identification	11
2. Principles of operation.....	12
2.1. Enterprise view	12
2.2. User view.....	12
3. Overview of the user interface.....	14
3.1. Resize and move navigation screen	14
3.2. Viewing the worklist	15
3.3. Status message display	15
3.4. Exiting the workstation	16
3.5. Online user manual.....	16
3.6. About box	16
4. Worklist and data management.....	18
4.1. Standard worklist	18
4.1.1. Customization	19
4.1.2. Navigation and Sorting	21
4.1.3. Filtering	21
4.2. Advanced worklist.....	24
4.2.1. Grouping	25
4.2.2. Customization	27
4.2.3. Filtering	28
4.2.4. Summaries.....	31
4.3. Worklist tools	32
4.3.1. Manual case add.....	36
4.3.2. Worklist multiple item selection	37
4.4. Manual query	38
4.5. DICOM file import	39
4.5.1. Standard import tool.....	40
4.5.2. Advanced import tool	41
4.6. Dictation trigger.....	47
4.7. Priority read and bookmark	47
5. Reading workflow.....	49
5.1. Workflow navigation.....	50
5.1.1. Overall viewing.....	50
5.1.2. Current study viewing and/or quality check	55
5.1.3. Current/Prior comparison	61
5.1.4. Systematic perception viewing	65
5.1.5. All pixels viewing	66
5.1.6. CAD display, finding interpretation and reports	69
5.1.7. Completing the review of a study	84
5.2. Viewing screening studies with multiple priors	85

5.3.	Viewing diagnostic studies	87
5.4.	Viewing breast tomosynthesis images	94
5.4.1.	Navigation aided by tomosynthesis CAD.....	100
5.4.2.	Navigation aided Decision Support workflow.....	102
5.4.3.	Navigation aided by 3D mapping.....	103
5.5.	Viewing contrast-enhanced breast images.....	103
6.	User interaction.....	105
6.1.	Toolbar	105
6.2.	Tool menu.....	107
6.3.	Markup correlator graphic	117
6.4.	Key (Quality) notes	120
6.5.	CAD and Decision Support	122
6.6.	Mouse.....	123
6.7.	Keypad	125
6.8.	Keyboard shortcuts.....	126
7.	Viewing other images and reports	137
7.1.	Viewing digital X-ray (DX or CR) images.....	137
7.2.	Viewing ultrasound images	137
7.3.	Viewing 3D breast ultrasound images.....	139
7.4.	Viewing magnetic resonance images.....	139
7.5.	Comparing images between modalities or studies	140
7.6.	Viewing SC documents.....	142
7.7.	Viewing DICOM encapsulated PDF documents	143
7.8.	Viewing text reports encoded in SR	143
7.9.	Generating reports and letters	145
7.9.1.	Theory of operation	145
7.9.2.	User interface.....	145
7.9.3.	Templates	147
7.9.4.	User options.....	148
7.9.5.	Template editor	151
7.9.6.	Template tokens.....	152
7.9.7.	Service configuration.....	153
7.10.	Viewing nuclear medicine images.....	153
7.11.	Viewing computed tomography images.....	154
7.12.	Viewing positron emission tomography images.....	154
7.13.	Viewing pathology images	155
7.14.	Multiple viewer layout.....	155
8.	Configuration options	157
8.1.	Workflow configuration.....	157
8.2.	View sequence configuration	160
8.3.	Diagnostic hanging protocol configuration.....	168
8.4.	User controls configuration	169
8.5.	Key code configuration	175
8.6.	Connectivity configuration	176
8.7.	Configuration backup and restore	178
9.	Printing.....	179
9.1.	Mammography standard printing.....	179
9.2.	Advanced printing	181
9.2.1.	Destination	181
9.2.2.	Formatting.....	183
9.2.3.	Images	185

10.	Hardware configuration.....	188
11.	References	190
12.	Conformance to standards.....	191
13.	Acknowledgements.....	192
14.	Contact information.....	193

SOFTWARE END USER LICENSE AGREEMENT

The license of the Software (as defined below) granted hereunder is contingent upon the Licensee's acceptance of all the terms provided herein, and any use of the Software by the Licensee shall be deemed as such acceptance. The term "Software" shall include any updates, upgrades, modified versions, additions and copies of the Software licensed to you by Three Palm Software ("TPS").

LICENSE

Grant of License. Subject to payment of any fees set forth in any related Quotation or Invoice, Three Palm Software ("TPS") grants to Customer a nonexclusive license to use one copy of the software on the equipment (the "Software"). TPS represents that it has title to or has the right to license the Software. Customer agrees to use the Software only in conjunction with the normal operation of the equipment, but not to use any of the diagnostic software included with the Software to perform maintenance service or for any other purpose without entering into a separate license agreement with TPS. Customer may not transfer the Software, or any of their rights in the Software, to any other party without the prior written consent of TPS. The term Software as used in this Agreement does not include, and this license does not apply to, any Microsoft operating system software provided with the equipment. Any Microsoft operating system software provided with the equipment is governed by a separate software end user license agreement.

Improved or Modified Versions. This license also applies to any improved or modified versions of the Software supplied to the Customer by TPS during the term of this Agreement

Copying and Nondisclosure. Nothing in this Agreement will be deemed to grant the Customer any proprietary rights in the computer program or any other work embodied in the Software. Customer may not copy or alter, and must take reasonable care to ensure that others do not copy or alter, the Software, in whole or in part, in any media for any purpose. Customer may not otherwise reverse engineer, decompile, or otherwise derive the source code for the Software program.

Copyright. The Software is owned by TPS or its suppliers and protected by copyright laws and international treaties. You may not copy the Software other than as expressly provided in this license. You may not reverse engineer, decompile, or disassemble the Software. If this Software is used within a country of the European Union, nothing in this Agreement shall be construed as restricting any rights available under the European Community Software Directive (91/250/EEC).

Term and Termination. This Software license will remain in effect for as long as the Customer rightfully retains possession of the Software as delivered by TPS or its Suppliers or Dealers. However, this license will terminate immediately (i) if the Customer transfers or modifies the Software except as provided under this Agreement, (ii) upon an uncured default by the Customer of this Agreement, or (iii) if the Customer becomes insolvent, makes an arrangement for the benefit of creditors, or becomes subject to bankruptcy proceedings. Within thirty (30) days after any expiration or termination of this license, in whole or in part, the Customer agrees to deliver to TPS all copies of the Software or media (whether in whole or in part) in the Customer's possession, or as to

any copy not in the Customer's possession, Customer agrees to certify in writing that the copy is either lost or has been destroyed.

LIMITED WARRANTY

For a period of one year from and after installation of Software, TPS warrants that the Software will substantially conform to TPS's specifications. TPS's sole obligation under this warranty will be limited to using reasonable efforts to ensure such conformity and to supply Customer with a corrected version of the Software as soon as practical after Customer has notified TPS of any non-conformity. TPS does not warrant that: (i) operation of any of the Software will be uninterrupted or error free, or (ii) functions contained in the Software will operate in the combinations which may be selected for use by, or meet Customer's requirements. This warranty will be void if the Software is modified without the written consent of TPS.

Subject to any applicable legislation which prohibits the following exclusions, TPS MAKES NO OTHER WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Some states and countries, including Australia, do not allow the exclusion of implied warranties, or have legislation that imposes certain statutory warranties that cannot be excluded, so the above exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights.

LIMITATION OF REMEDIES

The remedies set forth above are TPS's only obligation under the warranty. IN NO EVENT WILL TPS OR ITS SUPPLIERS OR DEALERS BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING ANY LOST REVENUES OR PROFITS, DOWNTIME COSTS, COST OF SUBSTITUTE EQUIPMENT OR SOFTWARE OR OTHER DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE THE SOFTWARE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. Some states and countries, including Australia, do not allow the limitation or exclusion of liability for incidental or consequential damages, or have legislation which restricts the limitation or exclusion of liability, so the above limitation may not apply to you.

GENERAL

If the Software was purchased in the United States, this Agreement is governed by the laws of the State of California. If purchased outside the United States, this Agreement is governed by the laws of the country in which it was purchased.

U.S. GOVERNMENT RESTRICTED RIGHTS

The SOFTWARE and documentation are provided with RESTRICTED RIGHTS. Use, duplication, or disclosure by the Government is subject to restrictions as set forth in subdivision (c)(1)(ii) of The Rights in Technical Data and Computer Software clause DFAR 252.227-7013 or such other applicable government or agency regulation providing equivalent protection. Contractor / manufacturer is TPS, 16 Yankee Point Drive, Carmel, California 93923.

1. WorkstationOne™ system

1.1. Device description

WorkstationOne™ is a medical device that implements the software for a vendor-neutral diagnostic breast imaging workstation. It obtains breast imaging screening or diagnosis exams from PACS (Picture Archiving and Communication System) or Modalities; then displays and manipulates the images for radiologists to perform the interpretation task. The workstation can also interface with a reporting system to generate an interpretation report. The workstation also supports media exchange and film printing.

The enterprise workflow of the workstation follows IHE (Integrating the Healthcare Enterprise) integration profiles, specifically, the MAMMO profile (Mammography Image Profile), the Digital Breast Tomosynthesis (DBT) profile, the KIN profile (Key Image Note Profile), some of the MAWF (Mammography (Acquisition) Workflow Profile to provide an operator the capability to correct view information in images), as well as IRW (Import Reconciliation Workflow) profile.

The workstation can be configured to use mammographic specific hanging protocols and reading workflow. The workstation obtains the source images, CAD SR (Structured Reports) reports and GSPS (Grayscale Softcopy Presentation State) annotations, either as the recipient of the push of that data, or by querying and retrieving them from a PACS archive. In both models, DICOM (Digital Imaging and Communications in Medicine) standard is used. The images can only be lossless compressed or non-compressed DICOM images.

The workstation supports the display of:

- MG (digital mammography, including breast tomosynthesis and breast projection) images
- CAD SR (structured reports) as an overlay detection mark on the image, plus integration of additional information such as computer assessment of the breast density categories
- digitized prior mammogram film images
- breast US (ultrasound) images
- breast MR (magnetic resonance) images
- breast NM (nuclear medicine) images
- breast CT (computed tomography) images
- CR or DX general radiography images
- associated documents (secondary capture or web documents), such as, referring doctor's letter, notes and previous reports
- SR (structured reports) in addition to CAD that are displayed as text
- Key Image Notes (KOS) that indicate images or frames of interest
- GSPS graphic annotations
- encapsulated PDF documents

The workstation provides the following functions to perform operations for, or by, users:

- image layout
- image manipulation
- image quantification

- annotations
- markup and assessment

The image layout functionality includes a number of mammographic-specific hanging protocols. The features for image manipulation include: image contrast, zoom, pan, invert, flip and mask. Image quantification mechanisms include caliper and measurements that are performed over a markup ROI or line that the user draws. Some of these functions may be performed automatically or manually by the user.

Automation of the mammography specific viewing protocol includes:

- automated image orientation and chest wall alignment for the mammography hanging protocol.
- automated size calculation so multiple images can be displayed at the same relative physical size.
- navigating the per-user configured mammography screening hanging protocol sequence.
- handling of *ad hoc* excursions to the mammographic viewing protocol.

WorkstationOne is a software system that can be installed on an off-the-shelf general-purpose computer, typically with one or two gray-scale high-resolution monitors and one color monitor. In the United States, WorkstationOne must be used with monitors cleared by the FDA for the review of mammographic images. The high-resolution monitors are used to display digital mammography images and associated overlays for the purpose of primary interpretation by radiologists. The color monitor is used for selecting studies, displaying color images, navigating the workflow, and other user interface elements.



1.2. Indication for use

The WorkstationOne Breast Imaging Workstation is intended for use with a regionally approved digital mammography system. The workstation displays images from multiple modalities, which include X-ray mammography MG, breast US and breast MRI. The workstation allows selection, display, manipulation, quantification, markup, print composition and media exchange of breast images. Here, quantification refers to measurements (such as area and distance) within a region of interest that the radiologist manually draws on the images. Similarly, markup refers to graphics that are manually drawn by the radiologist to indicate a region of interest. Note that the region of interest is not automatically generated by the computer.

The WorkstationOne Breast Imaging Workstation is intended for softcopy reading and interpretation of digital mammography images by Radiologists. The affected patient population is those patients who have presented for screening mammography.

The WorkstationOne Breast Imaging Workstation when used for interpretation of images acquired using a FFDM image acquisition system shall display the images only on FDA-cleared high-resolution monitors. The images used for primary diagnostic reading must be in a lossless format, unless lossy formats are approved for use in digital mammography.

1.3. Contraindications

There are no known contraindications for this device.

1.4. Warnings and Precautions

- **WARNING:** The recommended quality control procedure should be followed.
- **WARNING:** The device should be used with approved digital mammography acquisition systems. Images from un-approved mammography system may not meet the quality requirement for mammography. Therefore, reading such images may decrease reader's interpretation accuracy.
- **WARNING:** When images are displayed with a zoom factor larger than one (which happens more often with lower resolution images from some of the digital mammography acquisition systems), the displayed images are enlarged from the original source images and the pixel values between the source pixels are interpolated using bilinear or bicubic interpolation. The pixel characteristics in the enlarged images may differ from the original image pixels.
- **WARNING:** When studies are reconciled or merged from different patient IDs, it is the user's responsibility to determine and approve whether to open those studies together as a single case.
- **WARNING:** The device when used for primary diagnostic interpretation should display the mammography images only on approved high-resolution monitors. Otherwise the detailed image information, such as, microcalcifications or spicules that are associated with a mass density may not be visible.
- **WARNING:** The images should be in a lossless format. Otherwise the detailed image information, such as, microcalcifications or spicules that are associated with a mass density may not be visible.
- **WARNING:** The device includes no serviceable hardware parts. For service assistance, contact the vendor who supplied the hardware.
- **WARNING:** The images from the prior exam should not be used for diagnosis. The images from current exam always have a high-lighted frame around the images, so pay attention to this frame before making diagnosis on the current exam.
- **WARNING:** The physical size of the pixels in an image for the purposes of distance measurements and the display of a distance caliper is approximated by using the values of DICOM tag "Image Pixel Spacing" (0018,1164) divided by the value of DICOM tag "Estimated Radiographic Magnification Factor" (0018,1114) from the source image. The device *accurately* calculates the distance between two points based on the physical size of the image pixels. So, the limits of accuracy are inherited from the values of the "Image Pixel Spacing" (0018,1164)

and “Estimated Radiographic Magnification Factor” (0018,1114) in the source images.

- **CAUTION:** Those operations, such as, markup or magnify glass should not be used on the images from prior exam. So, if you notice those operations do not work on prior images, it is the design intention, not a software bug.
- **CAUTION:** US Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- **CAUTION:** The device should be used in a suitably dark environment when reading mammography images. The optimal ambient light level is 50 lux.
- **CAUTION:** If device is power-off without properly shutdown, the workstation local database corruption may occur. The device should be shutdown using Window's “Turn Off Computer” menu.
- **CAUTION:** Markups added by user over the images will not be stored after the study is complete.
- **CAUTION:** If network connection is down, the interpretation worklist may not be ready promptly. An error message will appear on screen if such situation occurs.

1.5. Residual risks

A hazard analysis has identified the following risks that are associated with WorkstationOne. These risks are mitigated by design controls. The risks and their controls are:

Hazard	Cause	Implemented control
H1. Patient is given over-diagnosis (i.e., unnecessary follow-up)	C1. System displays wrong (positive) images for this patient.	System testing considers this case to verify that the patient ID and associated images are from the same DICOM files displayed together correctly.
	C2. System displays wrong (negative) images for this patient.	
	C3. System mistakenly replaces current exam images with prior negative exam images.	System is designed to prevent the user from adding markup (for diagnosis) on prior images.
H2. Patient is given under-diagnosis (i.e., does not receive appropriate follow-up)	C8. System does not automatically save the radiologist's markup for patient recall when the radiologist opens another patient without completing the current patient.	System is designed so that when the user switches to another patient a popup dialog is used to warn the user the current case is not complete.
		System is designed to alert the user to save any markup when switching to another patient without explicitly closing the current patient.
	C9. User does not use the tools (full resolution) provided by the system, may miss calcification.	System is designed to enforce the user to follow a workflow, with full-resolution viewing included as one step of the workflow.
	C10. User does not use workflow tool, may miss to read all images, so may miss to see tumors.	

H5. Delay report may cause patient anxiety.	C11. System used in an environment where distraction can cause user error, may miss to finish the study, so no report.	System is designed so that when the user switches to another patient a popup dialog is used to warn the user the current case is not complete.
	C14. Computer components or network links fail intermittently.	Installer/support will warn site to monitor hardware, and replaced as needed.
H3. Operator gets eye strain	C4. Room ambient light too bright.	When an optimal viewing condition cannot be met, the system is designed so the user can change the font size larger and make the contrast of the images sharper in order to the improve viewing condition.
	C5. Monitor position too high.	
H4. Operator gets finger tiredness	C6. System requires too many mouse clicks.	System is designed to minimize the mouse clicks and mouse movement.
	C7. System requires large distance mouse moving.	
H6. Patient information exposed to unauthorized persons.	C12. Operating system defect allows unauthorized access.	Installer/support will warn customer to keep system patches current.
	C13. Site procedures do not control access to the software.	Installer/support will suggest to site IT that they implement appropriate physical and procedural security mechanisms.

1.6. Device identification

WorkstationOne includes an “about” box that displays the information that identifies the software. That information includes the Manufacturer name, address, web site, and product name, version, production date, as well as the UDI information (as required by the FDA and EU MDR). The “about” box is described further below in section 3.6.

2. Principles of operation

WorkstationOne is positioned as a conventional vendor-neutral mammography interpretation workstation, with support for other imaging modalities that are used for breast cancer screening and diagnosis.

The aim of the design of the workstation is to maximize the radiologist's efficiency and accuracy in order to enhance the level of the patient care, specifically; the workstation is designed to support a mammography specific interpretation workflow. Technically, the workstation follows the IHE conventions to support enterprise workflow; it pre-fetches images based on an interpretation worklist in order to manage high throughput; and it automates viewing workflow to improve reading efficiency.

The technology embodied within the system includes the infrastructure that moves the source images, the CAD reports and graphic annotations using DICOM communications, manages reading workflow (including worklist, hanging protocol, viewing sequencing), displays and manipulates the images, and generates the diagnosis reports.

2.1. Enterprise view

The intent is for this workstation to operate seamlessly within an enterprise that follows the IHE guidelines. The design of the workstation follows the *Mammography Image Profile* (MAMMO Profile), which specifies how DICOM Mammography images and related information are created, exchanged and used (refer to references 3 and 5 for more information on the IHE guidelines). The workstation also supports the *Digital Breast Tomosynthesis* (DBT) *Profile*, *Reporting Workflow Profile* (RWP), *Key Image Note Profile* (KIN), *Mammography Acquisition Workflow Profile* (MAWF), as well as *Import Reconciliation Workflow Profile* (IRWF).

WorkstationOne supports the following mechanisms for exchanging information with other network entities:

- Queries and retrieves a study's images and related information based on a worklist (e.g. modality worklist);
- Accepts the following DICOM objects when pushed unsolicited to WorkstationOne: MG, DBT, breast projections, CAD SR, KOS, SR, GSPS, digitized prior mammograms, as well as other modalities such as Ultrasound, MRI, CT, CR, NM, PET, etc.;
- Queries the configured archive(s) for a study's related information -- e.g., priors, other modalities, CAD reports, etc. (this query can be triggered automatically when a study arrives);
- Supports the DICOM query/retrieve mechanism;
- Supports media importation and reconciliation of patient demographic information;
- Prints a report to a networked printer, or sends the report to PACS or RIS (Radiology Information System);
- Prints images to DICOM film printer.

2.2. User view

The user's view of the workstation is that it consists of a general-purpose computer with one color monitor and one or more high-resolution monitors attached. It runs a standard Windows operating system and requires user login prior to operation of the workstation

software. The system looks like a standard piece of IT equipment within the hospital's organization that is managed by the local IT department, using standard security policies and procedures.

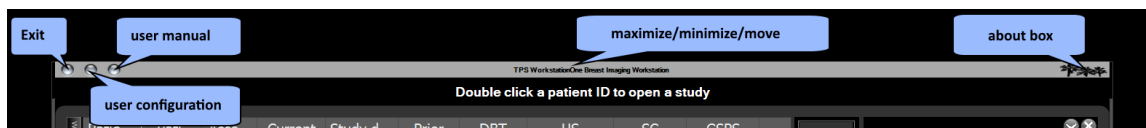
Once the workstation software starts, a list of exams (worklist) to be read is presented to the user on the color monitor. When a study is selected for review, the images from that study and any associated studies from other modalities are displayed. The layout of the images and the sequence of review steps that are followed to review a study are configurable (per site and per user) in order to provide an optimal review protocol for each user. If the case includes images from other modalities such as ultrasound or MRI, those images will preferably be displayed on the color monitor; with the high-resolution mammography images (current and prior) being displayed on the higher-resolution (typically gray-scale) monitors. If the study references CAD report(s) or GSPS graphic annotations, then those are made available to the user when the corresponding mammography images are displayed.

The next sections describe the worklist in more detail, and the protocol steps that are followed to review each study. Section 8.2 explains how to configure the viewing steps and corresponding handling protocols for each user.

3. Overview of the user interface

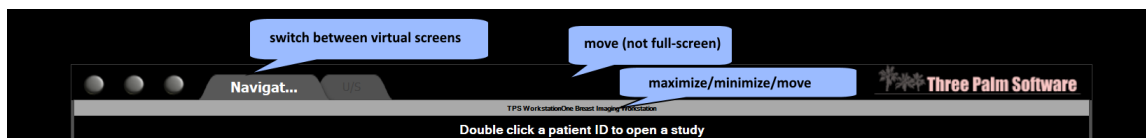
WorkstationOne can be configured in different ways to use the available screens. The most common layout is to have two high resolution (e.g. 5MP) screens and a lower resolution (typically color) image on the side for the worklist, reporting, and display of other modalities. Simple monitor configurations are detected automatically, but the setup can be controlled using the service tools (as part of the initial setup of the machine).

In this mode, the user interface on the low-resolution screen (referred to as the “navigation screen”) looks like:



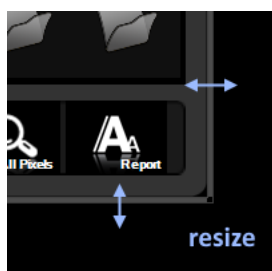
Where the 3 buttons at the top left are to “exit”, “user configuration” (see section 0), and “user manual” (see section 3.5). Clicking the logo on the upper right results in the display of an “about box” (see section 3.6). The large grey bar across the top is used to minimize (single click), or toggle between full-screen and partial screen sizes (double-click).

In other configurations, the display is configured with tabs – which looks like:



In this model, the buttons have the same arrangement and function, with the grey-bar having the same function. The blank area at the top can also be used to move the window when it is not set as full-screen. The tabs switch between virtual screens – the contents of which are configured as part of the system setup (e.g., a tab can be assigned to the display of a specified modality, or other plugin).

When the application is not running full-screen, the small grey edge of the window can be used to resize the application:



3.1. Resize and move navigation screen

When running in multi-screen mode, the navigation screen is opened in full screen mode by default. However, by dragging the left mouse button at the right and bottom edges, the navigation screen can be resized to a size smaller than full screen. Similarly, by dragging the top title bar, the navigation screen can be moved to a different location. A double-click on the top title bar causes the navigation screen to be maximized to the current full screen; whereas a single-click on the top title bar causes the navigation screen to be minimized to the Windows task bar.

When the system is configured in “single screen” mode (the navigation and image screens are separate tabs), the screen is not resizable.

3.2. Viewing the worklist

The worklist area on the navigation screen is also used for display of configured plugins (for those not assigned to their own tab). This is achieved by having the worklist either manually or automatically collapse when there is something else to be displayed in that area (the option to automatically collapse the worklist is described in section 8.1).

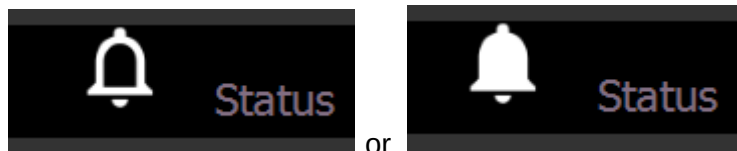
When the worklist is collapsed to share the space for multi-modality image display, a button call “Show Worklist” below the multi-modality folder icons is enabled to allow the user to display the worklist side-by-side with the multi-modality images. Clicking the “Show Worklist” button, results in the worklist being displayed over the mammogram thumbnail area:



A subsequent click of the toggle button (now it is labeled “Mammogram Thumbnail”) will hide the worklist, and again display the thumbnail view for the current mammography study.

3.3. Status message display

Status notification messages for the user can be viewed using the status icon on the navigation monitor:

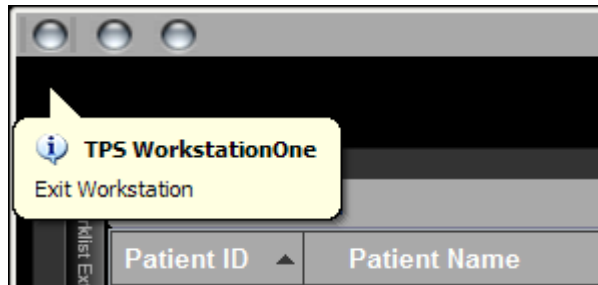


This icon changes from an empty bell to a filled-in bell when new messages are available. When the user clicks on this icon, a window is displayed with a list of the most recent messages. The message window automatically scrolls to the end of the messages. When the number of message characters exceeds a threshold (by default, 10000 characters), the older messages are automatically removed.

This mechanism is used, for example, to display the result of DICOM operations such as save and move requests, and print operations.

3.4. Exiting the workstation

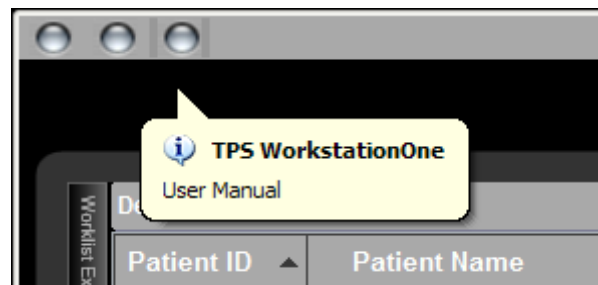
The user can exit from the workstation by selecting the leftmost round button in the upper left-hand corner of the screen:



The short-cut key combination “Alt + Ctrl + E” can also be used to exit the workstation.

3.5. Online user manual

This manual can be accessed by selecting the rightmost round button in the upper left-hand corner of the screen:



The short-cut key combination “Alt + Ctrl + M” can also be used to access the manual. The manual is distributed in “pdf” format, so that it can be viewed using a standard viewer that is part of the workstation environment (such as “adobe acrobat”). A paper version of the manual can be requested (see section 14).

3.6. About box

At the top right corner of the navigation screen UI is a logo (the logo appearance depends on the display screen, and the branding), but typically it looks like:



Clicking the logo results in the display of an “about box” that contains information specific to this version of the software, and to this machine. This information looks like:

The screenshot shows a window titled "TPS WorkstationOne" with a close button in the top right corner. The window content is organized into sections:

- Three Palm Software** (Header)
- Contact Information:**
 - Address : 16 Yankee Point Drive, Carmel, CA 93923, USA
 - EEA Authorised Representative: Wellkang Ltd
 - Enterprise Hub, NW Business Complex, 1 Beraghmore Rd, Derry, BT48 8SE, Northern Ireland
 - Web : threepalmsoft.com
 - Email : support@threepalmsoft.com
 - Phone : (408) 356-3240
- CE Mark** (Large logo on the right)
- Details** (Section header):
 - Name : WorkstationOne
 - Version : 1.9.0.10128
 - Date : 1/28/2021 1:12:11 PM
 - Serial : MAC=00:15:5D:24:BA:F6 (trial license)
 A "Copy details" button is located to the right of the details section.
- UDI** (Section header):
 - Labeller : Three Palm Software
 - DI : *+B148WSONE1900O*
 - PI : *+\$\$7-1.9.0.10128/S00155D24BAF6OT*
 "Copy DI" and "Copy UDI" buttons are located to the right of the UDI section.
- OK** (Button at the bottom center)

The information at the top of this display identifies the manufacturer: name, address, website, support email address and support phone number.

The second section contains “Details” of this installation: the name of the product, the detailed version, the build date, and the serial number of the software installed on this machine. The button to the right “Copy details” copies those 4 lines of information to the clipboard, so this information can, for example, be conveniently be placed in an email by clicking that button and then pasting the result into an email draft.

The third section contains the “UDI” information, as required by the FDA and the EU MDR. There are three pieces of information: the labeler (typically the manufacturer); the device identifier (DI); and the production identifier (PI). The labeler and DI are recorded in public databases – e.g., [AccessGUDID](https://www.accessgudid.com/) is the publicly available FDA UDI database. The DI is specific to this release (and is contained in the corresponding release notes). The PI is specific to this machine (it includes the serial number). The button “Copy DI” places the DI in the clipboard (for easy paste into a database search). The button “Copy UDI” places the full UDI (DI+PI concatenated and decorated) into the clipboard. Generally, it is the DI that is needed for database searches, but the full UDI uniquely identifies this device.

4. Worklist and data management

WorkstationOne can display its own worklist or be driven using an external worklist. When the system is configured to display its own worklist, the contents of that worklist reflect DICOM objects that are cached on the local machine. There are two versions of the built-in worklist: “standard” and “advanced”, which are described further below (the choice of worklist style is configured as a service option). Both versions show the same underlying data but have slightly different customization models. Most of the tools are shared across worklists, so the following descriptions describe each worklist and then describe the common tools.

When using one of the built-in worklists, the worklist is shown immediately when the workstation software starts and is updated periodically as new studies become known to the system for review.

Each item in the worklist includes the current mammograms, corresponding prior mammograms, optionally key image notes, CAD results, GSPS graphic annotation, and if they also exist, recent US, MRI, CT, NM, PET, DBT, CR/DX images and documents that are associated with the same patient. Each item on the worklist is also referred to as a patient “case”. Each case is listed with associated DICOM attributes, such as, Patient’s Name, ID etc. (the selection of attributes to display is configurable). Each case is also associated with a state that indicates if the exam is new, or has been read, or updated with additional views, etc. If configured, the status can be synchronized with peer WorkstationOne installations on other machines.

4.1. Standard worklist

The standard worklist looks like:

Worklist Explorer

All cases No procedure filter No ID filter No name filter

Patient ID	Patient Name	Study date	Time	Prior	CAD	US	MR	DBT	SC	GSPS	Status	
ewbchwise: filters EWBCH03		4/5	11:24 AM	0	2	0	3...	0	5	0	Reading	
ewbchwise: EWBCH01		10/10/2007	11:24 AM	0	3	72	1...	0	10	0	New	
ewbchwise:191599	Anonymous, Female 1952	8/22/2007	1:18 PM	6	0	4	0	0	0	2	2	New
ewbchwise:36580	Anonymous, Female 1940	12/4/2007	11:23 AM	4	4	4	0	0	0	0	0	Reading
ewbchwise:120895	Anonymous, Female 1950			0	0	0	0	0	0	0	0	Reading
ewbth0000230	ewbth0000230	10/8/2014	12:10 PM	4	0	1	0	0	4	0	0	Reading
ewbth0000237	ewbth0000237	7/12/2013	12:33 PM	4	0	1	0	0	4	0	0	Reading
FED4321	TPS Anonymized	7/14/2008	1:11 PM	5	0	0	0	0	0	0	0	Reading
GHI1234	TPS Anonymized	7/10/2008	6:35 PM	6	0	0	0	0	0	0	0	Reading
GLMC100	Patient, Second	12/13/2007	1:55 PM	6	6	0	0	0	0	9	0	Reading
GLMC101	Second Patient	9/19/2007	4:02 PM	6	6	0	6	0	0	1	0	New
GLMC102	Second Patient	10/3/2006	10:12 AM	5	0	0	0	0	0	1	0	Reading
GLMC103	Patient, Second	12/12/2006	1:57 PM	4	0	0	12	0	0	1	1	New
GLMC104	Patient, Second	7/31/2007	8:50 AM	4	4	0	0	0	0	1	5	Reading
GLMC105	Patient, Second	3/29/2007	10:02 AM	4	0	0	6	0	0	5	0	New
GLMC106	Second Patient	11/22/2006	1:13 PM	4	0	0	7	0	0	1	0	New

query

add

settings

Double-clicking an item on the worklist results in the images for that patient being opened for review. This means that the item is highlighted in the worklist, and thumbnail images of the current and prior (if present) images for that patient are displayed on the right-hand side of the screen (the side is configurable). In the image display area, the current study is indicated by a bounding box around those images. **Note that a single-click is used to select a patient item for further interaction within the worklist, so the highlighted item may not be the same as the item that is currently opened for**

viewing. If required, click the “Reopen” button on the navigation screen, so that the currently opened patient item can be highlighted in the worklist.

When configured to prevent mistakenly making a diagnosis on a prior study, a dialog is popped up to warn the user when the current study is missing, or when the date of the opened study is outside the window that is configured (by service personnel on the back-end) as a definition for the current study.

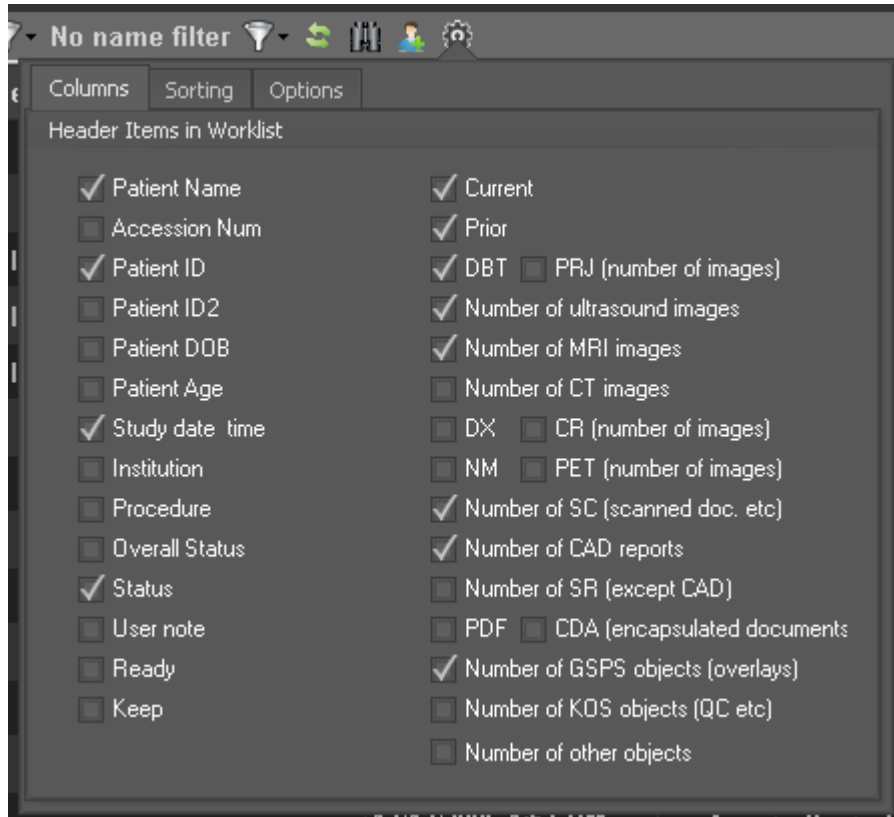
When the worklist screen is hidden or minimized, and the mouse cursor focus is on the image screen, the escape key can be used to switch and display the worklist screen.

4.1.1. Customization

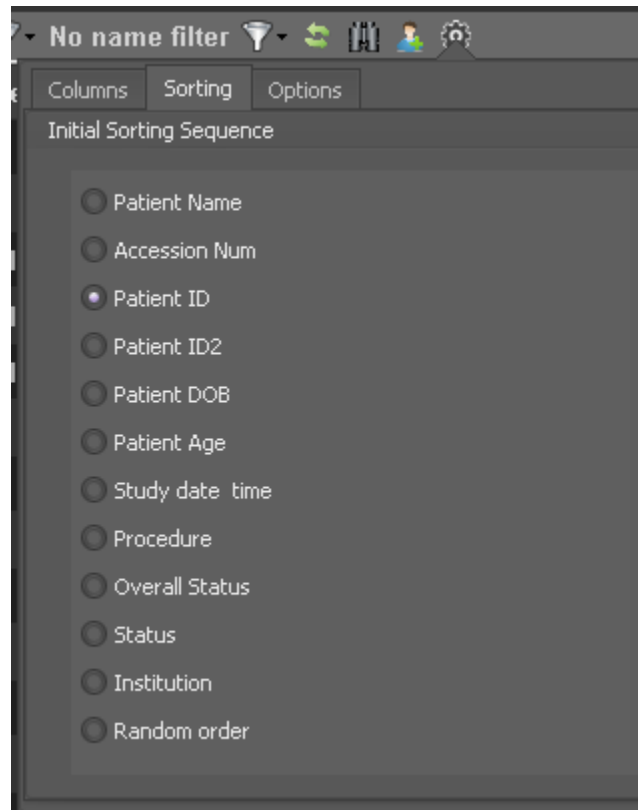
At the top of the worklist area, column headers identify the contents of each column. Above that, a set of tools are provided – to the left, several filtering options, and at the right edge, buttons to refresh, query a PACS, add a case to the worklist, and access settings for the worklist.

The column headers can be manually sized by dragging the edge of the column header. The orientation of each header string can be vertical when the column width is too narrow to fit that title. The location (order) of each column can be changed by drag-n-drop of the header to a new column position. These interactive changes to the column headers are retained as part of the user settings for the worklist and used the next time the system is operated by the same user.

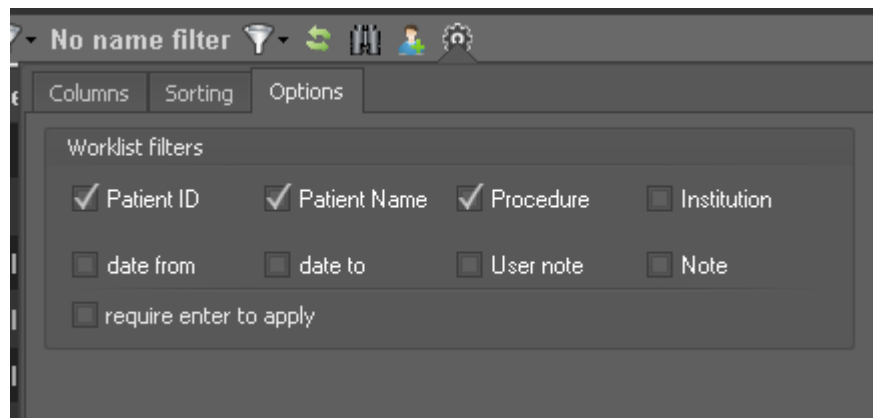
Clicking the settings buttons results in the display of additional options for the worklist, arranged into three tabs. The first tab allows selection of which columns are to be displayed on the worklist:



The sorting tab allows one of the most used columns to be set as the default for sorting when the application is started (but this can be changed at any time by clicking the column header – see below).



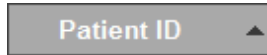
Any of the worklist filters can be enabled in the “Worklist filters” area of the “options” tab:



Once a filter is enabled here, it is then included in the set of filters that are shown towards the left side of the header. These filters are described further below. The option “require enter to apply” changes the interaction with a filter so that when checked, any text typed into a filter field does not occur immediately, but only once the enter key is clicked.

4.1.2. Navigation and Sorting

The worklist presents a sequential study reading model to the user. When the user has finished reading a study, by default (i.e., it is configurable) the next study in the worklist is automatically loaded for review. The user can influence the order of the studies in the worklist by sorting based on any of the attribute columns. To sort based on an attribute: left click on the heading of the appropriate column. If there is space, a small arrow will appear in the heading:



Clicking the same column header with the left mouse button will alternate sorting of the worklist in ascending and descending order according to that attribute.

4.1.3. Filtering

The per-user reading status of a case can be one of:

- New
- Reading
- Recall
- Complete

When a case has the status of either Recall or Complete, it means that the case is *read*. When a case has the status of either New or Reading, it means that the case is *unread*.

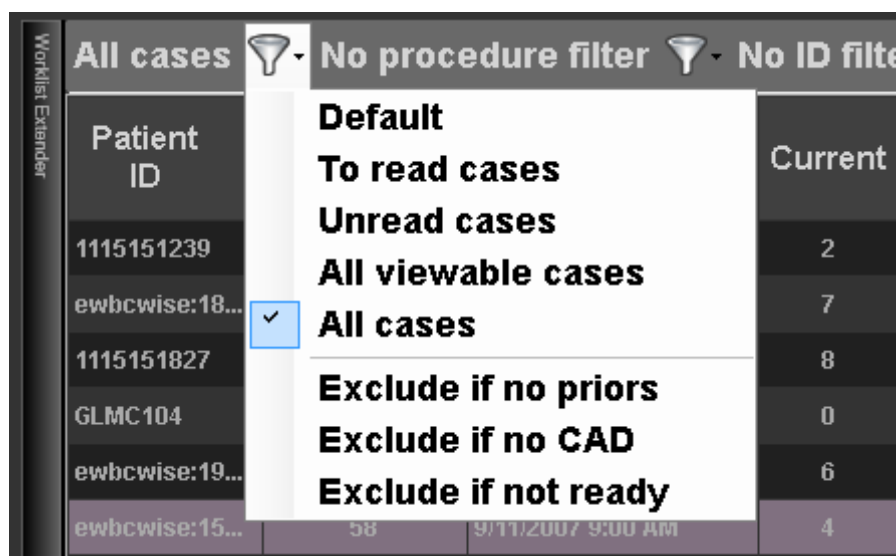
When appropriately configured, the reading status can be synchronized with an external radiologist worklist (such as, on PACS or RIS systems) via HL7 listener/sender, or TCP/IP listener/sender, or files. The reading status on WorkstationOne is typically mapped to IP (In Progress); and the Recall and Complete status values are mapped to CM (Complete) when the HL7 mechanism is used to exchange messages.

The following filters can be used together for filtering the worklist:

- Viewing status;
- Procedure description;
- Institution name;
- Patient name;
- Patient ID;
- User note; and
- Date range (of the current study).

The procedure filter, the institution filter, the patient name filter, the patient ID filter, the user note filter, and the study date range filters can be configured to be displayed or hidden above the worklist.

The viewing status filter can be selected from the first drop-down list provided above the worklist:



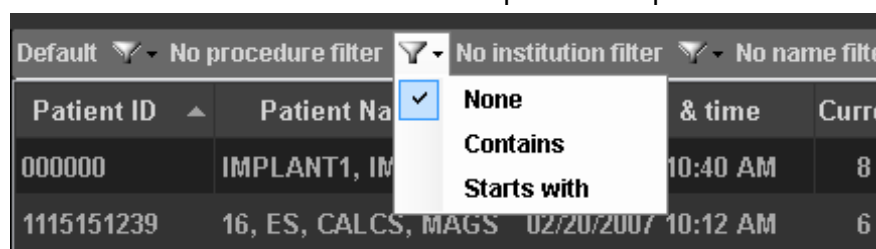
There are several options for the viewing status filter (which are based on the “overall viewing status” field to handle the situation where more than one reader may read the cases on the worklist):

- Default: all cases waiting (for any reader) to read, plus cases read within the last 24 hours.
- To read cases: all cases waiting for me (the current login reader) to read, i.e., if a case has not been opened by me and is being read by another reader, the case won't be in the list.
- Unread: all cases that have not yet been read (by any reader).
- All viewable: all cases that are viewable - i.e., have some current mammography images. This includes cases that have already been read.
- All cases: all cases in the local database - including read and unread, and cases with no images (yet).

In addition, three more check items can be used to exclude cases:

- Exclude if no priors: cases for which a prior study has not yet arrived at the workstation
- Exclude if no CAD: cases for which a CAD report has not yet arrived at the workstation
- Exclude if not ready: cases for which a "ready" (for review) check mark has not been flagged on the workstation

The procedure filter can be selected from the drop-down list provided above the worklist:



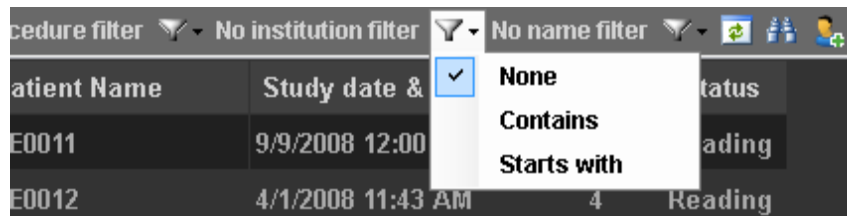
There are three options for the procedure filter:

- None: no procedure filter,

- Contains: filter the worklist to include only cases for which the procedure string contains a string that the user provides; the default string is “screening”,
- Starts with: filter the worklist to include only cases for which the procedure string starts with a string that the user provides.

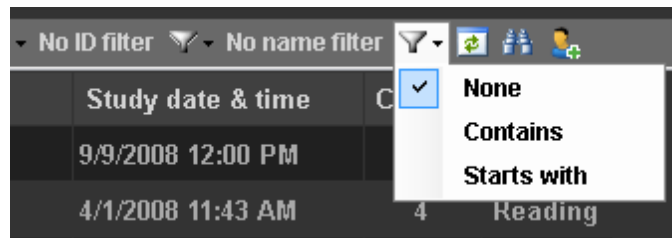
There are three options for the institution filter:

- None: no institution filter,
- Contains: filter the worklist to include only cases for which the institution string contains a string that the user provides,
- Starts with: filter the worklist to include only cases for which the institution string starts with a string that the user provides.



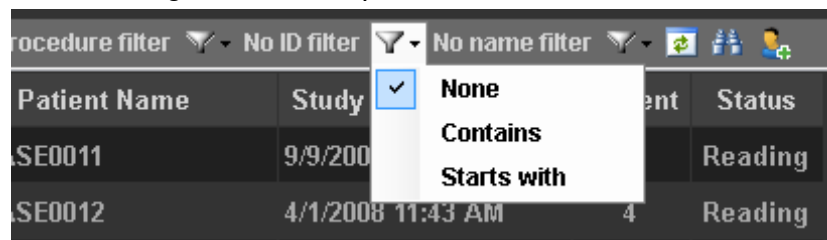
There are three options for the patient name filter:

- None: no patient name filter,
- Contains: filter the worklist to include only cases for which the patient name string contains a string that the user provides,
- Starts with: filter the worklist to include only cases for which the patient name string starts with a string that the user provides.



There are three options for the patient ID filter:

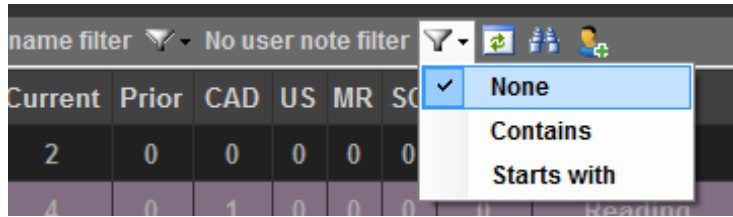
- None: no patient ID filter,
- Contains: filter the worklist to include only cases for which the patient ID string contains a string that the user provides,
- Starts with: filter the worklist to include only cases for which the patient ID string starts with a string that the user provides.



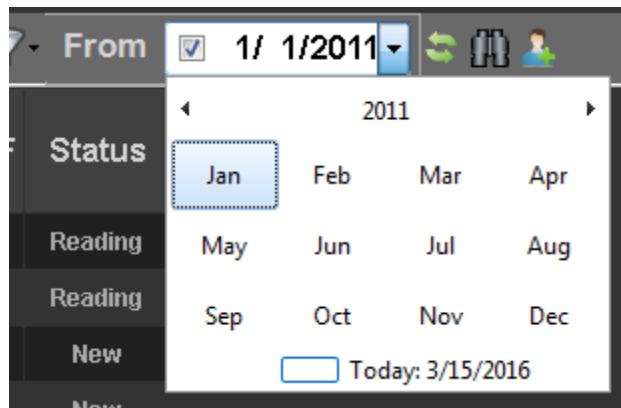
There are three options for the user note filter:

- None: no user note filter,

- Contains: filter the worklist to include only cases for which the user note string contains a string that the user provides,
- Starts with: filter the worklist to include only cases for which the user note string starts with a string that the user provides.



When the date filters are configured to be displayed, a “from” or “to” date selector is displayed:



The checkmark to the left enables the filter (either all cases “from” that date, or all cases “to” that date, depending on which filter is being used). The “from” and “to” filters can be used together, and the date range includes the selected date(s). The down-arrow at the right side causes the drop-down calendar to be displayed, which then allows specification of any year, month, and day. The “from” date filter implicitly uses a time of midnight in the morning of the selected date, and the “to” date filter implicitly uses a time of just before midnight of the selected date (thus to see all studies from a single day, the “from date” and “to date” should be set to the same date).

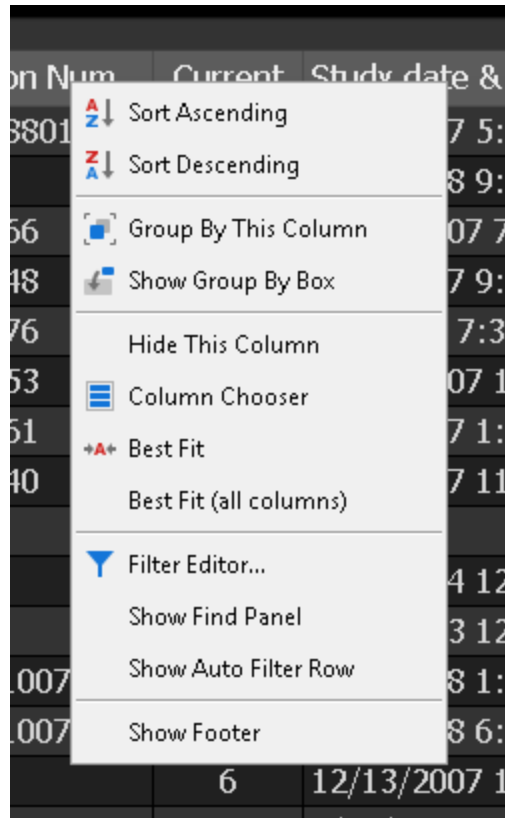
The worklist can be refreshed at any time by selecting the refresh icon to the right of the configured filters (note that this is generally not necessary, as the worklist refreshes automatically whenever anything changes). Two other icons (“query PACS” and “add patient”) are also displayed to the right of the worklist filter and are discussed further below (see 4.4 and 4.3.1).

4.2. Advanced worklist

When the system is configured to use the “advanced” worklist, the default display is very similar to the standard worklist, with the exception that there is no top filter row:

Patient ID	Patient Name	Accession Num	Current	Study date & time	Prior	DBT	US	SC	GSPS	Status
DD_004293_C_5_1	DD_004293_...	000437108801	4	1/17/2007 5:00 PM	0	0	0	0	0	Reading
DEF1234	TPS Anonymi...		6	7/18/2008 9:57 AM	0	0	0	0	0	Reading

In this case, additional functionality can be accessed by a menu which is displayed by right-clicking anywhere in the header row:



The first group of options (sort ascending and descending) have the same action as left-clicking that column header to change the sort.

4.2.1. Grouping

The second group of options control the grouping mechanism. Selecting the second option to show the group header results in:

Drag a column header here to group by that column			
Patient ID	Patient Name	Accession Num	Cur
00000000	LEE, SSM		
0001	RWS test, IH...		
00212	TPS Anonymi...		
00214	TPS Anonymi...		

Then dragging any column to that header area results in:

Status ▴		
Patient ID	Patient Name	Accession Num
▸ Status: Complete		
▾ Status: New		
00000000	LEE, SSM	
000001	NAME, NAME	WSW16101
10805128-80ab-...	Anonymous	
1115151239	16, ES, CALC...	Diagnostic

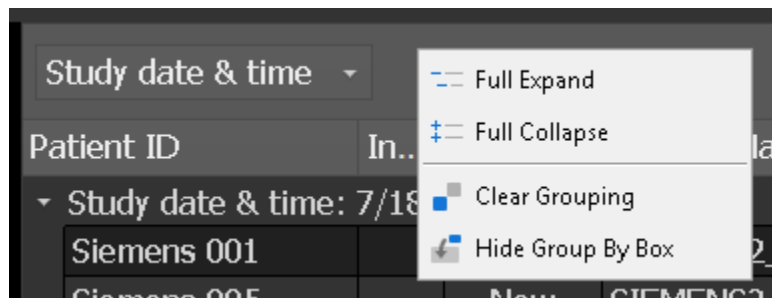
Which can be repeated to generate a complex grouping:

Institution ▾		
Status ▴		
Patient ID	Patient Name	Accession Num
▾ Institution: Three Palm Software		
▾ Status: Reading		
TOMO 099	TOMO 099	
▸ Institution: Three Palm Soft		

This grouping mechanism can be used with any columns, and date columns (“current study date & time”, “prior study date & time”, and “last change”) are handled specially, in that they group by day (ignoring the time of the day) – for example to see all studies from one day:

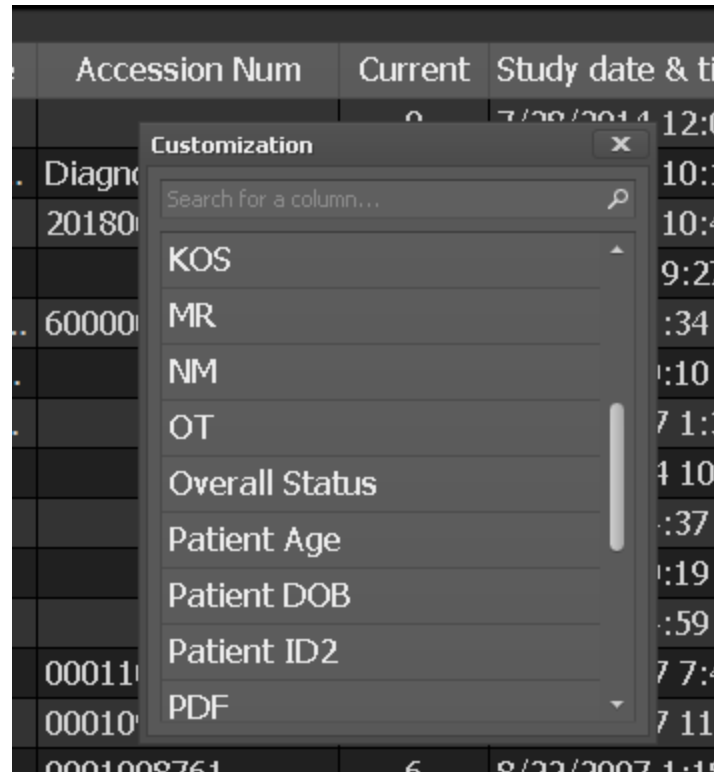
Study date & time ▾				
Patient ID	In...	Status ▴	Patient Name	Accession
▾ Study date & time: 7/18/2017				
Siemens 001		New	SIEMENS2_C...	
Siemens 005		New	SIEMENS2_C...	
Siemens 002		Reading	SIEMENS2_C...	
Siemens 004		Reading	SIEMENS2_C...	
Siemens 006		Reading	SIEMENS2_C...	
Siemens 009		Reading	SIEMENS2_C...	
Siemens 011		Reading	SIEMENS2_C...	
Siemens 012		Reading	SIEMENS2_C...	
▸ Study date & time: 7/11/2017				

When the group header is displayed, it has an additional menu:



4.2.2. Customization

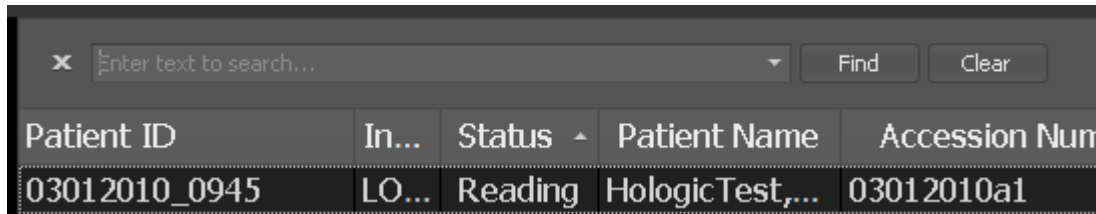
The third group of options control the columns that are displayed: hide a column; select which columns are to be displayed; “best fit” of any column; or “best fit” of all displayed columns. Selecting “column chooser” results in the display of a list of the available (i.e., not currently displayed) columns:



To add a column to the worklist, locate it in this list, and then left-click to drag it to the desired location in the column header. Columns from the header can be dragged back when not needed, which is the same as clicking the “hide this column” action.

