**Part A. All Screenings (pages 1-3)**

### I. Ultrasound Equipment

1. **Manufacturer**
   - (check manufacturer and provide model in space provided)
   - ☐ Philips/ATL Model __________________________
   - ☐ Siemens/Acuson Model _______________________
   - ☐ GE Model ________________________________
   - ☐ Toshiba ________________________________
   - ☐ Other, specify ____________________________

2. **Transducers utilized**
   - **2a. Center Frequency**: __________ MHz and Range: __________ MHz to __________ MHz linear array
   - **2b. Transducer Width** (at least 38mm)
     - ☐ 38 mm
     - ☐ 50 mm
     - ☐ Other, specify: __________ mm
   - **2c. Was a second transducer used?**
     - ☐ No (proceed to Q3)
     - ☐ Yes (proceed to Q2d and Q2e)
   - **2d. Center frequency**: __________ MHz and range
     - (high end) MHz to (low end) MHz
   - **2e. Transducer width of second transducer**
     - ☐ 38 mm
     - ☐ 50 mm
     - ☐ Other, specify: __________ mm

3. **Reader ID #**

4. **Time point in study**
   - ☐ Initial screening
   - ☐ 12 month screening
   - ☐ 24 month screening

### 4a. Was the scheduled exam performed?
   - ☐ No (complete and stop, sign form)
   - ☐ Yes

### 5. Date of scan __________ mm-dd-yyyy

### 5a. Date of Interpretation __________ mm-dd-yyyy

**Note:** Time recorded in Q6 is the (hr:min) format, e.g. 01:45.

### 6. __________:_________ Time Radiologist entered room.
   - __________:_________ Time scan initiated
   - __________:_________ Time scan completed
   - __________:_________ Time Radiologist exited room

### 7. Survey scanning was performed (check all that apply)
   - ☐ Conventional mode
   - ☐ With spatial compounding
   - ☐ With tissue harmonic imaging

### 8. Which breast(s) evaluated?
   - ☐ Bilateral
   - ☐ Right breast only
   - ☐ Left breast only

   - **8a. Did you scan the axilla?**
     - ☐ No
     - ☐ Yes (if yes, code side scanned)
       - ☐ Bilateral
       - ☐ Right axilla only
       - ☐ Left axilla only

### 9. Comparison is made to prior US?
   - ☐ None (never had US)
   - ☐ Not available
   - ☐ Yes (check all that apply)
     - ☐ Targeted Right
     - ☐ Targeted Left
     - ☐ Whole breast Right
     - ☐ Whole breast Left
     - ☐ Whole breast Left
     - ☐ Date of prior study: __________
     - ☐ Date of prior study: __________ (if different from right)
10. Greatest depth (thickness) of Breast by ultrasound

<table>
<thead>
<tr>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2 cm</td>
<td>&lt; 2 cm</td>
</tr>
<tr>
<td>2.0-2.9 cm</td>
<td>2.0-2.9 cm</td>
</tr>
<tr>
<td>3.0-3.9 cm</td>
<td>3.0-3.9 cm</td>
</tr>
<tr>
<td>4.0-4.9 cm</td>
<td>4.0-4.9 cm</td>
</tr>
<tr>
<td>5.0-5.9 cm</td>
<td>5.0-5.9 cm</td>
</tr>
<tr>
<td>6.0-6.9 cm</td>
<td>6.0-6.9 cm</td>
</tr>
<tr>
<td>&gt;7 cm</td>
<td>&gt;7 cm</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

11. Background Echotexture

- Homogeneous
- Diffusely Heterogeneous
- Focally Heterogeneous (If focally heterogenous, code all applicable quadrants)

<table>
<thead>
<tr>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>UOQ</td>
<td>UOQ</td>
</tr>
<tr>
<td>UIQ</td>
<td>UIQ</td>
</tr>
<tr>
<td>LOQ</td>
<td>LOQ</td>
</tr>
<tr>
<td>LIQ</td>
<td>LIQ</td>
</tr>
</tbody>
</table>

