EXACT IMAGING

Quick Reference Guide

CE 2797

Exact Imaging Inc.
7676 Woodbine Avenue, Unit 15
Markham, ON L3R 2N2, Canada
+1 (905) 415 0030
info@exactimaging.com

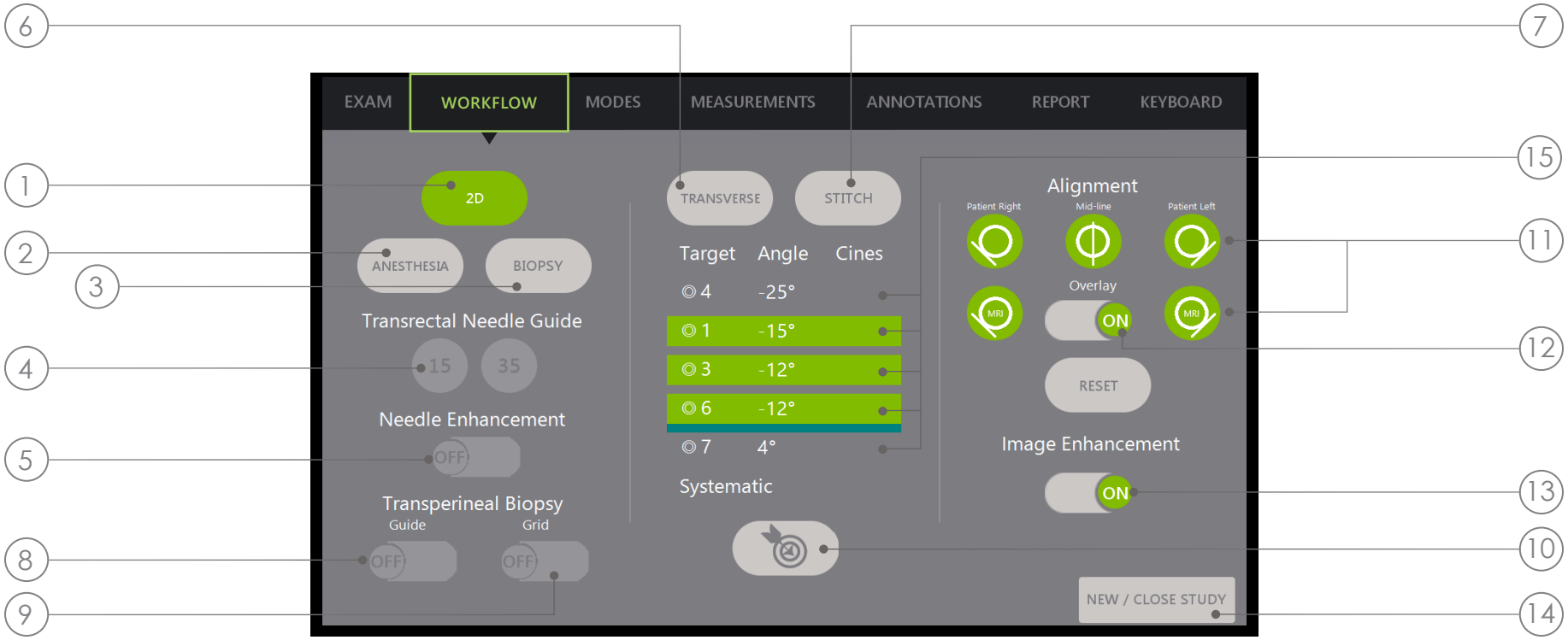
PN 6699 Rev 3.4

EXACTVU™

micro-ultrasound system
for targeted prostate biopsies

ExactVu™ System Components

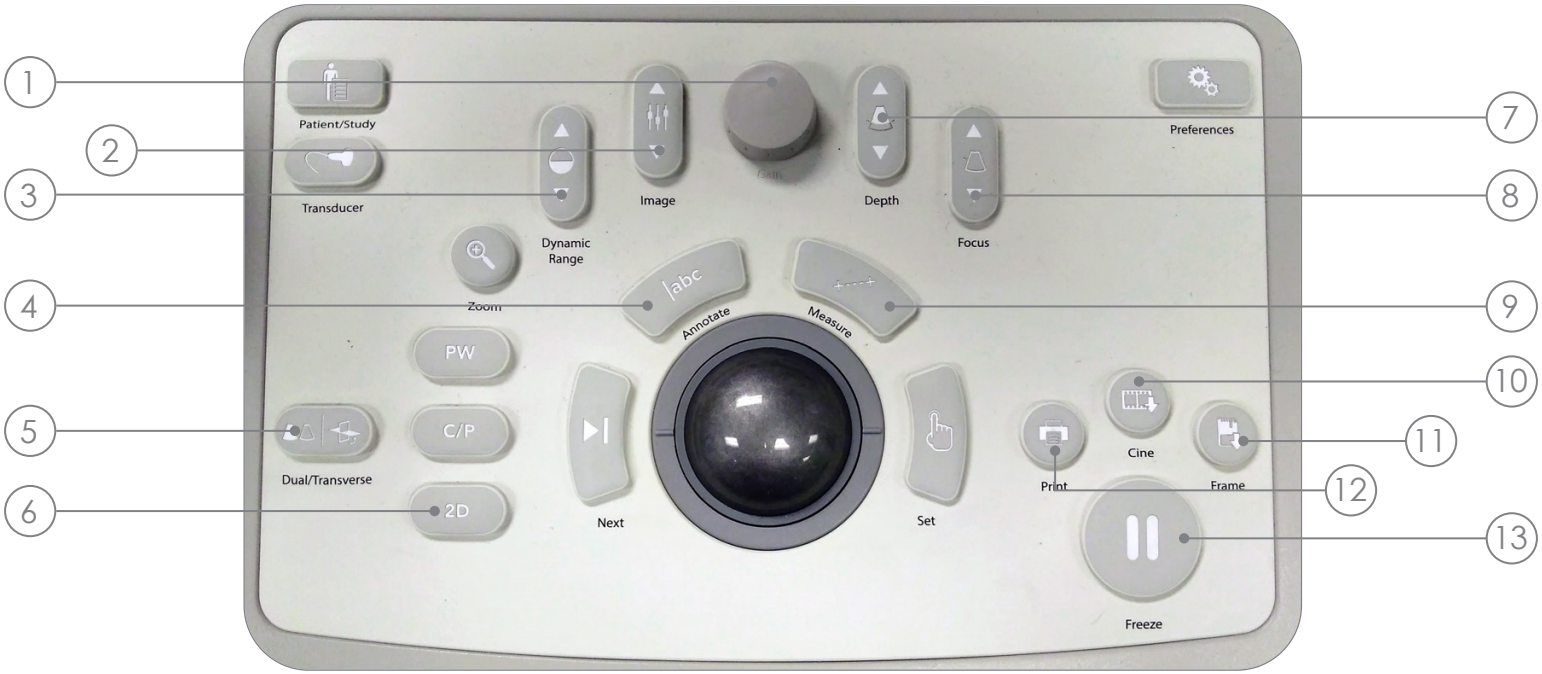
Workflow Screen



1. **2D:** The "default" imaging mode. Allows the user to quickly go back to this imaging mode (and imaging settings) from the **Biopsy/Anesthesia** Sub-modes. In Transperineal, allows user to go back and activate **Transverse** and **Angle Reset**.
2. **Anesthesia:** Optimizes settings for anesthesia delivery.
3. **Biopsy:** Optimizes settings for biopsy.
4. **Needle Guide:** Switches between **15°** and **35°** needle guide overlays.
5. **Needle Enhancement:** Toggles visualization of biopsy needle on/off.
6. **Transverse:** Allows a transverse image to be constructed in real time.
7. **Stitch:** Allows images to be combined for measurement of large prostates.
8. **Transperineal Biopsy Guide:** Activates needle guides on the screen for sagittal plane when using the EV29L Sterile Transperineal Needle Guide.
9. **Transperineal Biopsy Grid:** Activates needle guides on the screen for transverse plane when using the template.
10. **Target:** In 2D Mode, appears with a bullseye graphic, and adds a target angle to the Target List and saves a frame.