4.2.3. Filtering

The fourth group of options on the header menu relate to filters: “filter editor”, “show find panel”, and “show auto filter row”. The “find panel” appears above the worklist:



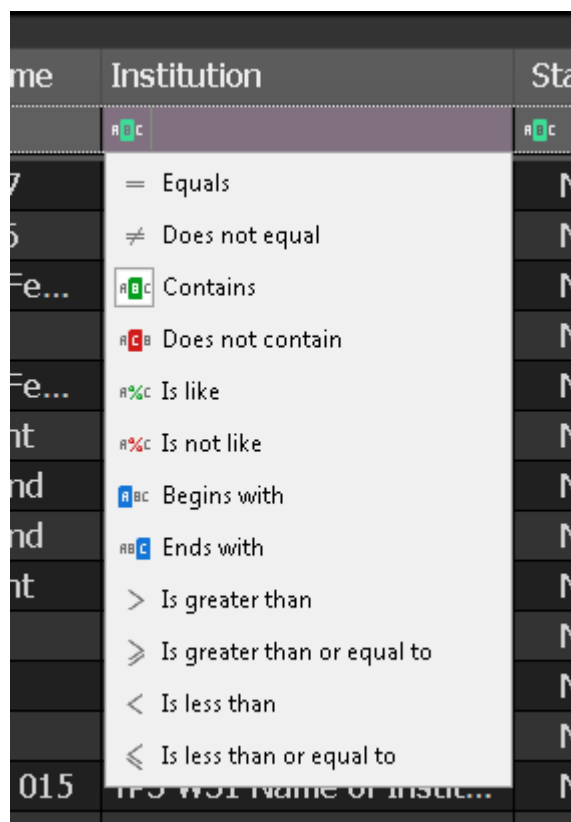
This filter operates essentially as a search of all columns for the relevant information. For example, in this case matching items are found matching the patient name and institution fields:

X TPS Find		
Patient ID	Patient Name	Institution
Priors352479	MorePriors, TPS...	Three Palm Soft
319737	TPS, Anonymized	Sally Jobe Breas
SenoClaire 015	SENOCLAIRE 015	TPS WS1 Name
TOMO 098	TOMO 098	TPS WS1 181 Re

The “x” to the left of the filter closes that panel. The option to show the auto filter row results in an extra row appearing below the header:

Patient ID	Patient Name	Institution	Status	A
				
cimtg0000157	cimtg0000157		New	
csetg0000186	csetg0000186	GEHC	New	

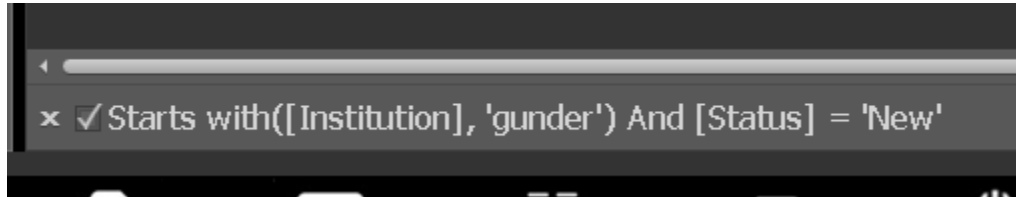
For each column, values can be entered to filter on that column, and the logic operation for that value can be changed by clicking the icon at the left of each filter box:



Entry of information into a filter field results in that filter becoming active, and it also appears in the “filter editor”, which is automatically shown at the bottom of the worklist:

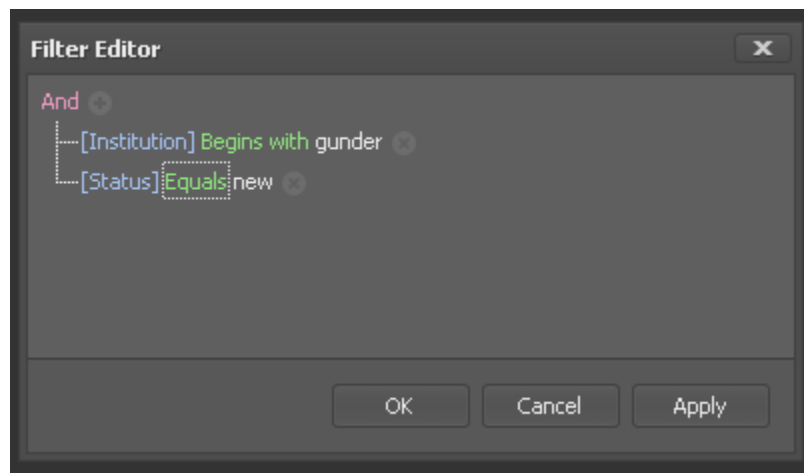
Institution	Status	
ac gunder	= New	AC
GUNDERSEN CLINIC - D...	New	
GUNDERSEN CLINIC - D...	New	

And

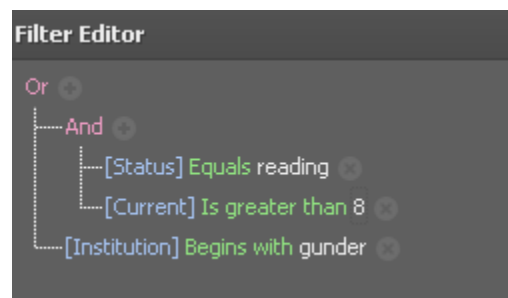


When the footer filter area is displayed, the filter can be toggled on and off using the checkmark, and completely deleted using the “x”.

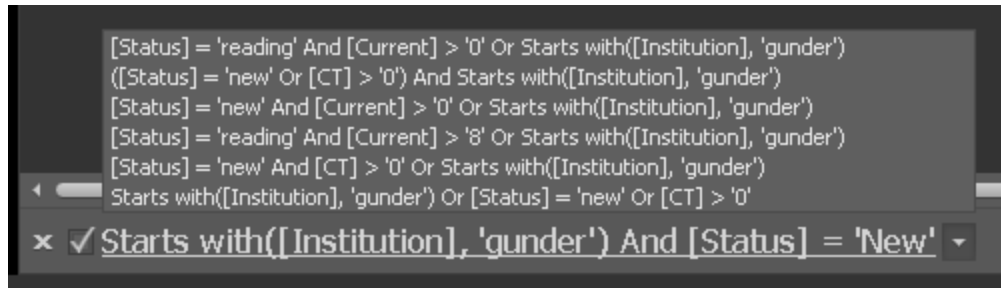
At the right side of the filter panel is an “edit filter” button, which operates the same as the “filter editor” menu option:



This editor allows interactive modification of the filter – such as change of the logical operations; the fields to be compared; and logical grouping.

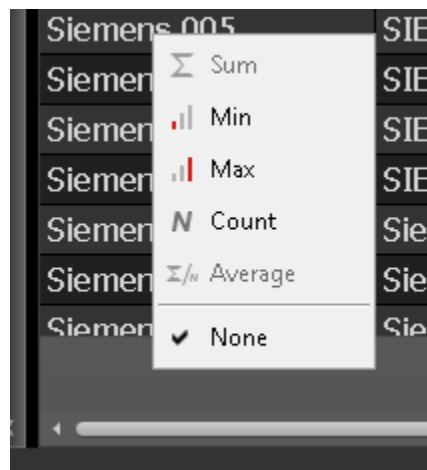


This mechanism allows each construction of complex filters. Once a filter is defined, it is remembered, and can be selected from the list of recent filters (using the drop-down arrow that appears in the filter panel once more than one filter has been created).

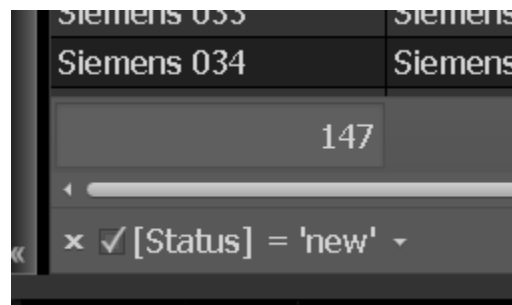


4.2.4. Summaries

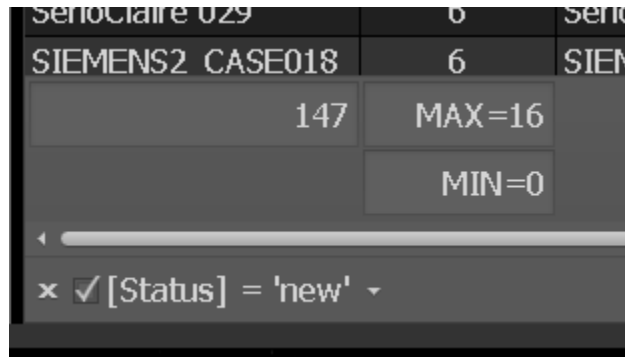
The final group in the right-click header menu is to show the footer. Initially the footer panel is empty, but right-clicking in that area results in another menu that allows column summaries to be created:



The operations in the footer are based on the filtered rows – so for example filtering to see on the cases which are in status “new”, and enabling the count:

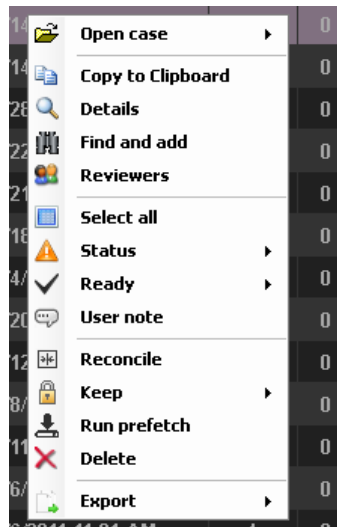


Shows that there are 147 cases in “new” state. Operations other than “count” make sense for some columns, for example to see the maximum and minimum number of images in the current studies of the cases waiting to be read (new state), those summaries can be enabled for the “current” column:



4.3. Worklist tools

Within either the standard or advanced worklist, right-click the mouse on a patient item (anywhere in the row associated with a patient ID), or on any one of the highlighted patient items, to display a drop-down context menu for interacting with the patient item(s):



The menu item "Open case" can be used to open the images of the high-lighted patient item for review. A context menu is automatically formed to list the current study and any known prior studies. Selecting the context menu item "Newest study (default)" is equivalent to "double-clicking" an item on the worklist to open the case. Other menu items are dynamically generated for the case, and are formatted as "Prior mm/dd/yyyy [? images] as current" (where "mm/dd/yyyy" is the prior study date and "?" is the number of images in each prior study):



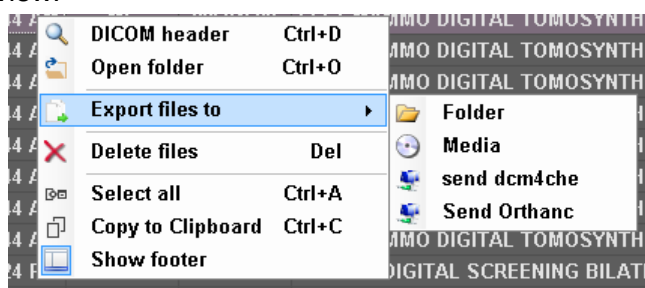
Clicking one of the prior studies in this list opens that study and treats it as the "current" study with all earlier studies considered as priors to that, and newer studies effectively

hidden. This allows all hanging protocols for a current study to be used for reading any prior study.

The menu item "Copy to clipboard" saves all displayed columns of the selected items to the clipboard, from where the user can paste them to other tools such as Microsoft Excel.

The menu item "Details" can be used to obtain more information about one patient item that is clicked – such as the accession number, study ID, etc. Within the details view, a context menu can be used to:

- display the DICOM header of the selected item (first item, if there are multiple selected);
- open the folder (using Windows Explorer) where the selected file is located;
- export the selected items (files to a folder; files to a folder in DICOM media format; or to any of the configured DICOM destinations);
- delete the selected items (i.e., delete the entries and associated files);
- select all items on the "detail table";
- copy the detailed information of selected items to the clipboard (e.g., so that they can be pasted to an external tool such as Microsoft Excel);
- show (and hide) a summary footer which can be displayed at the lower edge of the details view.



The menu item "Find and add" is a duplication of the function provided by the search icon at the top of the worklist (small binoculars icon, see the above and following sections). However, when used from the menu (and from the large icon below the worklist), the patient ID of the selected row is automatically entered into the "Patient ID" field of the query dialog, and the query action is automatically initiated to obtain the list of studies associated with the patient ID (see section 4.4). The large binoculars icon below the worklist is a duplication of the "Find and add" menu item, to provide quick access to a search of the PACS for the high-lighted patient ID (i.e., without the need to open the drop-down menu and to select the menu item "Find and add").



The menu item "Reviewers" can be used to view or override the multi-reader overall status of the selected case. Note that when a study has not been previously opened by a user, then that user does not appear in the list of reviewers of that case.

Reviewers					
Patient ID	00212	Patient Name	TPS Anonymized	Overall Status	Reading
Name	Date Time	Status			
TPS/pbh	1/21/2014 3:05 PM	Reading			
Override -> Recall Override -> Complete Close					

The multi-reader overall status values are:

- New
- Reading
- In progress
- Recall
- Complete

The overall status is generated by combining the single reader status of all users who have read that case, using the rule that has been configured by service personnel for this system. Currently the following three arbitration rules are supported:

- **simple majority:** more than half the readers have set the same status; otherwise the overall status is "In progress", which can be arbitrated by an additional reader.
- **any recall takes priority:** if any reader has set the status to "Recall", then the overall status is "Recall"; otherwise the overall status is "Complete".
- **any recall requires manual arbitration:** if any reader has set the status to "Recall", then the overall status is required to be manually set.

Independent of which rule is in effect, the multi-reader overall status can be explicitly overridden to be either "Recall" or "Complete" by any reader.

The single reader status of the current case is automatically updated based on its reading status. However, the menu item "Status" can be used to manually set the single reader status for highlighted items in the worklist. The single-user status values are:

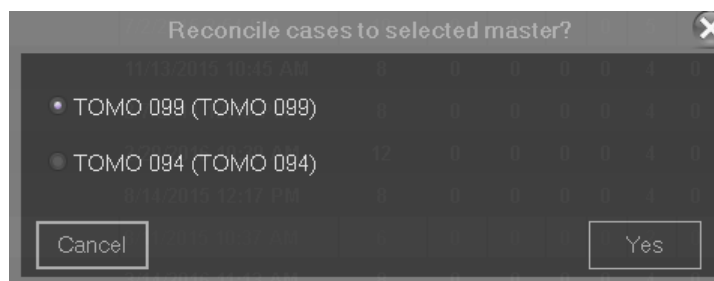
- New
- Reading
- Recall
- Complete

Sometimes, even when all images from the current and prior studies are pre-fetched to the workstation, a technician may need to check that everything is ready, or that all other documents for the patient are available before the radiologist reads the case. This communication can be accomplished by use of the menu item "Ready". The selection "yes" (resulting in a checkmark icon in the worklist) on a technician workstation allows the technician to prepare a worklist that is ready for the radiologist to read on the radiologist workstation. Exchanging the "ready" information between the technician workstation and the radiologist workstation is configured by service personnel on the system backend.

The menu item "User note" can be used to open a dialog for the user to add a note to a patient item or to multiple highlighted patient items. A note can be up to 64 characters in

length. An example of using the note is to add a comment (text string) for a teaching file. As a convenience for the user, the note dialog also provides a checkbox called "Keep" allowing the user to mark the case to not be deleted (i.e., keep it permanently regardless of the status). Another example of using the note is to allow the user to add an ordering string to each item in the worklist, so the worklist can be sorted in a specific sequence defined by the user.

When a patient has her prior studies performed outside the facility, the prior study DICOM data may contain a different patient ID from the current study that is performed locally. Reconciling patient IDs is usually performed when importing the prior studies to a PACS. The system can also be configured to perform this automatically as studies arrive at the workstation. However, a completely manual mechanism is also provided - the menu item "Reconcile" can be used to (locally) join the images from multiple selected rows into one case. Selecting multiple rows and clicking Reconcile results in the dialog:

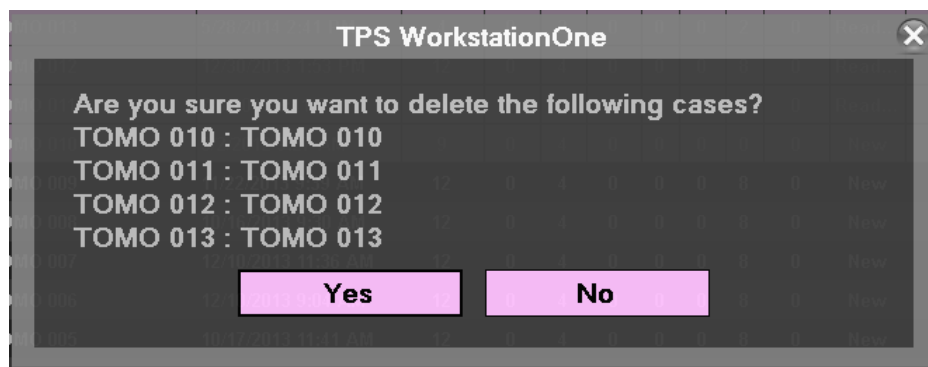


Which shows a list of all the selected cases, with one marked as the "master". Once "yes" is clicked, all objects (images, etc.) from the other cases are copied into this one master patient, which then has all the images, with the other cases emptied and deleted from the worklist. Depending on the number of images to reconcile, this could take a few seconds, but once it is complete, the updated "master" case can be opened to view all the images for that patient.

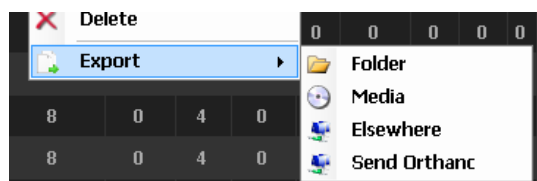
The menu item "Keep" provides the same functionality as the checkbox "Keep" on the user note dialog. The selection "yes" with this menu item (resulting in a lock icon in the worklist) marks the case as not able to be deleted.

When the system has configured pre-fetch rules and DICOM Q/R is configured, the menu item "Run prefetch" is enabled, and selecting it forces the system to immediately run the configured rules for the selected patients.

An item or multiple highlighted items that are not set to "keep" (i.e., without the lock icons) can be deleted from the worklist using the menu item "Delete". Highlighting items and clicking "delete" results in a confirmation dialog:



Once “Yes” is clicked, all the data for the selected patients is permanently deleted from the local system.



The menu item “Export” can be used to export all studies associated with the selected patient(s) to local folder or removable media, or a configured DICOM destination. Export to a “Folder” simply places the DICOM files in a folder (with the patient-id as the name of this folder) below the folder that the user selects. Export to “Media” is similar, except that it is intended for the destination to be removable media, so the files are written following the DICOM media standard. If an externally provided viewer is available, it can also be placed on the same media as the files, so that the cases on removable media can easily be viewed by referring physicians. Support for this must be configured by technical support. The list of DICOM destinations (non-media) reflects the “Send” destinations configured on the system. These destinations can even be external to the site, connected securely via a VPN, or simply using DICOM TLS (secure transport).

4.3.1. Manual case add

In routine use, cases appear on the worklist once they are announced by an external system (e.g., routed from PACS, or triggered using modality worklist or an HL7 message). However, cases can also be added manually. One way to do this is using the “Manual Query” mechanism (see 4.4), in which the retrieval of a patient not already included in the worklist causes it to be added. In situations where the system is configured to pre-fetch the required studies from the PACS, an even simpler mechanism can be used. This is the “Add” button above the standard worklist, and menu item for the advanced worklist:



Clicking the add button results in the display of a simple dialog:

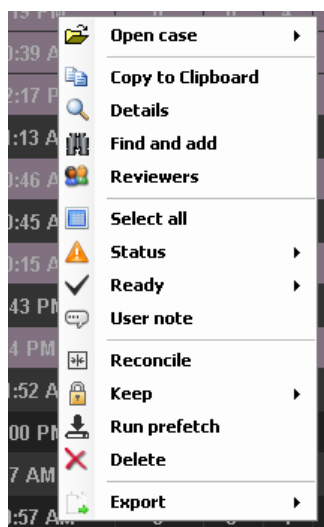
A patient to be added is identified by the corresponding ID which is typed into the above box. Once an ID is typed in, it is inserted into the worklist when the “Add” button is clicked, or when the keyboard “enter” key is pressed. The dialog remains open, so several cases can be conveniently entered in one session, but if only one case is to be added, the “Add and close” button can be used. The dialog can also be closed using the “x” button or the keyboard “escape” or “left” keys.

Once a case is added to the worklist, any pre-fetch rules defined for the system are immediately executed. When such rules are defined, this triggers the corresponding studies to be retrieved, and the worklist updated to reflect their arrival.

The checkbox "Mark as ready" has the same functionality as the drop-down menu item "Ready" (described above), and the text box "User note" has the same functionality as the drop-down menu item "User note" (described above). Even without pre-fetch, this "add" feature with the "ready" check and the user note can be used to communicate messages between workstations (or between technician and radiologist) about a patient's study, even without the images being available.

4.3.2. Worklist multiple item selection

Some of the worklist drop-down context menu items can interact with multiple patient items. There are several ways to select multiple items on the worklist – e.g., on the standard worklist, multiple items can be selected by dragging the left mouse button over sequential items on the worklist. Alternately, a range can be selected by selecting the first item, and then left-clicking, with the **shift** key pressed, the last item in a sequence to be grouped. Non-sequential items can be grouped as a selection by clicking each while holding the **ctrl** key down and clicking the left mouse button on each row to be selected. Once item(s) are selected, right-clicking anywhere on the selected items displays a drop-down context menu, as shown in the following picture, where multiple non-sequential items in the worklist that have been selected:



Note that some of the menu actions only work with a single patient item, and in those cases the item that was right-clicked is selected and the other items are de-selected. The menu actions that work with multiple patient items are:

- Status
- Ready
- User note
- Reconcile
- Keep
- Run prefetch
- Delete (other than those items with the lock icon, indicating that they are to be kept)

- Export

4.4. Manual query

When DICOM Q/R is configured, a specific case can be manually queried and retrieved from PACS by using the binoculars icon to the right of the refresh icon above the standard worklist or using the “find and add” option of the tools menu for either the standard or advanced worklist. The query attributes can include Patient ID, Patient last name and first name. Matching studies can be further restricted based on date ranges. The “approximate” check option allows partial matches on the patient name. Click the button “Query” to get a matching list, for example:

The screenshot shows a window titled "Browse PACS and retrieve studies". It contains a "Connection" section with fields for Configuration (query), AE title (ORTHANC), Host (aiwendll), Port (4242), and TLS. Below this is a "Query" section with fields for Patient ID (740476), Last name, First name, a date range (between 2/5/2020 and 2/4/2021), and a "Maximum matches" field set to 100. There are "Clear" and "approximate" checkboxes, and a green "Query" button. To the right is a "Retrieve" section with a green "Retrieve all checked items" button. Below the query section is a "Matches" section containing two tables. The first table lists patient information, and the second table lists studies for a selected patient. At the bottom, there is a filter bar showing "Starts with([Modalities], 'MG')".

Patient ID	Patient Name	Sex	Date of birth	Modalities
740476	VolparaSR, R2SR Anonymize	F	1/11/1960	MG,SC,SR

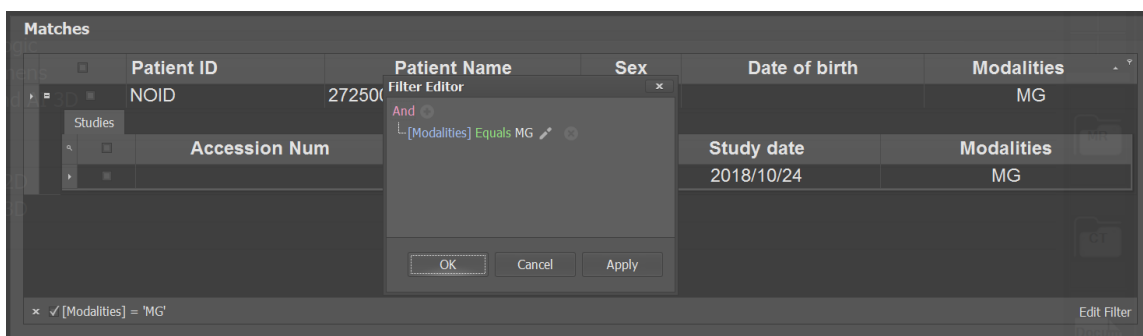
Accession Num	Description	Study date	Modalities
PT000014356	SCREENING BILATERAL MAM...	2012/04/25	MG,SC,SR

Note that the matching patient list is filtered so that it includes only patients which have at least one study matching the search criteria.

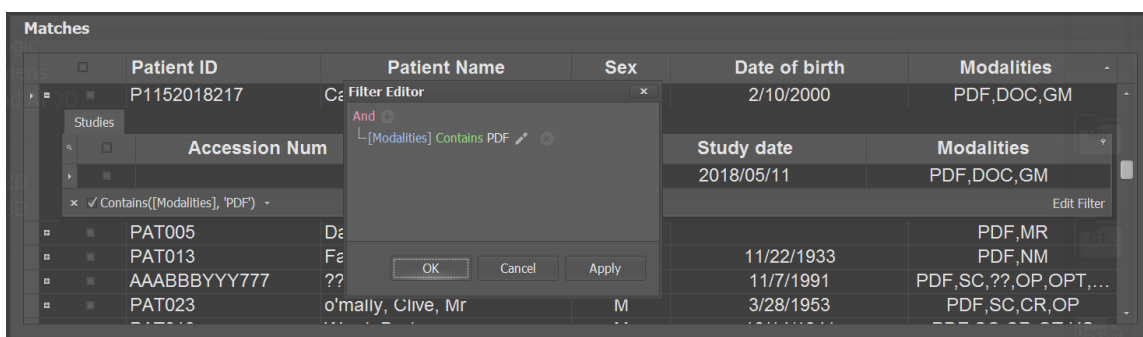
To retrieve all studies associated with a patient, check the box next to that patient (or check boxes for multiple patients) and click the button “Retrieve all checked items”. Fetching of the images is then performed in the background, so you can close the Q/R window.

To retrieve a sub-set of the studies for a selected patient, click the “+” icon to the left of that patient in the list, which results in that patient being expanded to show the list of studies associated with this patient. Then check the box (or boxes) next to the studies to be retrieved and then finally click the “Retrieve all checked items” to retrieve those studies to this workstation.

The column headers in the above list can be clicked to sort by that column, and to edit column filters. For example, at the patient level it is possible to click the header, and define a filter that shows only patients that have “MG” as one of their contained modalities:



Similarly it is possible to filter within a patient (i.e., the studies to be shown for a patient), by clicking on the column headers for the studies, and editing a custom filter at that level. For example, here the patients are filtered by those that contain MG, and the studies for the expanded patient are filtered by those containing the modality “SR”:



Filters can be turned off and on using the checkbox to the left of each filter. The studies for a patient can be expanded to occupy the full display area using the magnify icon (and restored to the original layout by using the corresponding “x” button).

Use the standard Windows “X” button on the top-right corner or the left arrow key to close the Q/R window.

When an image already exists in the local database, the re-retrieved image over-writes the existing image. If the new retrieved image has a different patient ID from the existing image in the local database, the image count associated with the existing patient ID is updated (i.e., decreased as that image is re-filed under the new patient ID).

The selected patient ID can be automatically filled-in within the Query window by using the big binoculars icon to the right of the printer icon below the worklist. This button then initiates a query for all studies associated with the selected patient.



4.5. DICOM file import

An institution may receive media containing prior mammography images for a current patient which is being read. To import the image data directly to the workstation, click on the “disk” icon under the worklist to get the “import” user interface.

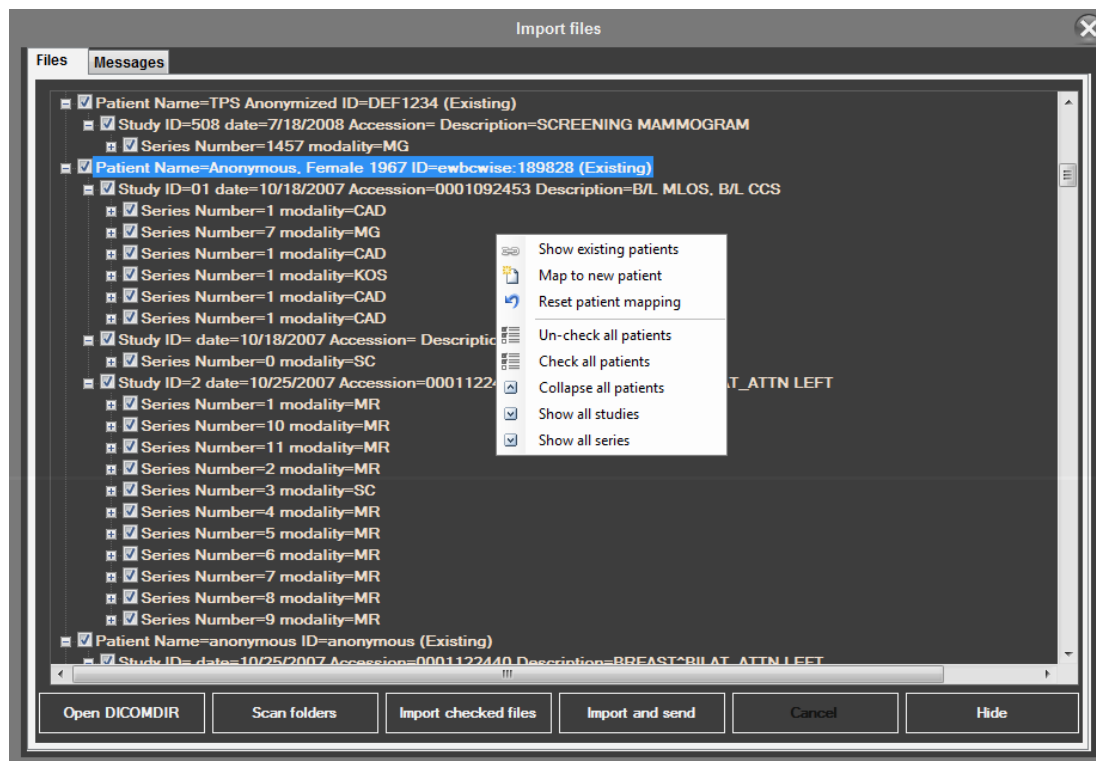


There are two styles of import tool included with WorkstationOne (as of the 1.9.0 release). These are configured on the service tool and are referred to as the “standard” and “advanced” import tools. The core functionality of each is the same, but they differ in the user interface and reconcile mechanisms.

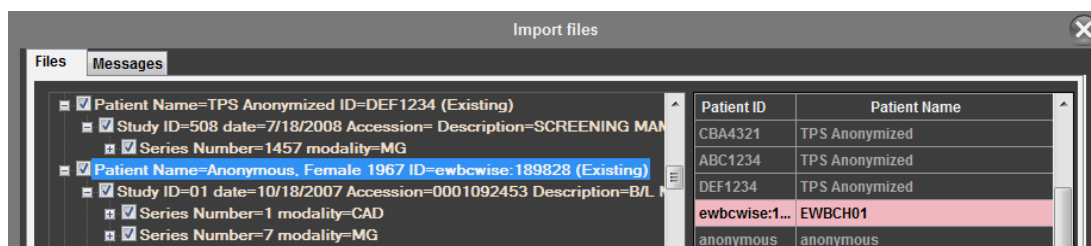
4.5.1. Standard import tool

The standard import dialog allows the user to select a DicomDIR (click the button “Open DicomDIR”) or browse folders for DICOM files (click the button “Scan folders”), to get a list with patient/series/file structure. Note that there are slight differences between what is displayed from a DicomDIR and scanning the folders, as the DicomDIR contains information such as the modality for a series which may differ from that in individual images. Once a list of files is displayed, click the button “Import checked files” to import those selected files into the system. Alternatively, click the button “Import and send” which imports the selected files and simultaneously sends them to the configured “Send” destination(s).

Within the import dialog, a right-click of the mouse on the background area displays a drop-down menu. The menu item “Check all patients” can be used to select all files; and the menu item “Un-check all patients” to de-select all files. Options to “Collapse all patients”, “Show all studies” and “Show all series” are also available from this drop-down menu:



When the image data is being imported to the workstation and when the image data contains different patient identifiers to those already in the system, the critical patient demographics (e.g. Patient Name, Patient ID) and order/procedure Information (e.g. Accession Number) can be reconciled using the local worklist. The workstation provides a mechanism to preserve a copy of the original values inside the imported DICOM Composite Objects. To reconcile a case during import, right-click on a patient’s name, and select the drop-down menu item “Show existing patients”, which then allows you to select a patient from the local worklist, which is then displayed on right side of the dialog:



Once an existing patient is selected, during the subsequent import, the following DICOM attributes will be copied from the local selected patient information into the imported composite data (if the associated application loading setting is 'true'):

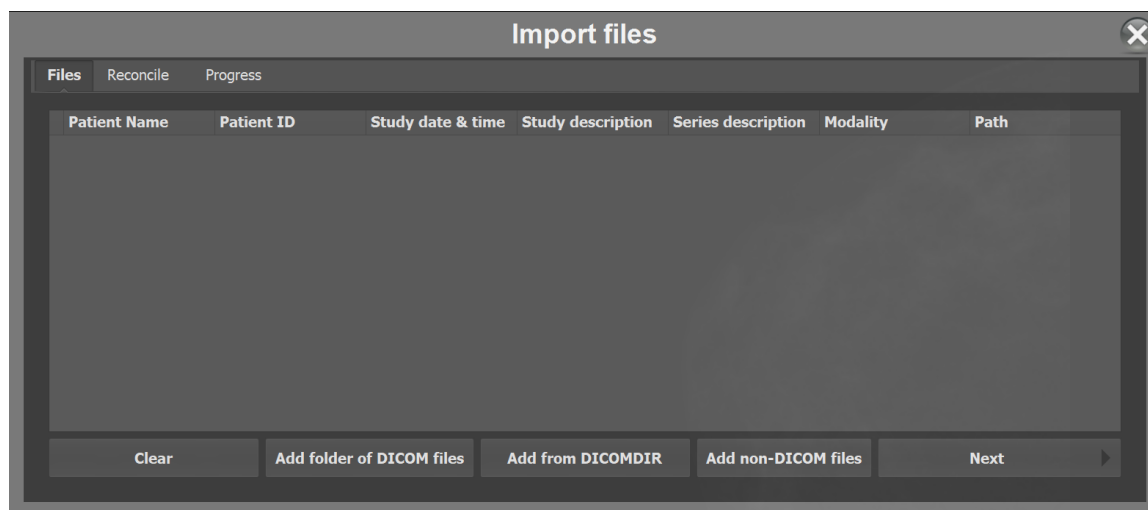
- Patient ID
- Patient Name (setting ImportReconcilePatientName)
- Patient's Birth Date (setting ImportReconcileBirthDate)
- Accession Number (setting ImportReconcileAccession)

Patient's Sex reconciliation and importation of "Other Patient Ids" to be merged with the local "Other Patient Ids" are not implemented in the current release.

The menu item "Reset patient mapping" can be used to remove the "reconcile patient" selection. When a patient ID does not exist in the local worklist, a new ID can be created using the menu item "Map to new patient".

4.5.2. Advanced import tool

The advanced import tool is organized with 3 tabs, which can be switched manually by clicking a tab, and can be sequenced using the "next" / "previous" buttons at the bottom of the window.

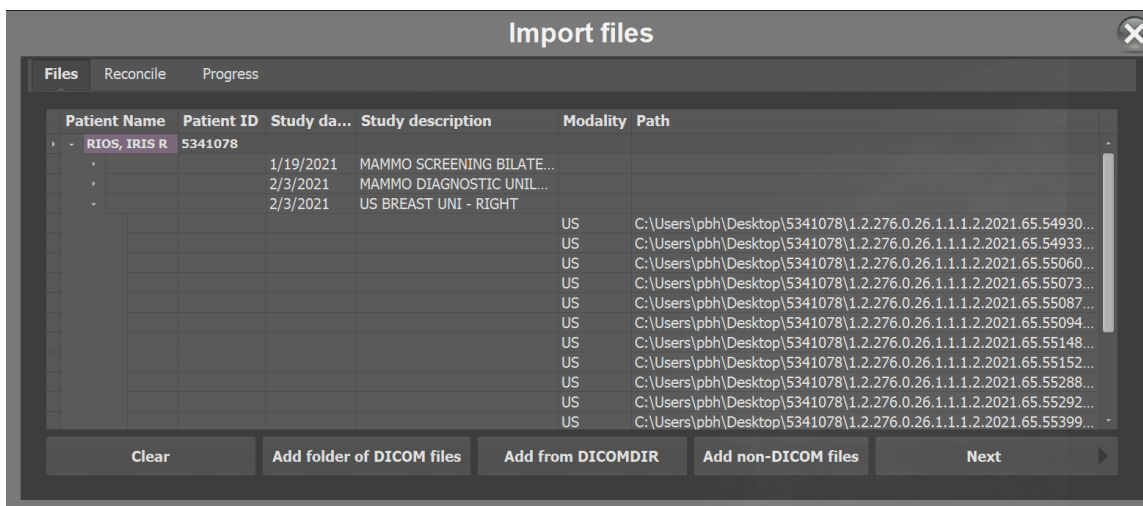


The theory of operation is that the "Files" tab is used to select files which are to be imported; the "Reconcile" tab is used to map patients or studies to existing items on the worklist; and the "Progress" tab is used to initiate and monitor the progress of the import action once it has been started.

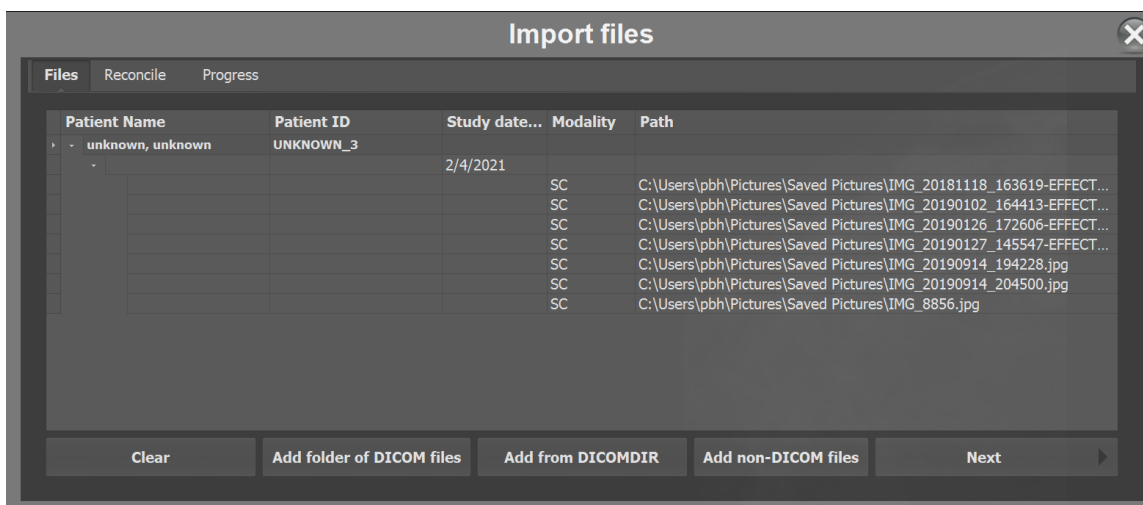
4.5.2.1. Files

This tab allows adding existing DICOM files to the list and to add non-DICOM files for import. DICOM files can be added as a folder (and sub-folders) using the "Add folder of

DICOM files” button, or indirectly via a DicomDIR (using the “Add from DicomDIR” button). Typically, removable media such as a patient-CD has a DicomDIR, which is then recommended as the preferred selection mechanism as it will provide a list faster than scanning folders on a DVD (for example). Selection of either of those buttons causes the display of a folder or file browser, so that you can select the folder (or location of the DicomDIR file) to be used. Once that is selected, the folder (or DicomDIR) is scanned, and the located files are added to the list:



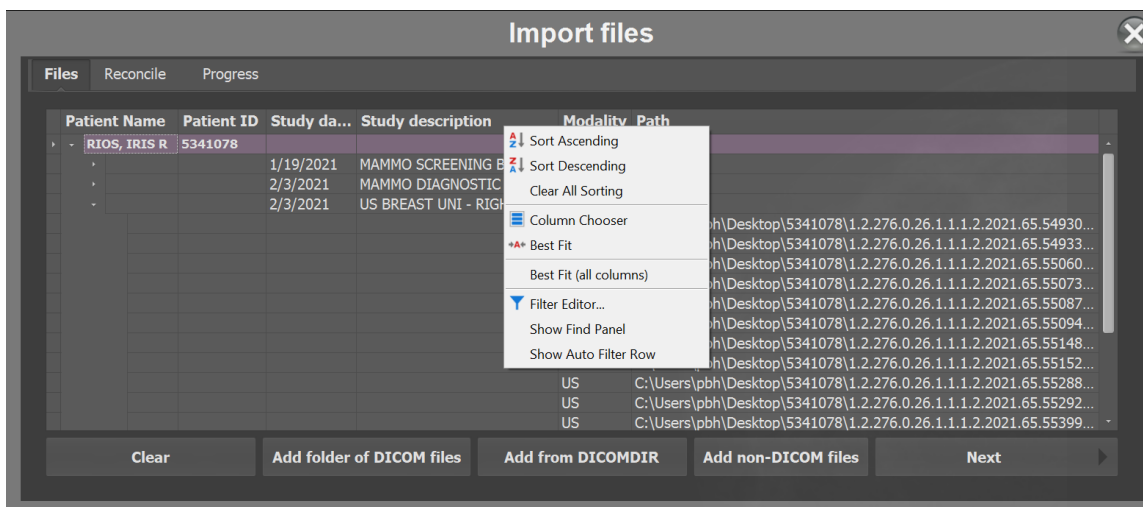
Similarly, when the “Add non-DICOM files” button is clicked, a folder browser allows you to select a folder, which is then searched for any importable files (pictures and pdf documents):



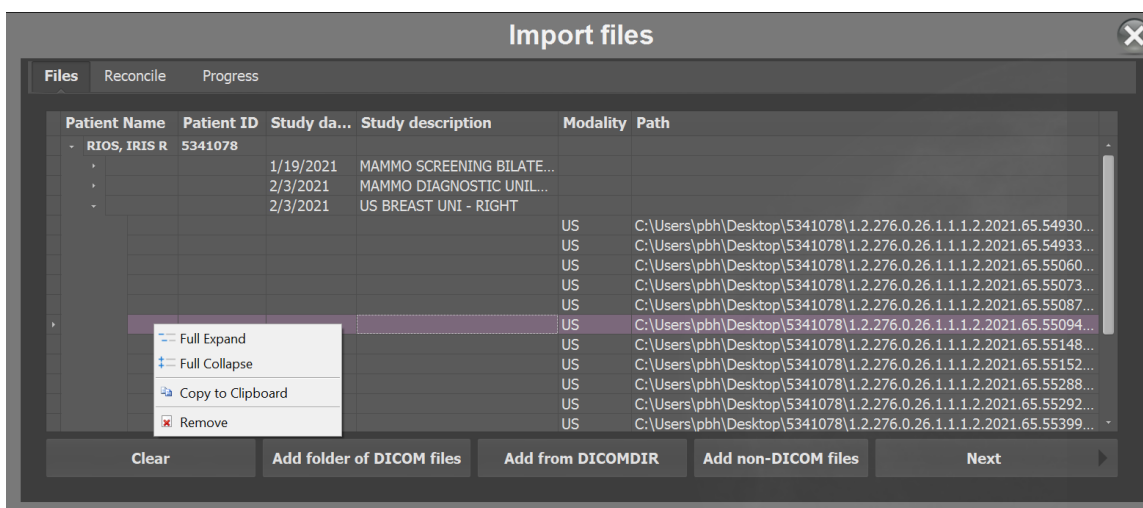
In this situation the “patient name”, “patient ID” are fake, and for such imports, the “Reconcile” tab will be most useful to then associate that patient or study with specific existing, or a new, case in the worklist.

The buttons can be used multiple times to add files to the list from different locations.

The columns shown in this tree can be customized from the menu shown when the header is right clicked:



And individual items (all selected rows) can be removed from the list by using the “remove” option on the right-click menu shown within the grid:



All files can be removed using the “Clear” button. Files are automatically removed from the list once the import is initiated (see below).

4.5.2.2. Reconcile

This tab allows incoming patient and studies to be mapped to existing or new patients and studies. This is a task that is normally not needed when importing DICOM files, provided the patient-id is “correct”. In some situations, however, the incoming (e.g., from DVD) files have an external ID (MRN) which needs to be mapped to an internal ID. This can easily be achieved on this tab. In the case of importing non-DICOM files, use of the “reconcile” tab is more important, as it provides the way to map the arbitrary (fake) patient ID and name to an existing patient on the worklist, or to assign it a new ID.

The theory of operation for reconciling is to first select the incoming patient-id (and study, if desired):

Three reconcile actions are defined:

- Do nothing – which means leave the specified ID as it is (the default)
- Map to existing patient (or study)
- Map to new patient (or study)

When “map to existing...” is shown, the corresponding region of the UI is enabled:

Patient ID	Patient Name	Patient DOB
000001	NAME, NAME	1/1/1950
0000108079	P0000108079	1/1/1900
000724289		1/1/1900
001004	IHEMammoTest, Current a...	1/1/1901
01-017	VA1-C29	1/1/1900
06183	ANONYMLN, ANONYMFN	8/12/1955
10161316	10161316	1/1/1947
107911	TPS Anonymized	1/29/1958
148655	NEESE SUSAN	3/10/1956
15266PPI	TPS Anonymized	10/8/1963
20.12.02-11:39:51-STD-1.3...	Tomo_ML	12/2/1990
206643	VERRILL, MICHAEL W	3/28/1951
24261702	Hologic_Genius_AI_Detecti...	1/1/1960
250721	NAPOLITANO, LUISA	9/7/1977
30101008	30101008	1/1/1937

Allowing the “Existing patient ID” drop-down to be shown, and hence any patient from the internal worklist can be selected as the target. The drop-down list is itself customizable – by a right-click on the header row to show a menu that allows further customization (hence the columns, size, etc. are all controllable by the user).

The “map to new patient” is similar, in that the “patient” area is enabled, but now the “existing patient ID” is hidden, and the other values can be entered manually (so any arbitrary patient-id and patient-name can be typed in):

Once the patient-id is selected to be mapped to an existing or new patient-id, then during the import, the headers of those files are automatically edited to map them to the specified target. This allows non-DICOM files to be added to any patient, and for any file to be re-mapped to any existing or new patient.

Similarly, for a study being imported, the incoming study can be kept as is, or mapped to an existing study, or a completely new study.

4.5.2.3. Progress

The “progress” tab is where the importing occurs. This tab consists of two areas:

Where:

- “Options for sending” refers to the simultaneous sending of the images to remote destination(s) as part of the import task.
- “Perform import” is where the actions (import and possibly sending) are initiated and can be cancelled. Progress is displayed here also.

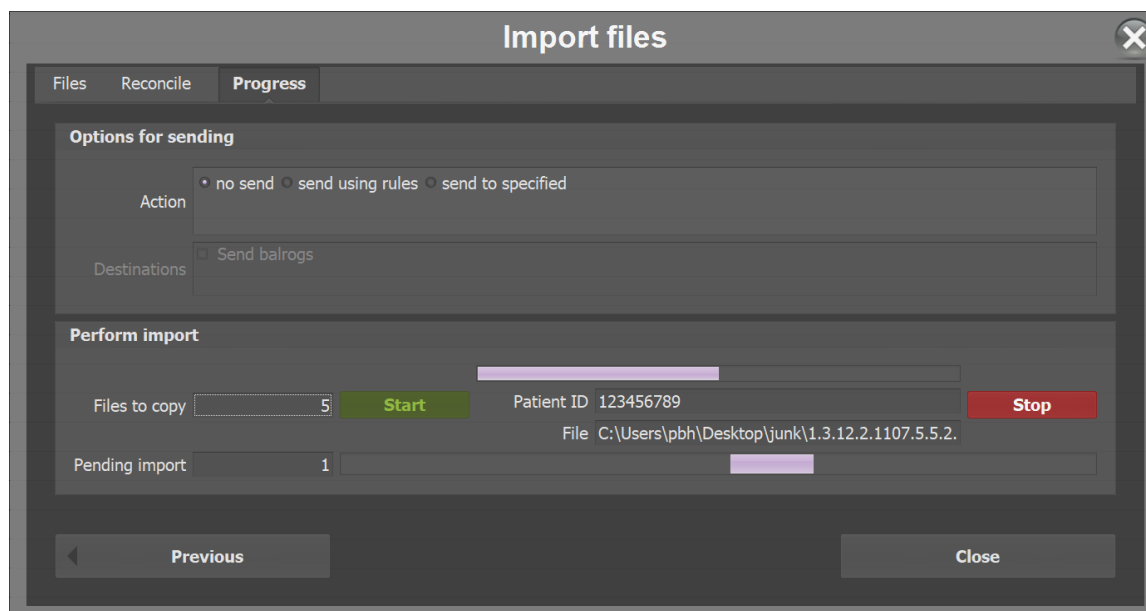
The send options are:

- “no send” (the default) means that the specified files are only imported to the local database, and not sent to any PACS.
- “send using rules” means that the specified files are imported to the local database, and if there are routing rules specified (as part of the system configuration) for “arriving” data, then they are applied, and the files are then sent to whatever destinations are specified in those rules.
- “send to specified” means that the specified files are imported to the local database, and to any destination that is checked in the list of “Destinations” (the contents of that list reflect whatever destinations are configured on this system).

The import process starts when the “Start” button is clicked and can be cancelled by use of the “Stop” button. When “Stop” is clicked, any files not yet copied are ignored, and removed from the list of pending imports. Any files copied but not yet processed are still processed.

The import process proceeds in two parallel phases: 1) copy from the source location to the internal database, and 2) filing within the internal database. The number of files waiting to be copied is listed as “Files to copy” and once the process starts, this number counts down to zero, with a slider showing the process from N to zero. Once this process is started, the “Stop” button is enabled, and it becomes disabled once the “to copy” number reduces to zero. The “import files” dialog can be closed (“x” or “close” button) at any time without impacting the progress of the import.

As each file is being copied, its corresponding “Patient ID” and “File” name are displayed. The “Pending import” box shows the number of items that have already been copied to the internal database but are still waiting to be filed within the internal database. This number starts from zero (typically) and can go higher and then reduce to zero once everything is complete. While there are files pending, the busy indicator to its right shows that the system is still busy with the import.

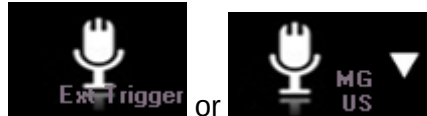


The relative speed of the “file copy” and “pending import” depends on factors such as the speed that the data can be copied (e.g., if the source is on a DVD, then the copy could be quite slow), what type of data is being imported (some data may require decompression or other actions as part of the import), and how busy the system is with

other tasks (e.g., it could be simultaneously receiving and processing files being sent from a PACS). Once the “files to copy” has gone to zero, then the source location is no longer needed (so for example, if that is a removable media device, it could be ejected once the copy has completed, even if there are >0 files waiting for “pending import”).

4.6. Dictation trigger

The dictation icon is displayed on the navigation monitor below the worklist:



By default, no action is associated with the button (so it appears disabled), but it can be configured (see Service Manual) to send a message to an external system (such as a dictation system) whenever it is clicked. That message allows the external system to synchronize with the case that is currently being viewed by the user. Configuration of the button requires information on the messages that the external reporting system supports.

Multiple triggers can be associated with the dictation button (e.g., as shown in the right-hand example above). The reason this is useful is that the system can be used to dictate with different systems, or for specific modalities. In the example above, the system is configured with different triggers for “MG” and “US”. Which of those is enabled, depends on the contents of the data, and which the user wants to enable or disable – e.g., clicking the arrow next to the dictation trigger in this case:



Unchecking one of the options (e.g., US) means that the dictation button will subsequently fire for only the remaining configuration (here “MG”) when clicked (explicitly, or via a short-cut key):



When multiple triggers are associated with different modalities, then only if the current study has the specified modality will that configuration be selectable.

This dictation trigger action (single or multiple) can also be invoked by a user configured short-cut key, such as Alt+D (see “Key Code Configuration” above in section 8.5).

4.7. Priority read and bookmark

WorkstationOne provides a means to interrupt the reading of a case when a higher priority study arrives and is required to be read immediately before the current (first) study is complete. In this model, the first study is remembered or simply closed, and the second, high priority, study then can be opened for reading. After the high priority study is completed, the first study can be re-opened, so that its reading can be continued. This scenario can be handled using the so-called “bookmark” folders.

A “drop” button (left button in the following picture) is used to drop the current study to a bookmark folder:



A “quick” close button (“X” button above) can be used to simply close the current study without any bookmark (i.e., only the study status is kept in the worklist). These two buttons are located at the top outer corner of the thumbnail mammogram image area on the navigation screen.

To bookmark a study while it is open, click the “drop” button, and the current study is remembered (the patient ID is remembered, and user markups may also be cached, based on the configuration) and the study is visually dropped into a bookmark folder. The bookmark folder or folders (the number of the folders is configurable) are arranged below the thumbnail image area:



In this example, the first two icons show studies which were previously dropped into the folders. The remaining three folders are still empty. Once any high priority study is completed, the user can just click on a bookmark folder icon to re-open the contained, previously dropped, study and continue to complete the reading of the study as usual. The bookmark folder is changed back to empty once the bookmarked case is re-opened.

The bookmarks are remembered for the user when WorkstationOne is closed, so when it is opened again, each bookmarked case can be resumed from a bookmark folder (may not be the same folder as before exiting the application).

5. Reading workflow

The reading workflow which is followed when making a diagnosis on the workstation follows three phases:

(1) loading and layout of the case (including the current exam and a prior or baseline exam) and quality checks.

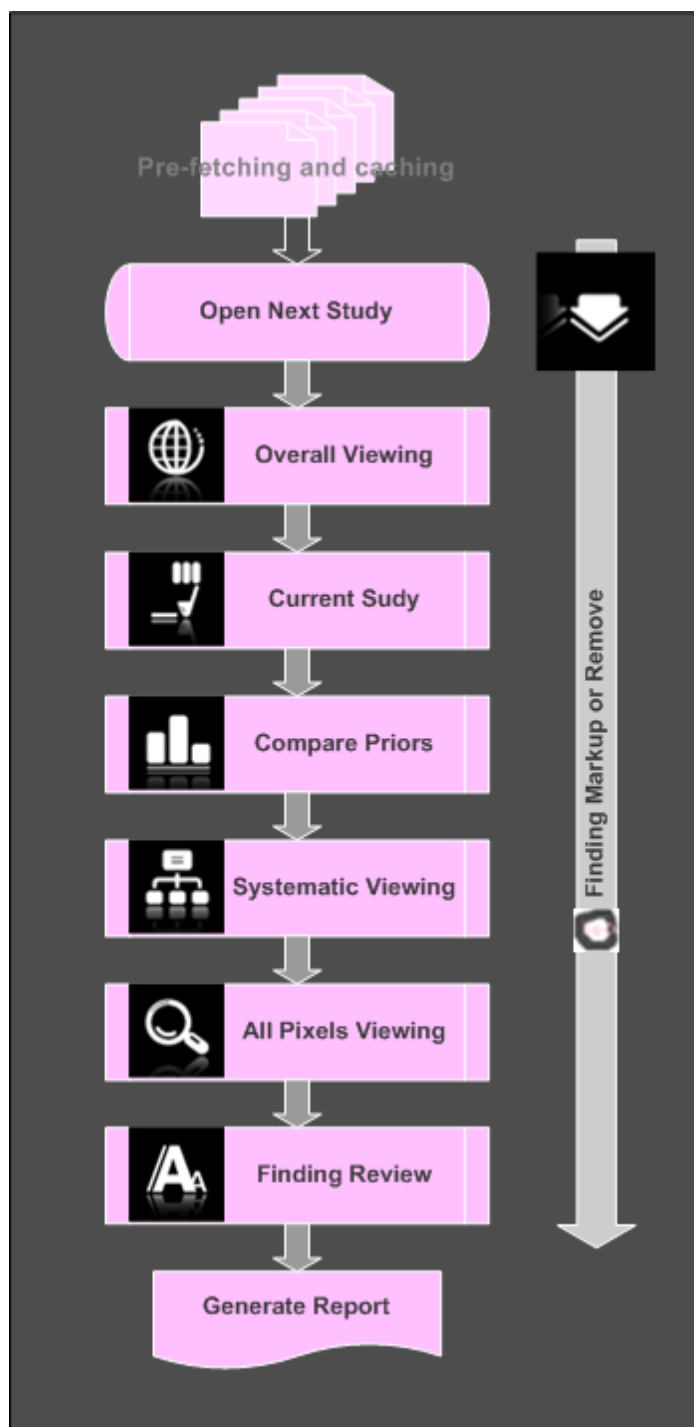
(2) viewing of the images (as well as associated clinical meta data) and generation of a list of findings. This includes the following steps:

- overall viewing (including current and prior comparison, and quality control check);
- systematic viewing, allowing comparison of left and right breasts by masking enhances the detection of structural asymmetries;
- all pixels viewing for enhancing the detection of micro-calcifications, and the automatic tracking of the viewing path helps to ensure that there are no areas from the images that were missed in the viewing.

(3) interpretation of the findings that were generated from the viewing phase and, optionally, the findings generated by off-line CAD processing, and construction of an assessment report.

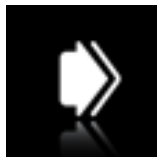
The three phases are provided as a series of steps, as shown to the right.

The user can decide to always skip any of the above steps, or to change the order of the steps by changing the user configuration settings (described in Section 8.2).



5.1. Workflow navigation

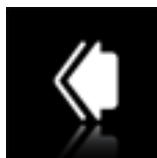
The reading protocol is stepped through using the button with the forward icon:



When configured this way and when there is more than one prior study, all the prior studies can be navigated using the circular loop icon:



A user can navigate one step backwards in the protocol using the button with the backward arrow icon:



The toolbar can also be configured to contain icons for each of the steps:

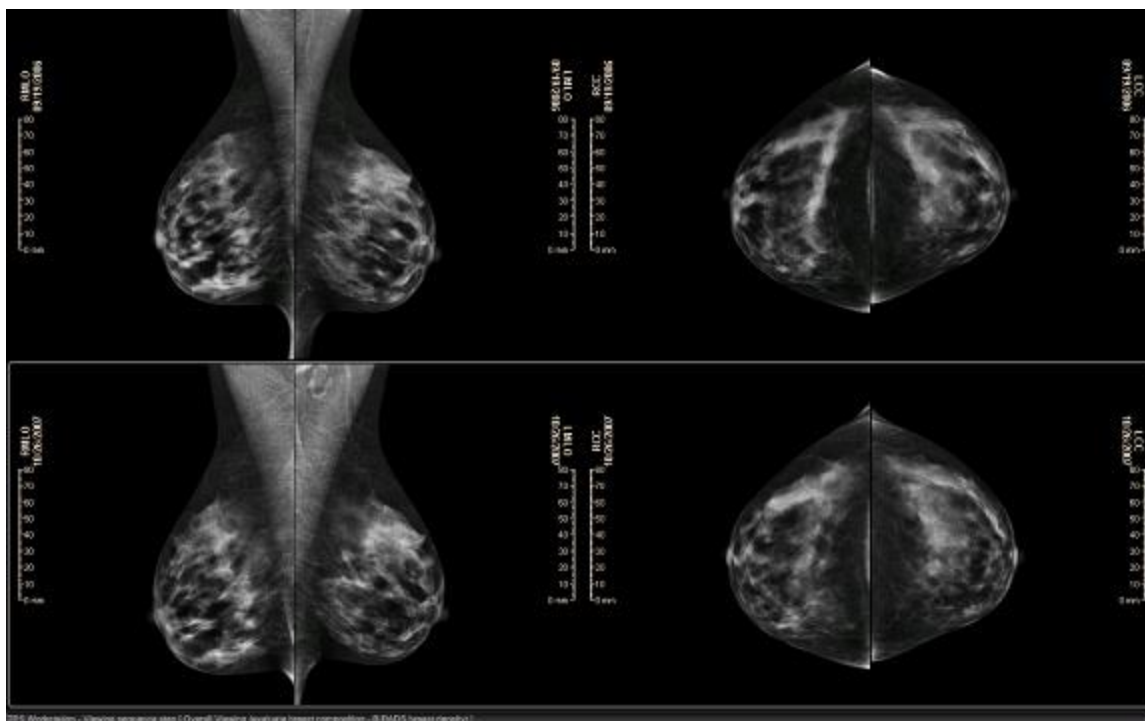


The user can jump to a specific step by selecting the corresponding icon. The currently active step icon is highlighted by a bright bounding box.

