EnCor Enspire™ Breast Biopsy System

Quick Reference Guide

Ultrasound/Stereotactic

BD

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1

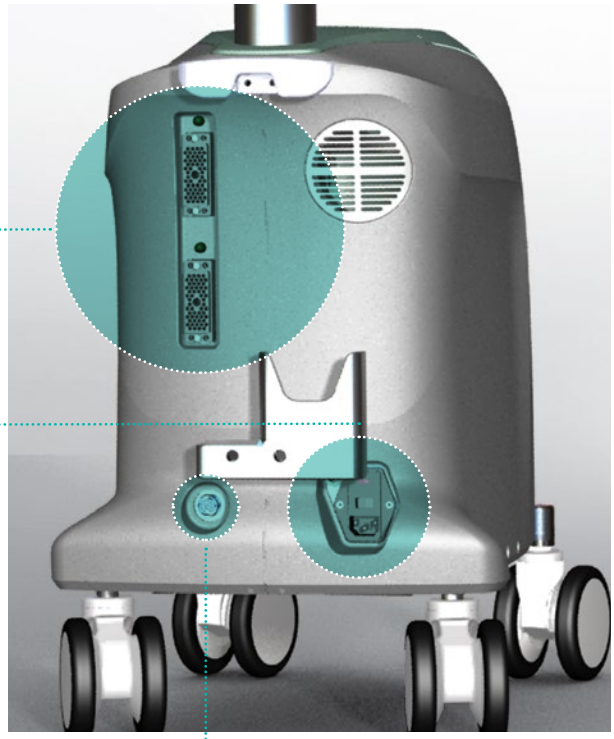
Easy setup

System power up
Vacuum setup
Probe setup

System power up

1 Main power switch

2 Driver connectors



3 Standby power switch

4 Foot pedal

Easy setup 4 steps

1. Turn Main Power Switch ON (rear of console).
2. Connect appropriate EnCor® Driver/s to rectangular connector on rear of console. The Active Driver is indicated by a green LED light above connector.
3. Turn Standby Power Switch ON (front of console).
4. Connect the Foot Pedal at rear of console (if desired).

1

Easy setup

System power up
Vacuum setup
Probe setup

Vacuum setup

1

Secure lid onto canister.

2

Secure large cap and
tandem cap to lid of canister.

3

Place canister into console.

4

Load tubing cassette
(ensure it “clicks” into place).

5

Connect elbow to
center of canister lid.

6

Connect tubing cassette
to patient port on canister.

1

Easy setup

System power up
Vacuum setup
Probe setup

Probe setup

1

Spike saline bag prior to inserting into designated slot.

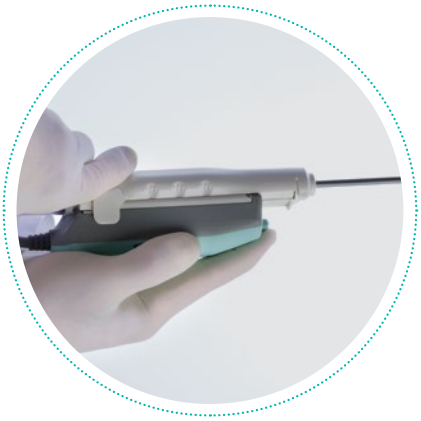
2

Align probe.

3

Slide front of probe under front latches.

4



Snap rear of probe into rear latches.

5

Connect probe tubing to large port (purple). Connect optional rinse tubing to small port (blue).

BARD
EnCor ENSPIRE
BREAST BIOPSY SYSTEM
Stereotactic 10G
Basic Mode
Cutter is closed. To open press SAMPLE handswitch/footswitch. To vacuum press VAC handswitch/footswitch.
Sample
Anesthetic
Marker
Options
Full
Half
12
2
4
8
10
VAC

2

Routine procedures

Sampling
Marker placement
Clean ups

Sampling

The EnCor Enspire™ Breast Biopsy System status is displayed on the Touch Screen. Sample acquisition options may be selected via this screen.