    In Biopsy Mode, appears with a needle gun graphic. The Target control saves a cine image, and links it to a selected target angle.
11. **Alignment:** Used to align edges of the prostate in ultrasound and MRI when using FusionVu™ and Reporting features.
12. **Overlay:** Turns on/off scouting image (FusionVu)
13. **Image enhancement:** Turns on/off image post-processing
14. **New/Close Study:** Adds new study or closes and saves current study.
15. **Target List:** A list of sequentially numbered targets in both the status panel and on the touch screen, showing the angle when the Target control was pressed.

Control Panel



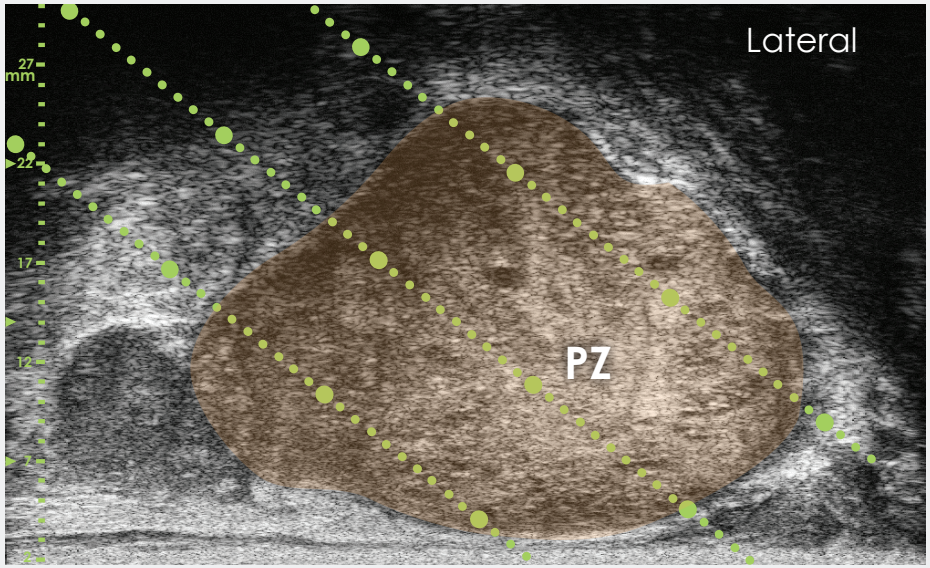
1. **Gain:** Increases/decreases the **intensity of the image.**
2. **Image:** Cycles through **image presets.**
3. **Dynamic Range:** Increases/decreases the **contrast** of the ultrasound image.
4. **Annotate:** Opens the **Annotations** touch screen.
5. **Dual/Transverse:** Begins imaging in **Dual** or **Transverse Mode**.
6. **2D:** Begins imaging in **2D Mode**.
7. **Depth:** Increases/decreases the **image depth**.
8. **Focus:** Increases/decreases the **depth of a single focal zone**.
9. **Measure:** Initiates **default measurement type** for current mode.
10. **Cine:** Saves up to the last 300 frames as a **cine**. 60 frames are saved in Biopsy Mode.
11. **Frame:** Saves a **single frame**.
12. **Print: Prints** the current Screen image on the (optional) thermal printer.
13. **Freeze:** Toggles between **live/paused imaging**.

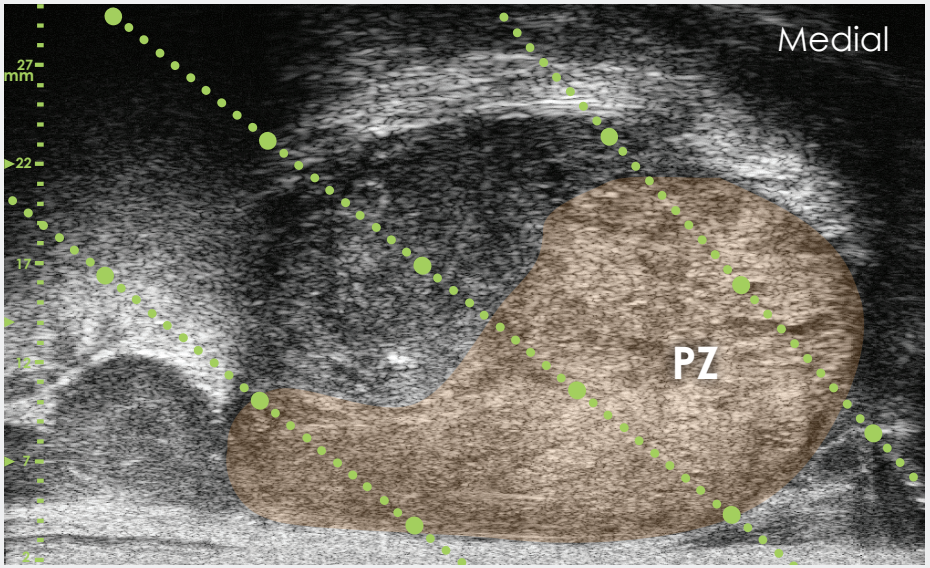
1. Dim room lights
2. **TGC** "**J**" **shape** in center. Adjust **Gain**
3. **Large** Image setting
4. **Sweep** through prostate to the **lateral edges**
5. Save "**Cine**"
6. **Volume** Measurement:
   - I. Find **MID-LINE**
   - II. For **Normal Prostate**:
     + Press "**Dual/Transverse**"

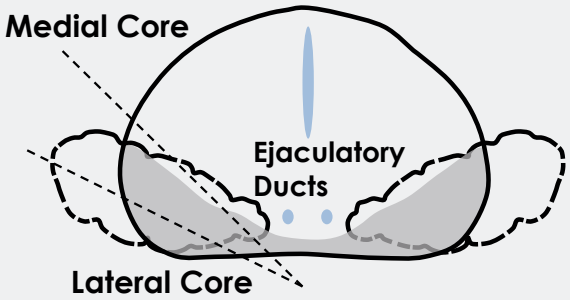
     OR

     For **Large Prostate**:
     + Press "**STITCH**"
     + Press "**Dual/Transverse**"
   - III. Press 

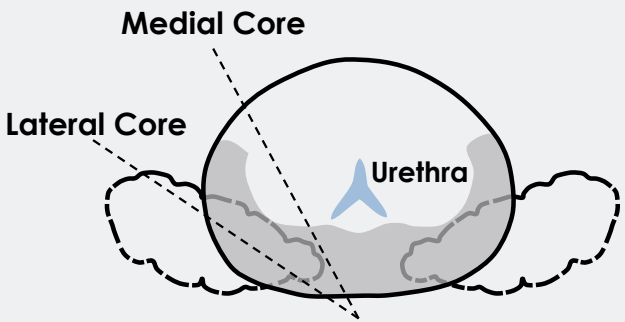
.
7. Press "**2D**"
8. Press "**Image**" preset and change to "**SMALL**"
9. **Slow sweep** through prostate to the **left and right lateral edges**
   - I. **Identify Targets**
10. Press "**Cine**" to save the **sweep in small**
11. **Interrogate** the gland for **suspicious areas**
12. Press "**ANESTHESIA**" (**white line**)
13. Press "**BIOPSY**" (**green line**)
14. Press  after each biopsy