Keyboard (and hence key-pad) shortcuts are also provided for navigation (see section 6.8). One further option for navigation is using the mouse wheel. If the “mouse wheel stepping” option is selected in the User Configuration panel (section 8.4), the mouse wheel can be used for navigating forwards and backwards through the protocol steps.

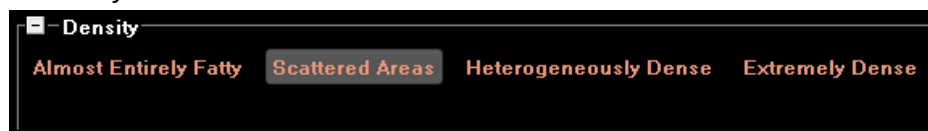
5.1.1. Overall viewing

The workstation displays the standard four views of a mammogram from both the current and prior exams based on the configured hanging protocol. Whenever a prior exam is displayed simultaneously with the current exam, the images in the current exam are framed by a bold bounding box to ensure that the radiologist makes his diagnosis on the current exam (see the following figure).



The chest walls are automatically aligned vertically and horizontally for optimal viewing. The overall viewing step provides a viewing layout for estimation of breast density. The user interface allows a breast density assessment to be recorded by clicking one of the following 4 option buttons (based on ACR BIRADS 5 categories):

- Almost Entirely Fatty
- Scattered Areas
- Heterogeneously Dense
- Extremely Dense



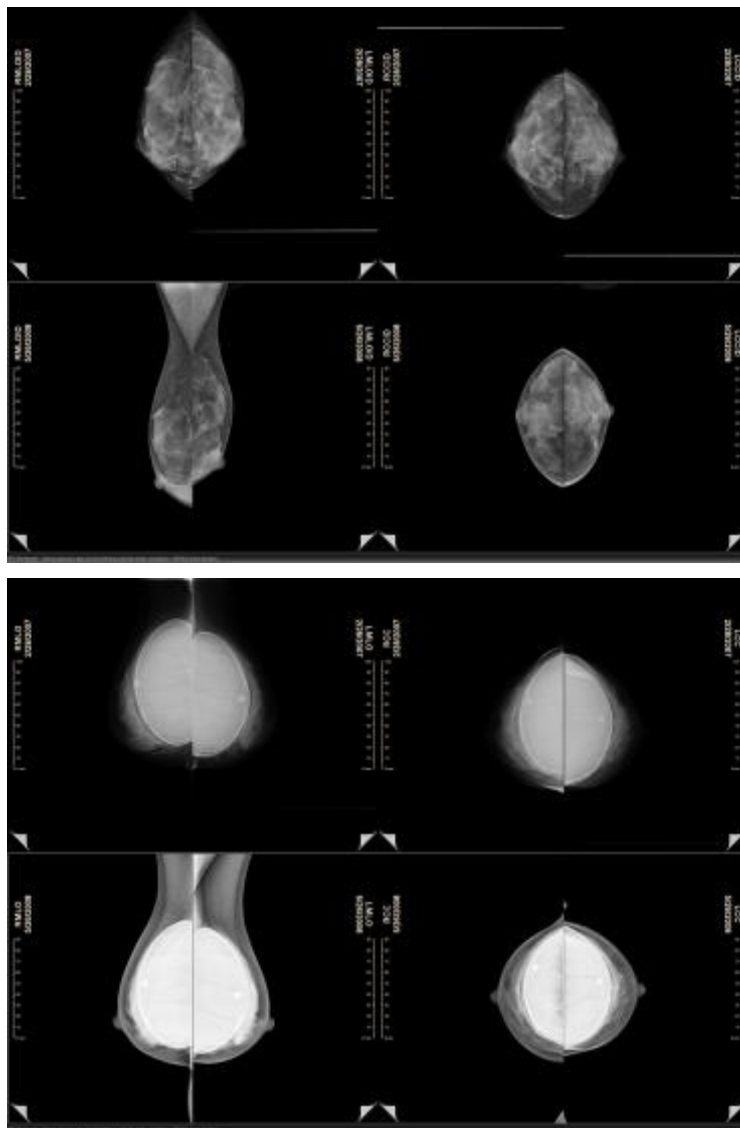
Clicking on the highlighted button de-selects the density assessment. In this way, a user interface is provided for the situation where no density assessment is wanted. This is so that when WorkstationOne is integrated with a RIS or a reporting system, the breast density string “Undefined” is sent to that destination.

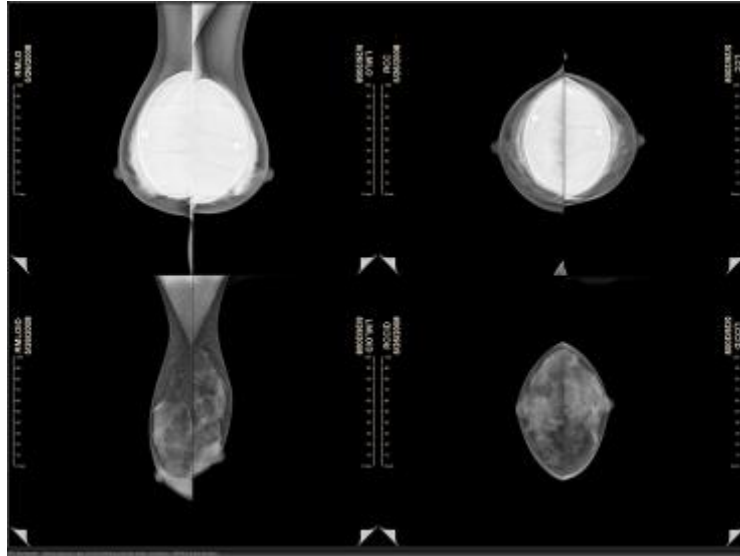
If a DICOM SR (e.g., from CAD or an automated breast density system) is part of the case and contains a breast density assessment, that information is used as an initial assessment, otherwise “Scattered Areas” is the initial value. Note that this initial assessment is calculated by averaging the percent glandular tissue from the CAD SR of the initially displayed images.

When the current study contains implant displaced (ID) views, the single click forward button can be used to display the overall views in the following sequence:

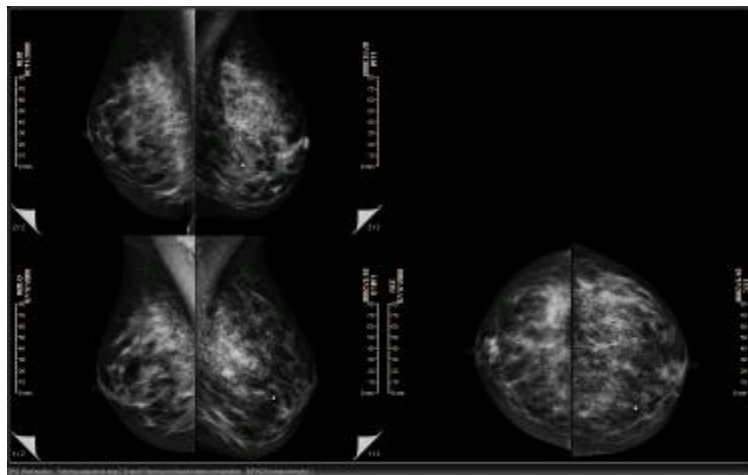
- ⇒ 8 ID views: 4 standard current ID views and 4 standard prior ID views
- ⇒ 8 implant views: 4 standard current views and 4 standard prior views

⇒ 8 current views: 4 standard current ID views and 4 standard current views
For example:

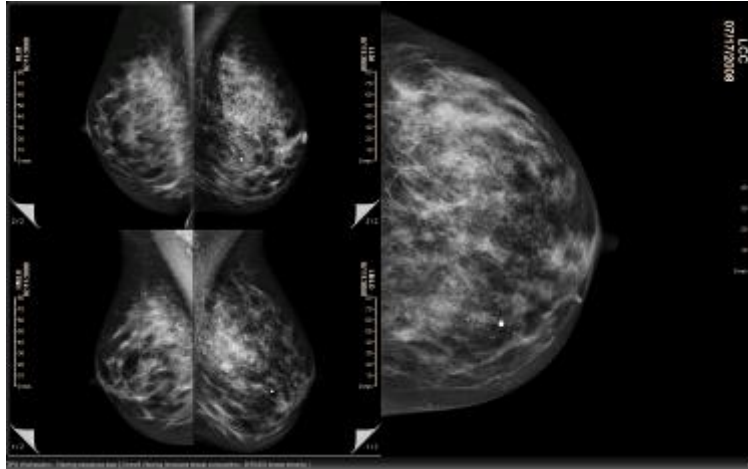




When the current study contains more than 4 standard screening views, and when it is configured (i.e., on the user configuration, the checkbox “Step through current study up to 4 extra images if exist” is checked), the single click forward button can be used to display all images on the same screen. In the following example, 6 images are thus displayed together:



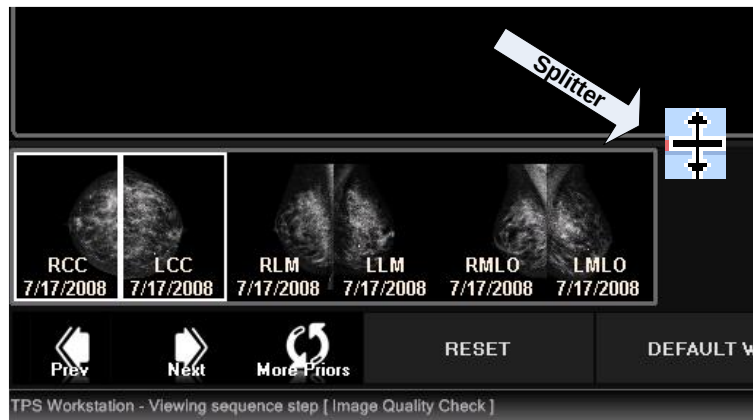
Double-clicking on any viewport, for example the LCC viewport above, results in enlargement of that viewport to the full height of the display:



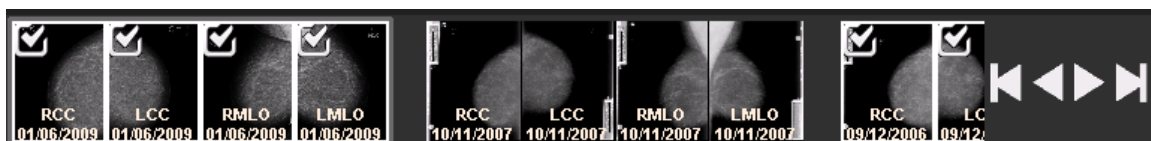
The tool panel can be hidden or shown by clicking on the double arrow icon at the lower right corner of the image screens:



The size of the thumbnail images can be changed by dragging the splitter line up or down:

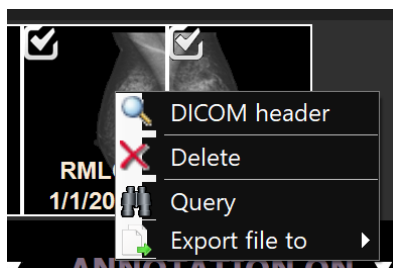


A checked graphic over the top-left corner of a thumbnail image indicates that the image has been displayed in a viewport, i.e., has been viewed:



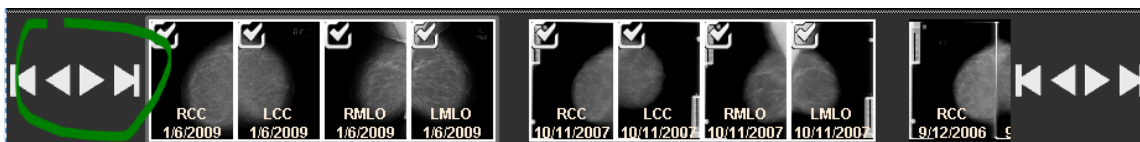
Not only are these image thumbnails visual indicators, they also have some active roles:

- Hovering the mouse over a thumbnail causes the display of a popup message summarizing the properties of that image.
- A left-click and drag allows the corresponding image to be dragged to a viewport on the screen (by default a current image can be dragged to a current viewport, and a prior image to a prior viewport, but this behavior can be over-ridden using the “allow drop to any viewport” option on the user configuration, diagnostic tab).
- A right-click on a thumbnail displays a small context menu which has options to view the header, delete the file from the local cache, query the PACS for the open case, and to export the corresponding file to any folder, to media, or to any of the configured DICOM destinations.



To the right of the thumbnail images, the left and right arrow buttons can be clicked to scroll the thumbnail images when there is insufficient space to show all the thumbnail images for the case. The outer left or right button with a left arrow or right arrow and a vertical bar graphic can be clicked to jump to the first thumbnail image or the last thumbnail image.

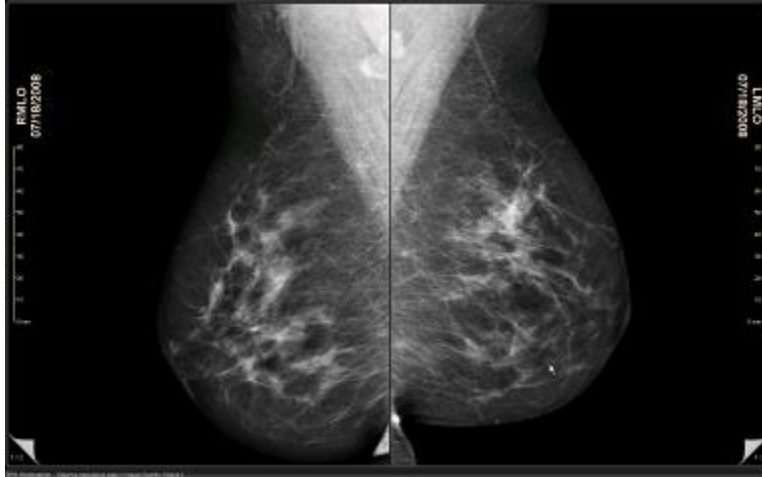
When it is configured, the scroll buttons are duplicated to the left of the thumbnails:



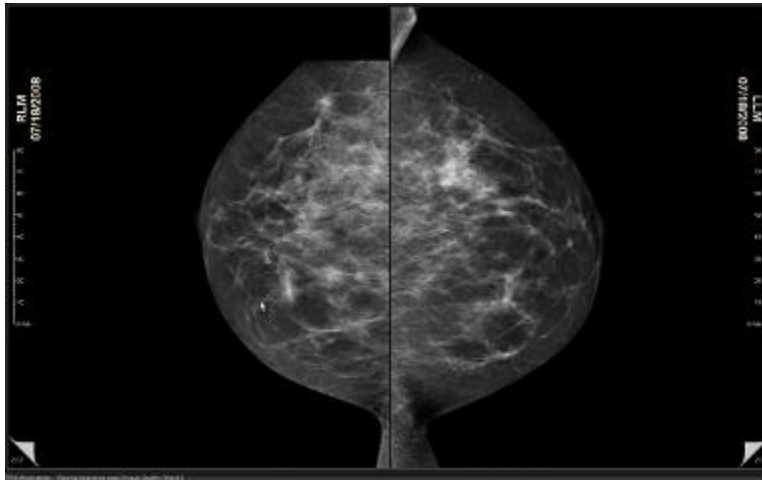
5.1.2. Current study viewing and/or quality check

In this viewing step, there are several layout selections for displaying the images from the current study, including extra views if configured (i.e., on the user configuration, the checkbox “Step through extra views” or/and “Step through standard view with extra” is/are checked). For example, using single click forward button, to view the sequence of MLO views; ML extra views (if the checkbox “Step through extra views” is checked and the checkbox “Interleave extra views” is checked); then CC views:

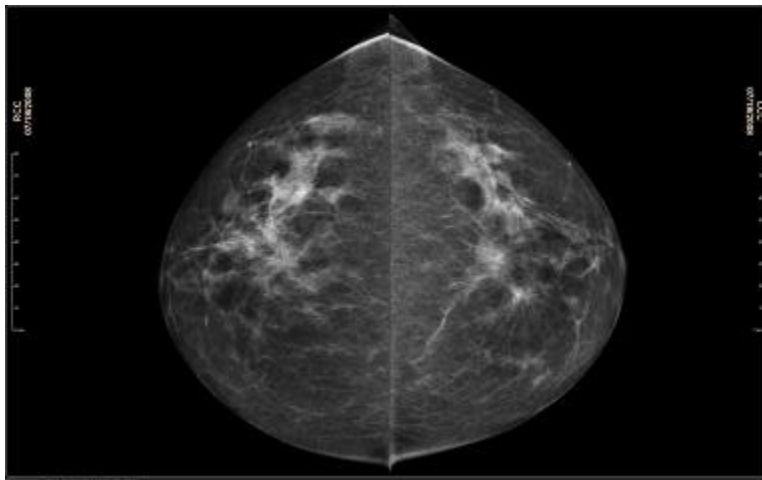
⇒ the bilateral MLO views



⇒ the bilateral ML views (or extra MLO views)

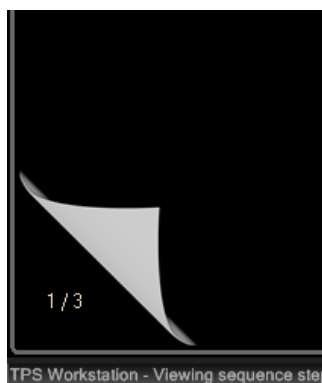


⇒ the bilateral CC views



When so configured, and extra views or ID implant views are present, a single-click on the page-flip icon at the lower corner of an image results in the “flip” and display of the next available extra view, such as, MLO, ML etc. The current “view order” number and the total number of extra views are also displayed with the page-flip icon. The font size

of the numbers is the same size as the overlay font and can be configured using the text box “font size for overlay” on the “User Controls” tab of the user configuration window.



In addition to a single-click on the page-flip icon, the up and down arrow keys can be used to display the next (or previous) available extra view. Note that the up and down arrow keys are only available for extra view stepping when they are not assigned to other tasks, such as: scrolling to the next prior study in the overview or comparison viewing steps; moving the mask in the systematic viewing step; scrolling to the next portion of an image in the “all pixels” viewing step.

The extra views matching a CC projection include the following views represented by the DICOM view tag:

- R-10242 (CC)
- R-10244 (FB)
- R-102CF (XCC)
- R-1024A (XCCL)
- R-1024B (XCCM)

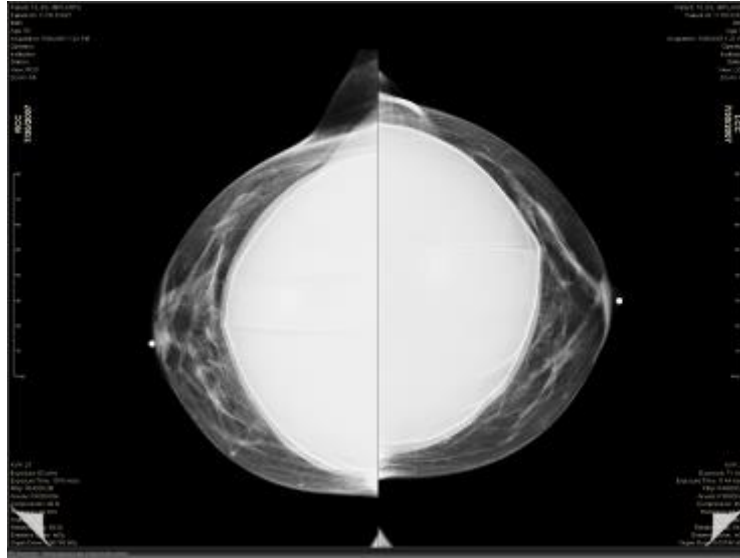
The extra views matching a MLO projection include the following views represented by the DICOM view tag:

- R-10224 (ML)
- R-10226 (MLO)
- R-10228 (LM)
- R-10230 (LMO)
- R-102D0 (SIO)

When the current study contains implant displaced (ID) views, the single click forward button can be used to display the study in the following sequence when the checkbox “Interleave extra views” is checked on the user configuration:

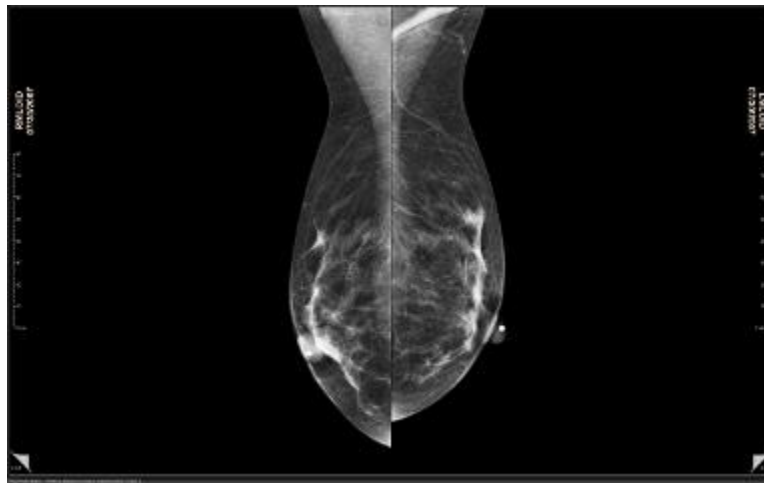
- ⇒ 2 ID MLO views
- ⇒ 2 MLO views
- ⇒ 2 ID CC views
- ⇒ 2 CC views

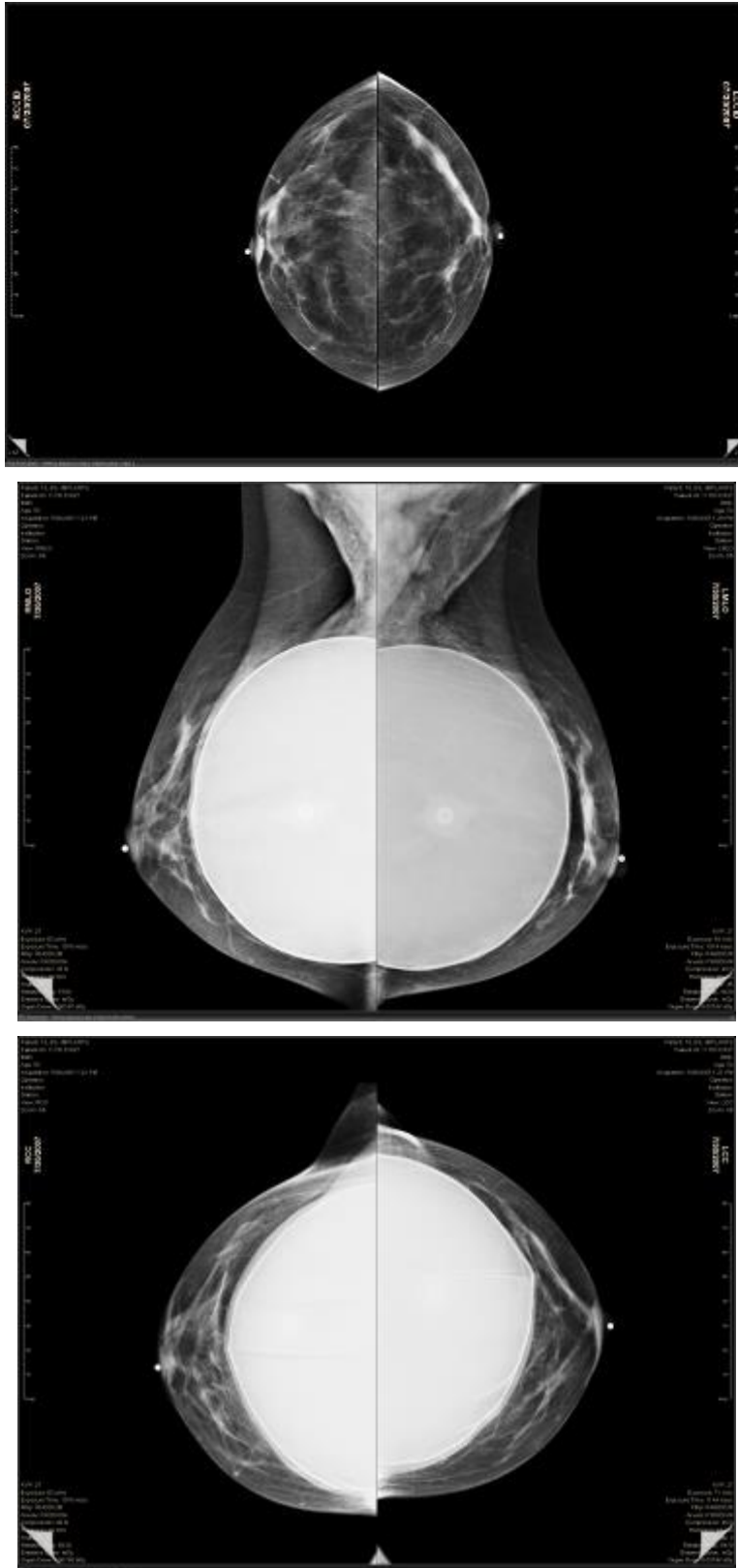




Or when the checkbox “Interleave extra views” is not checked on the user configuration, using single click forward button:

- ⇒ 2 ID MLO views
- ⇒ 2 ID CC views
- ⇒ 2 MLO views
- ⇒ 2 CC views





If the “QC list” is checked, the user is prompted to review the current study for any missing images or images of insufficient image quality. A popup dialog can be configured to display a QC dialog as a reminder checklist to the user.

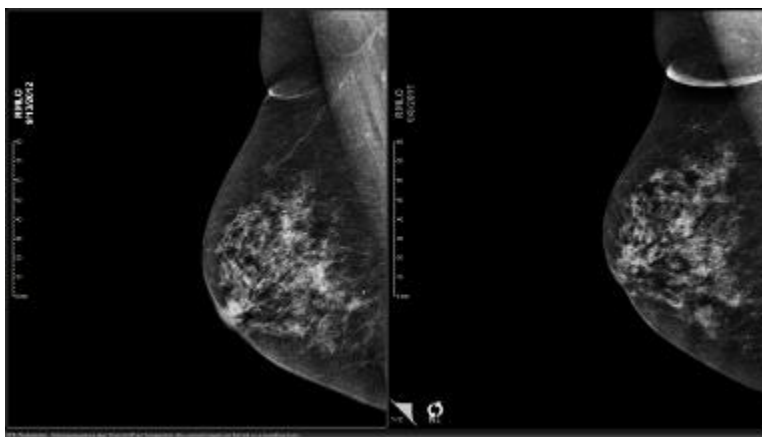
The tools described in Section 6 can be used for adding a finding markup to an image. The single and dual magnifying glass may also be helpful to examine specific areas of an image in more detail.

5.1.3. Current/Prior comparison

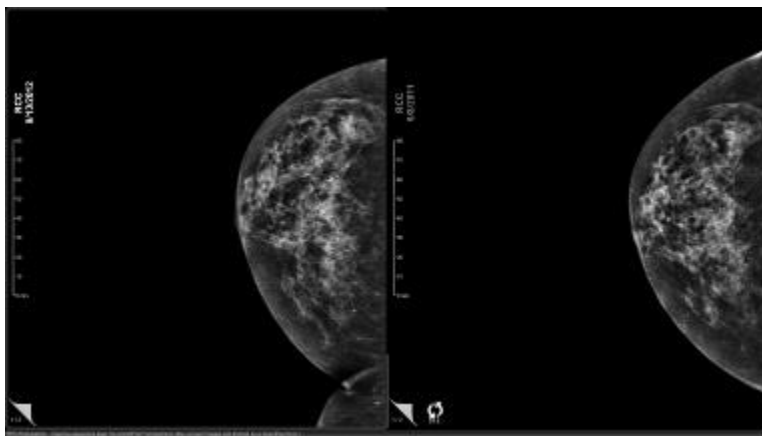
Based on user’s preference, the user can step through comparison of a single current view with a single prior view (i.e., to compare a current RCC view with its prior RCC view on one screen; and then a current RMLO view with its prior RMLO view on next screen), or multiple views on each side of breast (i.e., to compare the RCC and RMLO views with the prior RCC and RMLO views on the same screen).

For example, the user can view side by side the right current and prior MLO views, followed by the right current and prior CC views, then the left current and prior MLO views, and finally the left current and prior CC views, as shown in the following figures:

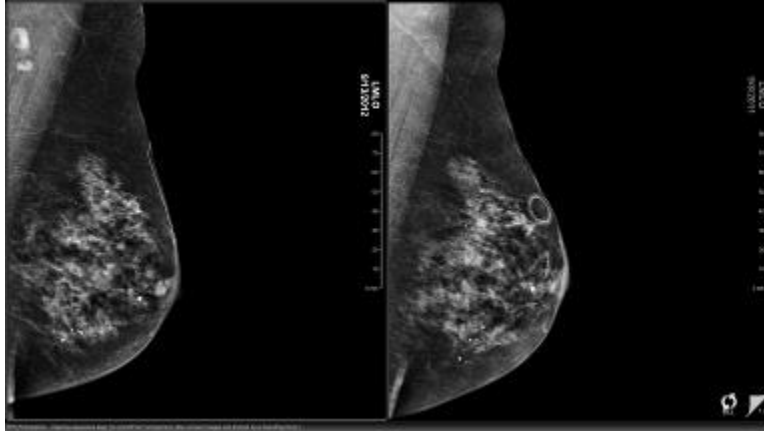
⇒ Current and prior 2 images of right MLO views



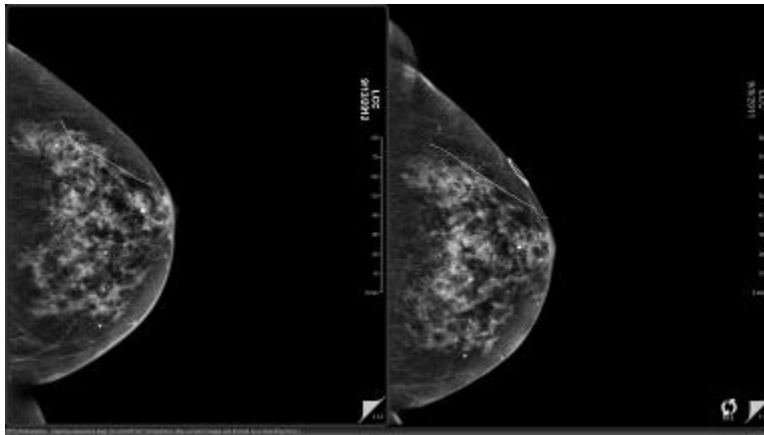
⇒ Current and prior 2 images of right CC views



⇒ Current and prior 2 images of left MLO views

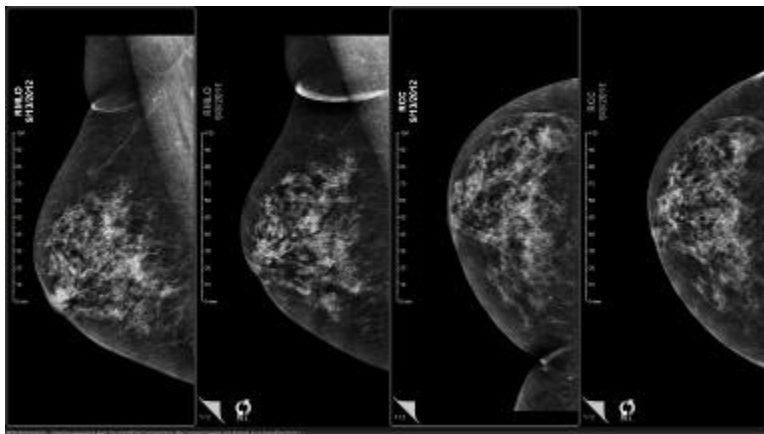


⇒ Current and prior 2 images of left CC views

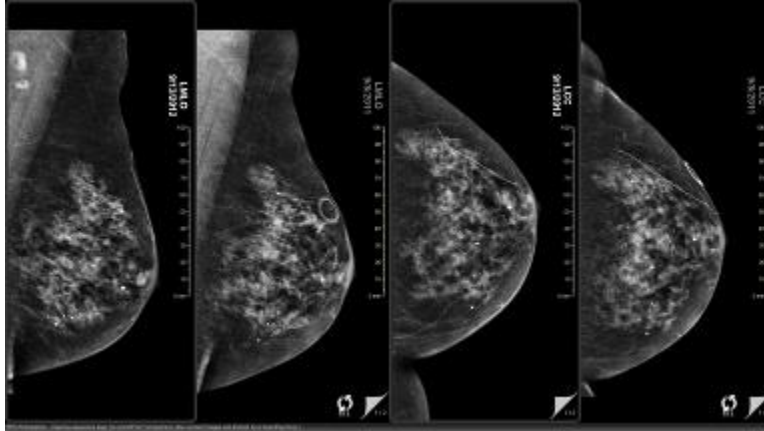


Another example, where the user can view the right current and prior CC and MLO views side by side, followed by the left current and prior CC and MLO views side by side, is shown in the following figures:

⇒ Current and prior 4 images of right MLO and CC views



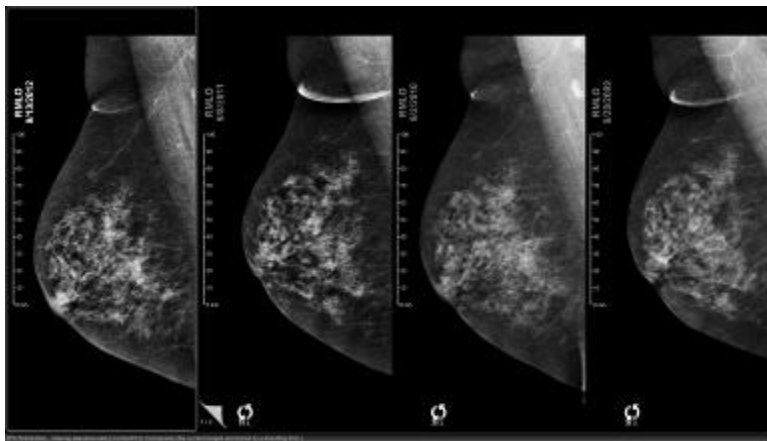
⇒ Current and prior 4 images of left MLO and CC views:



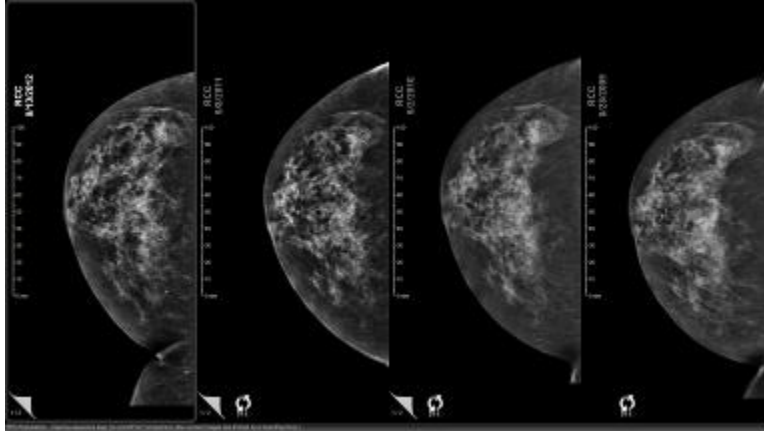
When more than one prior is present, the current view can be displayed with each prior sequentially, using the “more priors” icon or the up and down arrow keys on the keyboard. See section 5.2 for more details.

When the checkbox “Append diagnostic HP” (on the user configuration “View Sequence” panel) is checked, multiple priors for the same view can also be displayed together with the current view in one layout. For example, the user can view side by side the current and 3 prior right MLO views, and then stepping to the next step which shows the current and 3 prior right CC views, then stepping to show the current and 3 prior left MLO views, and finally the current and 3 prior left CC views, as shown in the following figures:

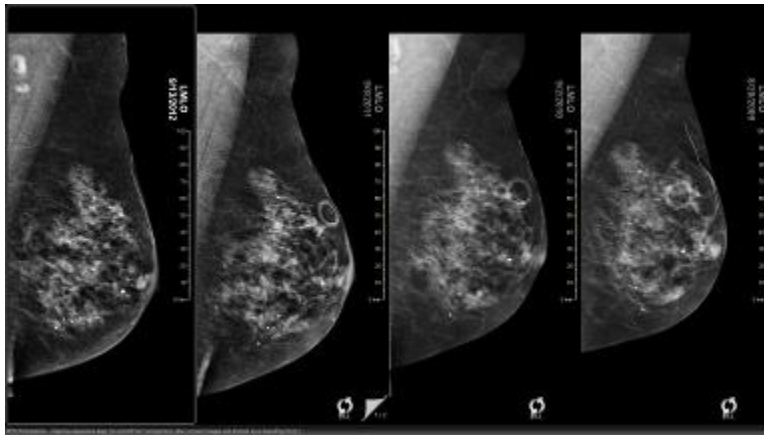
⇒ Current and 3 prior right MLO views:



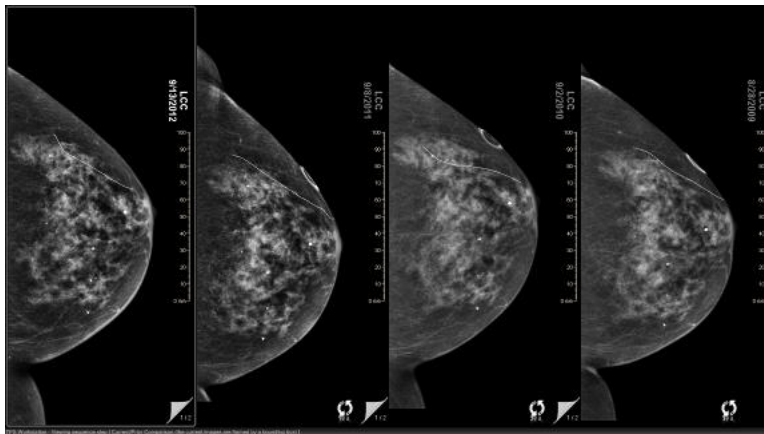
⇒ Current and 3 prior right CC views:



⇒ Current and 3 prior left MLO views:



⇒ Current and 3 prior left CC views:



If the number of priors is more than 3, more prior views can be viewed sequentially using the “more priors” icon or the up and down arrow keys on the keyboard. See section 5.2 for more details.

The tools described in Section 6 can be used for adding a finding markup to an image. The single and dual magnifying glass may also be helpful to examine specific areas of an image in more detail.

5.1.4. Systematic perception viewing

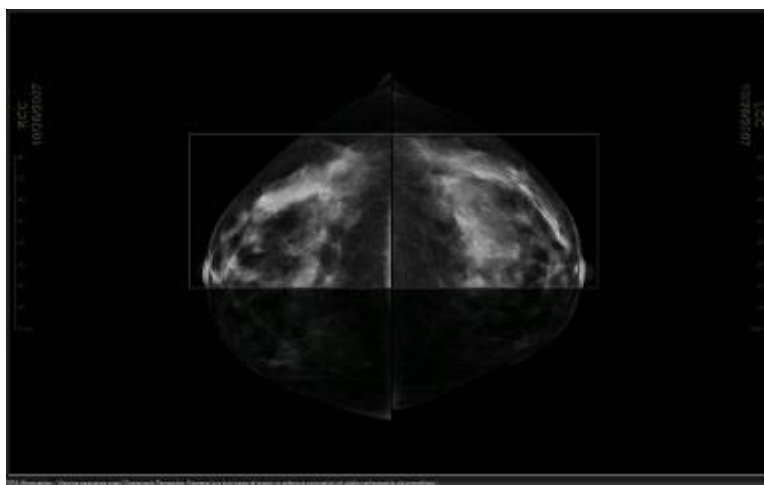
The systematic viewing approach is based on the expert viewing methodology that has been developed for viewing films ([1] and [2]). The idea of the systematic viewing is to use three types of “masks” to enhance perception of subtle radiographic abnormalities: a horizontal mask, a vertical mask, and an oblique mask. The horizontal mask is moved step-by-step, cranial to caudal, either on the bilateral MLO views or the bilateral CC views. The oblique mask is moved away from the pectoral muscle on the bilateral MLO views. The vertical mask is moved away from the chest wall on the bilateral CC views. By use of these masks, special attention can be given to asymmetric densities in regions with a high probability of malignant lesions.

In this viewing step, there are several layout selections for displaying the masks overlaying on images from the current study. For example, using single click forward button, to view the sequence of oblique masks over the MLO views; horizontal masks over the CC views; then vertical masks over the CC views again:

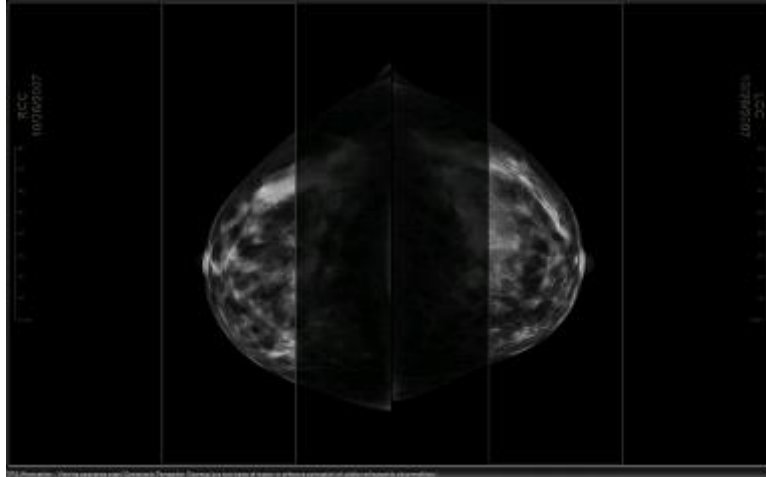
⇒ Oblique systematic viewing masks



⇒ Horizontal systematic viewing mask



⇒ Vertical systematic viewing mask



The mask can be moved by using the **mouse wheel**, the up or down arrows, or by selecting the up and down arrows in the Tabar icon:

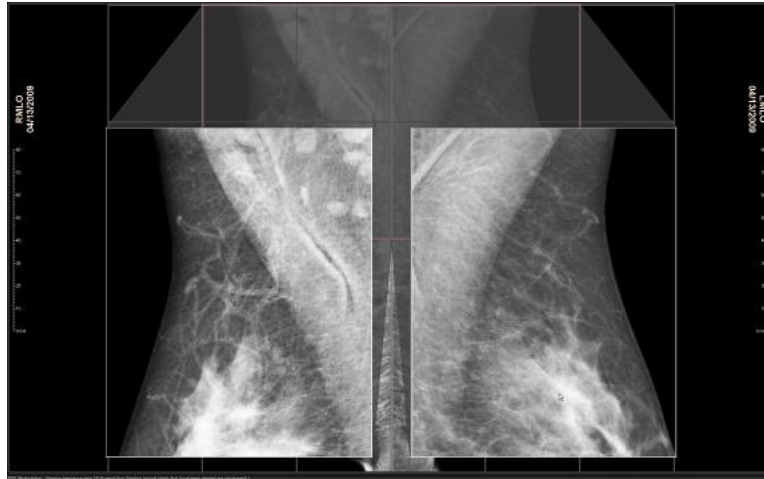


The width of a mask can be adjusted by selecting (using the left mouse button) the bottom or top edge of the mask bounding box and dragging the line. Note that for the oblique mask, the bottom edge of the bounding box can be selected to adjust the width of the mask. Selecting the upper edge of the bounding box and dragging the mouse adjusts the angle of the oblique mask.

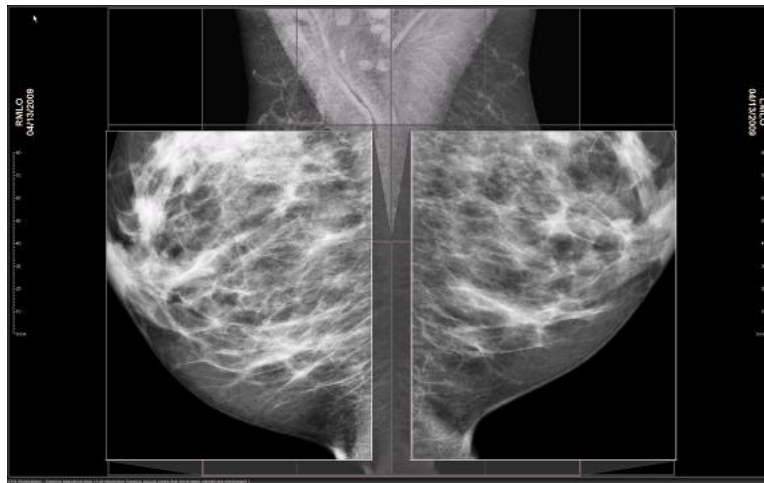
During systematic viewing, the right click drop-down menu can be used to display the magnify glass or the dual magnify glasses to view the details in a user selected area.

5.1.5. All pixels viewing

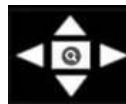
The purpose of the “all pixels” viewing step is to provide the ability to view all the actual pixels in the images (i.e., in full resolution), with optimal reading speed. In this step, a virtual grid is placed over the source images, with the grid also displayed if the configured region is smaller than the viewport size, i.e., the value in the text box for “1:1 ROI Size” is less than 100% (of the viewport size). The user can easily scroll through the boxes of the (virtual) grid (magnified so that each pixel in the underlying image is shown) - see the following example for some MLO views:



Navigating through the grid boxes can be achieved either by scrolling the **mouse wheel** or the up or down arrows, to move to the next set of the grid boxes:



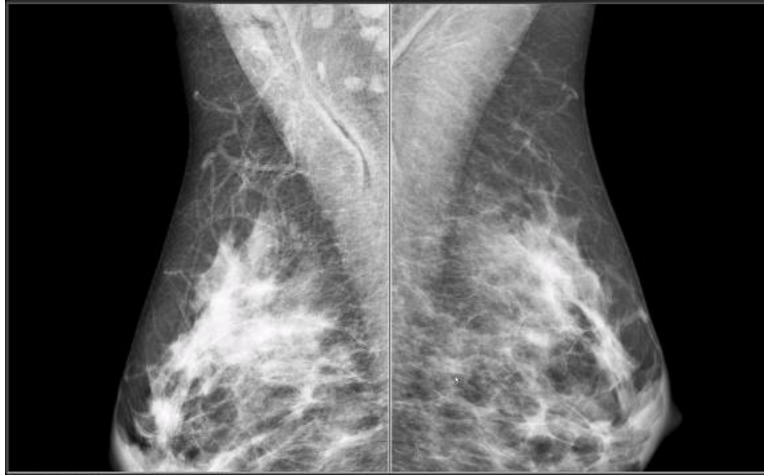
Navigating through the grid boxes can also be achieved using the arrows in the toolbar icon:



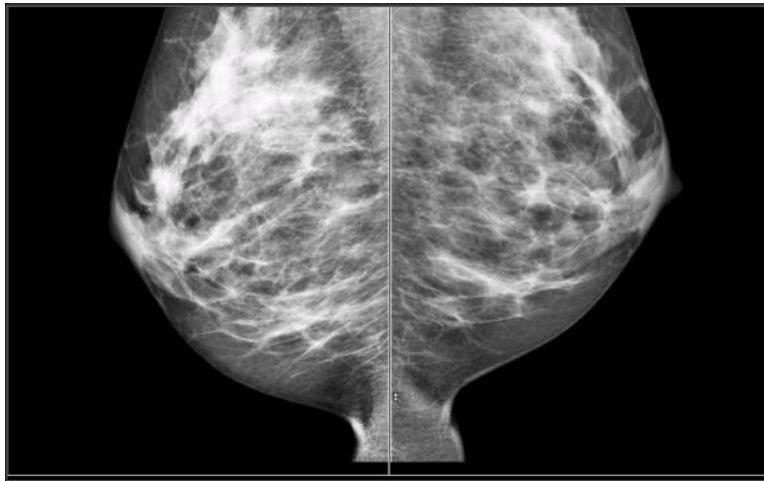
Selecting the magnifying glass in the above toolbar icon (middle button) moves the magnifying glass to the other image on the screen (when not running in dual-roi mode).

Note that the size of each grid box and the size of the magnifying glass can be configured (see section 8.2). The dual magnifying glasses can be configured to enable viewing both the MLO views and both CC views simultaneously. In this mode the left arrow and right arrow on the toolbar icon are disabled as their action is undefined.

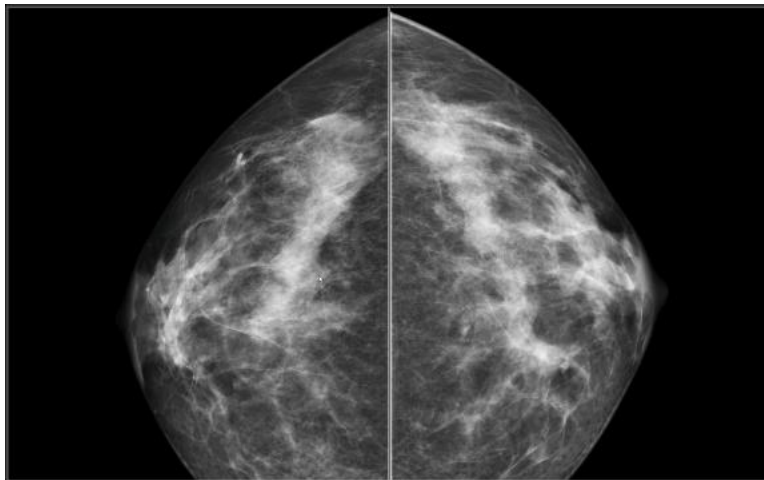
In routine use, the value in the text box for “1:1 ROI Size” on the user configuration should be set to 100%, to take advantage of the full screen area. For example, considering the same study as above, when the value of “1:1 ROI Size” is set to 100%, the grid boxes are hidden and a larger portion of the images in full resolution are displayed. In this case, the bilateral MLO views appear as:



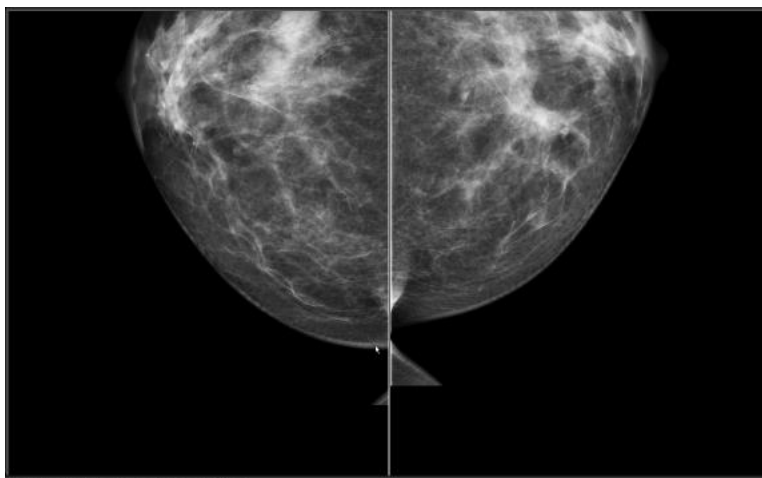
The **mouse wheel**, or the down arrow, can then be used to show the lower portion of the images in full resolution:



Continuing to navigate to the next layout, CC views in this example, results in:



With the next step completing a review of all actual pixels in the images:



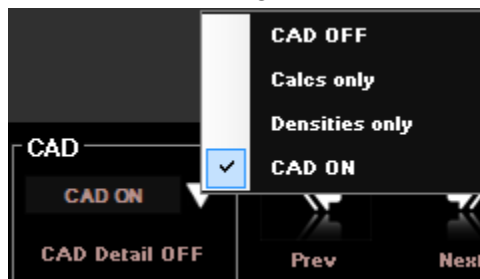
The tools described in section 6 can be used for adding a finding markup to an image.

5.1.6. CAD display, finding interpretation and reports

This step (by default, the last) in the reading protocol, displays a summary of any user markups made during the previous steps. The markup can be removed by the user or retained for subsequent save or export to a PACS.

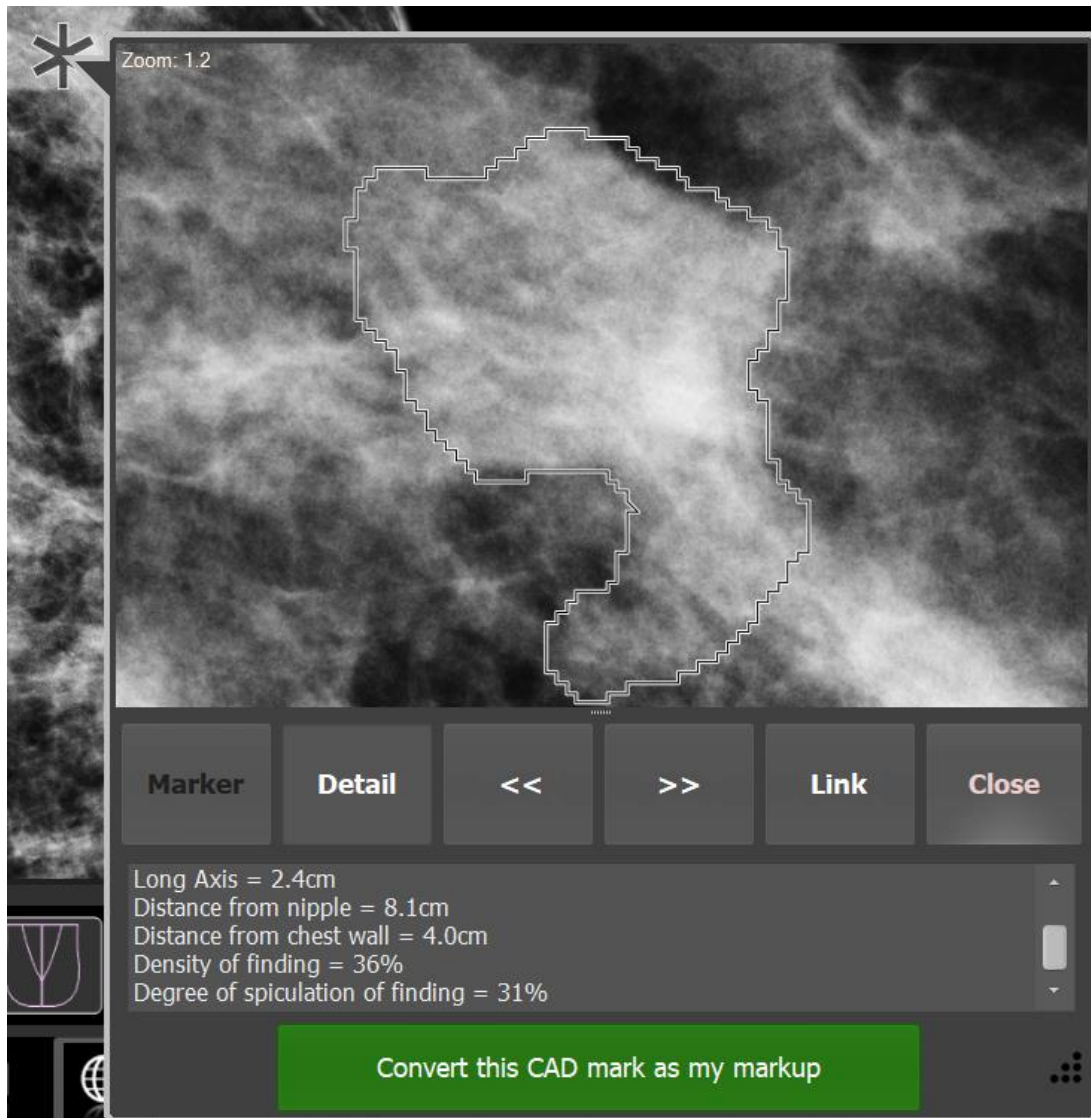
5.1.6.1. CAD SR (Structured Report) display

If available, CAD marks can be toggled on / off by selecting the “CAD ON” or “CAD OFF” button (or short-cut F8 key). If additional details (e.g. outlines) are available in the CAD report, the details can be displayed by clicking the “CAD detail” button:



This button has a drop-down to select display of only the density or calcification markers. Note that additional detail is often not available. There is a site setting (i.e., application setting) that can be configured to hide the “CAD Detail ON/OFF” UI button.

When the CAD SR provides more information about each CAD mark, a dialog can be used to display that information – this is achieved by selecting the “Assess this Markup or CAD mark” menu from right-click drop-down menu, or automatically on clicking a CAD mark, if the “user controls” option “Access CAD on click” is checked. This results in:

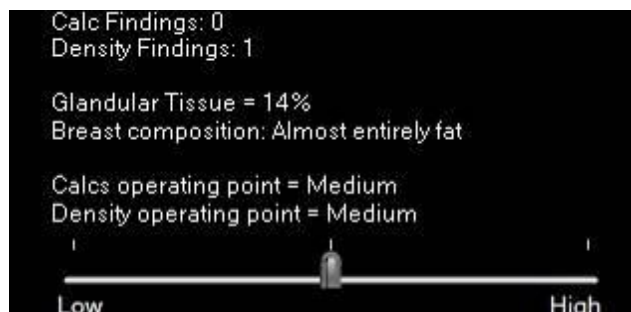


The UI buttons (displayed in the middle of the balloon window shown above) can be used to interact with the CAD marks:

- Marker (short-cut key “M”): toggle the CAD marks on / off in the balloon window.
- Detail (short-cut key “D”): toggle the detailed CAD outline and information on / off in the balloon window.
- << or >> (short-cut left or right arrow keys): move the balloon window to the previous or the next CAD mark.
- Link (short-cut key “L”): move the balloon window to the CAD mark correlated with the current CAD mark to the same finding on the alternative view (e.g., if the current view is RCC, to the mark for the same finding on the RMLO view).
- Close (short-cut key “C”): close the balloon window.

