

5.6.2. PICC Electrocardiogram Localization


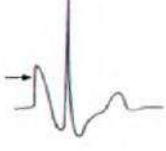



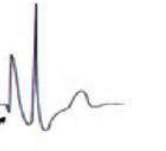


After confirming that the catheter has entered the superior vena cava correctly, you can use intracardiac ECG to locate the position of the catheter tip, ensuring that the catheter is in the most suitable position within the superior vena cava. This involves several aspects:

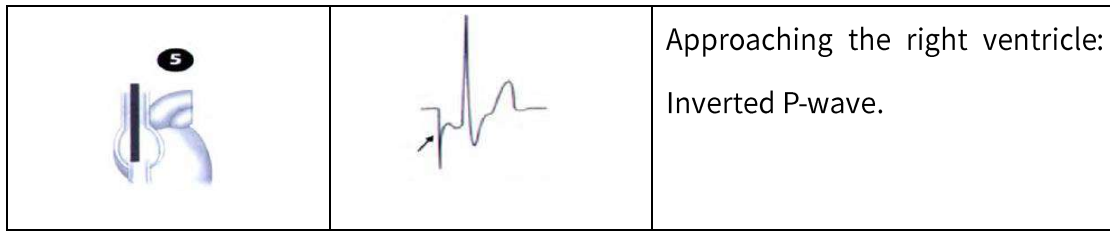
Real-time display of internal waveform.

A display area for stored waveforms, including waveform name, storage time, and catheter length record.

Observing P-Wave Changes:

As the catheter tip gradually advances, the P-wave of the intracardiac electrocardiogram will change accordingly. There are several stages of P-wave changes (Source: "Application of Specific P-Wave Morphology Changes in Intracardiac Electrocardiography in Valve-type PICC Tip Positioning," Chinese Nursing Journal, November 2015, Vol. 50, No. 11). The optimal position for the catheter tip should be at the junction of the superior vena cava and the right atrium. When observing a negative P-wave, gently withdraw the catheter outward by 1-2 cm.

Catheter Tip Position	P-Wave Change	Explanation
		After entering the superior vena cava: P-wave amplitude gradually increases.
		At the junction of the superior vena cava and the right atrium: High-amplitude positive P-wave.
		At the junction of the superior vena cava and the right atrium: High-amplitude positive P-wave.
		Mid-section of the right atrium: Biphasic P-wave.



Storing Waveforms

You can store waveforms during the electrocardiogram localization procedure for printing and output. The electrocardiogram localization interface supports two layout options for displaying stored waveforms: 3-window or 4+1-window, which can be switched by touching the storage window button on the touchscreen.

3-Window (default): In addition to the real-time display of surface and intracardiac waveforms, it displays three waveform channels for recording surface waveforms, internal bidirectional waveforms, and the best internal waveform. You can click the buttons on the touchscreen labeled "Surface," "Internal Bidirectional," and "Best Internal" to store the corresponding waveforms.

4+1-Window: In addition to the real-time display of internal waveforms, it also displays four waveform channels for recording internal waveforms 1/2/3/4. Click the touchscreen buttons labeled "Internal 1," "Internal 2," "Internal 3," and "Internal 4" to store the corresponding waveforms. To store a surface waveform, click the "Surface" storage button on the touchscreen, and the stored waveform will be displayed in the area where the surface waveform is real-time. To view the real-time surface waveform again, click the "Refresh Surface" button on the touchscreen to switch.

Recording Catheter Length

If you need to record the catheter's length, ensure that "Record Catheter Length" is selected in the system settings -> POC settings. Press the depth knob on the control panel to select the stored waveform in the main interface. Then, turn the depth knob to switch between "Catheter Inserted Length" or "External Scale." You can click the "External Scale" button on the touchscreen to switch between the two length recording modes.

Printing Reports

After storing waveforms, the system generates PICC electrocardiogram waveform reports. These reports can be previewed, printed, and exported in PDF format.

Other Settings

- Click the "Gain" button on the touchscreen to adjust the gain of the electrocardiogram waveform.
- Click the "Speed" button on the touchscreen to adjust the scanning speed of the electrocardiogram waveform.
- Click the "Mode" button on the touchscreen to switch the filtering mode.
- Click the "End Exam" button on the touchscreen to clear the patient information and stored waveform signals on the current interface. You can view historical data in the examination database.
- Set the layout of PICC electrocardiogram waveform reports: Enter the system settings -> POC settings and set the report layout to landscape or portrait.
- Set AC filtering: Enter the system settings -> POC settings and set AC filtering to 50Hz.

5.6.3. Viewing Historical Data

In the ultrasound system, you can browse historical data. Press the "Browse" button on the control panel to enter the examination database, select historical data, and click the "View PICC Waveforms" button on the touchscreen to view stored electrocardiogram waveform reports, print them, and export them.

5.7 eWorks

The eWorks automatic workflow feature provides workflow template protocols for each application site to efficiently screen and store exam sections. This function simplifies the operation and provides reference for image scanning and retrieval.

Each exam protocol contains a complete template section, and is set up with corresponding image mode, Comment and Body Mark, which is easy to operate more quickly.

To use eWorks function:

1. Connect the probe and select either Emergency or GI Clinical Preset.
2. Tap the eWorks icon on the screen to access the eWorks function.
3. The bottom left corner of the image area will display the workflow indicator box. eWorks includes FAST and Lung protocols, each containing FAST & eFAST schemes, and the BLUE scheme. Under the Lung protocol, you can also choose lung views of 3*2, 4*2, or 6*2.
4. Click the image save button to automatically move to the next view. The names of saved views will appear in blue in the indicator box with a completed icon.
5. Repeat step four until all views are acquired.
6. Click 'X' to close the indicator box, your data will be saved. Clicking the eWorks icon again allows you to continue collecting views.