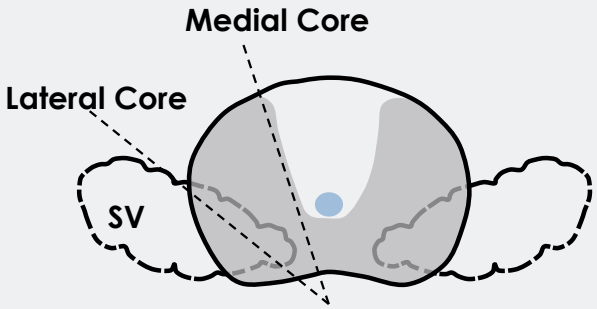




Base



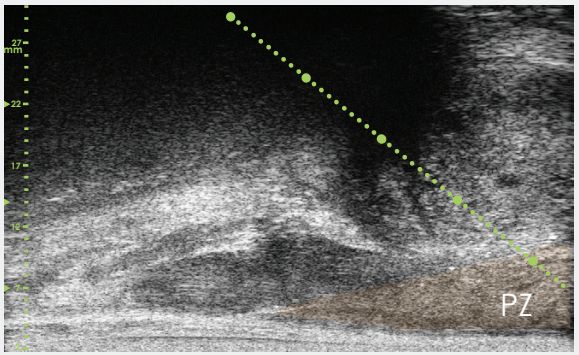
Mid

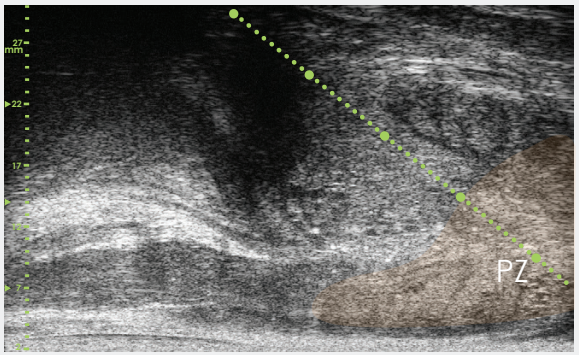


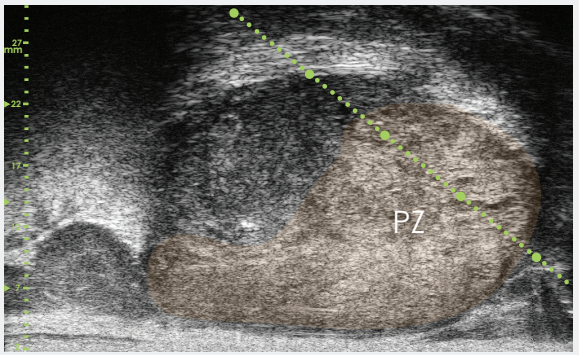
Apex

Systematic Sampling Example

MEDIAL

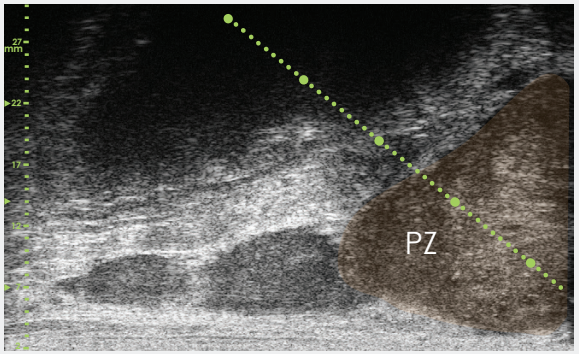


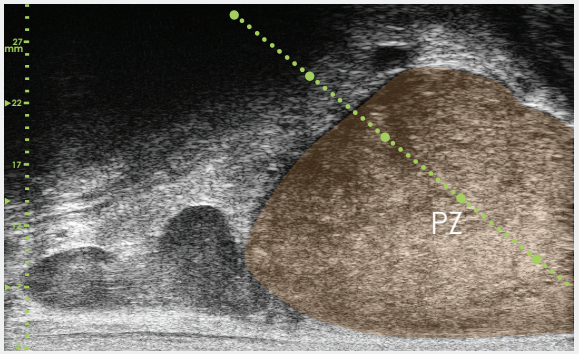


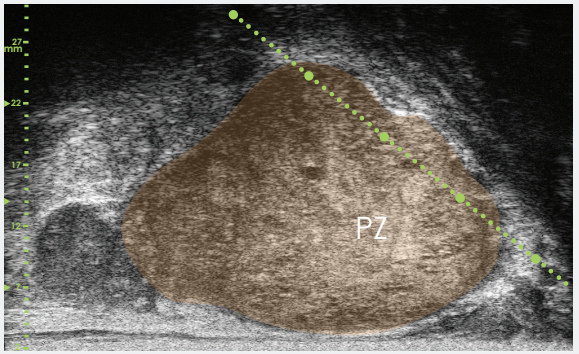


BASE | **MID** | **APEX**

LATERAL







BASE | **MID** | **APEX**

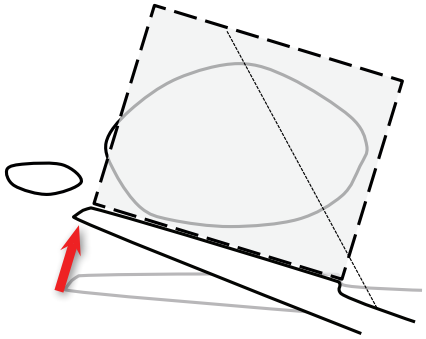
* The green dotted line (in the images above) is the needle guide overlay.

*The distance between each of the two “large” green dots is 1 cm.