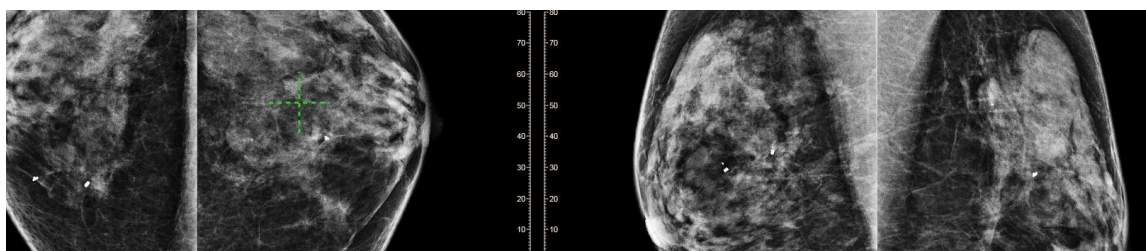
When the CAD SR contains the CAD marks for multiple operating points, the default marks are displayed at the recommended operating point provided in the SR object and an operating point track-bar is displayed below the CAD summary area on each viewport

(this can be disabled by the user setting “CAD Multiple operating point” – see 8.2). The operating point can be changed by dragging the tick on the track bar:

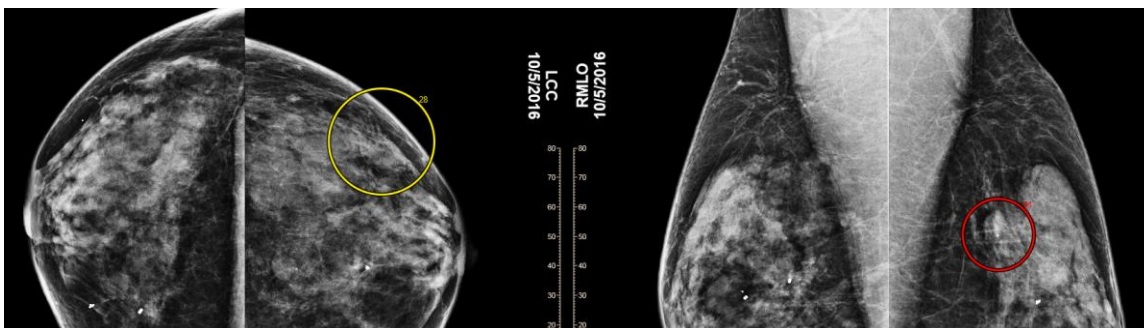


Note that the density mass and calcification marks may be provided at different recommended operating points. The UI track bar in each viewport for handling multiple operating points includes N number of points. The N number is calculated by taking the maximum number of operating points among the mass and calcification marks plus the difference of the recommended operating point between mass and calcification marks. The UI change of an operating point is synchronized to keep the difference of the recommended operating point constant.

Some CAD reports (e.g., from ScreenPoint) contain “decision support” findings (in addition to conventional marks as discussed above). Such decision support findings are displayed only on demand. This behavior can be used implicitly when there is no tool selected (left mouse action reset) or explicitly, by selecting the “Decision Support” cursor mode from the menu (or short-cut key Ctrl+Shift+D). In implicit mode, holding the left-mouse button down and dragging over an image with such a report causes the system to dynamically display information, whereas in explicit mode each click results in the display of that information. If the image contains decision support information, a dashed cross (green on a color display) is displayed to indicate that there is such information, but the mouse is not at a point of interest:



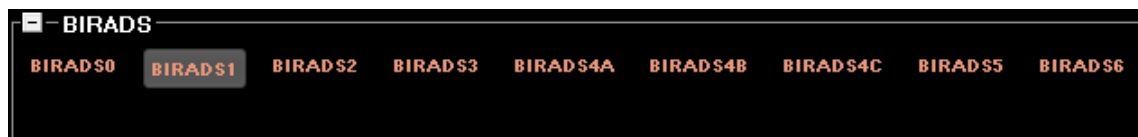
If the cursor hits within an area that has decision support, then the region at that point is displayed, along with any corresponding suspicion that this region references. Each region is displayed with its associated confidence score, and with a color that is conveyed in the CAD report for that decision support finding:



CAD mechanisms can also pertain to 3D (tomo) studies. For example, CAD reports from iCAD's PowerLook Tomo, iCAD's Profound AI, and ScreenPoint Transpara 3D products include marks within the 3D volume and can be displayed as conventional CAD on tomo frames and used as navigation aids. Additionally, ScreenPoint has a model where decision support marks on 2D images (e.g., synthesized 2D) can be used to highlight (including navigate) to corresponding regions in the 3D stack. GE has a similar mechanism called "enhanced v-preview" which can be used to navigate within a tomo stack from the synthetic 2D (although in this case the CAD information driving the implementation is not exposed). Hologic's equivalent is called "smart mapping" and operates similarly. More information on those models can be found from the relevant vendors. Their use within WorkstationOne is described further in the section on displaying tomosynthesis images (as it also relates to the navigation concepts) – see 5.4.

5.1.6.2. Finding interpretation

In this finding interpretation and report step, a user interface is provided to enter the BIRADS assessment – which is then achieved by clicking one of the following 9 option buttons:

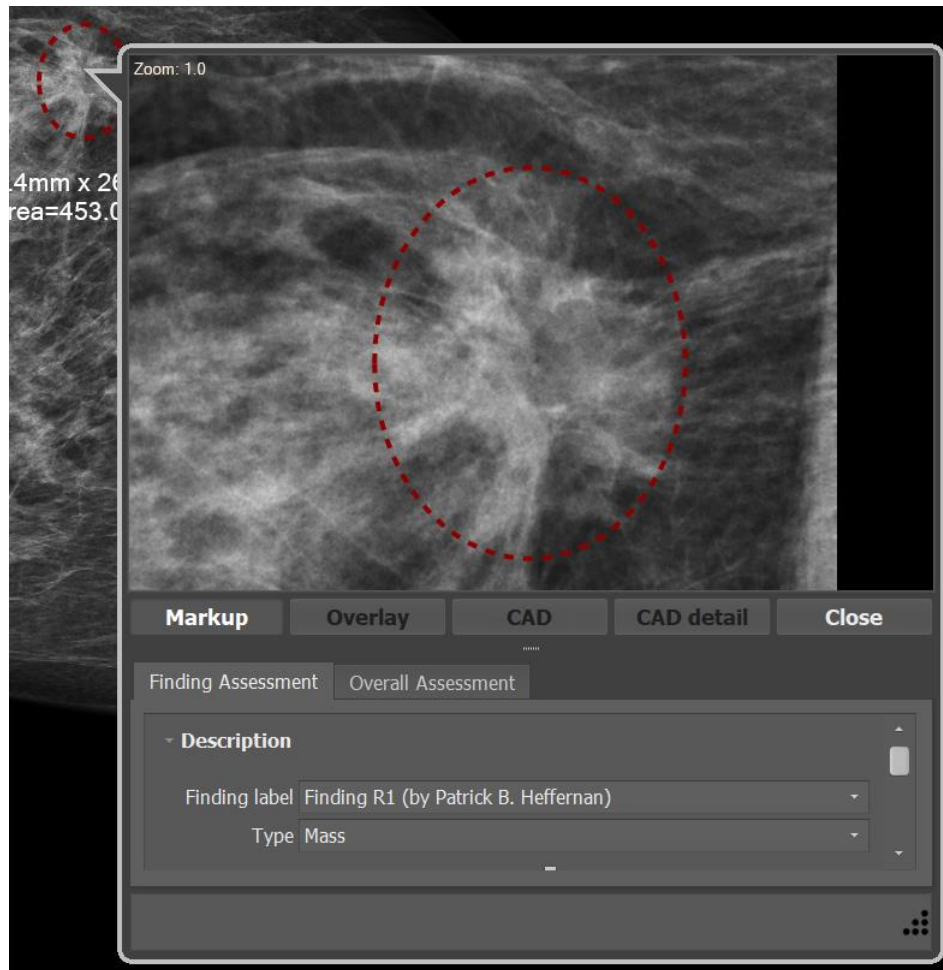


Clicking on the highlighted button will de-select the assessment. In this way, a user interface is provided for the situation where no BIRADS assessment is wanted. This is so that when WorkstationOne is integrated with a RIS or a reporting system, the BIRADS string "Undefined" is sent to that destination.

When any markup results in callback, "BIRADS0" is selected as an initial assessment, otherwise "BRADS1" is the initial value for a negative study.

A right-click of the mouse at any location on an image, and selection of the "Magnify Glass" enables a detailed review of any findings.

A markup can be assessed by selecting the "Assess this Markup or CAD mark" menu from the right-click drop-down menu which results in the display of the assessment form. Alternatively, if the "user controls" option "assessment follow markups" is checked, the assessment form can be displayed automatically after a markup is drawn. The displayed dialog allows the user to edit the lesion finding assessment:



The buttons below the image area perform utility actions – with the first four displayed as toggle states – bright when on, and dark when off. These allow the markup, overlay and CAD (and separately any CAD details) to be turned on/off within the magnified region.

Below these buttons is a splitter, that can be used to change the sizes of the top image area and the lower assessment area. The assessment area is organized with tabs – “Finding Assessment” for information about this specific region, and “Overall Assessment” for case-level results.

The options for each entry are configurable, and the default option values within the “**Finding Assessment**” category are:

Location

(77mm, 121mm)

Clock face: Upper

Depth: Posterior

Location (clock face; depth):

- Clock face options:
 - Upper Outer Quadrant
 - Upper Inner Quadrant

Page 74

- Category 4B: Moderate suspicion for malignancy;
- Category 4C: High suspicion for malignancy;
- Category 5: Highly suggestive of malignancy;
- Category 6: Known biopsy-proven malignancy

Morphology and density features (shape, margin and density):

- Shape options:
 - Round
 - Oval
 - Lobular
 - Irregular
- Margin options:
 - Circumscribed
 - Microlobulated
 - Obscured
 - Indistinct (ill-defined)
 - Spiculated
 - Angular margins
- Density
 - High
 - Equal (isodense)
 - Low, but not fat-containing
 - Fat-containing radiolucent

Calcification features (type and distribution):

- Type options:
 - Amorphous or indistinct calcifications
 - Coarse heterogeneous calcifications
 - Fine pleomorphic calcifications
 - Fine linear or branching calcifications
 - Coarse popcorn-like calcifications
 - Large rod-like calcifications
 - Lucent-centered calcifications
 - Milk of calcium
 - Round calcifications
 - Skin calcifications
 - Vascular calcifications
 - Dystrophic calcification
 - Eggshell calcification
 - Punctate calcification
 - Calcified suture material
 - Heterogeneous calcification
 - Macrocalcifications
- Distribution options:
 - Clustered or grouped
 - Diffuse or scattered
 - Linear
 - Regional
 - Segmental
 - Calcifications within a mass
 - Calcifications outside of a mass

▼ Recall procedure

Other Procedure - Ultrasound ▼

Recall procedure (for this specific finding):

- None
- Diagnostic Mammography - MLO
- Diagnostic Mammography - CC
- Diagnostic Mammography - XCC
- Diagnostic Mammography - ML 90
- Diagnostic Mammography - Mags
- Diagnostic Mammography - Spot compression
- Diagnostic Mammography - Rolled
- Diagnostic Mammography - Fronts
- Diagnostic Mammography - Nipple in profile
- Diagnostic Mammography - Step obliques
- Diagnostic Mammography - Other
- Other Procedure - CBE
- Other Procedure - Ultrasound
- Other Procedure – MRI
- Other Procedure - Biopsy (US-guided)
- Other Procedure - Biopsy (Stereo-guided)
- Other Procedure - Biopsy (MRI-guided)
- Other Procedure - Surgical eval
- Other Procedure - Other 1
- Other Procedure - Other 2

The default option values for “**Overall Assessment**” are:

Overall Assessment ^

Indication for exam: Screening exam with no presenting symptoms ▼

Breast composition: b: There are scattered areas of fibroglandular density ▼

Overall impression: Category 0: Incomplete - need additional imaging evaluation and/or p... ▼

Options for breast composition (*Breast Density*):

- The breasts are almost entirely fatty
- There are scattered areas of fibroglandular density
- The breasts are heterogeneously dense, which may obscure small masses
- The breasts are extremely dense, which lowers the sensitivity of mammography
- Undefined

Options for overall impression (*BIRADS*):

- Category 0: Incomplete - need additional imaging evaluation and/or prior mammograms for comparison;
- Category 1: Negative;
- Category 2: Benign;
- Category 3: Probably benign;
- Category 4A: Low suspicion for malignancy;
- Category 4B: Moderate suspicion for malignancy;
- Category 4C: High suspicion for malignancy;
- Category 5: Highly suggestive of malignancy;

- Category 6: Known biopsy-proven malignancy
- Undefined

The BIRADS assessment can also be entered directly using the user interface displayed within the Report step.

Other tracked information

In addition to the items described above, which are exposed on the UI, the system internally tracks other items that are recorded internally and can be exported in various formats.

The “recall procedure” for the case is generated from the union of the procedures for each finding.

The side to be followed-up is based on the individual findings, and is one of:

- L
- R
- B

The system also uses the “type” from each finding to determine an overall abnormality for the case, so that *Abnormality* can be one or more of the following:

- Mass
- Calcification
- Architectural distortion
- Asymmetry
- Lymph node
- Other

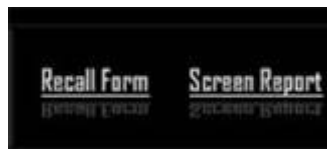
The system also tracks *RepeatViews* which is not exposed on this UI, but it can be one of the following:

- LCC
- LMLO
- RCC
- RMLO

5.1.6.3. Recall form

Note: This mechanism is still supported but will be removed in a future release. The “Reporting” plugin (see 7.9) supersedes this going forward.

A recall report or screening report can be generated using the “Recall Form” button or “Screen Report” button, which results in the display of a recall summary report or screening diagnostic report:



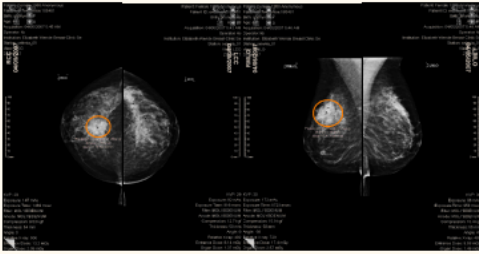
These two buttons can be hidden if not used, as a site setting.

The recall form allows the user to identify certain summary findings, and the recommended recall imaging procedure and reason, if applicable.

Internal Recall Form (ewbcwise:185481) 09/30/2010

Patient: [REDACTED] Accession #: 0001062576
 Patient ID: ewbcwise:185481 DOB: anonymous Age: 46
 Radiologist: [REDACTED] Referring Dr.: [REDACTED]

Abnormalities

<u>Side</u> ☒ Right ☐ Left ☐ Both <u>View</u> ☒ RMLD ☒ RCC ☐ LMLD ☐ LCC		<u>Type</u> ☐ Mass ☐ Calcs ☒ Architect ☐ Asym. D ☐ Lymph N ☐ Other
--	--	--

Recall Patient Requirements and Time Estimation

Diagnostic Mammography

☐ MLO	☐ ML 90	☐ Rolled	☐ Nipple in profile
☐ CC	☒ Mags	☐ Fronts	☐ Step obliques
☐ XCC	☒ Spot compression	☐ Other-0	

Imaging / Procedures

☐ CBE	☐ Biopsy (US-guided)	☐ Surgical eval
☒ Ultrasound	☐ Biopsy (Stereo-guided)	☐ Other-1
☐ MRI	☐ Biopsy (MRI-guided)	☐ Other-2

☐ 15 Minutes
 ☐ 30 Minutes
 ☐ 45 Minutes
 ☐ 60 Minutes

☐ Screening recall
 ☐ Technical recall
 ☐ Supplemental views

Radiologist Notes:

The checkboxes for “Side” and “View” information on the form are automatically checked using the user finding (i.e., user markups) information. However, when *Screening recall* or *Technical recall* checkbox is checked by the user, the “View” checkboxes (RMLD, RCC, LMLD and LCC) are enabled for the user to provide the repeat screening mammograms. When *Supplemental views* checkbox is checked by the user, the “Side” checkboxes (Right, Left and Both) are enabled for the user to provide the laterality information of recall diagnostic mammograms.

Note that the “Side” and “View” checkboxes are only enabled for those sides and views that do not have any user markups. The view names of the mammograms on the UI are limited to the standard four views. However, more information, such as, the names of the extra views, can be provided free-style in the “Radiologist Notes” text box.

The report can be printed to any networked printer, saved locally on the workstation, email, sent to RIS, or sent to PACS as a DICOM SC (secondary capture) format. The saved report can be viewed after the study is reopened.

Some of the entries on the form can be modified or the initial value can be defined by each user. Those entries are high-lighted in a gray background color when in edit mode, which is enabled by clicking the button “Edit Template” at the lower-left corner:

Internal Recall Form {Patient ID}

Patient: ██████████
Patient ID: 1115165003
Institution: TPS WS1
Radiologist: ██████████

Accession #: 0100914927
DOB: ██████████ Age: 44
Referring Dr: ██████████
3/22/2015

Abnormalities

Side

☐ Right
☐ Left
☐ Both

View

☐ RMLLO
☐ RCC
☐ LMLLO
☐ LCC

Type

☐ Mass
☐ Calcs
☒ Architect
☐ Asym. D
☐ Lymph N
☐ Other

Recall Patient Requirements and Time Estimation

Diagnostic Mammography

☐ MLO
☐ CC
☐ XCC

☐ ML 90
☒ Mags
☒ Spot compression

☐ Rolled
☐ Fronts
☐ Nipple in profile
☐ Step obliques
☐ Other-0

Imaging / Procedures

☐ CBE
☒ Ultrasound
☐ MRI

☐ Biopsy (US-guided)
☐ Biopsy (Stereo-guided)
☐ Biopsy (MRI-guided)

☐ Surgical eval
☐ Other-1
☐ Other-2

☐ 15 Minutes
☐ 30 Minutes
☐ 45 Minutes
☐ 60 Minutes

☐ Screening recall
☐ Technical recall
☐ Supplemental views

Radiologist Notes:

Finish Edit

Print & Close

Save & Close

Send & Close

Cancel

The title of the form can be formatted to include the following contents, where the “{}” surround replaceable elements:

- patient name: {Patient}
- accession number: {Accession #}
- patient ID: {Patient ID}
- patient date of birth: {DOB}
- patient age at exam: {Age}
- radiologist name: {Radiologist}
- referring physician name: {Referring Dr.}

The recall procedure strings “Other-0”, “Other-1” and “Other-2” can be replaced by user defined strings. The initial check state of finding type and recall procedure checkboxes can be defined by simply checking or un-checking the corresponding checkbox while in editing mode.

Click the button “Finish Edit” at the lower-left corner to complete the modification. The changes then are saved for this user.

Copyright © Three Palm Software 2007-2021

Page 79

5.1.6.4. Screening report form

Note: This mechanism is still supported but will be removed in a future release. The “Reporting” plugin (see 7.9) supersedes this going forward.

The screening report can be produced in a similar fashion as the recall form, for example:

Ontario Breast Screening Program Screening Report

Patient: [redacted] Accession #: 000000570
 Patient ID: ewbcwise:185481 DOB: anonymous Age: 40
 Institution: Elizabeth Wende Breast Clinic Referring Dr.: [redacted]
 Radiologist: Heidi D. Zhang 09/30/2010

Compared to prior mammograms: Yes ☐ No ☒

Indication for exam: Screening exam with no presenting symptoms

Breast composition (density): The breast is almost entirely fat (<25% glandular)

Overall impression: Category 0 - need additional imaging evaluation

Findings

R L

Mass ☐ ☐

Calcification ☐ ☐

Arch. Distortion ☒ ☐

Asym. Density ☐ ☐

Other ☐ ☐

finding size (cm) 3.8

Radiologist Results

R L Radiologist Notes:

Normal/Benign ☐ ☒

Needs Additional Evaluation ☒ ☐

Special Views ☐ ☐

Breast Ultrasound ☐ ☐

Surgical Consultation ☐ ☐

Breast MRI ☐ ☐

Other ☐ ☐

OBSP to recall client in 1 year ☐

Edit Template Print & Close Save & Close Send & Close Cancel

Like the recall form, when in edit mode, the title of the screening report can be formatted to include the following contents, where the “{}” surround replaceable elements:

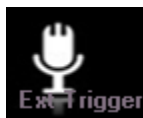
- patient name: {Patient}
- accession number: {Accession #}
- patient ID: {Patient ID}
- patient date of birth: {DOB}
- patient age at exam: {Age}
- institution name: {Institution}
- radiologist name: {Radiologist}
- referring physician name: {Referring Dr.}

The radiologist result strings can be replaced by user defined strings. The initial check state of each result checkbox can be defined by simply checking or un-checking the corresponding checkbox while in editing mode.

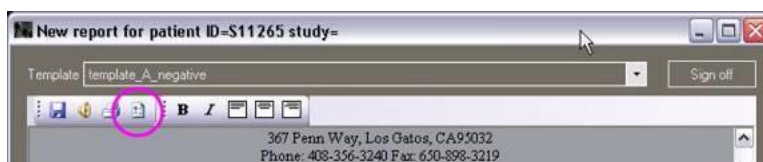
5.1.6.5. Simple report and patient letter

Note: This mechanism is still supported but will be removed in a future release. The “Reporting” plugin (see 7.9) supersedes this going forward.

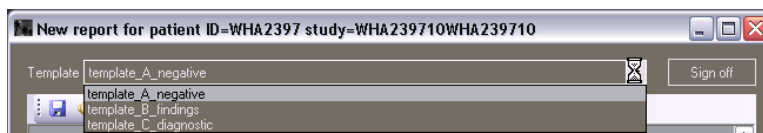
If the “Simple Report Generator” is installed, and the “Dictation trigger” is configured to use that mechanism, clicking on the dictation trigger icon on the navigation monitor:



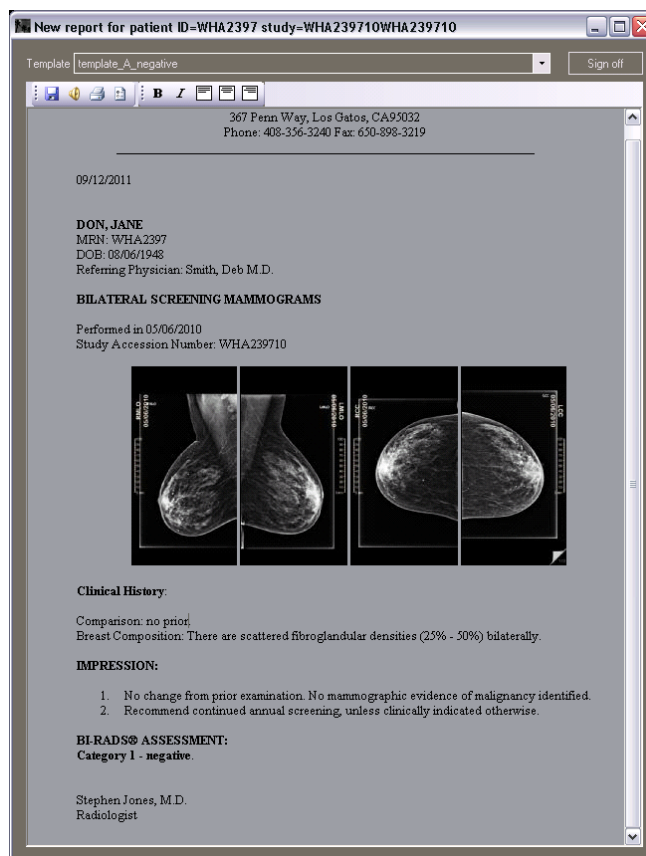
(or a user configured short-cut key, such as Alt+D) allows a simple report to be dictated or a patient letter to be generated. Three default templates are provided as part of the “Simple Report Generator” installation option: a negative report (template_A_negative), a finding report (template_B_findings), and a diagnostic report (template_C_diagnostic). Any number of custom templates can be added on the “Simple Report Generator” UI using the “User options” icon:



A template can be selected using the template drop-down menu:



The following is an example of the default negative report:



Even though much of the information that is automatically inserted into the report is captured during the reading, the report should be carefully edited to ensure its accuracy. Editing can be achieved either by direct typing or voice recognition (which needs to be configured separately).

When the user clicks on the button “Sign off”, the report is saved and can later be viewed again within WorkstationOne using the plugin “Simple Report”, which shows as a highlighted folder when there are simple reports for the current patient. The reports can also be printed at that time.

5.1.6.6. Generation of a DICOM breast imaging report (SR)

Note: This mechanism is still supported but may be removed in a future release. The “Reporting” plugin (see 7.9) contains some of this functionality and will be enhanced in future to replace this.

The user configuration (Connectivity tab – see section 8.6) allows the user to configure generation of a DICOM SR (following the “Breast Imaging Report” template). Once so configured, a report is automatically generated on completion of the review of each case, based on information entered during the review. The report can be reviewed and manually edited prior to saving – this is achieved using the “Review” button (described in the following section on completing the review). When the Review button is clicked, a pre-view of the populated report is displayed:

Preview of Mammography Report for EWBCH02 ID=ewbcwise:158643

Procedure reported

Reason for procedure
 Screening exam with no presenting symptoms
Reset
Clear

Breast composition
 There are scattered areas of fibroglandular density
Reset
Clear

Comparison to previous exams
 Prior Accession Number: 0000978724 Study ID: 01 Performed on: 8/8/2006
Reset
Clear

Findings
 On the right breast, in the CC view:
 Label: Finding R1, Shape: Ellipse at the Upper Outer Quadrant;Middle
 Size=14x10mm Diameter=12mm Area=116mm²
 Type: Mass
 Assessment: Category 0: Incomplete - need additional imaging evaluation and/or prior mammograms for comparison
 Suspicion: 0%
Reset
Clear

Impressions
 Category 0: Incomplete - need additional imaging evaluation and/or prior mammograms for comparison
Reset
Clear

Overall Assessment
 Need additional imaging evaluation.
Reset
Clear

Accept
☒ Complete ☐ Verified
Cancel

Each of the sections of the report is shown with a title (which is fixed, based on the DICOM template), and each section is pre-populated based on information from the review. The sections can be collapsed and expanded using the “⤴” symbol at the right side of each section title. Common DICOM header information is not shown but is automatically included when the report is saved.

Within each section, the current text is displayed, and is manually editable. The “reset” button for each section reverts the text of that section to the default (so is a way to undo any edits), and the “Clear” button resets the section to empty, and it can then be further edited. If a section is left as empty, it is not included in the generated report. The “Accept” button causes all changes to be used for saving the report, whereas “Cancel” ignores all changes. The “Complete” and “Verified” check options fill-in options of the DICOM structured report, and then may be of use for later processing on other systems or displayed on a viewer.

The structured report is saved once the “Yes” option is selected on the closing dialog. A saved report can be viewed in the “SR” plugin (see 7.8) – either immediately when the

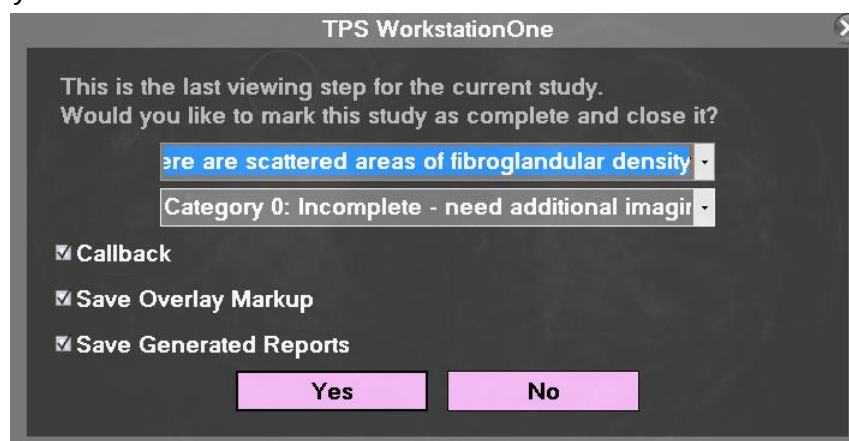
case is re-opened, or in subsequent years when that report is brought back from a PACS to the system with the priors for comparison with the new study at that time.

5.1.7. Completing the review of a study

Once the review of a study is complete, the user can navigate to the next study by selecting the forward icon:

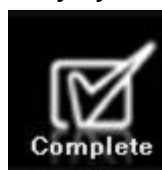


The user is then prompted to indicate whether the review of the study is complete (as part of this prompt, when it is configured, the user is warned it they have not viewed every image in the case). The user can also optionally indicate if a callback is warranted; if the markup is saved or to be sent to PACS as DICOM GSPS graphic annotations (or secondary capture); and if the recall/screening report in xml format is saved or sent to a Reporting System (such as PenRad or MRS). If the “Callback” box is checked, the worklist status will then indicate that a callback has been specified for this patient study.

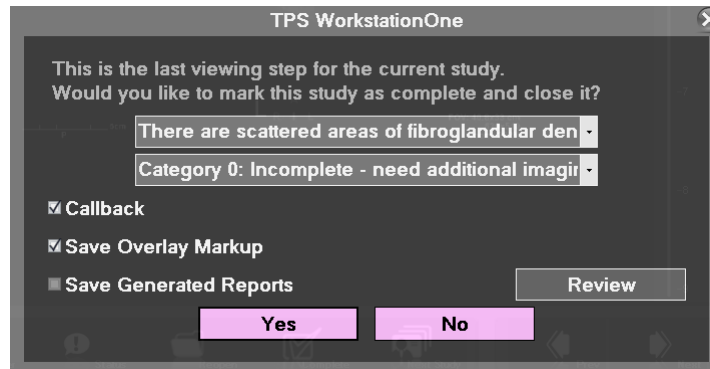


When the workstation is configured to integrate with a RIS or similar system, the interpretation result can be automatically sent to that system. On the completion dialog, two pieces of the report (the breast density and BIRADS result) can be reviewed and edited by the user. More details of the information to be sent can be reviewed by clicking the “Review” button – which results in the display of the “structured report” editor (see 5.1.6.6) if that mechanism is configured, or if a dictation trigger is configured, then that editor tool is used (if neither are available, the “Review” button is disabled). However, the “Review” button and the breast density and BI-RADS selectors can be configured to not be shown (a site setting).

The user can also explicitly mark the current study status as “complete” and close all contents that are associated with this study by clicking the complete icon:



When the worklist is used to open another study, the currently open study can be closed while maintaining its status as “reading”. If save or send markup is configured and if markup has been made, before the study is closed, a dialog prompts the user to save or send the markup as DICOM GSPS graphic annotations:



In the completion dialog, click the “Yes” button to ensure that the markup is saved or sent, or the “No” button to discard the markup.

Instead of explicitly clicking the "No" button, the following mechanisms can be used to implicitly answer "No" and close the dialog:

- Left arrow key on the keyboard.
- Moving mouse wheel backwards when mouse wheel stepping is configured.
- The letter 'N'.

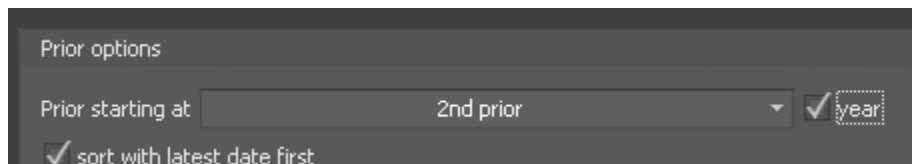
Similarly, when the user setting "implicit Yes by -> or wheel" is checked on the "Workflow" tab, the following mechanisms can be used to implicitly answer "Yes" and close the dialog:

- Right arrow key on the keyboard.
- Moving mouse wheel forwards when mouse wheel stepping is configured.

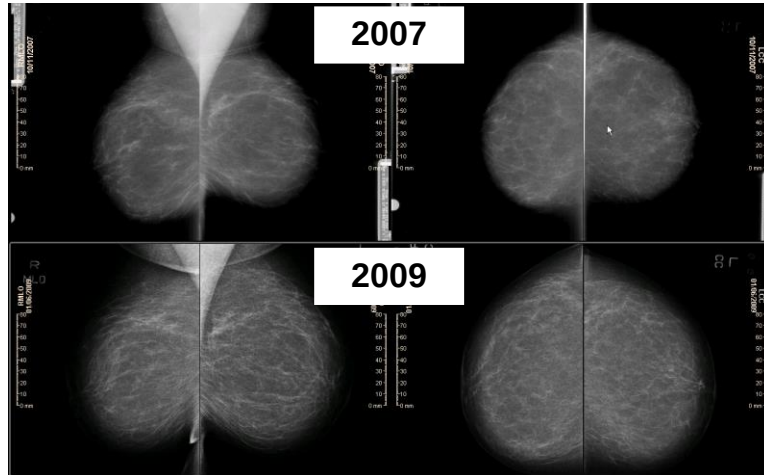
The letter 'Y' can also be used.

5.2. Viewing screening studies with multiple priors

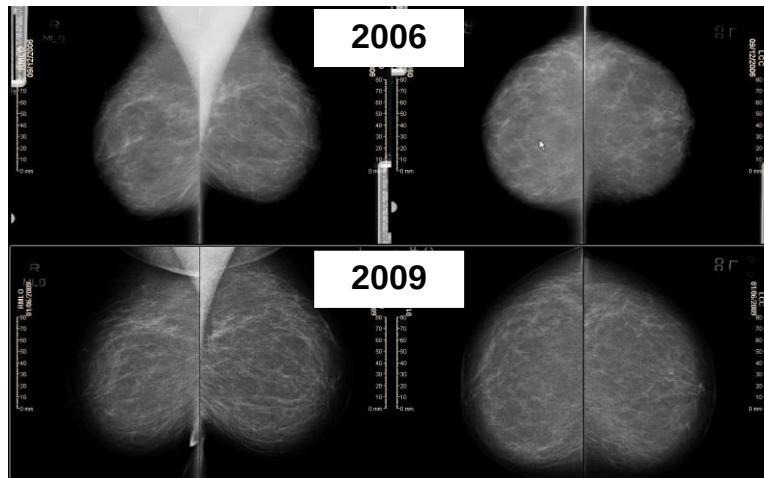
If multiple prior studies are available for viewing, they can be viewed sequentially in the protocol. For example, in the “Overview” step, the first screen shows the current study together with the prior study that is configured on the user configuration (see 8.1), such as, the second (by year) most recent prior study:



For example:



The next screen shows the current study and the next most recent prior study:



When configured (uncheck “force stepping through priors” in the “Prior options” section of the workflow tab in the user configuration), the step forward icon only shows the first prior study and other prior studies can be navigated using the circular loop icon, or **the up-arrow key or down arrow key**:



The same workflow approach is provided in the “Compare” step. For each of the layout screens in the Compare step, the current image(s) is compared to the first prior study that is configured on the user configuration, followed by the current image(s) compared to the next most recent prior image(s), etc.

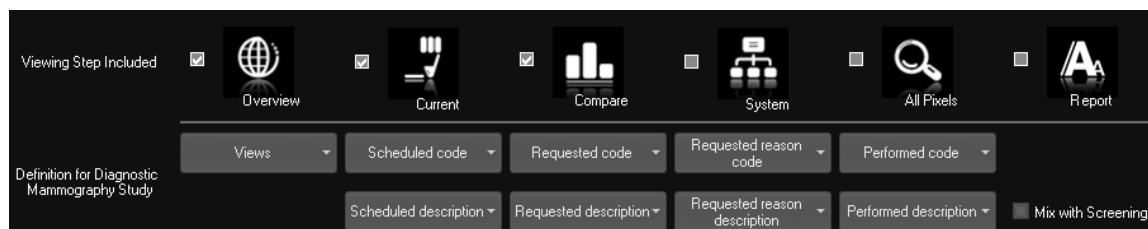
The **down arrow key** navigates to the next prior study and stops at the last prior study. The **up-arrow key** navigates to the previous prior study and stops at the first prior study.

The “sticky” checkbox in the prior settings determines which prior is first shown when stepping (e.g., through comparisons). The default (unchecked) is to always show the configured prior first, but when the sticky option is checked, the prior study for the next step is whatever prior the user last viewed (so for example, if the review started at the

second prior year, and then the user navigated to the third year, then for the next step the third year would be used).

5.3. Viewing diagnostic studies

Like the workflow for screening studies, the reading protocol for viewing diagnostic studies can be configured separately to include or skip any of the viewing steps used for screening studies. This is configured on the “Diagnostic HP” tab:



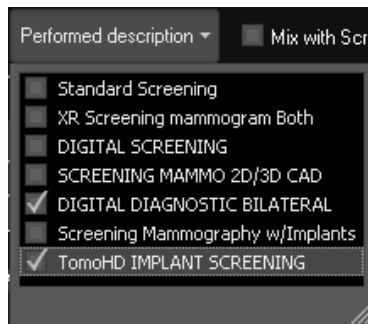
Where the first row defines the steps to be included (checked) in the workflow when a case is considered to be diagnostic. The second row controls whether a case is considered to be diagnostic. The tests specified there are applied to each image in the current study – by default, if all views match the criteria, then the case is considered to be diagnostic. If “Mix with Screening”, then the logic is the reverse – the case is considered to be diagnostic if any view in the current study matches the criteria. There are nine sets of criteria that can be checked for each image – a match of any one marks that image as diagnostic. The criteria are:

- Views: this is the information in the “View code” sequence (54,220) – including the view modifiers.
- Scheduled codes: within the “Request Attributes” sequence (40,275), this is the sequence “Scheduled Protocol Code Sequence” (40,8) – multiple items may be present, and each is checked.
- Requested codes: within the “Request Attributes” sequence (40,275), this is the sequence “Requested Procedure Code Sequence” (32,1064). Only a single item is permitted in this sequence.
- Reason requested codes: within the “Request Attributes” sequence (40,275), this is the sequence “Reason for Requested Procedure Code Sequence” (40,100A) – multiple items may be present, and each is checked.
- Performed codes: this is the sequence “Performed Protocol Code Sequence” (40,260) – multiple items may be present, and each is checked.
- Scheduled description: within the “Request Attributes” sequence (40,275), this is the tag “Scheduled procedure step description” (40,7).
- Requested description: within the “Request Attributes” sequence (40,275), this is the tag “Requested Procedure Description” (32,1060).
- Reason requested description: within the “Request Attributes” sequence (40,275), this is the tag “Reason for the Requested Procedure” (40,1002).
- Performed description: this is the tag “Performed Procedure Step Description” (40,254).

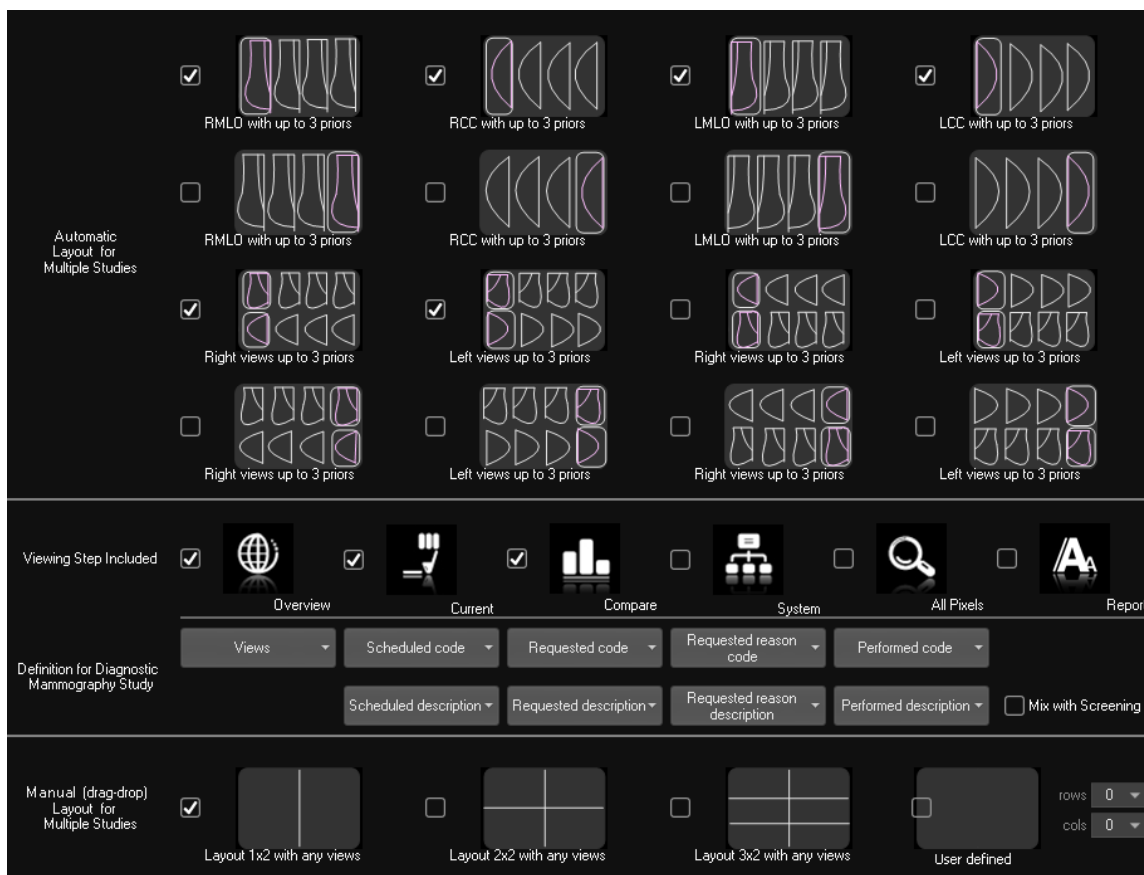
The “Views” button allows selection of any combination of the following:

- Unilateral study
- Magnification view
- Spot compression view
- Cleavage view
- Axillary tail view
- Tangential view
- Rolled views

The contents (list of options) shown in the remaining 8 diagnostic criteria buttons (“Scheduled code”, etc.) are set at the site level – either by internal support, or by the vendor. In most cases the contents of those lists will be based on what is in use at the site (so depends on the configuration of the acquisition devices). There are default values in some of the lists, but they should be changed by the site. The “Requested reason code” by default has a complete list of the reasons defined in the DICOM standard. For each of the diagnostic criteria buttons, selection can be made of any combination of the values shown, for example:



The following figure shows the default diagnostic reading protocol, which includes Overview step, Current step and Compare step.

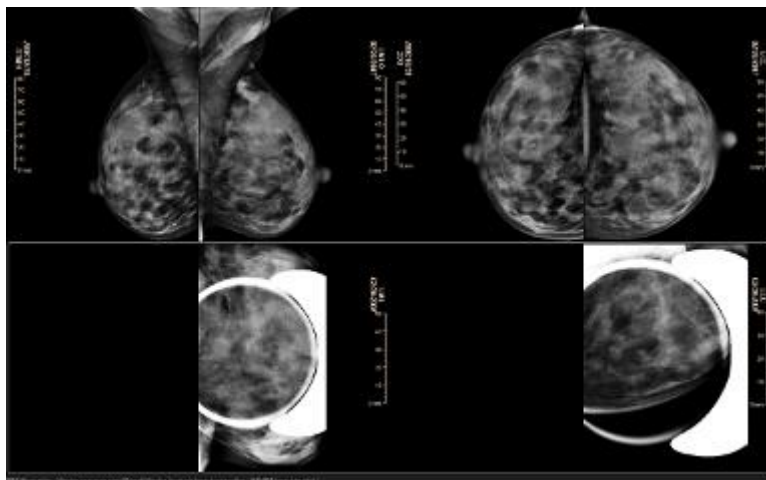


Note that when a diagnostic study is a unilateral study, the hanging protocol of 1x2 MLO-CC layout is used to replace 1x2 bilateral CC or bilateral MLO layouts. Also, note that, instead of using the configured prior order, in the diagnostic workflow the default is to use the **most recent prior study as the first prior for comparison** (this is the option “first prior when current is diagnostic” on the priors drop-down which is shown above in section 5.2). To take advantage of the full size of diagnostic images, the view size is automatically switched to “FIT VIEWPORT”, so a diagnostic image, such as a mag view, can be viewed to fit into the viewport as large as possible.

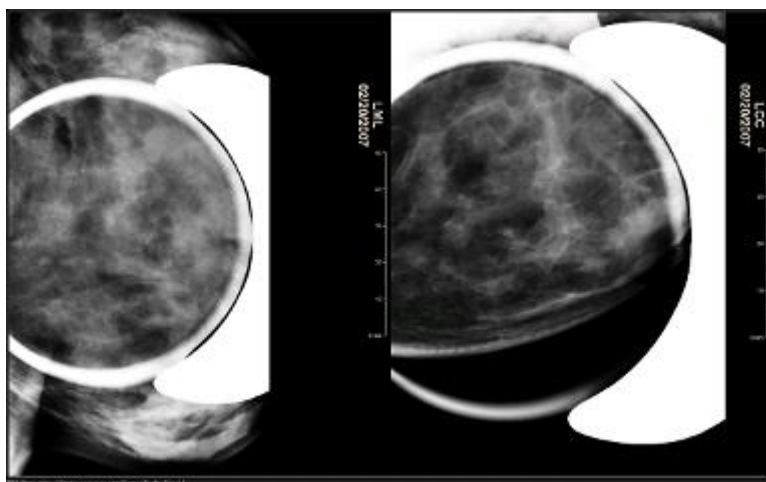
The diagnostic reading protocol is stepped through using the same navigation model as for screening, i.e., forward arrow icon, backward arrow icon and the circular loop icon.

The figures below show an example of the reading protocol for a unilateral study, which contains the following steps:

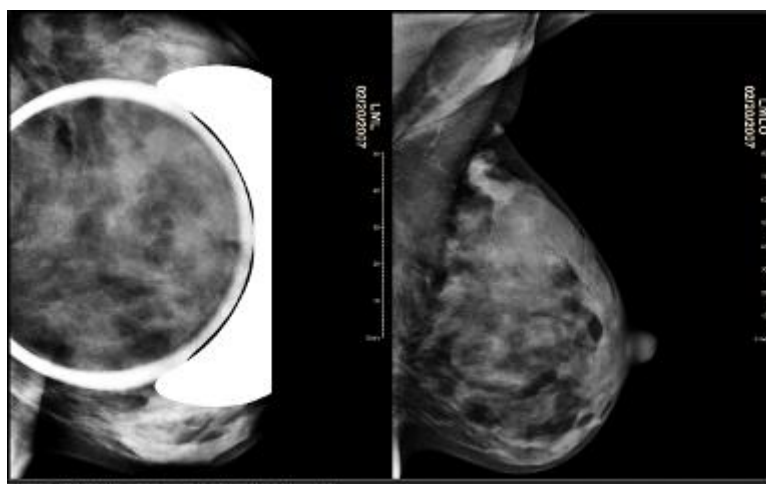
⇒ Overview screen



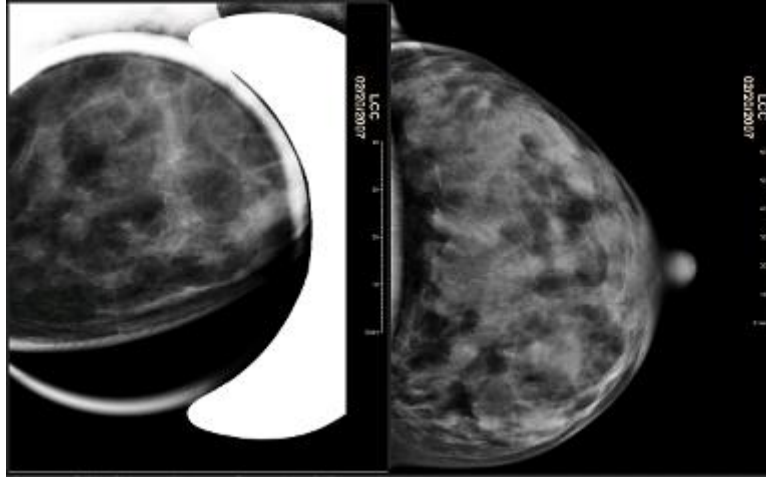
⇒ Current unilateral 1x2 hanging protocol



⇒ Comparison with the most recent prior LMLO view



⇒ Comparison with the most recent prior LCC view

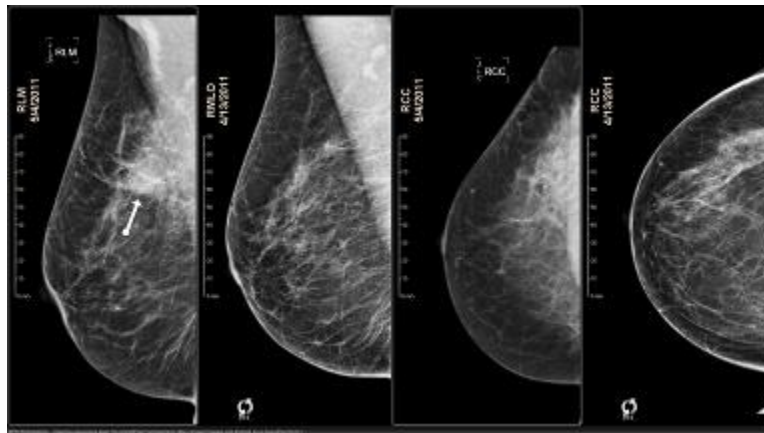


⇒ Complete the study

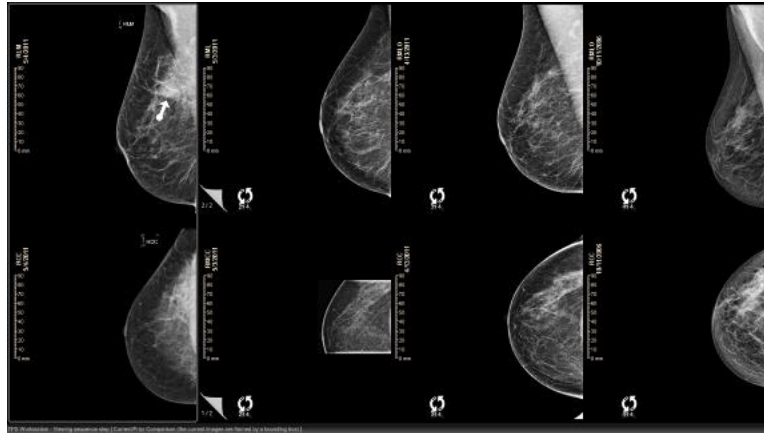
The system also provides 8 diagnostic layouts to automatically arrange up to 4 studies (1 current study plus 3 prior studies) for display at the same time for side-by-side comparison of the changes to a possible abnormality. An additional 12 diagnostic layouts are provided for the user to manually arrange a larger number of studies with up to 24 diagnostic images displayed at the same time.

Use of the diagnostic layouts is integrated within the screening or diagnostic viewing protocol. This means the diagnostic hanging protocols, i.e., layouts, can be accessed any time during the screening viewing sequencing to allow the user close analysis of a possible abnormality. Once the diagnostic analysis task is completed, the system allows the user to return immediately to the viewing step and corresponding hanging protocol of the screening viewing protocol.

For example, at the current and prior comparison step in the screening viewing protocol, a possible abnormality is noticed, and a pointer markup is placed as shown in the following:



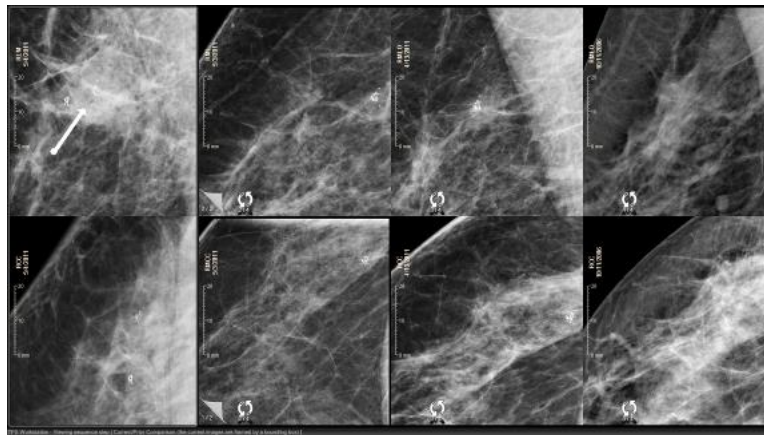
Then the user clicks a diagnostic hanging protocol icon, such as, 2x4 right views, at which point the system automatically arranges prior left views (up to 3 years) together with the current left views, as shown in the following figure:



When more than 3 years of prior studies are available, the circular loop icon, or the down and up arrows key on the keyboard, can be used to display additional older or newer prior images.

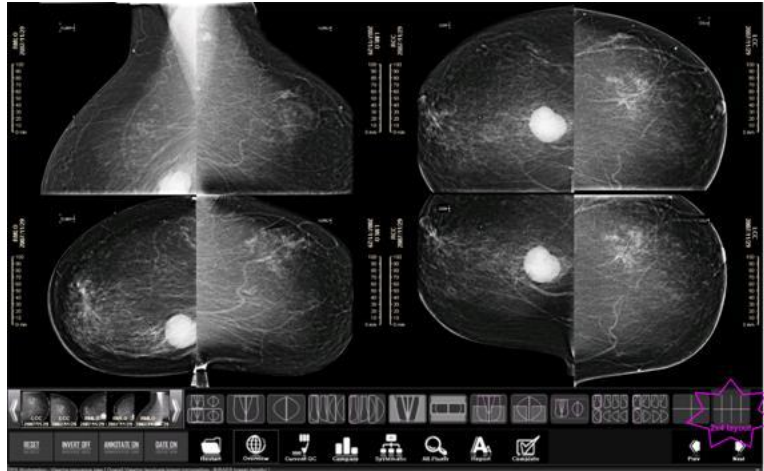


By using the zoom/pan tools, the possible abnormality is magnified and arranged for side-by-side comparison as shown in the following:



Once the task is complete, using the step forward button causes the system to return to the original screening viewing sequence.

The manual layouts are initiated by clicking the corresponding hanging protocol icon, which results in the display of *row x column* empty viewports. The images can be dragged into those viewports. For example, a mosaic study of a large breast using a small detector plate can be assembled by manually dragging images into a 2x4 layout:



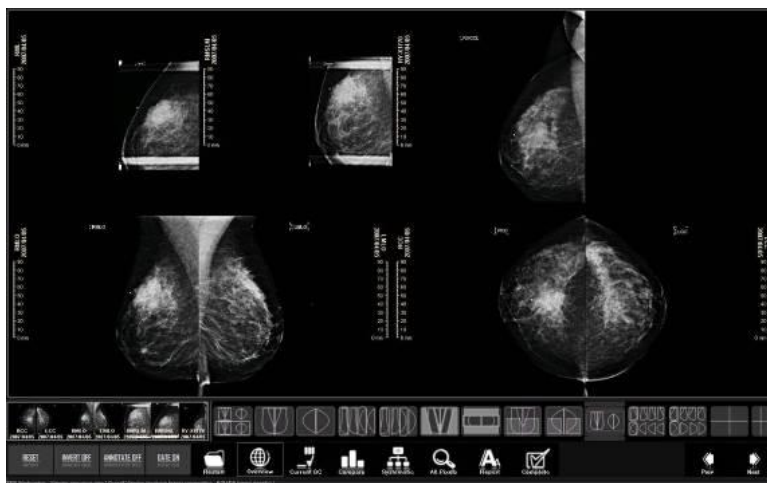
Use of zoom/pan to arrange and stitch the images to make them appear as 4 standard views results in:



In general, if a study contains more than 4 images, thumbnails of the additional images are displayed near the toolbar area (see the following figure). To view one of the additional images, drag the thumbnail image to one of the viewports.



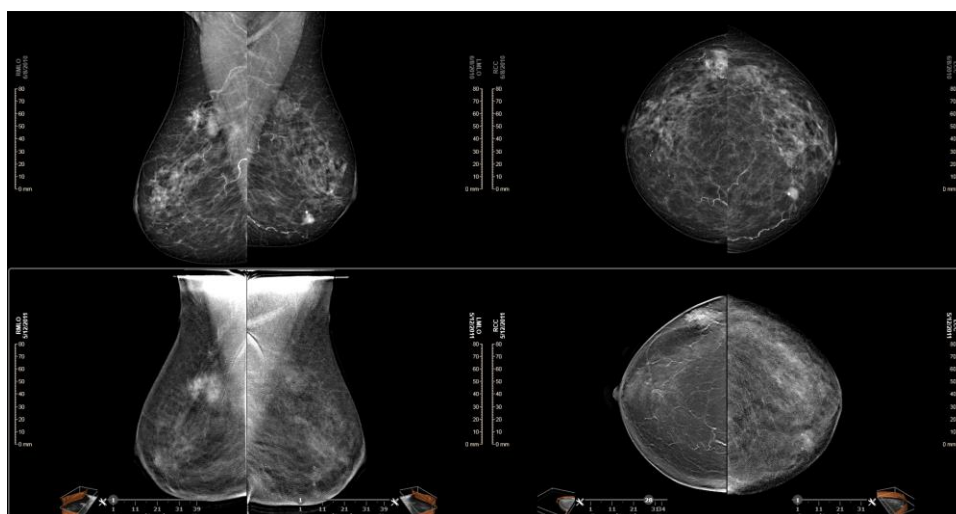
When configured (check “Step through up to 4 additional images if exist” in the configuration options for the overview step), additional images can be navigated using the step forward icon, so that all images are displayed together:



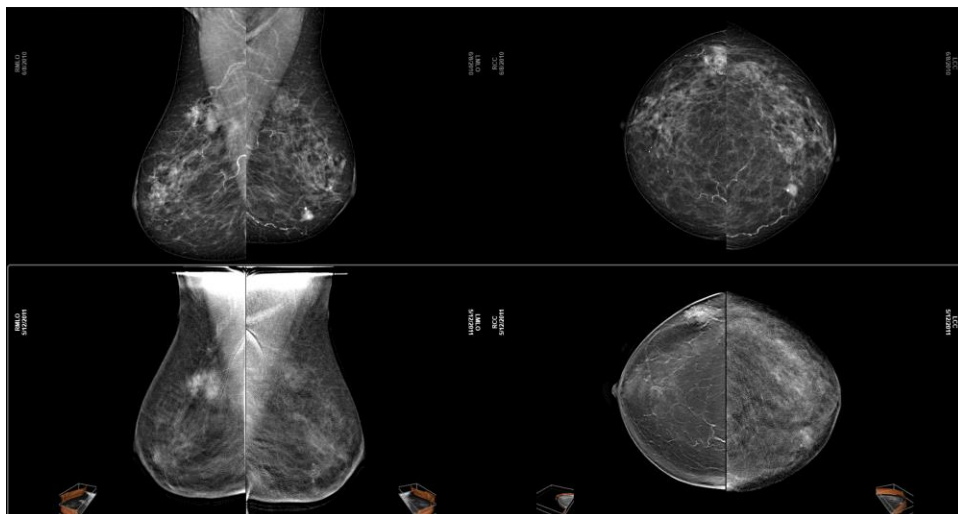
5.4. Viewing breast tomosynthesis images

In standard mammograms, each view contains one 2-dimensional image, whereas in a Digital Breast Tomosynthesis (DBT) study, there is a stack of images (i.e., 3 dimensions) for a single view. WorkstationOne handles DBT studies in standard DICOM DBT (including compressed) format. Breast Projection Images are handled similarly (also as a 3D stack).

