DynaCAD 4.0

Instruction for Use

MRI Study Review, Analysis and Reporting Software

Launched from Philips IntelliSpace Portal

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DynaCAD 4.0

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About the Instructions for Use

These Instructions for Use are intended to assist users in the safe and effective operation of the product described. Within are basic operational instructions for the DynaCAD MRI Study Review, Analysis and Reporting Software. The purpose of this manual is to provide general information for use with DynaCAD software, with emphasis on safety, privacy and security. This guide does not attempt to cover all the details or provide for every possible condition that could occur during setup, operation, or maintenance. Should further information be necessary, please contact your service representative.

Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all WARNINGS and CAUTION notices.

Pay special attention to all the information given and procedures described in the SAFETY section.

Keep this document in a convenient location for easy reference during the operation of this software.

These Instructions for Use describe the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

Explanation of Symbols used marking the DynaCAD Software:

Symbol	Description
	Manufacturer
	Date of Manufacture
	Refer to Manual
	***WARNING*** A WARNING alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
	***CAUTION*** A CAUTION alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.
	***NOTE*** Notes provide advice and highlight unusual points. A note is not intended as an instruction.
	CE Mark
SN	Serial Number
REF	Model or Catalogue Number

CAUTION Federal law restricts the sale, distribution, and use of this device to or on the order of a physician.

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1 DynaCAD Device Labeling

1.1 Intended Use

This Invivo product is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions given in this Instructions for Use for the purposes for which it was designed. The purposes for which the product is intended is given below. However, nothing stated in this Instructions for Use reduces users' responsibilities for sound clinical judgment and best clinical procedure.

1.2 Brief Device Description

DynaCAD is used to review, analyze, and generate reports for MRI studies. Post-processed and raw MR images directly from the scanner may be viewed. When used in conjunction with DynaCAD Breast, Prostate and Advanced processing, the viewer displays and provides tools to analyze the post processed image series generated from the analysis performed by the DynaCAD Breast, Prostate and Advanced Analysis software using the available time points. DynaCAD allows a small application to be placed on any computer which enables thin client communication to a visualization server for review and analysis of images across a network.

1.3 Regulatory Compliance

DynaCAD complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Invivo representative, or by the manufacturer.

1.4 Safety

Electromagnetic Compatibility

This Invivo product complies with relevant international and national law and standards on EMC (electro-magnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

- Medical electrical products needs special precautions regarding EMC, and needs to be installed and put into service according to EMC information provided in the accompanying documents.
- The use of accessories and cables other than those specified may result in increased emission or decreased immunity levels.
- The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

Portable and Mobile Phones

CAUTION Portable and mobile RF communications can affect medical electrical equipment. Use caution when using such communication devices within the specified range of medical electrical devices.

1.5 Indications for Use

DynaCAD

The DynaCAD software consists of the MR Analysis Server software and the viewer workstation software.

The MR Analysis Server software, which includes the DynaCAD Breast, DynaCAD Prostate, and DynaCAD Advanced PK for other MR Analysis modules, is intended to be used as a post-processing software package designed to provide a reliable means for analyzing MR datasets. The software facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review and additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including parametric images overlaid onto source MRI images.

The viewer workstation software is intended for use in conjunction with the MR Analysis Server software and facilitates the analysis and presentation of datasets generated by the MR Analysis Server software and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.

DynaCAD software serves as a workflow roadmap tool that organizes and guides the radiologist through the series of sequential tasks that must be performed in order to arrive at a diagnosis. The specific configuration of product features drives the DynaCAD software underlying workflow solution for lesion characterization and reporting. This inherent workflow regimen integrates easily into the radiologist‘s existing departmental workflow and can be adapted to fit the needs of each user, thereby streamlining diagnosis. In the hands of a trained physician the information provided by the data analysis could yield information that may assist in the interpretation of dynamic and non-dynamic MR studies.

DynaLOC Breast

The DynaLOC Breast Interventional Planning software module supports the use of interventional breast coils and MR stereotactic localization devices to perform MR-guided breast interventional procedures. Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion, relative to the interventional device.

The accuracy of DynaLOC software depends on the resolution of the acquired dataset. If the sum of the slice thicknesses for marker and target series does not exceed 5 mm, the 3-dimensional accuracy is 5 mm. Otherwise it is equal to the sum of two slice thicknesses for marker and target series. The accuracy can be negatively affected by any of the following:

- Significant patient movement after the breast is securely immobilized in the biopsy device
- Significant displacement of tissue during needle penetration

- Image distortion in the MR dataset.

DynaLOC Prostate

DynaLOC Prostate Interventional is a computer-based image-guidance accessory for use with commercially available Magnetic Resonance (MR) imaging systems and interventional devices.

The application provides the user with patient data processing, visualization and storage functions. It allows image analysis, display and recording of simulated images of a tracked insertion tool, such as a needle guide or sleeve, on a computer monitor or other display that shows images of the target organs and the current and/ or projected path of the interventional instrument.

The device is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional and/or diagnostic procedures of the prostate.

1.6 Contraindications

There are no contraindications for this device.

1.7 Adverse Effects

The use of DynaCAD software review workstation adds no known additional patient risks, as there is no direct contact with the patient.

1.8 Warnings

DynaCAD

⚠ Hardware used shall meet the minimal hardware specifications.

⚠ DynaCAD software shall be installed on supported Operating Systems only.

⚠ For optimal performance of the MR Analysis Software it is recommended not to load additional software onto the DynaCAD server hardware.

⚠ Notify Invivo service to assess the integrity of the system in case of computer virus infections.

⚠ Always send studies first to a DICOM storage device such as a PACS, since the DynaCAD and its database is a temporary storage and shall not be used for long term archiving of any patient data.

⚠ DynaCAD shall receive data from DICOM 3.0 compliant devices only.

⚠ The site and user are responsible for ensuring the uniqueness criteria of a patient so that studies of a patient can be grouped correctly.

⚠ User shall ensure all necessary image and analysis information are available and read, and that the user shall use multiple pieces of information to make a diagnostic decision.

- User shall be aware that JPEG lossy compression is applied during transmission of the rendering output from the DynaCAD server to the client for display. Compression ratios depend on many factors, but are generally expected to be less than 14:1 in 95% of typical data sets. This applies to viewports that display grayscale images without color overlay, RGB images such as screen captures and report, and image fusion of the DynaCAD Registration feature.
- User shall be aware that left click and drag scrolling is designed to scroll quickly to allow user to navigate to an image location. Not all images may be displayed.
- When interpreted by a physician, DynaCAD provides information that may be useful in screening, diagnosis, intervention planning and monitoring. Patient management and all other clinical decisions are the responsibility of the interpreting physician and should not be made based solely on the results of DynaCAD software analysis. When reviewing a case, all image sequences should be reviewed and taken into account for interpretation. Images should be interpreted only by trained physicians.
- Orientation and laterality labels displayed on the image viewport are specified in English abbreviation, regardless of the languages displayed in the UI: L (Left), R (Right), A (Anterior), P (Posterior), H (Head), F (Foot).
- Take care to note the Study Date and Time in the image overlay when comparing studies.
- Significant patient motion or differences in acquisition resolution between MRI sequences may impact the image position accuracy when using the correlate feature. Check alignment prior to correlating the overlaid dataset. If the image position appears to be incorrect between different sequences, manually scroll one of the image stacks to make them inline.
- Always check the grayscale motion-corrected DCE MRI series by scrolling through them, to make sure that Motion Correction was successful or without apparent failures. It is also strongly recommended that you process studies with and without motion correction (no need for re-processing, since MR Analysis Server allows for both simultaneously) for further comparison.
- Motion correction helps to compensate patient movement, and it is important for analyzing DCE. The motion corrected DCE series is identified by "*DCAD-MC-DYN-*< DCE Series Description>".
- Motion Correction helps to register dataset together, but cannot completely eliminate all misalignments. When interpreting the original and/ or motion corrected data, the user is required to check the amount and impact of any mis-alignment, and to use the information from other acquisition sequences.
- Motion Correction may fail to remove the effects of patient motion. Registered images should only be used as a supplemental source of information. Diagnosis should be made on the basis of original images. Diagnostic analysis of contrast enhancement should not depend on the availability of registered images.
- Motion Correction changes image spatial dimensions. Registered images must not be used to quantify dimensions such as distance, angle, area or volume.
- Confirm the dynamic curve of the known anatomical region(s); they should be evaluated to ensure that the correct dynamic phases were used in the analysis, for example, an expected contrast enhancement in the heart.

- QuickTP or Pharmacokinetic (PK) analysis requires a pre-contrast dataset. Verify that the dynamic sequence to be used has at least one pre-contrast dataset. Erroneous outputs will occur if pre-contrast phases/ time points are missing.
- DynaCAD's MR Analysis Server should not be used with manipulated settings to process a study, as it will result in erroneous output.
- QuickTP or PK colorization on every slice should be carefully examined along with subtraction images. If there is no colorization in the areas that significantly enhance, use the Correlate tool for viewing the dynamic curves to analyze the cause.
- Visually inspect the colorized parametric/ motion-corrected images for unusual appearance: e.g., there is a lot of enhancement in the subtraction images, but no colorization in parametric images. These could be due to problems with the original images or processing configuration setup. For example, too much motion in the original DCE MRI images may result in much less than expected colorization, or incorrect timing setup may result in inadequate colorization. Shall verify the image quality and the scanning protocol (timing, injection detail, sequence parameters) to assure optimal analysis and avoid erroneous results.
- When reviewing breast images, verify the left and right images are loaded correctly in the image viewport. This can be done by checking the location text information in the upper left corner of the viewport.
- When reviewing breast images in the 3D rendering mode, verify the left and right images are loaded correctly in the image viewport when selecting the left/right shortcut icon. This can be done by checking the location text information in the upper left viewport.
- Review and edit if necessary the prostate boundary prior to drawing an ROI. Failure to do so may cause some measurements in the lesion analysis summary to be inaccurate.
- Displaying biopsy core from ultrasound involving an elastic transformation based on matching two prostate boundaries. Exact mapping of biopsy cores cannot be guaranteed due to the elastic nature of the prostate tissue. In addition, only the end points of the biopsy cores are mapped to the MR coordinates, and the core is approximated by a straight line.
- Do not save the biopsy core registration result if the resulting prostate boundary does not align with the reference boundary. Click the **Cancel** button to abort the operation. Check the prostate boundary using the Prostate Editor to ensure the prostate boundary is acceptable. If no improvement can be made to the prostate boundary, do not display the biopsy cores.
- Inter-sequence Registration is based on a global translation and rotation of the Registering dataset. Because of the non-rigid nature of the tissue, the resultant mapping may not be exact because of the local deformation of the tissue. Always inspect the location when reading and performing analysis.
- Do not apply the inter-sequence registration if the result does not align. Click the **HOME** tab to exit the operation. If a saved registration is not satisfactory, select Rollback to remove the registration. A sub-optimal registration may affect your reading and analysis.
- AVI movie clips and secondary capture images are to be used for presentation only. User shall be aware that image transformation such as zoom, window level may have been

applied, and the captured images are different from the original. They may also be captured from viewports that display images that have undergone lossy compression operation.

⚠ Hardcopy printouts shall not be used for diagnostic interpretation.

DynaLOC Breast

In addition to the DynaCAD warnings:

⚠ DynaLOC Breast software shall be used and the intervention shall be performed by a trained physician. Any misuse of the interventional planning information can result in potential patient injury.

⚠ Only to be used with validated devices including grid and needle guide.

⚠ Only MR-compatible intervention devices and other instruments shall be used in the MR scanner room.

⚠ All the devices used in the MR scanner room and during intervention shall be used in accordance with manufacturer's instructions.

⚠ DynaLOC Breast software shall be used only with recommended biopsy devices, fiducial markers, needle and needle guides.

⚠ The MR scanner and sequences to be used shall be tested for spatial distortion of produced images to avoid spatial miscalculations of target and marker locations and needle path.

⚠ DynaLOC Breast software supports only prone position interventional procedures.

⚠ It is recommended that the slice thickness be less than 2.5mm for the marker series and less than 4mm for the target series. If the slice thickness for your target series is higher than recommended, a warning will be displayed in the Workflow panel. You may continue with intervention planning but accuracy may be affected.

⚠ Acquire a confirmation scan with needle sleeve inserted at the target location prior to interventional procedure to assure the proper target localization.

⚠ The user shall make sure that the marker and target series are acquired with the patient and the biopsy device/markers in the same exact positions in the breast coil and the MR scanner; the user shall make sure that the intervention takes place with the patient in the same position in the breast coil with biopsy device fixed. If there was a shift in patient/target position, the old series and data shall be discarded, new marker and target series shall be acquired and new settings calculated. The possible shift of the target during needle/wire insertion shall also be taken into account.

⚠ The marker shall be filled with diluted contrast agent. The marker cavity shall be completely filled to ensure optimal localization of the marker.

⚠ The extracted markers shall be verified and confirmed by the physician for accuracy. If incorrect, the user shall move or set the marker at the correct location.

⚠ DynaLOC Breast MR guided needle calculations are based on the latest information from each biopsy manufacturer. If a discrepant result occurs it is recommended to perform a manual calculation and check the MR breast intervention system manual for any changes

to the hardware that may affect the calculation. The specific breast intervention manuals take precedence over DynaLOC Breast.

- The physician shall take into account the needle overshoot and where the biopsy needle opening is located. DynaCAD may not show the trough and overshoot information for all needles. In this configuration, only the direct distance from the front face (nearest to the user) of the needle block to the target will be provided.
- The physician shall evaluate the suggested path for needle/wire insertion prior to intervention, to assure that no vital organs or vessels are on the path, or that there could be a potential danger of thorax puncture. Other suggested paths (if available) or manual operating mode shall be selected to assure a safe path for intervention.
- In case DynaLOC software fails to produce acceptable settings for intervention or simply fails to produce any, manual intervention planning should be performed.
- A confirmation scan with needle sleeve or wire inserted at the target location shall be used to assure proper target localization prior to intervention.
- If the lesion being biopsied is likely to be malignant, but the results of biopsy are negative, this is a discordant biopsy and performing another biopsy procedure should be considered.
- Take into account the needle throw or where the intervention needle opening is located. Breast Interventional Planning provides the direct distance to the target.
- Compression force may cause tilting of the grid in the H-F or A-P direction; this will impact the accuracy of the calculation.

DynaLOC Prostate

In addition to the DynaCAD warnings:

- DynaLOC software shall be used by a trained physician. Any misuse of the interventional planning information can result in potential patient injury.
- The MR scanner and sequences to be used shall be tested for spatial distortion of produced images to avoid spatial miscalculations of target locations and needle path.
- The recommended Pixel Spacing is 1mm or less, and Slice Thickness is 2mm or less to improve the needle detection result and location of the target.
- Only validated MR safe and validated interventional devices, including needle and needle guide, should be used with the DynaLOC software.
- Use only validated MR safe and compatible needles to avoid harm to patient and staff. All equipment trays and components should be double checked with a hand held magnet before being brought into the magnet room.
- Only MR safe and compatible intervention devices and other instruments shall be used in the MR scanner room.
- All the devices used in the MR scanner room and during intervention shall be used in accordance with manufacturer's instructions.

- If DynaLOC does not calculate an acceptable setting for intervention or simply fails to produce any setting, manual intervention planning should be performed.
- The physician shall evaluate the suggested path for needle insertion prior to intervention, to assure that no vital organs or vessels are on the path. Other suggested paths (if available) or manual operating mode shall be selected to assure a safe path for intervention.
- The needle should not be inserted until you are satisfied with the needle guide alignment and needle trajectory.
- The blue line beyond the yellow line (needle trough) away from the needle guide denotes the needle throw. Needle path and needle throw should be reviewed to assure the needle path is optimal, without risk to vital organs or vessels. Choose a different needle trajectory and type of needle as required to minimize risk to the patient. Use of a manual biopsy device may be required. Proceed with extreme caution.
- Do NOT proceed with the needle insertion if the blue line (projected needle guide) does not align with the needle guide that appears in the verification scan as erroneous depth and angulation will result if parameters are not defined correctly. The discrepancy could be the result of patient and/or DynaTRIM movement, incorrect adjustment of the DynaTRIM settings, and/or incorrect needle guide calibration.
- The physician should always read and follow the step by step interventional instructions. In particular, the user should be cautious after the confirmation scan when there is need to adjust the needle after it has been inserted inside the patient.
- Before the intervention is performed a confirmation scan shall be acquired with the needle guide (and possibly stylette) inserted, to ensure that the needle is positioned as desired. Incorporate the effects of needle throw into the risk evaluation. The needle path should be as desired, without risk to vessels. Choose a different needle trajectory and type of needle as required to minimize risk to the patient. Use of a manual biopsy device may be required. Proceed with extreme caution.
- To assure the proper target localization, a verification scan shall be acquired to confirm needle trajectory will hit the target location prior to needle insertion.
- Do NOT proceed with the biopsy procedure if the needle appearing in the verification scan does not reach the target.
- Do NOT proceed with the interventional planning if the blue overlay does not match up with the visible needle guide as erroneous depth and angulation will result if parameters are not defined correctly. Contact Technical Support for assistance.
- If the lesion being biopsied is likely to be malignant, but the results of biopsy are negative, this is a discordant biopsy and performing another biopsy procedure should be considered.

1.9 Cautions

- Federal law restricts the sale, distribution, and use of this device to or on the order of a physician.
- Ensure that the voltage and current requirements are within system specifications to avoid bodily injury from electrical shock or fire hazard.

- Do not place liquids on or near the hardware components which contain the DynaCAD software. If a liquid is accidentally spilled on electrical components, immediately shut down the hardware system to prevent any potential electrical shock. Contact your authorized Invivo service provider for further instructions.
- The intervention planning software requires hard drive storage space on the DynaCAD Server. The disk should always be less than 90% full before starting any intervention planning.

2 Privacy and Security Features

The following section relates to the privacy and protection of patient information, and the security of the Invivo Clinical Solutions Products.

Customer Role in the Product Security Partnership

- We recognize that the security of Invivo Clinical Solutions products is an important part of your facility's security in-depth strategy. However, these benefits can only be realized if you implement a comprehensive, multilayered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

- Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The actual implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, authentication technologies, etc.

- As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems. Although the system incorporates protection mechanisms to protect it against the intrusion of malware (e.g., viruses), a remote probability remains that a system can become infected. In all circumstances, system safety remains guaranteed, but the user might notice unfamiliar system behavior and/or performance. If this happens repeatedly, e.g., after the system has been switched off and on again, the user is advised to call service to have the system checked and, if needed, cleaned from malware.

Access Control

The following functionality with respect to access control is implemented:

- A user logon/logoff procedure is required to gain access to the system. Only username/password authentication is supported; no additional mechanisms, e.g., two-factor authentication using smart-cards are supported. It is recommended to manually log off when leaving the system unattended and that the site change any interactive passwords when first accessing the sytem.

- The system supports only single-user sessions. It does not provide functionality to register multiple simultaneous users or to switch between users other than via log-off/log-on.

- Invivo Clinical Solutions products do not support single sign-on or node authentication

- Remote login into the system is restricted to Invivo Service personnel only and is password protected.

- Invivo server products do not require direct user operation and therefore are not equipped with a keyboard, mouse, & monitor.

Audit controls

- In general, Invivo Clinical Solutions products do not support local or central audit log creation, and storage on the system. The IHE-ITI ATNA (Audit Trail and Node Authentication) profile and IHERAD Audit Trail Options are not supported.

- DynaCAD supports HIPAA logging functionality.

- By default, user login and logoff events are recorded.

Confidentiality of personal data

- Invivo Clinical Solutions products support remote access by Invivo service personnel; provision of service to your product may involve access to and viewing of personal health information on the product. Customers are notified by the system that a remote session is in progress.

Configuration

- Default security related configuration of Invivo Clinical Solutions products can be modified up to a limited and supported extent. Please contact Invivo Service.

- Recommend that only Admin and/or Invivo Field Service be allowed to set operating system parameters (eg Date, Time, Synchronization, etc).

Contingency, data backup and storage

- Invivo Clinical Solutions products are not intended to serve as an image archive; backups are neither required nor advised. If backups are made, be advised that certain backup media (e.g., DVD) may not be supported in future releases due to technology obsolescence. If backups are made, be advised that these backups may contain personal data (including protected health information).

- Invivo Clinical Solutions products may contain patient information, including protected health information. Deleting patient studies may not permanently remove patient data.

Encryption and de-identification

- Invivo Clinical Solutions products do not support the encryption of personal data (including DICOM data) for transmission or storage (internally or on removable media).

- Invivo Clinical Solutions products do not support de-identification of DICOM data for export functionality.

Emergency access procedure

- Invivo Clinical Solutions products do not support emergency access/backup functionality; this is outside of the scope of their intended use.

Integrity

- Invivo Clinical Solutions products do not have a built-in check for application or data integrity for storage or transmission.

Malware protection

We require customers who use Invivo Clinical Solutions products equip their systems with anti-virus software which is designed to detect viruses and to deny access to infected files, before they can do any damage.

- Anti-virus definitions should be updated on a regular (daily) basis. The Anti-virus definitions update mechanism automatically checks for new virus definition files at a pre-configured time and installs them, if available. It is the responsibility of the system operator to check the status of the anti-virus definitions, as well as whether the system has detected malware.

- We recommend a daily check to verify that the definitions are up to date, and that the computer is free of viruses and malware.

- If the virus scanning software has detected infection by malware, it will attempt to remove the virus and clean any infected files. Be sure to adhere to local procedures regarding malware infection of customer systems (e.g., may include disconnect from the network).

WARNING In case of infections, always notify Invivo service to assess the integrity of the system.

Physical access

The following physical characteristics of the Invivo Clinical Solutions products shall be taken into account for system operation and access control:

- Invivo Clinical Solutions products do not disable physical I/O device interfaces (e.g., USB) by default.

- Invivo Clinical Solutions products do not restrict access to external bootable devices by default.

- Invivo Clinical Solutions products are “service friendly” and do not require special tools to open chassis and remove hard drives.

- There is no detection of unauthorized physical access into the system, e.g., tamper proof seals.

- The Invivo Clinical Solutions products have no built-in check for application or data integrity for storage or transmission.

System and application hardening

- Invivo Clinical Solutions products do not remove or disable all unnecessary services.

- Invivo Clinical Solutions products do not block or disable unused ports by default.

- Invivo Clinical Solutions products do not contain an active firewall; it is the customer’s responsibility to provide a secure operating environment for these devices.

- Invivo Clinical Solutions products do not password protect the BIOS; please consult Invivo service before changing this setting.

3 Compatibility

3.1 Compatibility

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Invivo Corporation.

Changes and/or additions to the product should only be carried out by Invivo or by third parties expressly authorized by Invivo to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.

WARNING Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Invivo warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

3.2 Supported Platforms

DynaCAD client runs on the following Microsoft Windows® operating systems:

- Windows Server 2012 R2 Standard
- Windows Server 2008 R2 Standard SP1
- Windows 10 Professional, 32 and 64-bit
- Windows 8.1 Professional, 32 and 64-bit
- Windows 7 Professional SP1, 32 and 64-bit

3.2.1 Languages

DynaCAD client user interface is available in the following languages:

- Danish
- Dutch
- English (default)
- French
- German
- Italian
- Norwegian
- Spanish
- Swedish

The displayed language is based on the system locale setting. The system locale can be changed under the Windows's **Region Settings**. The **Region Settings** dialog can be invoked from Windows **Control Panel**.

4 Overview

4.1 Operational Use

Do not start up the product unless you and all other users present have read, fully understood and know all the safety information and emergency procedures given in the SAFETY section of this Instructions for Use. Operation of the product without having read, understood and knowing ALL the safety information and procedures in the SAFETY section could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis.

5 DynaCAD Login

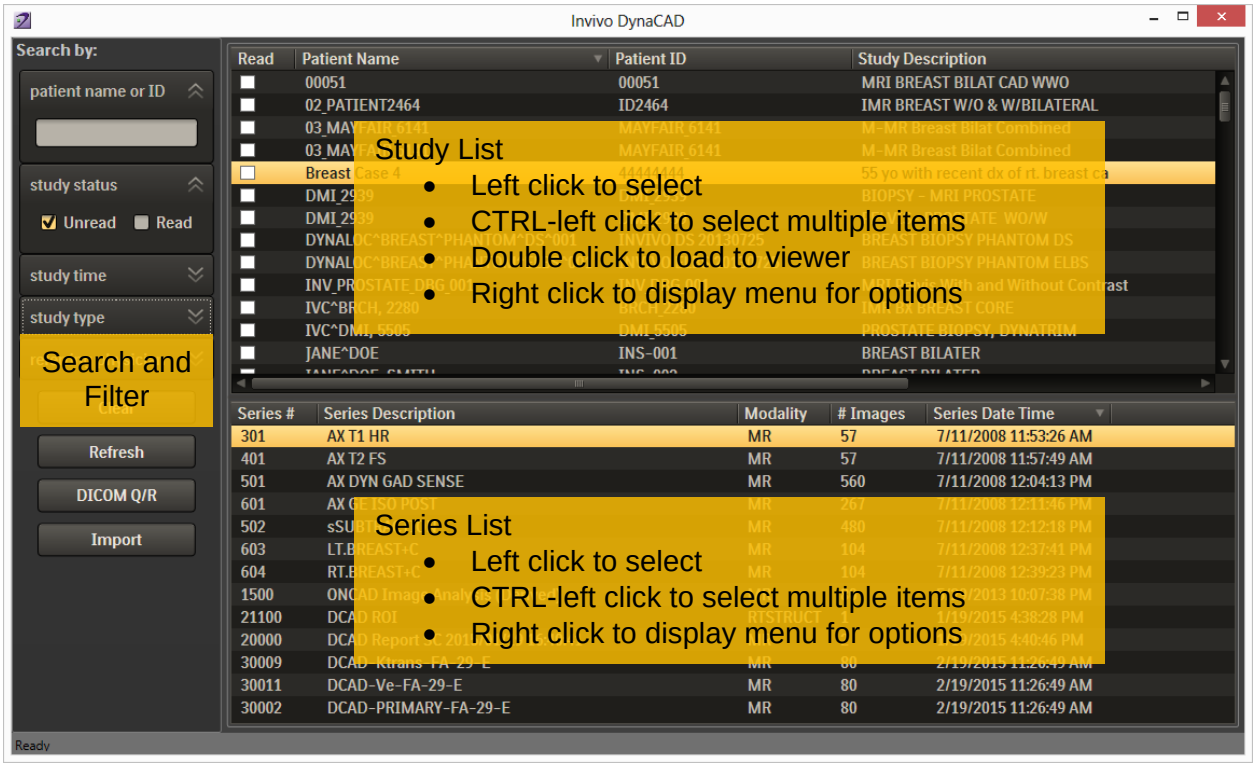
5.1 User Login Authentication

The Web Server address should be provided. For example, if the DynaCAD Web Admin URL is http://*192.168.80.118*/viz, then enter *192.168.80.118* for the **Web Server** in the login window. The web address information will be remembered for subsequent login.