Ultrasound

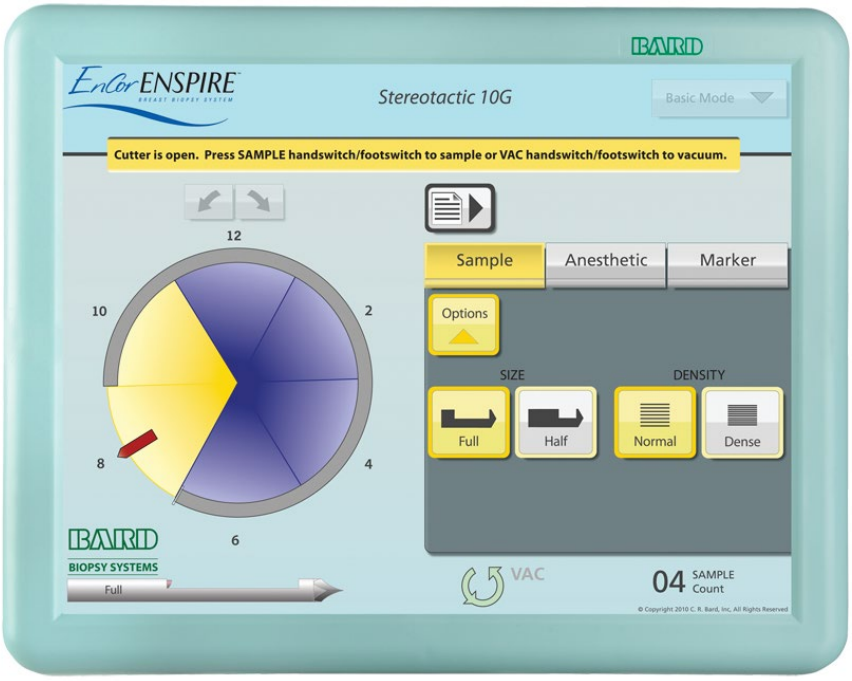
12 o'clock Single Sampling is default for ultrasound

Press and hold "Sample" handswitch or footswitch for continuous sampling during an ultrasound biopsy.

Stereotactic

12-12 Sampling Pattern is default for stereotactic

Press and hold "Sample" footswitch for continuous sampling during a stereotactic biopsy.



Probe will automatically index to take samples from each of the designated sample sections.

Remove sample tray to access samples.

2

Routine procedures

Sampling
Marker placement
Clean ups

Marker placement

The EnCor Enspire™ Breast Biopsy System allows operator to deploy a marker through the probe.

1 Enter Marker Mode by touching "Marker" tab.
Probe aperture will open to allow for marker placement.

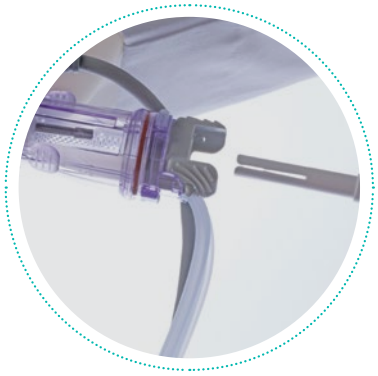
2 To clear the biopsy cavity prior to marker placement, press "VAC" handswitch or footswitch to access Vacuum options.

Select "Quad" to index aperture through quadrants.

3

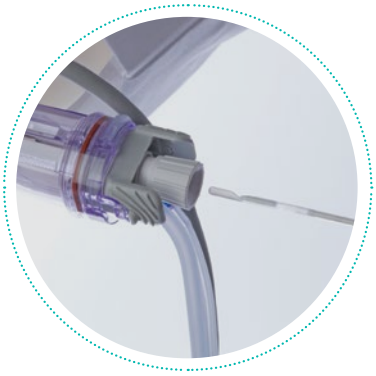
Remove gray cap (twist to the left) from collection chamber.

4



Insert marker tip guide.

5



Insert marker through marker tip guide.

Align the yellow indicator on the marker with the red indicator on the probe (open aperture position).

6

Depress plunger to deploy marker.

Touch "Rotate 180°" icon on screen.

Remove the EnCor® probe/marker applicator together as one unit.