6 Probes and Biopsy

6.1 Probe Cleaning and Disinfecting

Probes should be cleaned and/or disinfected as necessary or between use with a recommended cleanser or disinfectant. Disconnect the probe from the system prior to cleaning and disinfecting.

6.1.1. Cleaning

The validated cleaning agents for cleaning the probes are:

- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, sterile, non-abrasive cloth or paper towel.

To clean the probes:

1. Disconnect the probe from the system.
2. Wear sterile protective gloves to prevent infection.
3. Remove all residual foreign matters from the probe using sterile cloth or paper towel immediately after examination. For the situation where a protective sheath is used, the protective sheath should be removed first and discarded.
4. Wipe the surface of probe and cable with a sterile cloth dampened with the cleaning solution until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a new sterile cloth dampened with tap water until no visible cleaning agent remains.
6. Wipe off with a dry sterile cloth to remove residual moisture.
7. Leave the probe to air dry.
8. If the probe is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.

9. Inspect the probe to ensure that there is no damage. The probe should be disposed of properly when any damage is found.

WARNING

1. Disconnect the probe from the system prior to cleaning or disinfecting.
 2. To avoid infection, always use protective gloves when performing cleaning and disinfecting procedures.
 3. Prohibit infiltration of any type of liquid into the device or the probe.
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6.1.2. Disinfection

Selecting a proper way to disinfect your probes based on your probe applied region:

Probe Applied Region	Disinfecting Intensity	Disinfecting Method
Contact intact body surface	LLD	Spraying or wiping
Note:LLD=Low-level Disinfection		

The validated disinfectants for probe are:

Disinfectants	Disinfecting Intensity	Disinfecting Method
Ethanol (75%)	LLD	Spraying or wiping
Isopropanol (70%)	LLD	Spraying or wiping

WARNING

1. Disconnect the probe from the system prior to cleaning or disinfecting.
 2. To avoid infection, always use protective gloves when performing cleaning and disinfecting procedures.
 3. To avoid infection, ensure that expiration date of the disinfecting solution has not passed.
 4. Please clean the probe prior to disinfection.
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Disinfecting by spraying or wiping:

1. Disconnect the probe from the system.
2. Wear protective gloves to prevent infection.
3. Clean and dry the probe according to the methods in section 6.3.1 *Cleaning*.
4. Prepare the disinfectant solution (75% ethanol or 70% isopropanol).
5. Spray the solution to the probe interface or wipe it with a sterile cloth dampened with the disinfectant solution. Follow the disinfectant manufacturer's recommended contact time and mode.
6. Rinse the probe according to the disinfectant instructions. Wipe the probe with a dry sterile cloth or leave the probe to air dry.
7. Inspect the probe to ensure that there is no damage.

Note: If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new sterile cloth is required for the disinfection step.

WARNING

1. Do not immerse the probe connector. If the cable connector is immersed, do not plug the connector into the portable device. Rinse the connector under running water and dry it thoroughly. If necessary, contact EDAN for service.
 2. Prohibit infiltration of any type of liquid into the device or the probe.
 3. Do not immerse the cable and connector of the probe into solutions. Probes can be submerged to, but not including, the strain relief of the probe array. Do not immerse or soak any part of a probe in any cleaning material not listed in the recommended list of disinfectant.
 4. Only non-immersion method can be used with solution of ethanol or isopropanol.
 5. The immersion time should not exceed the time that is specified by the disinfectant manufacturer.
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6.1.3. Storage

WARNING

1. Do not use the carrying case for storing the probe, because the carrying case may become a source of infection.

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1. Ensure the probe is cleaned, disinfected, sterilized and completely dried before storage.
 2. Store the probe in a sterile environment or in a disposable sterile package.
 3. Store the probe under the following conditions:
 - a) Atmospheric Temp.: -20°C~+45°C
 - b) Relative Humidity: 15%~95% (Non-condensing)
 - c) Atmospheric Pressure: 62kPa ~ 106kPa.

6.2 Needle Biopsy Guide

NOTE:

Use proper sterile technique at all times when performing a biopsy.

Always follow these basic precautions:

WARNING

1. Sterilize the needle guide kit before the first use and after each subsequent use.
2. When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. Manage the ultrasound gel properly to ensure that it does not become a source of infection.
3. Calibrate the needle guide kit (see section 6.4.3) under any of the following conditions:
 - a) The first time that each bracket/probe combination is used.
 - b) If the bracket or probe head is dropped or struck, or has evidence of wear.
 - c) If previous use has shown some drift of the needle from the center of the guidelines.
4. The displayed needle guide pathway on the display monitor is intended for reference during biopsy procedures. A variety of factors outside EDAN's control, such as changing tissue

density, bending of the needle, off-axis pressure by the person holding the probe, etc., may cause deflection of a needle outside of the displayed video pathway even when the probe, needle guide, and the system software are all performing as intended and within manufacturing specification. The specialist performing a biopsy procedure must be aware of potential external factors when performing an invasive procedure.