6 Study Manager

6.1 Basic Operations

The Study Manager is divided into three main areas:



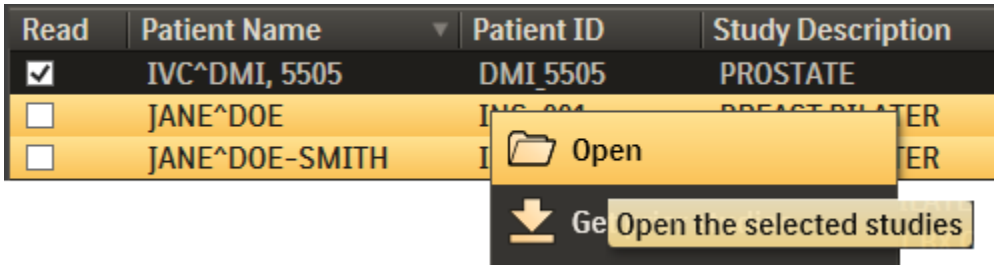
***NOTE*:** When a study is opened into the viewer, it will automatically make all studies of the patient available. Therefore, there is no need to manually select all studies of a patient. Always select the target study for reading and reporting.

WARNING Take care to note the Study Date and Time in the image overlay when comparing studies.

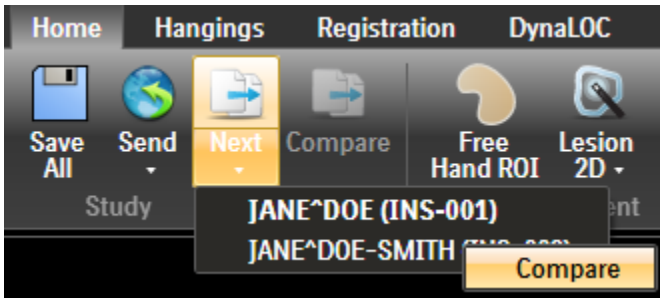
6.2 Studies with Variations in Patient Name/ ID

Current and prior studies of the same patient may not have consistent patient name and/ or ID. They may not be loaded together into the viewer automatically. The user can override by:

- Selecting both studies from the Study Manager:



- On the viewer:



Left click on the **Next** button label

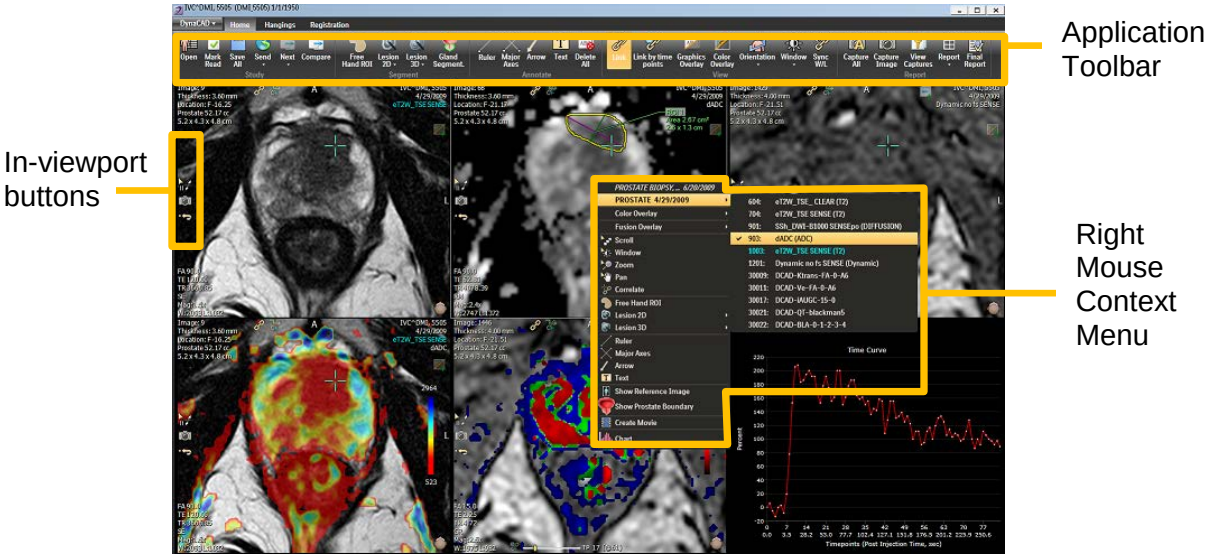
Move mouse to the patient name

Right click and select **Compare**

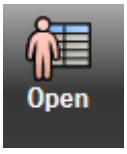
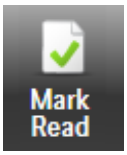
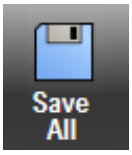
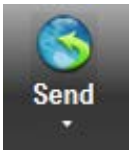
Both studies will then be available for display together in the viewer. Right click on any viewport will display the context menu with both studies for assignment to the viewport.

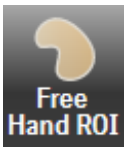
7 DynaCAD Viewer

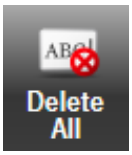
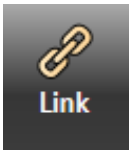
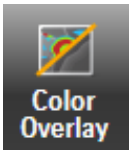
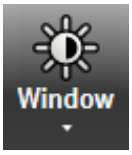
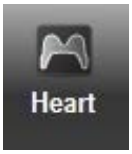
7.1 DynaCAD Client User Interface

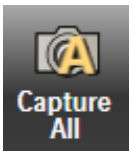
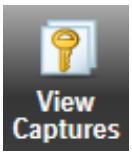


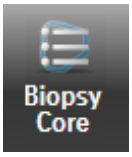
7.1.1 Application Toolbar

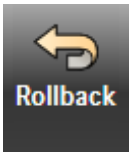
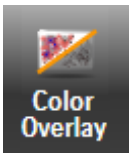
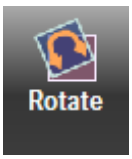
Icon	Application Toolbar Function
Study Group Icons	
	Open the **Study Manager** displaying the list of patients.
	Mark the current study as READ.
	Save all measurements, annotations and 2D, 3D ROIs.
	Send pre-configured series to a DICOM destination.
	Load the next selected patient. Left click on the text or arrow displays the list of the selected patient for random selection.

Icon	Application Toolbar Function
	Switch the layout to compare multiple studies. Only enabled when more than one studies is available.
Segment Group Icons	
	Enable the free hand ROI function.
	Enable the last selected 2D ROI Segment function based on the color overlay. Left click on the text or arrow displays a list of 2D ROI Segment functions.
	Enable the last selected 3D ROI Segment function based on the color overlay. Left click on the text or arrow displays a list of 3D ROI Segment functions.
	Open the **Prostate Edit** window.
Annotate Group Icons	
	Enable the ruler tool in an active viewport.
	Enable the long and short axes tool in an active viewport.
	Enable arrow drawing in an active viewport.
	Enable an annotation to be created in an active viewport.

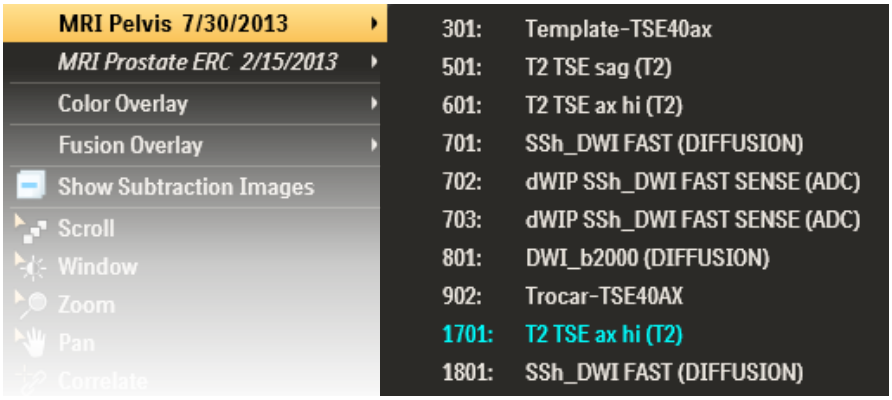
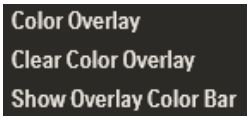
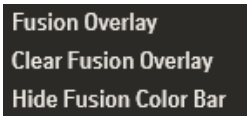
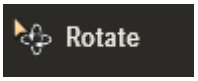
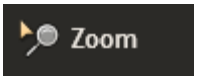
Icon	Application Toolbar Function
	Deletes all measurements, annotations and ROIs.
View Group Icons	
	Enable spatial linking of all image viewports.
	Enable temporal linking of all image viewports that display time sequence such as original and motion corrected DCE, subtraction series.
	Enable or disable graphic overlays in all viewports.
	Toggle ON/ OFF PK color overlays for all viewports.
	Display the image of the active viewport in the acquisition plane. Left click on the text or arrow displays the MPR options.
	Apply auto-window levelling to the active viewport. Left click on the text or arrow displays a dropdown menu that lists the related functions including window presets and inversion for the user to select.
	Enable window level linking of all image viewports that display same image sequence type.
	Toggle ON/ OFF the heart mask. Only available for breast study.
Report Group Icons	

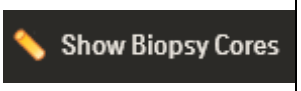
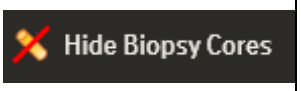
Icon	Application Toolbar Function
	Capture all images in current layout and places them in the Key Images clipboard or reports.
	Capture an image or chart of the active viewport.
	Display captured key images and charts.
	Create an ROI based automatic report. Left click on the text or arrow displays a dropdown of the list report options.
	Display the final report. Only enabled when a final report is available.
Hanging Protocols Group Icons	
	Left click on one of the twelve F keys applies the associated user definable hanging protocol. Right click to save the current layout assignment or to edit the hanging protocol name.
	Left click on the text or arrow displays multiple options of screen layouts.
Viewing Tools Group Icons	
	Apply 2D display mode to the active viewport. Left click on the text or arrow displays multiple layout options for the 2D viewport.
	Apply MIP mode to the active viewport. Left click on the text or arrows displays multiple layout options for the MIP viewport.

Icon	Application Toolbar Function
	Apply MPR mode to the active viewport. Left click on the text or arrows displays the option of Axial, Coronal, Sagittal and Oblique MPR.
	Display DICOM header information of the image in the selected Viewport. It only displays the information when the display mode is either 2D or MPR displaying in the original acquisition plane.
 	Left click on the icon flips image based on the last chosen options. Left click on the text or arrow displays the different flip options. Once selected, the icon and text label will be updated accordingly.
	Left click to apply subtraction to the active viewport. Right click will display a dialog for selecting the reference time point. The button will only be available if the active viewport is a DCE series, including original and motion corrected DCE.
	Left click to setup configuration for on-the-fly ADC and b-value calculation.
Chart Types Icons	
	Display the **Time Curve** chart in the active viewport.
	Display the **Lesion Analysis Summary** chart in the active viewport.
	Display the **Curve Analysis** chart in the active viewport.
	Display the list of biopsy core items in the active viewport.

Icon	Application Toolbar Function
	Display the list of all the histograms that can be selected to display in the active viewport. The histograms include WashIn, WashOut, QuickTP (QTP), PK Joint Histogram, K^{trans}, V_e, K_{ep}, V_p, T10, iAUGC and ADC
	Display the list of all the **Compare** charts that can be selected to display in the active viewport. The **Compare** charts include K^{trans}, V_e, K_{ep}, V_p, T10, iAUGC and Volume Compare.
Registration Icons	
	Apply the registration.
	Delete the saved registration.
	Reset the registration to previously applied setting.
	Toggle the display of the control points.
	Toggle the display of the color overlay on the result viewports.
	Change mouse mode to pan the Registering Sequence.
	Change mouse mode to rotate the Registering Sequence.

7.1.2 Right Mouse Context Menu

Icon	Right Mouse Context Menu Function
Study label at top of menu.	All the studies of the patient will be available to be selected for display. The study that is selected from the **Study Manager** will be displayed in normal font. Other studies will be displayed in italics.  ***NOTE*:** For prostate study, the series that is referenced by the prostate boundary is colored in cyan.
	**Color Overlay** lists the PK and QuickTP data that can be selected to display as color overlay. Left click **Clear Color Overlay** to remove an existing color overlay. Left click **Show/Hide Overlay Color Bar** to remove the color bar.
	**Fusion Overlay** lists the available ADC and Diffusion data that can be selected to display as color overlay. Left click **Clear Fusion Overlay** to remove an existing fusion overlay. Left click **Show/Hide Fusion Color Bar** to show/hide the fusion color bar.
	Change the left mouse interaction mode to scrolling for 2D and MPR.
	Change the left mouse interaction mode to rotate for 3D/MIP.
	Change the left mouse interaction mode to window leveling.
	Change the left mouse interaction mode to zoom.
	Change the left mouse interaction mode to pan.
	Change the left mouse interaction mode to correlate.

Icon	Right Mouse Context Menu Function
	Change the left mouse interaction mode to free hand ROI creation.
	2D/ MPR: Left click enables 2D ROI function.
	2D/ MPR: Left click enables 3D ROI function.
	Display the biopsy core graphics. This item will only be available if the UroNAV biopsy core data is available.
	Hides the biopsy core graphics. This item will only be available if the biopsy core(s) are currently displayed.
	Enable the ruler tool for 2D and MPR.
	Enable the long and short axes tool for 2D and MPR.
	Enable arrow drawing for 2D and MPR.
	Enable annotation for 2D and MPR.
	Display the Reference Image inset at the bottom right of the viewport. It shows an orthogonal series with a reference line indicating the location of the image being displayed. Only available for 2D and orthogonal MPR viewport.
	Apply the heart mask for breast.
	Hide the heart mask.
	Edit the heart mask.
	Display prostate boundary. Only available for prostate case with an approved prostate boundary.
	Display the **Create Movie** dialog.
	Left click Chart to display a pop-out menu of charts available to display in the viewport.

7.1.3 In-viewport Tools

Icon	In-viewport Tools
2D/ MPR In-viewport Tools	

Icon	In-viewport Tools
	Press and drag left mouse to change slice thickness for 2D and MPR display.
	Capture the current viewport.
	Reset image to original pan, zoom, window and Level.
	Left click the button to enable or disable colorized overlays.
	Left click to cycle QuickTP Uptake Percent Threshold to the Slow, Medium and Rapid setting. Only available when QuickTP is displayed as overlay.
	Enable/ disable spatial linking of image viewports.
	Enable/ disable spatial linking sequences across studies. The linking is based on the Image Position. This is only available for viewports displaying the original acquisition plane.
	Enable/ disable temporal linking of image viewports that display time sequence.
	Toggle between original and motion corrected series.
	Toggle between original and the corresponding subtraction.
  	Cycle between axial, sagittal and coronal view.
MIP In-viewport Tools	
	Toggle between MIP and volume rendering.
	Capture the current viewport.
	Reset image to original pan, zoom, window and Level.
	Left click the button to enable or disable colorized overlays. Middle mouse click to display different PK overlay (PRIMARY, K^{trans}, K_{ep}, V_e).

Icon	In-viewport Tools
	Left click to cycle QuickTP Uptake Percent Threshold to the Slow, Medium and Rapid setting. Only available when QuickTP is displayed as overlay.
	Enable/ disable temporal linking of image viewports that display time sequence.
	Toggle between original and motion corrected series.
	Toggle between original and the corresponding subtraction.
  	Cycle between bottom-top, left-right and front-back view.
	Horizontal Swivel: Left/ right clicking horizontal swivels the image ± 10°, SHIFT and click swivels image ± 30°. Clicking and holding will auto advance.
	Vertical Swivel: Left/ right clicking vertical swivels the image ± 10°, SHIFT and click swivels image ± 30°. Clicking and holding will auto advance.
In-viewport Tools for breast:	
  	Switch between entire image/ volume, left breast and right breast.
	Enable/ disable linking of left and right sagittal images. This function applies only when left and right breasts are hung side by side in 2D and the display orientation is sagittal.

7.1.4 Keyboard Short-cut

Cursor	Mouse and Keyboard Shortcut	Action
	Keyboard arrow left/right	Scroll through the time phases for time sequence data.
	Keyboard arrow up/ down	2D: Scroll through image series slice by slice.
	Keyboard Home/ End	2D: Scroll to the first/ last image.
	Mouse wheel scroll	2D: Scroll through the images spatially.

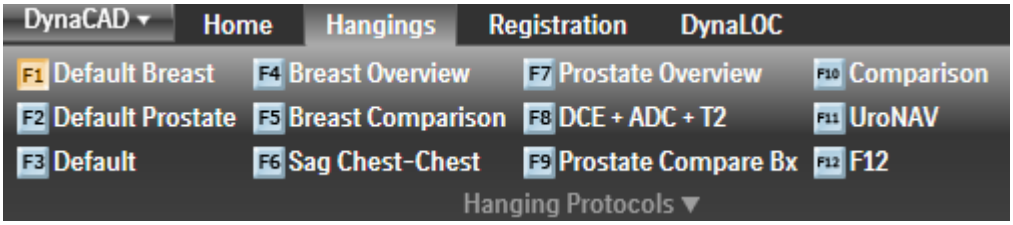
Cursor	Mouse and Keyboard Shortcut	Action
		MIP: Rotate 3D.
	CTRL+ Mouse Wheel scroll, or Press and hold right and left mouse button, or Press and hold right mouse button and mouse wheel	Zoom location under mouse cursor. ***NOTE*: *Left button will be reserved when the mouse interaction mode is Correlate.***
	Press and hold left and center mouse button	Pans the image up/down and left/right to position the image. ***NOTE*: *Left button will be reserved when the mouse interaction mode is Correlate.***
	Press and hold middle mouse wheel, then drag in horizontal and vertical to change window width and level	Changes window/level settings.
	Press ALT and left click over image	Correlate images in viewports by superimposing crosshairs. Moving crosshair in one viewport moves crosshair in other viewports to indicate same location.
	Press CTRL and left click over image	Set the Oblique MPR rotate pivot to the click location. Only applicable in Oblique MPR.
	Double Left click	Toggle between current layout and 1x1

8 Hanging Protocol

8.1 Applying a Hanging Protocol

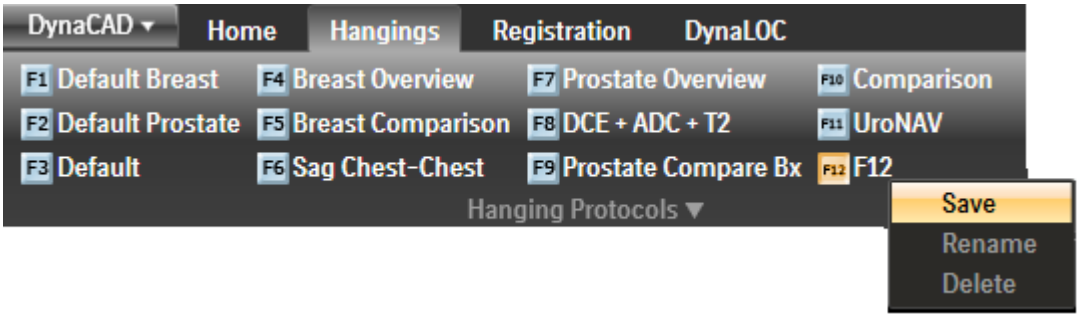
During data loading, a best matched Hanging Protocol will be applied.

A different Hanging Protocol can be applied either by left clicking the corresponding button under Hanging Protocol or hitting the F1 … F12 key.



8.2 Saving the current Hanging

The current viewport layout and series assignment can be saved to a specific Hanging Protocol by right clicking on the corresponding button, and select **Save**.



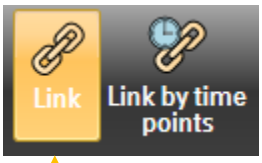
9 Viewing Features

9.1 Basic Image Manipulation

Operations such as image scroll, window level, pan and zoom can be performed interactively by left click and dragging the mouse on the viewport when the corresponding interactivity mode is active. The interactivity mode can be select from the Right Mouse Context Menu.

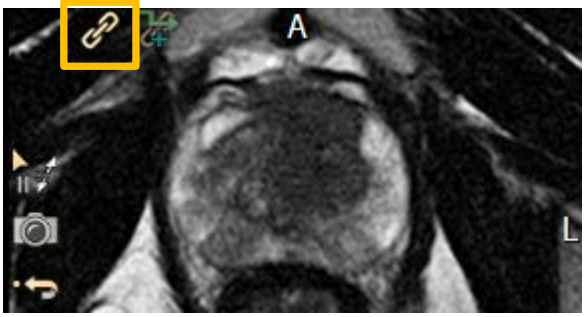
Keyboard short-cut keys are available for commonly used operations. Please refer to Section 7.1.4.

9.2 Spatial Link Scrolling



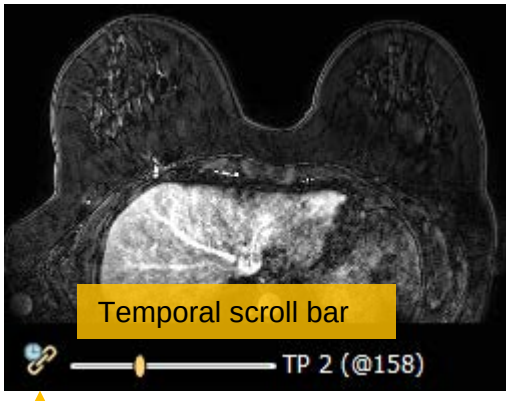
Spatial Link all viewports displaying 3D or 4D dataset.

Left click to enable/ disable spatial linking for this viewport only.

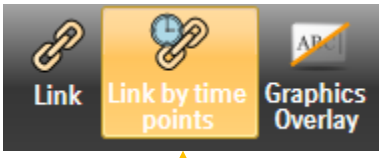


9.3 DCE Temporal Scrolling

For time sequence dataset, a scroll bar is available at the bottom of the viewport to scroll between the time phases. Viewports can be linked temporally by turning temporal linking ON.

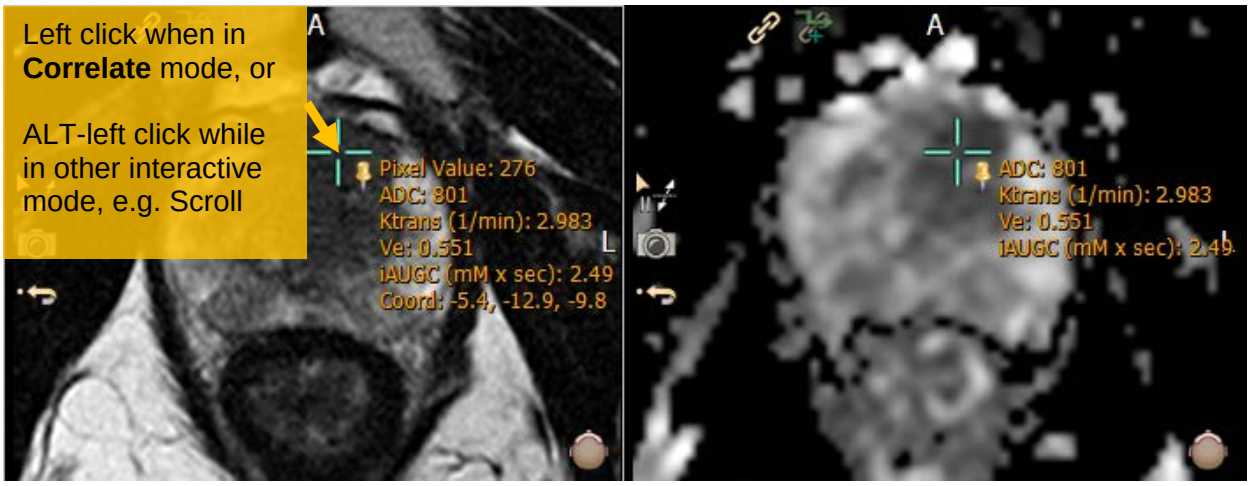


Link button next to the temporal scroll bar toggle temporal linking for the viewport.