2

Routine procedures

Sampling
Marker placement
Clean ups

Clean up

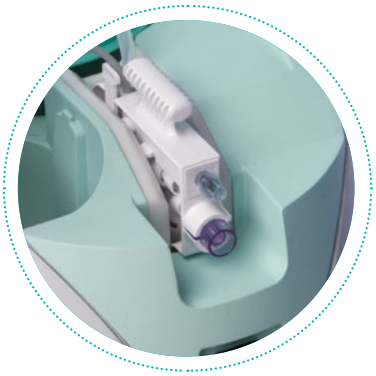
1

Remove and dispose of marker applicator.

2

Disconnect tubing from system, cap end of the tube and roll up.

3



Disconnect tubing and sample collection chamber from probe and dispose in red bag.

4

Remove probe from driver and dispose in sharps biohazard container.

5

Remove and dispose of canister, tubing cassette and optional saline bag.

3

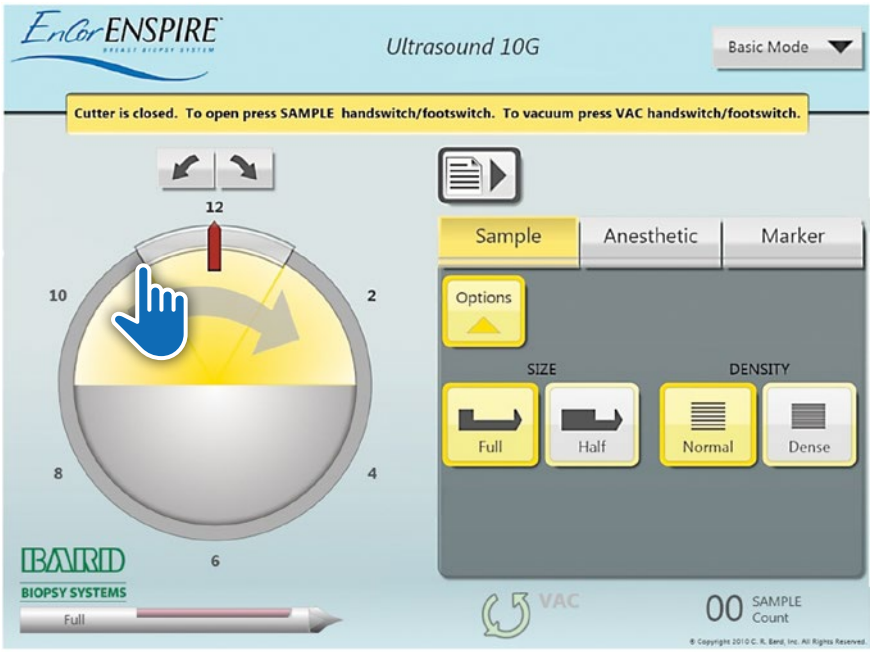
Advanced options

Sample pattern selection
Sample size and tissue density
Anesthetic mode
Biopsy site fluid management
Sample rinse option
Probe specifications

Sample pattern selection

Sample acquisition options are selected via the touch screen. To change the sampling pattern, touch finger to the desired sample section within the Sample Pattern Selector or select pattern by swiping area within the Sample Pattern Selector.