5. Do not freeze the system when performing a biopsy.
 6. EDAN needle guides are designed and manufactured to attach firmly to designated probes and should not require excessive force to assemble or disassemble. Do not use a needle guide that requires excessive force or manipulation to assemble or disassemble.
 7. A single-use sheath should be used on probe when performing a biopsy.
 8. Use the needle guide kit that meets the standard sterile technique requirement.
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6.2.1. Installing Needle Guide Bracket

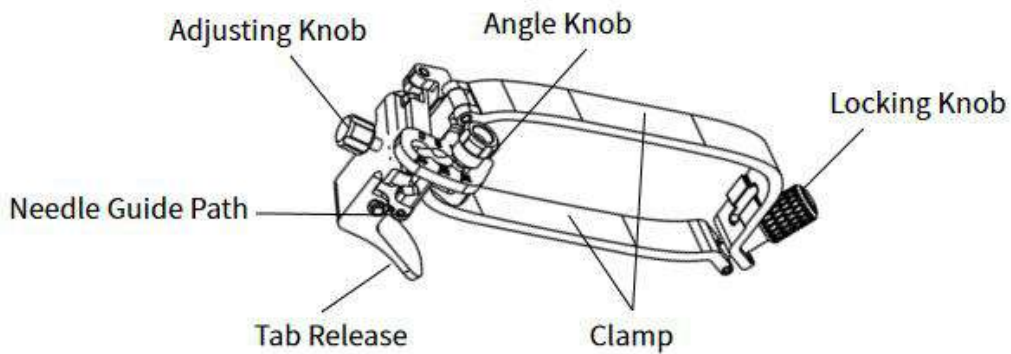
WARNING

1. For illustration purpose only, probe and bracket may be shown without a protective sheath. Always place a protective sheath on probe and bracket to protect cross infection.

■ BGK-017

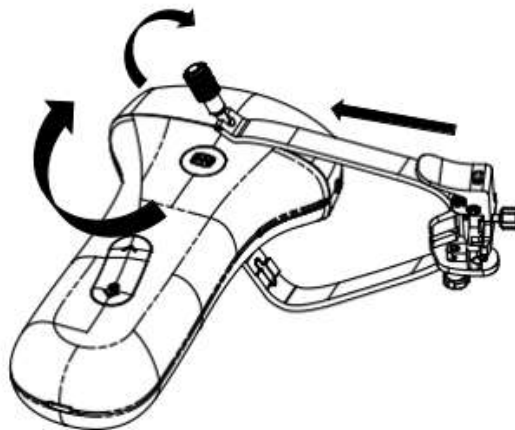
The installation steps for these brackets are the same. Here we take one bracket for illustration.

Structures:

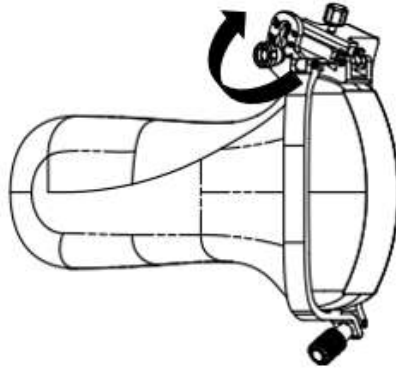


Installation and Use Steps:

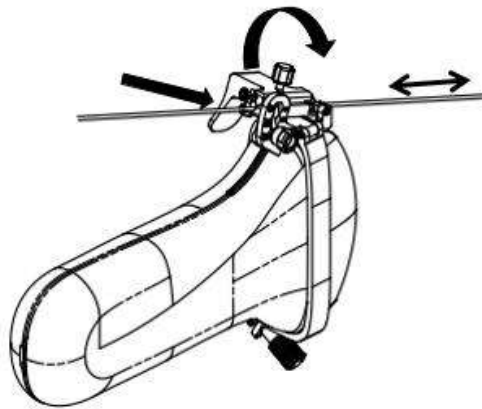
1. Place an appropriate amount of gel on probe surface, and insert probe into the sheath.
2. Loosen the locking knob to open the clamp of bracket. Attach the bracket to the probe by aligning the locating markers on the bracket and the probe. Properly secure the clamp of bracket with the locking knob. Ensure the bracket is firmly attached.



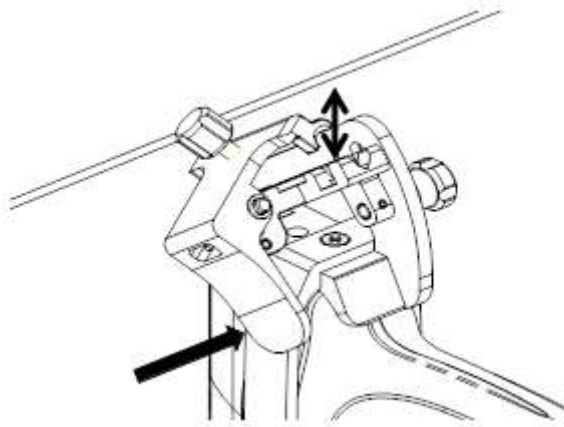
3. Loosen the angle knob to select a needle guide angle, and secure the angle knob.



4. Press the tab release and place the biopsy needle into the needle guide path. Use the adjusting knob to properly secure the needle.





5. After biopsy, press the tab release to remove the needle, and loosen the locking knob to remove the bracket from the probe.



6.2.2. Activating Needle Guide Function

To enable the needle guide function:

1. In the B mode imaging, press **Needle Guide** icon  on touch screen to activate the Needle Guide function.
2. Press **Double Line** button to switch double line and single line as the Needle guide Line graphics.
3. Some needle guide brackets support multiple angles. If the current probe supports such a guide then the **Line** key appears. Pressing it selects guide lines of different angles. Each line represents a corresponding angle marked on the needle guide bracket.
4. If you wish to edit the guide line again, long press the icon  and activate editing.