Configuration of the hanging protocols and use of the workflow for tomosynthesis images are like the same operations for standard digital mammography on WorkstationOne. However, a slider, which indicates the location of the displayed image within its stack, appears whenever a viewport contains a DBT image – for example, the current study viewports in the following screen capture contain a DBT study:



The slider on the DBT images is like the caliper on a 2-dimensional image as it shows the position in the 3rd dimension, and similarly it can be toggled on/off using the “Caliper” button, for example:



Two right-click menu options are provided to allow the use of mouse scrolling within a DBT image stack:

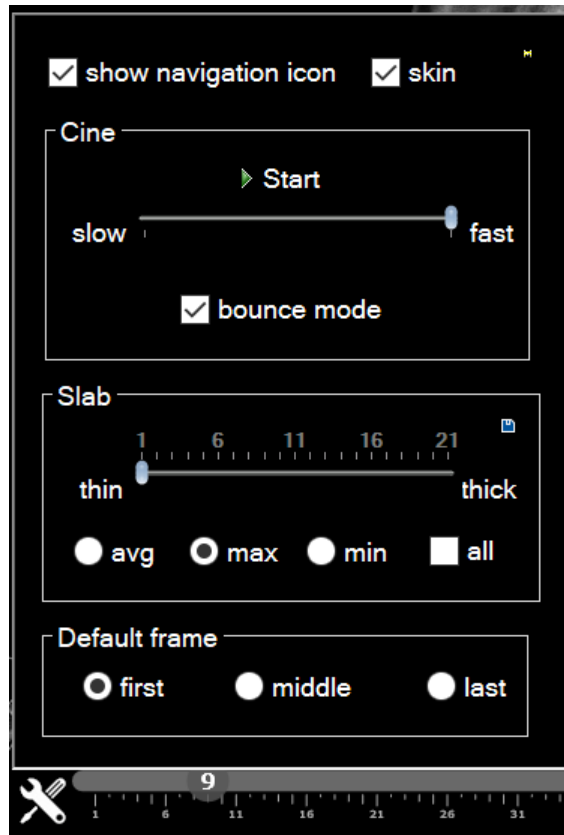
- Scroll Synchronized – when this menu item is selected, push and hold the left mouse button down and move the cursor to scroll through the images in the stacks contained in all viewports.
- Scroll One – when this menu item is selected, push and hold the left mouse button down and move the cursor to scroll through the images in the stack contained in the viewport.

Note that when scrolling images in all viewports, they are synchronized relative to each other. This means the number of slices in each stack is normalized, and the scroll positions are synchronized to the same fraction of the number of slices in each stack.

The up and down arrow keys and the mouse wheel can also be used to scroll through images in a DBT stack.

A DBT-specific control panel can be opened by clicking the tools icon which is shown at the side of the slider in each DBT viewport. The top two check-boxes control the 3D icon which is shown to the side of the scroll bar in each tomo viewport. If the first option is unchecked, then no icons are shown. If the “skin” checkbox is unchecked, the icon is shown only with the acquired slices (cut plane as the slider moves) with the detected skin surface not displayed. The default is to display the icon with the skin surface.

The start/stop button can be used to start or stop the cine in the associated viewport. The horizontal slider can be used to change the cine speed - it controls the delay between changes of the frame index to be displayed when the cine is running – from a maximum of 250 msec (slow) to 1 msec (fast). Note that the actual speed is determined by several factors (including the image size, screen size, display adapter, CPU and disk speed, etc.). The checkbox “cine bounce mode” determines whether the cine operates in “loop” or “bounce” mode (meaning that it reverses direction at each end). When cine is enabled in more than one viewport, they are automatically synchronized. Note that the short-cut key **Alt+C** can be used at any time, independent of this control panel, to start or stop synchronized cine of images in all DBT viewports. The short-cut key **Alt+B** can be used to start or stop cine of images in one DBT viewport.



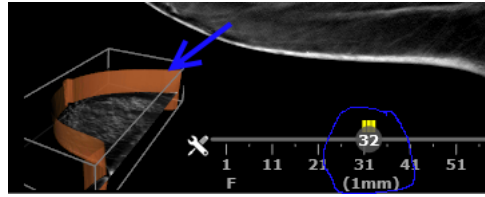
Rendering (display) of images from the DBT stack can also be achieved using a “slab” of slices. The thickness of the slab and the compositing algorithm can be interactively selected as the display cines through the stack. The thickness can be a number from 1 to 21 (number of slices from the DBT stack), and the full stack can also be selected (“all” checkbox) so that all slices in the DBT stack are composited to a single image. The compositing rendering algorithm can be one of the following:

- avg: average of the pixel values from each pixel position across all images in the DBT slab
- max: maximum pixel value from each pixel position across all images in the DBT slab
- min: minimum pixel value from each pixel position across all images in the DBT slab

The default is a slab thickness of 1 frame, and “maximum pixel” rendering, but the current settings can be saved as the default by clicking the small “save” icon in the upper right corner of the slab options.

When a tomosynthesis image is first displayed, the “default frame” to be shown can be the first, middle, or last one in the stack. The “Cine”, “Slab” and “Default frame” parameters are automatically saved as part of the user settings.

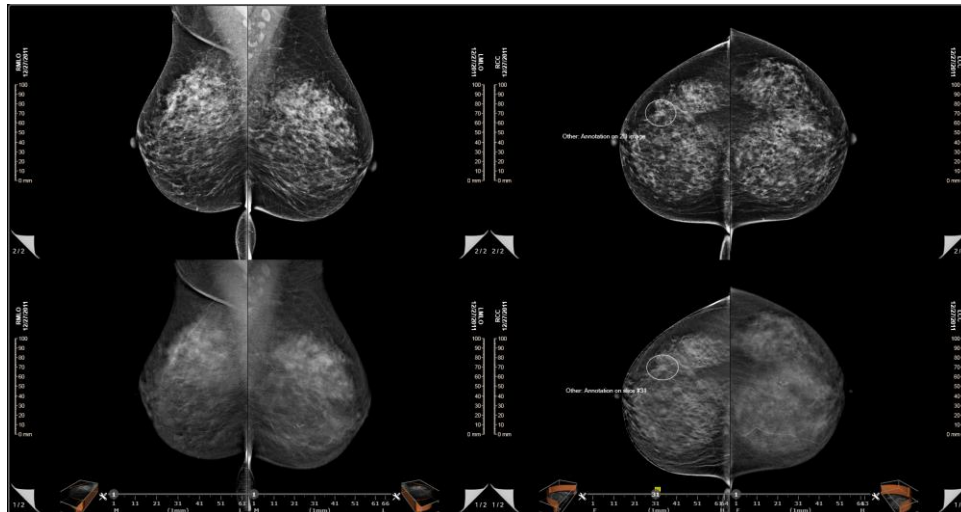
A 3D icon is shown in each DBT viewport to visually assist navigation through each slice of a DBT stack. The navigation icon is marked with a blue arrow as shown at the left corner of the following screen capture:



Note that the 3D icons in all DBT viewports can be configured in the user configuration panel ("user controls" tab) to be shown or hidden initially (i.e., by default, whether the icon should appear when a tomo is first shown). The "Show navigation icon" checkbox can be used to show or hide the 3D icons within the DBT viewports interactively. The 3D icon can also be completely disabled at the system level (a service option). The slider position marker (grey circle) shows the current slice number (32 in this case), and the slice thickness (in millimeters) is shown below the slider (the displayed thickness changes based on the slab thickness set on the DBT tool slider). At each end of the slider is a single character reflecting the anatomical position (F=foot and H=head for CC images, and M=medial and L=lateral for ML images).

Just like for viewing standard mammograms, a routine viewing and hanging protocol sequence is seamlessly integrated into the tomosynthesis reading workflow. For example, a study of 4 MG images and 4 DBT images can be viewed using single button workflow as captured in the following screens (note that cine automatically turns off as the user navigates the viewing sequence):

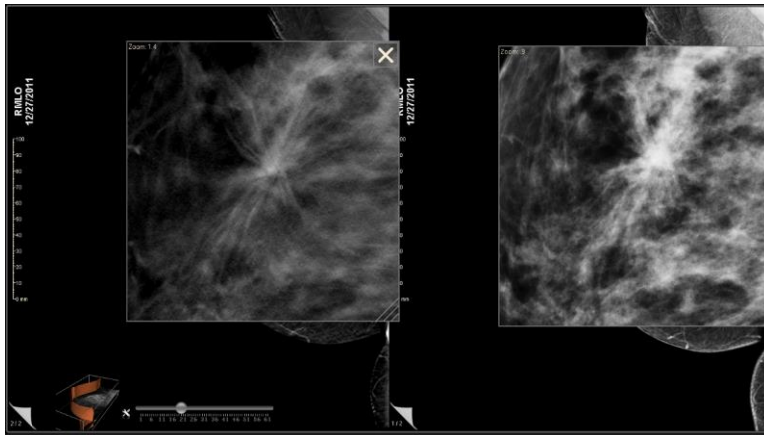
⇒ overview: 4 DBT images + 4 standard MG images



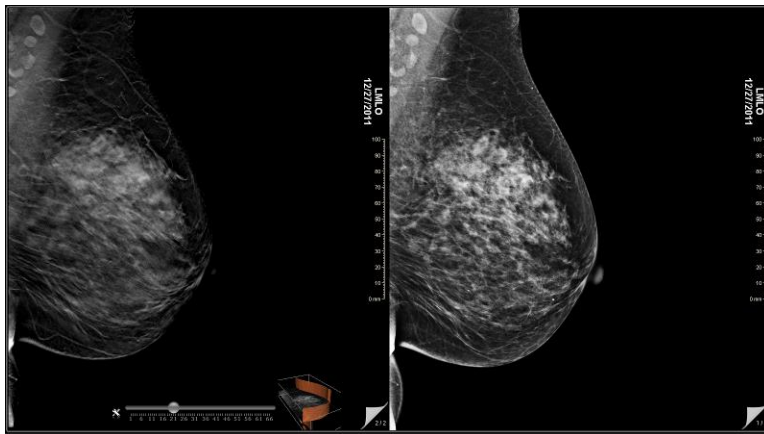
⇒ current study: bilateral standard MLO views



⇒ current study: standard RMLO and DBT RMLO views (also using dual magnify glass)

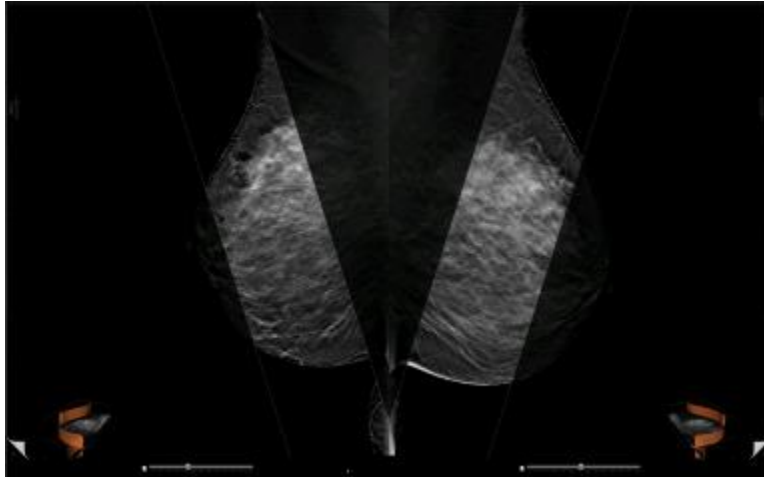


⇒ current study: standard LMLO and DBT LMLO views

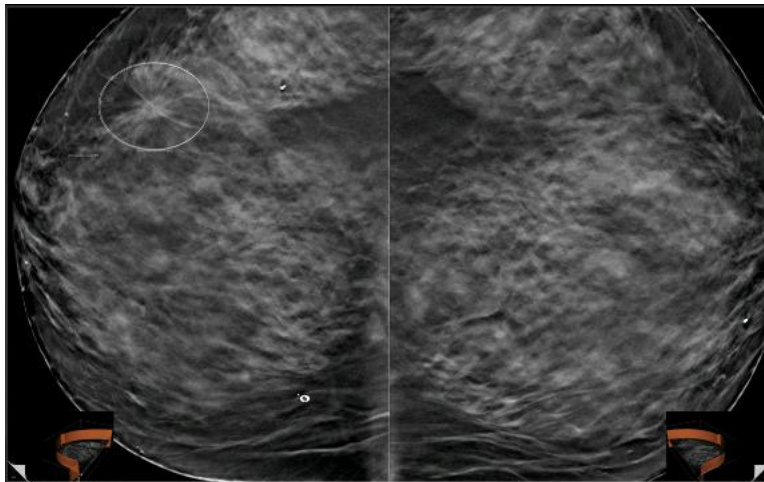


⇒ repeat for bilateral CC views

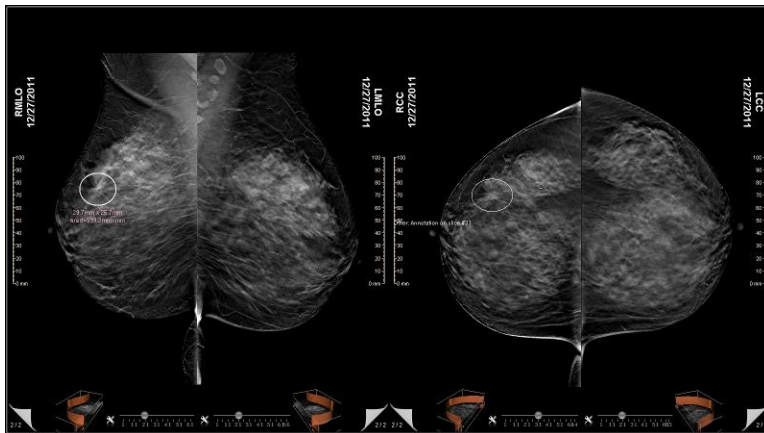
⇒ systematic viewing: oblique mask over bilateral DBT views



⇒ all pixel viewing: lower quadrant of the bilateral CC views

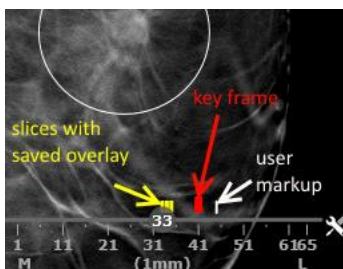


⇒ report



Other tools, such as mark-up and measurements, can be used just like when viewing standard mammograms.

Indicators are displayed above the slider to allow the user to quickly jump to slices that contain the overlay objects, such as, user markup, retrieved overlay graphics, CAD marks, and key notes:



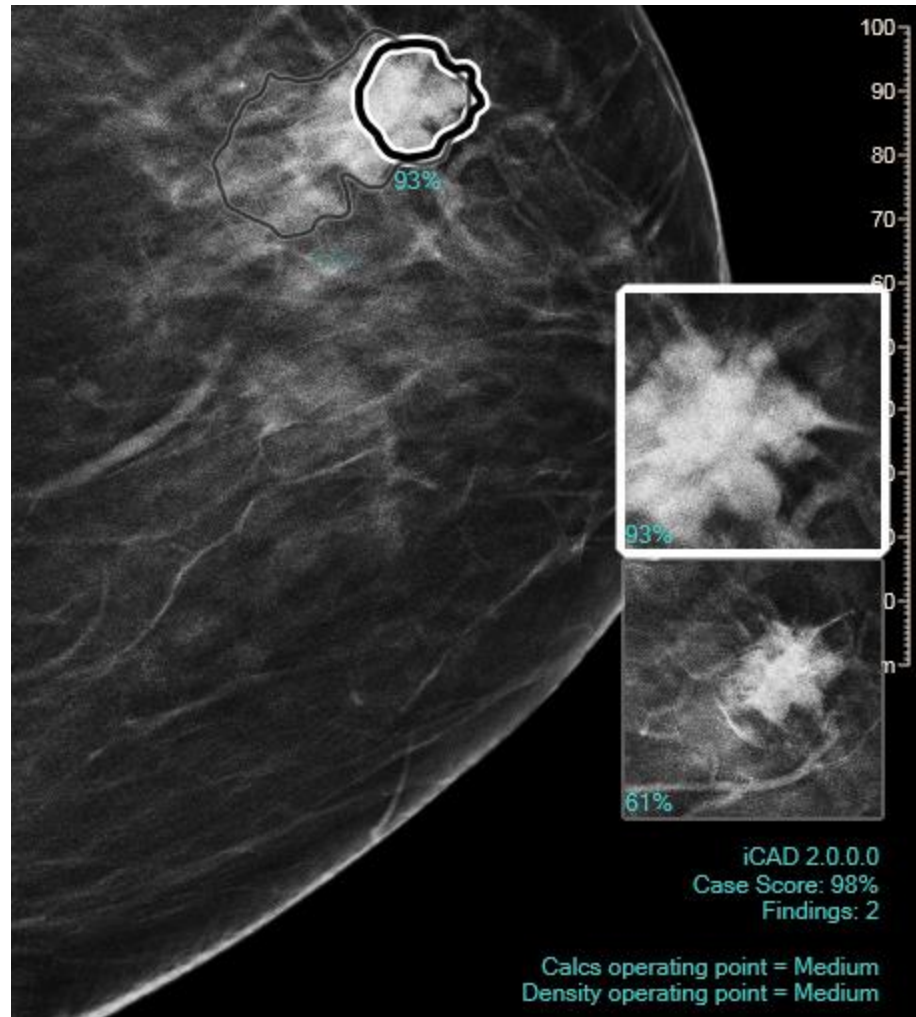
Clicking the area above the slider causes the display to jump to the closest of the marks – e.g., to the closest slice with CAD, marked as a key frame, or has saved markup, or markup drawn in this session. The different types of marks have different colors, but also have different thickness and heights, so they can be differentiated on a grey-scale screen.

CAD reports for tomo can be further utilized to aid navigation, and WorkstationOne includes support for the common mechanisms. Details on the availability of these inputs can be found from the corresponding vendors.

5.4.1. Navigation aided by tomosynthesis CAD

When CAD reports are available with a tomosynthesis image (currently iCAD PowerLook Tomo, iCAD Profound AI, or ScreenPoint Transpara), then the marks are known in the 3D space. WorkstationOne can use this information to simply display the marks on their appropriate frames, but the marks can also be used to aid navigation. The following mechanisms are supported:

- **Thumbnails** – these can be shown at the side of each DBT image, summarizing the area surrounding the N most suspicion findings in that stack, with the region around each displayed as a thumbnail. A thumbnail can be clicked to jump to the corresponding frame in the stack.
- **Shadow marks** – these can be shown on each frame – when a mark is present, but not on the currently displayed plane, then it is rendered as a “shadow” (lighter/transparent), whereas it is solid when displayed on the current frame. Clicking a shadow mark jumps the stack to that frame (so it becomes the current frame).



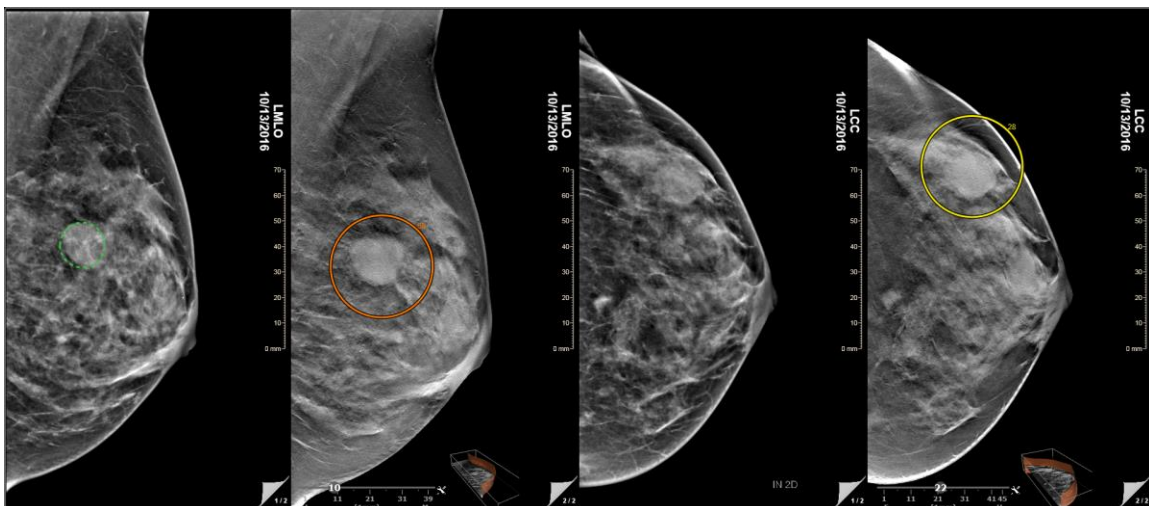
- Assessment dialog – using the CAD assessment dialog at a marker allows navigation to the next/previous marker in the study (using the “<<” and “>>” buttons). The next and previous marker can be on different frames, so this navigates through the volume. Navigation progresses across all displayed views, so a single UI can be used to navigate through marks in the complete study.



- Keyboard navigation – the “tab” key can also be used to navigate through the marks – bringing each mark in turn into “focus” – i.e., if it is not currently displayed on the current plane, then the stack scrolls to that point to display that marker.

5.4.2. Navigation aided Decision Support workflow

When CAD reports containing decision support information (currently only those from ScreenPoint Transpara) are present, and reference the current image, then as described above in section 5.1.6.1, decision support can be used implicitly or explicitly to display information, and additionally to navigate in the tomo stack. When the cursor is positioned to an area which has decision support information, a mark is displayed (a cross for a “miss” and a circle if that position refers to another image, and the corresponding decision support regions are shown on corresponding views:



In this example, the mouse is depressed in the 2D LMLO, and corresponding regions are shown on the tomo LMLO and tomo LCC views (at frames 10 and 22 respectively). The tomo views navigate to the corresponding frame as the 2D view is clicked.

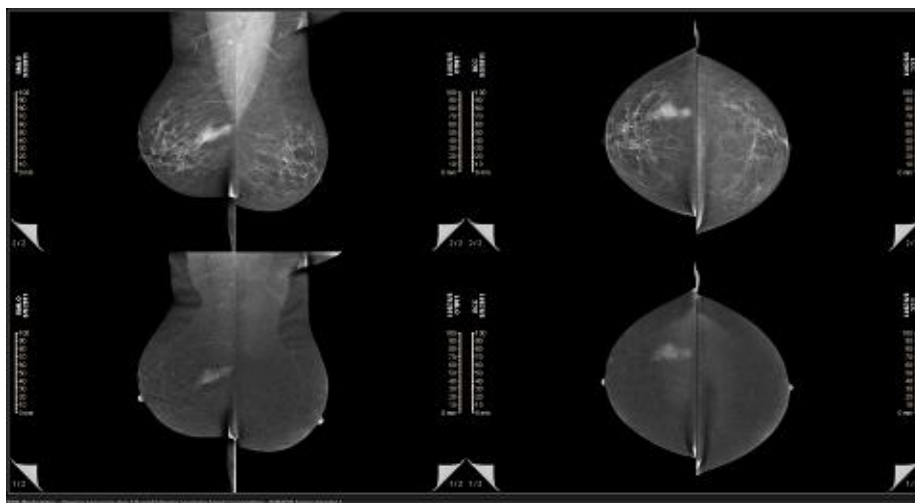
5.4.3. Navigation aided by 3D mapping

When synthesized images containing 3D correspondence information are present (currently those from GE enhanced v-preview or Hologic Smart Mapping), the user interaction is similar to the decision support model described above, but in this case, there is not necessarily an associated CAD-SR on the workstation – the navigation information is encoded within the 2D (synthesized 2D) image. However, the effect is similar – when an image is present with this information, depressing the left mouse with no other tool active causes the cursor to change to a dashed cross shape (red), and the position in the 2D image is used to internally navigate to the corresponding 3D to the plane with the corresponding position. In the following example the mouse is depressed in the RMLO 2D image, and the tomo frame is automatically scrolled to the 3D position (in this case frame #41). For the GE data, the corresponding (X,Y) location in the tomo frame is indicated by a cross:



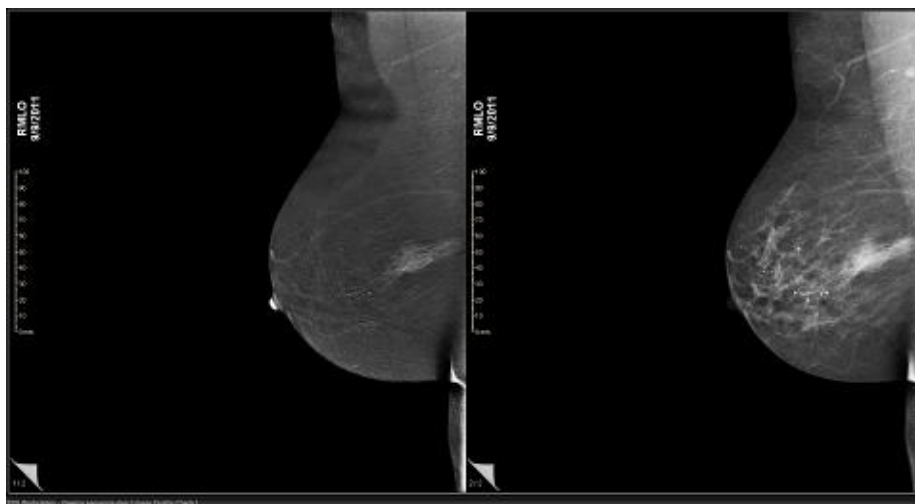
5.5. Viewing contrast-enhanced breast images

Using an iodine contrast agent, the contrast-enhanced spectral mammography (CESM, mainly from GE Healthcare) creates two images per view at different X-ray exposures; a standard mammographic image showing tissue density (called low energy images, marked with the value LOW_ENERGY for the tag "Image Type" in the DICOM header) and a contrast-enhanced image in the same position with the background signal subtracted out (called enhanced image, marked with the value RECOMBINED for the tag "Image Type" in the DICOM header). So, each CESM study typically consists of 8 images, 2 images per view for a 4-standard view study. WorkstationOne handles CESM studies in standard DICOM MG format and utilizes the DICOM tag "Image Type" to group the images. Therefore, configuration of the hanging protocols and use of the workflow for CESM studies on WorkstationOne are like the same operations for standard 4-view mammography study, with the enhanced images as standard views and the low energy images as the extra views. For example, the "overview" steps through all images from the current study as shown in the following screen capture for a CESM study:

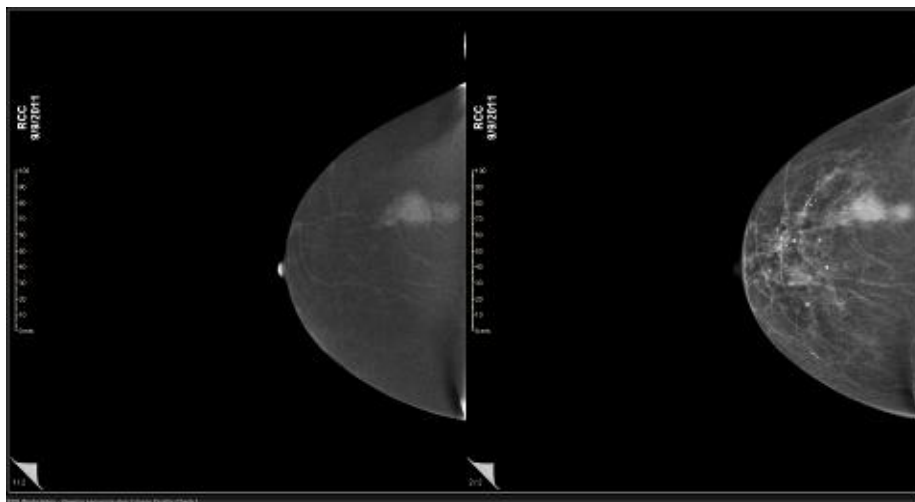


Similarly, for the “current” step, when it is configured to step through each standard view with its corresponding extra view:

=> RMLO: enhanced and low-energy



=> RCC: enhanced and low-energy



6. User interaction

The workstation provides two sets of tools for users to interact with the images: tools available on the toolbar and tools available on the “right clicking” tool menu.

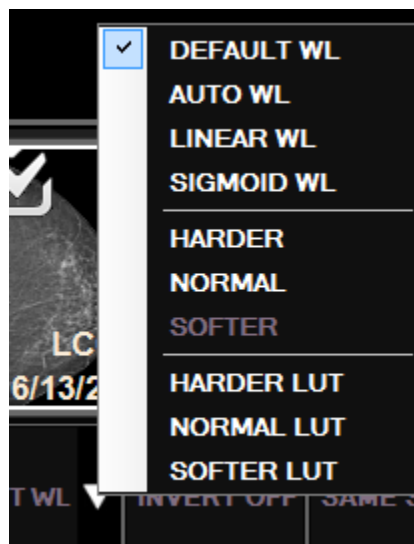
6.1. Toolbar

The first set of tools is available on the toolbar:



The buttons perform the following operations:

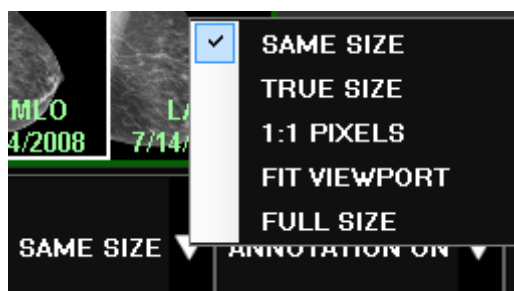
- The “Reset” button sets the image zoom and pan to the default for the current size policy (such as “Same Size”); “Invert” to “off”; and the Image Contrast (WL) to “Default”.
- The “Image Contrast” setting has four built-in options: default, auto, linear, and sigmoid. The arrow icon to the right displays a drop-down menu that duplicates the above four basic image contrast options, plus any available custom window width/level (WL) and lookup tables (LUT), as provided by the acquisition modality manufacturer with the images that are currently displayed. The basic set of contrast settings and the custom settings are all available for selection from this menu:



A right-click on the items in this menu has a special meaning: if one of the lower entries (not the built-in top 4) is right-clicked, then that name becomes the “preferred” definition to be the “Default WL” for this user (i.e., it is remembered), whereas if one of the first 4 values is right-clicked, the user “preferred” name is removed (i.e., it is forgotten). When one of the listed names is the preferred

setting, it is shown in a different color (in the above picture, the “SOFTER” item is indicated as the user preferred default). When a case is first opened, or the “Reset” button clicked, the system reverts to a “Default WL” setting. This setting is based on the window values in the image header, with the system selecting one set of values from those provided in the header. The logic for this selection is that the preference is first to any user-specified preferred name (specified as described above), then to a setting called “NORMAL” if it exists, then to a setting called “USER” if it exists. If none of those are found, then the first supplied definition is used. Note that the background air or any burned-in lead markers present in the image outside the breast or skin line will not be affected by the image contrast manipulations.

- The “Invert” button allows the user to invert the grayscale scale of the displayed image. Note that only the pixels inside the breast border are inverted.
- The scale of the displayed images can be one of: “same size”; “true size”; “1:1 pixels”; “fit viewport”; and “full size”. Like the image contrast button, the arrow icon to the right of the size button can be clicked to display a drop-down menu that duplicates the above three options for selection.
 - The “same size” means to display multiple images such that all images are at the same relative physical size, regardless of whether they have the same values of image pixel size or not. This allows for evaluation of developing densities and of changes in size of known lesions.
 - The “true size” is defined as the display of an image such that an object in the image when measured with a hand-held ruler on the surface of the display measures as closely as possible to the true physical size of the object if located on the front face of the detector housing.
 - The “1:1 pixels” displays actual pixels of an image in a viewport.
 - The “fit viewport” is defined as the display of an image such that the size of the breast bounding box as big as possible to fit into its image viewport.
 - The “full size” is defined as the display of an image such that the size of the full image as big as possible to fit entire image into its image viewport.

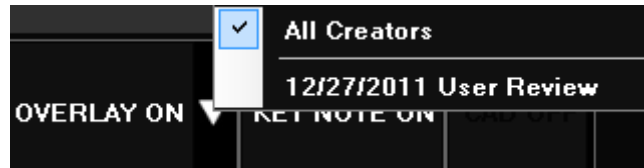


- The annotations on the displayed image can be toggled on/off using the “Annotate” button. Like the image contrast button, the arrow icon to the right of the annotation button can be clicked to display a drop-down menu for the following categories of annotation: "Clinical", "Technical" and "Investigative". Each category of annotation can be displayed or hidden using the checkbox associated with each:



By default, the annotation is off in the all pixel viewing. However, it can be configured to keep it on by the user setting (see section 2.6.2).

- The large font date annotation on the displayed image can be toggled on/off using the “Date” button.
- A caliper can be toggled on/off using the “Caliper” button. Note that the same “Caliper” button is also used to show or hide the depth sliders in the DBT and projection viewports.
- Any markups on the images can be toggled on/off using the “Markup” button.
- The GSPS graphic annotations on the displayed image can be toggled on/off using the “Overlay” button. The graphic annotations may have been generated by different creators on the same or different studies. Each creator's graphic annotation can be selectively displayed using the checkbox associated with each study date and creator's name from the drop-down menu associated with the “Overlay” button:



- The key notes icon on the displayed image can be toggled on/off using the “Key Note” button.
- The CAD marks of the study (if available) on the displayed image can be toggled on/off using the “CAD” button.

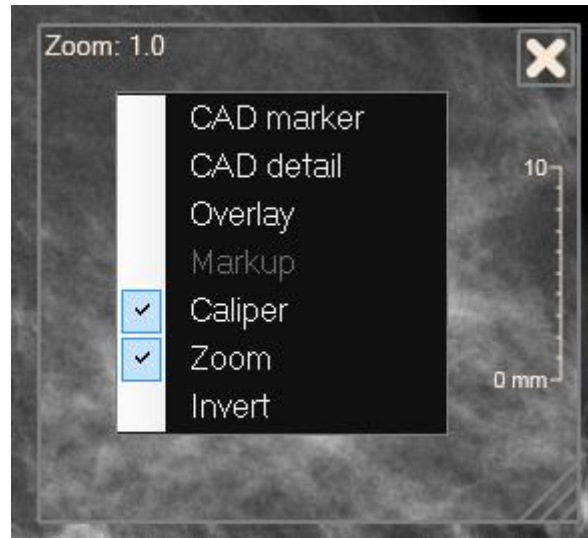
6.2. Tool menu

A second set of tools is available by “right clicking” on an image, which results in the display of a menu of tools:

	Reset Mouse Action	Alt+R
	Magnifying Glass	Ctrl+M
	Dual Magnifying Glass	Ctrl+D
	Tabar Viewer	Ctrl+T
	Free-hand Markup	Ctrl+R
	Ellipse Markup	Ctrl+E
	Rectangle Markup	Ctrl+B
	Arrow Markup	Ctrl+A
	Line Measurement	Ctrl+L
	User Annotation	Alt+A
	Edit or Pan Graphic	Ctrl+S
	Remove this Graphic	Ctrl+U
	Remove All Graphics	Ctrl+V
	Decision Support	Ctrl+Shift+D
	Assess this Markup or CAD Mark	Ctrl+F
	Cross Ref. this Markup on Other View(s)	Alt+O
	Pan Synchronized	Ctrl+H
	Pan One	Ctrl+G
	Zoom Synchronized	Ctrl+Z
	Zoom One	Ctrl+Y
	Window Synchronized	Ctrl+W
	Window One	Ctrl+X
	Scroll One	Alt+T
	Probe	Ctrl+Q
	Key Image add/remove	Ctrl+K
	Key (Quality) Notes	Ctrl+N
	Pre-defined LUTs	
	Blank Contents	Alt+Del
	Save All Markup as GSPS	Ctrl+J
	Copy to Clipboard	Alt+Z
	Save as DICOM SC	Alt+I
	Save as JPG	Alt+J
	Print Viewport to DICOM	Alt+V

The following are the tools available through this menu:

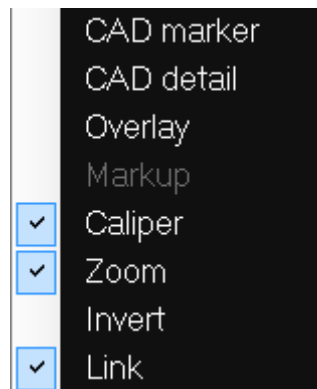
- Reset Mouse Action: Select this menu item, the left mouse button is reset so all menu items are deselected.
- Magnify Glass: Displays a magnifying glass that can be panned over the image. To pan the magnifying glass, click and drag the mouse anywhere inside the magnifying glass. Note that the magnifying glass can be panned across different image viewports, the size of magnifying glass can be changed dynamically by dragging the lower-right corner of the ROI, and the zoom factor can also be dynamically changed using the mouse wheel. Right clicking on the magnify glass results in a drop-down menu within the magnifying glass:



The menu items “CAD markers”, “CAD detail”, “Overlay” and “Markup” are disabled if the corresponding content does not exist. Click on a menu item to select or de-select the function that the menu item provides.

Image contrast within the magnify glass, as window width and level settings, can be altered independently of the underlying source image by holding down and dragging the right mouse button within the magnify glass area.

- Dual Magnify Glass: Displays two magnifying glasses that move in concert when dragged. Similar functions that are supported for single magnify glass are supported for the dual magnify glass except that the dual magnify glass cannot be panned across different image viewports. The two images in the two magnifying viewports are scaled in same relative physical size. The zoom factors displayed on the viewport may be different if the pixel sizes of the images are different. Like the single magnifying glass, right-clicking on either of the magnify glasses results in a drop-down menu within the magnifying glass:



Uncheck the "Link" item to decouple the dual magnifying glasses.

- Tabar viewer: Display masks on a pair of images.
- Free-hand Markup:



Use the left mouse button to draw an arbitrary shape around an area of interest. When the left mouse button is released, if configured, the markup label, the width and height, as well as the area are displayed. Also, when the left mouse button is released, unless the clinical study application setting (ClinicalStudyMarkupNoAutoSetEditMode) is set, the menu item “Edit and Pan Graphic” is automatically selected for the user to edit a markup shape or position.

- Ellipse Markup:



Use the left mouse button to draw an ellipse shape around an area of interest. When the left mouse button is released, if configured, the markup label, the width and height, as well as the area are displayed. Also, when the left mouse button is released, unless the clinical study application setting (ClinicalStudyMarkupNoAutoSetEditMode) is set, the menu item “Edit and Pan Graphic” is automatically selected for the user to edit a markup shape or position.

- Rectangle Markup:



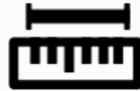
Use the left mouse button to draw a rectangle shape around an area of interest. When the left mouse button is released, if configured, the markup label, the width and height, as well as the area are displayed. Also, when the left mouse button is released, unless the clinical study application setting (ClinicalStudyMarkupNoAutoSetEditMode) is set, the menu item “Edit and Pan Graphic” is automatically selected for the user to edit a markup shape or position.

- Arrow Markup:



Use the left mouse button to place an arrow markup such that the pointer end points to the area of interest. When the left mouse button is released, if configured, the markup label is displayed. Also, when the left mouse button is released, unless the clinical study application setting (ClinicalStudyMarkupNoAutoSetEditMode) is set, the menu item “Edit and Pan Graphic” is automatically selected for the user to edit a markup shape or position.

- Line Measurement:



Use the left mouse button to draw a straight line. When the left mouse button is released, the length of the line is displayed. Also, when the left mouse button is released, the menu item “Edit and Pan Graphic” is automatically selected for the user to edit the line length or position.

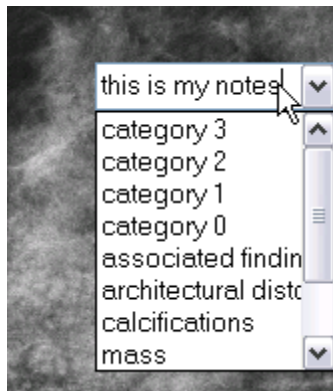
When a line measurement is drawn inside a “shape” markup, such as inside an ellipse or rectangle shape, the line measurement is automatically associated with that markup. So, the measurement number can be interpreted as the size of the finding that is “circled” by the ellipse or rectangle. This size is used on the screening report and can also be used within an integrated reporting system.

- User Annotation:

Aa

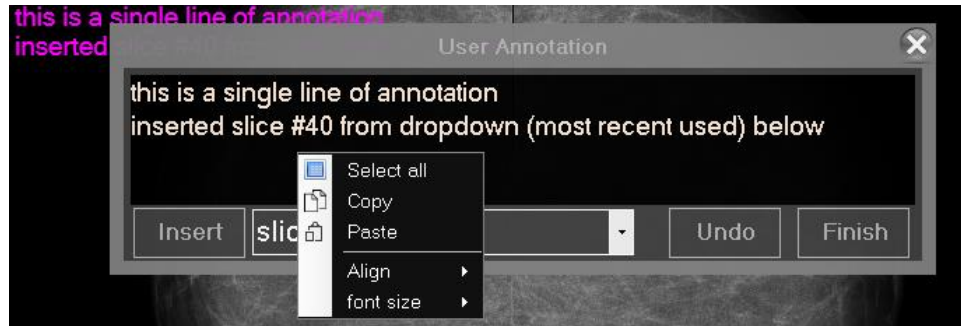
Once this menu item is selected, move the mouse cursor to a location where the annotation string is to be placed, and then click the left mouse button to enter new text. The system can be configured to use either a simple single-line editor, or a multi-line editor.

When the single-line editor is configured, a simple text box is displayed, which allows typing of the annotation string. A dropdown menu is also attached to this text box to provide selectable template strings:



Use the “return” or “enter” key to close the text box, which results in the annotation string being shown over the image. Each selected or typed string is automatically added to the template list for future reuse.

When the multi-line editor is configured, the following dialog is displayed:



Which shows multiple of lines of text that have been typed, along with a right-click menu that allows selection of all text, and copy and paste (standard short-cut keys for copy and paste can also be used). Text alignment (left, center, or right justified), and font size can also be changed. Note that once the markup is saved, the text becomes “overlay”, and then the “font size for overlay” (see 8.4) is used. Once the “Finish” button is clicked, the text is accepted and becomes the user annotation displayed at the point clicked. The “Undo” button resets the contents of the text to that which was initially displayed (this option is most useful when existing user annotation is being edited). This dialog also allows provides a mechanism to insert saved short text strings - on click of the “Insert” button, text from the drop-down is inserted at the cursor position. The text string can be manually entered, with the last “N” values retained in the drop-down for future selection.

- Edit and Pan Graphic:



Select this menu item, then click the left mouse down over a graphic or text string and drag it to a new position. When the mouse cursor is moved on the edge of a graphic or the end line point, the graphic shape can be resized. A single click on a text item, or any text associated with a graphic, allows that text to be edited. When the multi-line editor is configured and the item is user annotation, the multi-line text editor is used for editing (as described above). For other shapes (which can have a single line of associated text) or when the system is configured to use the single-line editor, then a simple text box is shown for the user to edit the text. Use the return key to close the text box.

To allow a user to draw a markup or a line for measurement over an existing graphic, this menu item is automatically de-selected whenever one of the following drawing menu items is selected:

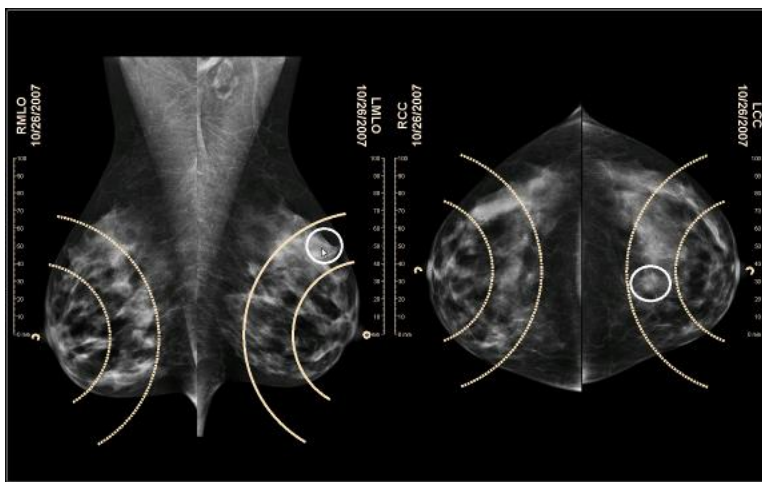
- Free-hand Markup
 - Ellipse Markup
 - Rectangle Markup
 - Arrow Markup
 - Line Measurement
- Remove this Graphic: Right click on a graphic markup and select “Remove this Graphic” to remove the graphic drawing and associated measurement information.

- Remove All Graphics: Remove all graphic drawings on an image.
- Decision support:



Selecting this item puts the mouse into “explicit” mode for decision support, for CAD reports that support this mechanism – see 5.1.6.

- Assess this Markup or CAD Mark: Right click on the finding markup, and a dialog is showed for the user to enter information for finding assessment or view CAD assessment information if available.
- Cross Ref. this Markup on Other View(s): Move the mouse to a location (to be correlated) over an image, right click to select this menu item, and the software then displays multi-view cross-correlation arc graphics superimposed on all displayed images. The arcs can be used to interactively inspect suspicious regions in two or more views within one study or across current and prior studies, based on the distance of those regions from the nipple position. For example:



- Pan Synchronized:



Dragging the left mouse button causes all images to be panned and synchronized relatively to the chest walls.

- Pan One:



Dragging the left mouse button causes only the underlying image to be panned.

- Zoom Synchronized:



Dragging the left mouse button causes all images to be zoomed and synchronized relatively to the chest walls.

- Zoom One:



Dragging the left mouse button causes only the underlying image to be zoomed

- Window One:



Dragging the left mouse button adjusts the window width and level contrast on the underlying image in the current viewport – but only for this viewport. If the same image is shown in multiple viewports, then only the current is changed, and if the image is not shown as part of the workflow, and then subsequently re-displayed, then it will revert to its original W/L.

- Window Image:



Dragging the left mouse button adjusts the window width and level contrast of the image displayed in the current viewport. This change is to the image properties – so is used where-ever that image is displayed within this workflow. Thus if the same image is displayed in two viewports, both change together, and if the image is not shown at some point during the workflow, but subsequently re-displayed, then it will have the changed W/L again.

- Window Synchronized:



Dragging the left mouse button adjusts the window width and level contrast for the images shown in all visible viewports (current and prior studies, if both are displayed in the current hanging protocol). This is only for the images as shown in the viewports (so acts like “Window One” above) – i.e., the change is only to what is displayed, and any subsequent redisplay of an image will revert to the saved W/L values.

- Window One Study:



Dragging the left mouse button adjusts the window width and level contrast for all the images of the study that the current viewport is part of (for example, if the

current viewport contains an image which is part of the current study, then this change affects all images in the current study). This change is to the image properties – like “Window Image” above. Thus if any image from this study is redisplayed later in the workflow, it will utilize the changed W/L values.

- Scroll Synchronized:



this menu is enabled only if the current study contains tomosynthesis images. Drag the left mouse button to scroll through images in all viewports.

- Scroll One:



this menu is enabled only if the current study contains tomosynthesis images. Drag the left mouse button to scroll through images only in the underlying viewport.

- Rotate: this sub-menu includes horizontal flip, vertical flip, rotate 90 degrees, rotate -90 degrees and rotate 180 degrees. The correction UI (key-quality notes, see 6.3) is the recommended mechanism for correcting the image orientation.
- Probe:



Click the left mouse button to display the (x,y) position in the image and pixel value at that location. The pixel value readout is not available on all display adapters (i.e., for some cards the position is shown, but not the underlying pixel value).

- Mark as Key Image: This allows a user to flag an image (or frame within a tomo stack) as of interest for teaching purposes, which results in the saving of a DICOM KOS object.
- Key (Quality) Notes: This mechanism provides support for various image corrections, which are available on the dialog that is displayed (see section 6.3). The correction values include: View Code Sequence; View Modifier Code Sequence; Image Laterality and Preformed Protocol Codes.
- Pre-defined LUTs: this option is enabled when image contrast width/level and/or lookup tables are provided with this image by the manufacturer.
- Expand View: this menu allows the user to expand a viewport to a larger size or to collapse it back to its default size.
- Blank Contents: enabled only on diagnostic layouts, to enable clearing of all contents (image and overlays) in the selected viewport.
- Save All Markup as GSPS: Save and send all user’s drawing markup to PACS as a DICOM GSPS object (normally this is configured to occur automatically – this option is not needed in such cases).

- Copy to Clipboard: the image in the current viewport (including all overlay information) is saved to the Windows clipboard, so it can be pasted elsewhere (such as the Reporting plugin, or an external tool such as Microsoft Word).
- Save as DICOM SC: the image in the current viewport is saved locally (and sent to PACS if there is a configured send destination) as a DICOM Secondary Capture object.
- Save as JPG: the image in the current viewport is saved in JPG format for subsequent external use in a presentation or as a teaching case. By default, a simple “save file” dialog is displayed, allowing selection of either a “jpg” or “png” format screen capture of the viewport. An advanced save mechanism can be configured (on the service tool), which supports the same 2-D screen capture save, and also a video save (if the viewport contains a tomosynthesis or projection image). The video save dialog looks like:



- Which allows the selection of the frame-rate of the generated cine, and also the start and stop frame (in the source image) which is to be captured. The captures include whatever information is currently displayed (caliper, slider, annotation, markup, etc.), but not the capture of the 3D icon if it is currently shown in the viewport. The generated video is in “avi” format.
- Print Viewport to DICOM (printer): selecting this menu item allows the user to send the image that is displayed in the selected viewport to any one of the configured DICOM printers. This operation sends the viewport contents exactly as displayed, which is different to the “print” tool (see section 0), which supports grid layouts and printing in a standard format (true-size, etc.).

For ergonomic reasons, the forward and backwards stepping icons can be duplicated on both sides of the high-resolution monitor displays.

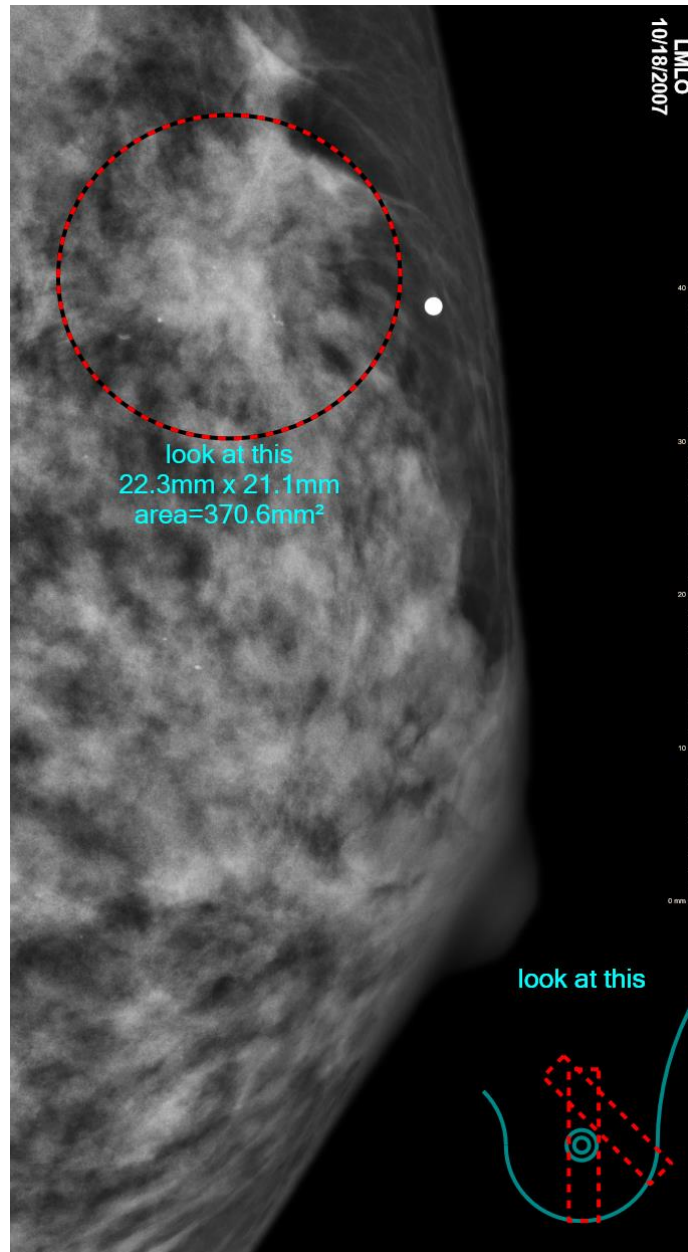
Based on the configuration, the marking menu items (free-hand markup, ellipse markup, rectangle markup or arrow markup) can be automatically de-selected after each drawing. This minimizes the chance of accidentally marking-up the image when using the mouse cursor.

The currently selected menu item, e.g., “Pan One”, is saved as part of the user settings, so that the same menu item is selected by default when WorkstationOne is next started.

6.3. Markup correlator graphic

WorkstationOne supports a visual mechanism for correlating the position of a region across views – this is called the “cross reference tool” (see above). There is also a “markup correlator” graphic that can be configured to display at the side of a viewport. This graphic is enabled using the “markup actions” – see the options on the “user controls” tab of the user configuration (8.4).

When displayed, the markup correlator graphic looks like:

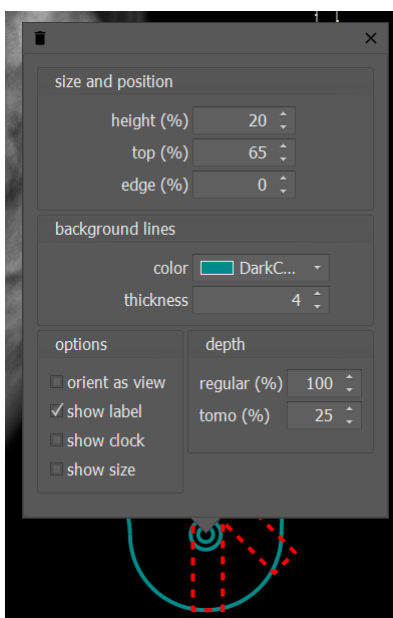


The graphic (right lower in the above picture) consists of two parts: 1) an idealized breast outline (in this case for the left side) with two small circles indicating the nipple position, and 2) projected regions of the specified markup onto the idealized shape.

The projected markup shapes correspond to the selected (using a configured “markup action”) markup. Multiple projections (in this case two) are displayed using the label (in this example “look at this”) – i.e., all markups with the same label are shown. The same label can occur only once in an image.

The size and position of each projection is based on the information from the image(s) and the drawn markup. For example, the width of the rectangles shown above correspond to the diameter of the drawn ellipses. The angle information is encoded in the header – and may not always correspond to the nominal “view” (e.g., a view labelled as “MLO” may not always be oriented at 45 degrees, depending on the encoded information).

Properties of the markup correlation graphic can be changed by clicking within the idealized breast area (e.g., click near the nipple) to show:



Clicking the “x” or anywhere outside the popup results in the settings closing, and any changed parameters taking effect (and being saved). The top-left icon (garbage can) causes the graphic to be removed from the display (not the markup itself).

The size and position of the markup correlator graphic are controlled by its “height”, “top” and “edge” as percentages of the size of the viewport. The default is that the graphic appears below the caliper, close to the edge (the edge percent is relative to whichever side of the view-port that is being used (i.e., the default is to display it opposite the chest-wall)).

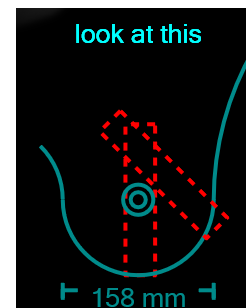
The background (the idealized breast outline) is drawn with a line whose color and thickness can be changed in the “background lines” section of this dialog.

The “options” section has 4 options that control how the graphic is displayed:

- Orient as view – By default (option unchecked), the graphic is displayed in “standard” form (patient’s right on the viewer’s left side - as though the patient is being viewed from the front). If the user selects the top level hanging protocol option “chestwall to the right for left breast and to the left for the right breast” then the graphic still appears in standard form. Checking this option (orient as view)

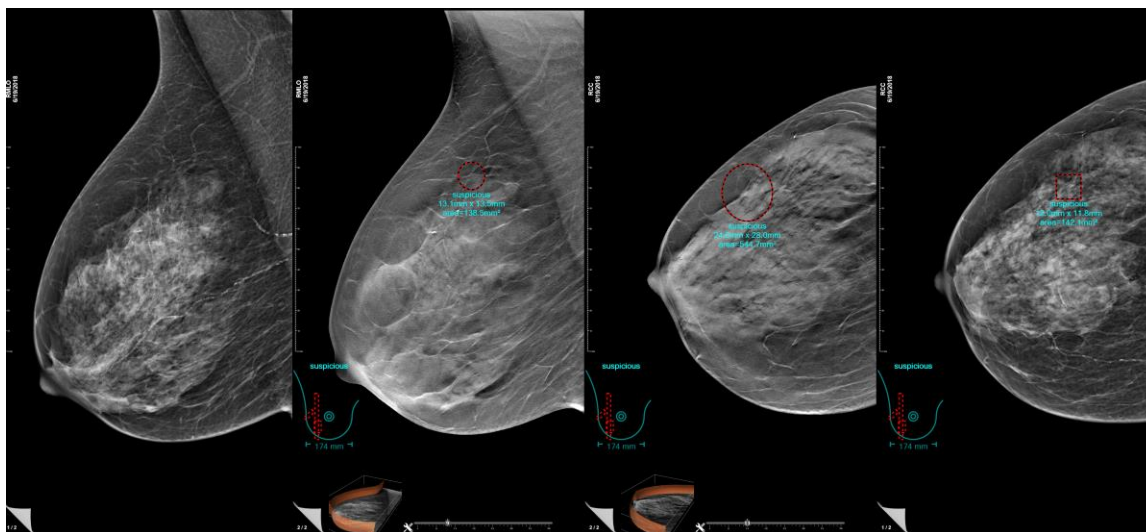
results in the graphic also being flipped in this situation (i.e., the graphic is then oriented the same as the view).