12. Were any simple cysts identified?
- No (proceed to Q13)
- Yes (If yes, proceed to Q12a)

12a. Right
- Solitary
- 2-3
- Numerous (>4)

12b. Detail Largest Cyst

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface</th>
<th>Distance from skin to center of cyst</th>
<th>Largest Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>R or L</td>
<td>o'clock</td>
<td>cm</td>
<td>mm</td>
</tr>
</tbody>
</table>

12c. Are any previously enumerated lesions from any prior sonograms now gone?
- No (proceed to Q13)
- Yes (If yes, detail below)

Note: Do not reuse Lesion # once it has been reported as gone.

13. Were any discrete lesions other than simple cysts identified?
- No (proceed to Q14)
- Yes (complete and proceed to Q20)

   - Bilateral
   - Right breast only
   - Left breast only
14. Final Assessment of Right Breast

14a. □ Not on study (proceed to Q17)

14b. [ ] [ ] [ ] % Likelihood of malignancy for the right breast (best guess from 0-100)

15. Final assessment for the entire right breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

16. Recommendation for right breast

- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  □ Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  □ Additional Imaging (check all that apply)
    □ Comparison to current mammograms is required
      (lesion seen on US)
    □ Comparison to prior mammograms is required
    □ Additional mammographic projections

17. Final Assessment of Left Breast

17a. □ Not on study (sign and date form)

17b. [ ] [ ] [ ] % Likelihood of malignancy for the left breast (best guess from 0-100)

18. Final assessment for the entire left breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

19. Recommendation for left breast

- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  □ Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  □ Additional Imaging (check all that apply)
    □ Comparison to current mammograms is required
      (lesion seen on US)
    □ Comparison to prior mammograms is required
    □ Additional mammographic projections

Stop, sign and date form.

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Signature of Radiologist responsible for the data 1

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web 2
Part B. Positive Findings (pages 4-27) as needed

20. List lesions other than simple cysts (maximum of 4 per breast)

20a. Number of solid findings/lesions other than simple cysts: Right Breast [ ] Left Breast [ ]

(Note: If there are multiple bilateral similar-appearing circumscribed masses, code this as one bilateral lesion).

20b. Lesion # [U] (e.g. UR1, UB1, UL1 etc.)

(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?

- Not applicable, no prior breast sonograms
- No
- Yes
  - Gone
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses?

- No
- Yes

Breast

- Clockface (report on the hour)
  - (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)

- Distance from the nipple cm

- Depth from skin to center of lesion (to nearest 0.5 cm) cm

20c. Lesion Size

- Largest Horizontal Meas (mm) D1
  - o Trv mm
  - o Sag mm
  - o Rad mm
  - o Arad mm
  - o Oblique

- Second Measured Plane
  - o Trv mm
  - o Sag mm
  - o Rad mm
  - o Arad mm
  - o Perpendicular Oblique

20d. Is this lesion at the site of prior biopsy?

- No
- Yes (if yes, select prior procedure)
  - o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - o Surgical biopsy site (if procedure was performed, select diagnosis)
    - o Benign
    - o Atypical/high-risk lesion
    - o Cancer site
    - o Unknown
    - o Biopsy details unknown
    - o FNAB
- o Not applicable, multiple bilateral circumscribed masses

20e. Special Case (see choices below)

- No
- Yes (if yes, detail below then proceed to Q20n)

(Special Case Features)

- o Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q20e, proceed to Q20f and indicate "complex cystic" at Q20j.)
  - o Homogeneous low-level echoes
  - o Fluid-Debris Level
  - o Mobile internal echoes
  - o Multiple bilateral complicated cysts in company of simple cysts
  - o Multiple bilateral solid oval, circumscribed masses
  - o Mass in or on skin
  - o Clustered microcysts
  - o Intraductal mass
  - o Lymph node
  - o Calcifications without a mass
  - o Foreign body
  - o Post-Surgical scar
  - o Other, specify: __________
20f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