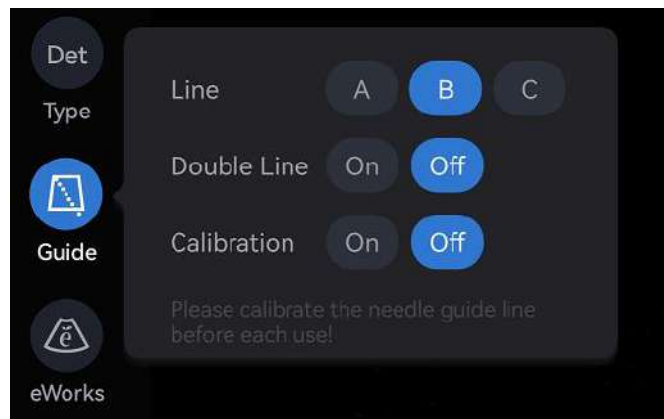


Figure 6-4 Needle Guide Touch Screen

WARNING

1. To avoid patient injury when using a multi-angle bracket, make sure that the same angle (A, B or C) is selected on both the bracket and the ultrasound system.

NOTE:

The distance between each dot of the needle guide line indicates 0.5 cm.

6.2.3. To Adjust the Needle Guide Line

WARNING

1. Calibrate the needle guide under any of the following conditions:
 - a) The first time a needle guide is used with a given probe.
 - b) Any time the needle guide or probe has been dropped or struck against a hard surface.
 - c) After repeated use.
2. Do not use the needle guide bracket if the needle does not track with the guide during calibration.

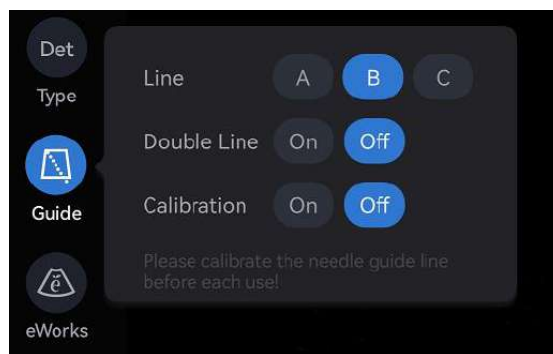



Figure 6-5 Needle Guide Calibration Touch Screen

To calibrate the guide line

1. Assemble the needle guide bracket on the probe, and use the probe to image a water bath or needle guide phantom.
2. Press the **Line** key to select a guide line.
3. Press the **Calibration** button on the touch screen to display the **Angle** and **Position** paddle button.
 - Tap the blue point of the guide line to adjust the line horizontally until the origin aligns with the actual needle.
 - Tap the body of the guide line to adjust the angle of the line until the entire line aligns with the actual needle.
4. Any changes will be saved as the default value automatically.

5. If you wish to edit the guide line again, long press the icon  and activate editing.

6.3 Center Line

The Center Line is a vertical dotted line displayed at the middle of the image field, representing the middle of ultrasound beam. The Center Line helps to locate the position and depth of a target disease focus for out-of-plane biopsy, lithotripsy and etc..

To use Center Line:

1. In the image settings interface, you can enable the display of the Center Line, which will be shown on the B-mode image. See section 11.2 for details on how to configure these.
2. A dotted center line is displayed vertically at the middle of the image field. The position and direction of the center line cannot be changed.
3. Move the probe to locate the target.
4. Use distance measurement to obtain the depth of the target.

6.4 Needle Guide Bracket Cleaning and Sterilization

NOTE:

1. Use proper sterilization technique at all times when performing a biopsy.
2. Ensure that protective gloves are worn.

WARNING

1. The needle guide bracket kits are not disinfected or sterilized before delivery. The operator should sterilize the needle guide kit before the first use and after each subsequent use.
 2. Inspect the bracket for damage such as cracks or breakage. If damage is evident, discontinue use of bracket and contact your Edan representative for disposal guidance.
 3. Sterilize the bracket before disposal or sending back to manufacturer for repair.
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6.4.1. Cleaning

1. Wear sterile protective gloves to prevent infection.
2. Disconnect the needle guide bracket from the probe after each use, and remove all visible residues from the needle guide bracket using a small and soft-bristled brush or other similar devices. Do the cleaning quickly before the needle guide bracket dries out.
3. Soak the needle guide bracket in the cleaning solution (Ethanol 75% or Isopropanol 70%) for at least five minutes. Use a soft-bristled brush to clean the needle guide bracket during the soaking.
4. Take out the needle guide bracket from the cleanser and wipe all residues with a sterile cloth.
5. Let the bracket air dry, or dry the bracket with a sterile cloth.
6. If the bracket is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 3 to step 5.
7. Inspect the bracket to ensure that there is no damage. The bracket should be disposed of properly when any damage is found.

6.4.2. Sterilization

1. Wear sterile protective gloves to prevent infection.
2. Disconnect the bracket from the probe, and remove all visible residues from the bracket using sterile cloth.
3. Clean and dry the bracket according to the methods in section 6.7.1 *Cleaning*.
4. Sterilize the bracket assembly by dynamic air removal steam sterilizer for at least four minutes at 132°C. Dry the bracket for at least 30 min after sterilization.
5. Inspect the bracket to ensure that there is no damage.