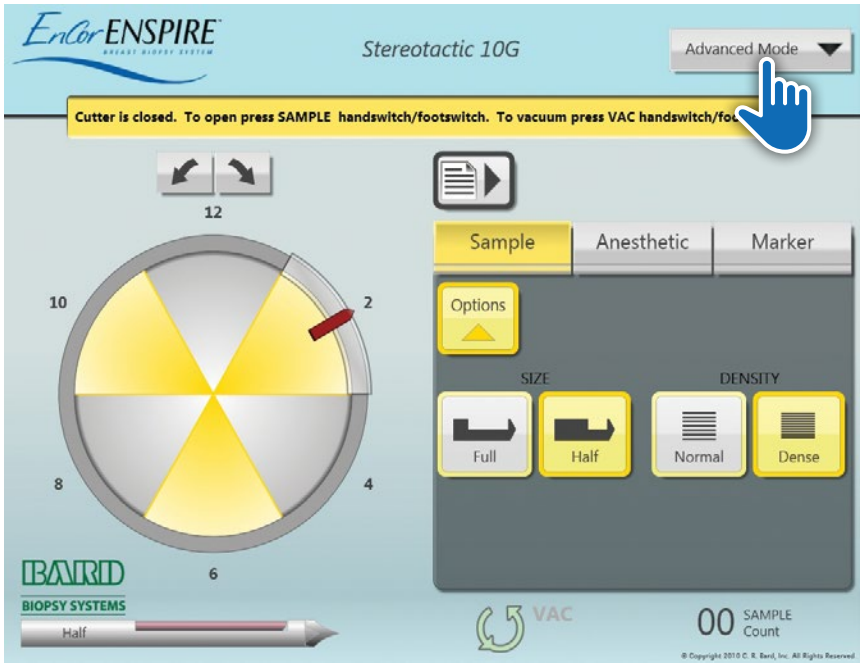
Ultrasound



To rotate aperture orientation to even and odd clock positions, **push the arrow** indicating desired starting position.

Stereotactic

In "Advanced Mode" non-contiguous sample selection is possible.



3

Advanced options

Sample pattern selection
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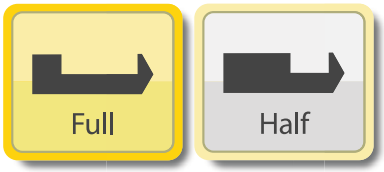
Sample size and tissue density

Full sample (Default)

In sample mode the following options are available:

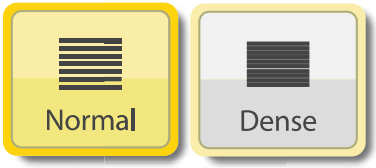
SIZE



Full vs. Half Sample

Aperture Opening
(Full = default)

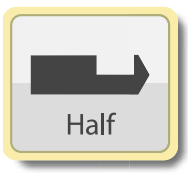
DENSITY



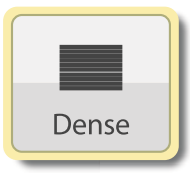
Normal vs. Dense

(Normal = default)

When icon is selected on screen, icon will appear in bright yellow. Choose these options at any time during the procedure.



To change sampling from Full to Half, touch "Half" sample icon. Touch "Full" sample icon to return to full sampling.



To change sample mode from normal tissue to dense tissue, touch "Dense" icon. Touch"Normal" icon to return to normal tissue sampling.