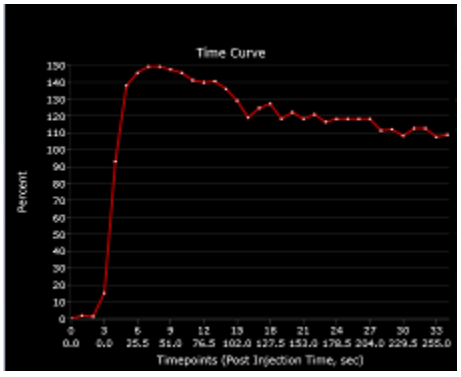
Link by time points button on the application toolbar links all viewports temporally.

9.4 Correlate



The displayed text can be turned ON/ OFF from the **User Options**.

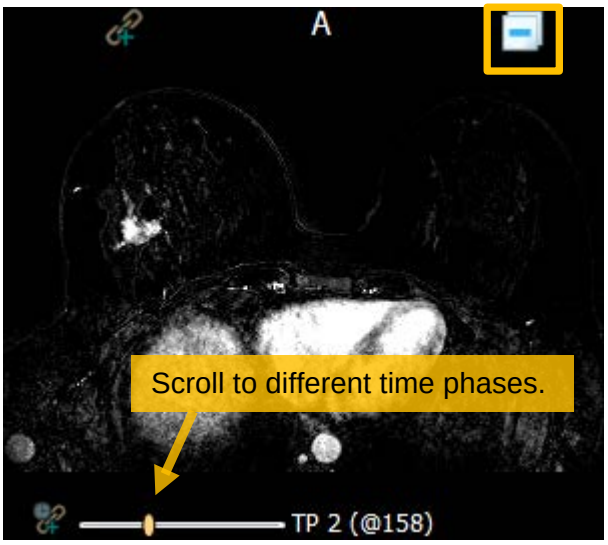
The pin/ unpin icon next to the Correlate crosshair will pin/ unpin the displayed text. When pinned, the text will always be displayed. If it is unpinned, the text will only be displayed when the Correlate crosshair is moved.



The **Time Curve** chart displays the time curve at the Correlate location.

9.5 Subtraction

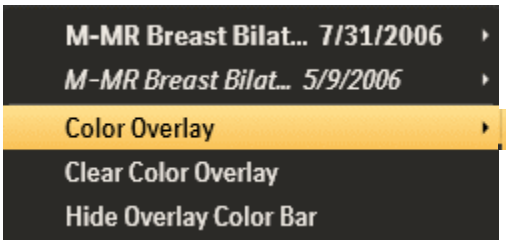
Subtraction can be applied to DCE or motion corrected DCE sequence by left click on the subtraction button in the viewport.



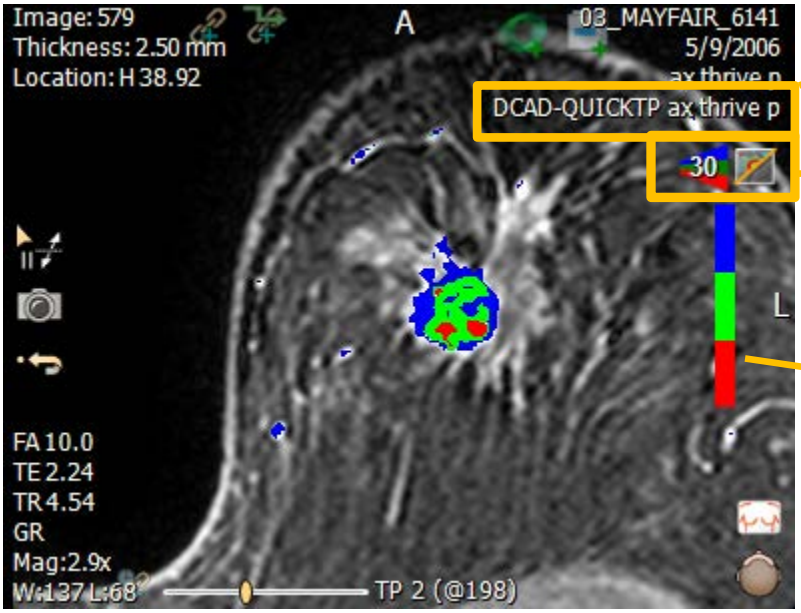
***NOTE*:** The first time phase is the default baseline. Scrolling to the first subtraction time point will usually show a blank image.

10 QuickTP

QuickTP analyzes the early uptake and delayed phase pattern using three time points within a DCE series and generates a color overlay which can be displayed over any grayscale sequences of the same study.



Select QuickTP overlay under **Color Overlay** of the Right Mouse Context Menu.



Right click on the QuickTP label to display the configuration dialog.

Uptake Percent Threshold: left click the % number to toggle between slow, medium and rapid setting.

Color bar: right click to display option to change settings.

WARNING QuickTP and PK analysis requires a pre-contrast dataset; verify that the dynamic sequence to be used has at least one pre-contrast dataset. Erroneous outputs will occur if pre-contrast phases/ time points are missing. DynaCAD's MR Analysis Server should not be used with manipulated settings to process a study, as it will result in erroneous output.

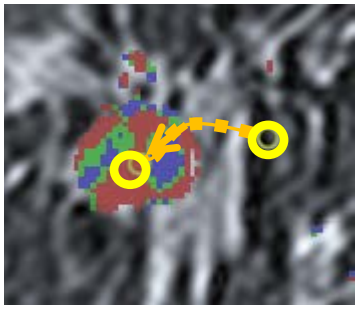
WARNING The QuickTP and PK colorization on every slice should be carefully examined along with subtraction images. If there is no colorization in the areas that significantly enhance, use the Correlate tool for viewing the dynamic curves to analyze the cause.

10.1 QuickTP Setup

The QuickTP Configuration window is displayed when the user right clicks the QuickTP label displayed in the upper right hand corner of the viewport either in 2D or MPR mode.

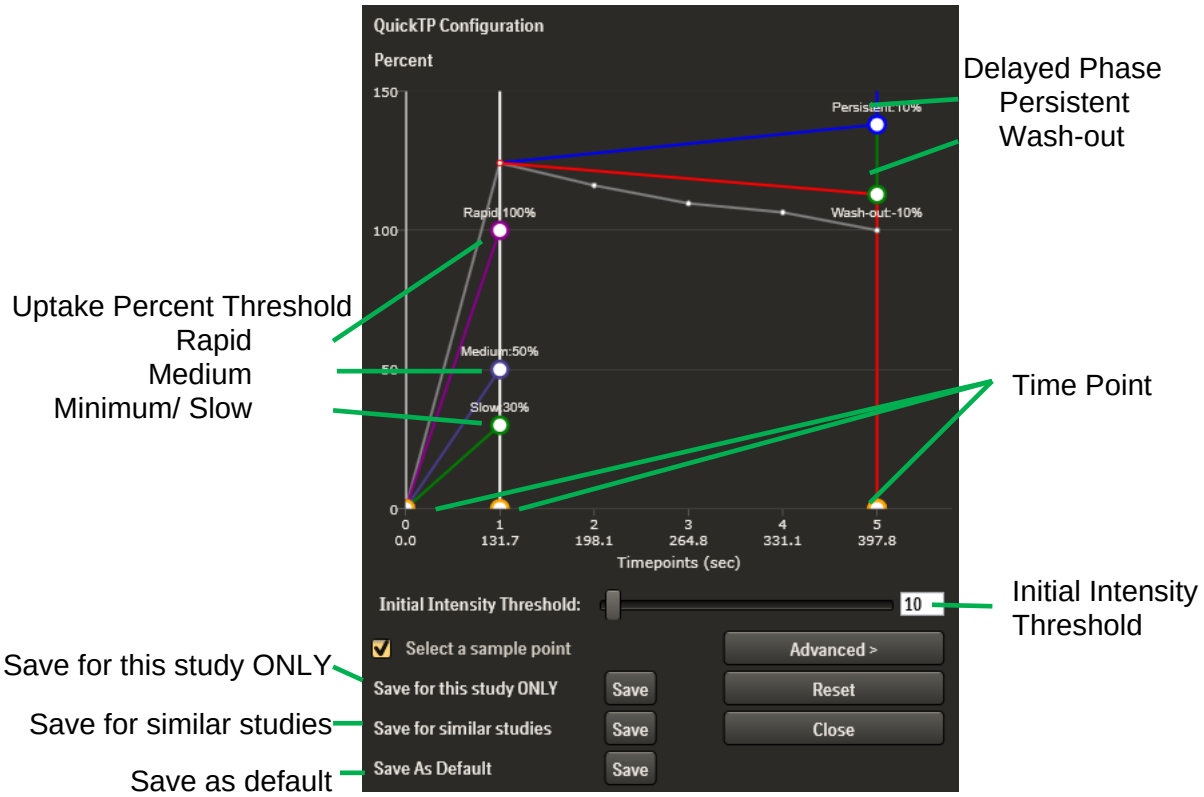
When the configuration window is displayed, it uses a voxel in the active viewport as the sample point to be shown in the graph. The sample point should be moved to a suspected lesion that

demonstrates the characteristics so that the parameters can be tuned for the type of acquisition under configuration.



Move the yellow circle to a region showing suspected characteristics.

NOTE: The QuickTP Configuration window is designed for configuring QuickTP, and is not meant to evaluate 'hot-spots". The latter can be done with the Time Curve Chart.



Time Point Selection – Left click and drag the respective orange circles on the time axis.

Initial Intensity Threshold – Voxels with an intensity above the threshold in the baseline time point (TP0) will be used for QuickTP Analysis.

Uptake Percentage (Minimum/Slow, Medium, Rapid) Thresholds – The Slow, Medium, and Rapid lines connecting TP0 and TP1 are configurable by left clicking and dragging the respective circle and raising\ lowering the threshold.

Delayed Phase Percentage (Persistent, Wash-out) Thresholds – The thresholds are represented by the slanted Blue Persistent and Red Wash-out lines connecting the uptake TP1 point to the selected delayed phase TP2. Each setting is configurable by left click and drag the circle and raising/ lowering the corresponding threshold.

Save and Reset –

- **Save for this study ONLY**: The settings will be saved for the loaded sequence only.
- **Save for similar studies**: The settings will be saved so that the same parameters will be used on subsequent studies with the same Series Description from the same scanner.
- **Save As Default**: The settings will be saved as the system default. It will be applied when there is no matching settings for a study, i.e. a new study from outside the institution.
- **Reset**: Reset parameters back to the last saved parameters.

In addition to the above, additional configuration settings are available under the **Advanced** section.

11 Pharmacokinetic Analysis and Display

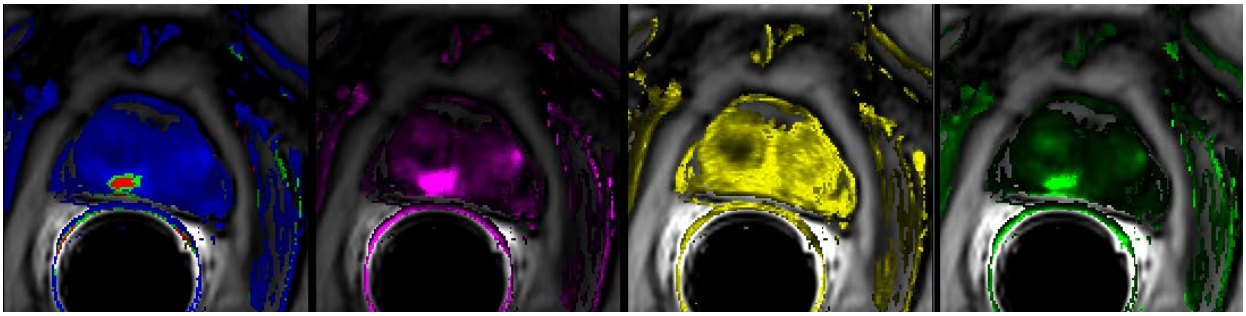
Pharmacokinetic (PK) analysis is performed on the DynaCAD server on study arrival. The result is saved as a number of series including *DCAD-Ktrans*…, *DCAD-Ve*…, *DCAD-vp*…, *DCAD-Kep*…

WARNING QuickTP and PK analysis requires a pre-contrast dataset; verify that the dynamic sequence to be used has at least one pre-contrast dataset. Erroneous outputs will occur if pre-contrast phase/time points are missing. DynaCAD's MR Analysis Server should not be used with manipulated settings to process a study, as it will result in erroneous output.

WARNING The QuickTP and PK colorization on every slice should be carefully examined along with subtraction images. If there is no colorization in the areas that significantly enhance, use the Correlate tool for viewing the dynamic curves to analyze the cause.

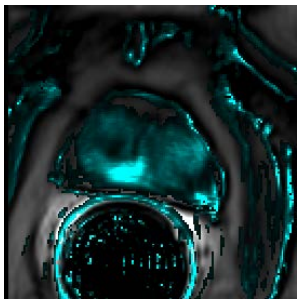
Select PK overlay under **Color Overlay** of the Right Mouse Context Menu.

NOTE**:** *DCAD-PRIMARY*… is a composite colormap based on K^{trans} and V_e.



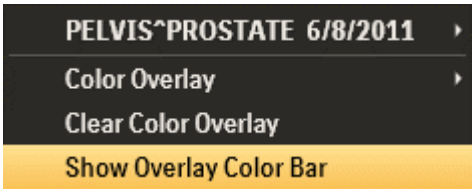
PRIMARY K^{trans} V_e K_{ep}

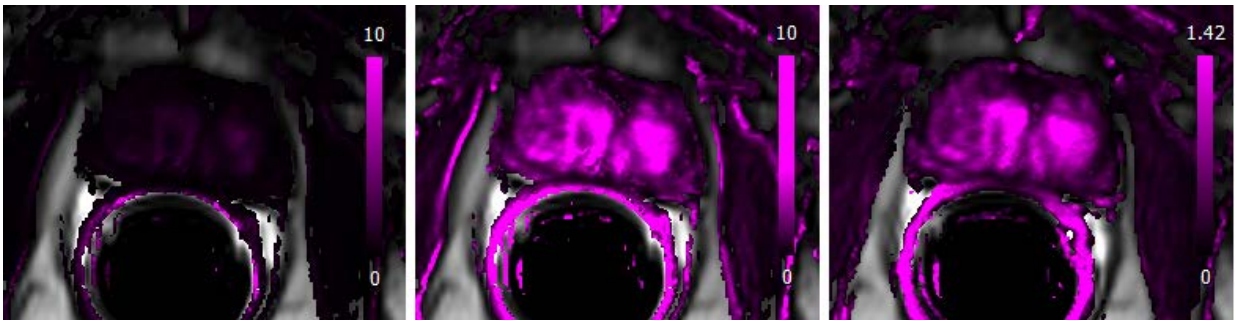
In addition, *DCAD-iAUGC*… represent the initial area under the contrast agent concentration curve.



iAUGC

A color bar can be displayed by select **Display Overlay Color Bar** from the Right Mouse Context Menu:





Left: Overlay with full dynamic range.

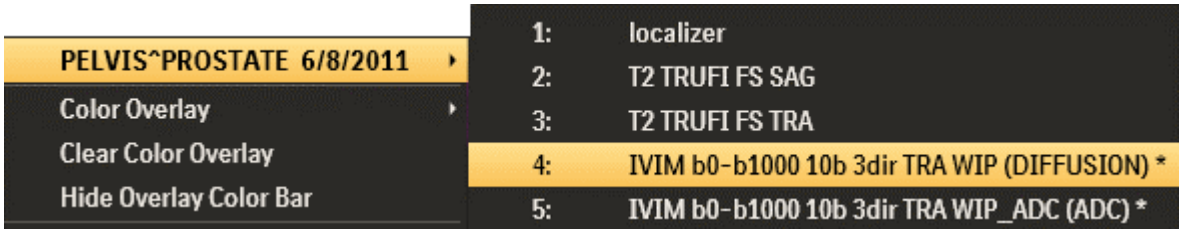
Middle: The brightness of the PK overlay can be changed by left clicking and dragging up and down on the color bar.

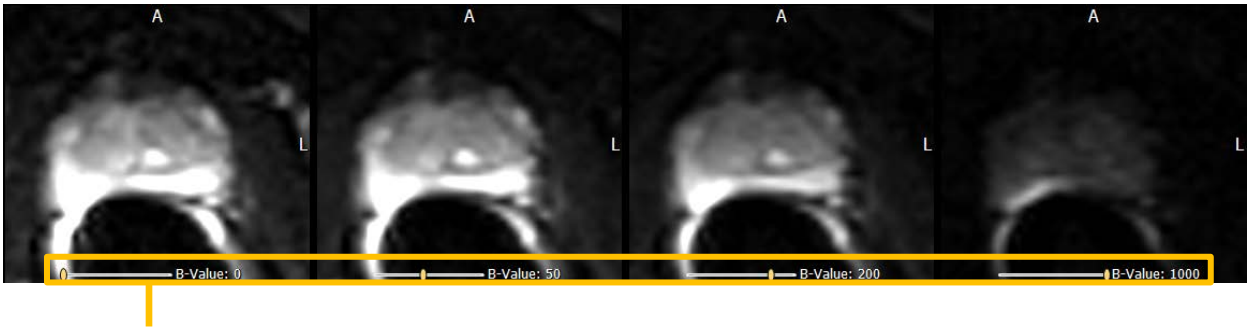
Right: The dynamic range of the color can be adjusted by left clicking and dragging up and down on the min and max number below and above the color bar.

12 Diffusion Weighted Imaging Sequence Display

12.1 Display as Greyscale

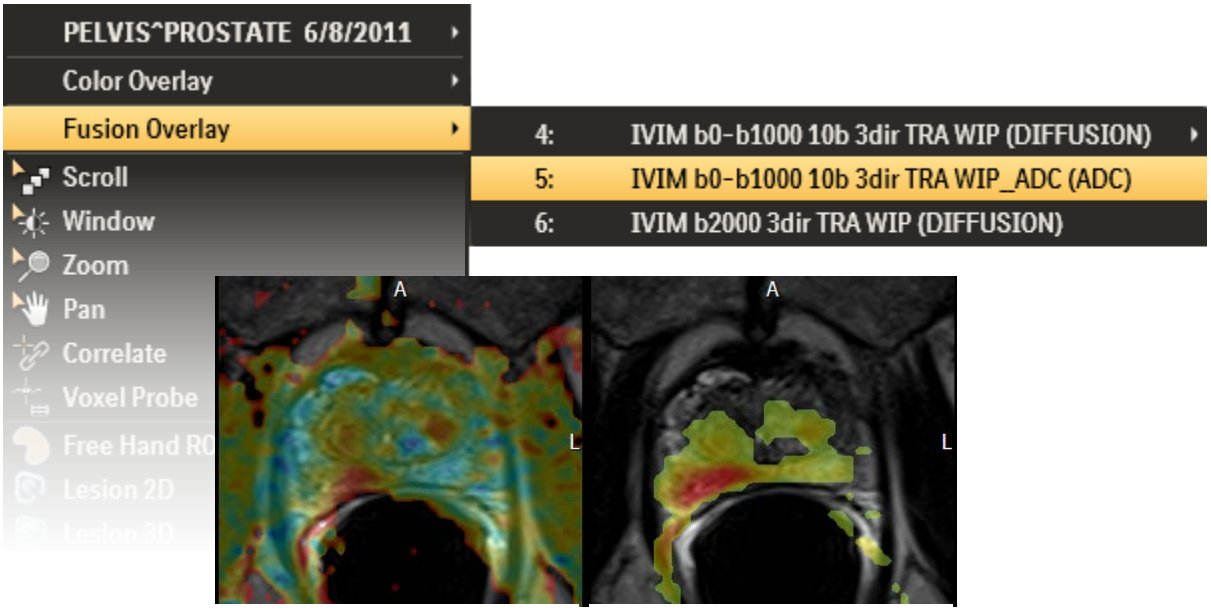
DWI and ADC data can be displayed by selecting the corresponding sequence from the Right Mouse Context Menu:





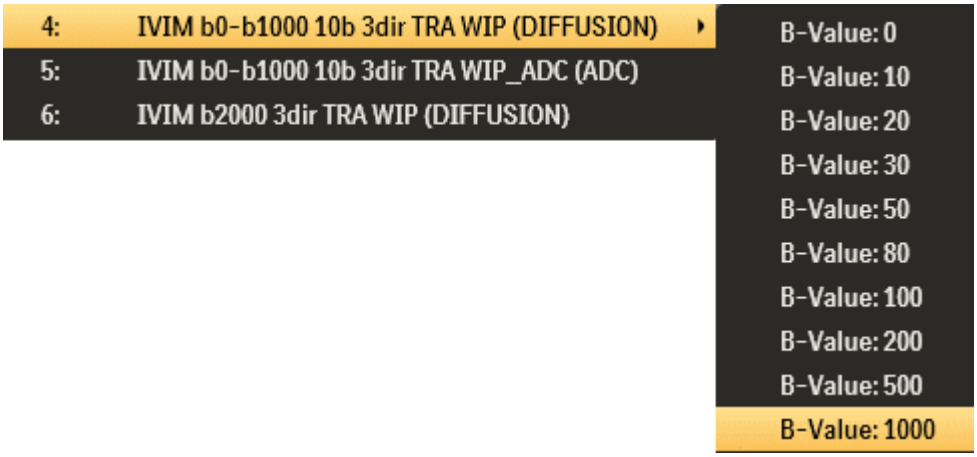
b-value scroll bar allows to select different b-value.

12.2 Display as Color Overlay



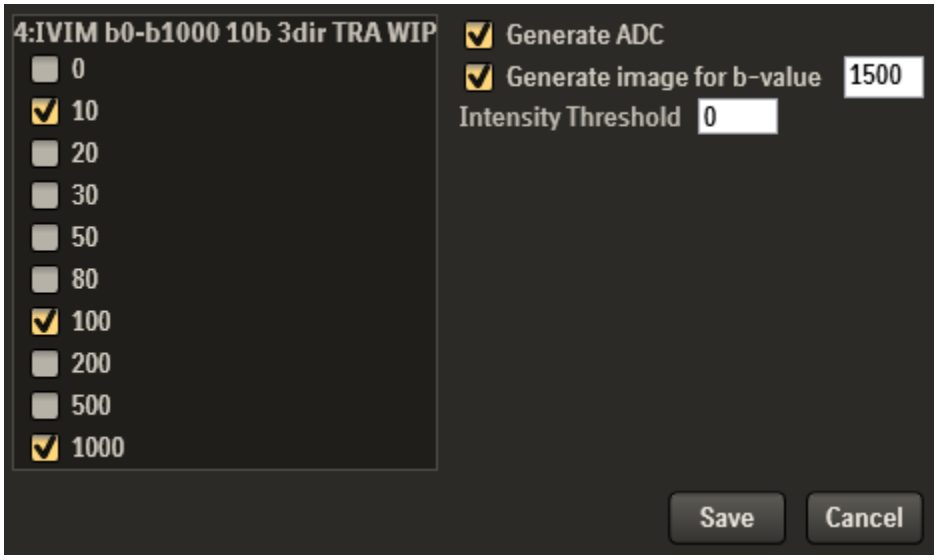
ADC b-value 1000

For DWI series that contains multiple b-values, a sub-menu will be available to select the corresponding b-value to be displayed as overlay.

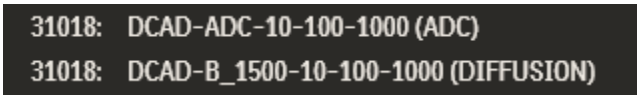


12.3 On-the-fly Computation

If the study contains a DWI series with at least 2 b-values, DynaCAD can calculate the ADC and another b-value. It can be configured by left click on the **ADC Config** button in the main toolbar. The configuration window will then be displayed:



Once it is configured, additional ADC and b-value entries will be available in the Right Mouse Context Menu for both grayscale and fusion color overlay display:



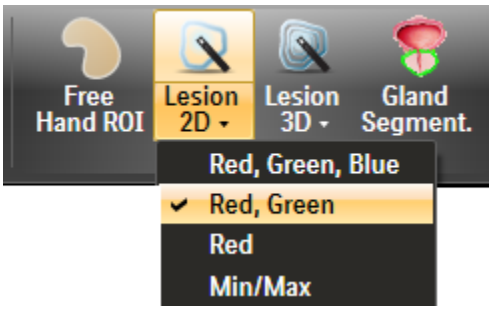
In the example above, b-values 10, 100 and 1000 from the scanner are used to compute the ADC and b-value 1500.