- Show label – this causes the selected markup's label to be displayed above the graphic (this is generally desirable, particularly if there are multiple markups on an image).
- Show clock – this results in the clock positions being displayed around the edge of the breast.
- Show size – the graphic is shown with markup and the normalized breast scaled to an estimate of the size of the breast. That size can be displayed by checking this option.



When the projected region is shown on the idealized breast, the depth (length of the rectangles in these examples) is drawn proportional to the size of the breast. For a standard 2D view a 100% ratio is reasonable, as the marked region could correspond to anything along that “depth” (orthogonal to the acquired view). Thus, for 2D, the default is to draw the projected depth at 100% of the breast size. However, for tomosynthesis views the situation is a bit more complex, as the frames are in theory separated in the orthogonal direction, so a markup in a specific plane is not expected to lie anywhere within a rectangle covering the full breast size – it should be limited to the inter-frame spacing or close to that. Thus, there is a separate setting “tomo (%)” for the depth to use for tomosynthesis views (the default is 25%).

Any combination of 2D and tomosynthesis views can be viewed this way, with the markup “correlated” in the graphic based on the label that the user assigns to each:



Which shows markup drawn on the right breast – in the 2D CC, tomo CC and tomo MLO. The graphic thus shows 3 rectangles – two are aligned vertically (the larger being from the 2D view), and one angled small rectangle (which is the projection of the markup region from the tomo MLO view). The two tomosynthesis markup projections are at 25% of the breast size (configured in this case, which is the default).

As suggested above, understanding the projections can be difficult, and there will be situations where problems in the image headers result in the graphic not representing

what is intended. Thus, the user should be careful to consider the geometric accuracy before passing that information to others.

The markup correlator graphic is included with the viewport when the viewport is captured (e.g., “copy to clipboard”, “save as jpg” and “save as DICOM SC”). The graphic is also included when the internal reporting mechanism includes an image with such a graphic.

6.4. Key (Quality) notes

The Key (Quality) notes dialog allows the user to make corrections to an image:

The image that is being corrected is the one under the top-left corner of this dialog (the dialog can be moved to allow correction of any displayed image).

The available options are in three groups:

- View Correction – this group covers several items which are related to the orientation of the source image, which in turn affects how that image is displayed. See below for more information.
- Quality Issues – this group does not change the image values but flags the reason for image rejection. This is useful if the site is using the IHE mammography image acquisition profile, as this then indicates to the remote system that the image needs to be retaken for the specified reason.
- Image Presentation – this group allows the system to “lock in” any manual change to the image window/level. The window width and level correction values can also be manually entered.

The most complex of the corrections concern the “View” information. Some of these are self-explanatory, whereas others are more complex:

- **Image Laterality:** this is the patient laterality for the image and can often be easily recognized from the image contents (e.g., a burned-in marker). The possible values are R, L and B (both). If this value is not correct, the image may not be assigned to the correct viewport for display.
- **View Code Sequence:** the codes used are defined within the DICOM standard, but a textual version of each is also displayed. Again, if this value is not correct, the image not be assigned to the correct viewport for display. Typically, the major views can be recognized from the image contents.
- **View Modifier Code Sequence:** these are refinements to the mammography view – e.g., things like “implant displaced”, and are used for detailed differentiation between images (e.g., for the diagnostic hanging protocols). The textual versions of the codes should allow the correct ones to be selected (more than one can be assigned to a single image).
- **Performed Protocol codes:** these values are only used for reporting - changes to this value currently do not affect subsequent display of the image.
- **Patient Orientation:** this is typically the most difficult correction to understand. In DICOM (see part-17, Annex A) the specified orientation is the orientation of the source pixel data (raw data that is received) relative to the patient. The orientation is defined by two vectors – the first being the direction of each row of pixels in the data, and the second being the direction of each column of pixels in the data. This is represented as character codes (one for the row and one for the column) – thus “P\F” means that the rows are in the “posterior” direction, and the columns are in the “foot” direction.

While it is sometimes difficult to visualize how to change these vectors to achieve a correction, a short-cut is provided to make this easier. To the right of the orientation vector is a drop-down that allows them to be changed visually:

Image Laterality	R = right				R
Patient Orientation	HR = head-right	P = posterior	rotate 90 cw		P\F
Performed Protocol Codes	Not specified				ROUTINE
Issues					
Reject or correct for patient safety reasons					
Reject or correct for quality reasons					
				do nothing	
				rotate 90 cw	
				rotate 180	
				rotate 270 cw	
				mirror LR	
				mirror TB	
				LR + 90 cw	
				LR + 270 cw	
					Correct Image
					+ Key Image Not
					Reject Image

Selection of any of the drop-down options results in the “patient orientation” vectors being updated in such a way that the selected transformation would be what will be seen on the screen. For example, if the currently displayed image appears to need to be rotated clock-wise by 90 degrees to be “correct”, then select “rotate 90 cw”. This results in the displayed “correction value” for “patient orientation” being updated immediately, and the image changed accordingly once the “Correct Image” button is clicked. The available transformations include rotations in increments of 90 degrees and mirror (left-right and top-bottom).

All specified changes to the image are performed once the “Correct Image” button is clicked. These corrections are performed on a local copy of the image (i.e., the version that is stored on the workstation) and not to the version in any remote system (such as a

PACS). If a permanent change is required in a PACS, the tools available on the PACS should be used to make a permanent change. After any correction has been performed, the original version of the image is retained, and can be restored by clicking the “Restore Original” button (the button is enabled only when the original is available).

The “Key Image Notes” functionality is currently disabled – in a future release this will allow the corrections to be sent to other systems that follow the IHE Mammo Acquisition Workflow Profile.

6.5. CAD and Decision Support

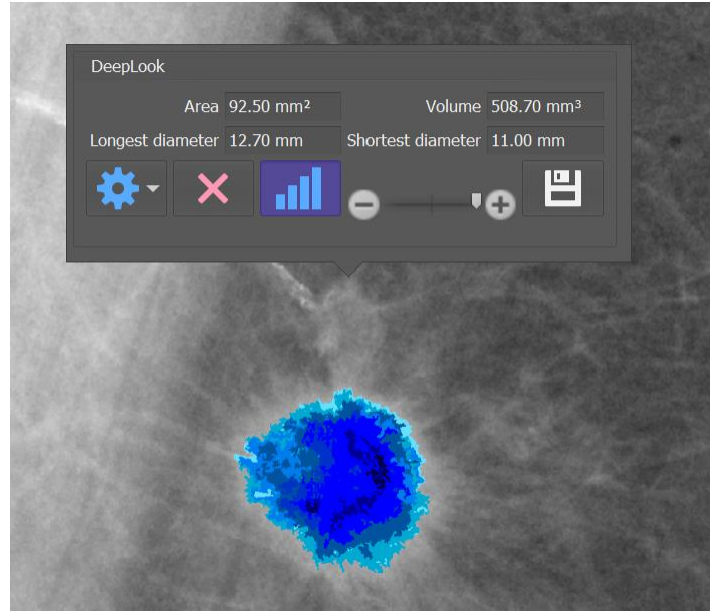
The classical way to use CAD (Computer Aided Detection) is that a case is read normally, and then at the last step of the workflow (finding review) the CAD marks are displayed, so that the reader can check to see that there is nothing that warrants additional attention. This workflow is described above in section 5.1.6. There are many vendors of mammography CAD reports, and over the years reports from the following vendors have been successfully displayed within WorkstationOne (not all these products are still available, and some are not yet available):

- Arcadia Galileo
- Carestream
- CureMetrix (cmTriage information on the worklist), and CM Assist.
- Cyclopus
- DeepHealth
- Densitas
- FujiFilm
- iCAD (2D and 3D) Powerlook and newer Profound-AI and includes breast density integration.
- Image Diagnost
- Kheiron
- Konica
- Lunit
- Parascript AccuDetect and Galileo
- Philips
- R2/Hologic
- ScreenPoint Transpara 2D and 3D, and decision support
- Siemens
- Therapixel
- TPS/CadOne
- VuComp
- Volpara (breast density integration)

With changes in labelling, and new (e.g., AI) systems, the usage may be somewhat different – e.g., the CAD can be used to drive the workflow (e.g., as described for iCAD and ScreenPoint in 5.1.6). With these new mechanisms, an additional concept is introduced – “implicit” and “explicit” decision support. This concept refers to how the mouse actions are interpreted. Implicit mode is when there is no assigned function to the left-mouse (e.g., the action was reset), and when this is the case and the underlying case contains decision support data, that mechanism is invoked, and the display updated accordingly (e.g., to display a region marker, scroll a tomosynthesis stack, etc). On the other hand, “explicit” mode refers to when the mouse action is explicitly assigned to “decision support” (one of the tools that can be displayed on the viewport drop-down

menu). If explicit mode is enabled, then the underlying decision support interaction only occurs when the user clicks when this tool is active.

Depending on the vendor, only “explicit” may be supported. For example, for DeepLook, a probe and display of generated overlay information only occurs in explicit mode (and provided DeepLook is installed and available):



In this scenario a menu is displayed once a region is found, allowing detailed examination of the region edge and contours. The axes and metrics can be displayed, and the shape retained as user markup (so this becomes a short-cut to generate a free-hand shape).

6.6. Mouse

Mouse wheel scroll up or down action causes the underlying image to be zoomed out or in, centered to the viewport. Dragging both left and right mouse buttons together causes the underlying image to be zoomed out or in, while maintaining alignment of the chest-wall side of the mammograms.

Based on the user selection (see section 6.2), dragging the left mouse button causes one of the following interactions with the underlying image or markup graphic:

- Free-hand markup
- Ellipse markup
- Rectangle markup
- Arrow markup
- Line measurement
- User annotation
- Cross correlation
- Edit or pan graphic
- Pan synchronized
- Pan one

- Zoom synchronized
- Zoom one
- Window synchronized
- Window one
- Probe
- Scroll synchronized
- Scroll one

When the magnify glass or dual magnify glass is active, dragging the left mouse button inside the magnify glass viewport causes it to roam around the screen.

When the “Key (Quality) Notes” menu item is selected, clicking and dragging the left mouse button within the title bar of the “Key Notes for Quality Check” window causes the window to move and its contents to be updated to reflect the contents of the current viewport. Once the mouse is released, the parameters can be manually checked and manually corrected if needed.

When the “Assess this Markup or CAD Mark” menu item is selected, clicking and dragging the left mouse button within the image shown in the finding assessment window causes the window to move, so that a different finding or CAD mark can be viewed for continued assessment as needed.

Based on the user configuration (see section 8.5 - Key Code Configuration), dragging the right mouse button causes one of the following interactions with the underlying image or markup graphic:

- ROI graphic (free-hand markup)
- Ellipse graphic (ellipse markup)
- Rectangle graphic (rectangle markup)
- Arrow graphic (arrow markup)
- Line graphic (line measurement)
- Edit graphic (edit or pan graphic)
- Pan All (pan synchronized)
- Pan One (pan one)
- Zoom All (zoom synchronized)
- Zoom One (zoom one)
- Window All (window synchronized)
- Window One (window one)
- Probe Pixel (probe)
- Scroll All (scroll synchronized)
- Scroll One (scroll one)

Inside the magnifying glass, the right mouse button is dedicated to adjusting the window width and level within the magnify glass image.

A programmable mouse is recommended to enhance the reading workflow. For example, it is convenient to map the mouse programmable “back” button to emit the keystroke assignment “Left” for backward stepping and map the mouse programmable “forward” button to emit the keystroke assignment “Right” for forward stepping. The

middle button on the mouse is convenient for opening the magnify-glass which is achieved by mapping the key code “Ctrl+M” to this programmable button.



6.7. Keypad

Almost all functionality of WorkstationOne can be accessed through short-cut key codes, allowing a commercial or custom keypad to be programmed to work with WorkstationOne. However, the combination of a programmable mouse (see above) and easy access all user-configured hanging protocols on the screen, typically renders a keypad as unnecessary. Another disadvantage of a keypad is that it takes up more desk space since typically there is a standard keyboard with each workstation.

If a keypad is desirable for a user, one can be setup using the supported key mappings. For example, the following picture shows an example of a keypad which has been programmed to match the default viewing sequence configuration:



When selecting a commercial keypad, keep the following considerations in mind:

- ergonomic factor

- scroll wheel
- number of programmable keys
- backlit for use in a dark room
- wrist pad
- user profile and application profile

6.8. Keyboard shortcuts

Keyboard shortcuts are provided for commonly used navigation actions and tools.

Top-level action keys are:

Action	Keyboard Shortcut
Exit from WorkstationOne	Ctrl+Alt+E
Display the user settings dialog	Ctrl+Alt+C
Display the user manual (in externally configured viewer)	Ctrl+Alt+M

The following table lists the keys for workflow navigation:

Action	Keyboard Shortcut
Can be configured to navigate forward one step in the hanging protocol, or to move right one grid in the 1:1 pixel viewing step.	“→” (right arrow)
Can be configured to navigate backwards one step in the hanging protocol, or to move left one grid in the 1:1 pixel viewing step. Can be used to close/hide the following dialog windows: QR window; import window, worklist detail window and all popup dialogs.	“←” (left arrow)
Can be configured to correspond to the “mouse wheel up” action or navigation to the previous prior study, or to navigate forward one step in the hanging protocol	↑ (up arrow)
Can be configured to correspond to the “mouse wheel down” action or navigation to the next prior study, or to navigate backwards one step in the hanging protocol	↓ (down arrow)
Can be configured to navigate forward one step in the hanging protocol, or to navigate backwards one step in the hanging protocol	spacebar
Mark the current case complete and close it	Ctrl+C
Re-open the current case	Ctrl+O
Open next patient case	Ctrl+P
Go to Overview Step	Ctrl+1

Go to Current Step	Ctrl+2
Go to Compare Step	Ctrl+3
Go to Systematic Viewing Step	Ctrl+4
Go to All-Pixels Viewing Step	Ctrl+5
Go to Report Step	Ctrl+6
Bilateral MLO layout, displaying prior RMLO and LMLO images	Ctrl+7
Bilateral CC layout, displaying prior RCC and LCC images	Ctrl+8
Bilateral MLO layout, displaying current RMLO and LMLO images	Ctrl+9
Bilateral CC layout, displaying current RCC and LCC images	Ctrl+0

The following table shows the shortcuts available for various tools:

Action or Tool	Keyboard Shortcut
Can be used to close/hide the following dialog windows: QR window; import window, worklist detail window and all popup dialogs.	ESC
When CAD is displayed on tomo images, this key jumps from one mark to the next (across frames, and across images). This is supported for CAD tomo reports from iCAD, ScreenPoint and DeepHealth.	TAB
Reset W/L and image size	F1
Toggle through W/L tool options	F2
Toggle “invert” tool on/off	F3
Toggle through image size tool options	F4
Toggle annotations on/off	F5
Toggle calipers on/off	F6
Toggle markups on/off	F7
Toggle CAD marks and CAD detail on/off	F8
In the reporting step, display the Recall Form	F9
In the systematic viewing step, toggle the mask on/off	F10
In the all pixels viewing step, switch between the two viewports	F10
In the reporting step, display the Screen Report	F10
Toggle date/view annotation on/off	F11
Toggle GSPS graphic overlay on/off	F12

Arrow shape graphic drawing	Ctrl+A
Rectangle (box) shape graphic drawing	Ctrl+B
Display dual magnifying glasses	Ctrl+D
Ellipse shape graphic drawing	Ctrl+E
Finding assessment or detailed CAD information	Ctrl+F
Pan one image	Ctrl+G
Pan all images	Ctrl+H
Flip image around the vertical axis	Ctrl+I
Save All Markup as GSPS	Ctrl+J
Mark Key Image	Ctrl+K
Line shape graphic drawing	Ctrl+L
Display the magnifying glass	Ctrl+M
Key (Quality) Notes	Ctrl+N
Probe Pixel Value	Ctrl+Q
Free-hand ROI graphic drawing	Ctrl-R
Enter the mode where a graphic can be modified (moved or resized) using the left mouse button	Ctrl+S
Display Tabar masks on a pair of images	Ctrl+T
Remove one (user-drawn) graphic	Ctrl+U or Delete key
Remove all (user-drawn) graphics on an image	Ctrl+V
Change W/L of images in all viewports	Ctrl+W
Change W/L of image in current viewport	Ctrl+X
Zoom one image	Ctrl+Y
Zoom all images	Ctrl+Z
Blank a viewport	Alt+Del
User text annotation	Alt+A
Cine display DBT one viewport	Alt+B
Cine display DBT all viewports	Alt+C
Trigger dictation of the current case (if configured)	Alt+D
CAD Finding assessment	Alt+F
Save image in a viewport as DICOM SC	Alt+I
Save image in a viewport as JPEG	Alt+J
Toggle from normal view to large view	Alt+L

Toggle from large view to normal view	Alt+N
Cross reference graphic drawing	Alt+O
Open film printing dialog	Alt+P
Reset mouse cursor	Alt+R
Scroll DBT images in all viewports	Alt+S
Scroll DBT one images in one viewport	Alt+T
DICOM print of one viewport	Alt+V
Change W/L of all images in the study containing the image in the current viewport	Alt+W
Change W/L of the image displayed in the current viewport no matter where it is (also or later) displayed	Alt+X
Copy the current image to the Windows clipboard (to allow paste into an external tool)	Alt+Z
Decision Support explicit mode	Ctrl+Shift+D
Custom key-code I, which can be mapped to any key action (or keystroke assignment)	Ctrl+Shift+1
Custom key-code I, which can be mapped to any key action (or keystroke assignment)	Ctrl+Shift+2

The use of the control key modifier can be configured so that the short-cuts can be invoked using a single key. However, if the system is configured to enable a barcode reader to open studies, the control key modifier must be present to use the short-cut keys in the above table.

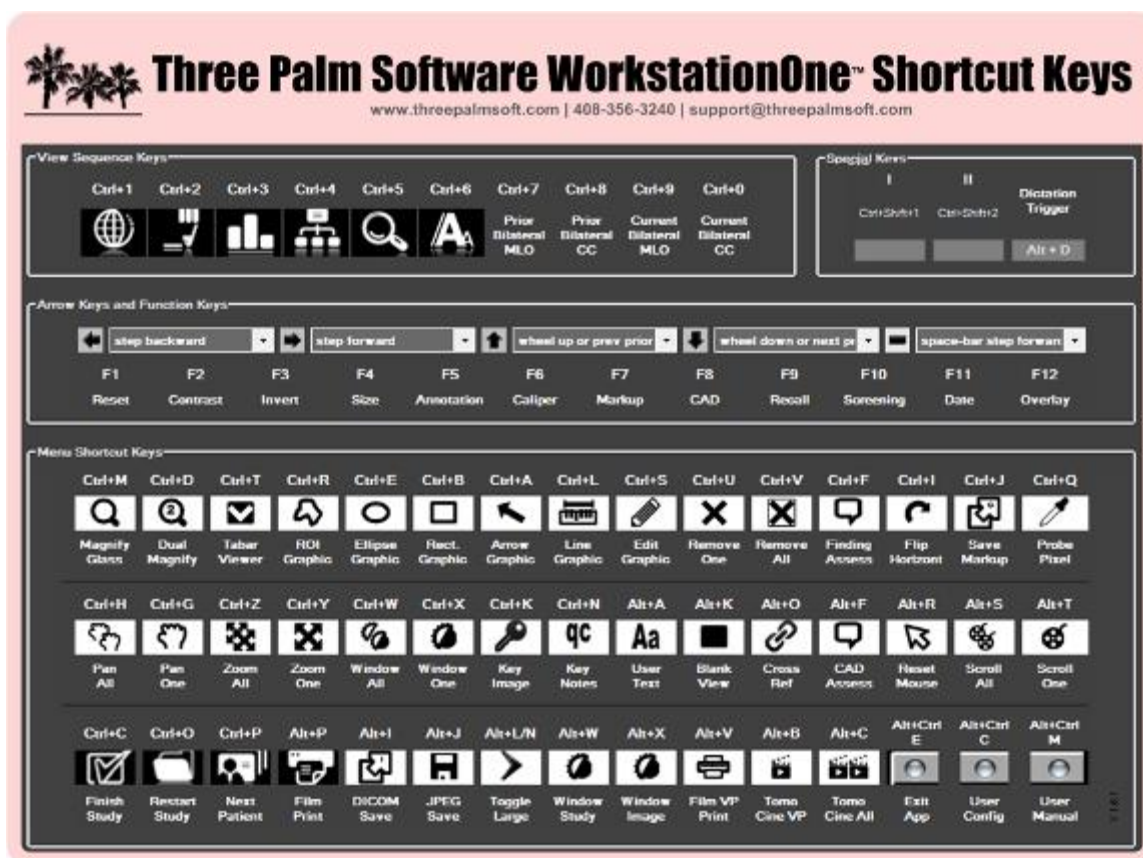
When a barcode reader is configured (on the “Key Codes” tab of the configuration dialog), and if a barcode reader is attached to the system as a “keyboard wedge”, then the codes from the barcode can be configured to open the corresponding case. The barcode corresponds to the patient ID, or if that doesn’t match, the alternate patient ID (ID2).

When the use of the control key modifier is not disabled, the number keys can be used by themselves in specific contexts to achieve additional actions:

Action	Keyboard Shortcut
In the report step, sets the BI-RADS value to zero	0
In the overall step, sets the breast density to the first category, and in the report step, sets the BI-RADS value to one	1
In the overall step, sets the breast density to the second category, and in the report step, sets the BI-RADS value to two	2

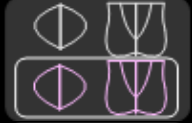
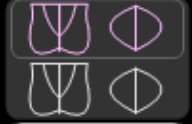
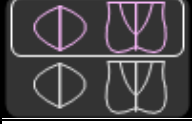
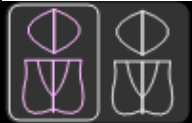
In the overall step, sets the breast density to the third category, and in the report step, sets the BI-RADS value to three	3
In the overall step, sets the breast density to the fourth category, and in the report step, sets the BI-RADS value to four	4
In the report step, sets the BI-RADS value to five	5
In the report step, sets the BI-RADS value to six	6

The key codes can be found on the “Key Codes” tab of the configuration window (see section 8.5), and they are also available on a custom mouse-pad (see below). Please contact support@threepalmsoft.com to obtain a copy of the mouse-pad.



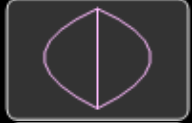
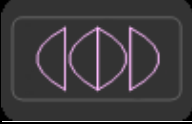
The following key codes are defined for directly accessing each hanging protocol. For the “overview” hanging protocols, the mappings are:

Hanging protocol	Keyboard Shortcut
	Ctrl+Alt+1

	8 viewports arranged in 2 rows, current study in the lower row and a corresponding prior in the upper row – CC images on the left side	Ctrl+Alt+2
	8 viewports arranged in 2 rows, current study in the upper row and a corresponding prior in the lower row – MLO images on the left side	Ctrl+Alt+3
	8 viewports arranged in 2 rows, current study in the upper row and a corresponding prior in the lower row – CC images on the left side	Ctrl+Alt+4
	8 viewports arranged in 2 rows, current study in the left 2 columns and a corresponding prior in the right 2 columns – MLO images in the upper row	Ctrl+Alt+5
	8 viewports arranged in 2 rows, current study in the left 2 columns and a corresponding prior in the right 2 columns – CC images in the upper row	Ctrl+Alt+6
	8 viewports arranged in 2 rows, current study in the middle 2 columns and a corresponding prior in the outer 2 columns – MLO images in the upper row	Ctrl+Alt+7
	8 viewports arranged in 2 rows, current study in the middle 2 columns and a corresponding prior in the outer 2 columns – CC images in the upper row	Ctrl+Alt+8
	8 viewports arranged in a single row, current study in the middle 4 columns and a corresponding prior study arranged in the outer 2 left and right columns – MLO images to the left	Ctrl+Alt+9
	8 viewports arranged in a single row, current study in the middle 4 columns and a corresponding prior study arranged in the outer 2 left and right columns – CC images to the left	Ctrl+Alt+0

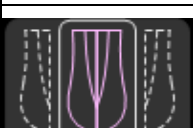
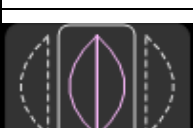
For the “current” hanging protocols, the mappings are:

Hanging protocol		Keyboard Shortcut
	Bilateral MLO layout, displaying current RMLO and LMLO images	Ctrl+9

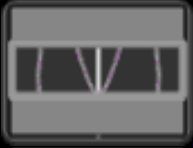
	Bilateral CC layout, displaying current RCC and LCC images	Ctrl+0
	2 viewports in a single row, Left images from the current study - MLO image on the left and CC image on the right	Ctrl+Alt+A
	2 viewports in a single row, Left images from the current study - CC image on the left and MLO image on the right	Ctrl+Alt+B
	2 viewports in a single row, Right images from the current study - MLO image on the left and CC image on the right	Ctrl+Alt+D
	2 viewports in a single row, Right images from the current study - CC image on the left and MLO image on the right	Ctrl+Alt+F
	4 viewports in a single row, bilateral MLO on the left, bilateral CC on the right.	Ctrl+Alt+X
	4 viewports in a single row, bilateral CC on the left, bilateral MLO on the right.	Ctrl+Alt+Y
	4 viewports containing MLO views in a single row, fanning layout.	Ctrl+Shift+A
	4 viewports containing CC views in a single row, fanning layout.	Ctrl+Shift+B

For the “comparison” hanging protocols, the mappings are:

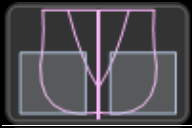
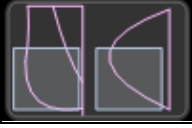
Hanging protocol		Keyboard Shortcut
	2 viewports in a single row, containing the Right MLO current image on the left viewport, and a corresponding prior on the right viewport	Ctrl+Alt+G
	2 viewports in a single row, containing the Right CC current image on the left viewport, and a corresponding prior on the right viewport	Ctrl+Alt+H

	2 viewports in a single row, containing the Left MLO current image on the left viewport, and a corresponding prior on the right viewport	Ctrl+Alt+I
	2 viewports in a single row, containing the Left CC current image on the left viewport, and a corresponding prior on the right viewport	Ctrl+Alt+J
	4 viewports in a single row, containing the Right images, MLO current and a corresponding prior on the left, CC current and a corresponding prior on the right	Ctrl+Alt+K
	4 viewports in a single row, containing the Left images, MLO current and a corresponding prior on the left, CC current and a corresponding prior on the right	Ctrl+Alt+L
	4 viewports in a single row, containing the MLO images, current study in the middle two viewports, and a corresponding prior pair in the outer two viewports	Ctrl+Alt+N
	4 viewports in a single row, containing the CC images, current study in the middle two viewports, and a corresponding prior pair in the outer two viewports	Ctrl+Alt+O

For the “systematic masking” hanging protocols, the mappings are:

Hanging protocol		Keyboard Shortcut
	2 viewports in a single row, containing the MLO images – oblique mask applied	Ctrl+Alt+P
	2 viewports in a single row, containing the MLO images – horizontal mask applied	Ctrl+Alt+Q
	2 viewports in a single row, containing the CC images – horizontal mask applied	Ctrl+Alt+R
	2 viewports in a single row, containing the CC images – vertical mask applied	Ctrl+Alt+S

For the “all pixel” hanging protocols, the mappings are:

Hanging protocol		Keyboard Shortcut
	2 viewports in a single row, containing the MLO images	Ctrl+Alt+T
	2 viewports in a single row, containing the CC images	Ctrl+Alt+U
	2 viewports in a single row, containing the Left (MLO + CC) images	Ctrl+Alt+V
	2 viewports in a single row, containing the Right (MLO + CC) images	Ctrl+Alt+W

For the “report” hanging protocols, the mappings are:

Hanging protocol		Keyboard Shortcut
	4 viewports in a single row, with the MLO images on the left.	Ctrl+Alt+X
	4 viewports in a single row, with the CC images on the left.	Ctrl+Alt+Y
	4 viewports arranged 2x2, with the MLO on the top row.	Ctrl+Alt+Z
	4 viewports arranged 2x2, with the CC on the top row.	Alt+O

The following mappings are available for the “diagnostic” hanging protocols:

Hanging protocol		Keyboard Shortcut
	4 viewports in a single row showing Right MLO images – current in the left-most viewport and up to 3 corresponding prior images to the right of that	Alt+E
	4 viewports in a single row showing Right CC images – current in the left-most viewport and up to 3 corresponding prior images to the right of that	Alt+G

	4 viewports in a single row showing Left MLO images – current in the left-most viewport and up to 3 corresponding prior images to the right of that	Alt+H
	4 viewports in a single row showing Left CC images – current in the left-most viewport and up to 3 corresponding prior images to the right of that	Alt+K
	4 viewports in a single row showing Right MLO images – current in the right-most viewport and up to 3 corresponding prior images to the left of that	Alt+M
	4 viewports in a single row showing Right CC images – current in the right-most viewport and up to 3 corresponding prior images to the left of that	Alt+Q
	4 viewports in a single row showing Left MLO images – current in the right-most viewport and up to 3 corresponding prior images to the left of that	Alt+U
	4 viewports in a single row showing Left CC images – current in the right-most viewport and up to 3 corresponding prior images to the left of that	Alt+Y
	8 viewports arranged in two rows, showing Right images – MLO in the upper row, and CC in the lower row, and current images in the left-most column and up to 3 corresponding prior sets in the columns to the right of that	Alt+1
	8 viewports arranged in two rows, showing Left images – MLO in the upper row, and CC in the lower row, and current images in the left-most column and up to 3 corresponding prior sets in the columns to the right of that	Alt+2
	8 viewports arranged in two rows, showing Right images – CC in the upper row, and MLO in the lower row, and current images in the left-most column and up to 3 corresponding prior sets in the columns to the right of that	Alt+3
	8 viewports arranged in two rows, showing Left images – CC in the upper row, and MLO in the lower row, and current images in the left-most column and up to 3 corresponding prior sets in the columns to the right of that	Alt+4

	8 viewports arranged in two rows, showing Right images – MLO in the upper row, and CC in the lower row, and current images in the right-most column and up to 3 corresponding prior sets in the columns to the left of that	Alt+5
	8 viewports arranged in two rows, showing Left images – MLO in the upper row, and CC in the lower row, and current images in the right-most column and up to 3 corresponding prior sets in the columns to the left of that	Alt+6
	8 viewports arranged in two rows, showing Right images – CC in the upper row, and MLO in the lower row, and current images in the right-most column and up to 3 corresponding prior sets in the columns to the left of that	Alt+7
	8 viewports arranged in two rows, showing Left images – CC in the upper row, and MLO in the lower row, and current images in the right-most column and up to 3 corresponding prior sets in the columns to the left of that	Alt+8

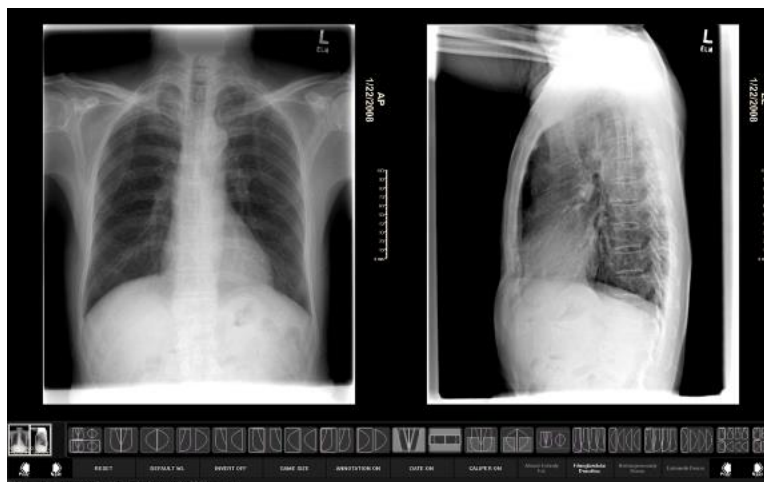
The following is an example where a sub-set of the hanging protocols and tool icons has been programmed on a commercial keypad with TPS customized icon stickers:



7. Viewing other images and reports

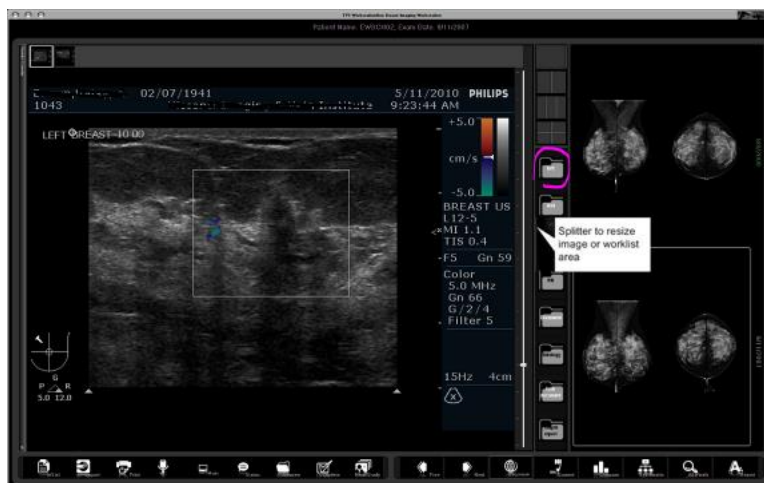
7.1. Viewing digital X-ray (DX or CR) images

When DX or CR images are part of the study, then they can be displayed on the main display using a 1x2 layout. All images are shown in the thumbnail icons and can be dragged and dropped into the main display. The workflow can be configured to include systematic viewing masks.

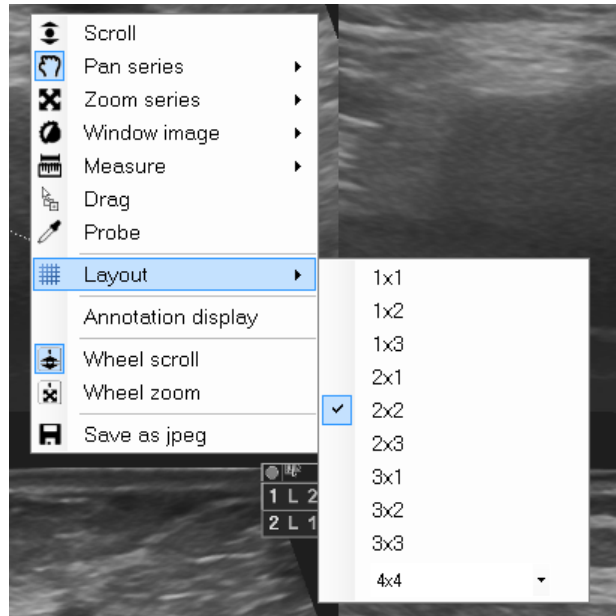


7.2. Viewing ultrasound images

When ultrasound images are available, the “U/S” folder icon is high-lighted, and the ultrasound images can be accessed by selecting that icon. A list of thumbnail ultrasound images is then displayed, and an ultrasound image or a series or a stack of multi-frame ultrasound images can be displayed by selecting its thumbnail:



The image area can be resized by dragging the splitter along the side of the viewport. This viewer has a right-click menu with several common tools:



Where:

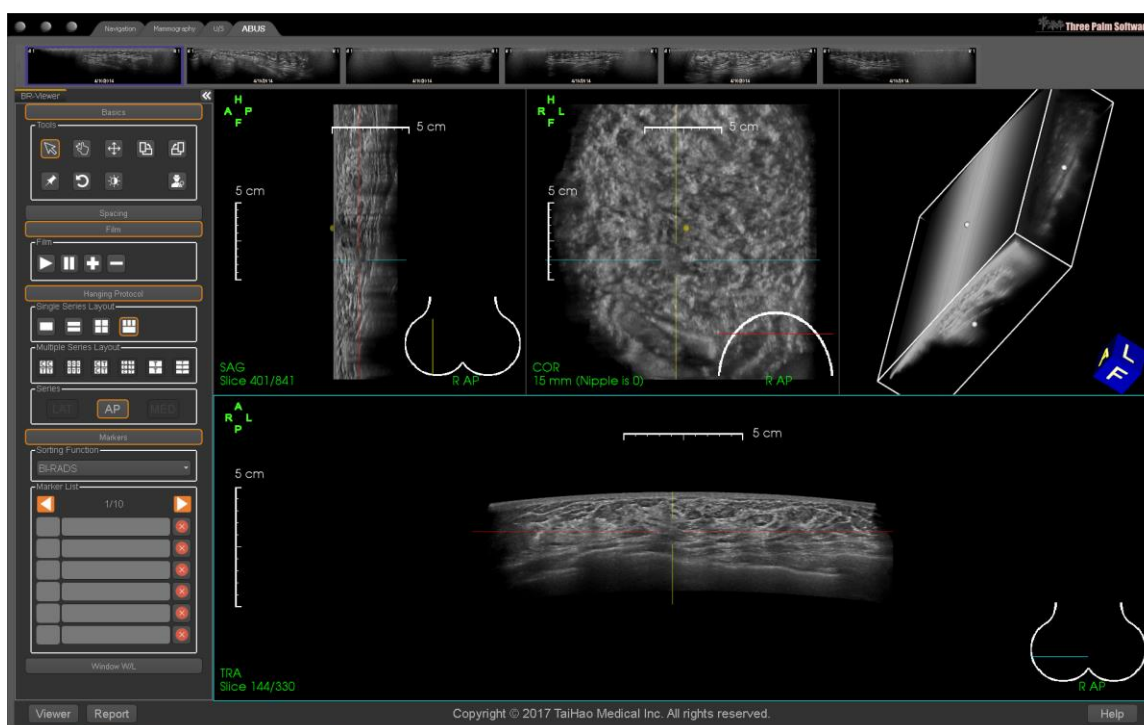
- Selection of the “Scroll” menu item causes the images to be scrolled when the left button is pressed and moved vertically. This is the same as the slider bar on the right, but if the viewport contains a multi-frame image, then that is scrolled first.
- The “Pan”, “Zoom” and “Window” can be scoped to affect the image or series. Once any of those options is selected, the mouse left-drag performs that action.
- The “Measure” option puts the left-mouse into a mode where an interactive ruler is shown as the mouse is clicked and dragged over an image. Note that the measurement graphic uses the same line drawing parameters as measurements on the main screen (see 8.4 to configure these). Linear measurement is displayed in units of “mm” if the image header contains suitable size information, but if that is not found, then the units are shows as pixels.
- When the “Drag” option is active, a left click and drag from that viewport results in the image being dragged. The drag destination (drop) can be an area on the image screens, if the settings are such that the destination viewport accepts any source, and it can also be a box in the print layout (generalized print model).
- The “Probe” option puts the left mouse drag into a mode where the image pixel value is shown interactively at the mouse position.
- The “Layout” option provides the ability to change the internal layout (when the images are organized by series) from 1x1 to 2x1, etc. as is convenient for the user. Note that this mechanism is in addition to the multi-modality layout (see below in section 7.14).
- The “Annotation display” option shows and hides the overlay text in the corner of the images.
- The “Wheel scroll” and “Wheel zoom” items control whether the mouse wheel is to be interpreted as a scroll action, or as an image zoom operation.

- “Save as jpeg” saves the current image (as displayed) to a file that the user specifies.

User menu selections are automatically saved and restored whenever this viewer is active.

7.3. Viewing 3D breast ultrasound images

The standard plugin for ultrasound images (see section 7.2) displays images from automated 3D breast ultrasounds systems – as multi-frame with a slider so that all frames can be scrolled, and any image viewed. However, if there is a need for 3D analysis (MPR, 3D rendering, lesion characterization, etc.) then a specialized package is needed for the task. WorkstationOne does not provide such a package by default, but it does include a plugin wrapper for one such application – “BR-Viewer” from “TaiHao Medical Inc”. The standard install includes this plugin (wrapper), but the application must be purchased separately. If this plugin and the application have been configured, then a viewer (here named “ABUS”) is available – either in the plugin area, or on a dedicated tab. When running on a separate tab, this looks like:



Contact Three Palm Software for more information on this capability (including the user manual for BR-Viewer).

7.4. Viewing magnetic resonance images

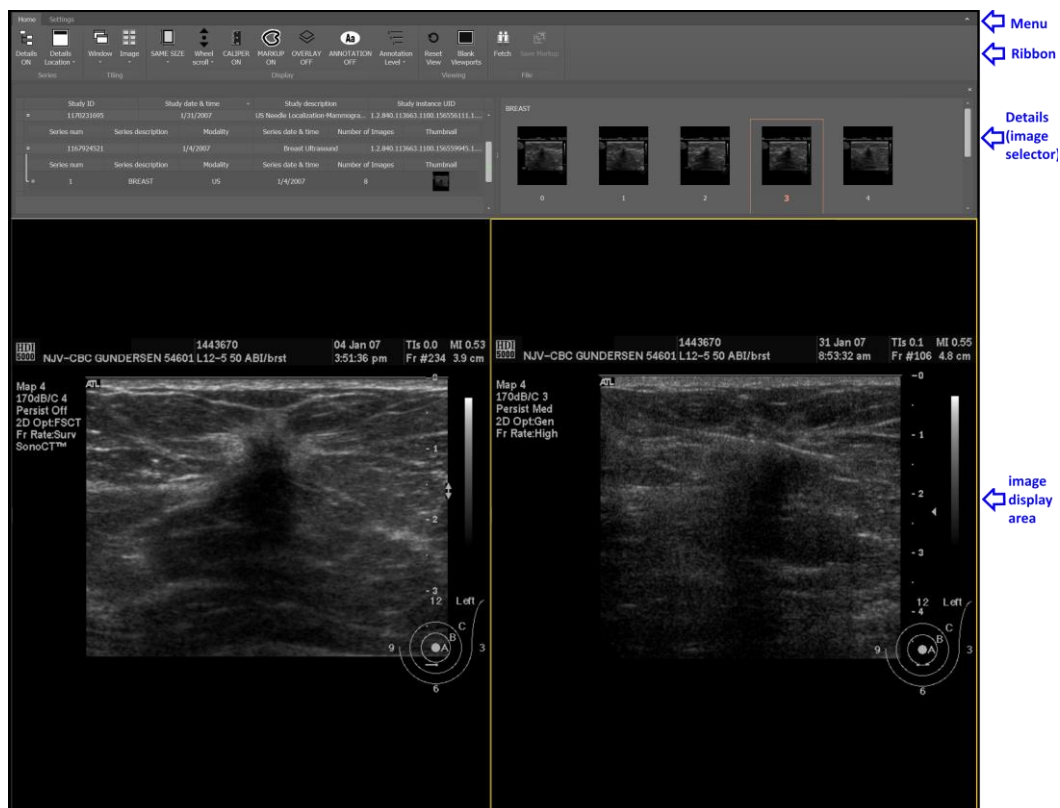
When Magnetic Resonance (MR) images are available, the “MRI” folder icon is highlighted, and the MR images can be accessed by selecting that icon. A thumbnail list of the MR series is then displayed. Each MR series is opened by selecting its thumbnail (see the following figure), and the images in the series can be scrolled through using the vertical scroll bar which is displayed at the side of the image.



This viewer has the same right-click menu as described above for the Ultrasound viewer.

7.5. Comparing images between modalities or studies

When the “compare” plugin is configured, it appears in the plugin area (or a separate tab, depending on the system configuration), and is enabled when specific modalities are present in the case that is being viewed. For example, it may be configured to be enabled when there are ultrasound or MRI images. When this plugin is open, it then provides mechanisms to select images for comparison – across modalities (e.g., mammography images compared with ultrasound), and across studies and series.



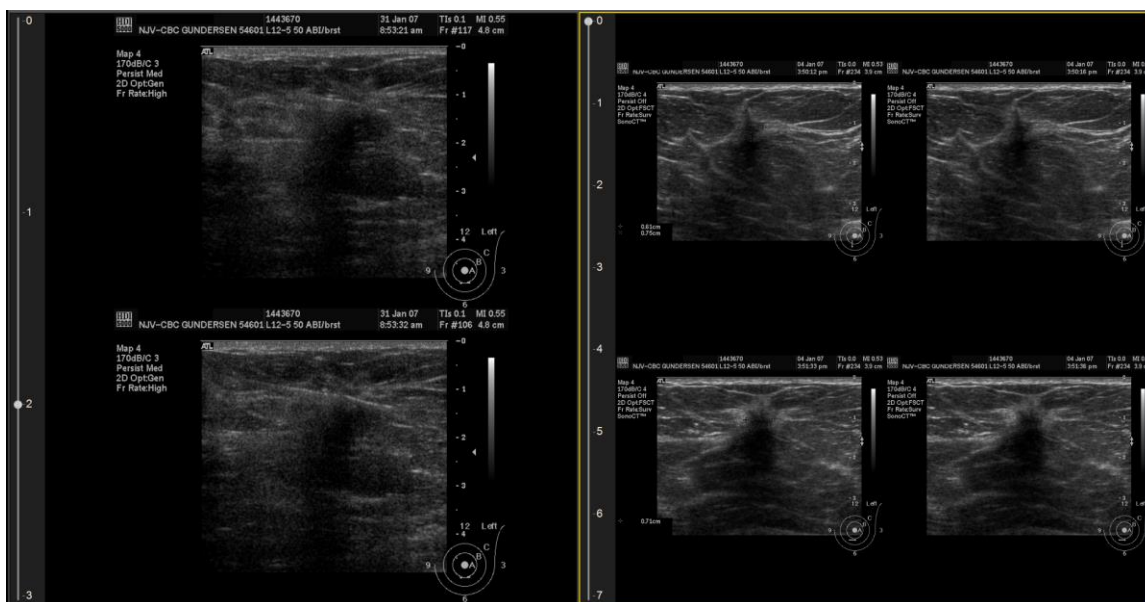
The user interface of the Compare plugin is divided into 4 main regions:

- Menu – this is always visible at the top of the plugin and is used to control the other regions.
- Ribbon – this appears dynamically under the menu whenever a top-level menu item is selected. The ribbon can remain displayed (click the pushpin in its lower right corner) or forcibly collapsed (push the “^” shown in the lower right corner when the ribbon is pinned).
- Details – this area appears when the button “Details” is clicked to “ON”. This region can be resized – vertically using a splitter at its lower edge, and the left and right sides of the region can be partitioned using a center splitter. This area can be hidden again by clicking the first button to show “Details OFF” or by clicking the “x” at the upper right of the area.
- Image display area – this fills the remainder of the plugin area, and its size is controlled by the above (ribbon visibility and the “details” visibility and size).

Control of the viewer is via:

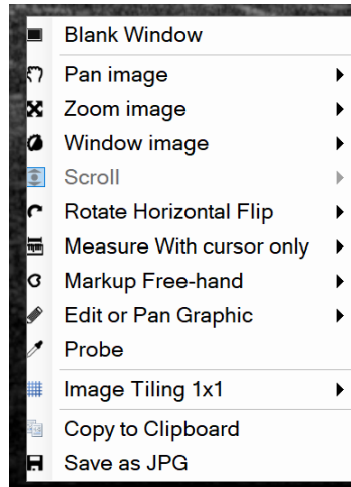
- Menu and ribbon to select options.
- Details view to select studies, series, and images to display – they are dragged to one of the areas in the lower image display region to be displayed.
- A right-click menu within each viewport (i.e., on the image) can be used to select specific tools.

The key concept for the display is that there is a “window” layout, and within each window there is an “image” layout – these concepts are controlled using the “Tiling” section of the “Home” ribbon:

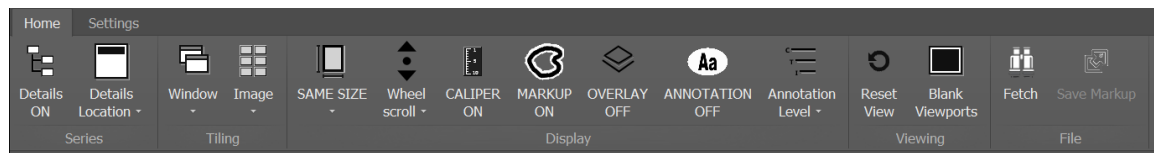


Which shows a study from one date on the left (2 of 4 images displayed), and on the right the images from another date (4 displayed at a time). The different windows can contain different modalities, so for example, it is possible to compare mammography images with corresponding ultrasound images side by side.

Detailed functionality includes a subset of the mechanisms that are available on the image screens for mammography:

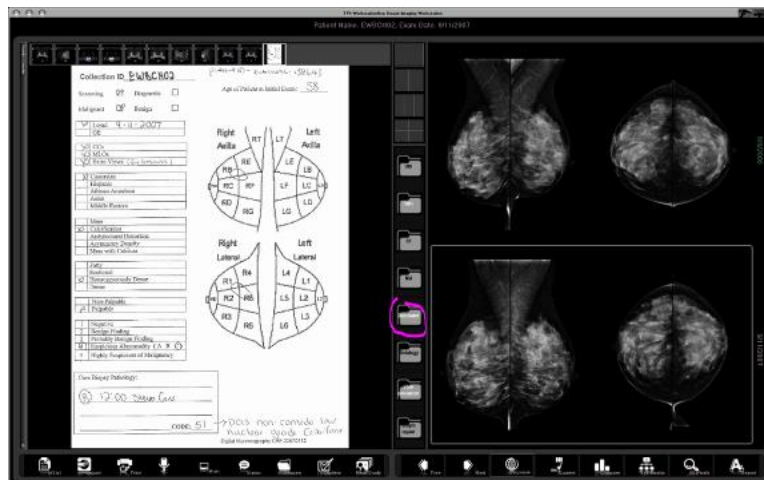


With the functions matching the similarly named items on the image screens. Key functions (such as sizing, scroll actions, toggling elements of the UI on and off) are available as buttons on the toolbar:



7.6. Viewing SC documents

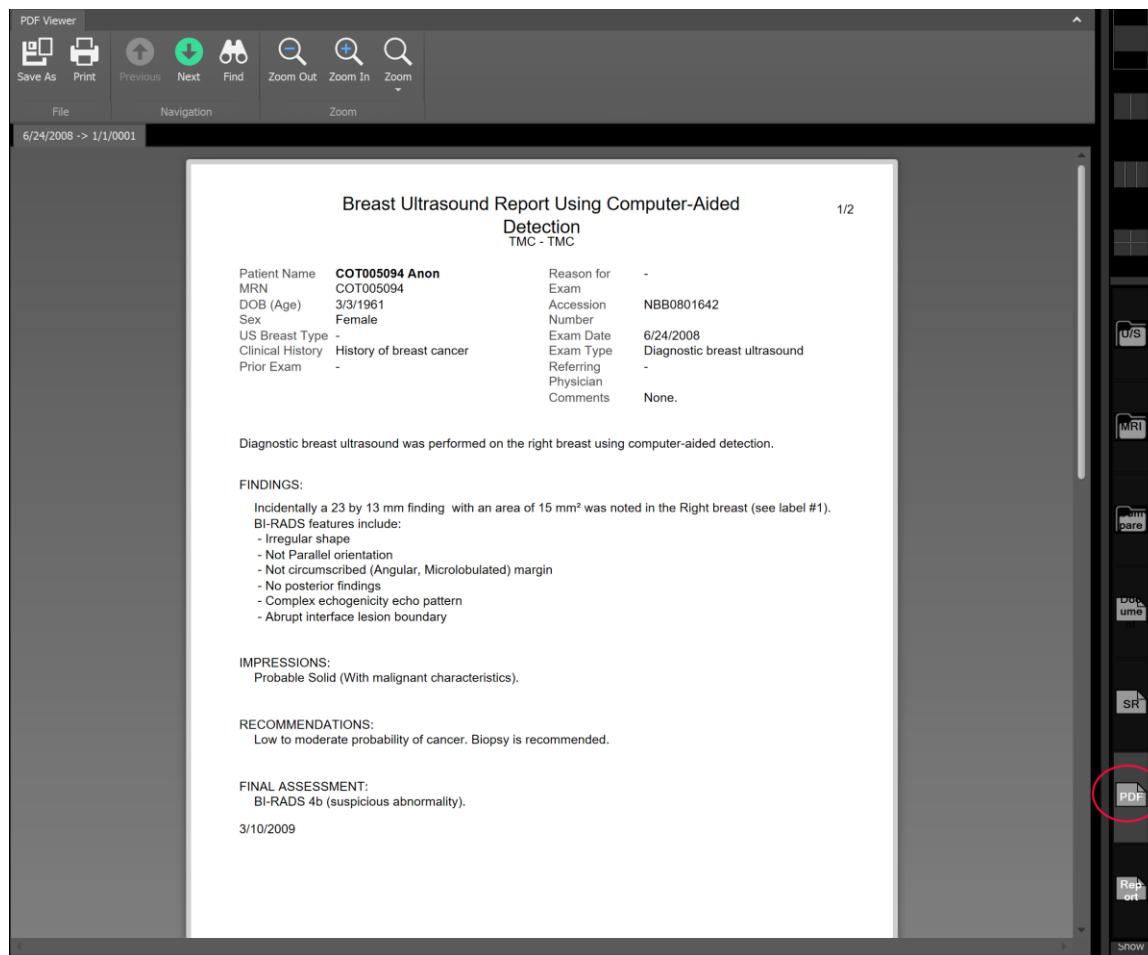
Documents (such as previous reports or referring physicians' letters) stored as DICOM Secondary Capture (SC) can be viewed on the screen displaying the worklist (see the following figure). When documents are available, the "Document" folder icon is highlighted, and the documents can be accessed by selecting that icon.



This viewer has the same right-click menu as described above for the Ultrasound viewer.

7.7. Viewing DICOM encapsulated PDF documents

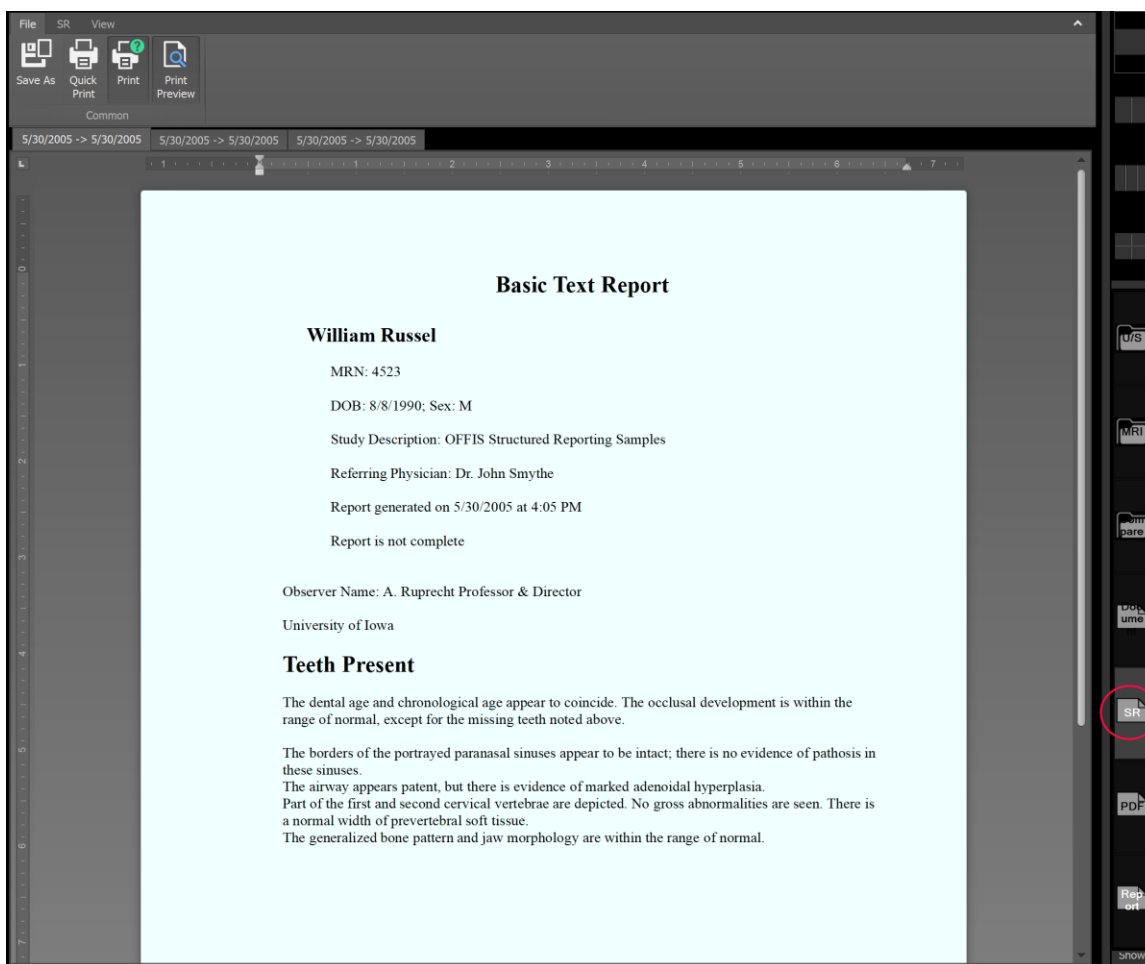
Documents stored in DICOM as encapsulated PDF can be brought to the system and displayed in the corresponding plugin viewer. The presence of such documents can be checked in the worklist when the “PDF” column is configured to be displayed. Such documents are then displayed in the PDF plugin (if it is configured at this site):



When there are multiple PDF documents, each is shown as its own tab. Hovering the mouse over a tab causes the display of a small popup that shows more details about the document displayed on that tab. The menu and (collapsible) ribbon at the top of the viewer provide options for displaying and saving the documents. The displayed document can be saved as a regular pdf file, and the document can be sent to any Windows printer. Controls also allow searching of the document and zooming to view the text larger.