Side-Fire Transducer Technique for Apical Horn Sampling

Step 1

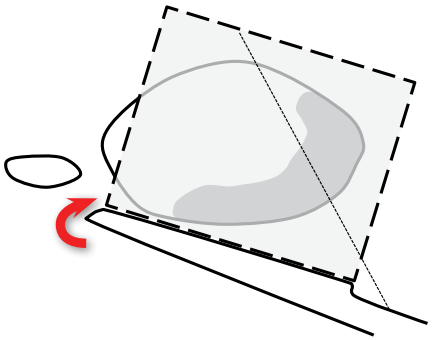
Tilt



Tilt the transducer to maximize the sample size

Step 2

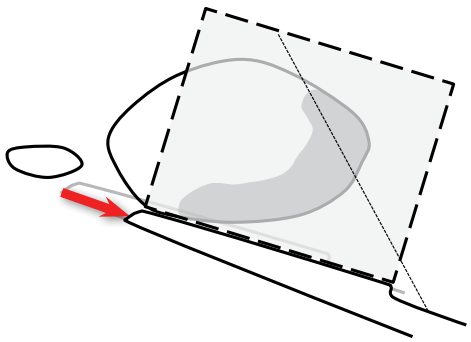
Rotate



Rotate the transducer to fully visualize the horn

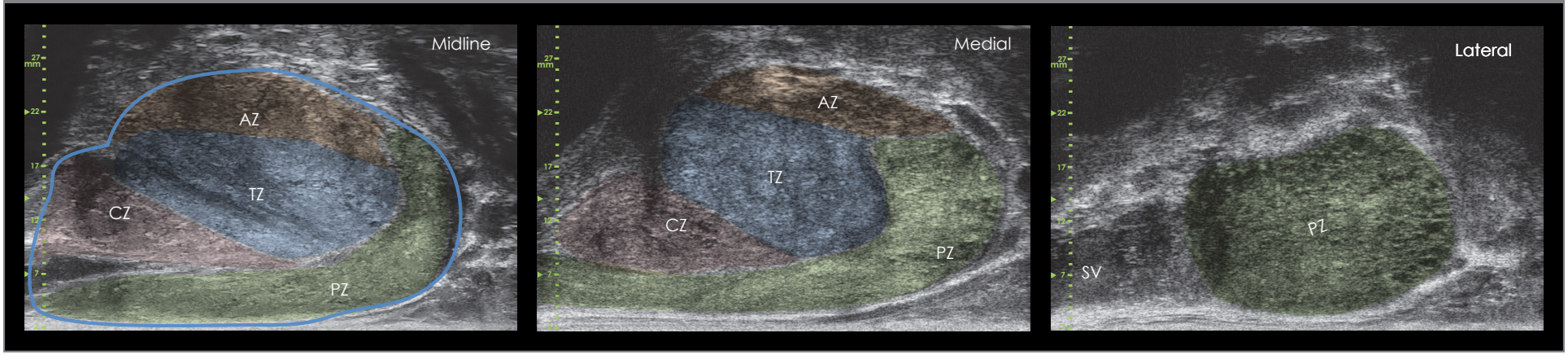
Step 3

Pull-Out

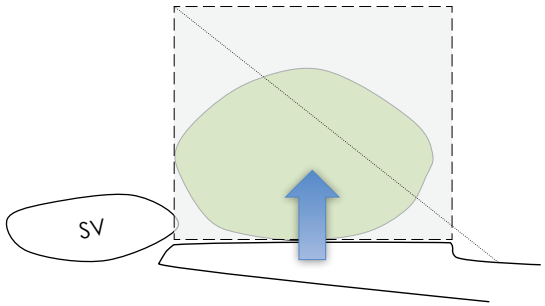


Pull-out the transducer to reach the Apex

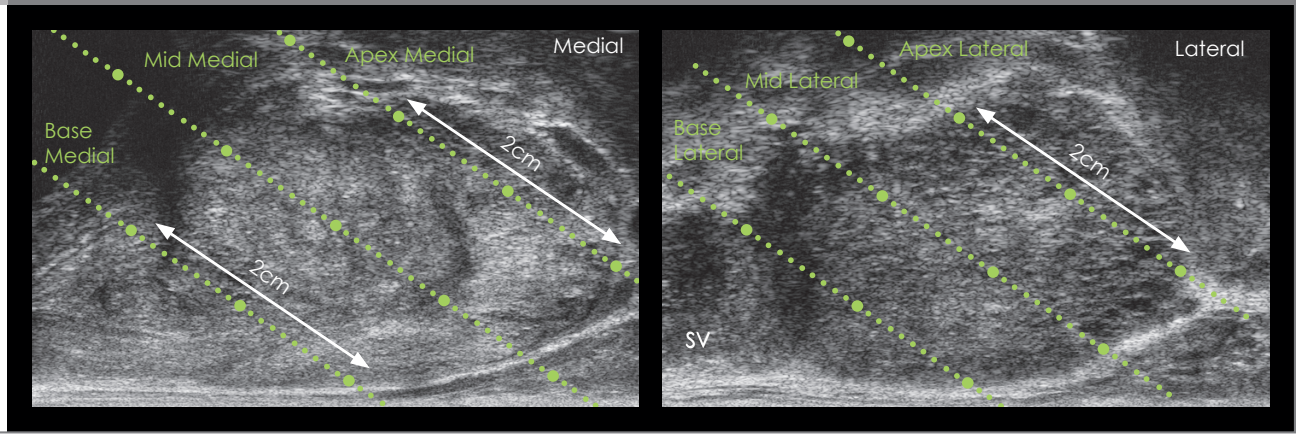
Prostate Anatomy (using high-resolution micro-ultrasound)



Core Length

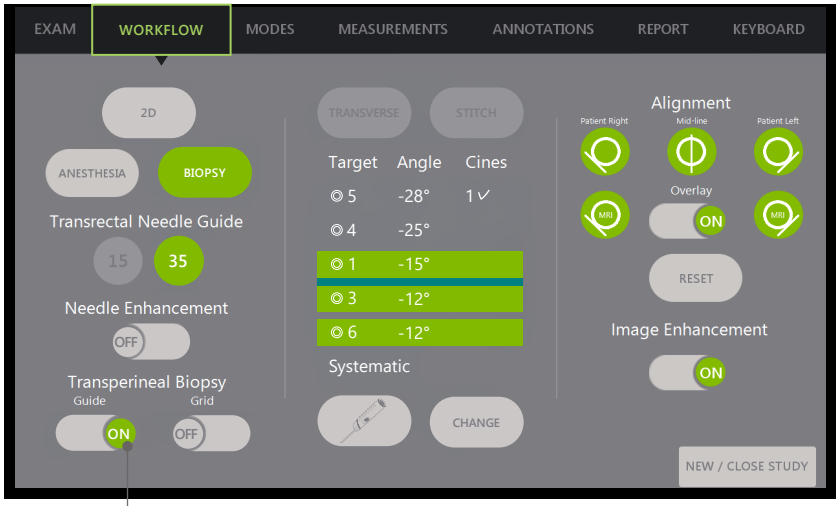


Core Spacing and Needle Guide Scale



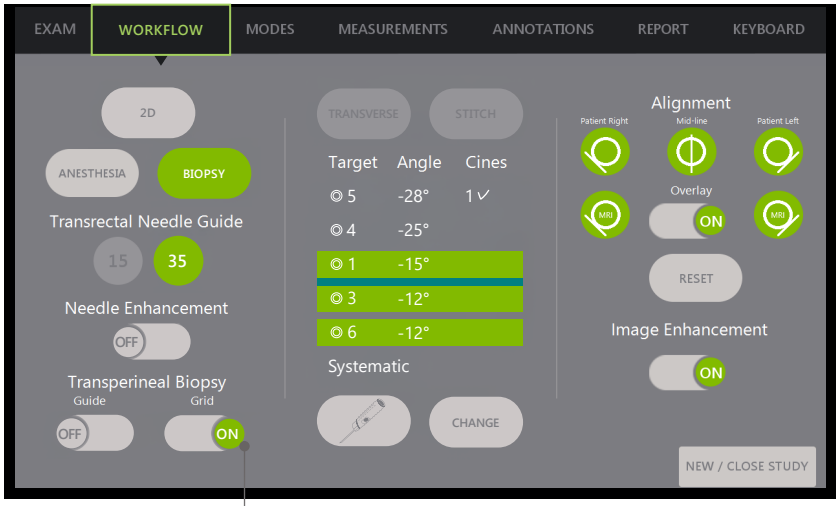
Transperineal Biopsy using Needle Guide or Template

For Transperineal Biopsy using Needle Guide:

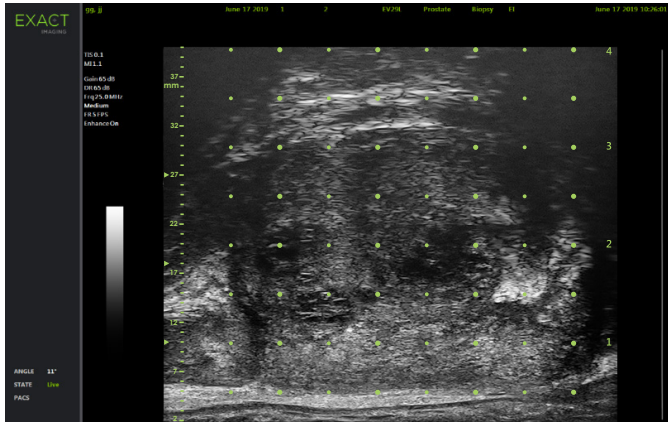


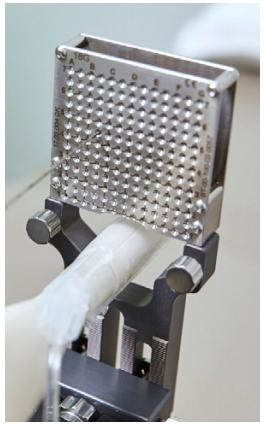
Turn **Transperineal Biopsy Guide ON.**

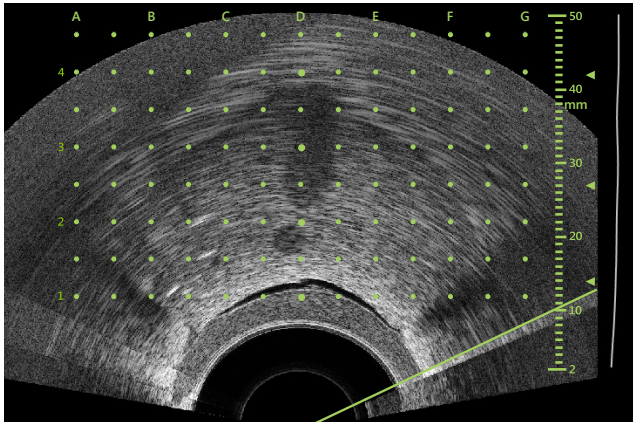
For Transperineal Biopsy Using Template:



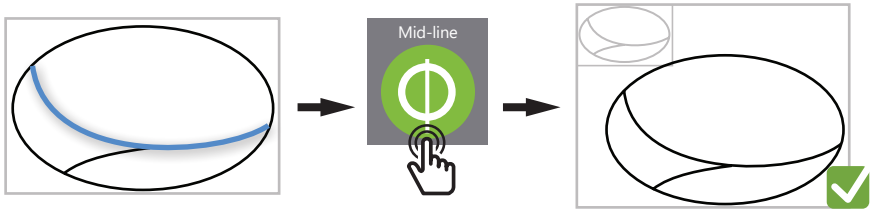
Turn **Transperineal Biopsy Grid ON.**





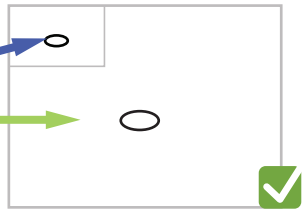


1. Mark and load your FusionVu MRI study as usual.
2. Perform your **Micro-Ultrasound** (**MicroUS**) assessment of the prostate.
3. Locate the **Urethra** and press "**Mid-line**" to align the MRI.



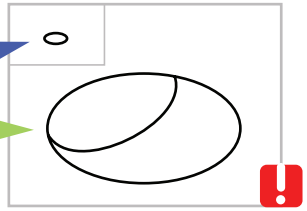
4. Rotate probe to observe whether the lateral borders on **MicroUS** match the lateral borders on the **MRI**.

GOOD ALIGNMENT.
No need to perform **Elastic Fusion**.

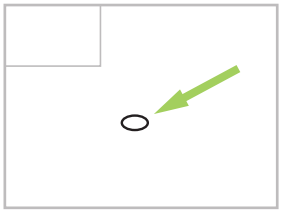


END

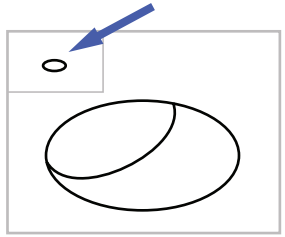
POOR ALIGNMENT.
Continue to **Step 5**.



5. Rotate the probe until you reach the **lateral** aspect of the prostate in the **MicroUS** image. Press the "**Patient Right**" button.

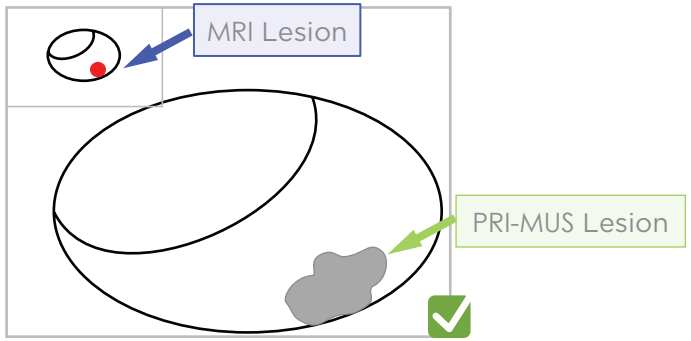


6. Rotate the probe until you identify the most **lateral** aspect of the prostate in the **MRI** image and press the "**MRI**" button.



The **Elastic Fusion** is now enabled on the right side, repeat for the left side if necessary.

7. Rotate the probe to locate the **MRI** target, and examine the live **MicroUS** image to identify the corresponding lesion according to **PRI-MUS™**.



If the alignment appears incorrect press "**RESET**" and repeat the process from **Step 3**.

FusionVu accuracy is dependent on rotating the probe along the patient's sagittal axis.

Remember to keep the transducer aligned with the patient's spine during the procedure to avoid alignment errors.

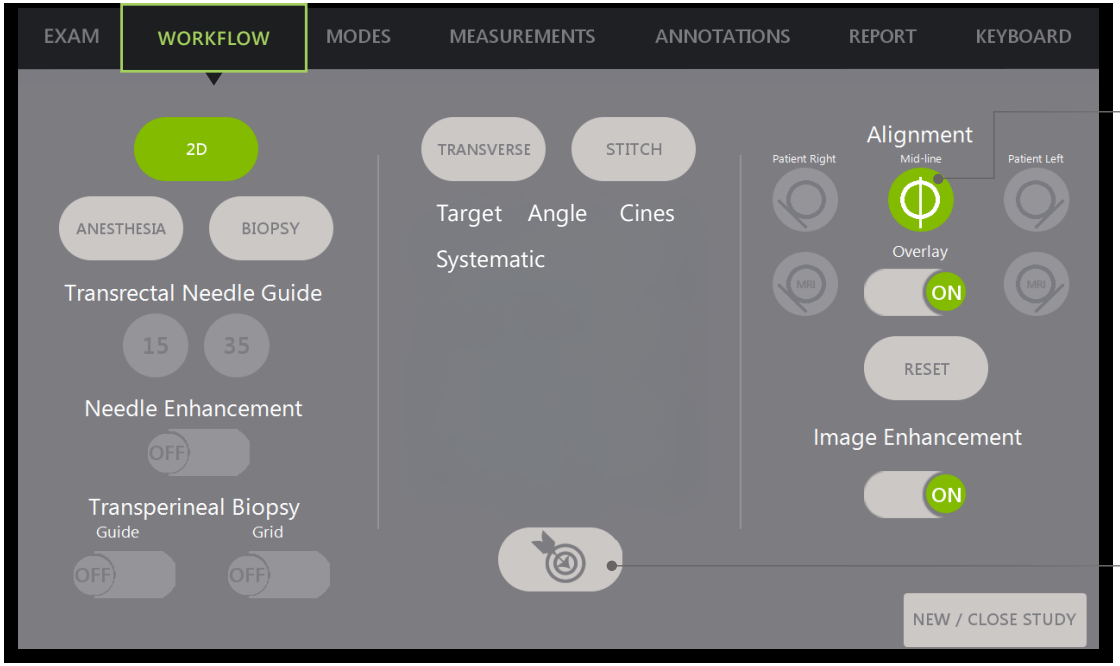
Rotation along the sagittal axis.
ACCURATE FUSION.

Lateral deviation from the sagittal axis.
POOR FUSION.