13 ROI Creation

13.1 Semi-automatic ROI

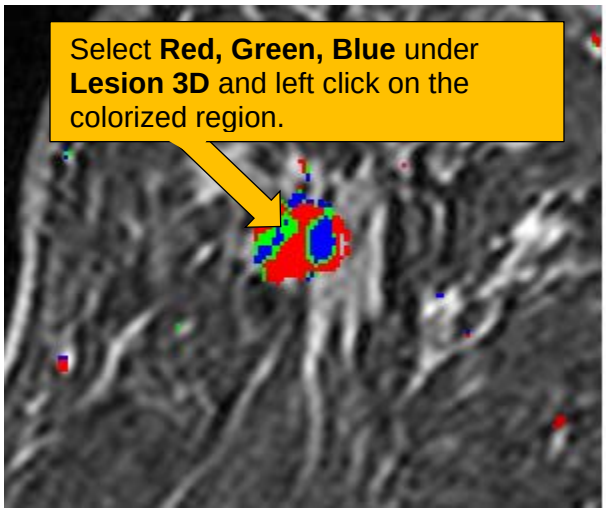
13.1.1 QuickTP and PK Color Segmentation

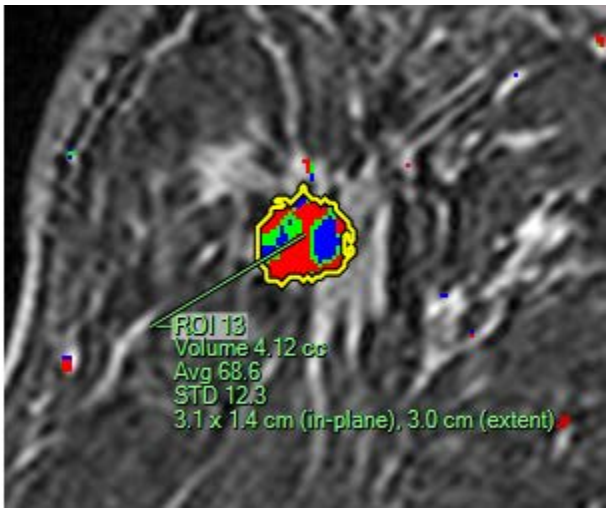
To create a ROI based on QuickTP or PK colorization:

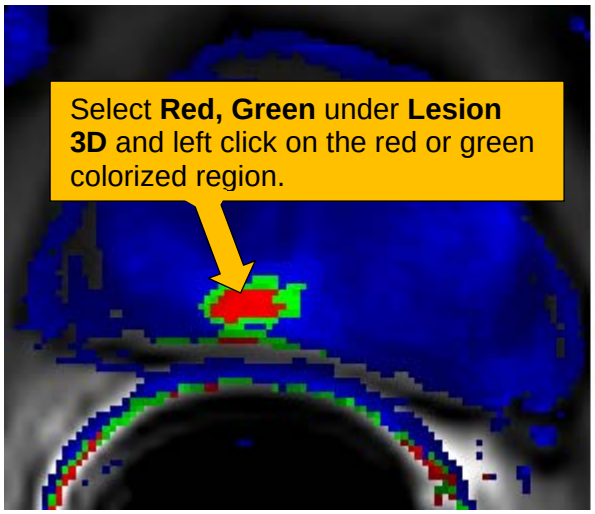


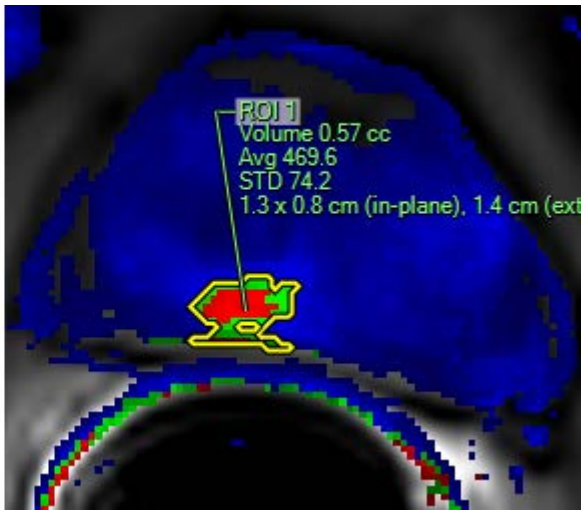
Select **Red**, **Red,Green**, or **Red,Green,Blue** from either the **Lesion 2D** or **Lesion 3D** button dropdown menu

Left click on the colorized region to be segmented. For example:









There can be leaks due to arteries feedback the tumor or patient motion artifacts. As a result, the ROI may leak into other regions, and a large ROI is created. Although this can be cleaned up using the clean-up tools (see later section), the ROI region can be limited during the ROI creation. To limit the size:

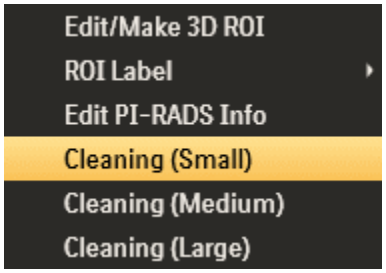
- Select the 2D/ 3D Lesion tool as above
- Left click, hold and drag on the region. The initial click should be close to the center of the ROI. A rectangular box will be displayed to indicate the bounding box of the ROI.
- Once the desirable region limit is shown, release the mouse button. The segmentation will then be limited to the size specified.

13.1.2 Threshold based Segmentation

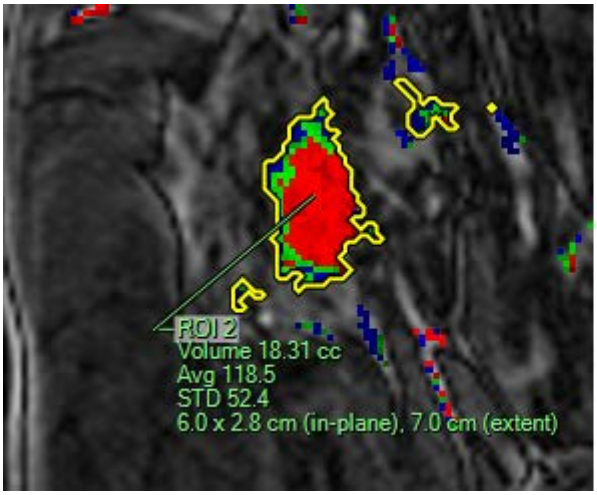
The threshold based segmentation works with DWI/ ADC and PK data.

13.1.3 Segmentation Clean-up

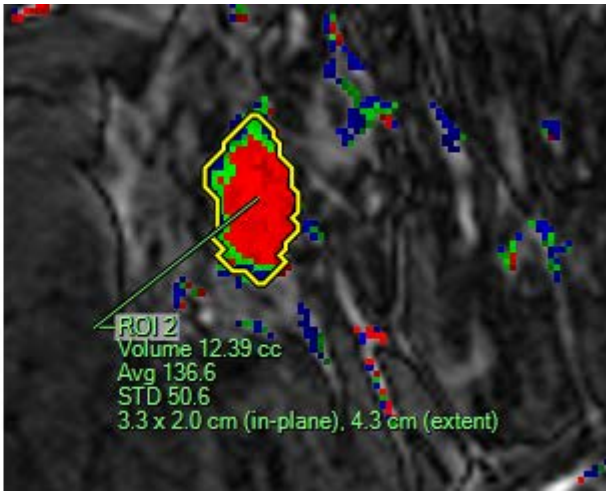
A clean-up utility is available to allow the leaks to be removed:



Select **Small**, **Medium** or **Large** cleaning options from the ROI Context Menu to remove leaks accordingly.

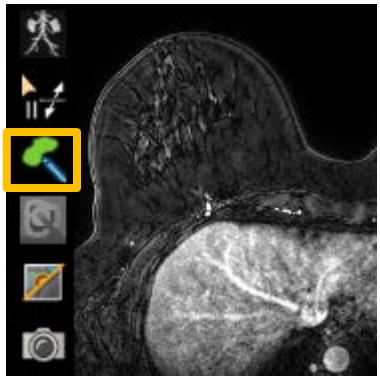


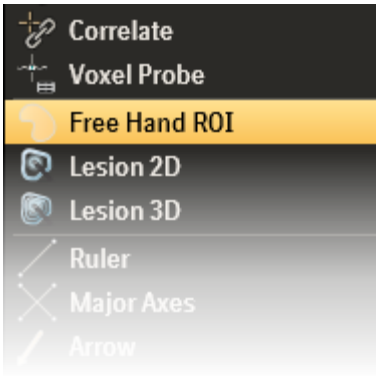
A 3D ROI leaks into other regions and appear as islands.

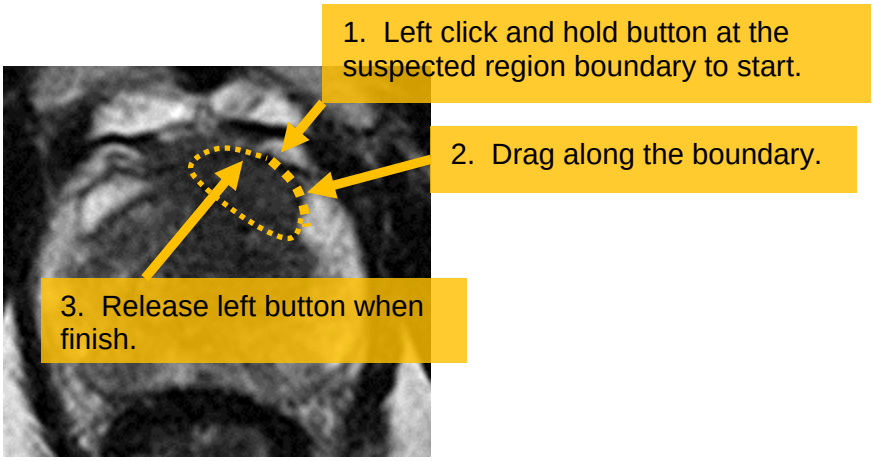


After cleanup.

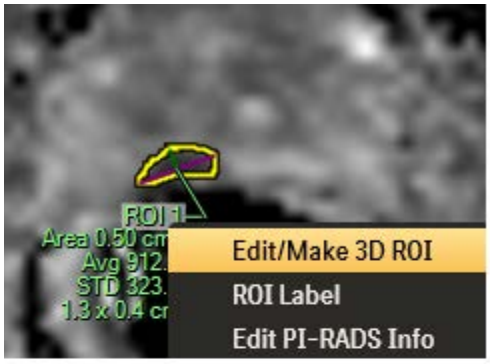
13.2 Manual ROI







This creates the ROI on the image plane. To continue creating a 3D by defining the boundary in the neighboring images:



Right click on ROI label and select **Edit/Make 3D ROI**.

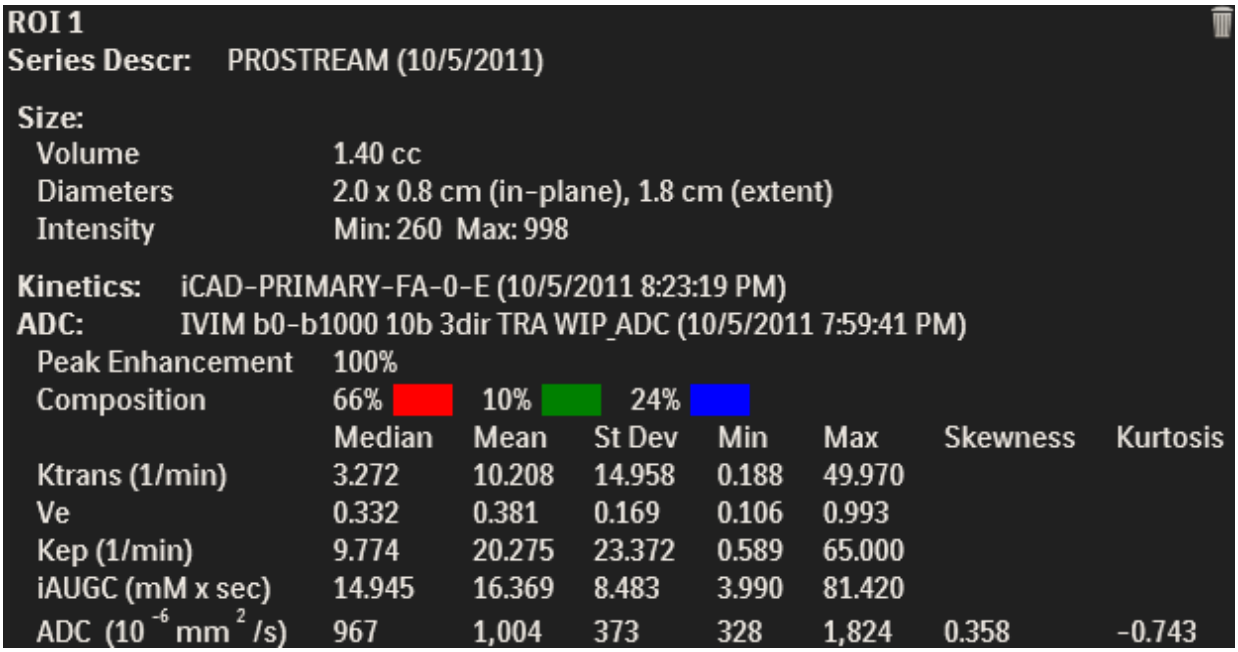
Scroll to neighboring images, and draw the ROI boundary.

Right click on ROI label and select **End Edit** to finish the 3D ROI creation.

***NOTE*:** It is not necessary to define the ROI boundary on every image that covers the ROI. If an image is skipped, DynaCAD will interpolate between the defined boundaries.

13.3 ROI Statistics

Basic measurements, e.g. area, volume and diameters, are calculated for the ROI. If PK, ADC data is available, it will also calculate the corresponding statistics. They will be displayed under the **Lesion Analysis** chart:



ROI 1

Series Descr: PROSTREAM (10/5/2011)

Size:

Volume	1.40 cc
Diameters	2.0 x 0.8 cm (in-plane), 1.8 cm (extent)
Intensity	Min: 260 Max: 998

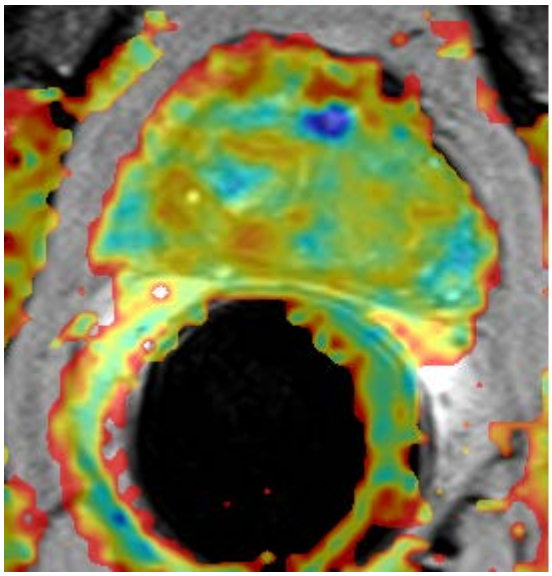
Kinetics: iCAD-PRIMARY-FA-0-E (10/5/2011 8:23:19 PM)

ADC: IVIM b0-b1000 10b 3dir TRA WIP_ADC (10/5/2011 7:59:41 PM)

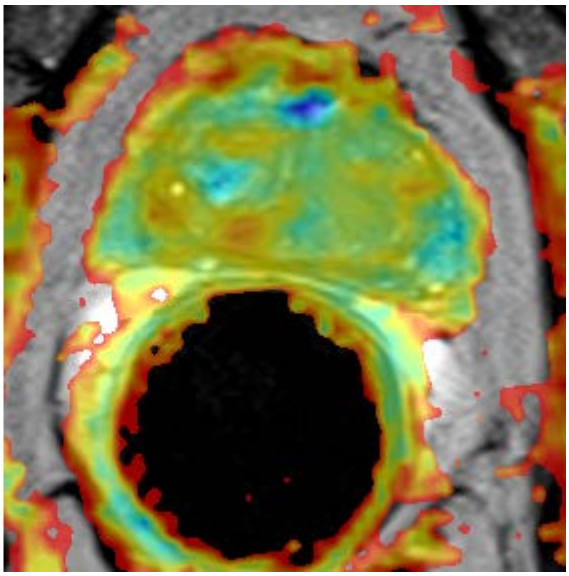
Peak Enhancement	100%						
Composition	66%	10%	24%				
	Median	Mean	St Dev	Min	Max	Skewness	Kurtosis
Ktrans (1/min)	3.272	10.208	14.958	0.188	49.970		
Ve	0.332	0.381	0.169	0.106	0.993		
Kep (1/min)	9.774	20.275	23.372	0.589	65.000		
iAUGC (mM x sec)	14.945	16.369	8.483	3.990	81.420		
ADC (10^{-6} mm^2 /s)	967	1,004	373	328	1,824	0.358	-0.743

14 Intra-sequence Registration

Intra-sequence registration allows sequences within a study to align with each other. The result is applied to operations such as Correlate, PK and DWI/ ADC overlay and ROI statistics.

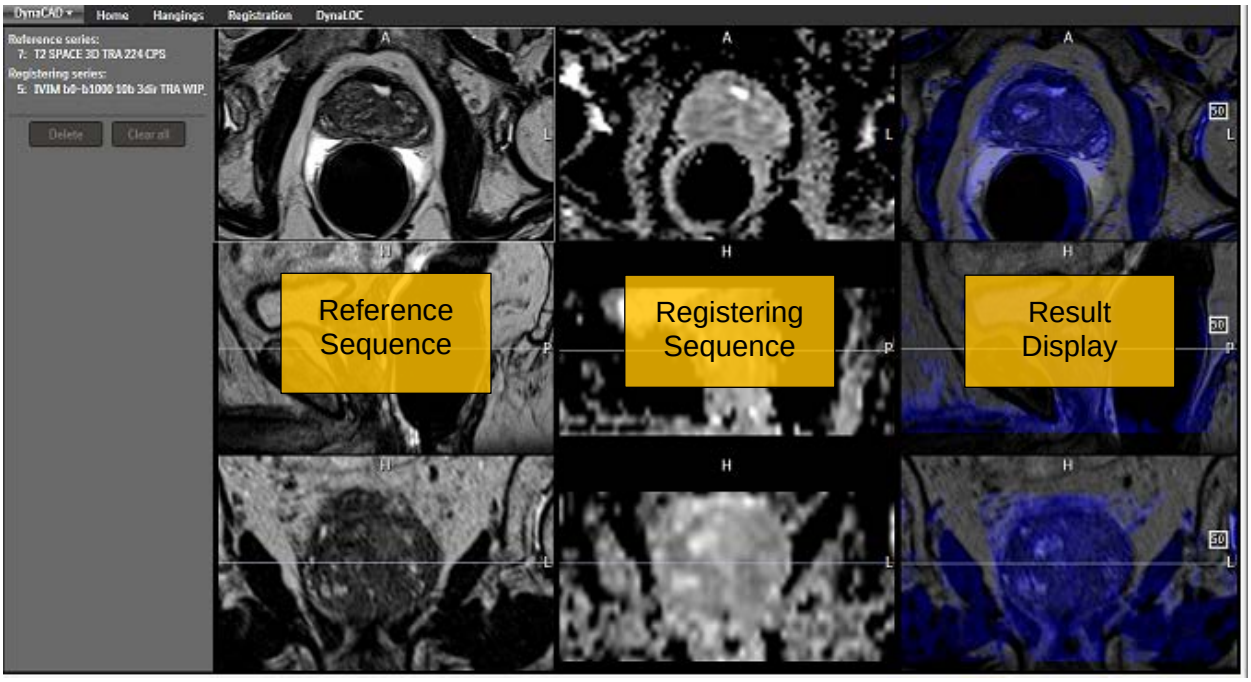


Before registration



After registration

It is recommended to inspect the alignment of the sequences that are of interest prior to reading. The Intra-sequence Registration feature is invoked from the **Registration** tab of the DynaCAD client application.



A study can only have one sequence defined as the Reference Sequence. For prostate study, it should be the one used for the prostate boundary segmentation. Registering sequence will be transformed to align with the Reference Sequence.

***NOTE*:** If one or more registration has been performed and a new Reference Sequence is chosen, then all previous registration will be deleted since a study can only have one Reference Sequence defined.

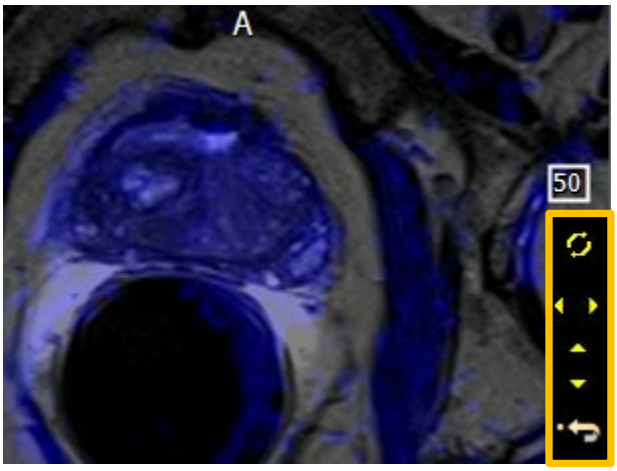
Middle column displays the three orthogonal MPRs of the Registering Sequence. A study can have multiple Registering Sequences. They will be transformed to align with the Reference Sequence.

Right column displays the three orthogonal MPRs of the registration result – the Reference Sequence is displayed as greyscale, and the Registering Sequence is transformed based on the registration results, and it is displayed as color blended with the Reference Sequence greyscale.

14.1 Manual registration

The Registering Sequence can be manually panned and rotated in any of the three orthogonal planes. They can be invoked from either the application toolbar or the in-viewport tool bar.

Pan and Rotate on the application toolbar: Left click and drag on one of the result MPR planes to pan and rotate the Registering Sequence accordingly.



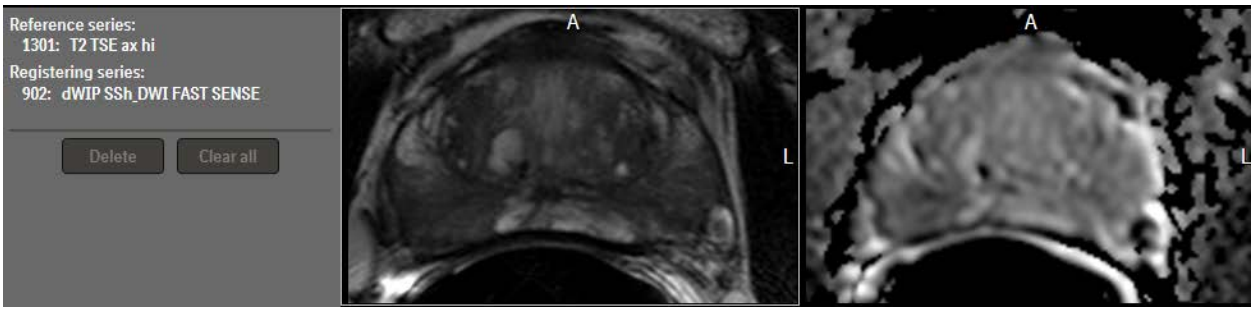
Left/ right click on the button will rotate or pan the Registering Sequence on the corresponding plane. Shift left/ right click will allow fine adjustment for the pan buttons.

14.2 Semi-automatic registration

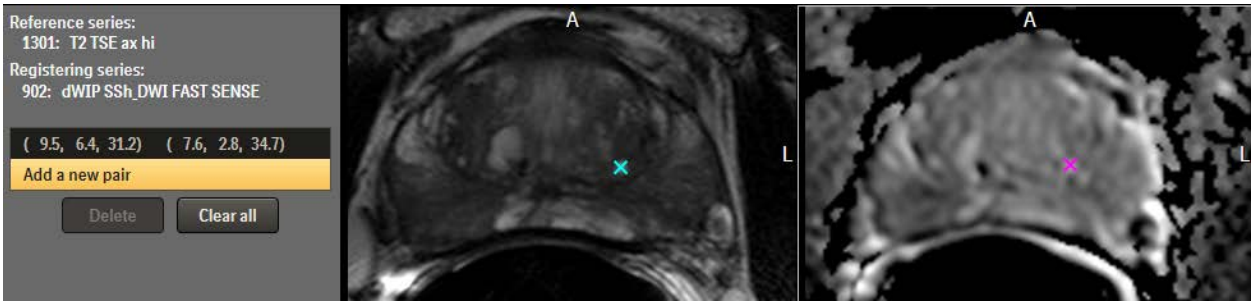
Semi-automatic registration computes the transformation between the Registering and Reference sequence by least square fitting of three or more landmark location pairs identified by the user.

A landmark point pair can be added by double left clicking the landmark identified on each of the Reference and Registering sequence:

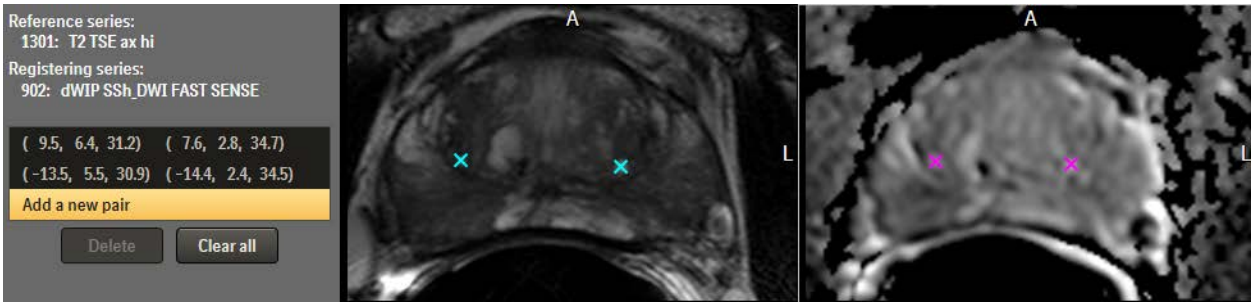
- Scroll the Reference and Registering sequence to identify the first landmark:



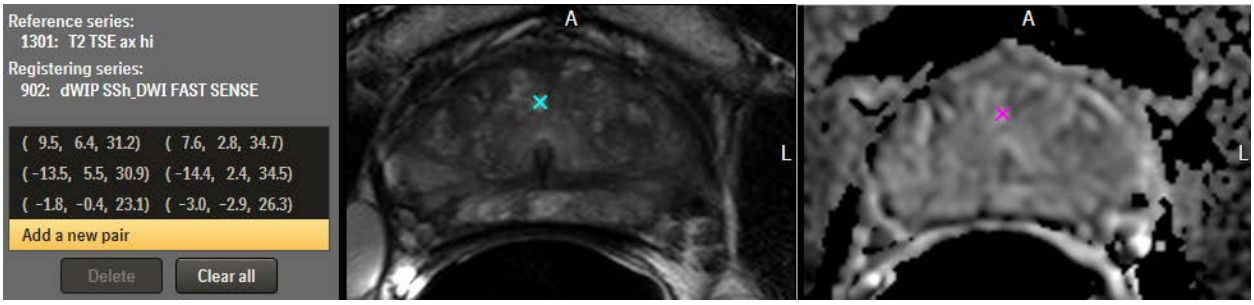
- Double left click on the landmark on both sequences:



- Identify the second landmark:



- Identify the third landmark:

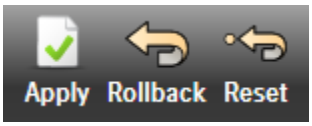


After three landmark pairs have been identified, DynaCAD will compute the registration. Additional landmark pairs can be added to refine the calculation.