7.8. Viewing text reports encoded in SR

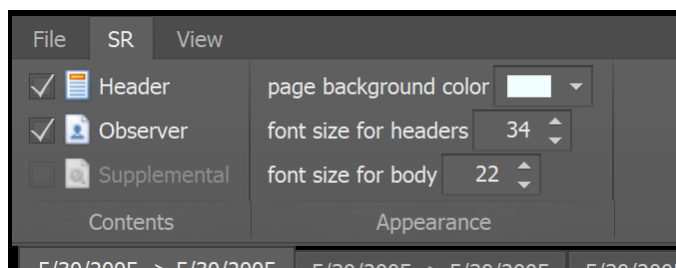
Documents stored as DICOM structured reports (chiefly “basic text”) can be brought to the system and displayed in the corresponding plugin viewer:



The presence of such documents is indicated by a >0 count in the “SR” column of the worklist. When there are multiple SR documents, each is shown as its own tab. Hovering the mouse over a tab causes the display of a small popup that shows more details about the document displayed on that tab. The menu and (collapsible) ribbon at the top of the viewer provide options for displaying and saving the documents.

This viewer interprets the DICOM “Breast Imaging Report”, “Diagnostic Imaging Report” and “X-Ray Radiation Dose Report” templates and formats those appropriately. Other basic and enhanced text reports are displayed, but their formatting may not be as clean.

The “SR” menu and ribbon has options:



Which exposes some functionality – e.g., to turn on and off the display of the DICOM header information (patient identification, study information, etc) and to display the

detailed observer information (identity of the reviewer, as encoded), and even to display the raw data (called “supplemental”) that is stored in the SR.

The “File” menu and ribbon provide mechanisms to print the displayed document (to any Windows printer) and to save it externally (in various standard formats).

7.9. Generating reports and letters

WorkstationOne supports several ways to generate reports, including integration with external reporting systems. For sites generating reports and letters directly within WorkstationOne, the recommended mechanism for this is the “plugin” Reporting module. This has functionality that subsumes that previously available through the dedicated “recall” and “screening” reports, and the “simple report generator” that some sites used via the “dictation trigger” mechanism. While those mechanisms are still supported, it is recommended that the plugin Reporting mechanism be used.

Note that while this Reporting plugin can meet a site’s needs for reporting, it does not address “tracking” – there is no database of cases read, or built-in mechanisms for patient scheduling.

7.9.1. Theory of operation

Reporting is a WorkstationOne plugin – i.e., it can be configured to occupy the region on the navigation screen where the worklist is typically shown. This is an optional item, and there can be more than one reporting plugin – so that the user can edit more than one type of report at the same time.

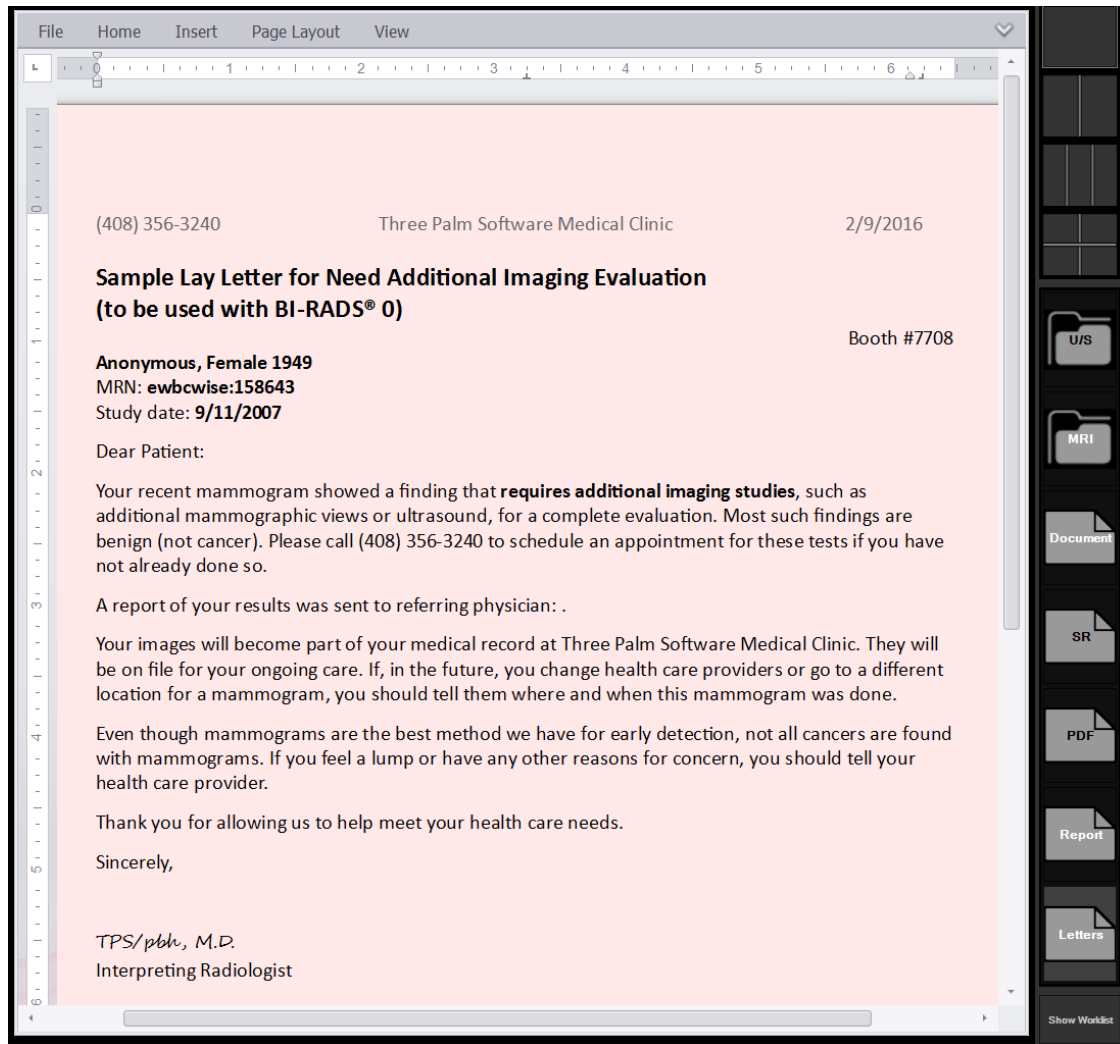
As a plugin, the reporting mechanism obtains information from the case that is currently open – simple text information such as the patient ID and name, but also information that is generated as part of the review (such as the BIRADS score, etc.), and it can include images (with markup, etc.) as screen captures inserted into the document.

The input to the report is a template – a “RTF” format document (like a Microsoft Word document) that includes replaceable fields (called “tokens”). Each token is delineated by “[[” and “]]”. When the report is opened for editing, the template is placed into the viewer, and each token is replaced by the corresponding information from the current case. Text in the document can be edited (using the keyboard or even dictation, if so configured), with the token contents replaceable at any time until the report is saved.

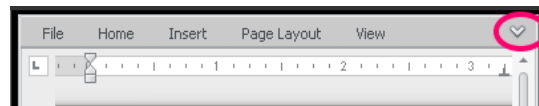
The output from the plugin can be configured to be saved locally as “rtf” files, and it can go to any DICOM destination in a format such as SC (secondary capture), encapsulated PDF, and SR (structured report). The output can also be configured to be sent via email as either a picture or PDF attachment. The use of DICOM and email means that a site can employ this reporting mechanism without external support (except perhaps a PACS, so that reports are archived for future years).

7.9.2. User interface

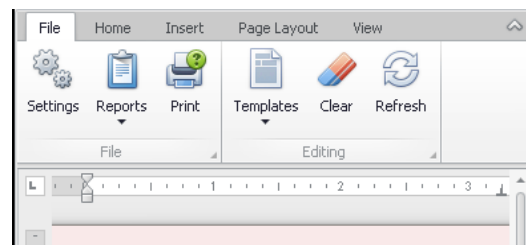
When active, the reporting plugin looks like:



Where the plugin icons (folder or paper icon) indicate which plugins are active (text highlighted) and displayed (light background). The displayed plugin occupies the worklist region (or a sub-region with the layout buttons). The reporting plugin displays a menu bar at the top, along with a “drop-down” button which enables show/hide of the ribbon menus:



Clicking to expand the ribbon shows:



Each of the top-level menu options (File, Home, Insert, etc.) shows different tools on the ribbon, so sophisticated editing can be achieved by switching menus (much like in

Microsoft Word). The “File” menu has the key actions for reporting (formatting functions are on the other menus). The key reporting actions on this ribbon are:

- **Settings:** this button displays a dialog of settings that are specific to this user (more information below).
- **Reports:** this drop-down shows a list of all reports that have previously been saved locally for the current case, plus the one currently being edited. Selecting a report from the list results in it being shown in the editor (in read-only mode if it is an old report).
- **Print:** this button brings up a standard Windows print dialog, allowing the currently displayed report (old or new) to be printed.
- **Templates:** this drop-down shows a list of all available templates (those in the configured shared template folder plus any local ones defined by this user). The default templates (see below) have a check-mark next to them, and the currently active one is highlighted. Clicking any template in the list switches the current report to that template. Switching templates results in the template default text being displayed, with all replaceable tokens evaluated.
- **Clear:** this button reverts the report to a blank. A blank report is not saved, so this is a way to prevent saving of a report, even when the system is configured to save it automatically.
- **Refresh:** this button causes the current report to be refreshed with any updated token values. Any text typed into the report is retained, but all tokens (text and thumbnail images) are updated to the values as of this point in time. This is particularly useful if the report is in progress, but another markup is needed, or a change in a measurement such as breast density is needed – clicking this button updates the report based on whatever is set elsewhere on the UI.



7.9.3. Templates

When WorkstationOne is installed, several templates are also placed on the machine, for use within the reporting plugin. Those templates are stored under the WorkstationOne\Config\templates folder, and organized into the following 4 folders:

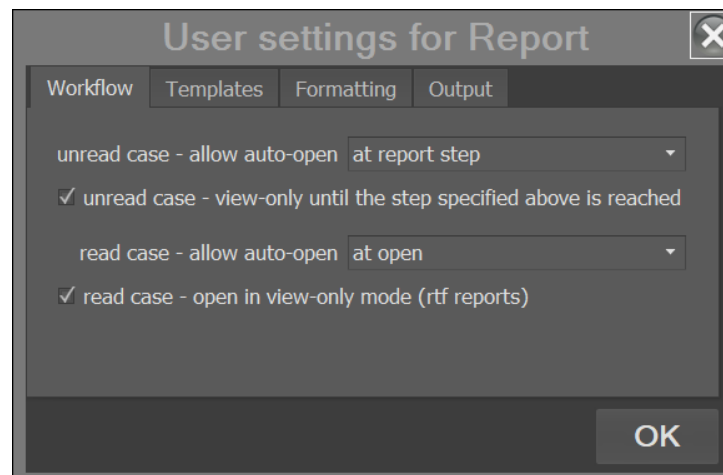
- Letter templates mammo – lay letter templates for mammography, based on the ACR templates:
 - BIRADS 0
 - BIRADS 1-2 (dense)
 - BIRADS 1-2 with signs (dense)
 - BIRADS 1-2 with signs
 - BIRADS 1-2
 - BIRADS 3
 - BIRADS 4-5
 - BIRADS 6
 - Checklist Letter (dense)
 - Checklist Letter

- Letter templates ultrasound – equivalent letter templates for ultrasound:
 - US BIRADS 0
 - US BIRADS 1-2 (dense)
 - US BIRADS 1-2 with signs (dense)
 - US BIRADS 1-2 with signs
 - US BIRADS 1-2
 - US BIRADS 3
 - US BIRADS 4-5
 - US BIRADS 6
 - US Checklist Letter (dense)
 - US Checklist Letter
- Misc. examples
 - RecallForm_Spanish
- Reports – these templates are typically used for internal reports (not intended for lay distribution):
 - Diagnostic
 - Findings
 - Negative
 - RecallForm
 - ScreeningForm

A given reporting instance will typically be configured to use one of these folders (e.g., “reports”), and augmented with any templates that the user copies and customizes or generates from scratch (stored in a folder that the user specifies).

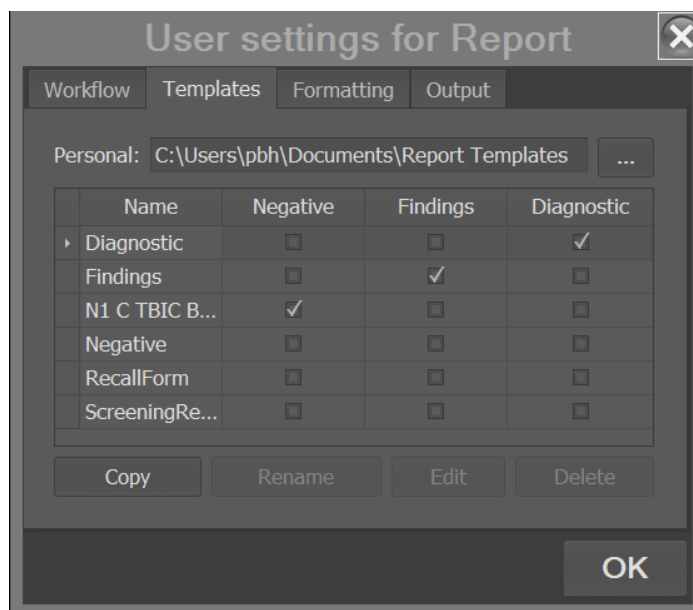
7.9.4. User options

When the settings button is clicked, the user settings dialog is displayed:



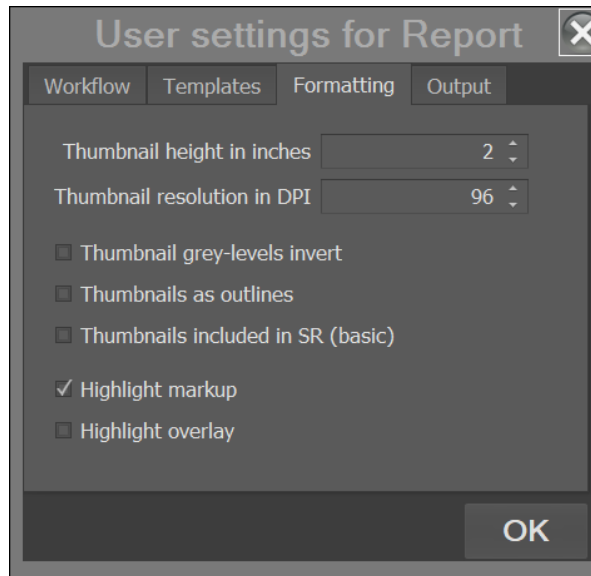
Which allows the user to customize the behavior of the reporting mechanism – with all settings specific to this user and this editor (so if there are two editors configured, each can have its own user settings). The settings are organized as:

- **Workflow:** this tab controls how the editor acts as part of the reading workflow. The key concept here is when the editor should auto-open (become visible, if the worklist is set to auto-collapse). This is separately settable for unread cases and already read (complete/recall) cases. Typically, (the default) the report is not auto-opened until the report step, so that the user reads the case as normal, and then views/edits the report at the last step in the workflow.
- **Templates:** this tab shows all available templates for this editor – those specified at the system level (configured by service personnel), and any custom user templates (in a separate local folder):



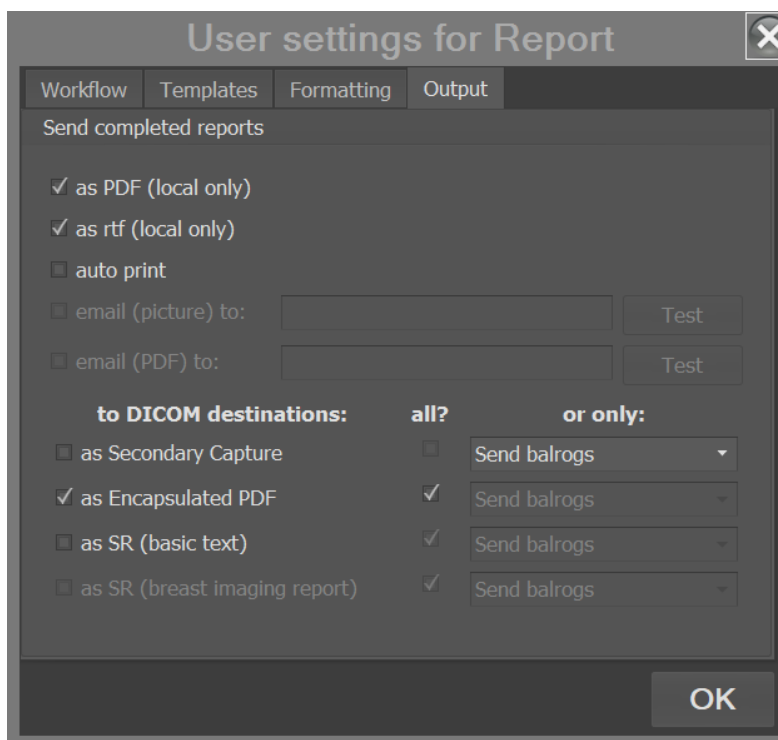
Templates can be copied, renamed, and edited, and the default template specified for cases that are negative, with findings, or diagnostic. The use of the template editor is described below, but this allows complete customization of the templates (along with information on the supported replaceable tokens).

- **Formatting:** this tab has formatting options that control the size and resolution of any thumbnails that are included in reports:



The option “grey-levels invert” inverts the image (including the background) when the thumbnail is an image (rather than an outline). The “thumbnails as outlines” option results in the border of the tissue being displayed (rather than a grey-scale version of the image), with any markup superimposed. When the option “Thumbnails included in SR (basic)” is checked, icons of the captured views (as used in the current template), are placed into the SR, so that a receiver can use both the text and thumbnails in the formatting of its report. The two “highlight” options control whether any markup and overlay (saved, displayed markup) is highlighted with a thick colored line, prior to capture and insertion into the report (this helps visibility of those items in the thumbnails).

- Output: this tab allows the user to determine which formats are to be saved, and where each should be sent:



The default is to send the generated report as encapsulated PDF, and to send it to all configured DICOM destinations. However, it is possible to save any combination of DICOM formats (SC, encapsulated PDF and SR) and to send each to a specific destination or to all destinations.

For email destinations, the “to” address is specified here, with the shared email parameters for the logged in user being set on the “connectivity” tab of the user settings (see 8.6). An email destination can only be selected if the shared parameters have already been configured.

The two “local only” options save the report in non-DICOM formats (PDF and RTF) on the local disk (the root folder for those files is specified via the service tool app-config).

The “auto print” option causes the report to be sent to the “default printer” on the current workstation – i.e., this is managed via the Windows “Printers & scanners” settings.

7.9.5. Template editor

Clicking the “Edit” button on the templates tab (it is enabled for user templates), results in the display of a template editor:



7.9.6. Template tokens

Tokens appear in the template

- Abnormality (1)

- Accession or AccessionNumber (2)
- AcquisitionDate (2)
- BIRADS (1)
- BreastDensityAssessment (1)
- FindingLocation (1)
- FindingSide (1)
- FindingType (1)
- Institution or InstitutionName (3)
- InstitutionAddress (3)
- InstitutionTelephone (3)
- ListPriorStudyDate (2)
- PatientAge (2)
- PatientDOB (2)

- PatientID (2)
- PatientName (2)
- PrimaryInstitution (2)
- PriorStudyDate (2)
- ProcedureReason (2)
- Reader (3)
- RecallProcedure (1)
- RecallReason (1)
- ReferringPhysician (2)
- StudyReason (2)
- Thumbnail_n (2) - where “n” is 1, 2, 3 ... – the thumbnail for the “nth” image displayed on the main screen, counting current study first, left to right.
- TodayDate (date report generated)
- Xpath:... (advanced option to retrieve any information from the internal XML report format).

Where information is obtained from:

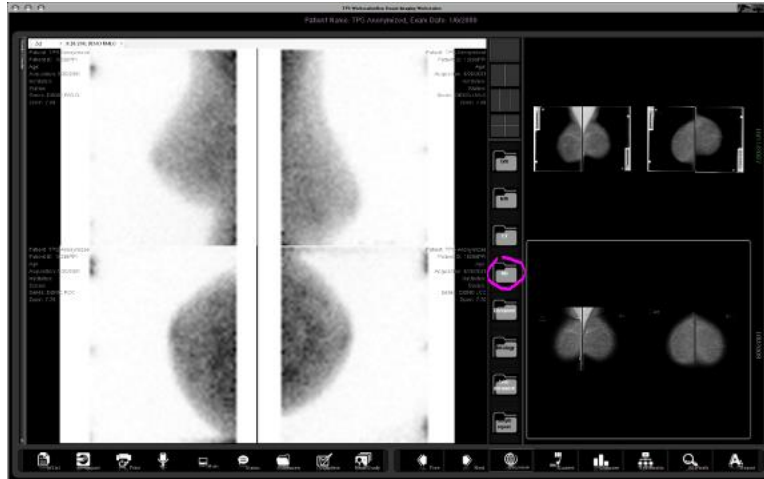
- 1) reporting information entered by the user during reading.
- 2) the source data.
- 3) system configuration.

7.9.7. Service configuration

The Reporting plugin is included with all installs, but it is made available as a service (site) configuration. Multiple instances of the Reporting mechanism can be setup – e.g., one with the **patient letter** templates the site wants to use, and another with the **report** templates that the site wants to use. Site settings include the locations of the shared templates, for which modalities the plugin(s) should be active, and where to store any locally saved documents.

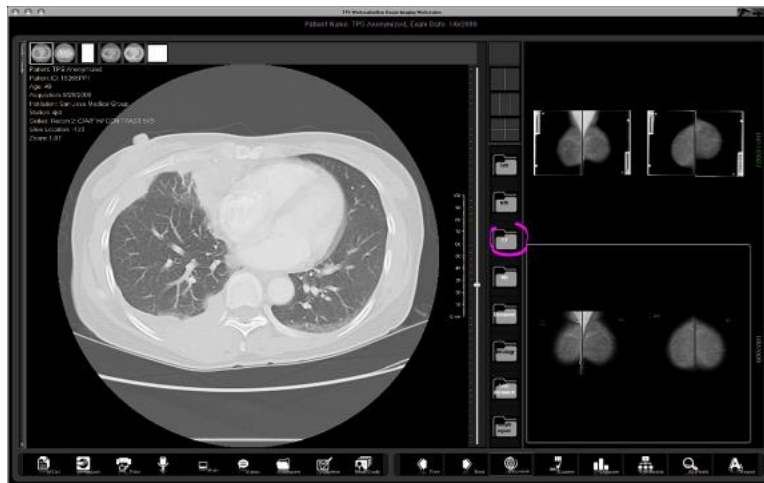
7.10. Viewing nuclear medicine images

When Nuclear Medicine (NM) images are available, the “NM” folder icon is high-lighted, and the NM images can be accessed by selecting that icon. A list of the HPs (hanging protocols) is then displayed. Each HP is displayed by selecting its layout menu item (such as, 2x2, see the following figure). This viewport has a right-click menu. Selection of the “Scroll” menu item causes the images to be scrolled through when the left button is pressed and moved vertically.



7.11. Viewing computed tomography images

When Computed Tomography (CT) images are available, the “CT” folder icon is highlighted, and the CT images can be accessed by selecting that icon. A thumbnail list of the CT series is then displayed. Each CT series is opened by selecting its thumbnail (see the following figure), and the images in the series can be scrolled through using the vertical scroll bar which is displayed at the side of the image.



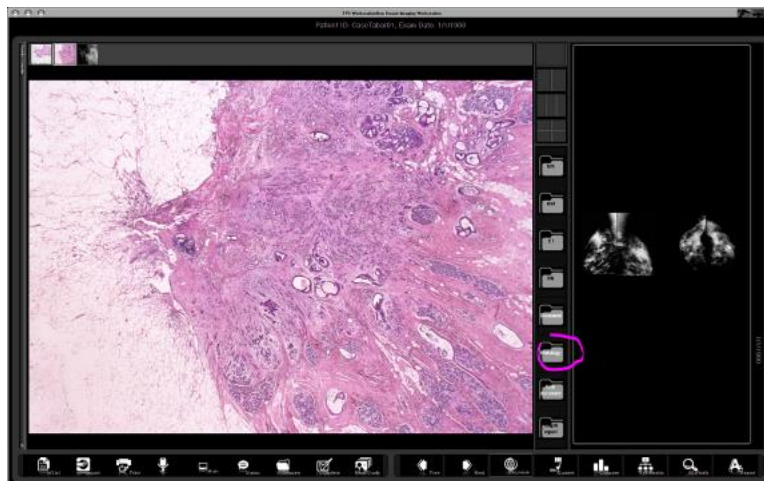
This viewport has the same right-click menu as described above for the Ultrasound viewer.

7.12. Viewing positron emission tomography images

When Positron Emission Tomography (PET) images are available, the “PET” folder icon is highlighted, and the PET images can be accessed by selecting that icon. A thumbnail list of the PET series is then displayed. Each PET series is opened by selecting its thumbnail, and the images in the series can be scrolled through using the vertical scroll bar which is displayed at the side of the image. This viewport has a right-click menu. Selection of the “Scroll” menu item causes the images to be scrolled through when the left button is pressed and moved vertically.

7.13. Viewing pathology images

Pathology images are currently stored in a custom format. When those images are available, the “Histology” folder icon is high-lighted, and the images or reports can be accessed by selecting that icon as shown in the following figure:



This viewer has the same right-click menu as described above for the Ultrasound viewer.

7.14. Multiple viewer layout

If configured, plugin viewers can be displayed on their own tab (see section 3). In addition, viewers can share the area on the navigation screen that is also used by the worklist. That area can be divided so that multiple viewers can be active at the same time. There are four different layouts supported for the simultaneous display of images from multiple modalities. The layouts include: 1x1; 1x2; 1x3 and 2x2, as shown in the following figure. In this example, the layout 1x2 is selected and the Ultrasound images and the MRI images are being viewed side-by-side. When the “Rotate Layout” checkbox is checked, two additional layouts are available: 2x1 and 3x1.



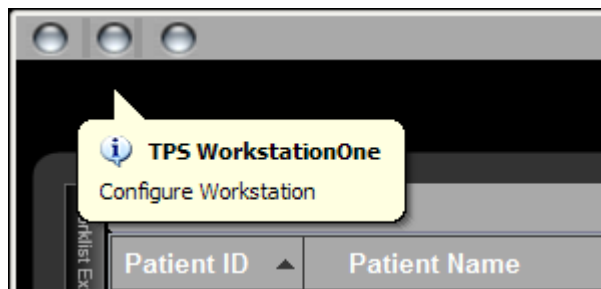
Any modality folder icon can be dragged and dropped into any viewport of the selected layout. For example, to display two series of ultrasound images side-by-side and two series of MRI images side-by-side on the same screen, select the 2x2 layout and then

drag the U/S icon to the two left viewports and drag the MRI icon to the two right viewports.



8. Configuration options

WorkstationOne allows the site and user to set preferences to optimize the use of the workstation. The user configuration options are accessed by selecting the middle round button in the upper left-hand corner of the screen:

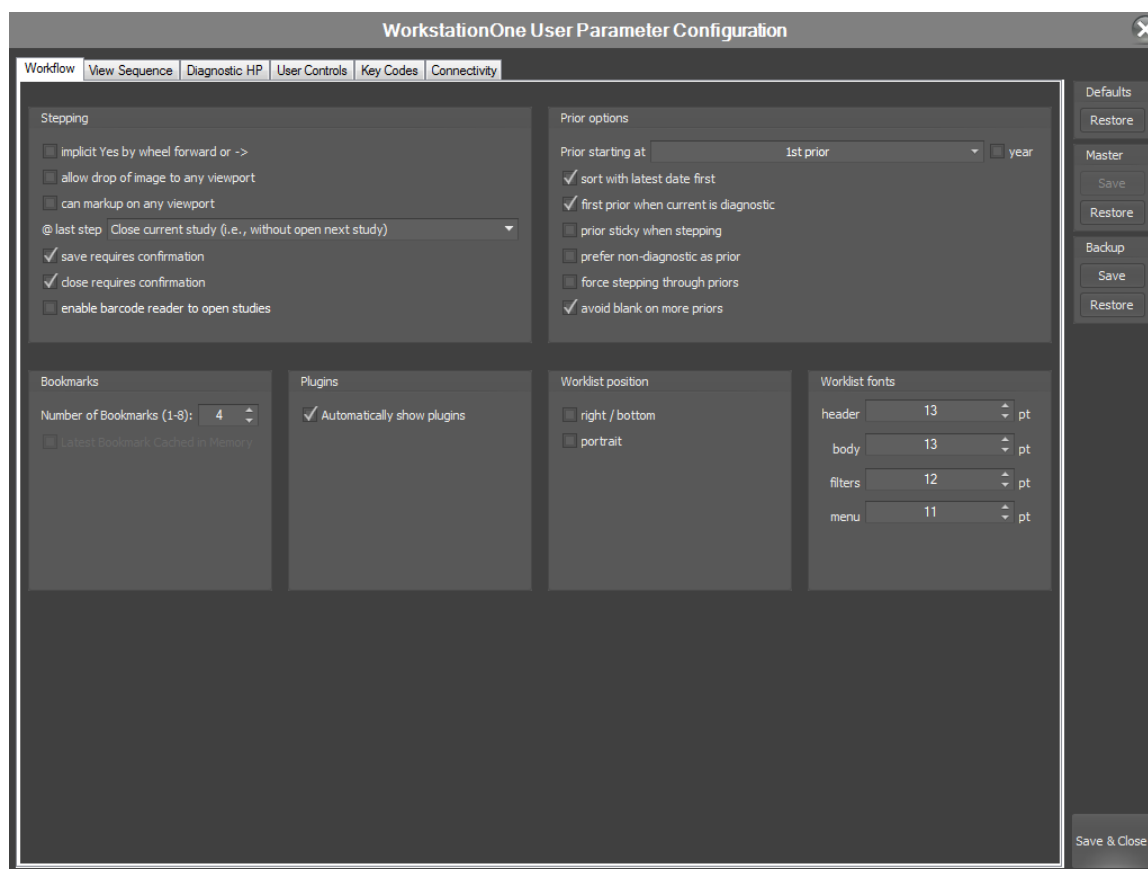


The user is then presented with configuration panels for “Workflow”, “View Sequence”, “Diagnostic HP”, “User Controls”, “Key Code”, and “Connectivity”.

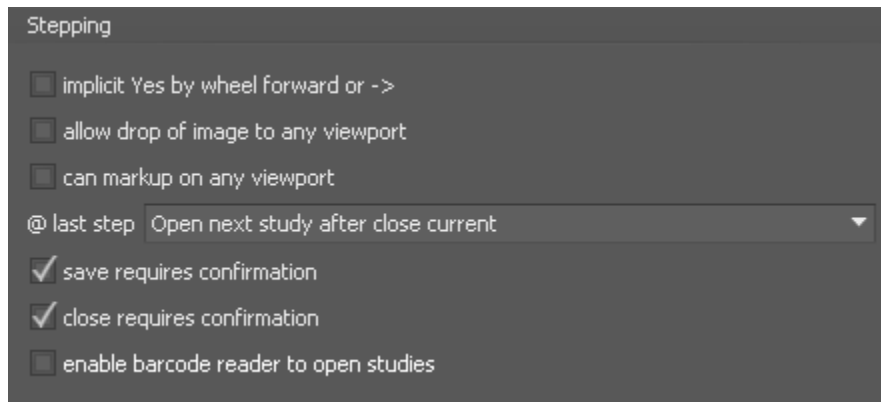
The short-cut key combination “Alt + Ctrl + C” can also be used to access the configuration panels.

8.1. Workflow configuration

The workflow configuration panel allows the user to select some high-level options for the workflow, with details specified on the following “view sequence” and “diagnostic HP” tabs.



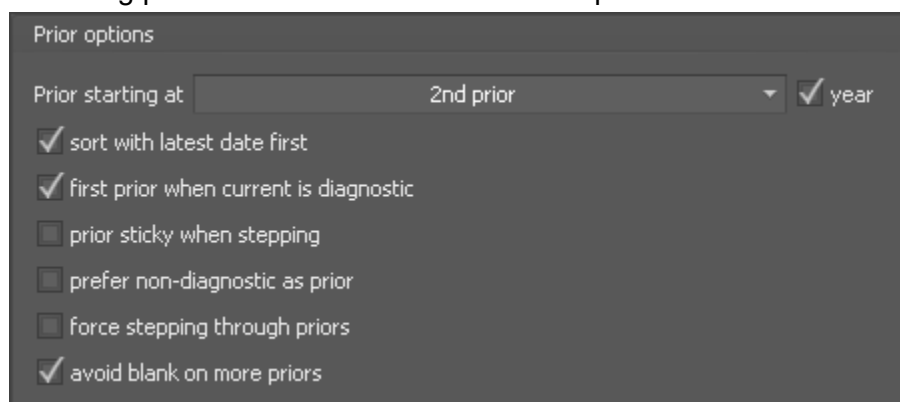
The “stepping” options are:



where

- The option “implicit Yes by wheel forward or ->” controls whether to automatically or implicitly click the “Yes” button in a popup window when using the mouse wheel forward action or the right arrow key.
- When the checkbox “Allow drop of image to any viewport” is checked, the thumbnail images can be dragged and dropped to any viewport regardless of whether the current and prior images are matched with the viewports that are dedicated to current or prior images. When unchecked (the default), the user is prevented from dropping a prior image into a viewport assigned to the current study, and a current image into a viewport assigned to the prior studies.
- When the checkbox “Can markup on any viewport” is checked, a markup can be drawn on any image, regardless of whether that image is considered to belong to a current or prior study. When unchecked (the default), the user is prevented (warning dialog) from drawing markup on prior images.
- The option “@ last step” controls whether to automatically open the next patient’s studies after the last viewing step of the current patient.
- When the option “save requires confirmation” is checked (the default), completion of a read with information to be saved (markup, reports, etc.) requires an explicit acknowledgement (via a dialog) in order to continue. If this option is unchecked, then the save is implicitly assumed to be agreed, but there is still a close dialog if the option “close requires confirmation” is checked.
- When the option “close requires confirmation” is checked (the default) completion of a read requires an explicit acknowledgement (via a dialog) for the action to occur. If this option is unchecked, then close is implicitly assumed to be agreed, but there is still a close dialog if the option “save requires confirmation” is checked and there is information to save.
- Checking the option “Enable barcode” allows the use of a barcode reader (configured as a keyboard entry device) to trigger the opening of a corresponding case. The case to be opened is identified by its corresponding “Patient ID” or “Patient ID2”, with the contents of ID2 being configured for the site. The barcode mechanism can also strip fixed leading characters from the barcode (this is a site configuration setting). Use of the barcode option requires use of the “Ctrl” modifier for the menu short-cuts (see section 8.5).

Options for viewing prior studies are set on the “Prior options” area:



Where:

- When there is more than 1 prior study, it is configurable which prior is displayed first (using the drop-down menu “Prior Starting at”).
- The prior to be displayed first can be configured to be the one closest to the Nth year (when check the checkbox “year”) or the Nth prior in the sorted list of the prior studies (uncheck the checkbox “year”).
- By default, prior studies can be sorted latest first (by checking the checkbox “sort with latest date first”) or last (i.e., uncheck this checkbox).
- By default, when a case is diagnostic (see 5.3), the default prior is determined to be the first (option “first prior when current is diagnostic” checked) – ignoring the “prior starting at”.
- When the option “prior sticky when stepping” option is checked, manual changes of the prior (e.g., using the “more priors button”) make the selected prior the default for this case until it is closed. Opening the next case reverts the prior select to the configured default.
- When the “prefer non-diagnostic as prior” is checked, then the system attempts to ignore prior studies that are classed as “diagnostic” (see 5.3), when determining the default prior for a case.
- The option “force stepping through priors” changes the behavior of the “overview” and “compare” steps, so they step through a separately configured number of prior studies. When this option is not checked, the user is not forced to view the priors as part of the stepping; however, the user can still see any priors using the “more priors” button that is automatically displayed in this mode
- The option “avoid blank on more priors” allows a prior to be skipped when the “more priors” button is used, when there is no view in the prior study matching the currently displayed current study images.

The number of bookmark folders can be configured, and the number can be set from 1 to 8. The latest bookmark can be cached in the memory if its checkbox is checked (this option is not currently supported).

By using the checkbox “Automatically show plugins”, the worklist can be configured to automatically collapse so the area can be used to display multi-modality images (plugin viewers for other modalities, including the Reporting plugin).

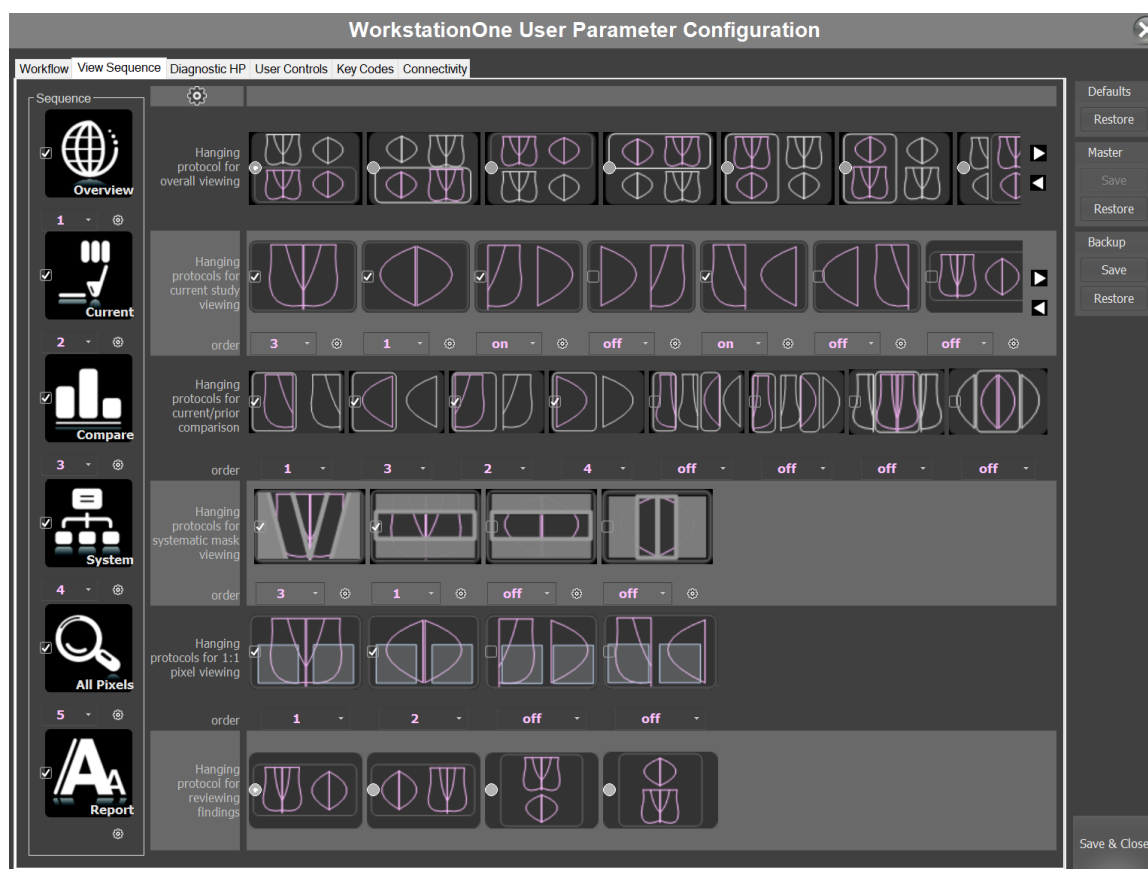
The area “Worklist position” is used to configure whether to display the worklist on the left (default) or right-hand side of the navigation screen, or to layout the navigation

screen for a portrait monitor (in which case the default worklist position is at the top, and the “right/bottom” checkbox allows it to be switched to the lower part of the screen in portrait mode).

The size of the text used in the worklist can be configured using the settings in the “Worklist fonts” section. The header text (patient name title, etc.), filters, as well as the right-click menu and the text in the body of the list can be independently set to the desired sizes. The default sizes are 13 point for the header and body, and 12 and 11 point for the filters and menu respectively.

8.2. View sequence configuration

The view sequence configuration panel allows the user to identify which of the reading workflow steps (described in section 5) the user wants to include in their review protocol, and to select preferences for each step. Any changes to the view sequence configuration settings take effect when the next image is loaded.



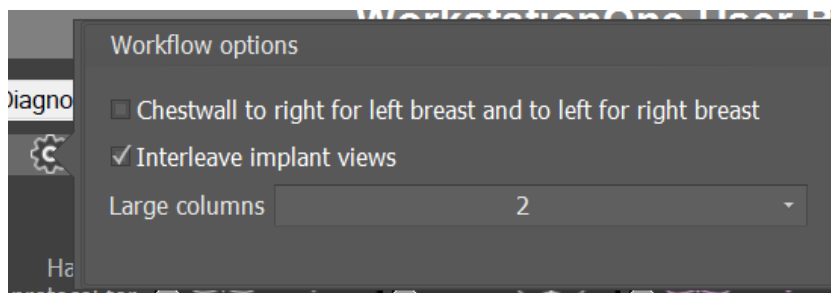
Ordering

Selecting the steps to include in the reading workflow is achieved by clicking a checkbox (using the left mouse button) next to the “Sequence” steps on the left-hand side of the view sequence configuration panel. By default, all the steps are included (“checked”) in the reading protocol. The order of the steps (except the Report step) can be changed using the drop-down box below each step icon. Each step’s order selection can be one of: off, 1, 2, 3, 4 or 5.

A similar concept is used for ordering hanging protocols with each step (if there is more than one HP in a step). When a view (HP) with a step is selected in the order drop-down box as “off” or “on”, the corresponding hanging protocol will not be used in the view sequence steps; however, if it is set to “on” (rather than a number); the corresponding hanging protocol icon will be displayed on the main screen for easy access by the user (just click it to jump to that HP).

Overall settings for workflow

At the top of this tab is a “gear” icon that sets some properties for all steps:



When the checkbox “Chestwall to right for left breast and to left for right breast” is checked, all bilateral views in the above hanging protocols are switched between right and left views; and each view is flipped so the chest-wall of the left breast is aligned to the right edge of its viewport and the chest-wall of the right breast is aligned to the left edge of its viewport.

To minimize eye stress from interleaved display of dim ID (implant displaced) views followed by bright implant views, the checkbox "Interleave implant views" can be unchecked. This causes the entire set of viewing steps to be repeated for implant views after stepping through the ID view (treated like standard views) hanging protocol sequence. Note that the systematic masking step and all-pixel viewing step are currently skipped when repeating the implant views. For example, for a typical 8-view implant study, the sequence is:

- ⇒ RCCID + LCCID + RMLOID + LMLOID +
prior RCCID + prior LCCID + prior RMLOID + prior LMLOID
- ⇒ RCCID + LCCID
- ⇒ RMLOID + LMLOID
- ⇒ RCCID + prior RCCID
- ⇒ LCCID + prior LCCID
- ⇒ RMLOID + prior RMLOID
- ⇒ LMLOID + prior LMLOID
- ⇒ systematic RCCID + LCCID
- ⇒ systematic RMLOID + LMLOID
- ⇒ all-pixel RCCID + LCCID
- ⇒ all-pixel RMLOID + LMLOID
- ⇒ RCCID + LCCID + RMLOID + LMLOID

now repeat for implant views (note skip the systematic view and all-pixel view):

- ⇒ RCCID (implant) + LCCID (implant) + RMLOID (implant) + LMLOID (implant) +

prior RCCID (implant) + prior LCCID (implant) + prior RMLOID (implant) + prior LMLOID (implant)

- ⇒ RCCID (implant) + LCCID (implant)
- ⇒ RMLOID (implant) + LMLOID (implant)
- ⇒ RCCID (implant)+ prior RCCID (implant)
- ⇒ LCCID (implant) + prior LCCID (implant)
- ⇒ RMLOID (implant) + prior RMLOID (implant)
- ⇒ LMLOID (implant) + prior LMLOID (implant)
- ⇒ RCCID (implant) + LCCID (implant) + RMLOID (implant) + LMLOID (implant)

in comparison, when the checkbox is checked, the sequence is interleaved between ID view and implant views:

- ⇒ RCCID + LCCID + RMLOID + LMLOID +
prior RCCID + prior LCCID + prior RMLOID + prior LMLOID
- ⇒ RCCID (implant) + LCCID (implant) + RMLOID (implant) + LMLOID (implant) +
prior RCCID (implant) + prior LCCID (implant) + prior RMLOID (implant) + prior
LMLOID (implant)
- ⇒ RCCID + LCCID + RMLOID + LMLOID +
RCCID (implant) + LCCID (implant) + RMLOID (implant) + LMLOID (implant)
- ⇒ RCCID + LCCID
- ⇒ RCCID (implant) + LCCID (implant)
- ⇒ RMLOID + LMLOID
- ⇒ RMLOID (implant) + LMLOID (implant)
- ⇒ RCCID + prior RCCID
- ⇒ RCCID (implant)+ prior RCCID (implant)
- ⇒ LCCID + prior LCCID
- ⇒ LCCID (implant) + prior LCCID (implant)
- ⇒ RMLOID + prior RMLOID
- ⇒ RMLOID (implant) + prior RMLOID (implant)
- ⇒ LMLOID + prior LMLOID
- ⇒ LMLOID (implant) + prior LMLOID (implant)
- ⇒ systematic RCCID + LCCID
- ⇒ systematic RMLOID + LMLOID
- ⇒ all-pixel RCCID + LCCID
- ⇒ all-pixel RMLOID + LMLOID
- ⇒ RCCID + LCCID + RMLOID + LMLOID

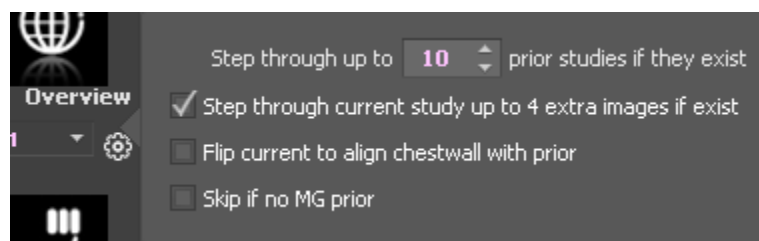
The option “Large columns” controls the size of the image when double-clicked. The default setting is “2” – meaning that the complete image screen area is split into two regions which can accept a large image – when there is a double-click in a viewport. The number can be changed to “1” or “4” to achieve one full (or all) screen viewport, or 4 virtual columns of large views.

Settings for individual steps

Each step has its own parameters, which include the hanging protocols to use, and step-specific preferences that are shown on the “gear” icon displayed with that step:

- **Overview Step:** There are ten options for the layout for the overall viewing step:
 - 1) Prior study (RMLO, LMLO, RCC, LCC) over Current study (RMLO, LMLO, RCC, LCC)
 - 2) Prior study (RCC, LCC, RMLO, LMLO) over Current study (RCC, LCC, RMLO, LMLO)
 - 3) Current study (RMLO, LMLO, RCC, LCC) over Prior study (RMLO, LMLO, RCC, LCC)
 - 4) Current study (RCC, LCC, RMLO, LMLO) over Prior study (RCC, LCC, RMLO, LMLO)
 - 5) Current study on the left (RMLO, LMLO over RCC, LCC) with the prior study (MLOs on the top, CCs on the bottom) on the right
 - 6) Current study on the left (RCC, LCC over RMLO, LMLO) with the prior study (CCs on the top, MLOs on the bottom) on the right
 - 7) Current study in the middle (RMLO, LMLO over RCC, LCC) with the prior study (MLOs on top, CCs on the bottom) on either side of the current study
 - 8) Current study in the middle (RCC, LCC over RMLO, LMLO) with the prior study (CCs on the top, MLOs on the bottom) on either side of the current study
 - 9) Current study in the middle (RMLO, LMLO, RCC, LCC) with the prior study (RMLO, LMLO on the left, RCC, LCC on the right) on either side of the current study
 - 10) Current study in the middle (RCC, LCC, RMLO, LMLO) with the prior study (RCC, LCC on the right, RMLO, LMLO on the left) on either side of the current study

The “overview”-specific settings are:



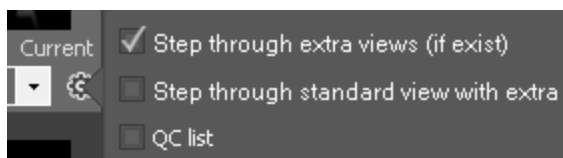
When the overall workflow option “Force stepping through priors” is checked, the overview step progresses through the specified number of prior studies (starting at the prior configured on the worklist tab – see section 8.1). When that option is not checked, stepping shows only the configured first prior, but other priors can still be viewed by using the “more priors” action (e.g., via the circle icon shown on the prior images or at the bottom of the screen).

When the checkbox “Step through current study up to 4 extra images if exist” is checked, the view sequence will include viewing up to 4 extra views from the current study together with the 4 standard views in a same hanging protocol (i.e., 2x4 layout).

The checkbox called “Flip current to align chest-wall with prior” is provided to allow the flip of the current study so that the chest-wall of the current study can be aligned with the chest-wall of the prior study.

- **Current study Step:** There are eighteen layout options that can be selected for inclusion in the current viewing and image quality check step (multiple views can be selected):
 - 1) Current bilateral MLO views
 - 2) Current bilateral CC views
 - 3) Current alternative MLO and CC left views
 - 4) Current alternative CC and MLO left views
 - 5) Current alternative MLO and CC right views
 - 6) Current alternative CC and MLO right views
 - 7) Current standard 4-view with MLOs on the left
 - 8) Current standard 4-view with CCs on the left
 - 9) Current standard 4-view with MLOs on the top
 - 10) Current standard 4-view with CCs on the top
 - 11) Current 4-view bilateral MLO views + 1 set of corresponding “extra” views (such as tomo, etc.)
 - 12) Current 4-view bilateral CC views + 1 set of corresponding “extra” views (such as tomo, etc.)
 - 13) Current 8-view bilateral MLO views + 3 sets of corresponding “extra” views (such as tomo, projection, etc.)
 - 14) Current 8-view bilateral CC views + 3 set of corresponding “extra” views (such as tomo, projection, etc.)
 - 15) Current single view right MLO
 - 16) Current single view left MLO
 - 17) Current single view right CC
 - 18) Current single view left CC

The “current”-specific settings are:



When the checkbox “QC list” is checked, a quality check dialog will be popped up to remind the user to check the image quality.

When the checkbox “Step through extra views” is checked, the view sequence will include viewing one additional set of the extra views from the current study. For example, when a study includes the following 6 views: RCC, LCC, RXCC, LXCC, RMLO and LMLO, when the layouts bilateral CC views with order 1 and bilateral MLO views with order 2 are selected, the sequence of the hanging protocols are:

- ⇒ RCC + LCC
- ⇒ RXCC + LXCC

⇒ RMLO + LMLO

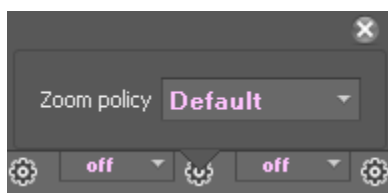
When the checkbox “Step through standard view with extra” is checked, the view sequence will include viewing two additional pairs of bilateral or alternative standard view with its corresponding extra view side-by-side. For example, when a study includes the following 6 views: RCC, LCC, RXCC, LXCC, RMLO and LMLO, when the layouts bilateral CC views with order 1 and bilateral MLO views with order 2 are selected, the sequence of the hanging protocols are:

- ⇒ RCC + LCC
- ⇒ RCC + RXCC
- ⇒ LCC + LXCC
- ⇒ RMLO + LMLO

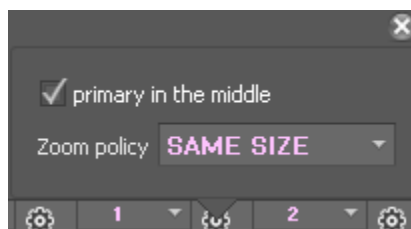
Another example is for tomosynthesis study when a study includes 4 standard MG images and 4 DBT images (and DBT is not set in the sort order as primary):

- ⇒ standard RCC + standard LCC
- ⇒ standard RCC + DBT RCC
- ⇒ standard LCC + DBT LCC
- ⇒ standard RMLO + standard LMLO
- ⇒ standard RMLO + DBT RMLO
- ⇒ standard LMLO + DBT LMLO

Each sub-step of the current step (i.e., each of the selected HP) also has its own settings. For most this is:



Which allows a custom zoom policy for each sub-step. For the two “fanning” views (#9 and #10 above) there is an extra option:

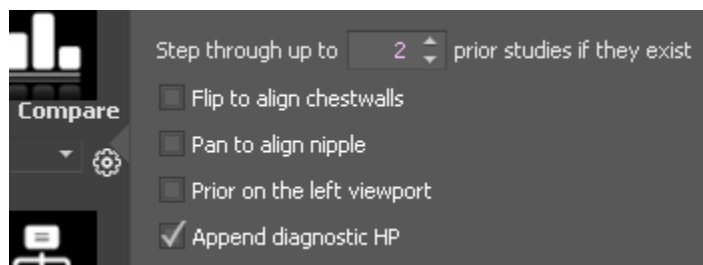


The option “primary in the middle” allows the system to place the primary pair of images in the center, or at the outside. What is determined to be “primary” is a site setting (set by service personnel). This is typically used to control 2D and tomo views – whether the 2D is in the middle or on the outside of the two corresponding tomo views.

- **Current/Prior Comparison:** There are ten views that can be selected for inclusion in the current/prior comparison step (multiple views can be selected):
 - 1) Current and prior RMLO views
 - 2) Current and prior RCC views

- 3) Current and prior LMLO views
- 4) Current and prior LCC views
- 5) Current and prior RMLO and RCC views
- 6) Current and prior LMLO and LCC views
- 7) Current and prior MLO views (current in center)
- 8) Current and prior CC views (current in center)
- 9) Current and prior MLO views (current on left)
- 10) Current and prior CC views (current on left)

The comparison-specific settings are:

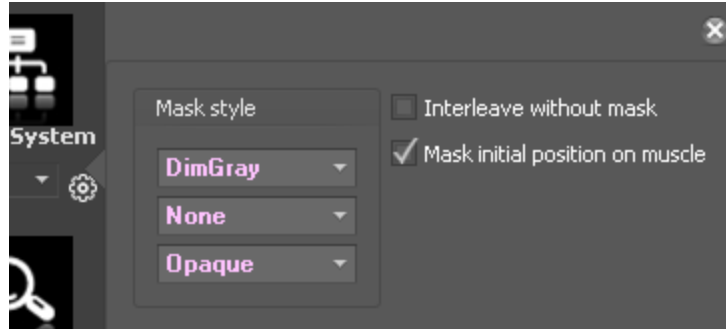


When the overall workflow option “Force stepping through priors” is checked, the comparison step progresses through the specified number of prior studies (starting at the prior configured on the workflow tab – see section 8.1). When that option is not checked, stepping shows only the configured first prior, but other priors can still be viewed by using the “more priors” action (e.g., via the circle icon shown on the prior images or at the bottom of the screen).

For each of the views that are selected for inclusion in the current/prior comparison step, the current image(s) are highlighted by a bold bounding box. The checkbox “Flip to align chest-walls for comparison” can be used to flip images so that the chest-wall of the current study can be aligned with the chest-wall of the prior study. A checkbox “Pan to align nipple for comparison” can be used to automatically pan images so the nipple and chest-wall of the current and prior studies are aligned closely for comparison. The checkbox “Append diagnostic HP” allows the user to integrate the selected diagnostic hanging protocols (configured on the “Diagnostic HP” tab) into the reading workflow for screening studies.

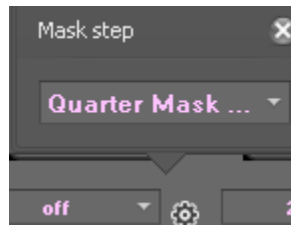
- **Systematic Mask Viewing:** There are four hanging protocols, utilizing the three types of systematic viewing masks, that can be selected for inclusion in the systematic mask viewing step (multiple hanging protocols can be selected):
 - 1) Oblique masks on the bilateral MLO views
 - 2) Horizontal mask on the bilateral MLO views
 - 3) Horizontal mask on the bilateral CC views
 - 4) Vertical mask on the bilateral CC views

Settings for this step are:



The thickness of the mask border and the line style can also be configured. Additionally, the mask style can be set to “Opaque” (areas of the image not viewed in the mask are black) or “Transparent” (areas of the image not viewed in the mask are dimmed). The mask initial position on MLO views can be at the edge of the pectoral muscle or at the top edge of the image.

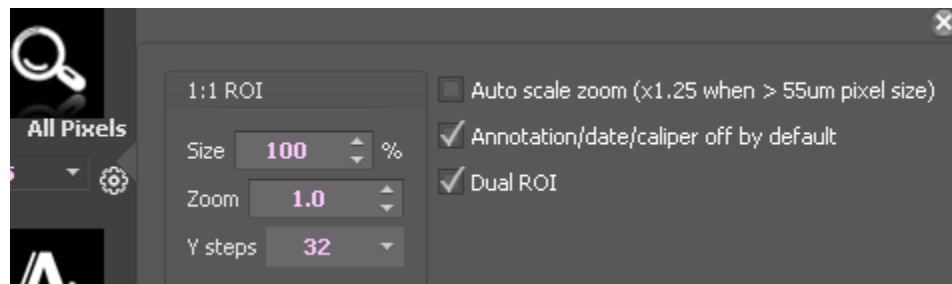
For each type of mask (i.e., for each hanging protocol), there is an option to set the spacing between successive steps of the mask: quarter mask height, half mask height, or full mask height:



- **All Pixels Viewing:** There are four hanging protocols that can be selected for inclusion in this workflow step:

- 1) Bilateral MLOs
- 2) Bilateral CCs
- 3) RMLO and RCC
- 4) LMLO and LCC

The specific settings for this step are:



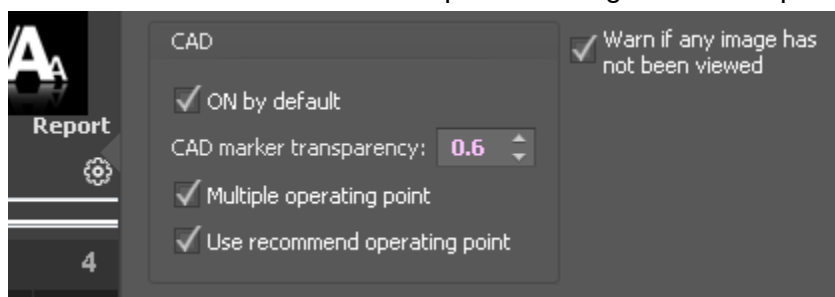
The ROI viewing area can be set by percentage of total viewport width. The zoom factor can be set as well. When the checkbox “Auto scale zoom” is checked, it means the zoom factor is automatically set based on the image resolution, i.e., the zoom factor is scaled up by a factor of 1.25 when the image pixel size is larger than 55um (these are the defaults, but the over-zoom and thresholds can be changed as a service option). The “Y steps” option controls granularity of the vertical scroll steps. The default is “2”, which means that each

step is $\frac{1}{2}$ of the size of the area. The steps can be made as small as 32 (1/32 increments), which results in much smoother (but more) steps.