6.4.3. Storage

WARNING

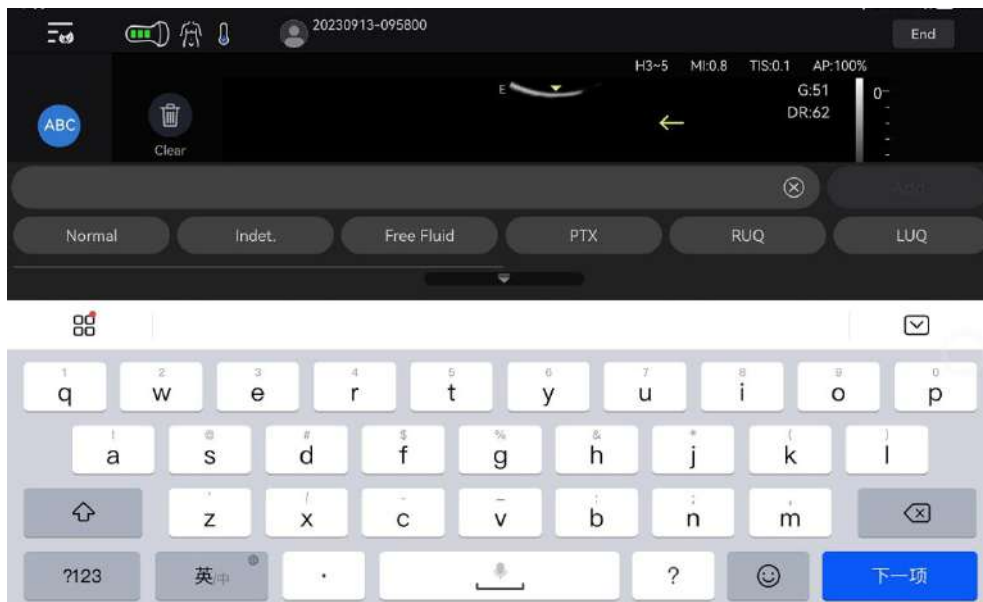
1. Dry the bracket after sterilization and store it in sterile environment.
 2. Do not use the carrying case for storing the bracket, because the carrying case may become a source of infection.
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1. Ensure the bracket is cleaned, sterilized and completely dried before storage.
 2. Store the bracket in a sterile environment or in a disposable sterile package.
 3. Store the bracket under the following conditions:
 - a) Atmospheric Temp.: -25°C~+45°C
 - b) Relative Humidity: 15%~95% (Non-condensing)
 - c) Atmospheric Pressure: 62kPa ~ 106kPa.

7 Features


7.1 Annotations

7.1.1. Comments

Nano allows users to add clinical comments to ultrasound images to record their observations, interpretations, or findings during a patient's examination. These comments can be useful for reference and communication with colleagues.



Adding Comments:

1. Freeze the image when you want to add annotations.
2. Click the Annotation button  and select Comment.
3. The system will display a keyboard, allowing you to type your comment. Above the keyboard are preset comments provided by the system. By tapping on ↓ you can expand to view all comments. Click on the comment you want to add, and it will automatically populate the input field.
4. Click Add to confirm the Comment.


Deleting Comments:

Click on the Comment you want to delete, then press the Delete button to remove it.

7.1.2. Body Mark

Body Mark allows you add a body mark graph into an image and indicate the location of the probe using a probe icon on that graphic.

Adding Body Marks:


1. Freeze the image when you want to add body marks.
2. Click the Annotation button  and select Body Mark.
3. At the bottom of the screen, preset body marks will be provided based on your current clinical application. Swipe left to view more body marks.
4. Click on the body mark you want to add, and it will automatically appear in the bottom left corner of the image.
5. The ! mark indicates the probe's position, and the dot represents the direction indicator. You can control the position of the ! mark by tapping the circle where the ! mark appears and dragging it to the desired probe location.
Click on the dot, and by following the dotted circle path with your finger, you can adjust the orientation of the probe direction indicator.

Deleting Body Marks:

Click on the Body Mark you want to delete, then press the Delete button to remove it.

7.1.3. Arrow

Adding Arrows:

1. Freeze the image when you want to add arrows.
2. Click the Annotation button  and tap the arrow button to add an arrow.
3. You can control the arrow by clicking in the center area and dragging it to your desired location.
To adjust the arrow's direction, place a single finger in the gray circle area at the front of the arrow, and rotate your finger to control the arrow's orientation.
4. Click the arrow again to complete the operation.
5. If you wish to edit the arrow again, tap the arrow you want to edit to activate editing.

Deleting Arrows:

Click on the arrow you want to delete, then press the Delete button to remove it.

7.2 Zoom

The system supports two types of zoom: Spot Zoom and Full Screen Zoom.

7.2.1. Spot Zoom


Spot Zoom focuses on processing the image of the selected area and enlarges the image with higher resolution. In the image area, use two fingers to pinch and zoom in on the desired area to zoom in or out.

Note:

1. In Spot Zoom mode, the thumbnail image is not updated. It is the last image before Spot Zoom mode was activated.
2. In Color mode, the Spot Zoom mode is activated when you first press the Zoom knob, and the position of the zoom box is the same as the Color ROI box, but 10% bigger in size. When the box size or box position is changed, the Color box and zoom box are adjusted so that above relation remains constant.

7.2.2. Full Screen Zoom

Full screen zoom function can zoom in the image to full screen display. In the image area, click

the magnifying glass icon  in the lower right corner to go full screen.

8 eVocal

The eVocal function enables the user to operate the system by inputting voice commands through a microphone device.

To use eVocal Function:

1. Connect the microphone device to the microphone port on the back of the device.
2. To activate voice control, enter the settings interface, then click the eVocal button and select to enable voice control. A microphone icon will appear in the upper right corner of the main screen, indicating that the eVocal feature is activated.
3. Speak to the microphone to input a voice command. After the system recognizes the voice command, it will automatically perform the corresponding operations. The microphone icon displays the voice volume in real time when you input voice commands.

The default voice commands supported by the system are listed in the table below. You can view them on the main screen by clicking the microphone icon or inputting "Help" voice commands.

