

8 Performing Medical Procedures

The Terason uSmart3200T Ultrasound System can aid in performing medical procedures such as biopsies. Depending on whether you purchased the additional equipment required for these procedures, you may have to understand:

- [Performing a Biopsy](#); see page 120
- [Verifying the Alignment](#); see page 125
- [Calibrating Needle Guide Positioning for Biopsies](#); see page 126
- [Cleaning the Probes and Brackets](#); see page 128

Equipment Description

To perform a biopsy, you need a probe, needle, needle guide kit, and bracket. The biopsy feature can be used with the following probes:

- 5C2A
- 12L5A
- 15L4



Warning: Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Terason recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.



Warning: The biopsy guidelines that display on the system monitor are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.



Warning: To reduce the risk of injury to the patient, conduct a biopsy procedure during real-time imaging. When an image is frozen, the correct positioning of the needle cannot be assured.



Warning: Ensure the accessories for a probe are properly cleaned, sterilized, or disinfected as appropriate before each use to avoid possible patient contamination.



Warning: For needle guides in sterile packaging:
The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.



Warning: For needle guides not in sterile packaging:
Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.



Warning: If a needle guide becomes contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, then the needle guide should be destroyed. Sterilization is not effective against Creutzfeld-Jacob contamination

Performing a Biopsy

When all of the preparatory steps are complete, and you have recently verified the alignment (see [Verifying the Alignment](#) on page 125), perform the biopsy on the patient. Note the following warnings that pertain to the biopsy procedure.



Warning: For each procedure, use a straight, new needle. Using a bent needle, or re-using a needle, can injure or infect the patient.

If the needle does not follow the expected path, discontinue the biopsy and contact a Terason representative.

The biopsy guide lines indicate only the expected path of the needle. Verify the actual needle position by identifying the echoes from the needle.



Note: If the needle strays outside of the guide lines, no warning displays.

Performing a biopsy requires that you understand:

- [Assembling the Bracket and Guide](#) on page 123
- [Biopsy Procedure](#) on page 123

Needle Guide Display

The Terason software displays guide lines for the specific probe, bracket, and needle gauge used in a biopsy or other medical procedure.

The needle guides work only in these modes:

- 2D
- Color Doppler mode

You cannot use the needle guides in:

- M-Mode
- Pulsed-Wave Doppler mode
- Triplex
- Zoom mode
- Split Screen mode

The Terason software freezes the Target Indicator when you freeze the image. probe.

Needle Guide Kits

A needle guide kit contains several parts that fit together to attach the needle to the probe and provide a guide that directs the needle into the patient.

There are two types of needle guide kits, which are ordered directly from Civco (www.civco.com) or Protek (www.protekmedical.com):

- Starter needle guide kit
- Replacement needle guide kit

Starter needle guide kits contain both disposable and reusable parts that you need to perform a biopsy. Replacement needle guide kits contain only disposable parts. After the first time, you must use a new replacement needle guide kit each time you perform a biopsy.

Different needle guide kits are required for each type of probe. The following table lists the Terason probes that can be used to perform biopsies, and lists the contents of the starter and replacement needle guide kits that must be ordered for each probe.

Terason Needle Kit Numbers

Model	Starter Kit Contents	Replacement Kit
5C2A	Protek #7138 • Reusable biopsy bracket #6138 • (2) 16 Ga biopsy kits* #4216 • (2) 18 Ga biopsy kits* #4218 • (2) 22 Ga biopsy kits* #4222 • Guideline verification kit #4200	16 Ga biopsy kit #4216 18 Ga biopsy kits #4218 22 Ga biopsy kits #4222 Biopsy kits include needle guide, probe cover and gel

Terason Needle Kit Numbers (Continued)

Model	Starter Kit Contents	Replacement Kit
12L5A and 15L4	Civco 612-085 <ul style="list-style-type: none"> • Non-sterile L5-9EC single-angle bracket (2.5cm) • Ultra-Pro II needle guide • CIV-Flex cover (14 x 91.5cm 3D)(5) • Cleaning brushes (5) 	Civco 610-608 Sterile Ultra-Pro II guide with 14x91.5 cm CIV-Flex cover (24)
	Civco 683-002 <ul style="list-style-type: none"> • Non-sterile single-angle bracket • 14 x 147cm (5.5" x 58") CIV-Flex cover (3D)-21/22 gauge only 	Civco 610-1017, (18 gauge) Civco 610-1018, (20 gauge) Civco 610-1019, (21-22 gauge)

Observe the following warnings with regard to the needle guide kits and their contents.