There is also an option to enable dual magnifying glasses (one for each image in the views). The default is to use dual regions – corresponding images zoomed and panned in unison.

To avoid the annotations overlapping with breast tissue of the full resolution images, the checkbox “Annotation/date/caliper off by default” is checked to turn off the annotation, date and caliper display during this step. However, the annotation, date and caliper can be kept on by un-check this checkbox.

- **Report:** The hanging protocol for the summary of findings view can be configured to either: a) RMLO, LMLO, RCC, LCC in a horizontal layout, or b) bilateral MLOs over bilateral CCs. The specific settings for this step are:

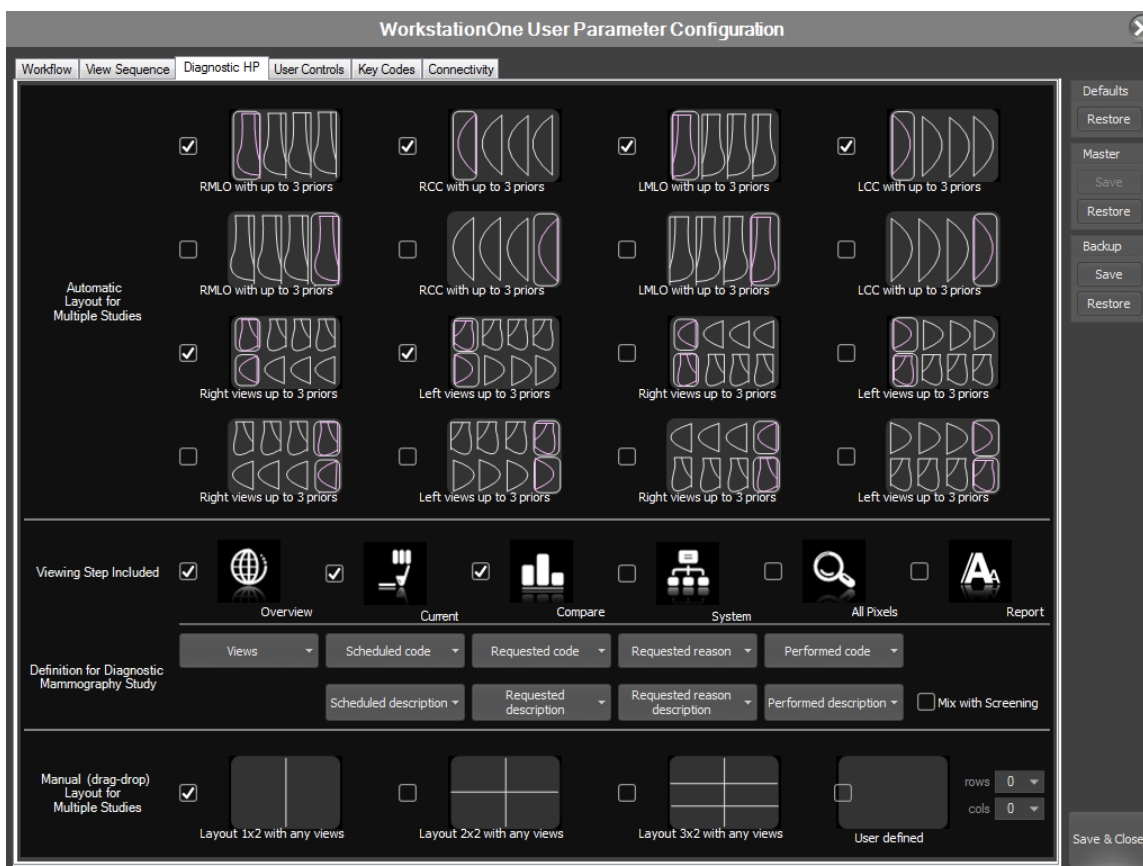


The “Enable CAD” option allows the user to indicate whether CAD information (if available) is displayed when the user navigates to the Report step. If “Enable CAD” is not selected, the user must manually select the “CAD ON” button to view the CAD information. The transparency of the marker graphics can be set using a number between [0, 1], where 0 means clear and 1 means opaque.

When CAD operates on multiple operating points and this information is available, checking the checkbox “Multiple operating point” allows the user to interactively select an operating point, and the selected operating point can be kept if the checkbox “Use recommend operating point” is not checked.

8.3. Diagnostic hanging protocol configuration

See section 5.3 for a description on how the diagnostic hanging protocols are used.



In addition to the 16 automatic hanging protocols which smartly layout multiple studies on the same screen, 4 manual hanging protocols are provided here to support manual drag and drop of thumbnails:

- 1x2 (1 row with 2 columns)
- 2x2 (2 rows and columns)
- 3x2 (3 rows in 2 columns)
- user defined

When this last option is checked, the user defined layout is defined by the rows and cols drop-down boxes. The choices for rows are 1, 2, and 3 and the choices for columns (cols) are 1, 3, 4, and 8. So one of the following hanging protocols can be defined: 1x1, 2x1, 3x1, 1x3, 2x3, 3x3, 1x4, 2x4, 3x4, 1x8, 2x8, and 3x8.

8.4. User controls configuration

The types of textual annotation information displayed on each image are grouped as:

- Clinical annotation
- Technical annotation, and
- Investigative annotation.

Although these can be customized for a site, the clinical annotation usually includes:

Patient's name and patient ID
 Patient's birth date and age
 Acquisition date and time

- Operator's name
- Institution name
- Station name
- Side and view
- Magnification factor
- Display zoom factor

The technical annotation usually includes:

- KVP
- Exposure
- Exposure time
- Filter material
- Anode target material
- Compression force
- Body part thickness
- Positioner primary angle
- Relative X-ray exposure
- Entrance dose in mGy
- Organ dose

The investigative annotation usually includes:

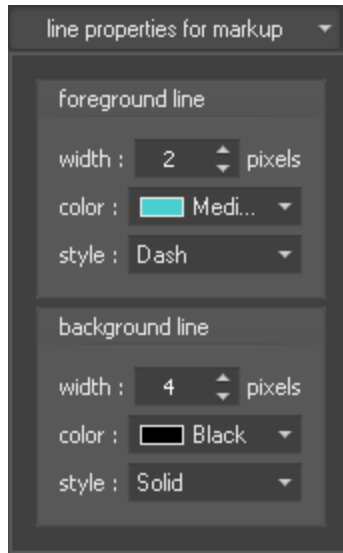
- Manufacturer
- Institution address
- Manufacturer's model name
- Device series number
- Detector ID
- Software version
- Date of last detector calibration
- Window level width
- Pixel size

These textual annotations accompanying a view must be displayed opposite the chest wall and toward the axilla. However, the "User Controls" configuration panel allows the user to select the upper or lower corner location for each type of annotation.

The location of the toolbar can be set to align with either the top, bottom, left, or right of the image screen, and the tools to display on the toolbar and the tool initial states can be configured. The check boxes above each tool button can be used to select or de-select the button to be displayed or hidden. When clicking on the tool buttons, the text content can be toggled to set the tool initial states.

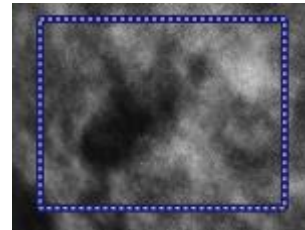
- turns on a “dark menu” style for menus displayed on the image screens;
- disable or enable pop-up help;
- hide or show the "3D navigation" icon in the viewports when DBT images are present;
- hide or show the “page flip” icons in the viewports when extra views are present;
- hide or show the “circular loop” icons in the viewports when more prior studies are present;
- hide or show the "menu action" icon which is displayed with the cursor when interacting with an image (e.g., using an action selected from the drop-down viewport menu);

The **appearance** group controls the line properties for the drawing of markup, measurements, arrows and overlay (saved GSPS). Each has an identical drop-down menu which controls a foreground and background line:

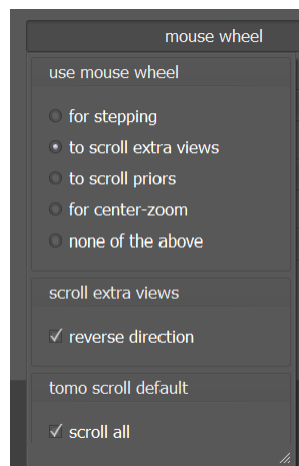


The model is that lines (as part of markup, measurement, etc.) are drawn first with a background line, which is then re-drawn with a foreground line. Each of these lines has parameters for style, width and color. This allows a contrasting white on black for easy visibility on grey-scale monitors or contrasting colors for use on a color monitor. A typical use would be to have a thicker background line with a thinner foreground line in contrasting color. The supported line styles are:

- Off – i.e., no line is drawn (which is the default for the background line)
- Solid
- Dot
- Dash
- DashDot
- DashDotDot



The **actions** group controls mouse interaction. The **mouse wheel** drop-down controls how the mouse wheel is utilized (“use mouse wheel”):



- for navigating through the protocol steps;
- scroll through the extra views (including tomo frames);

- to scroll through the prior studies;
- to zoom images around an image center;
- not mouse wheel at all;

When “scroll extra views” is active, the “reverse direction” option means that the scroll direction is interpreted as the reverse of the direction of wheel rotation. The “tomo scroll default” option controls whether the wheel in tomo mode is considered to scroll just the current image or all images by default.

The **markup details** drop-down allows control of settings for markup:

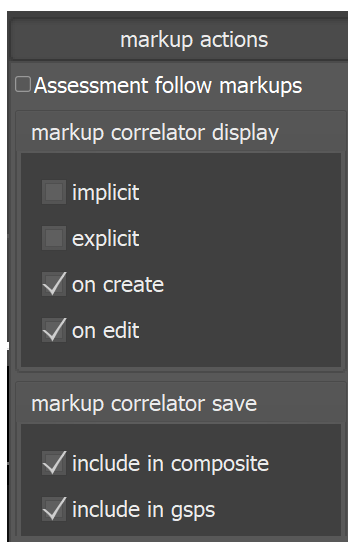
	arrow	line	free-hand	ellipse	rectangle	text
is markup?	☒	always	always	always	always	always
add label?	☐	n/a	☐	☐	☐	n/a
with measure?	n/a	always	☐	☐	☐	n/a
with SD?	n/a	n/a	☒	☐	☒	n/a
reset menu?	☒	☒	☒	☒	☒	☒
fixed size?	☒	☐	☐	☐	☒	n/a
X units	cm	mm	cm	mm	cm	
X length	5	0	5	5	100	
Y units	inch	mm	cm	mm	inch	
Y length	0	50	5	5	0	

Where the columns **arrow**, **line**, **free-hand**, **ellipse**, **rectangle** and **text** list the properties for each of those types of markup. The entries in each column are described in the row labels (left column), which are:

- is markup? – whether that drawing type is considered “markup” for the purpose of reporting (any markup indicating a finding). This is only changeable for “arrow” – the other types are always considered to be markup.
- add label? – controls whether a label (identifier) is displayed with the markup.
- with measure? – controls whether measurement information is to be displayed as part of the label.
- with SD? – controls whether the measurement information includes the standard deviation.
- reset menu? – controls whether the default tool reverts to “none” once that drawing operation is completed. When this is unchecked, then each drawing can be followed by another drawing of the same type, without switching tools manually.
- fixed size? – when this option is checked, that markup is a fixed size (i.e., only a single click is needed to add it), with the size determined using the settings X units/length and Y units/length.
- X units – for a fixed size markup, this is the unit for the specification of the width. This can be one of: pixels, mm, cm or inch.
- X length – for a fixed size markup, this is the width (in “X units”).
- Y units – for a fixed size markup, this is the unit for the specification of the height. This can be one of: pixels, mm, cm or inch.
- Y length – for a fixed size markup, this is the height (in “Y units”).

The text “n/a” means “not applicable” and so that criteria does not apply (e.g., a label with markup type of text does not make sense – the markup is text). Similarly, the text “always” means that the behavior cannot be turned off – it is always on (e.g., a rectangle is always considered to be markup).

The **markup actions** drop-down controls actions that occur when interacting with a markup:



The “assessment follow markups” option controls the automatic display of the assessment dialog. When this option is checked the markup assessment dialog (see 5.1.6.2) appears automatically once a markup is created.

The options under **markup correlator display** control when the markup correlator graphic is displayed (see section 6.3 for a discussion of the markup correlator graphic):

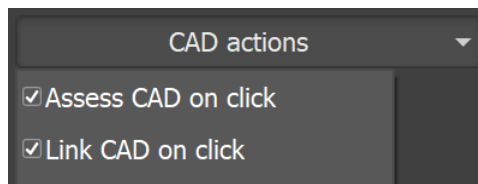
- Implicit – this means that if no tool is defined (e.g., after a “reset tool action”), then a mouse click within a markup causes that markup to be mapped to a markup correlator graphic within that viewport.
- Explicit – this means that if the selected tool is “decision support”, then the action of the mouse click within a markup is to display that markup as a markup correlator graphic within that viewport.
- On create – this means that whenever a markup is created, it is mapped to the markup correlator graphic within that viewport.
- On edit – this means that whenever a markup is selected for edit, it is mapped to the markup correlator graphic within that viewport.

The options under **markup correlator save** control how any correlator graphic is saved:

- Include in composite – a composited image is generated by WorkstationOne for saving in certain settings. For example, when markup is configured to be saved as “SC”, or when image thumbnails are included in a report, etc. When this option is checked, the markup correlator graphic is included in that image (i.e., it is burnt-in).
- Include in gsps – the most common format for saving user markup (see 8.6) is as a DICOM GSPS (grey-scale soft-copy presentation state) object. The markup

correlator graphic is included in that object when this option is checked. Note that the graphic is in “screen space” rather than “image space”, so it can look different on a target system (e.g., aspect ratios may be different).

The **CAD actions** drop-down controls actions that occur when there is a click on a CAD mark:

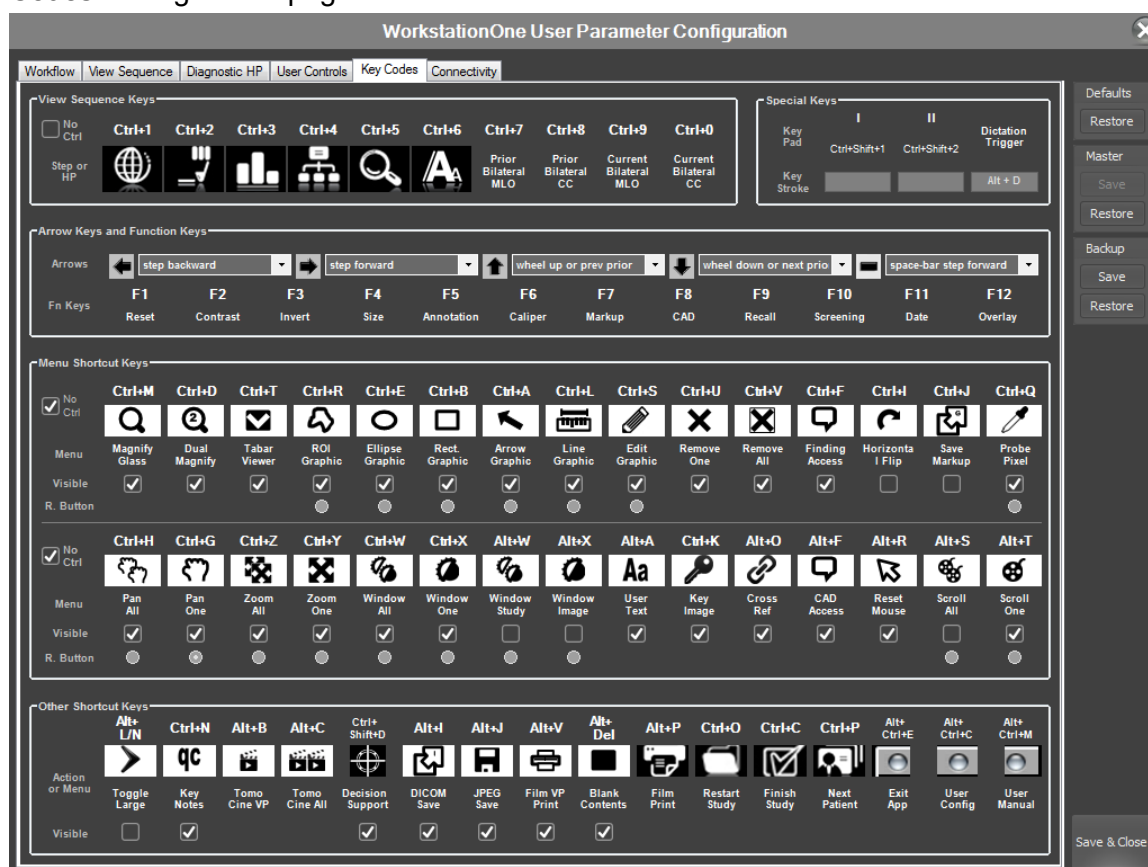


When the option “access CAD on click” is checked, then clicking a CAD mark results in the display of the CAD assessment dialog (see 5.1.6.1).

When the option “link CAD on click” is checked, then a click on a 2D marker will force any displayed tomosynthesis views with the same marker to scroll to the frame that shows that marker. This mechanism requires that the markers be appropriately labelled within the CAD report that was received.

8.5. Key code configuration

Most of the commonly used actions and features of WorkstationOne can be accessed through keyboard shortcuts in addition to user interface elements (see the tables in section 6.8). The actions that are taken by certain keyboard keys are listed on the “Key Codes” configuration page:



The preferred action for the arrow keys can be set on this configuration page using the settings in the group box “Arrow Keys and Function Keys”.

In the group boxes “Menu Shortcut Keys” and “Other Shortcut Keys”, the check-box graphics under each Ctrl or Alt key allows the corresponding menu items to be added or removed from the right-click drop down menu. The right mouse button actions can be configured to directly interact with image or markup graphics using the radio-button graphics displayed under each shortcut key in the group box “Menu Shortcut Keys”. Thus, the right mouse button can perform one of the following actions:

- ROI graphic (i.e., “free-hand markup” menu item)
- Ellipse graphic (i.e., “ellipse markup” menu item)
- Rectangle graphic (i.e., “rectangle markup” menu item)
- Arrow graphic (i.e., “arrow markup” menu item)
- Line graphic (i.e., “line measurement” menu item)
- Edit graphic (i.e., “edit or pan graphic” menu item)
- Pan All (i.e., “pan synchronized” menu item)
- Pan One (i.e., “pan one” menu item)
- Zoom All (i.e., “zoom synchronized” menu item)
- Zoom One (i.e., “zoom one” menu item)
- Window All (i.e., “window synchronized” menu item)
- Window One (i.e., “window one” menu item)
- Window Study (i.e., “window one study” menu item)
- Window Image (i.e., “window one image” menu item)
- Probe Pixel (i.e., probe menu item)
- Scroll All (i.e., “scroll synchronized” menu item)
- Scroll One (i.e., “scroll one” menu item)

8.6. Connectivity configuration

Any external communication mechanisms that have been configured by a service engineer are displayed in this page. This information is provided here to help service when trouble-shooting in the event of a network problem. This page also allows the configuration of per-user destinations – e.g., even when the system is configured with DICOM or HL7 connections, each user can determine when those mechanisms are used.

WorkstationOne User Parameter Configuration

Workflow View Sequence Diagnostic HP User Controls Key Codes **Connectivity**

Display Connectivity Services

StoreDefault (class = AdapterStore)
test (class = AdapterFileTrigger)

Send to PACS

☒ Send markup as GSPS ☒ Save markup as GSPS (local)
☐ Send markup as SC ☐ Save markup as SC (local)
☐ Send report as SR ☐ Save report as SR (local)
☒ Send Key Notes ☒ Save Key Notes (local)

Email Connection

SMTP host: From address: ☐ SMTP requires authentication
SMTP port: ☐ use SSL User name: Password:

Send Recall Form

☐ Send Recall Form via email ☐ email verified
email settings:
To address: Subject:
☐ send report as attachment Leading text: Markup color on Recall Form:
☐ Send to PACS as SC
☐ Send to RIS
☐ Send automatically

Send Screening Report

☐ Send Screen Report via email ☐ email verified
email settings:
To address: Subject:
☐ send report as attachment Leading text:
☒ screen capture
☐ Send to PACS as SC
☐ Send to RIS
☐ Send automatically

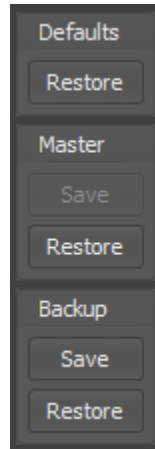
It is recommended that markup be sent as “GSPS” format, which allows it to be re-displayed on the images when they are displayed on a workstation at a future time. The user can select to save this format locally, and also to send it to PACS (recommended). When this is configured, the sending occurs automatically when the case is completed (with a confirmation option on the viewing sequence closing dialog). It is also possible to configure the system to send the markup as secondary capture (SC). This mechanism is provided for backwards compatibility with systems that cannot display markup contained within DICOM GSPS objects. Note that checking the box “Send Markup as SC” or “Save Markup as SC Local” will trigger the checkbox “Save Markup as GSPS Local” to also be checked. This will ensure that the markups are saved locally even if sending to PACS fails, allowing them to be retrieved and resent later.

Reporting information that is collected during the reading process is internally recorded for later use in reporting. That information includes BIRADS, breast density, findings assessment, and radiologist comments. This information feeds into the internal and external reporting mechanisms, including the Reporting plugin, the recall and screening forms (legacy), and it can be saved and exported in a variety of formats. One format is DICOM SR (Structured Reporting), which if selected on this configuration, causes the system to generate and automatically send a SR to the PACS at the completion of the reading sequence. The reporting mechanisms (such as the Reporting plugin) use the information to populate viewable reports, which can be sent in a variety of formats. The settings for the (legacy) recall and screening forms are configured here, but most of the export options for the Reporting plugin are set there (see 7.9.4). The “Email Connection” settings are used when the Reporting plugin or the legacy recall and screening forms are configured to send via email.

The color of the markup captured on the recall form can be changed using the drop-down “Markup color on Recall Form”.

8.7. Configuration backup and restore

The user settings are always saved when the configuration editor is closed (via the “Save & Close” button, or the dialog “X” button). The configuration dialog shows buttons at the right side for all tabs, allowing quick save and restore of the user settings:



The “Restore Default” button can be used to restore settings to the initial configuration defined by the manufacturer.

When a user has administrator privilege, the user’s configurations (i.e., the user settings) can be saved as a “master” copy by clicking the “Save” button in the “Master” group. Then other users who log onto the workstation can retrieve the master configuration by clicking the button “Restore” in the “Master” group. The retrieved master configuration is then used as the other user’s initial user settings. The user can modify the settings according to the user preferences.

The “Backup” group can be used by any user to save their own settings externally, and to later restore them (e.g., on a different machine). Clicking the save and restore buttons results in a prompt for the file location to save or read.

9. Printing

WorkstationOne includes the capability to print to a DICOM printer and to perform “pseudo-print” operations to a secondary capture receiver (such as a PACS). Printing is initiated by clicking the printer icon which is displayed below the worklist area on the navigation screen:

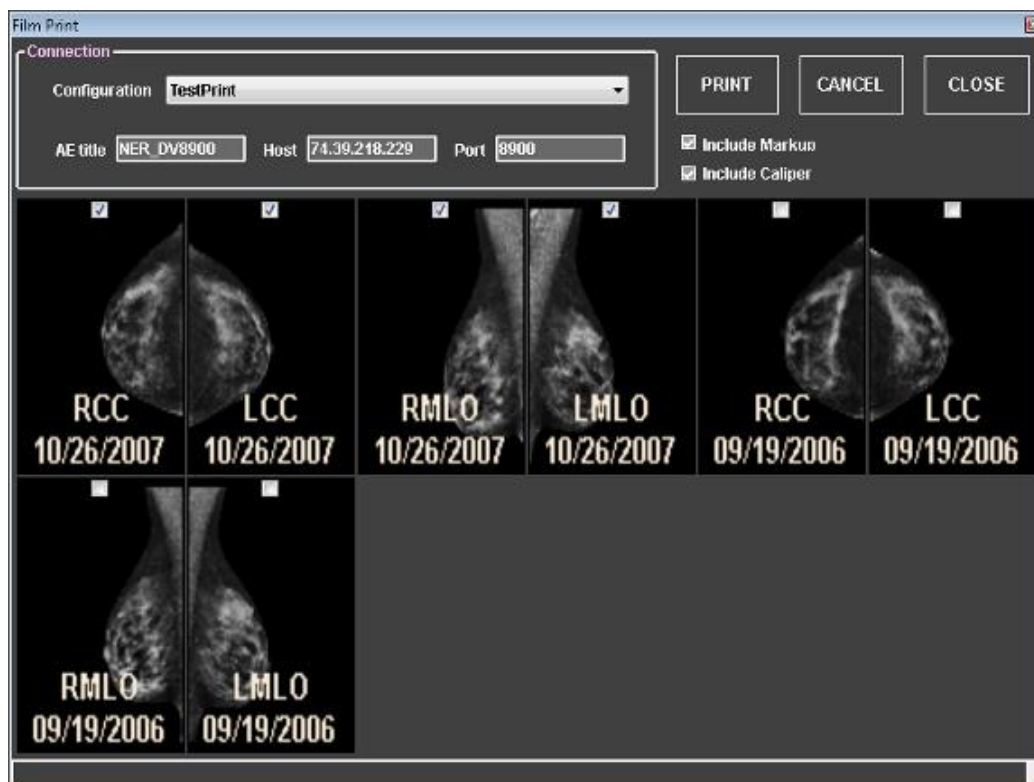


There are two print dialogs available, and which is used can be configured at the site level (see service manual). The “mammography standard printing” dialog is designed to meet the needs of mammography printing – it can print images that are displayed on the image screens in a way that is required for mammography (chest-wall to the edge of the film, true size). More advanced printing is available from the second print dialog (here called the “Advanced printing” dialog), which allows layouts on the film and printing of non-mammo images.

9.1. Mammography standard printing

When configured (and “AdapterPrint” or “AdapterSend” configured on the Backend), the dialog for DICOM film printing, or pseudo SC printing, can be displayed by clicking the printer icon on the navigation monitor (or using the short-cut keys Alt+P). By default, all images from the current study are selected and ready to be printed. The images from the prior studies can also be selected for printing.

The adapter instance that is selected from the “Configuration” drop-down list determines whether it is one of the configured DICOM film printers that is to be the destination, or a DICOM storage server which is to be the destination. When the destination is a DICOM storage server (i.e., pseudo SC printing), all selected images will be sent using a single (new) series UID for each send action.



The following list summarizes the film printing capability of the standard printing dialog of WorkstationOne:

- any depth gray-scale - the images sent to the printer are at their original depth (typically 10, 11, 12, and 14 bit), so the printer can actually show more gray-levels than are shown on the screen (e.g., up to 4096 for printers with the mammography option and the right film).
- presentation LUT - the gray-scale remapping function that comes from the source image is used for printing.
- chest wall alignment - the images sent to the printer have the chest wall on the edge, so that with the printer's mammography option configured correctly, the chest wall can be positioned at the edge of the film.
- annotation - this is displayed on the film on the opposite side from the chest-wall, so that tissue is not obscured by the text.
- annotation content – this includes:
 - Name of the patient and an additional patient identifier.
 - Date of examination.
 - View and laterality. This information is placed on the image in a position near the axilla.
 - Facility name and location.
 - Technologist identification.
 - Cassette/screen identification.
 - Mammography unit identification.
- true-size printing - mammography images are printed 1 per film, with the film size automatically selected so that the output is at the correct size (the breast is not minified or zoomed when it is on the film).

The overlays (both user markup and GSPS graphic annotations) and the caliper can be included on the printed images. The options are available on the printing dialog as shown in the above picture (the checkboxes “Include Markup” and “Include Caliper”):

9.2. Advanced printing

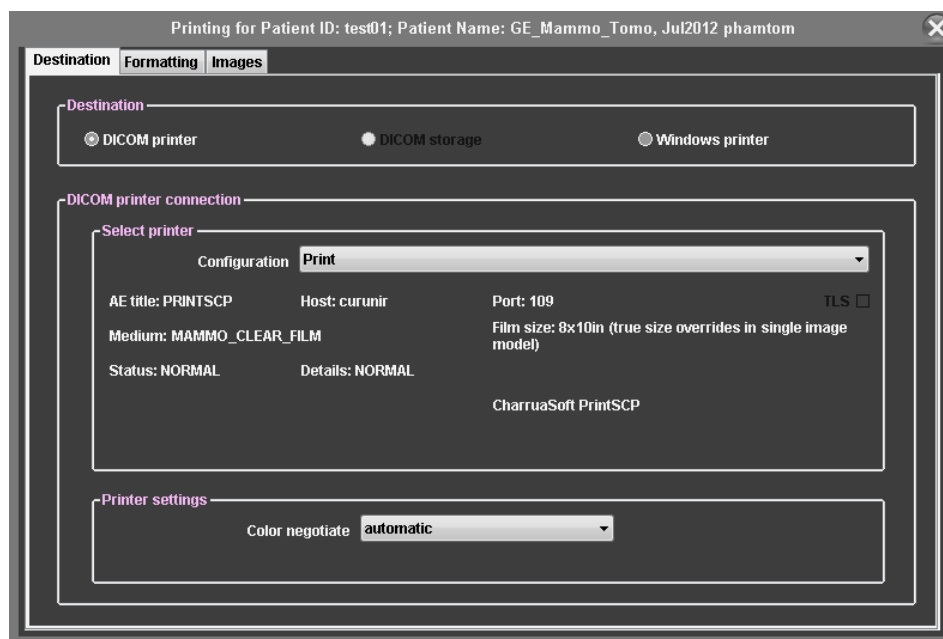
The advanced (or “general”) printing dialog is shown when the print button is clicked when the “multi-modality print UI” is configured for this machine. This dialog includes the functionality from the standard mammography printing mechanism, with some extra features. This printing user interface is divided into three tab pages: Destination, Formatting, and Images. These are discussed further below.

Note that printing occurs for the case that is currently open. Additionally, this dialog can remain open, so that when a different patient is opened, the images for that case become the current printing set within this dialog. If the newly selected patient has no images, the print dialog closes automatically.

9.2.1. Destination

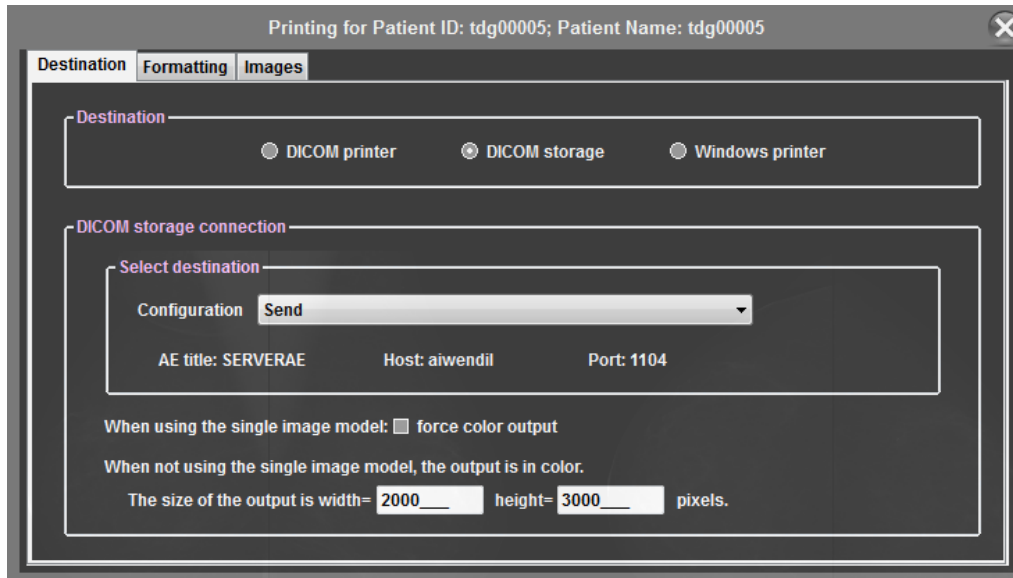
The destination tab allows the user to select the device to be used for printing. The available options depend on the configured devices on the system, but they are divided into three classes: DICOM printer (generally film printers), DICOM storage (to support pseudo-printing to a PACS archive), and Windows printers (for general paper printing). The printer class is selected from the corresponding radio button.

When a DICOM printer is selected as a destination, the user interface shows:



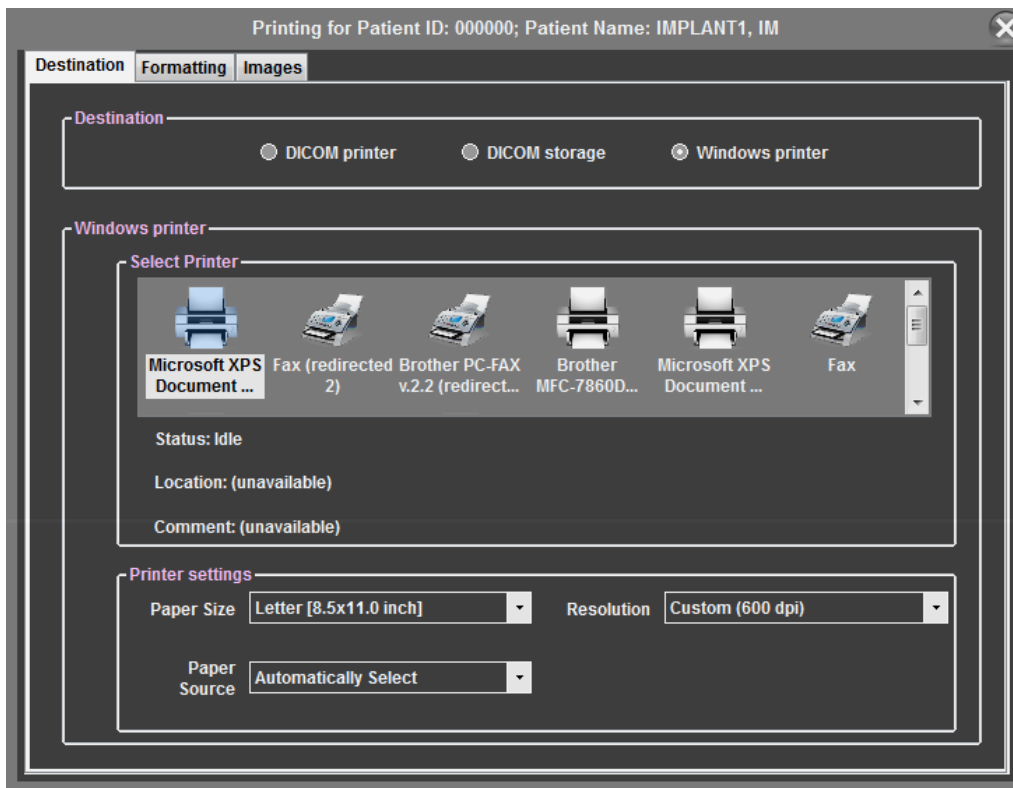
All configured DICOM printers show on the drop-down labelled “Configuration”. Select of a printer from that list shows its default parameters in the area below the configuration name. The only changeable setting is “Color negotiate”, which is normally left at “automatic”, but can be changed to “color” or “greyscale” to force that.

When a DICOM storage device is selected as a destination, the user interface changes to show the available storage devices, and as the selected configuration is changed, its corresponding parameters are shown:



The only parameters that can be changed for a storage destination are the “width” and “height” of the generated pseudo-print. When a layout is used, the images are composited into a matrix of that size, which is then sent to that destination. This size is not used when the system is operating in “single image mode” (see “Formatting” in 9.2.2) – as in that mode the output size is the same as each input image’s size.

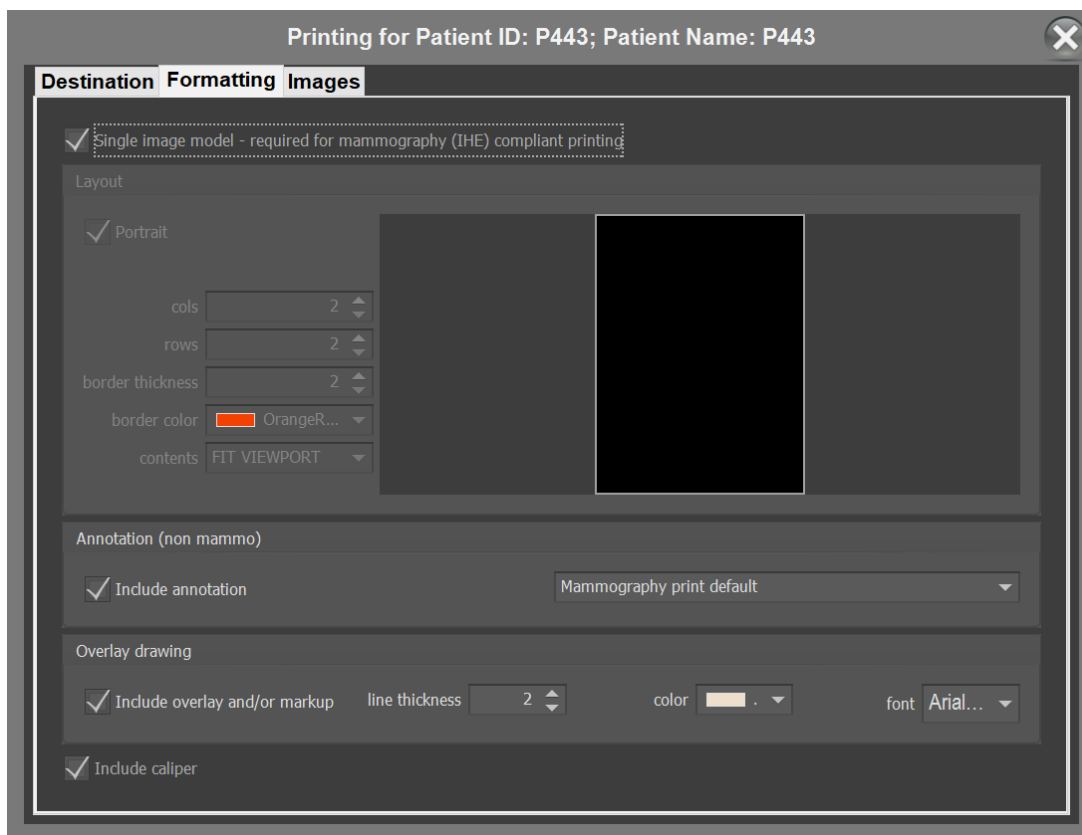
When the destination is changed to a Windows printer, the user interface shows:



which includes a list of the configured Windows printers. Selection of a Windows printer displays some information about it (e.g., Status, Location), and allows the user to change some of the printer settings (paper source, etc.).

9.2.2. Formatting

Advanced printing has two formatting models: “Single image” and a generalized layout model. The “Single image” model is typically what is used for mammography, as it allows the printer to properly align the chest-wall to the edge of the film. However, the general model can also be used for mammography, and for images from any modality. On the Formatting tab, when the “Single image model” is selected, the user interface shows:

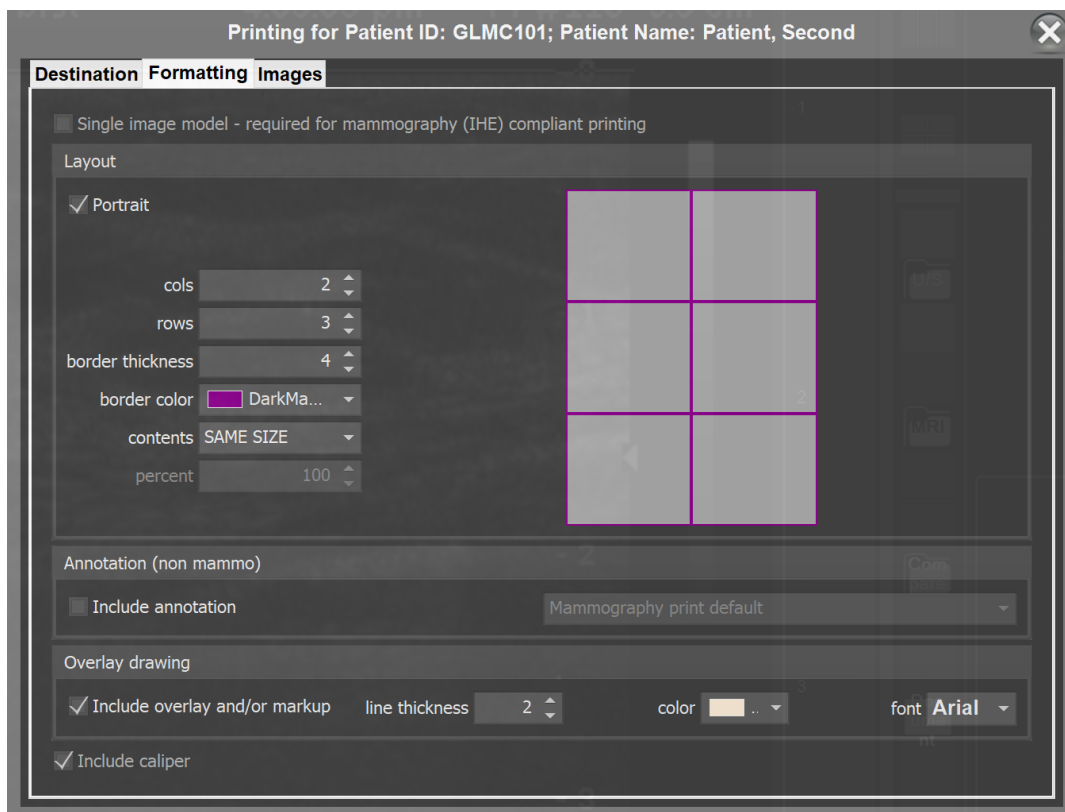


In this mode the “Layout” area is disabled, as the images are printed one on one. However, the options in the lower area apply to both the single image model and the general formatting model. Those settings include the ability to enable display of the annotation, overlay and caliper on the printed images.

For the annotation (text shown in the corners of the image area), pre-defined groups of annotation can be selected from the drop-down box. The selection of annotation definitions is configurable at the site. This setting is not used for mammography images – the annotation used there is one of the options but is set at the site level.

For the overlay, the options allow control of the line thickness, its color, and the font type and size used for any accompanying text.

When the single image model is not selected (i.e., generalized layout model), the formatting tab shows the Layout settings enabled:



In this mode, the user can define the output matrix in terms of columns and rows to be sent to the destination. For DICOM printing, the border information is not used (the grid is laid out by the printer), but for SC pseudo-printing and printing to a Windows printer, the grid border thickness and color can also be set.

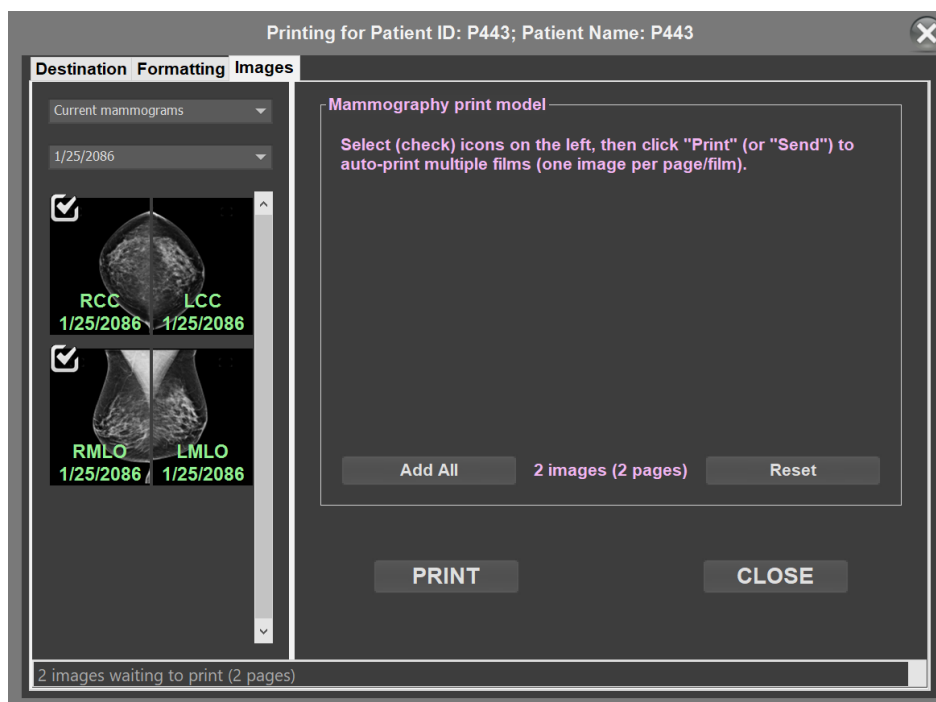
The “contents” option allows the user to define the sizing mode for the images in the printer “viewports”. The options (which mimic the on-screen sizing options) for this setting are:

- Full size – each source image pixel matrix is scaled to the output viewport in such a way that the image is as large as possible without clipping.
- Fit viewport – like “full size”, except that the “breast bounding box” for each image is scaled to the output viewport in such a way that the box is as large as possible without clipping.
- Same size – the “breast bounding box” of each image in the output page is considered so that none is clipped, and all have the same scaling applied (so sizes are equivalent across images on the page).
- True size – the images are scaled to the output so that they are 1:1 mapped to their real-world physical size (which can mean that the images will be clipped).
- True percent – this is a variation on “true size”, where the size is rescaled by the displayed “percent” (greyed out when this option is not selected). The default is 100% (i.e., true size), but the size can be under-scaled or over-scaled from ¼ to 4x true-size.

9.2.3. Images

The Images tab is where the user controls which images are to be printed and initiates the sending of the images to the selected destination. This tab consists of two areas – the left side allow selection of images to be printed, and the right side shows where they will go on the output. The relative size of the two areas is adjustable – move the center bar left/right to make one area or the other larger. At the top of the left area there are two selectors – the first allows selection amongst the modalities in the current case. The second allows the selection amongst the studies in the selected modality of that case. These lists are dynamic and contain only what is available for that case – e.g., the first list might contain “current mammograms”, “ultrasound images”, etc., and then once the “ultrasound images” are selected, several dates would be listed in the second selector. As the modality and study are changed, the list of icons displayed below that updates to reflect the selection. The size of each icon is selectable (right-click menu to select amongst “extra-large”, “large”, “medium” and “small” sizes). If all the icons in the selected study do not fit in the available space, the scroll-bar to the right allows scrolling through all the icons in that study.

Based on the selected formatting model (single image or generalized – see above), the Images tab provides one of two possible selection models for printing. In the first model (for when single image, mammography standard printing is selected), there is only one image per output sheet, so the selection of what to print is achieved on the left side of the screen – each image to be printed can be clicked, resulting in the display of a checkmark next to that icon. Clicking the icon again removes the checkmark (so that image will not then be printed). All icons not already assigned can be selected using the “Add All” button, and all icons can be de-selected using the “Reset” button.



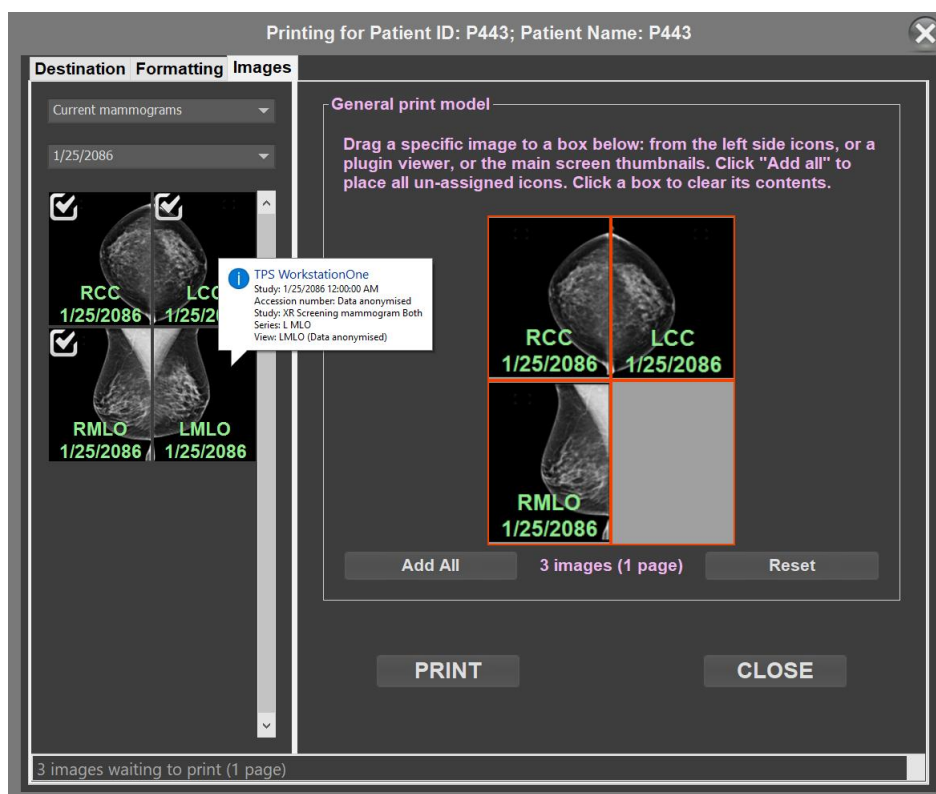
Once the appropriate images are selected in the specified study, clicking the “PRINT” button results in the images being sent to the specified destination, one image per film/page. Note that if the destination is a DICOM storage device, the PRINT button shows as “SEND”.

Once printing is initiated, the “CANCEL” button can be used to stop the process (it may not be immediate, depending on where the formatting process is currently). During printing, the status bar at the lower edge displays an activity graphic, and text status messages also appear there. For example, if there is an error, a message to that affect appears in that area, and in the application “Messages” area (see 3.3).

The second printing model (generalized – with layouts) results in a different selection model on the Images tab. In this model the right side of the tab shows a preview of what is to be printed. Each box in the displayed layout can have any content – it is even possible to mix images from different modalities on the same page. An image is placed into a layout by dragging it:

- From the icon area on the left side (select the appropriate modality and study, then drag that icon to a box on the right)
- From an icon on the image screens (e.g., any of the current or prior mammograms that have an icon on the image screens – click and drag the icon from there to the appropriate box on the preview layout area)
- From an image in the plugin viewers area (e.g., ultrasound, MRI, secondary capture, etc., image viewers). In those viewers (see 7.2), when the “drag” tool is active (right-menu action), an image can be dragged from that viewer and placed into a desired area in the preview layout area.

In this mode, the Images tab looks like:



Where the contents of the preview layout are completely free-format (e.g., both mammograms and ultrasound images on the same page). The source images with checkmarks are those that are present in the pending print pages. The source images are sorted the same way as the thumbnails on the main screen, and by default have a

popup tool-tip that shows the properties of that image. This example also illustrates the situation where an image contains multiple frames – such as a tomosynthesis (BTO/DBT image – the middle row in the layout example above), or a multi-frame ultrasound image. When a box contains such an image, a numeric selector shows in the lower right corner – and this allows the user to type the frame number, or scroll to any frame, so that frame will be printed. Thus, it is possible to have the same image on the same page, each time with a different frame selected for printing.

The “Add All” button places the first N unassigned images from the set on the left into the currently vacant boxes in the preview layout shown on the right. The “Reset” button empties all boxes from the preview layout. Clicking a single box clears its contents.

As with the single image model, once the page layout is as desired, clicking the PRINT (or SEND) button results in the selected page being formatted and sent to the selected destination, with progress messages displayed at the bottom of the area.

10. Hardware configuration

The WorkstationOne software can be installed on an off-the-shelf general-purpose computer with one or two gray-scale high-resolution monitors and one color monitor. The system can be operated without a color monitor, in which case the software automatically displays tabs at the top of the screen to allow switching between the virtual navigation and images screens. The general-purpose computer includes computer hardware, mouse, keyboard, network interface, and media reader/writer.

The recommended computer hardware includes platforms based on the Intel Core i7 or equivalent Xeon processor and later processors with at least 6GB RAM, running x64 version of OS. For systems that will be used to view DBT images, it is recommended that the computer have at least 8GB RAM. The system has to have a power supply capable of driving a high-end medical imaging graphic card (depending on the graphics card, an extra power connector or 2 or more PCI-express x16 slots may be needed). Disk speed is critical for loading performance. A typical configuration is a system with two disks in a RAID-0 configuration (stripping), e.g., two 750GB disks in a raid-0 configuration.

The gray-scale high-resolution monitors should be at least 3MP (mega pixels). The color monitor can be lower resolution, preferably 1440x900 or higher and 32-bit color quality.

A high resolution monitor is considered to consist of 3 components: display, controller board and calibration QA software. In order to take advantage of hardware acceleration, the recommended controller boards include NVIDIA Quadro cards, AMD FirePro cards, and Barco MXRT cards. Special attention should be paid to the compatibility of multiple card combinations when driving multiple displays (e.g., one color low-resolution monitor and 2 3MP or 5MP high-resolution gray-scale monitors). Detailed compatibility information can be obtained from the graphic card vendors, or by consulting with TPS support personnel.

The following table provides some of the manufacturers of high-resolution gray-scale mammography monitors, the trade names for their monitors and the corresponding 510(k) numbers:

Manufacturer	Trade Name	510(k) Number
Barco NV	Fusion 10MP	K093197
	Coronis 5MP	K091274
	5MP Mammo	K090603
	Nio 5MP	K072875
Eizo Nanao	GX1030 10MP	K103724
	RadiForce GS520	K080422
	RadiForce GS510	K062054
	RadiForce GS51	K042755
	RadiForce RX840-MG	K120451
National Display Systems	AXIS-V 5MP	K063066
Planar	DOME CX	K032202

Siemens	SMD 21500, DJSB-2103-D-5MP	K043122
Sony	MLD-DM30	
Totoku/ JVCKenwood	MS311i2 3MP	K090947
	MS33i2 3MP	K112145
	MS35i2 3MP	K133686
	MS51i2 5MP	K071794
	ME551i2 5MP	K061447
	MS55i2 5MP	K160326
	CCL550i2 5MP	K160326
WIDE	5MP (Mammo) LCD	K052312

The site should follow the manufacturer's recommended Quality Control procedure for the monitors.

11. References

The following documents are referenced by this manual:

1. Laszlo Tabar et al “Teaching Atlas of Mammography”, Thieme Stuttgart, New York 2001
2. Laszlo Tabar et al “Breast Cancer: The Art and Science of Early Detection with Mammography – Perception, Interpretation, Histopathologic Correlation” 2005 Georg Thieme Verlag
3. “Mammography Image (MAMMO) Integration Profile”, IHE Radiology Technical Framework Supplement 2006-2007. ACC, HIMSS and RSNA Integrating the Healthcare Enterprise.
4. “IHE Radiology: Mammography User’s Handbook”, Rev. 1.0 ACC/HIMSS/RSNA December 14, 2006
5. “IHE Technical Framework”, Revision 8.0 1998-2007: ACC/HIMSS/RSNA
6. NEMA XR 22-2006, "Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography
7. “Digital Imaging and Communications in Medicine (DICOM)”, PS3, 2020a.

12. Conformance to standards

Three Palm Software has obtained ISO 13485 certification for its quality management system. The quality management system has been certified by BSI. The accredited certification body has verified that the organization and all the functions of Three Palm Software fulfill the requirements stated in the standard ISO 13485:2016.

WorkstationOne is a Class I device under the European MDR, and under the Health Canada Medical Device Regulations.

WorkstationOne has FDA 510K clearance (K073272).

The product development for the WorkstationOne is in conformance with the following FDA recognized consensus standards:

1. NEMA PS 3.1 - 3.20, 2019c, Digital Imaging and Communications in Medicine (DICOM) Set
2. NEMA XR 22-2006, "Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography
3. ANSI/HIBC 2.6, "The Health Industry Supplier Labeling Standard for Patient Safety & Unique Device Identification"

In accordance with the standards, a specification for WorkstationOne system has been defined to specify the DICOM Service Classes, Information Objects, Communications Protocols and Media Storage Application Profiles supported on this workstation. The specification has also defined the requirements to meet NEMA quality control template for Displays and Workstations.

13. Acknowledgements

WorkstationOne includes software from external sources, as listed below with their corresponding copyright and/or license statements:

DEPLOYLX

The licensing software is redistributed in accordance with the XHEO [license agreement](#).

DEVEXPRESS

Redistributable components comply with the [end-user agreement](#).

FMJPEG2KOJ

The JPEG2000 codec for DCMTK is released under the [Apache License, Version 2.0](#).

INTEL IPP

Redistributable components comply with the Intel [end-user license agreement](#).

ISD TOOLKIT

© 2017 JVCKENWOOD Corporation.

NHAPI

This package is subject to the [Mozilla Public License Version 1.1](#).

OFFIS DCMTK

The DICOM toolkit is subject to the [dcmkt copyright notice](#).

OPENCV

The OpenCV toolkit is subject to the corresponding [license agreement](#).

OPENSSL

OpenSSL is redistributed according to its [license agreement](#).

OPENTK

The Open Toolkit is distributed under the [permissive MIT/X11 license](#).

SHARPDx

SharpDX is released under the [permissive MIT license](#).

VTk

VTk is an open-source toolkit licensed under the [BSD license](#).

14. Contact information

For any questions or comments regarding this manual or WorkstationOne please contact:

Three Palm Software:

Phone: 1-408-356-3240

E-mail: support@threepalmsoft.com

16 Yankee Point Drive, Carmel, CA 93923, USA

European Community Representative:

Wellkang Ltd

Enterprise Hub, NW Business Complex, 1 Beraghmore Rd,
Derry, BT48 8SE, Northern Ireland

Any serious incident that has occurred in relation to this device should be reported to the manufacturer, and to the competent authority of the Member State (of the EU) in which the user and/or patient is established.

A hardcopy (paper) version of this manual can be obtained by sending an email request to: support@threepalmsoft.com (include the serial number associated with the software in the request).