Command (English)	Function
B mode	Back to B mode
Color mode	Enter/Exit Color mode
PW mode	Enter/Exit Pre-PW mode
M mode	Enter/Exit Pre-M mode
Update	Update PW mode
Gain increase	Gain increase by 1 step
Gain decrease	Gain decrease by 1 step
Depth increase	Depth increase by 1 step
Depth decrease	Depth decrease by 1 step
Freeze	Freeze the system
Unfreeze	Unfreeze the system

Store image	Store Image
Store Clip	Store Clip

Note: The system only supports Chinese and English command in this version.

9 Measurements

The Measurement function lets you perform measurements on a live or frozen image.

9.1 Generic Measurements

Each imaging mode supports different types of generic measurements. This chapter describes all the generic measurements supported in each imaging mode.

9.1.1. B-mode Generic Measurements

9.1.1.1. Distance

The distance measurement measures the distance between two points.

1. Freeze the image and click the measurement function button.
2. Select Distance Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.2. Circumference/Area

Circumference/Area measurement can measure the circumference and area of a closed region.

1. Freeze the image and click the measurement function button.
2. Select Area Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing. Select any point on the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the area measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.3.Angle

The Angle measurement is always done with an angle tool. To measure Angle:

1. Freeze the image and click the measurement function button.
2. Select Angle Measurement; a virtual caliper will appear in the image area, consisting of two intersecting lines.
3. Click on the caliper to activate measurement line editing. Select any point on the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to complete the angle measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.4.Volume

Volume can be measured with 3 Distances or Ellipse1 distance method.

1. Freeze the image and click the measurement function button.
2. Select Volume Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing.
4. Select any point on the ruler, then drag to adjust the desired measurement range.
5. Click anywhere else in the image area to complete the first set of distance measurements. The system will automatically display the next active endpoint.
6. Repeat steps 5-6 to complete the second and third sets of distance measurements. The measurement results will display in the upper left corner of the image area.
7. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2. M-mode Generic Measurements

9.1.2.1. Distance

The distance measurement measures the distance between two points.

1. Freeze the image and click the measurement function button.
2. Select Distance Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.2. Slope

The Slope measurement measures the distance and time between two points, and calculates the slope. To measure Slope:

1. Freeze the image and click the measurement function button.
2. Select Slope Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.3. Time

The Time measurement measures the time interval between two points. To measure Time:

1. Freeze the image and click the measurement function button.
2. Select Time Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.4.HR

The HR measurement measures the time interval between two points, and calculates the heart rate. To measure HR:

1. Freeze the image and click the measurement function button.
2. Select HR Measurement; a virtual caliper will appear in the image area.
3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.
5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.3. PW-mode Generic Measurements

9.1.3.1.Velocity

Multiple types of velocity measurements are supported on Doppler Strip, for example velocity at any point, at PS or ED.

PS/ED: measures the velocity at PS and ED points.

1. Freeze the image and click the measurement function button.
2. Select **PS** , **ED** or **PS/ED** Measurement; a virtual caliper will appear in the image area.
3. Move the caliper to the PS or ED point on the strip.
4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.3.2.Auto Trace

The Auto Trace measurement can provide a wide range of results, as shown below.

- PS
- ED
- MD
- TAMax
- PGmax
- PGmean
- PI
- RI
- S/D
- VTI
- Time
- AT
- DT
- HR

Trace measurement is only available on a frozen strip.

Auto Trace Method:

1. Freeze the image and click the measurement function button.
2. Select Auto Trace Measurement
3. The trace waveform(s) automatically appear, and measurement result displays.

NOTE:

1. Auto trace measurement can only be activated on a frozen Doppler strip.
2. Live Auto Trace is available as a separate feature on the Doppler touch screen. To activate Auto Trace in real time mode, press **Auto Trace** button on PW touch screen.

9.1.3.3. Time

The steps of time measurement are the same as those of time measurement in M mode. Please refer to *section 9.1.2.3* for details.

9.1.3.4. HR

The steps of HR measurement are the same as those of HR measurement in M mode. Please refer to *section 9.1.2.4* for details.

9.2 Application Measurements

Application Measurements have a pre-defined meaning and can be entered into a report. The system supports the following application measurement packages, each with its own set of measurements, calculations and report:

- ABD
- OB
- GYN
- Cardiac
- Vascular
- PICC

When you select an application measurement from the touchscreen it will automatically invoke the type of measurement it needs. For example, if you select ‘BPD’ from the OB application it will automatically invoke a distance measurement. These measurements generally behave as described above for generic measurements.

Some application measurements can have multiple variations. For example, in a twin OB exam the OB measurements can be done on either fetus. As another example, in Vascular exams several measurements can be done in a Proximal, Mid, or Distal location. When a measurement has multiple variations you will see keys on the touchscreen that let you pick which variation you are measuring.

9.2.1. Abdomen Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	Pre-BL L	Pre-void Bladder Length	Distance in B-mode generic measurements
1.2	Pre-BL W	Pre-void Bladder Width	
1.3	Pre-BL H	Pre-void Bladder Height	
1.4	Post-BL L	Post-void Bladder Length	
1.5	Post-BL W	Post-void Bladder Width	
1.6	Post-BL H	Post-void Bladder Height	

9.2.1.1. Auto-B Line

Auto B-Line measurement can assist the orthopedic clinician to quickly complete the corresponding vital sign measurement and automatically complete the relevant measurement in the severe clinical environment where the patient's condition is complex and the vital signs are unstable.

NOTE:

1. Auto B-Line is optional and requires a license to activate it.
2. When the number of B lines is more than or equal to five, the system does not display the number of B lines.