Warning: Do not attempt to use a needle guide kit until you have read the instructions for selecting the settings and verifying the alignment of the guide lines. Improper use of biopsy needles can cause injury to the patient.

If a needle guide kit is open when you receive it, or if it has been damaged or has condensation inside, do not use it. Contaminated medical equipment can cause patient infection.



Caution: Prevent heat damage to needle guides. Keep them below 50°C (122°F).



Warning: To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose of hazardous or infectious materials according to local, state, and regional regulations.

Assembling the Bracket and Guide

Each probe works with only one bracket.

You can also follow the procedure provided in the biopsy kit to assemble the bracket and needle guide.

Before performing a biopsy, you must assemble the needle guide parts and prepare the probe for the biopsy by completing the following steps:

1. Place an appropriate amount of **gel** inside the cover or on the probe face. Poor imaging may result if no gel is used.



Caution: Use only water-based ultrasound gel. The system is not approved for use with other types of gel.

2. Insert the probe into the **cover**, making sure to use proper sterile technique. Pull the cover tightly over the probe face to remove wrinkles and air bubbles, taking care to avoid puncturing the cover.
3. Secure the cover with the **bands** packaged with the cover.
4. **Inspect** the cover to ensure there are no holes or tears.
5. Using proper sterile technique, snap the unlocked **needle guide** onto the attachment area of the bracket.
6. Push the **lock** into the locked position.
7. Select the appropriate size needle guide **insert** and slide it into position.
8. Use the appropriate length **needle** to reach the target area.

Biopsy Procedure

The Terason Ultrasound software provides two types of needle guides, which are used with different physical needle guides. A needle guide is only available when a probe that supports that guide is connected to the ultrasound system. If more than one needle guide is available for the connected probe, you must verify that the selected guide matches the hardware installed on the probe.

The in-plane guides work with the standard needle guide hardware. These guides are two parallel lines that indicate the path of the needle when the appropriate hardware is used. Use the procedure [Using In-Plane Needle Guides](#) on page 124.

The transverse guide is a circle that indicates the depth obtained when guide hardware that includes clips to set the angle and depth of insertion is used. Use the procedure [Using Transverse Needle Guides](#) on page 125.

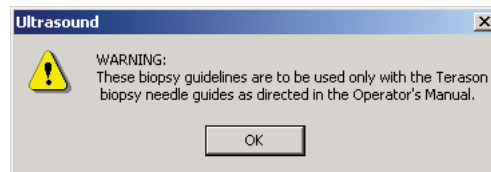
To turn off the needle guides, tap the lower Needle Guide button. If you were using the transverse needle guide, you may have to tap the lower Needle Guide button several times.

Using In-Plane Needle Guides

To perform a biopsy using the in-plane needle guides, complete these steps:

1. Start **live imaging**.
2. Tap the **Needle Guide** button.

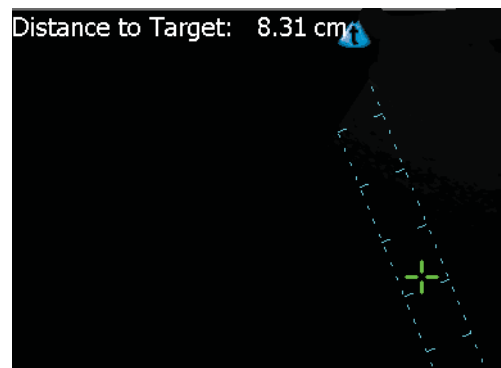
The needle guide lines show in the Imaging window, along with a warning message.



Biopsy Warning

3. Tap **OK**.

The warning closes and the Terason software displays the needle guides and target indicator. The guide lines show you where the needle should be inserted into the patient. The green target indicator can be moved within the guidelines to the exact location of the biopsy target. The Distance to Target: value then shows exactly how deep the needle must be inserted to reach that target.