3

Advanced options

Sample pattern selection
Sample size and tissue density
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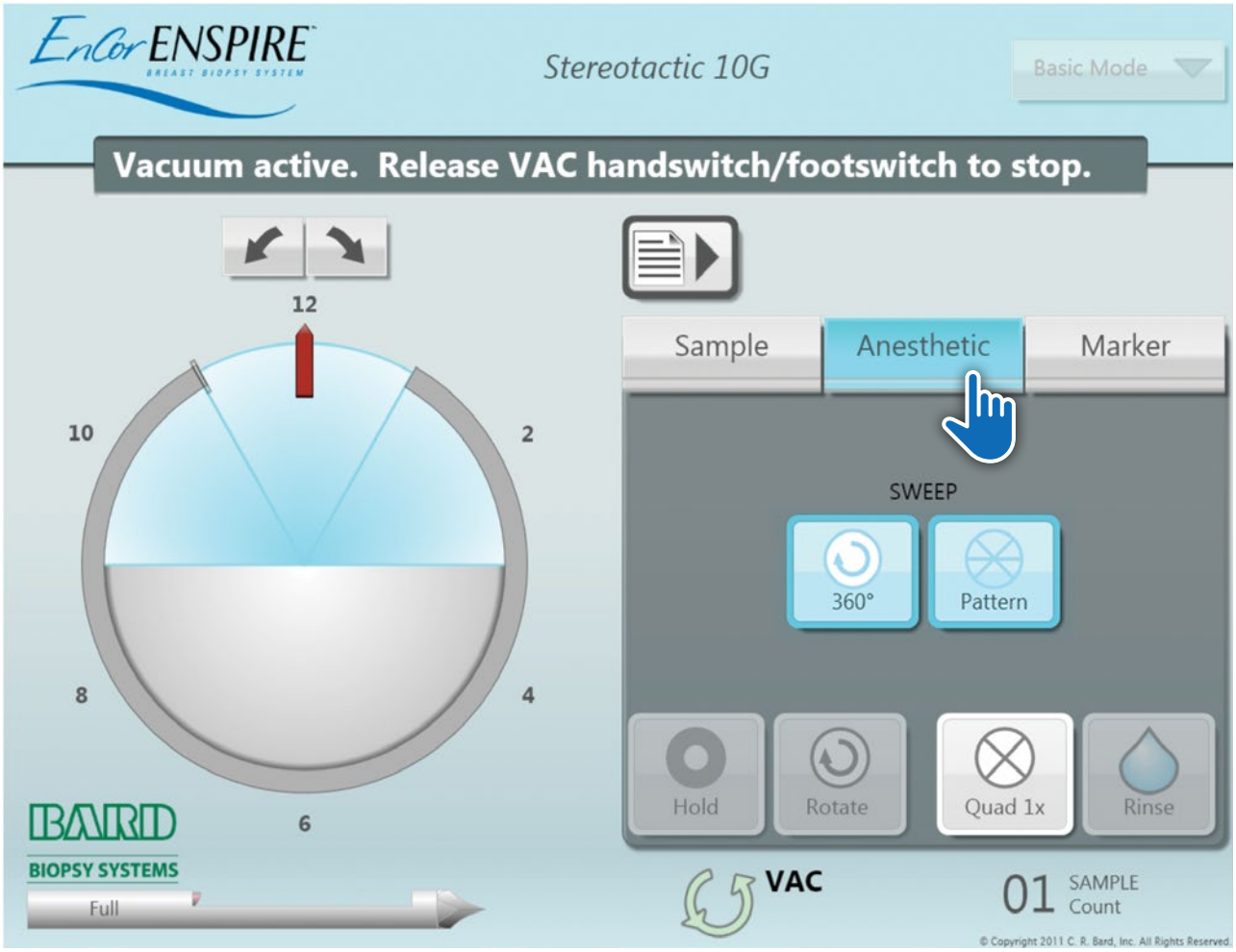
Biopsy site fluid management
Sample rinse option
Probe specifications

Anesthetic mode



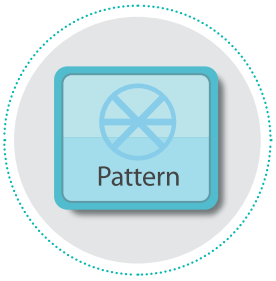
1 **Select** anesthetic mode by touching "Anesthetic" tab. Probe aperture will open.

2 **Remove** gray cap from back of probe.

Insert adapter and syringe and administer anesthetic.

3

While administering anesthetic, touch "360°" icon to index the aperture orientation and distribute anesthetic throughout the biopsy site.



Or match the sampling pattern by touching the "Pattern" icon.

Vacuum option is accessed by pressing "VAC" handswitch or footswitch.

Exit anesthetic mode by pressing "Sample" handswitch or footswitch.

3

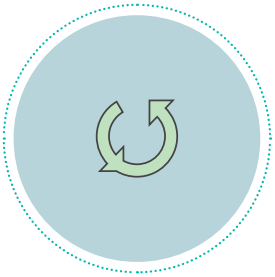
Advanced options

Sample pattern selection
Sample size and tissue density
Anesthetic mode
Biopsy site fluid management
Sample rinse option
Probe specifications

Biopsy site fluid management - vacuum option

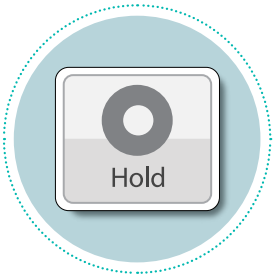
Vacuum options can be accessed at any time during procedure.

Press **"VAC"** handswitch or footswitch to make rinse option available.

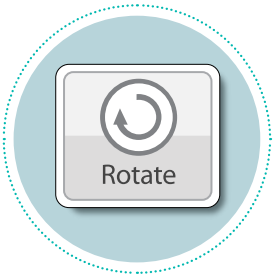


When vacuum is on this symbol will rotate.