Landmark location can be edited by left click on the corresponding crosshair on the image, or by left click on the item displayed in the left panel list first. Identified landmarks can be deleted by clicking on the **Delete** or **Clear all** button in the left panel.

14.3 Apply, Rollback and Reset

Three options are available from the registration toolbar:



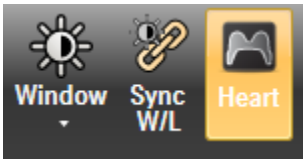
- **Apply**: When the sequence alignment is satisfactory, the result can be saved and applied by clicking on this button.
- **Rollback**: If a previous saved registration is not satisfactory, it can be deleted by clicking on this button.
- **Reset**: The current unsaved registration can be deleted by clicking on this button.

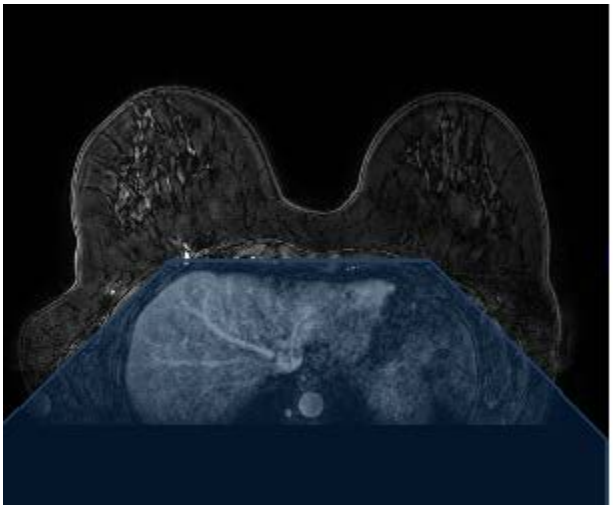
WARNING Do not apply the inter-sequence registration if the result does not align. Click the **HOME** tab to exit the operation. If a saved registration is not satisfactory, select **Rollback** to remove the registration. A sub-optimal registration may affect your reading and analysis.

15 Features for Breast Study

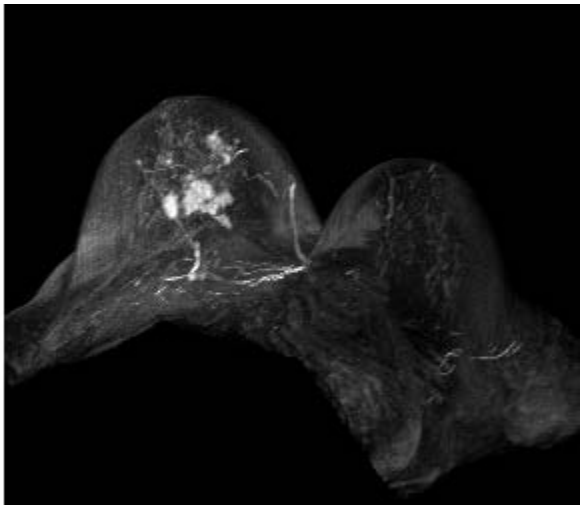
15.1 Chest Mask

Chest mask is computed as part of the pre-processing step on the DynaCAD server. It can be applied by left click on the **Heart** button of the application toolbar.



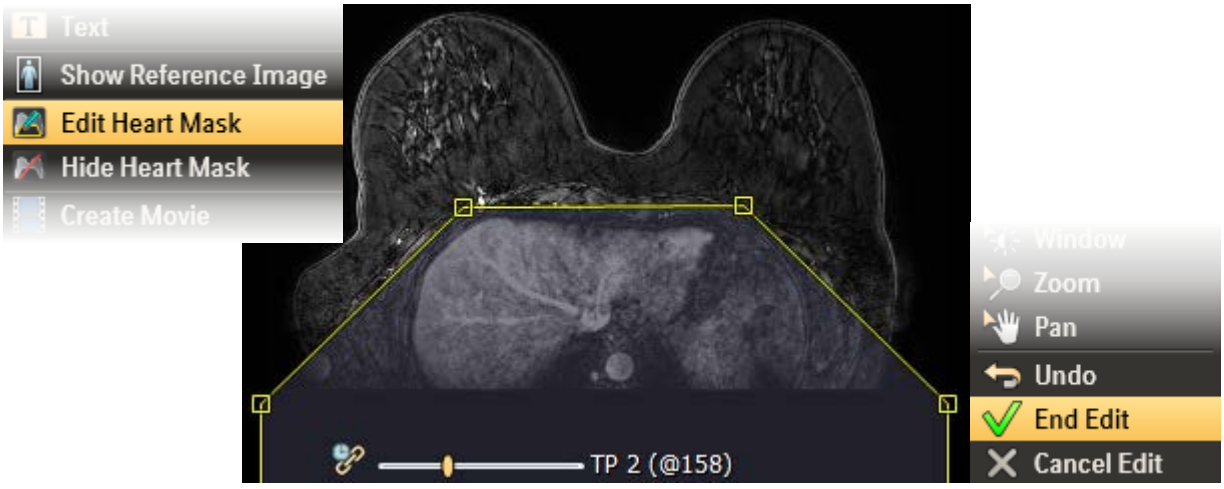


2D



MIP

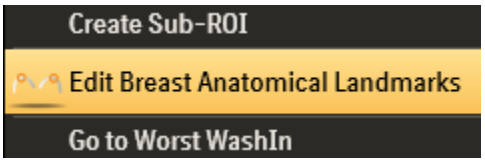
The heart mask can be edited if needed. Select **Edit Heart Mask** from the Right Mouse Context Menu. The control points can be left click and drag to the desirable locations.

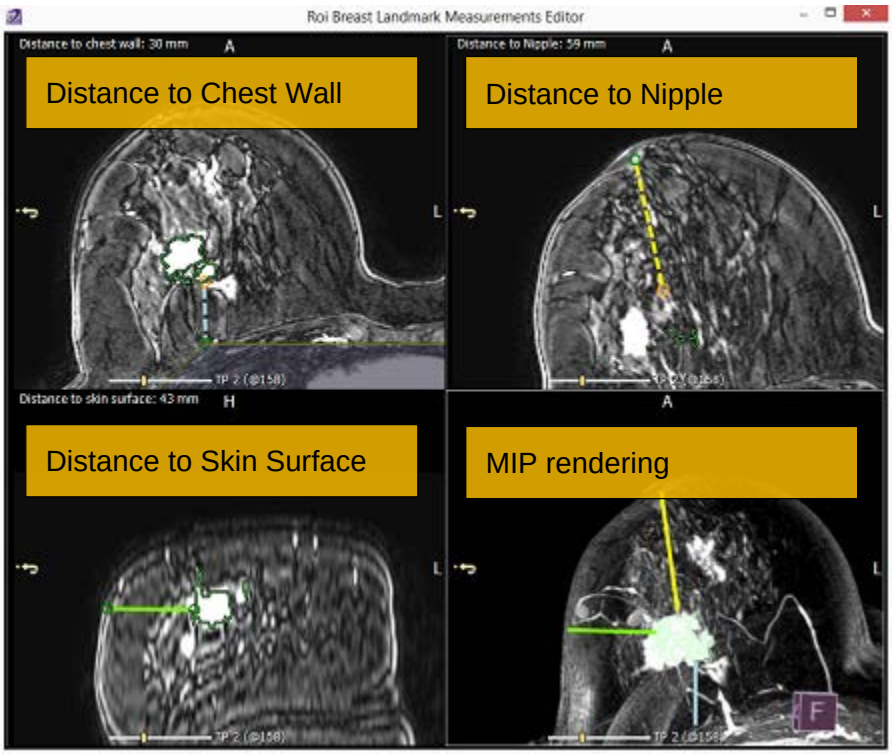


To save the edited mask, select **End Edit** from the Right Mouse Context Menu.

15.2 Distant to Nipple, Skin Surface and Chest Wall

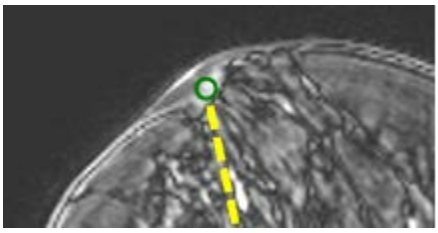
After a ROI is created, select **Edit Breast Anatomical Landmarks** from the ROI Context Menu. The Landmark Editor will be displayed.



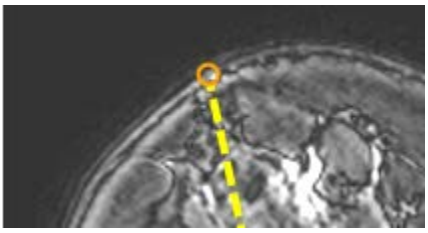


The Landmark Editor displays the 3 orthogonal MPRs and a MIP rendering with the distant measurements.

The end points of each distant measurement can be modified in their corresponding viewport by the left click and drag action. Because the points are 3D points, the color of the end point indicates if the end point lies on the displayed image.



Green: end point is on the displayed image plane.

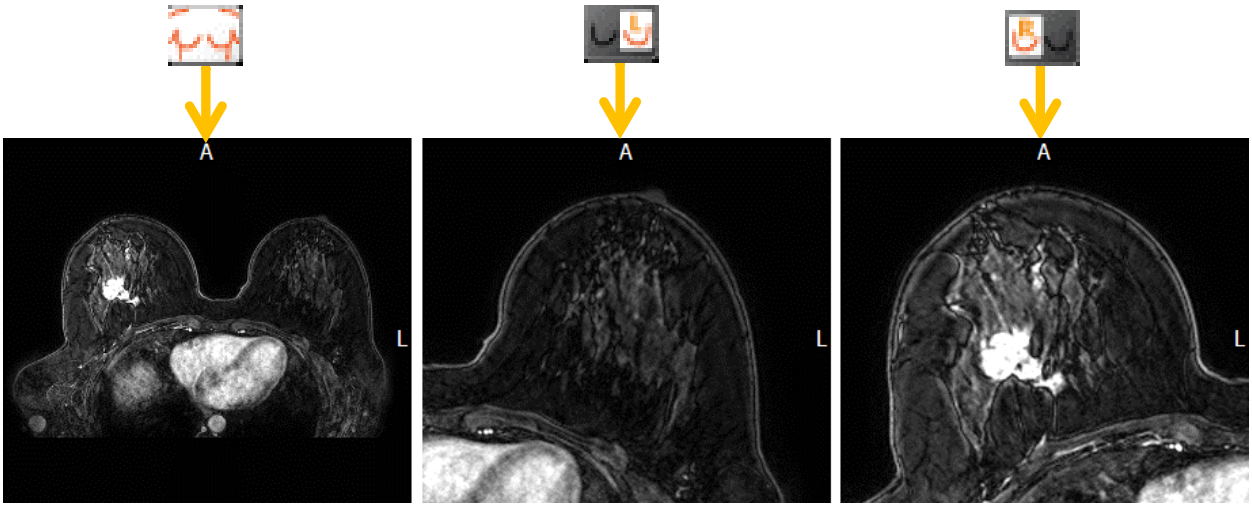


Orange: end point is not on the displayed image plane.

Once the location of each end points are reviewed, click on the exit button of the Editor window. It will prompt for saving. Once the information is saved, the distant measurements will be displayed in the **Lesion Analysis Summary** and reports.

NOTE: The nipple location is common to all ROIs that are on the same breast.

15.3 Left/ Right Breast Short-cuts



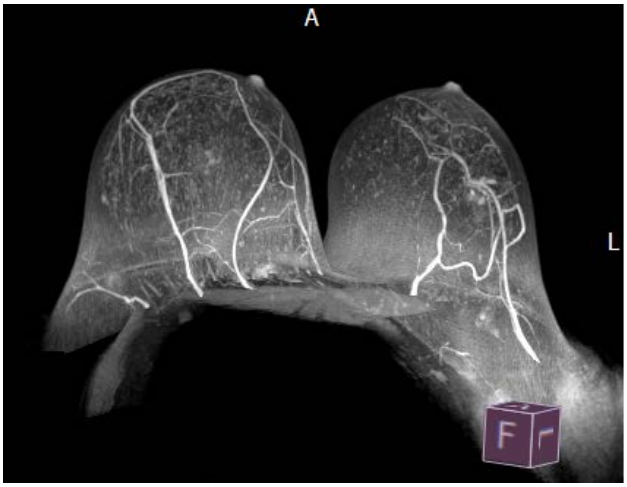
Whole image Left Breast Right Breast

Similar short-cuts are also available for MPR and 3D/ MIP.

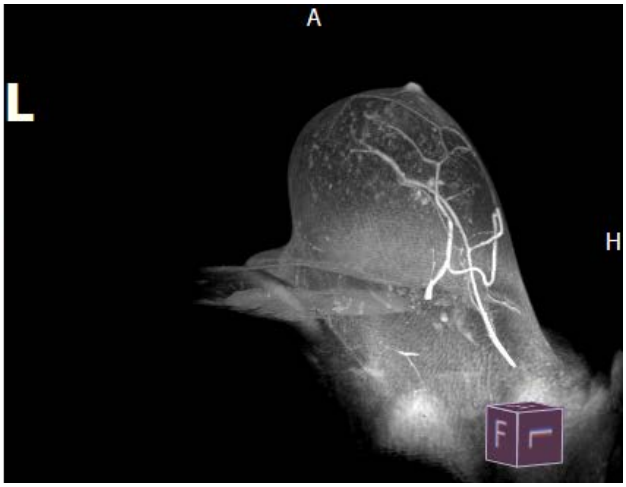
WARNING When reviewing breast images in the 3D rendering mode, verify the left and right images are loaded correctly in the image viewport when selecting the left/right shortcut icon. This can be done by checking the location text information in the upper left corner of the viewport.

15.4 Auto-hide during MIP rotation

The distant breast will be hidden automatically during MIP rotation when the view is at certain orientation that the left and right breasts will likely overlap each other.



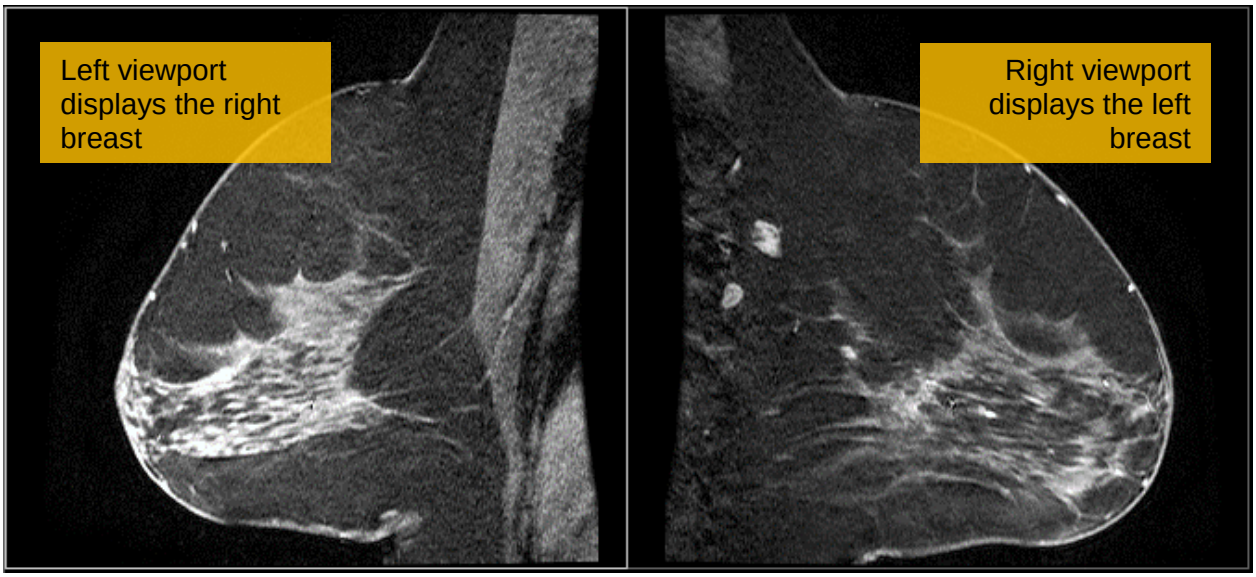
Both breasts are shown.



Right breast is hidden automatically when the left breast is further in front.

15.5 Chest Wall – Chest Wall Display

When hanging the left and right sagittal dataset side-by-side, they will be oriented so that they are displayed in the chest wall to chest wall position:



When scrolling, they are automatically linked. Scrolling the left breast towards the left direction (away from the center) and the right breast will be scrolled towards the right direction. Linking can be turned ON/ OFF by clicking the Left/ Right Link button located at the lower right corner of the viewport.

WARNING When reviewing breast images, verify the left and right images are loaded correctly in the image viewport. This can be done by checking the location text information in the upper left corner of the viewport.

16 Features for Prostate Study

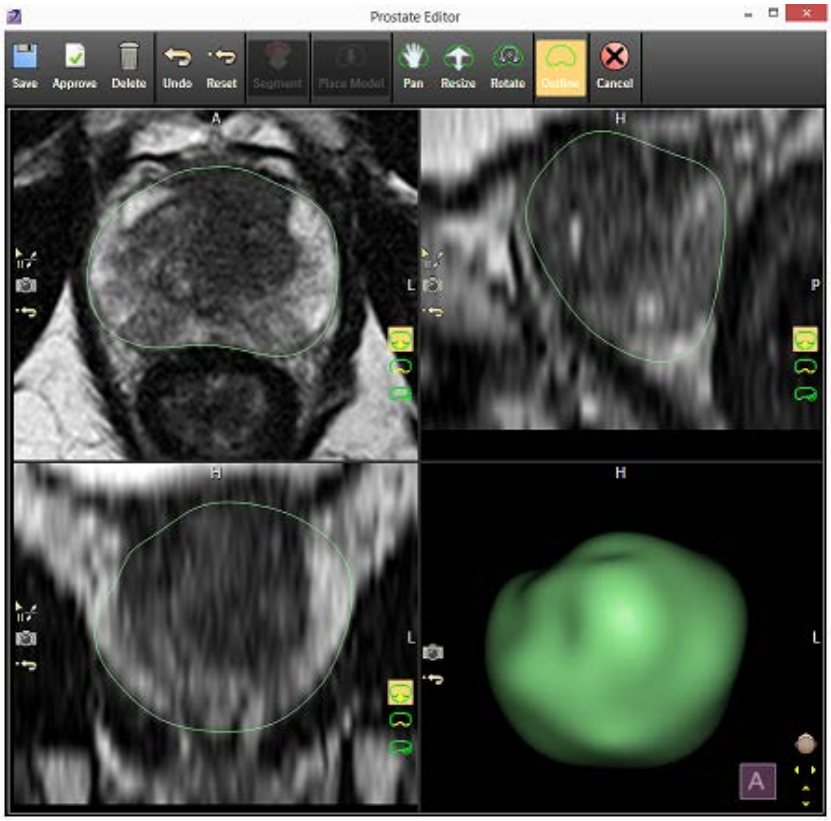
16.1 Prostate Boundary

The automatic computed boundary will need to be reviewed and approved before the boundary can be used, or DICOM export to other devices.

WARNING Review and edit if necessary the Prostate boundary prior to drawing an ROI. Failure to do so may cause some measurements in the lesion analysis summary to be inaccurate.

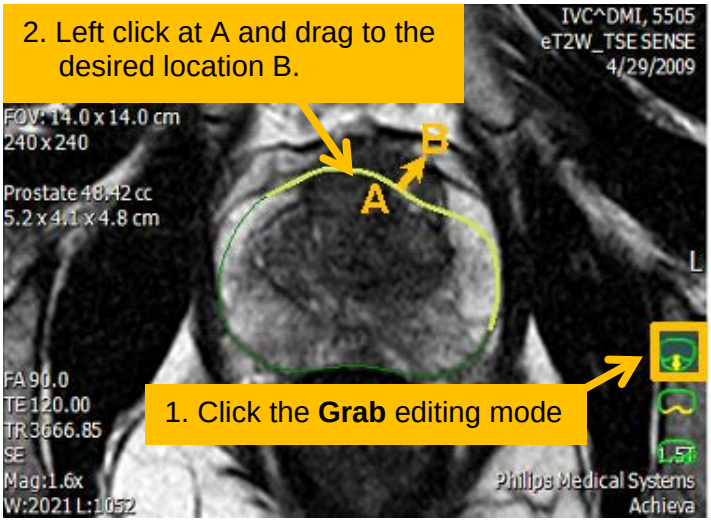
16.1.1 Editing Existing Boundary

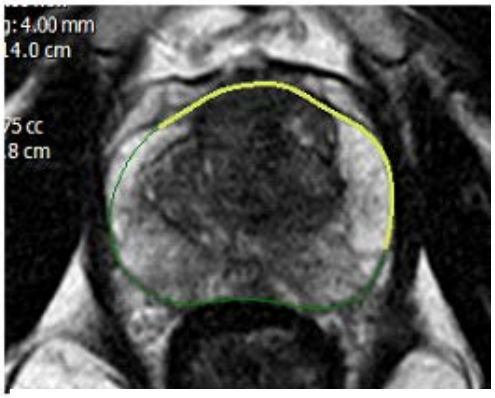
After loading a prostate study, click the **Gland Segment.** button to invoke the **Prostate Editor** window:



Depending on the configuration, the prostate central gland boundary can be displayed.

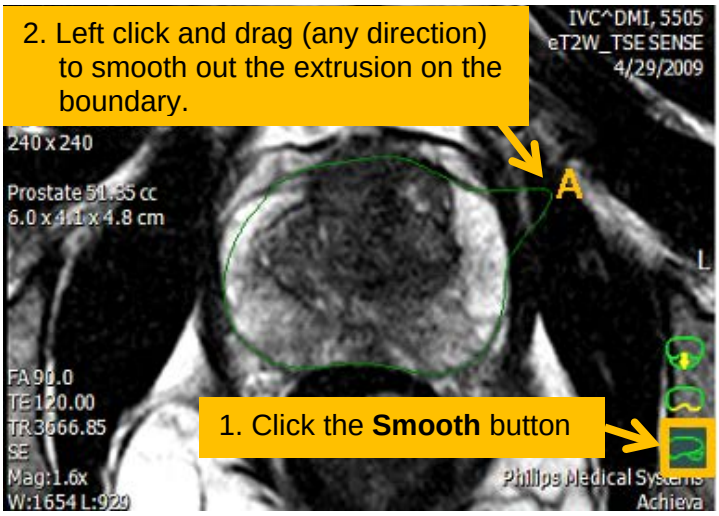
The boundary can be dragged to a new location by left click and drag, for example:

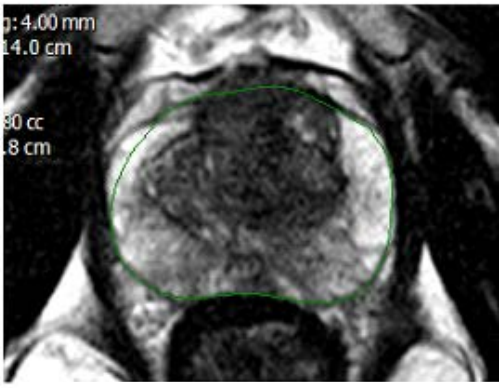




After editing

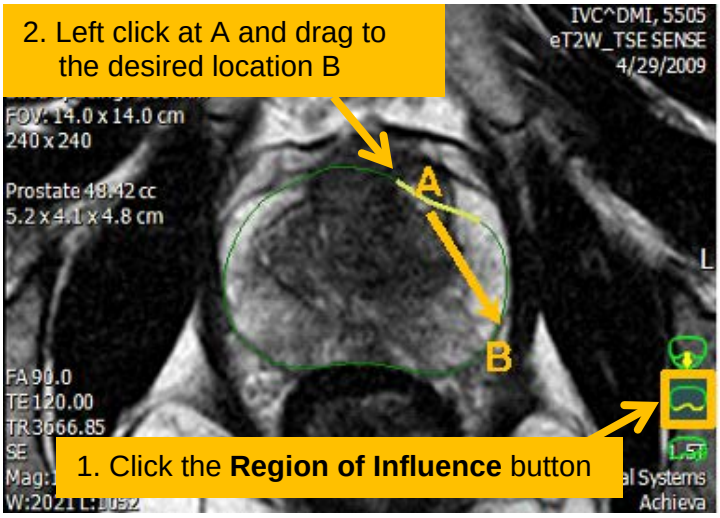
Irregularity on the boundary can be smoothed:





After smoothing

The length of the boundary segment (yellow) that are affected by the above editing mechanisms can be modified by left click and drag to the desirable length:



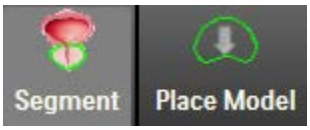
Updated segment

16.1.2 Undo, Reset and Delete

- **Undo** and **Reset** to undo previous editing or reset to the original state.
- **Delete** will delete the boundary.