Needle Guides and Target Indicator

The large tick marks on the guide lines are at 1 cm intervals, and the distance between the guide lines is fixed at 1 cm.

4. If the green Target Indicator does not show within the guides, tap the **Target** button.
The Terason software adds the “Distance to Target” value at the top of the image.



Warning: If the message “Uncalibrated” displays next to the “Distance to Target” text, the probe may be uncalibrated, or your calibration file may be missing or corrupted. Uncalibrated probes can apply harmful levels of energy to the patient. Contact your Terason representative.

5. Drag the **target indicator** to the correct depth.
You cannot move the target outside of the guide lines.

6. Follow the **proper medical protocol** to complete the biopsy.

The target distance is measured in centimeters and is calculated as the distance from the bottom of the clip to the patients' skin (as indicated by the top of the needle guide lines) plus the distance from the skin line to the target as indicated by the location of the green target indicator.

When you insert the needle, it should be located near the center of the guidelines. If the needle appears outside of the lines, verify that you have selected the appropriate needle guide. If you have, stop the procedure immediately and contact a Terason representative.

Using Transverse Needle Guides

To perform a biopsy using the transverse needle guides, complete these steps:

1. Start **live imaging**.
2. Tap the **Needle Guide button**.

The needle guide lines show in the Imaging window, along with the warning message. (See [Biopsy Warning](#) on page 124.)

3. Tap **OK**.
4. Tap the **Guide Type button**.

A transverse needle guide circle replaces the in-plane needle guides on the Imaging window, and the Needle Guide button displays the identification of the guide.



Transverse Needle Guide and Button

5. If the guide is not the correct one for the clip you have attached to the hardware guide, tap the **Guide Type button** until the correct guide displays.
6. Follow the **proper medical protocol** to complete the biopsy.

Verifying the Alignment

To ensure that the probe and biopsy attachment are accurately aligned, and that the needle path is within the stated specification, Terason strongly recommends that you periodically conduct a simulation test. To conduct this test, you must have an assembled biopsy bracket, needle guide, and a water tank.

Use 2D to verify the alignment, and do not use the Zoom tool. The needle guides do not show in zoomed displays.

To **verify the alignment** of the probe and biopsy attachment, complete these steps:

1. If the needle guides are not visible, tap the **Needle Guide** button. The biopsy guides appear in the Imaging window.
2. Tap the **Guide Type** button to select the needle guide to use for the test.
There may be only one guide available for the installed probe.
3. Assemble the **bracket, needle guide clip, and gauge insert pin** as described in [Assembling the Bracket and Guide](#) on page 123.
4. Insert the needle into the **gauge insert pin**.
5. Place the needle in a **water tank**, ensuring that you do not touch the side or bottom of the water tank (which can bend the needle and produce an inaccurate reading).
6. Verify that the **needle** appears clearly between the two guidelines.
7. Remove the **needle** from the biopsy bracket and safely dispose of the needle.
8. Detach the **biopsy bracket** from the probe.

Calibrating Needle Guide Positioning for Biopsies

The Terason software lets you make small adjustments to the positioning of the needle guides (used in biopsies) and the insertion grid (used for cryoablation or brachytherapy).

When you receive needle guides, they are already configured and tested for angle and depth. The angle is the number of degrees between the X-axis and the Y-axis (the needle axis). The depth, shown in millimeters, is the point at which the biopsy needle and guide lines intersect the vertical center line of the 2D image.

You can make marginal changes to the upper and lower limits for angle and depth on the Needle Guide Error Correction dialog box. Your changes to these settings are visible in the needle guidelines, and are saved by the system and used for all biopsies until you change them again.