20g. Orientation
- Parallel to skin
- Not parallel (includes round)

20h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

20i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

20j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

20k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

20l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

20m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

20n. Calcifications
- None
- Present (check all that apply)
  - Macrocalkifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

20o. Lesion palpable in retrospect during sonography?
- No
- Yes

21. [%] Likelihood of malignancy for this lesion (best guess from 0-100)

21a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q21b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

21b. Known benign by prior biopsy?
- No (proceed to Q22)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

22. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

23. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q24)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
24. For lesion evaluation, techniques used (check all that apply)
- [ ] Conventional imaging
- [ ] Spatial compounding
- [ ] Power Doppler
- [ ] Tissue Harmonic Imaging
- [ ] Panoramic display

24a. If spatial compounding was used, what was its influence? (please answer the following questions)
- [ ] No influence (proceed to Q25)
- [ ] Influenced (please answer the following questions in bold)
  - Margin depiction
    - [ ] Better
    - [ ] Same
    - [ ] Worse
  - Internal structure depiction
    - [ ] Better
    - [ ] Same
    - [ ] Worse
  - Posterior feature depiction
    - [ ] Better
    - [ ] Same
    - [ ] Worse
  - Confidence in lesion characterization
    - [ ] Better
    - [ ] Same
    - [ ] Worse

24b. Change in likelihood of malignancy with spatial compounding?
- [ ] None
- [ ] Looks more benign with spatial compounding
- [ ] Looks more malignant with spatial compounding

25. Are there additional lesions you wish to describe?
- [ ] No (proceed to Q14)
- [ ] Yes (proceed to Q26)
26. Additional lesions other than simple cysts (maximum of 4 per breast)

26a. Lesion # U (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

26b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- Not applicable, no prior breast sonograms
- No
- Yes
  - Gone
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
- No
- Yes

Breast

Clockface
(report on the hour)
(e.g. 7:00 = 0700, 12:30 = 1230)

Distance from the nipple

Depth from skin to center of lesion (to nearest 0.5 cm)

26c. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trv</td>
<td>Sag</td>
<td>Rad</td>
<td>Arad</td>
</tr>
<tr>
<td></td>
<td>Sag</td>
<td>X</td>
<td>X</td>
<td>Perpendicular Oblique</td>
</tr>
</tbody>
</table>

26d. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select prior procedure)
  - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - Surgical biopsy site (if procedure was performed, select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

26e. Special Case (see choices below)
- No
- Yes (if yes, detail below then proceed to Q26n)
  (Special Case Features)
    - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q26e, proceed to Q26f and indicate "complex cystic" at Q26j.)
    - Homogeneous low-level echoes
    - Fluid-Debris Level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Foreign body
    - Other, specify: ________________________________
26f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

26g. Orientation
- Parallel to skin
- Not parallel (includes round)

26h. Margin
- Circumscribed
- Not circumscribed (if not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

26i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

26j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

26k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

26l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

26m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

26n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

26o. Lesion palpable in retrospect during sonography?
- No
- Yes

26p. % Likelihood of malignancy for this lesion (best guess from 0-100)

27a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q27b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

27b. Known benign by prior biopsy?
- No (proceed to Q28)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

27c. % Likelihood of malignancy for this lesion (best guess from 0-100)

28. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
    - Comparison to prior mammograms is required
    - Additional mammographic projections

29. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q30)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
30. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

30a. If spatial compounding was used, what was its influence? (please answer the following questions)
  - No influence (proceed to Q31)
  - Influenced (please answer the following questions in bold)
    - Margin depiction
      - Better
      - Same
      - Worse
    - Internal structure depiction
      - Better
      - Same
      - Worse
    - Posterior feature depiction
      - Better
      - Same
      - Worse
    - Confidence in lesion characterization
      - Better
      - Same
      - Worse

30b. Change in likelihood of malignancy with spatial compounding?
  - None
  - Looks more benign with spatial compounding
  - Looks more malignant with spatial compounding