16.1.3 Create a New Boundary

New prostate boundary can be created by either calling the automatic segmentation or by placing a standard prostate model manually.

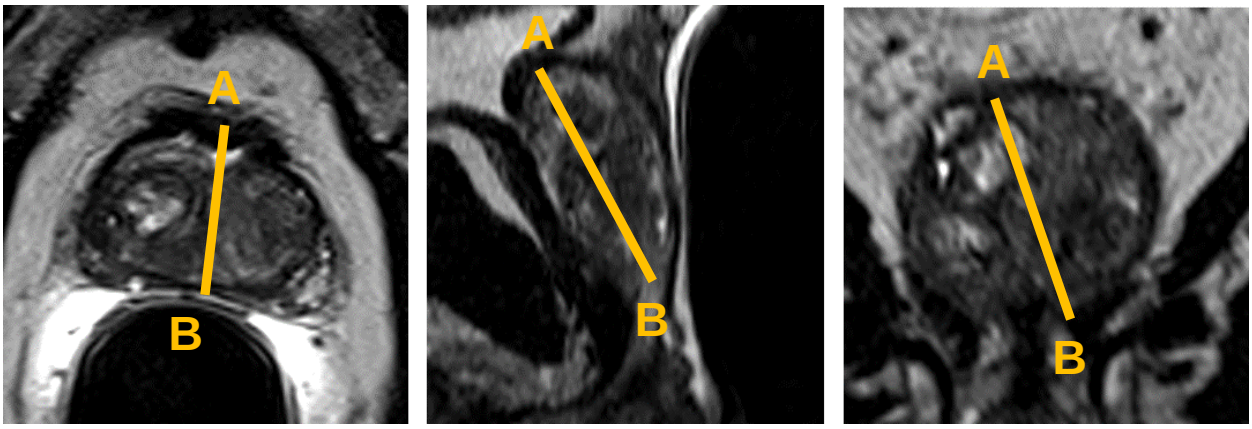


Automatic Segmentation

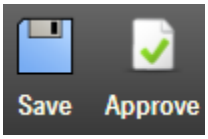
The prostate can be segmented by left click the **Segment** button. The automatic segmentation will take a few seconds to complete.

Manual Prostate Model Placement

- Left click the **Place Model** button.
- On the viewport that the prostate is the most clearly visible, left click and hold at A of the major axis, and drag to the bottom end B of the axis. Release the left button.



16.1.4 Save and Approval



Existing prostate boundary can be saved by left click on the **Save** button.

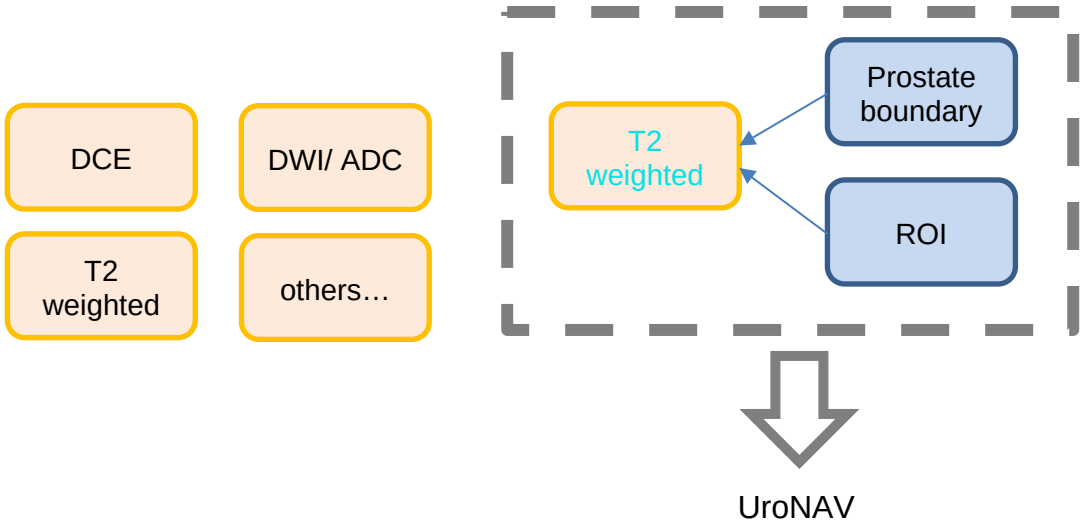
When the prostate boundary is satisfactory after inspection, it can be approved by left click on the **Approve** button. The prostate boundary information will then be used for providing information such as prostate volume and dimensions.

16.2 UroNAV

16.2.1 Preparing data for UroNAV

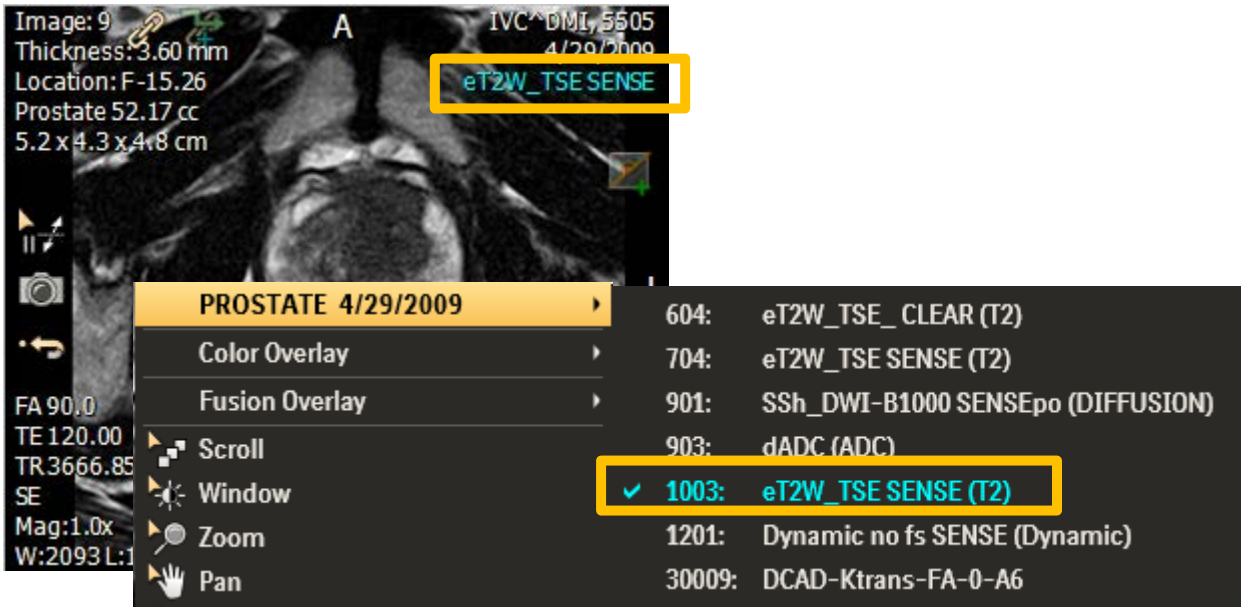
The following objects are typically DICOM transferred to UroNAV for performing prostate biopsy:

- T2 weighted series
- Prostate boundary (approved)
- ROI

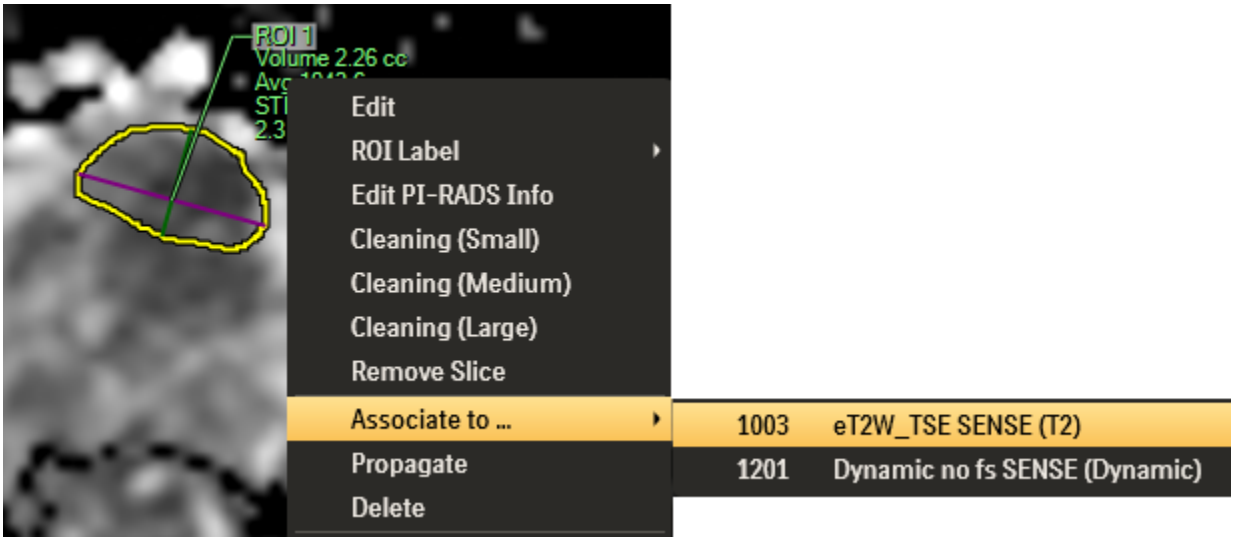


The prostate boundary and ROI must reference to the same T2 weighted series, otherwise UroNAV will not correlate the data together.

***NOTE*:** Series label in cyan color represents the sequence referenced by the prostate boundary.

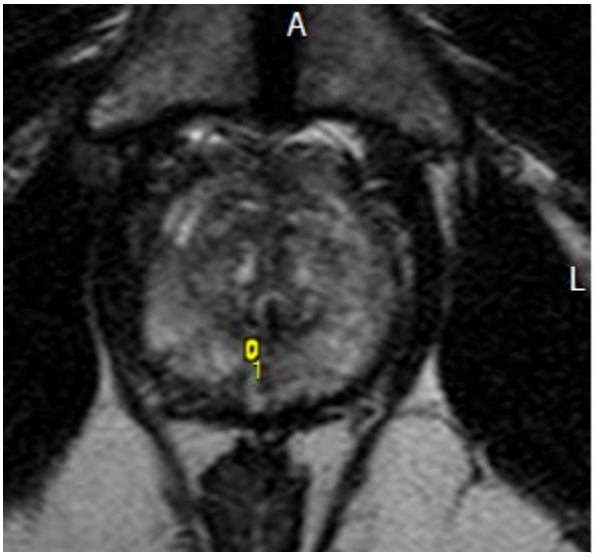


When creating a ROI, it is suggested to create the ROI on the same T2 weighted series. If the ROI is to be created in another sequence such as ADC, the **Associate to …** option from the ROI Right Mouse Context Menu allows the ROI to be transferred to the T2 weight series.

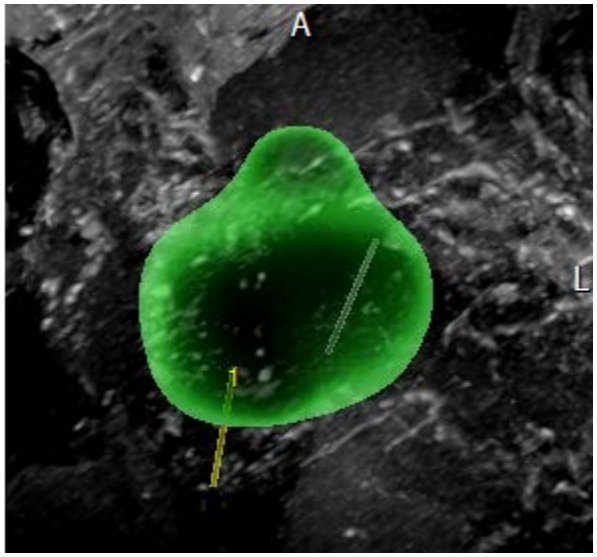


***NOTE*:** One-Click Send (Section 18.3) provides a convenient way to send pre-defined series to UroNAV.

16.2.2 Biopsy Core Display



2D/ MPR



MIP

WARNING Displaying biopsy core from ultrasound involving an elastic transformation based on matching two prostate boundaries. Exact mapping of biopsy cores cannot be guaranteed due to the elastic nature of the prostate tissue. In addition, only the end points of the biopsy cores are mapped to the MR coordinates, and the core is approximated by a straight line.

To display the biopsy cores, select **Show Biopsy Cores** from the Right Mouse Context Menu

Prior biopsy data can be displayed on current MR study based on the registration based on the matching the prostate boundaries of the two studies. DynaCAD automatically displays the **Registration** window when registration is required.

Save to save the biopsy cores based on the registration

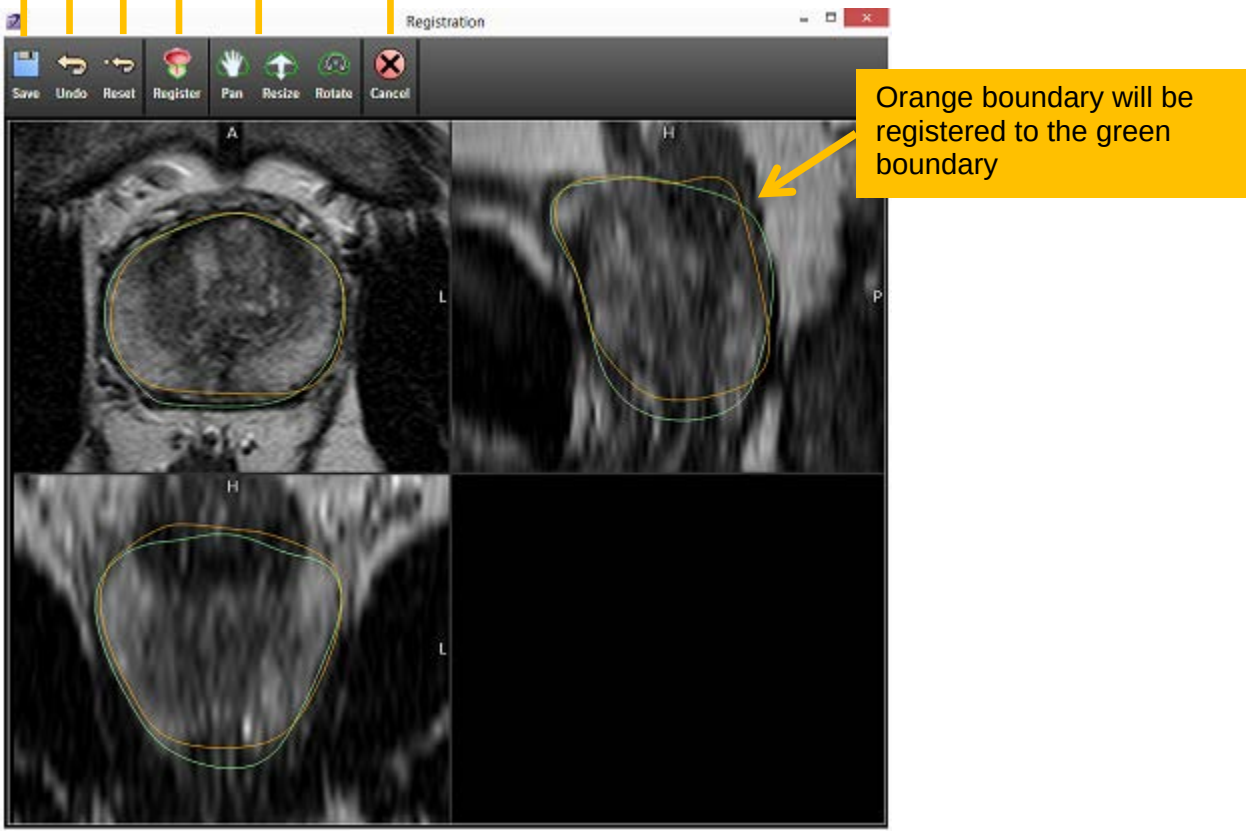
Undo last action

Reset registration

Register to start the automatic registration

Pan, Resize and Rotate to manually adjust the orange boundary

Cancel to exit without saving

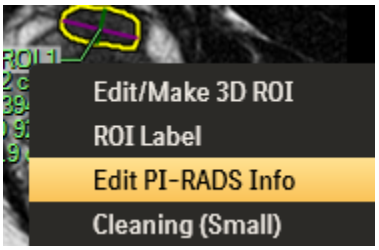


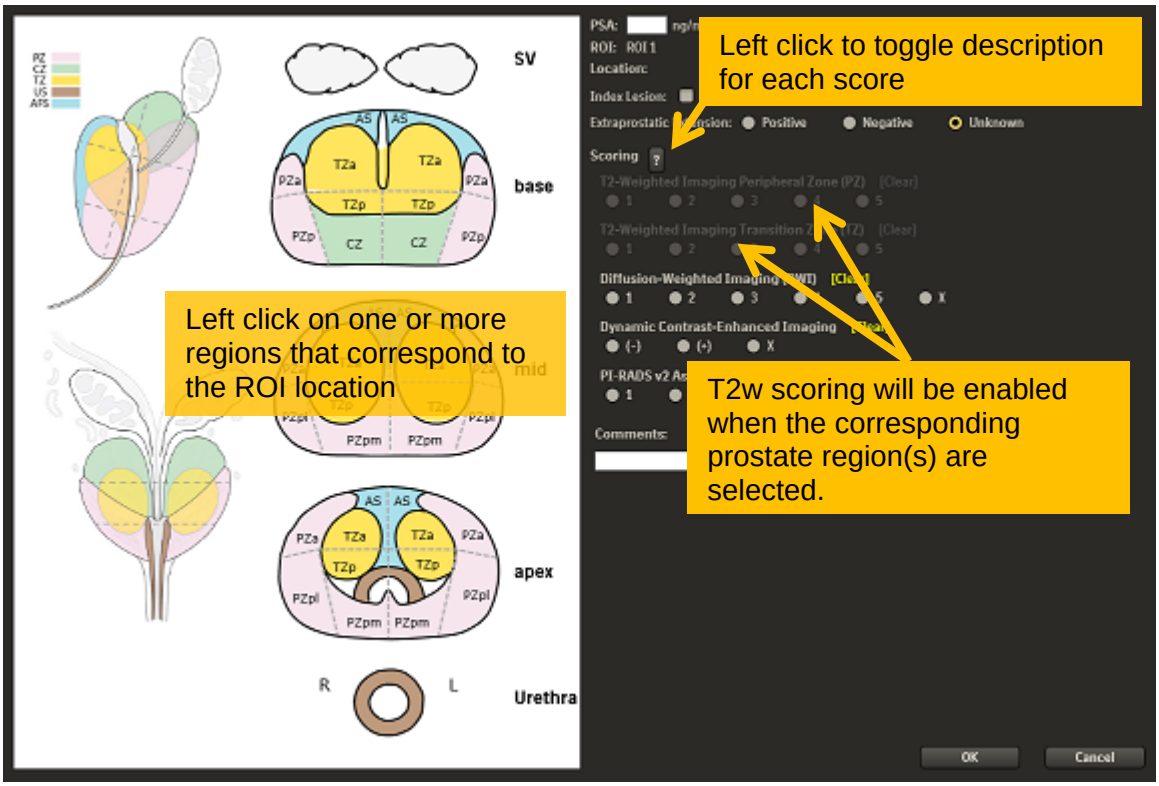
WARNING Do not save the biopsy core registration result if the resulting prostate boundary does not align with the reference boundary. Click the **Cancel** button to abort the operation. Check the prostate boundary using the **Prostate Editor** to ensure the prostate boundary is acceptable. If no improvement can be made to the prostate boundary, do not display the biopsy cores.

16.3 PI-RADS

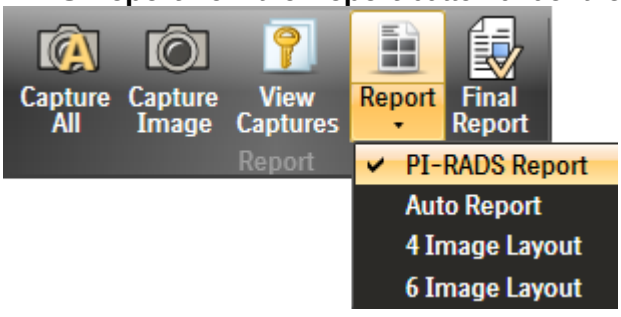
NOTE: DynaCAD supports the initial and second version of PI-RADS. Depending on the site settings (please see your administrator for the setting), the scoring and user interface may be different from that shown below that is based on PI-RADS version 2.

To enter PI-RADS data for a ROI, select **Edit PI-RADS Info** from the ROI Context Menu.





Once the PI-RADS information for each ROI has been entered, a PI-RADS report can be created by selecting **PI-RADS Report** from the **Report** button under the application toolbar.

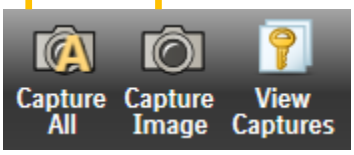


17 Key Images and Report

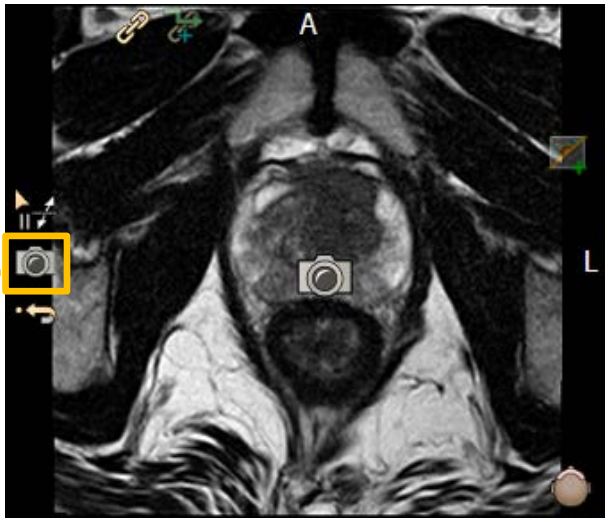
17.1 Key Image Captures

Capture All will capture all viewports displayed

Capture Image will capture the active viewport



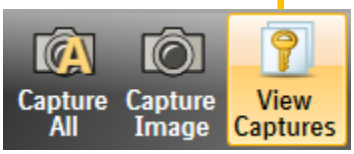
Capture button will capture the active viewport



The last captured image is also available in the Windows clipboard and can be pasted to 3rd party applications such as Microsoft Word.

17.2 Saving and Printing Key Images

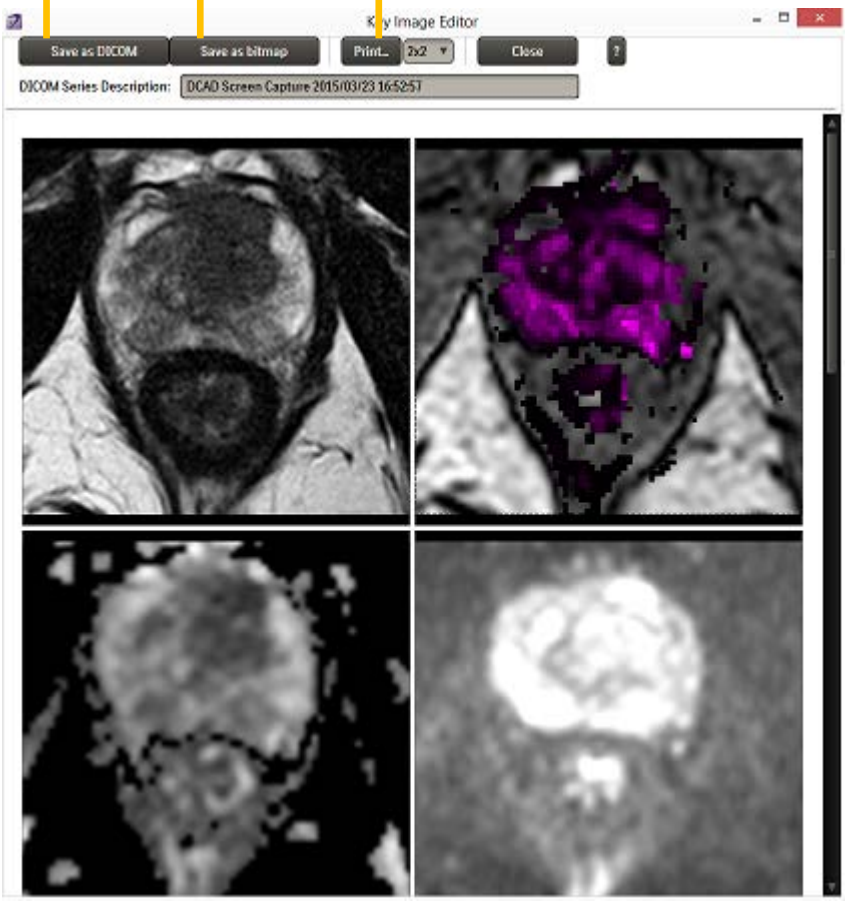
View Captures will display the **Key Image Editor**



Save as DICOM saves the capture images as DICOM Secondary Captures

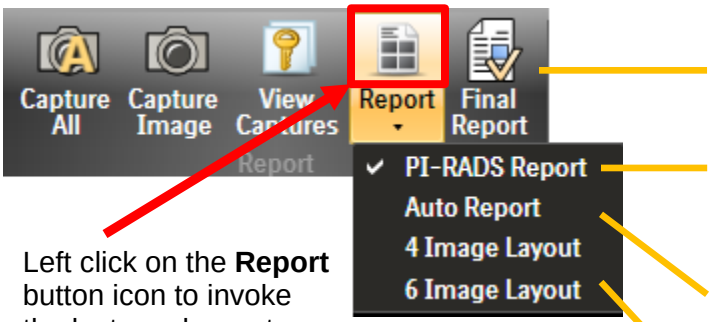
Save as bitmap saves the capture images as bitmaps to a user selectable location

Print… prints the capture images to a Windows printer in selected layout



WARNING Hardcopy printouts shall not be used for interpretation.