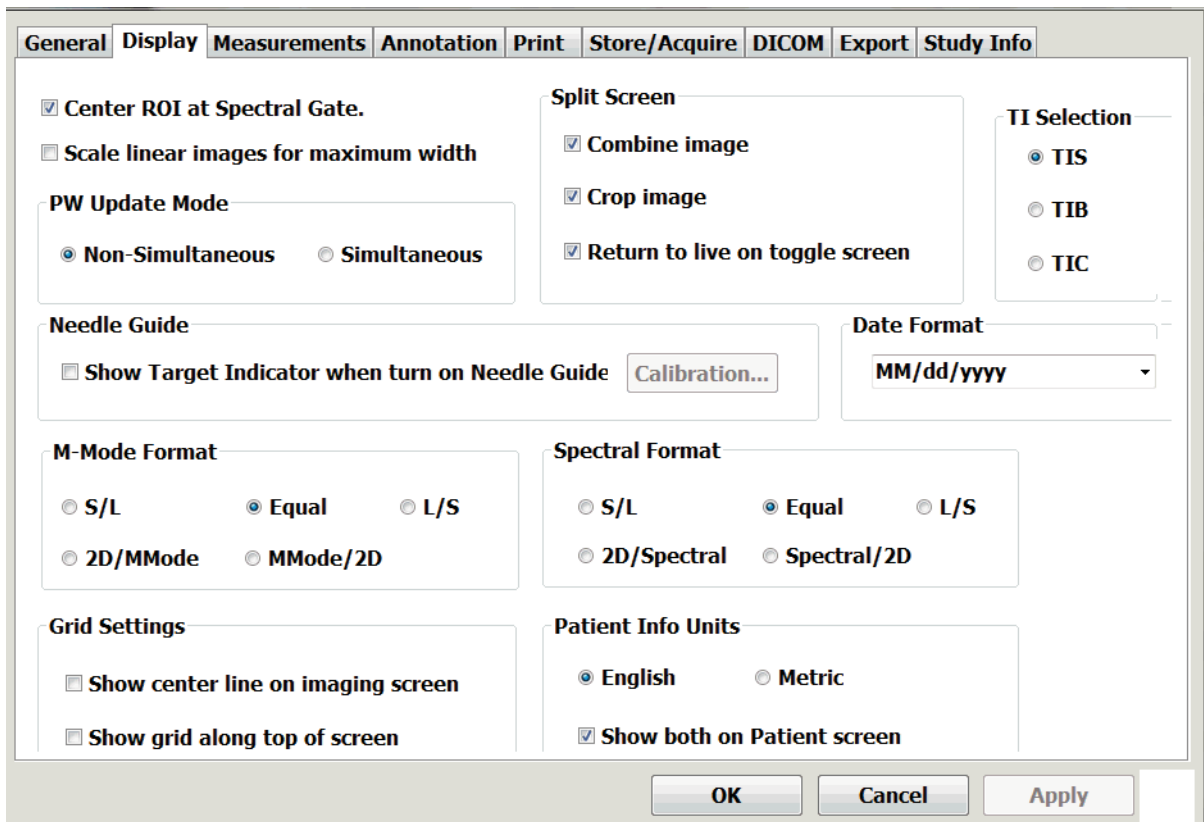
You can change the value within these ranges:

- Angle: -2° to 2°
- Depth: -1 mm to 1 mm

To **change the needle guide error correction values** for any probe except the biplanar probe, complete these steps:

1. Tap the **uSmart3200T** name at the top left of the screen.
2. Tap **Setup**.
3. Tap the **Display** tab.

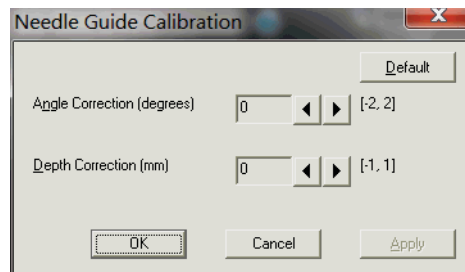
The Setup Display window opens.



Setup Display Window

- In the Needle Guide section, tap the **Calibration...** button.

The Needle Guide Calibration dialog box opens.



Needle Guide Calibration Dialog Box

You can tap the **Apply** button to see the effects of your choices without closing the dialog box. tap the **Default** button to reset the values to the factory-set values.

- Next to the **Angle Correction** field, tap the left and right arrows to correct the angle by one or two degrees.
- Next to the **Depth Correction** field, tap the left and right arrows to correct the depth by plus or minus one millimeter.
- Tap **OK** to save your entries and close the dialog box.

Cleaning the Probes and Brackets

The probe must be cleaned and high-level disinfected between patients. For instructions, refer to “Processing Terason Probes Between Uses” in *Volume 2* of this guide.