31. Are there additional lesions you wish to describe?
  - No (proceed to Q14)
  - Yes (proceed to Q32)
32. Additional lesions other than simple cysts (maximum of 4 per breast)

32a. Lesion #\(U\) (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

32b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
  - Not applicable, no prior breast sonograms
  - No
  - Yes
    - Decreased in size since previous exam
    - Stable in size since previous exam
    - Multiple bilateral circumscribed masses fluctuating in size since previous exam
    - Increased in size since previous exam
    - Other suspicious change
    - Increasing and other suspicious change

32c. Lesion Size

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

32d. Is this lesion at the site of prior biopsy?
  - No
  - Yes (if yes, select prior procedure)
    - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
    - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
    - Surgical biopsy site (if procedure was performed, select diagnosis)
      - Benign
      - Atypical/high-risk lesion
      - Cancer site
      - Unknown
      - Biopsy details unknown
      - FNAB
    - Not applicable, multiple bilateral circumscribed masses

32e. Special Case (see choices below)
  - No
  - Yes (if yes, detail below then proceed to Q32n)
    - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q32e, proceed to Q32f and indicate "complex cystic" at Q32j.)
      - Homogeneous low-level echoes
      - Fluid-Debris Level
      - Mobile internal echoes
      - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Post-Surgical scar
    - Other, specify: ________________________________
32f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

32g. Orientation
- Parallel to skin
- Not parallel (includes round)

32h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

32i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

32j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

32k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

32l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

32m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

32n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

32o. Lesion palpable in retrospect during sonography?
- No
- Yes

33. % Likelihood of malignancy for this lesion
   (best guess from 0-100)

33a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q33b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

33b. Known benign by prior biopsy?
   (only complete if Q33a = Benign)
- No (proceed to Q34)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

34. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
- Intervention
  - Aspiration w/core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by Mammo
  - Excisional biopsy
- Additional Imaging (check all that apply)
  - Comparison to current mammogram is required
  - Comparison to prior mammograms is required
  - Additional mammographic projections

35. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q36)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
36. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

36a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q37)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

36b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

37. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q38)
38. Additional *lesions* other than simple cysts (maximum of 4 per breast)

38a. Lesion #U[ ](e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

38b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- Not applicable, no prior breast sonograms
- No
- Yes
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
- No
- Yes

Breast Clockface Distance from Depth from skin to
(report on the hour) the nipple center of lesion  
(reported on hour and 1/2 hour  
(e.g. 7:00 = 0700, 12:30 = 1230)

| O R | O L | o' clock | cm | . cm |

38c. Lesion Size

<table>
<thead>
<tr>
<th>Largest</th>
<th>Measured Plane</th>
<th>Vertical A-P</th>
<th>Horizontal</th>
<th>Second</th>
<th>Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal Meas (mm)</td>
<td>Trv</td>
<td>Sag</td>
<td>Rad</td>
<td>Arad</td>
<td>Oblique</td>
</tr>
<tr>
<td>mm</td>
<td>mm</td>
<td>mm</td>
<td>mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

38d. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select prior procedure)
  - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - Surgical biopsy site (if procedure was performed, select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

38e. Special Case (see choices below)
- No
- Yes (if yes, detail below then proceed to Q38n)
  (Special Case Features)
    - Complicated Cyst (Note: Do not use this term for "complex cystic masses".
      For complex cystic masses code "No" for Q38e, proceed to Q38f and indicate "complex cystic" at Q38j.)
      - Homogeneous low-level echoes
      - Fluid-Debris Level
      - Mobile internal echoes
      - Multiple bilateral complicated cysts in company of simple cysts
      - Multiple bilateral solid oval, circumscribed masses
      - Mass in or on skin
      - Clustered microcysts
      - Intraductal mass
      - Lymph node
      - Calcifications without a mass
      - Foreign body
      - Post-Surgical scar
      - Other, specify: 