To exit vacuum and return to selected mode, press "VAC" handswitch or footswitch.



Touch VAC "Hold" icon to engage vacuum continuously.



Touch VAC "Rotate" icon to automatically vacuum in each quadrant.

3

Advanced options

Sample pattern selection
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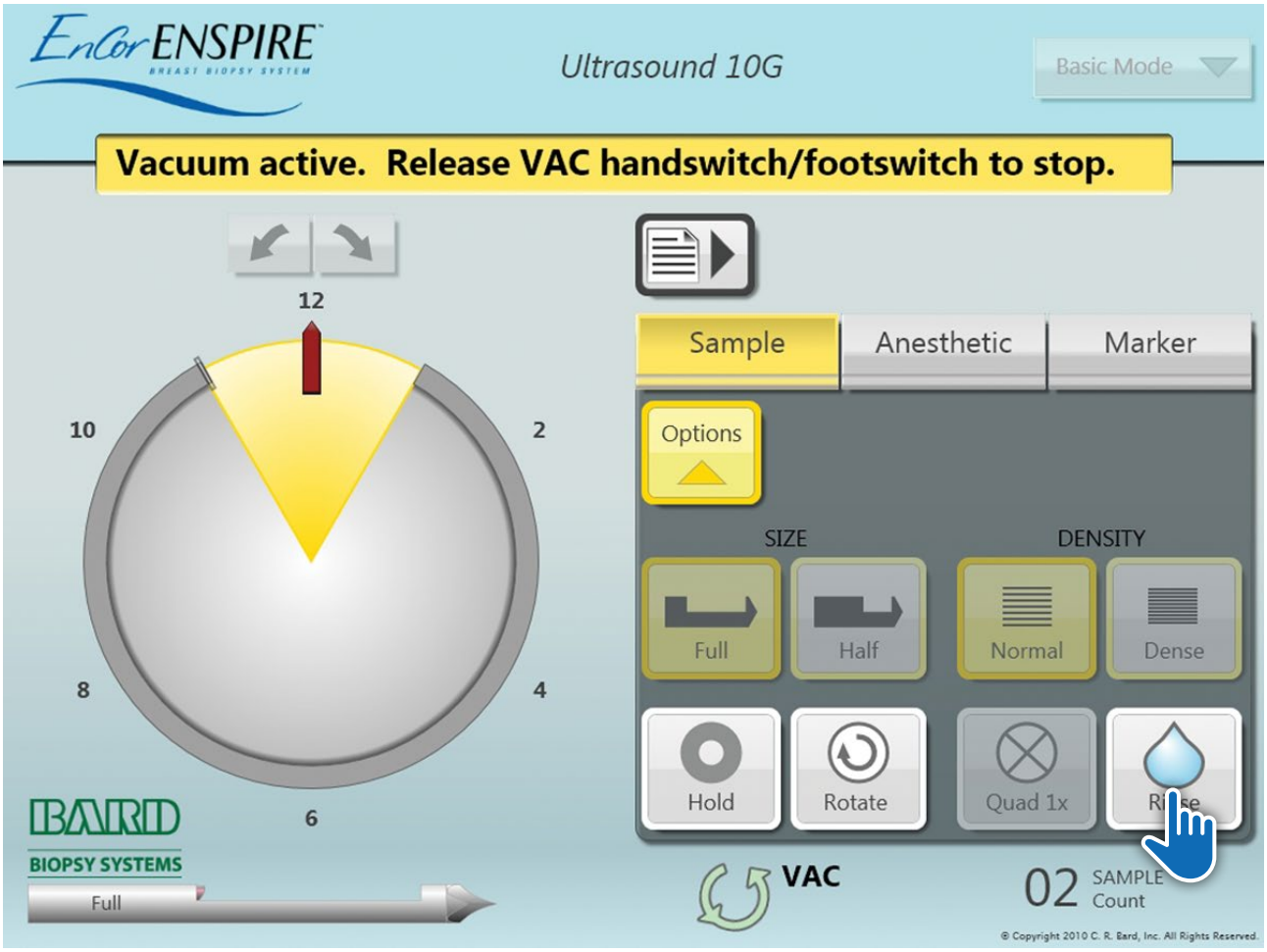
Sample rinse option
Probe specifications

Sample rinse option

This option allows you to apply a saline rinse to samples as desired.