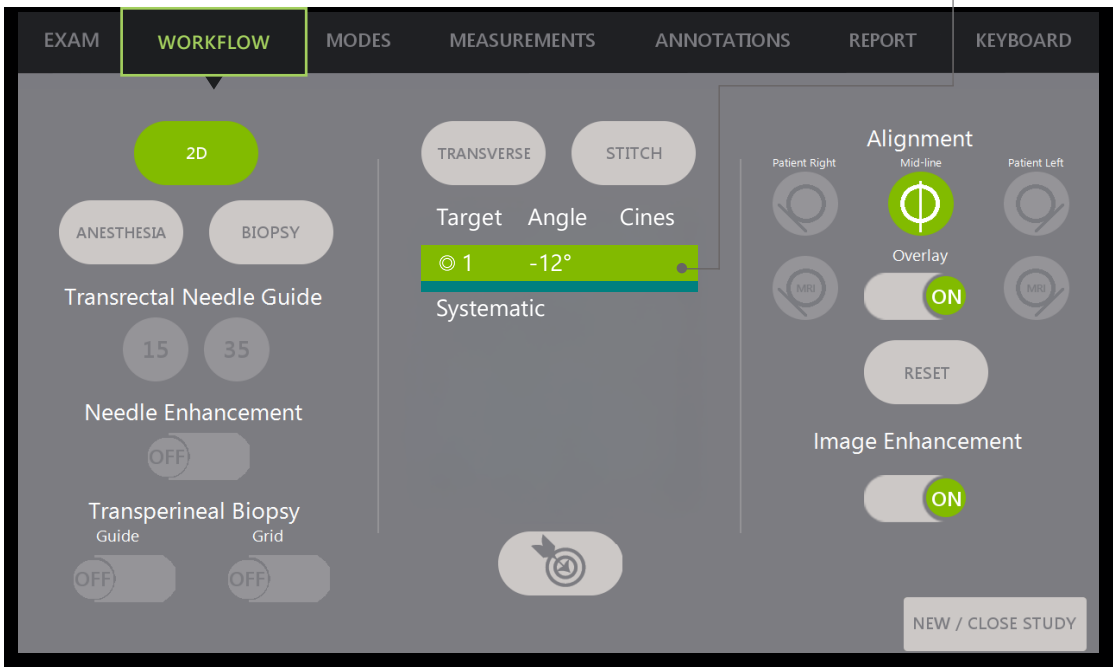
Angle is displayed in **yellow**

Angle is displayed in **red** with **OFF AXIS** label

Setting Mid-line Angle and Using Targets



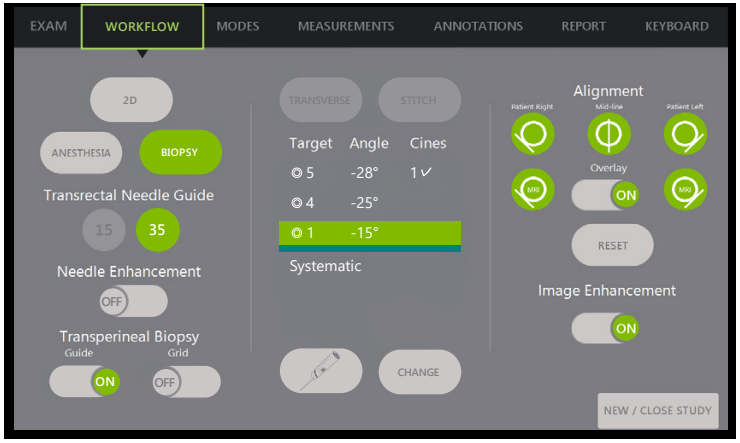
1. Align the Mid-line in **2D Mode**.
2. Find Target and tap  .
3. Target is added to **Target List** and Image is saved.



PREPARE TO TARGET

Target in the Target List is highlighted based on transducer rotation or by tapping the angle in the List.

PERFORM BIOPSY



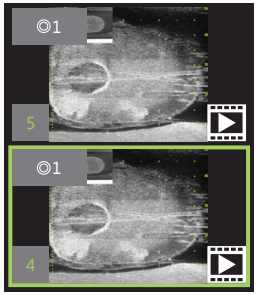
Perform Biopsy.

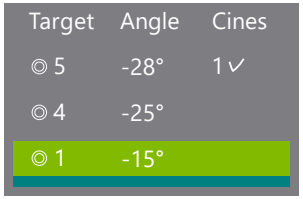
Press  .

Cine is saved and assigned to the highlighted target.

Use  in case of assignment error.

REASSIGN TARGET

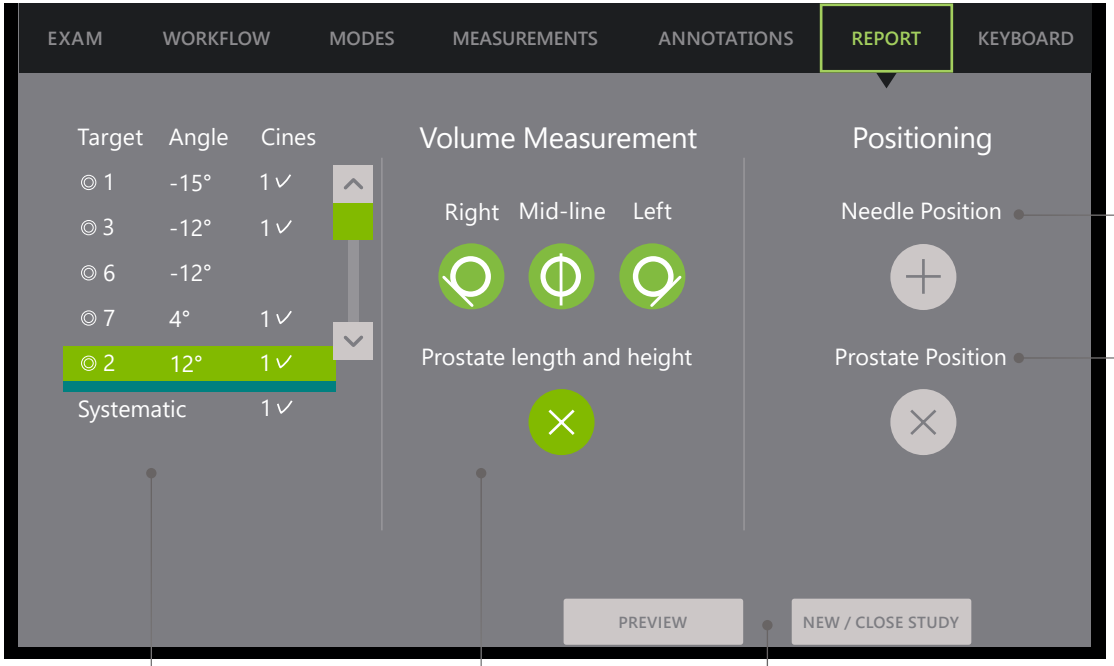




Select a thumbnail for Review.

Tap a target in the Target List to reassign it.

Optionally, complete Reporting when closing the ExactVu™ Study or when reviewing from the Patient List.

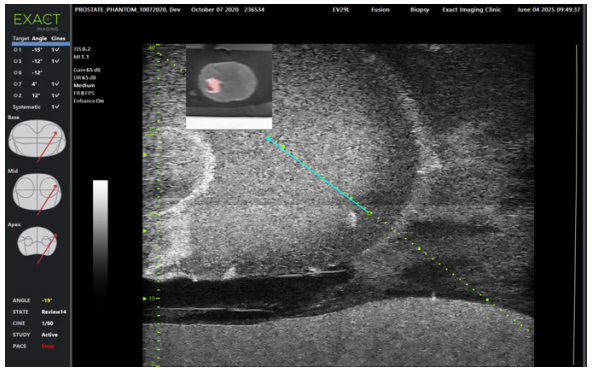


1 If needed, reassign cines to Targets

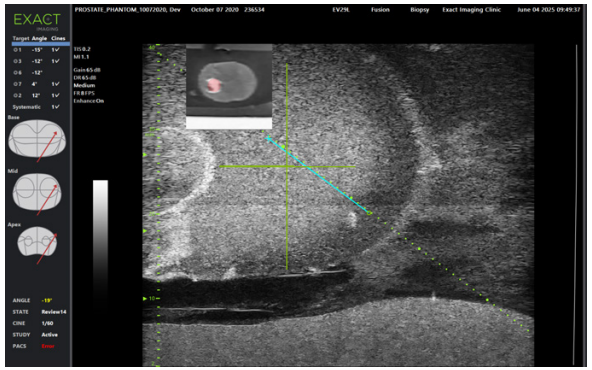
2 If not performed during the case:

- Mark the Mid-line and prostate edges
- Measure the prostate length and height

3 For each Biopsy cine, use **Needle Position** to trace the needle path.



4 Place crosshairs in the center of the prostate to mark the **Prostate Position**.

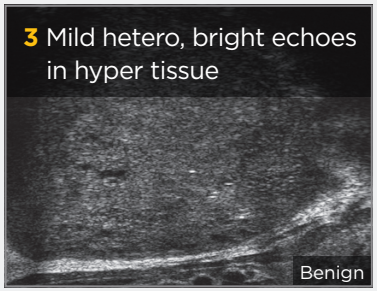
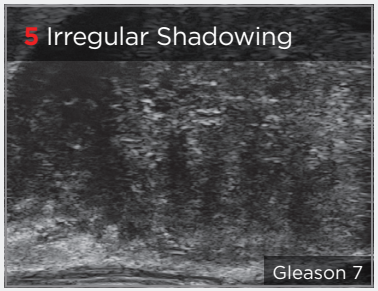
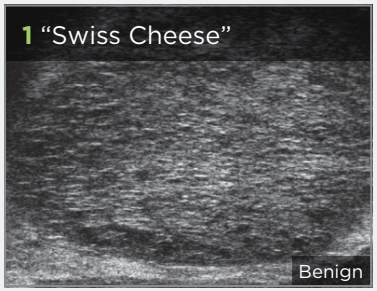
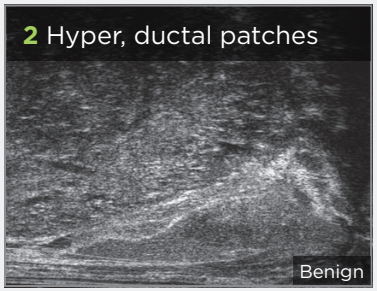
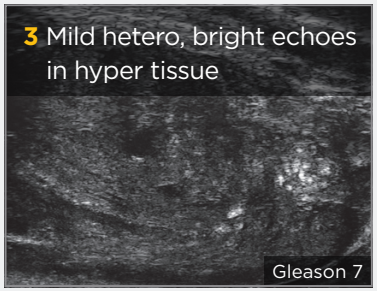
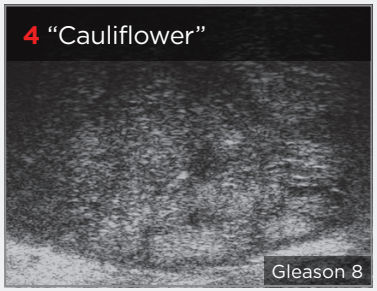
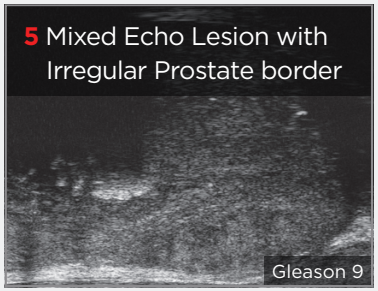
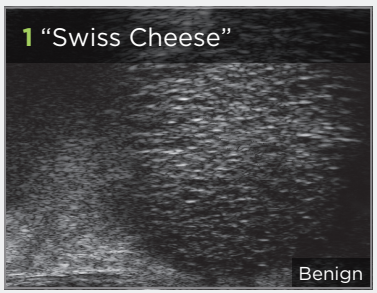
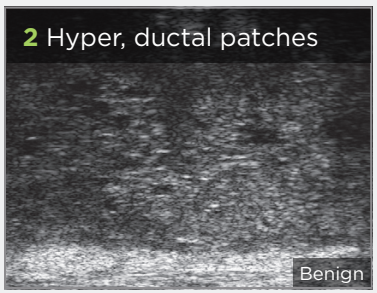
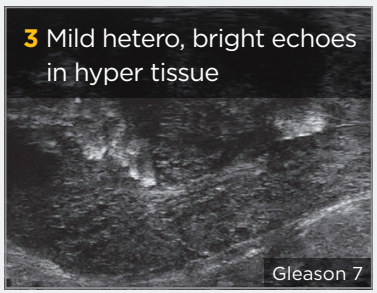
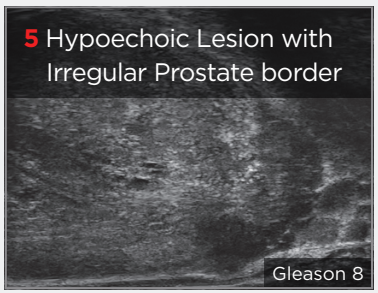
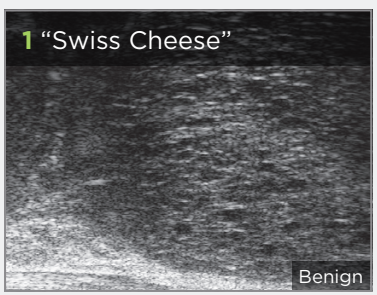
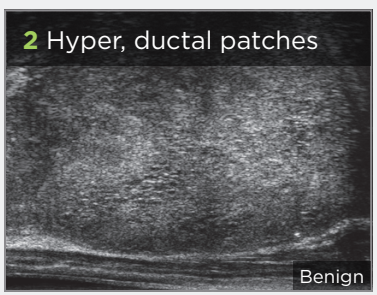
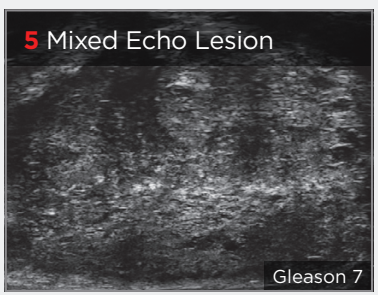


5 **Preview** the Report, or **Close** the Study to finalize it.