WARNING

1. The lung image for Auto B-Line measurement should be standard section, otherwise the measurement accuracy may be affected. When no valid lung image is recognized, the system will prompt you with "No valid measurement results."
2. Auto B-Line measurement is only available on a real-time image.
3. The measurement result of Auto B-Line is for reference only. The measurement accuracy can be affected by image quality, fetal image section, the position of ROI box, etc. Always confirm the detection of NT structure by visual inspection before storing the results in the worksheet and report. If the result is in doubt, manual or other effective methods should be applied to verify the correctness.

To use Auto B-Line measurement:

1. Connect the probe and select either Lung exam preset.
2. Scan lung images, then click the Auto B-Line icon to access the Auto B-Line function.
3. Automatic measurement will begin. The system will automatically scan lung images and calculate the number and spacing of B-Lines in the lung. Measurement results will automatically display on the main screen.

Evaluation criteria:

Scoring criteria and expression	
(0) N	Displays a lung sliding sign and A line, or isolated B lines (<3)
(1) B1	Displays multiple clearly-distributed B lines
(2) B2	Displays intensively fused B lines
(3) C	Displays the image similar to the liver lesion structure and air bronchogram
(3) C/P	The lung consolidation and pleural effusion occur at the same time

9.2.2. Obstetrics Measurements

Obstetric measurements are used to calculate the GA (Gestation Age), EDD (Estimated Delivery Date) and EFW (Estimated Fetus Weight).

The Obstetric package supports measurements on up to four fetuses. If you know the number of fetuses at the start of the exam then you can enter this in the Patient page (see section 4.4). When the number of fetuses is known, the system adjusts the user interface to optimize for that number. If no information is entered about the number of fetuses, the system will assume there is one.

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.7	BPD	Biparietal Diameter	B-mode generic

No.	Measurement Item	Description	Method
1.8	HC	Head Circumference	measurements
1.9	AC	Abdominal Circumference	
1.10	FL	Femur Length	
1.11	CRL	Crown Rump Length	
1.12	GS	Gestational Sac	
1.13	Q1	Amniotic Fluid Index	
1.14	Q2		
1.15	Q3		
1.16	Q3		
Section 1: PW-mode Measurement			
2.1	Umb. A	Umbilical Artery	Doppler generic measurement

* The measurement method including 1 Distance, 2 Distances and 3 Distances can be switched by the Tool Options key.

9.2.3. Cardiac Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	LA	Left atrial diameter	B-mode generic measurements
1.2	Ao	Aortic root diameter	
1.3	IVCmax	Abdominal Circumference	
1.4	IVCmin	Femur Length	
Section 2: M-mode Measurements			
2.1	IVSTd	Interventricular Septal Thickness at End-diastole	M-mode generic measurements
2.2	LVIDd	Left Ventricular Internal Diameter at End-diastole	
2.3	LVPWd	Left Ventricular Posterior Wall Thickness at End-diastole	
2.4	IVSTs	Interventricular Septal Thickness at End-systole	
2.5	LVIDs	Left Ventricular Internal Diameter at End-systole	
2.6	LVPWs	Left Ventricular Posterior Wall Thickness at End-systole	
2.7	LA	Left atrial diameter	
2.8	Ao	Aortic root diameter	
2.9	IVCmax		
2.10	IVCmin		

No.	Measurement Item	Description	Method
2.11	E-F Slope	Mitral Valve E-F slope	
Section 2: PW-mode Measurements			
3.1	E Vel		Doppler generic measurements
3.2	A Vel		
3.3	E Dur		
3.4	A Dur		
3.5	AccT		
3.6	DecT		
3.7	PHT		

9.2.4. Vascular Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	Auto Diam	Left atrial diameter	B-mode generic measurements
1.2	eSten%	Aortic root diameter	
1.3	IMT Far	Abdominal Circumference	
1.4	IMT Near	Femur Length	

9.2.4.1. Auto Diam

1. Connect the probe and set the clinical application to Renal or PICC.
2. In B-Mode, scan vascular images, then click the freeze button.
3. Click the measurement icon, select Auto Diam. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
4. Click elsewhere in the image area to fix the endpoint.
5. The system will automatically recognize and trace the area to be measured. The measurement

result will display in the upper right corner of the image area.

9.2.4.2.eSten%

1. In B-Mode, scan vascular images, then click the freeze button.
2. Click the measurement icon, select eSten%. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
3. Click elsewhere in the image area to fix the endpoint.
4. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.3.IMT Far

1. Connect the probe and set the clinical application to Renal.
2. In B-Mode, scan vascular images, then click the freeze button.
3. Click the measurement icon, select IMT Far.
4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
5. Click elsewhere in the image area to fix the endpoint.
6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.4.IMT Near

1. Connect the probe and set the clinical application to Renal.
2. In B-Mode, scan vascular images, then click the freeze button.
3. Click the measurement icon, select IMT Near.
4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
5. Click elsewhere in the image area to fix the endpoint.
6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.5.Live VF

1. Connect the probe and set the clinical application to Renal.
2. In PW-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select Live VF.
4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
5. Click elsewhere in the image area to fix the endpoint.
6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.6.eVol.Flow

1. Connect the probe and set the clinical application to Renal.
2. In PW-Mode, scan vascular images, then click the freeze button.
3. Click the measurement icon, select eVol.Flow.
4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
5. Click elsewhere in the image area to fix the endpoint.
6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

NOTE:

1. All these automatic measurements above are optional and require a license to activate them.

9.2.5. PICC Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.5	Auto Diam	Left atrial diameter	/

9.2.5.1.Auto Diam

1. Connect the probe and set the clinical application to Renal or PICC.
2. In B-Mode, scan vascular images, then click the freeze button.
3. Click the measurement icon, select Auto Diam. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.
4. Click elsewhere in the image area to fix the endpoint.