Press **"VAC"** handswitch or footswitch to make rinse option available.

Initiate rinse by touching "Rinse" icon on the touch screen.

Note: Only available when vacuum and rinse tubing cassette is installed and connected to saline bag.

3

Advanced options

Sample pattern selection
Sample size and tissue density
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Biopsy site fluid management
Sample rinse option
Probe specifications

Probe specifications

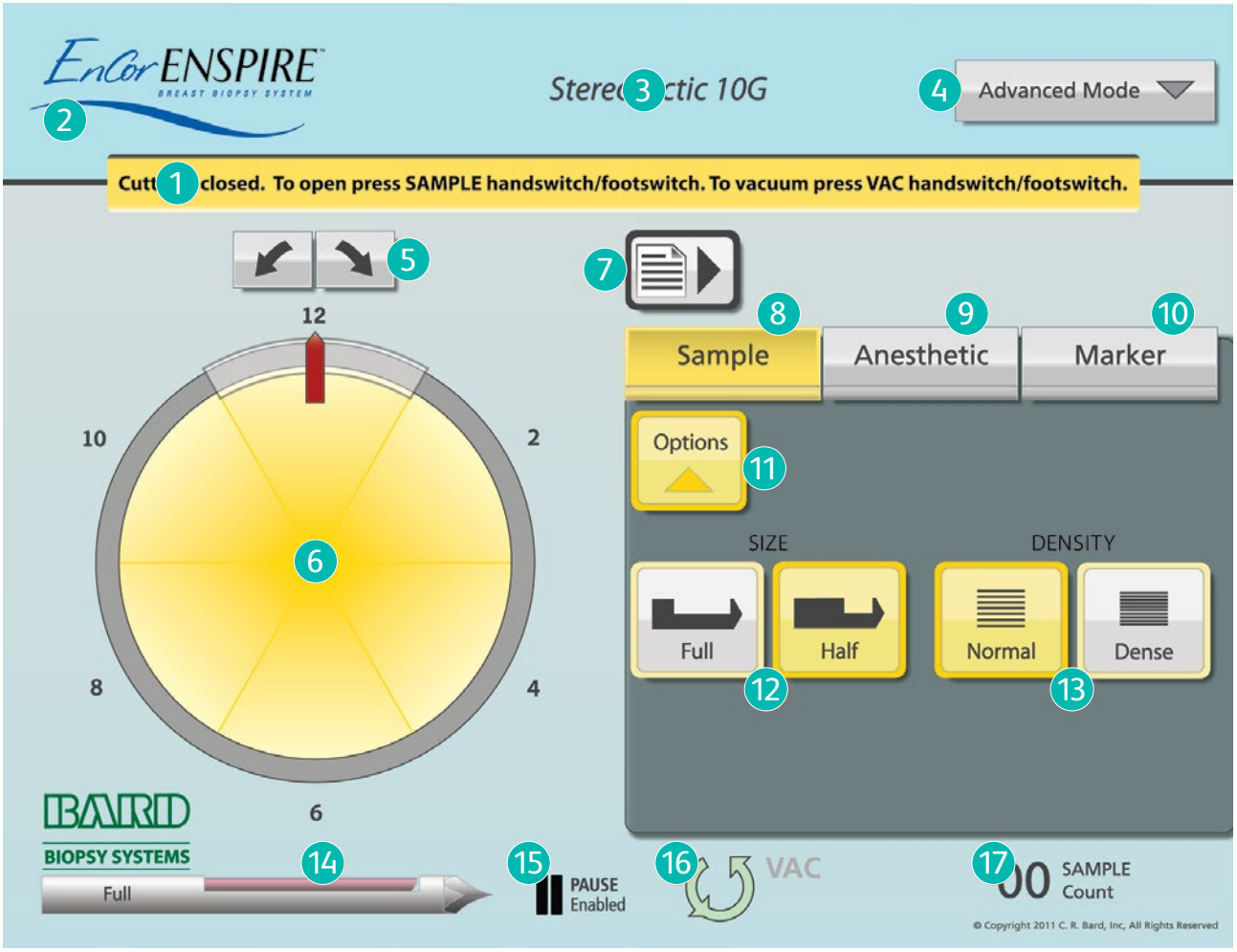
Probe size			
Description	7G	10G	12G
Overall probe length	34.3 cm	34.2 cm	34.1 cm
Needle length	11.4 cm	11.3 cm	11.2 cm
Needle circumference	5.0 mm	4.0 mm	3.4 mm
Dead space	10.8 mm	9.9 mm	8.7 mm
Sample notch	19.0 mm	19.0 mm	19.0 mm
Tip to centre notch	20.3 mm	19.4 mm	18.2 mm
Fill volume	3.5 cc	2.0 cc	1.2 cc
Pull back	0	0	0
Pull back for half sample	-4.5 mm	-4.5 mm	-4.5 mm
Minimum breast compression full sample	29.8 mm	28.9 mm	28.0 mm
Minimum breast compression half sample	19.5 mm	18.9 mm	18.0 mm
Stroke	19.3 mm	19.3 mm	19.3 mm