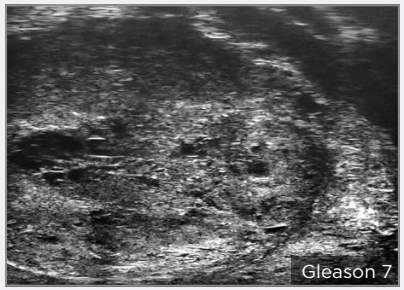
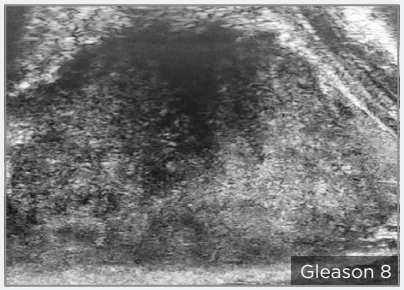
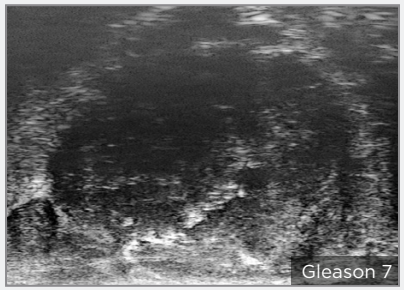
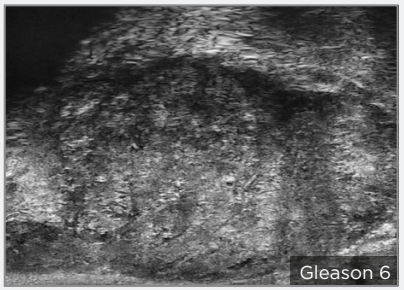
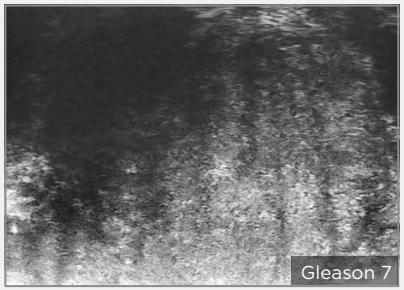
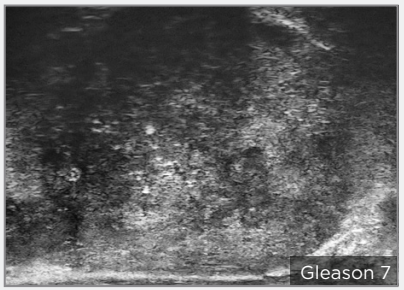
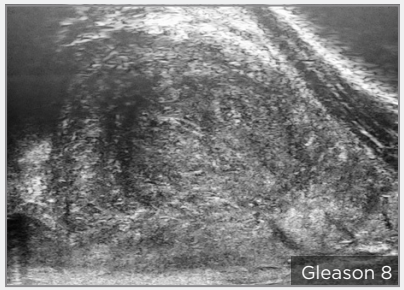
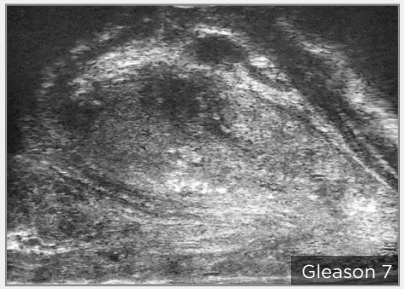
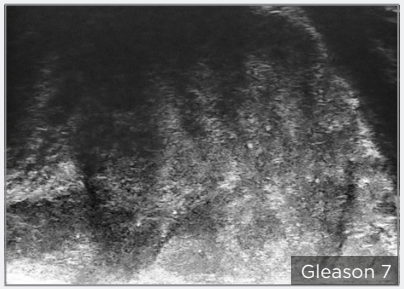
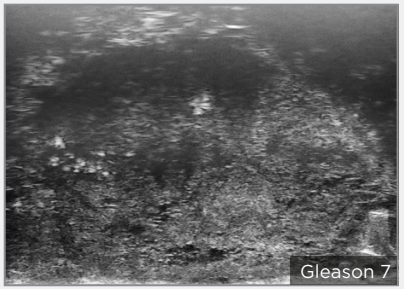
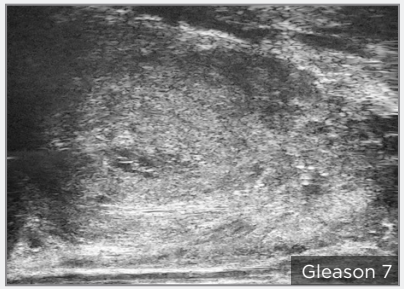
PRI-MUS™: Prostate risk identification using micro-ultrasound

REFERENCE: Ghai, S. et al., "Assessing Cancer Risk on Novel 29 MHz Micro-Ultrasound Images of the Prostate: Creation of the Micro-Ultrasound Protocol for Prostate Risk Identification", *Journal of Urology*, 2016 Aug;196(2):562-9

SYSTEMATIC BIOPSY | **TARGET SUSPICIOUS REGION**

PRI-MUS 1	PRI-MUS 2	PRI-MUS 3	PRI-MUS 4	PRI-MUS 5
				
				
				
				

HIGH-RISK FEATURES (NO PARTICULAR ORDER OF RISK)

Focal Anterior Lesions	Hypoechoic Finger-like Projections	Storm-cloud	Lesions Occupying the Anterior Horn and Lateral Anterior Prostate
 Gleason 7	 Gleason 8	 Gleason 7	 Gleason 7
 Gleason 7	 Gleason 7	 Gleason 6	 Gleason 8
 Gleason 7	 Gleason 7	 Gleason 7	 Gleason 8
 Gleason 7	 Gleason 7	 Gleason 7	 Gleason 7

Key Points for Anterior Prostate Imaging

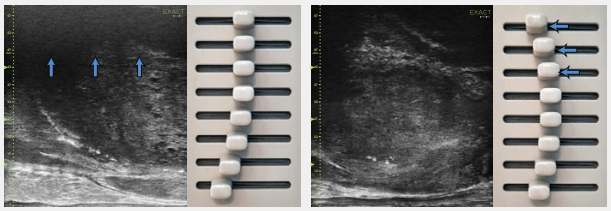
PRI-MUS Anterior - Pitfalls

Anterior Apex

Most common locations for AP cancer.

- Use the existing PRI-MUS chart to evaluate the anterior apical horn and lateral anterior PZ for suspicious features.
- Use the correct apical horn sampling technique to ensure good coverage of the anterior apex.
- Pay close attention to the capsular anterior mid gland and anterior apex during assessment. This is where most AP cancer occurs.

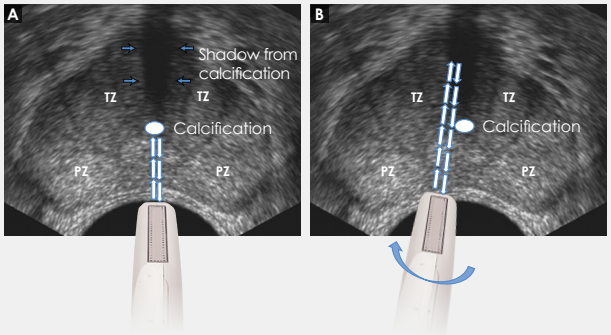
TGC Optimization



Adjustment of the top TGC sliders to minimize 'noise' in the far field.
A hazy, noisy far field can be rectified by 'bending' the top TGC sliders to the left.

- Use an appropriate depth setting for interrogating the AP and AP capsule. AP Cancer is just as likely a finding in a small gland as in a very large gland.
- Linear zone boundaries can be balanced with use of appropriate gain and TGC settings.
- Try 'bending' the top three TGC sliders to the left to reduce any far field noise in the image.

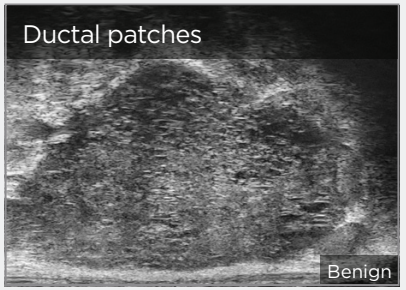
Handling Calcifications

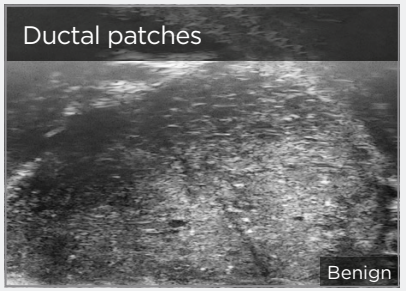


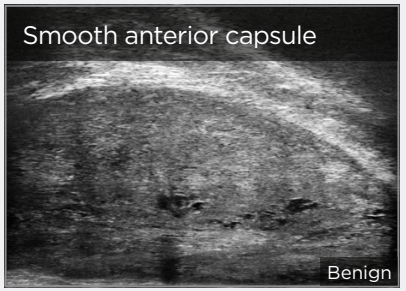
- Apply gentle probe pressure to dissipate subtle shadowing artifacts.
- Manipulate and angle the probe to overcome dense calcifications along the line of the urethra.

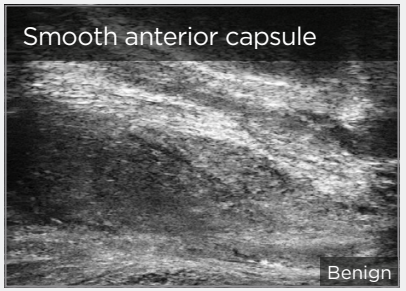
LOW-RISK FEATURES

Ductal Patches in Hyper or Hypoechoic Tissue









Pitfalls and Nodules