5. The system will automatically recognize and trace the area to be measured. The measurement result will display in the upper right corner of the image area.

9.3 Measurement Accuracy

Table 1 Measurement accuracy

Parameter	Range	Accuracy
1. B Mode Measurement		
Distance	Full Screen	< $\pm 5\%$
Circumference (Ellipse)	Full Screen	< $\pm 5\%$
Area (Ellipse)	Full Screen	< $\pm 8\%$
Angle	Full Screen	< $\pm 3\%$
2. M Mode Measurement		
Distance	Full Screen	< $\pm 5\%$
Time	Timeline display	< $\pm 3\%$
HR	Timeline display	< $\pm 5\%$
3. Doppler Mode Measurement		
Velocity(PW mode)	10-200cm/s	When angle $\leq 60^\circ$, < $\pm 10\%$
Time	Timeline display	< $\pm 3\%$
HR	Timeline display	< $\pm 3\%$

Table 2 Accuracy of Auto measurements

Auto Measurements	Error
Auto B-Line	$\leq \pm 15\%$

Live VF	$\leq \pm 10\%$
eVol Flow	$\leq \pm 15\%$
Auto Diam	$\leq \pm 10\%$
eStenos%	$\leq \pm 10\%$
Auto IMT	$\leq \pm 10\%$

Note: The performance specification listed above was verified on the Elasticity QA phantom, and the accuracy of strain ratio measurement were verified within the range mentioned above on the Elasticity QA phantom.

10 Exam Data Management

10.1 Storing Images

The system supports storing static images and cine clips. What is displayed in Information area, Image area and Image parameter area on the main screen will be stored.

Nano has two store keys, as shown below:

No.	Key	Name	Function
1		Store Image	Stores static images.
2		Store Clip	Stores cine clips.

Storing an image:

Pressing a Store key will always capture what is on the image area of the screen. This includes live, frozen, or Cine images. It also includes reports or other GUI screens and review.

Storing a clip:

Pressing a Store key will capture the moving images in scanning or cine review status. If the image is frozen or a non-image screen is displayed then a static image is stored.

The store starts with the press of a Store key and continues for the configured length of the clip or until the clip store is interrupted. The length of the clip can be configured on the **Store** page (See section 10.1.3 for details).

The following events can cause the clip store to stop:

- A second press of the store key
- Display of a GUI screen or dialog
- Mode change
- Image parameters change

- Cine play pause

NOTE:

1. If the image is frozen or a non-image screen is displayed, a static image is always stored when pressing a store key.
2. In panorama mode, a static image is always stored when pressing a store key.

10.2 Reviewing Images

If Static or Clip images have been stored for the current exam then they can be reviewed by pressing the <Review> key .

NOTE: If nothing has been stored in the current exam then the <Review>key will invoke the Patient Database function .

10.3 Exam Database

The Exam Database provides a list of recently performed studies. It can be accessed by pressing the <Review> key when there is no active exam.

The main part of the display shows a list of studies. Clicking on the header of a field will sort the list by that field. Fields can be displayed or hidden. If Password Protection is enabled, admin can view and operate all the studies, operators can only view and operate the studies they created.

Filter: The database filter field at the top-left of the screen provides a powerful tool to find the study of interest. It filters the list based on whatever text is typed in this field. The filter applies to all fields. For example, typing ‘ Ab’ ’ into the filter will show exams that either have that text in either the patient name or in the Exam preset. By default the filter is set to blank, so the default list shows all exams.

Storage Area: There is a database storage area field at the top-right of the screen. User can select to review the studies in local or USB storage, and also can send the studies from local to USB or from USB to local. Select the required studies and click Send to complete. When sending the studies from USB to local, only images in DCOM format can be sent.

Storage Size: There is a box displaying current disk usage. It contains text with the current usage and is filled with a solid color to the extent that the current capacity is used. The text shows

‘ <current usage> of <total capacity> ’ . The units are ‘ Mb ’ for values less than 1 Gb, and ‘ Gb ’ for anything larger. The solid color fill is green when usage is less than 75% of capacity, yellow for usage between 75% and 95%, and red when disk usage is above 95%.

Destination: The location where the highlighted exam(s) shall be exported, including:

- Available DICOM server location(s).
- Available FTP server location(s).
- Any inserted USB disk or DVD drive.

Export Format: This location displays export format for static images and clips. BMP, JPEG, TIF and DICOM formats are available for static images. AVI, WMV and DICOM formats are available for clips.

Send/Burn: Pressing this will send/burn the highlighted exam(s) to the destination. This button is available when one or more exams are selected.

➤ **Working with one study:**

A study is selected by clicking on it. When a study is selected thumbnail images from that study are shown on the right side of the screen. Operations such as editing report, reviewing, deleting and restarting of the selected study can be accessed on the touch screen.

A study can also be send to a network server, saved to a USB device or DVD drive, or deleted. If the study has been copied to either a server or to a USB device or DVD drive a small disk icon appears next to it, indicating that it has been saved.

CAUTION:

- Studies stored on the system hard drive should be archived regularly. The system is not intended for long term storage of patient information. Confirm successful archiving before deleting a study from the hard drive.

➤ **Working with multiple studies:**

Multiple studies can be selected by clicking the small box at the left of each listed study. Multiple studies can be stored to a network server, saved to a USB device or DVD drive, or deleted. Only one study can be reviewed at a time.