17.3 Report



Left click on the **Report** button icon to invoke the last used report option

Final Report displays the frozen report that has been marked final.

PI-RADS Report creates a report with PI-RADS information and auto-captured images

Auto Report creates a report with auto-captured images

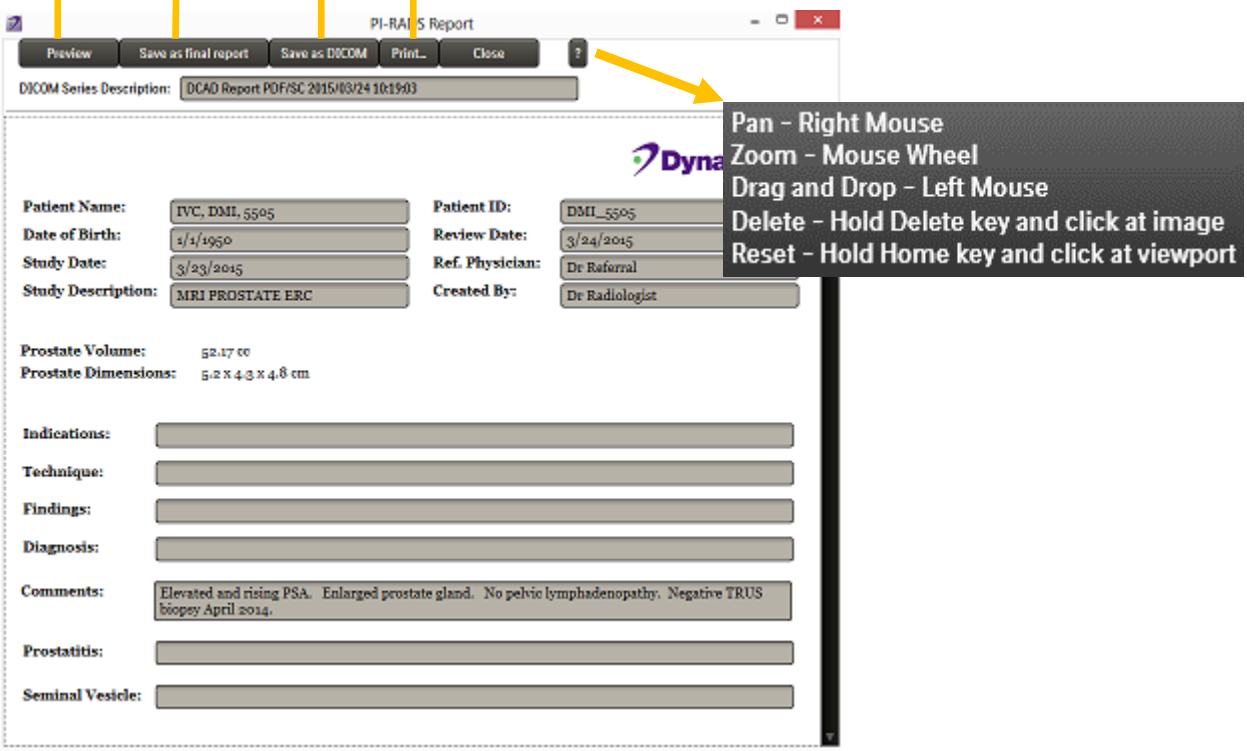
4 Image and 6 Image Layout Report creates a report with manual captured images

Preview converts the report to PDF and displays in another window. It can then be saved as a PDF.

Save as Final Report saves the report as a final report to the DynaCAD server. Based on the Final Report Settings, the report will either be saved as DICOM Encapsulated Document, or sent to PowerScribe 360, or both.

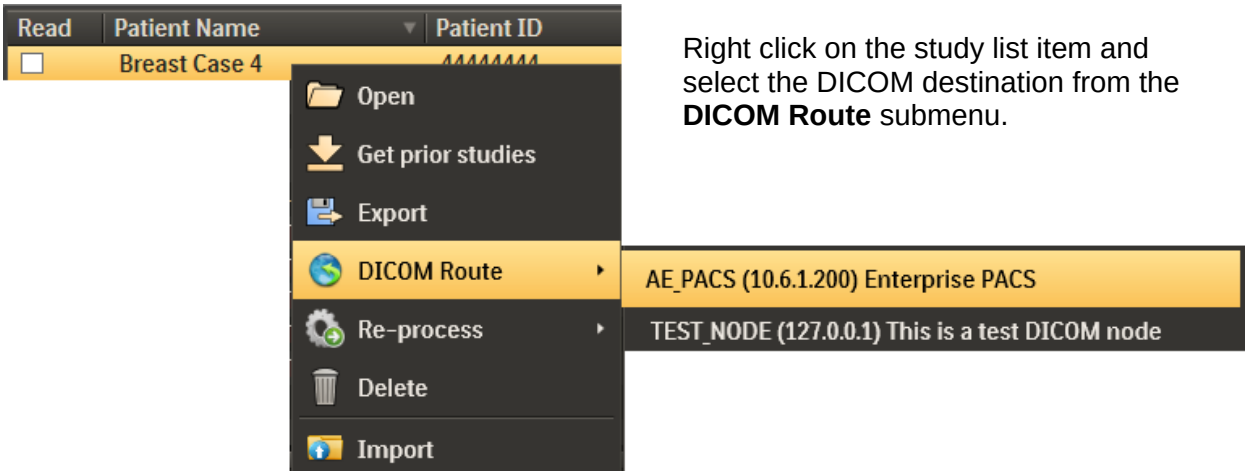
Save as DICOM saves the report as DICOM Secondary Capture

Print… prints the report to a Windows printer



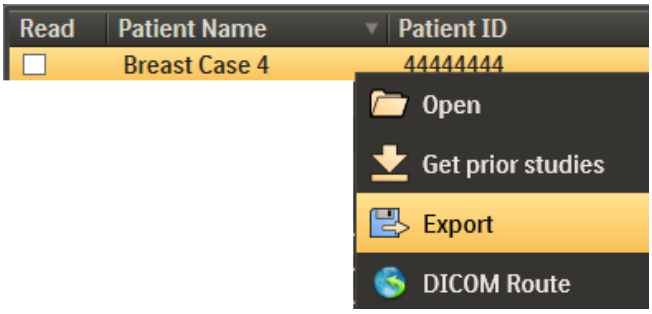
18 DICOM Export

18.1 DICOM Route



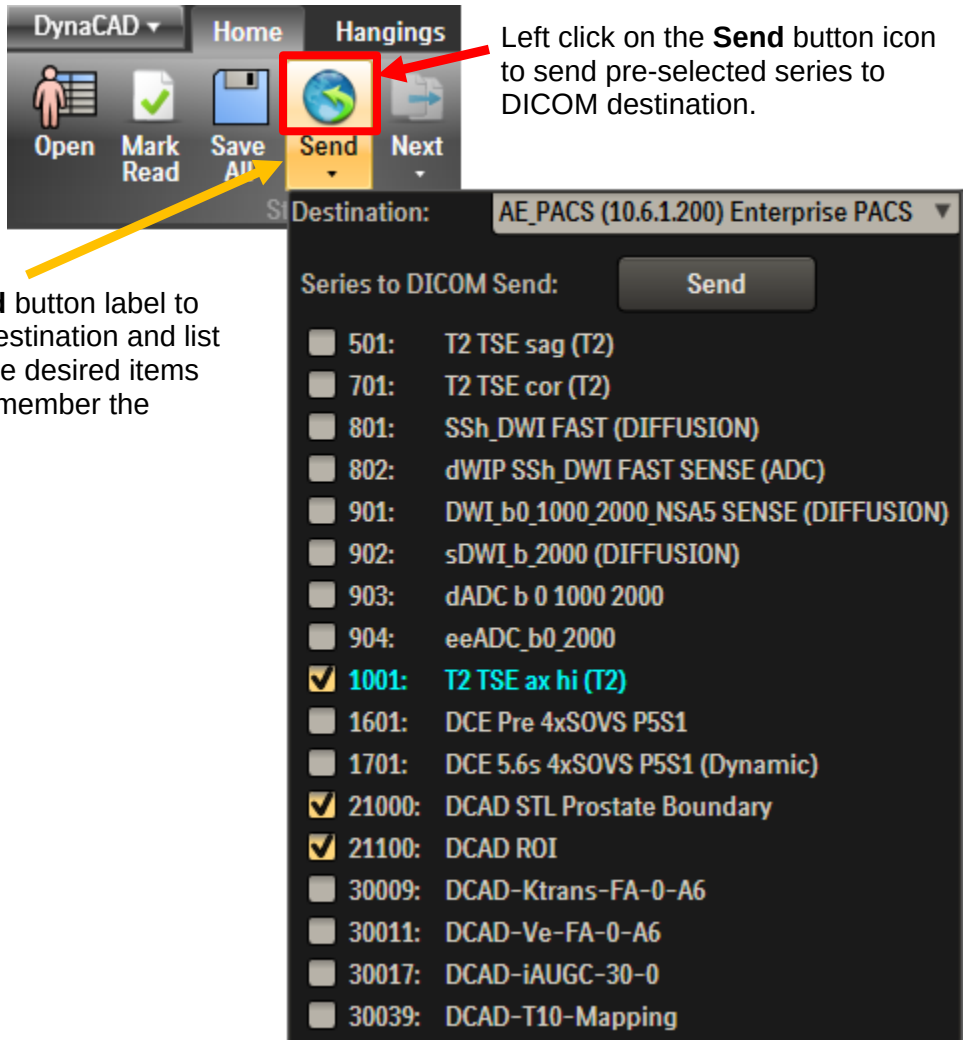
Right click on the study list item and select the DICOM destination from the **DICOM Route** submenu.

18.2 Export to Media



Right click on the study list item and select the **Export**.

18.3 One-click Send

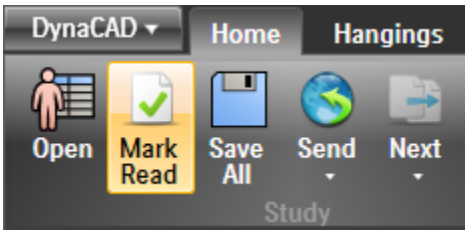


Left click on the **Send** button icon to send pre-selected series to DICOM destination.

Left click on the **Send** button label to display the DICOM destination and list of series. Choose the desired items and DynaCAD will remember the selection.

18.4 Send on Mark READ

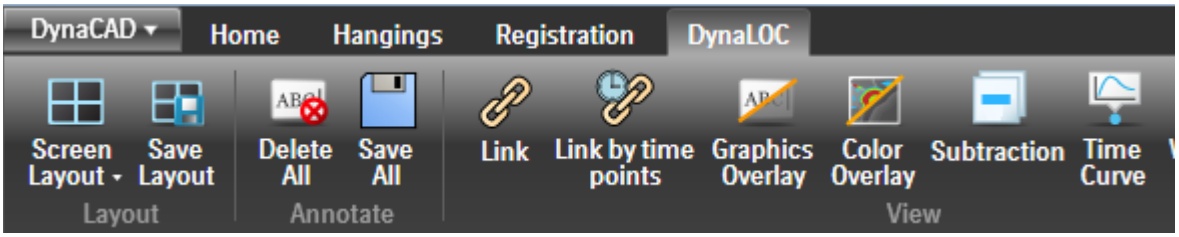
DynaCAD can be configured to automatically DICOM route selected series created by the user when a study is Mark READ by left click the **Mark Read** button:



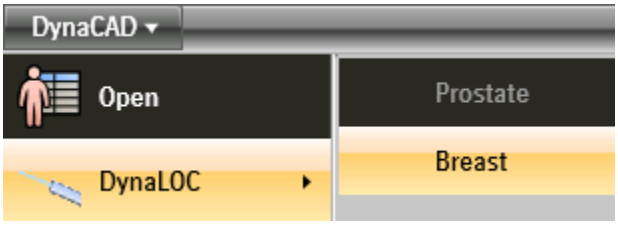
19 DynaLOC Breast

19.1 Launching DynaLOC Breast

DynaLOC Breast can be launched by left click on the **DynaLOC** tab:



If the **DynaLOC** tab is not available, it is likely that the study is not identified as a BREAST case, e.g. unrecognized Study Description by the *OrganType* Filter. Select **Breast** from the **DynaLOC** option under the application menu:



19.2 User Interface

Screen Layout provides a list of m x n layout options

Save Layout to save current layout for DynaLOC Breast hanging

Delete All deletes annotation and measurement

Save annotation saves annotation and measurement

Link all viewports spatially

Link by time points links all viewports temporally

Graphic Overlay toggles viewport overlay text

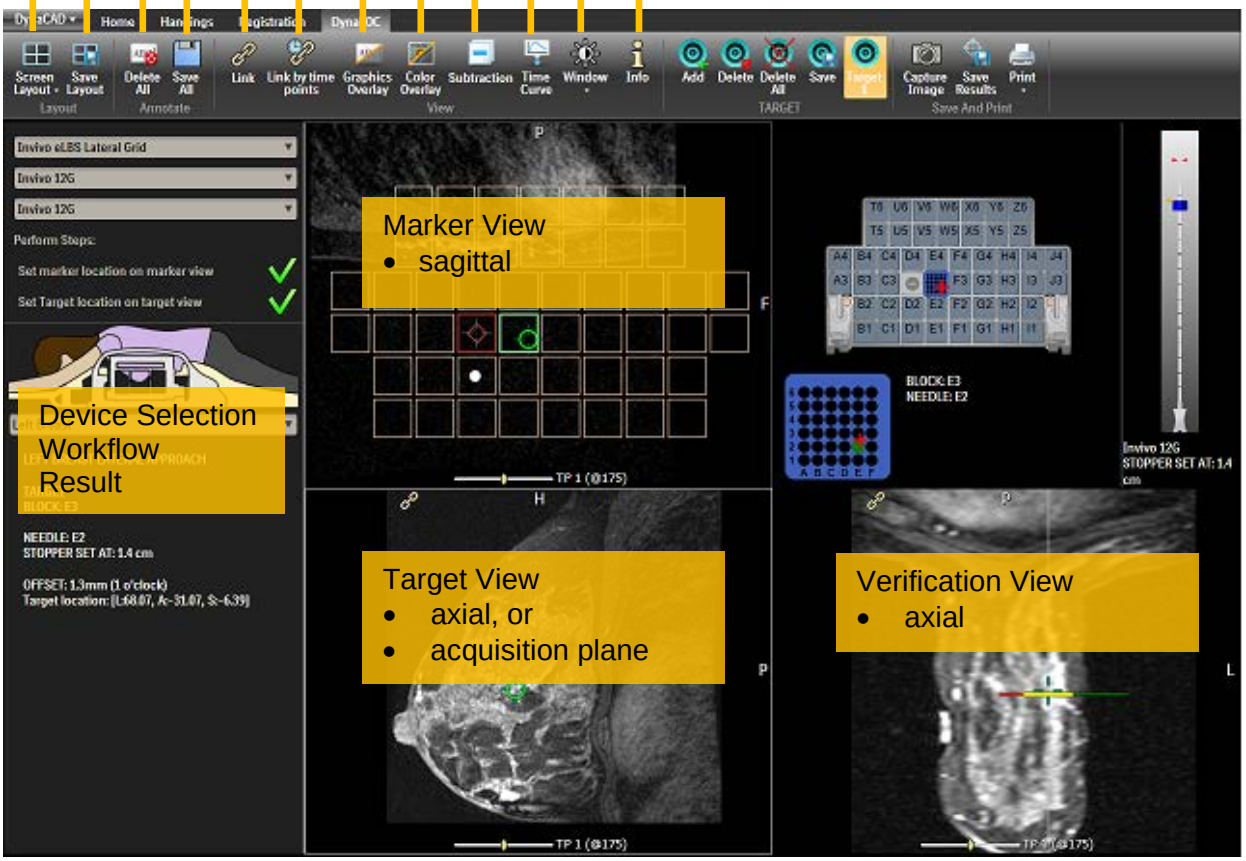
Color Overlay toggles QuickTP overlay if applied

Subtraction toggle subtraction for active viewport

Time Curve displays time curve for DCE

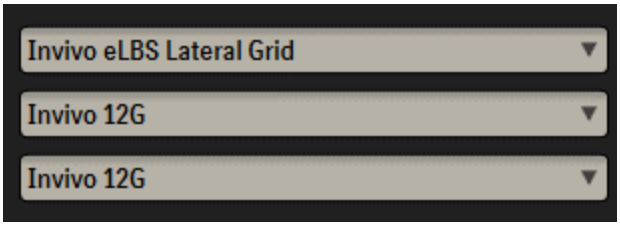
Window: Auto-windowing, presets

Display DICOM **Info** for 2D viewport



19.3 Device Selection

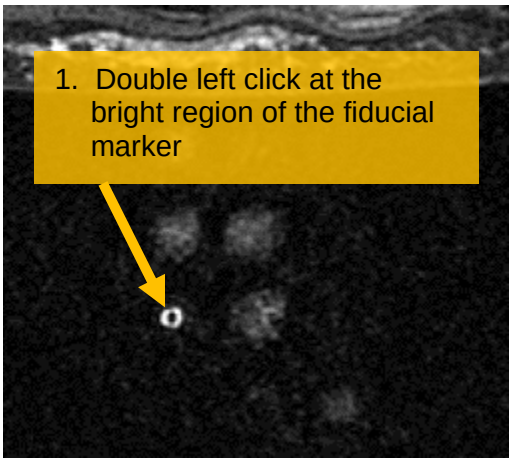
Select the biopsy device and needle from the corresponding dropdown box:

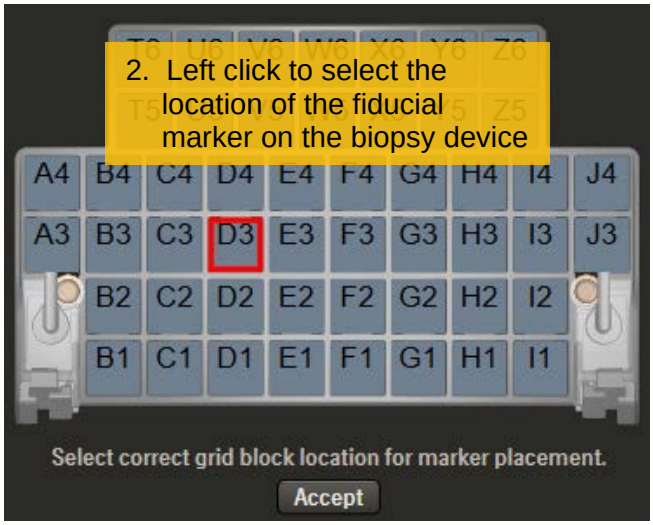


WARNING DynaLOC Breast software shall be used only with recommended Biopsy Devices, Fiducial Markers, and Needle Guides.

19.4 Fiducial Marker Selection

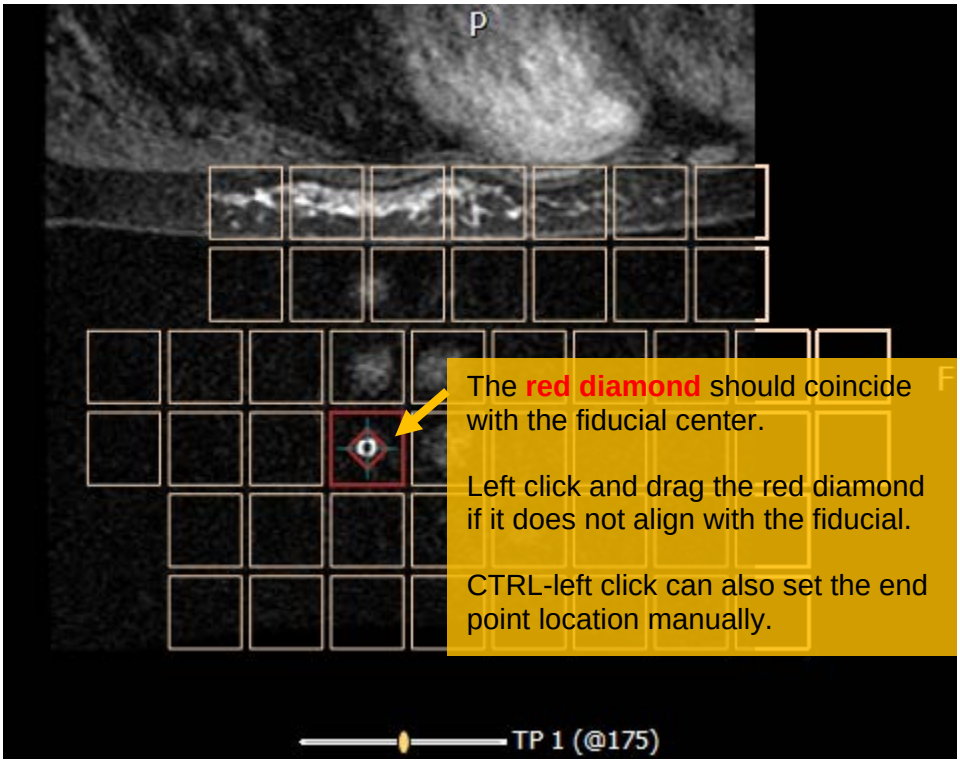
On the Marker View viewport, scroll to the location that shows the fiducial marker, and:



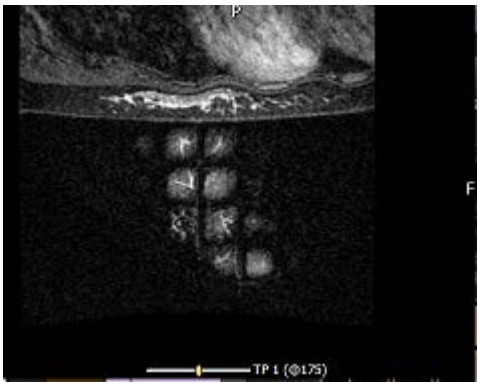


***NOTE*:** No need to specify the fiducial marker location on a Standard grid.

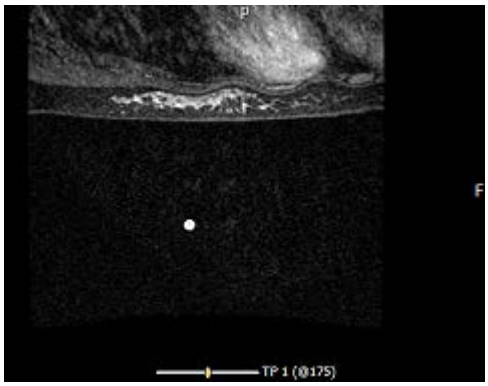
DynaLOC will detect the location of the fiducial and display the biopsy device graphic at the end of the fiducial that is closest to the skin. Scroll back and forth to check.



This image location is at the end of the fiducial that is closest to the skin surface – grid overlay is displayed.



One image closer to the skin surface – no grid overlay is displayed

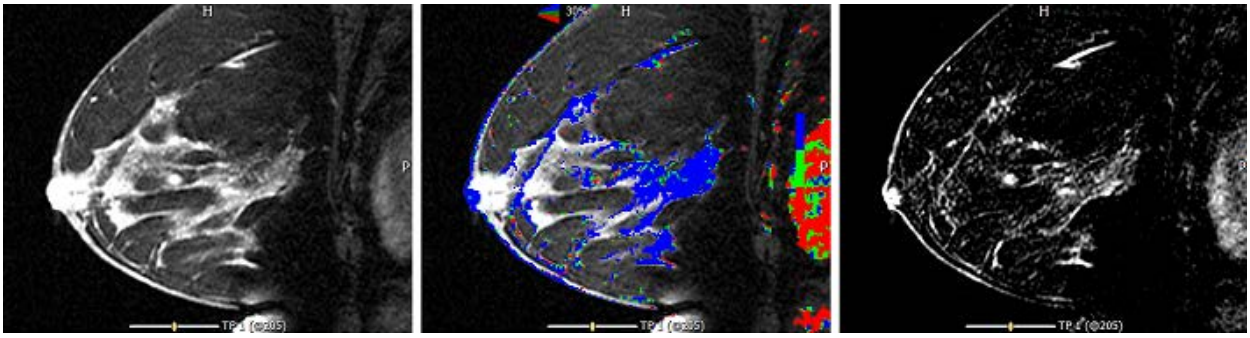


One image towards the operator – no grid overlay is displayed

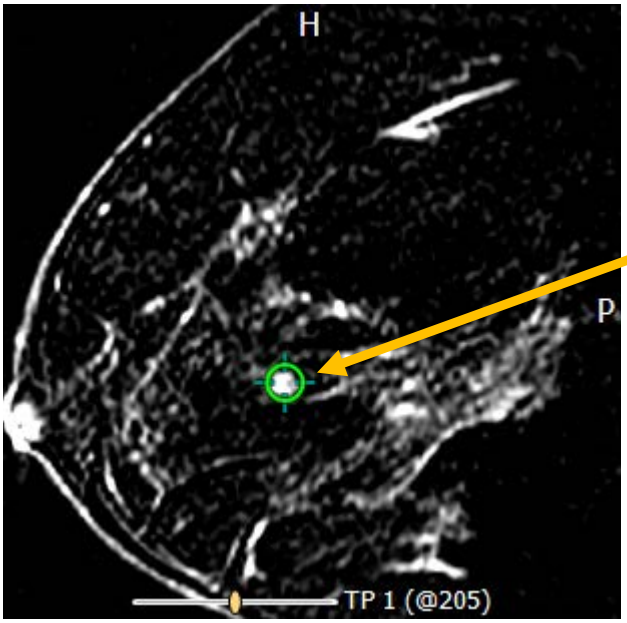
If the detected location is not correct, it can be overridden by CTRL-left click at the end location of the fiducial closest to the skin surface.