4

Procedure screen

Descriptions

Procedure screen descriptions



Key description

1. System Status/User Instructions Indicator.
2. Double-press to activate the Stereotactic Table Configuration Window.
   Note: Must be in Stereotactic Mode and done prior to sample being taken.
3. Modality and Probe Size Indicator.
4. User Settings Selector/Indicator. Note: Selector is not enabled after a sample has been taken.
5. Cutter Rotation Buttons (Odd/Even Positions).
6. Sample Pattern Selector – press or swipe pattern sections.
7. Application Note Show/Hide Tab.
8. Sample Mode Tab/Indicator.
   Note: Tab highlighted in yellow when active mode.
9. Anesthetic Mode Activation Tab/Indicator.
   Note: Tab highlighted in blue when active mode.
10. Marker Mode Activation Tab/Indicator.
    Note: Tab highlighted in pink when active mode.
11. Sample Options Show/Hide Button.
12. Sample Size Options Buttons/Indicators.
    Note: Active setting highlighted in yellow.
13. Tissue Density Options Buttons/Indicators.
    Note: Active setting highlighted in yellow.
14. Cannula Cutter/Sample Size Status Indicator.
15. Sample Pause Enabled Indicator
    (enable through configuration settings).
16. Vacuum Indicator.
17. Sample Count

INDICATIONS FOR USE:

The Encor Enspire™ Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities
- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the Encor Enspire™ Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

CONTRAINDICATIONS:

1. This device is not intended for use except as indicated. **2.** The Encor Enspire™ Breast Biopsy System is contraindicated for those patients where, in the physician's judgment, there is an increased risk of complications associated with percutaneous removal of tissue samples.

WARNINGS:

1. The Encor Enspire™ Breast Biopsy System must be properly grounded to ensure patient safety. The system is supplied with a medical grade power cord with AC plug. Do not connect the included power cord to extension cords or three-prong to two-prong adapters. **2.** To minimize interference with other equipment, cables should be positioned in such a manner to prevent contact with other cables. **3.** Use of accessories not compatible with the Encor Enspire™ Breast Biopsy System may create potentially hazardous conditions. **4.** Only use Encor® and Encor® MRI drivers with script version 1.19 or greater, or Encor® 360 drivers with script version 1.05 or greater with the Encor Enspire™ Breast Biopsy System. The system is not compatible with earlier driver scripts. The script version is identified on the touch screen display during system initialization. **5.** The Encor Enspire™ Breast Biopsy System console may not be placed in an MRI suite. Place the console outside of the MRI suite and use the appropriate Encor® MRI accessories when performing a biopsy under MRI guidance. **6.** Do not remove the Encor Enspire™ Breast Biopsy System housing. Removal of the housing may cause electrical shock. Contact Bard for service. **7.** The Encor Enspire™ Breast Biopsy System is not classified as an AP or APG classified device. The system is not suitable for use in the presence of flammable anesthetic.

Please consult package insert for more detailed safety information and instructions for use.

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