19.5 Target Selection

On the Target View, scroll to the target location. To help localization, there are 3 options if DCE is acquired:



Original DCE grayscale With QuickTP color overlay Subtraction



Double left-click to mark the target location.

Left click and drag the **green circle** to adjust the location.

Multiple targets can be created for evaluating lateral vs. medial approach, and/ or if there are multiple locations for biopsy.

Add a new target

Delete current target

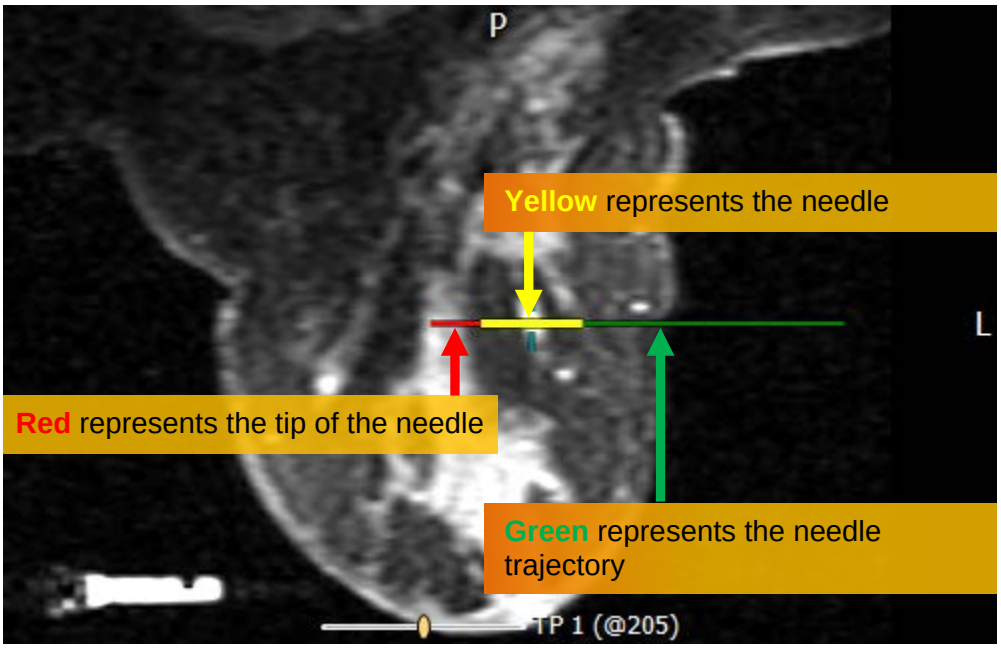
Delete All deletes all targets

Save saves all targets

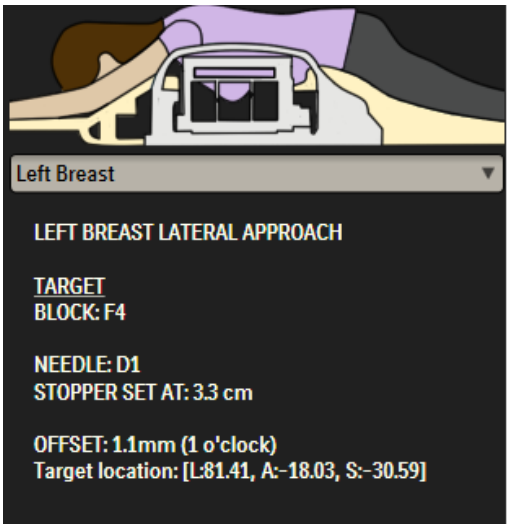
Target 1, 2… to select the corresponding target to display

19.6 Result Display

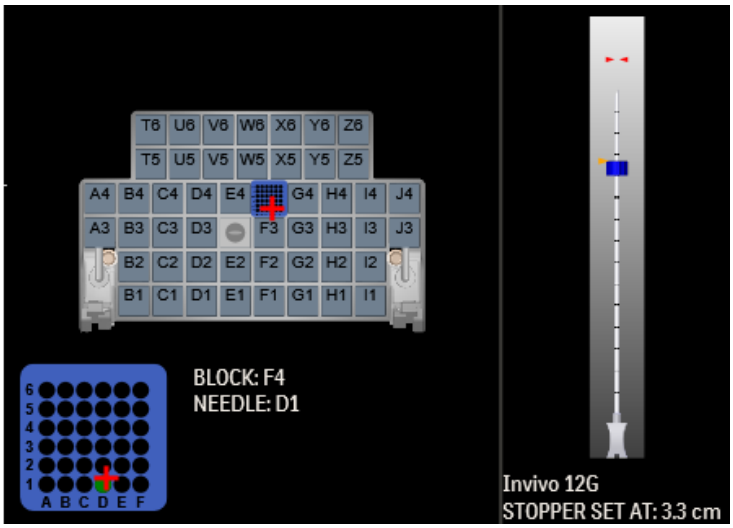
The Verification View displays the axial plane with the needle graphics for the user to evaluate the needle insertion:



Instructions for the current target are both displayed in text and graphical form.



Workflow panel



Result Viewport

WARNING DynaLOC Breast MR guided needle calculations are based on the latest information from each biopsy manufacturer. If a discrepant result occurs it is recommended to perform a manual calculation and check the MR breast intervention system manual for any changes to the hardware that may affect the calculation. The specific breast intervention manuals take precedence over the DynaLOC Breast manual.

WARNING The physician shall take into account the needle overshoot and where the biopsy needle opening is located. DynaCAD may not show the trough and overshoot information for all needles. In this configuration, only the direct distance from the front face (nearest to the user) of the needle block to the target will be provided.

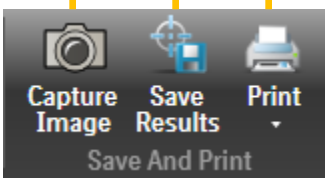
WARNING In case DynaLOC software fails to produce acceptable settings for intervention or simply fails to produce any, manual intervention planning should be performed.

WARNING A confirmation scan with needle sleeve or wire inserted at the target location shall be used to assure proper target localization prior to intervention.

Capture Image to capture the active viewport

Save Results automatically captures images for the current target and provides option to save as DICOM Secondary Captures, or save as bitmaps, or print to a Windows printer

Print to send the instructions with the graphical results (configurable) of the current target to the default Windows printer

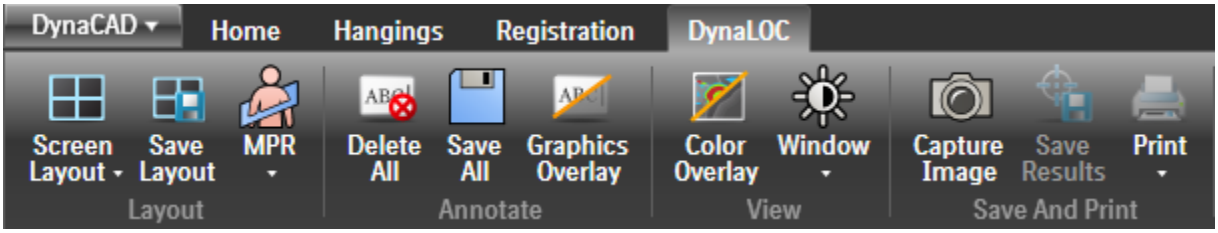


WARNING Hardcopy printouts shall not be used for interpretation.

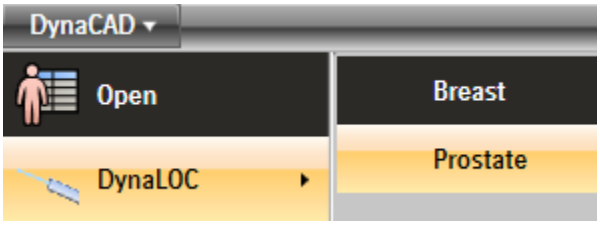
20 DynaLOC Prostate

20.1 Launching DynaLOC Prostate

DynaLOC Prostate can be launched by left click on the **DynaLOC** tab:



If the **DynaLOC** tab is not available, it is likely that the study is not identified as a PROSTATE case, e.g. unrecognized Study Description by the *OrganType* Filter. Select **Prostate** from the **DynaLOC** option under the application menu:



20.2 User Interface

Screen Layout provides a list of m x n layout options

Save Layout to save current layout for DynaLOC Prostate hanging

MPR provides options for displaying in different orientation

Delete All deletes annotation and measurement

Save All saves annotation and measurement

Graphic Overlay toggles viewport overlay text

Color Overlay toggles QuickTP overlay if applied

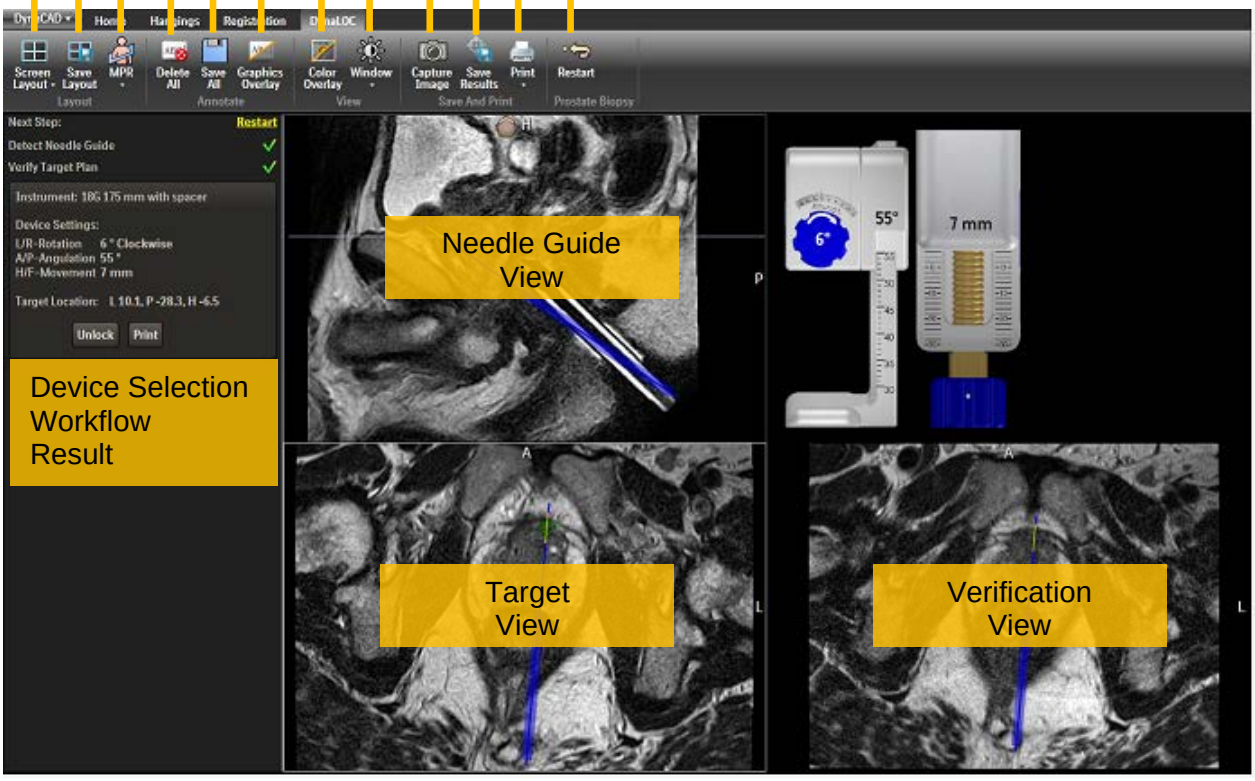
Window: Auto-windowing, presets

Capture Image captures the active viewport

Save Results automatically captures images

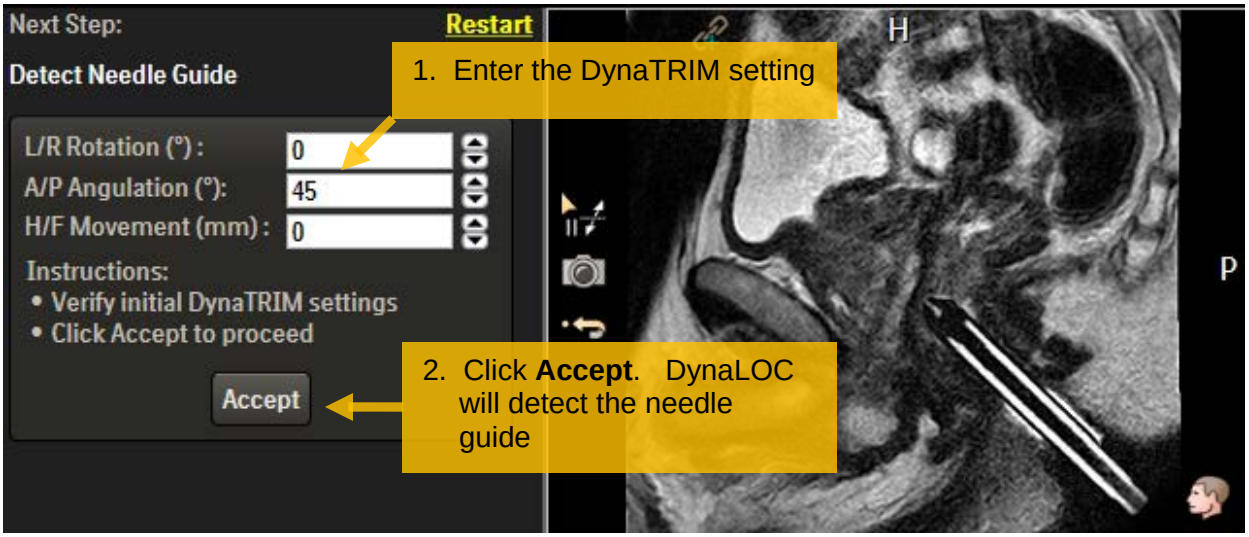
Print sends result to the default Windows printer

Restart resets the settings for next target

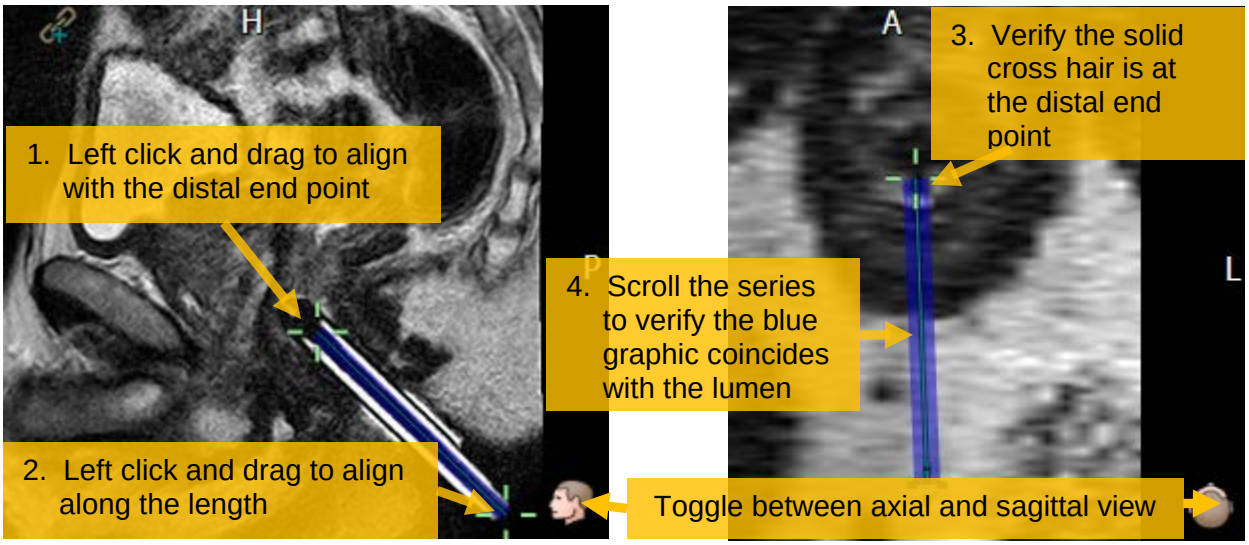


20.3 Needle Guide Detection

Step 1: Enter DynaTRIM setting:

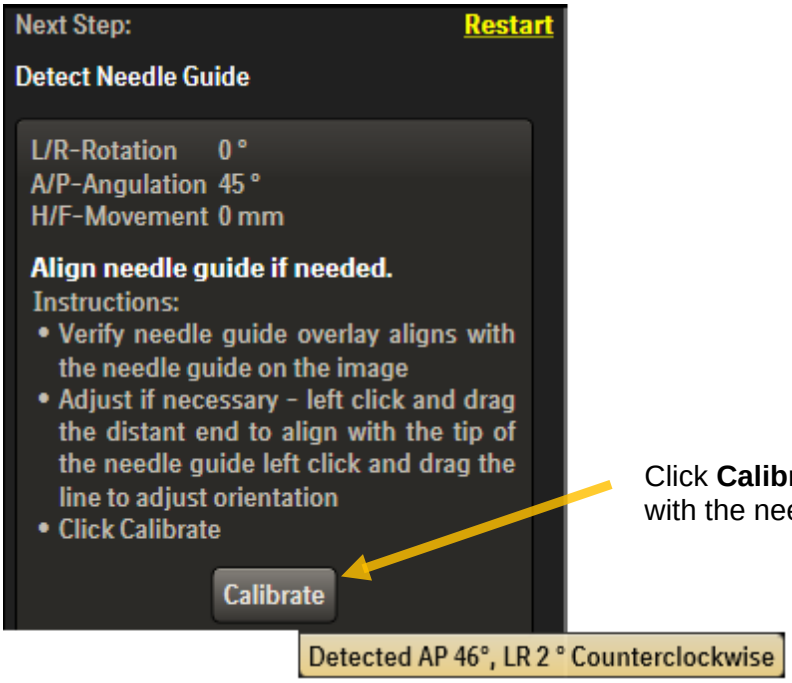


Step 2: Align needle guide



Sagittal view Axial view

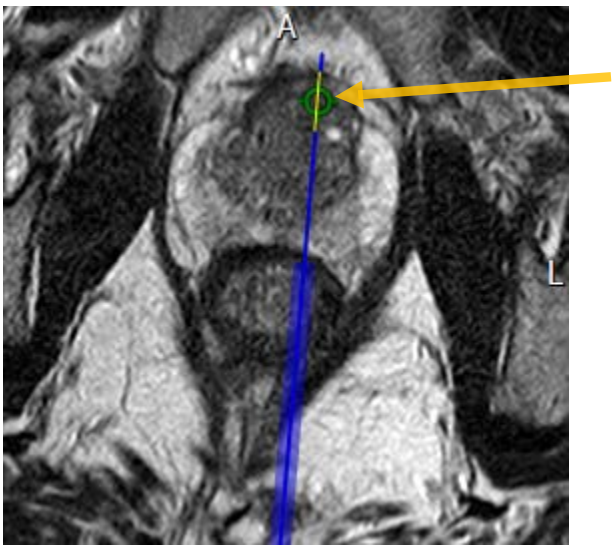
Step 3: Confirm the calibration



Click **Calibrate** if the blue graphic aligns with the needle guide.

20.4 Target Selection

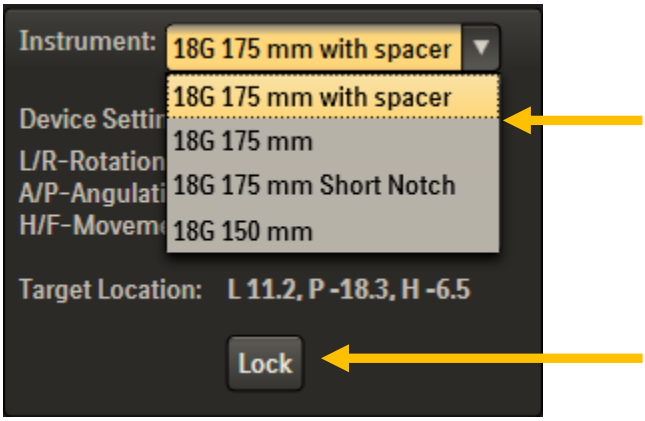
Step 1: Identify target location



Double left click at the target location.

Left click and drag green circle to re-position.

Step 2: Select device



WARNING If DynaLOC does not calculate an acceptable setting for intervention or simply fails to produce any setting, manual intervention planning should be performed.

WARNING The physician shall evaluate the suggested path for needle insertion prior to intervention, to assure that no vital organs or vessels are on the path. Other suggested paths (if available) or manual operating mode shall be selected to assure a safe path for intervention.

WARNING The needle should not be inserted until you are satisfied with the needle guide alignment and needle trajectory.

WARNING The blue line beyond the yellow line (needle trough) away from the needle guide denotes the needle throw. Needle path and needle throw should be reviewed to assure the needle path is optimal, without risk to vital organs or vessels. Choose a different needle trajectory and type of needle as required to minimize risk to the patient. Use of a manual biopsy device may be required. Proceed with extreme caution.

WARNING Do NOT proceed with the needle insertion if the blue line (projected needle guide) does not align with the needle guide that appears in the verification scan as erroneous depth and angulation will result if parameters are not defined correctly. The discrepancy could be the result of patient and/or DynaTRIM movement, incorrect adjustment of the DynaTRIM settings, and/or incorrect needle guide calibration.

WARNING The physician should always read and follow the step by step interventional instructions. In particular, the user should be cautious after the confirmation scan when there is need to adjust the needle after it has been inserted inside the patient.

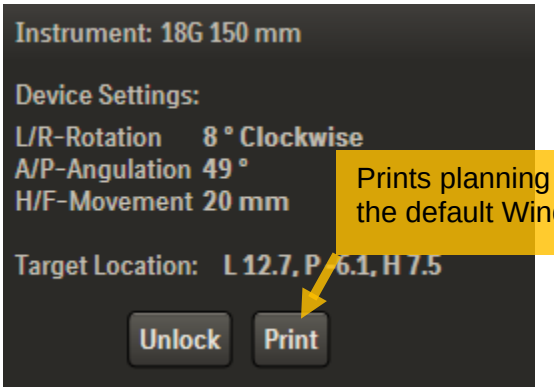
WARNING Before the intervention is performed a confirmation scan shall be acquired with the needle guide (and possibly stylette) inserted, to ensure that the needle is positioned as desired. Incorporate the effects of needle throw into the risk evaluation. The needle path should be as desired, without risk to vessels. Choose a different needle trajectory and type of needle as required to minimize risk to the patient. Use of a manual biopsy device may be required. Proceed with extreme caution.

WARNING To assure the proper target localization, a verification scan shall be acquired to confirm needle trajectory will hit the target location prior to needle insertion.

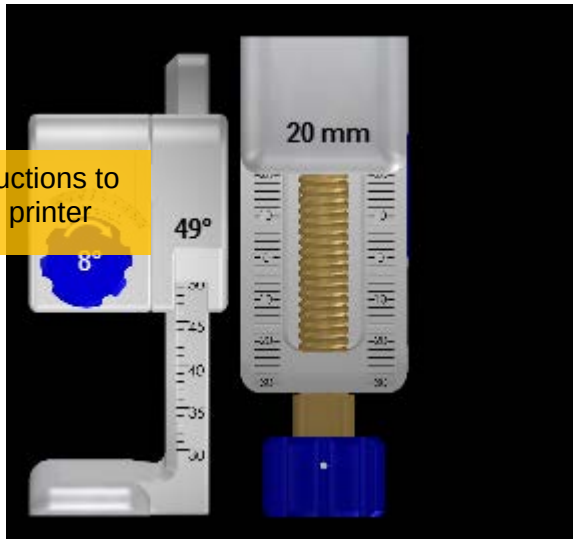
WARNING Do NOT proceed with the biopsy procedure if the needle appearing in the verification scan does not reach the target.

WARNING Do NOT proceed with the interventional planning if the blue overlay does not match up with the visible needle guide as erroneous depth and angulation will result if parameters are not defined correctly. Contact Technical Support for assistance.

20.5 Result Display



Prints planning instructions to the default Windows printer



Instructions displayed in the left hand panel, and graphical result displayed in the viewport.

WARNING Hardcopy printouts shall not be used for interpretation.

APPENDIX A – SUPPORT INFORMATION

Phone support

Telephone support is available from 8:00 AM to 8:00 PM EST
1-877-INVIVO1 or 1-877-468-4861

E-mail support

Send email to dynasupport@invivocorp.com

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