Horizontal Perpendicular Meas
(mm) | D2 | D3 |
| mm | mm |

Volume D1XD2XD3 ÷ 2

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

*(Copyright 2005)*
38f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

38g. Orientation
- Parallel to skin
- Not parallel (includes round)

38h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

38i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

38j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
-Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

38k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

38l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

38m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

38n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

38o. Lesion palpable in retrospect during sonography?
- No
- Yes

39. _________% Likelihood of malignancy for this lesion (best guess from 0-100)

39a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q39b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

39b. Known benign by prior biopsy?
- No (proceed to Q40)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

40. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
    - Comparison to prior mammograms is required
    - Additional mammographic projections

41. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q42)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
42. For lesion evaluation, techniques used (check all that apply)
- □ Conventional imaging
- □ Spatial compounding
- □ Power Doppler
- □ Tissue Harmonic Imaging
- □ Panoramic display

42a. If spatial compounding was used, what was its influence? (please answer the following questions)
- o No influence (proceed to Q43)
- o Influenced (please answer the following questions in bold)
  - **Margin depiction**
    - o Better
    - o Same
    - o Worse
  - **Internal structure depiction**
    - o Better
    - o Same
    - o Worse
  - **Posterior feature depiction**
    - o Better
    - o Same
    - o Worse
  - **Confidence in lesion characterization**
    - o Better
    - o Same
    - o Worse

42b. Change in likelihood of malignancy with spatial compounding?
- o None
- o Looks more benign with spatial compounding
- o Looks more malignant with spatial compounding

43. Are there additional lesions you wish to describe?
- o No (proceed to Q14)
- o Yes (proceed to Q44)
ACRIN Study 6666

Institution No. ____________________________

Case No. ____________________________

Participant Initials ____________________________

**44. Additional lesions other than simple cysts** (maximum of 4 per breast)

- **44a. Lesion U**
  - (e.g. UR1, UB1, UL1 etc.)
  - (Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

- **44b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?**
  - o Not applicable, no prior breast sonograms
  - o No
  - o Yes
    - o Decreased in size since previous exam
    - o Stable in size since previous exam
    - o Multiple bilateral circumscribed masses fluctuating in size since previous exam
    - o Increased in size since previous exam
    - o Other suspicious change
    - o Increasing and other suspicious change

- **Is this "lesion" multiple bilateral circumscribed masses?** If yes, describe location and measurement of largest mass.
  - o No
  - o Yes

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>o R o L</td>
<td>_______ o’ clock</td>
<td>______ cm</td>
</tr>
</tbody>
</table>

- **44c. Lesion Size**
  - **Largest Horizontal Meas (mm) D1**
  - o Trv
  - o Sag
  - o Rad
  - o Arad
  - o Oblique

- **Vertical A-P meas (mm) D2**
  - o Trv
  - o Sag
  - o Rad
  - o Arad
  - o Perpendicular Oblique

- **Horizontal Perpendicular Meas (mm) D3**
  - o Trv
  - o Sag
  - o Rad
  - o Arad
  - o Oblique

- **Volume D1XD2XD3 ÷ 2**
  - _______ mm³

**Note:** Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

- **44d. Is this lesion at the site of prior biopsy?**
  - o No
  - o Yes (if yes, select prior procedure)
    - o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
    - o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
    - o Surgical biopsy site (if procedure was performed, select diagnosis)
      - o Benign
      - o Atypical/high-risk lesion
      - o Cancer site
      - o Unknown
      - o Biopsy details unknown
      - o FNAB
    - o Not applicable, multiple bilateral circumscribed masses

- **44e. Special Case** (see choices below)
  - o No
  - o Yes (if yes, detail below then proceed to Q44n)
    - (Special Case Features)
      - o Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q44e, proceed to Q44f and indicate "complex cystic" at Q44j.)
        - □ Homogeneous low-level echoes
        - □ Fluid-Debris Level
        - □ Mobile internal echoes
        - □ Multiple bilateral complicated cysts in company of simple cysts
      - o Multiple bilateral solid oval, circumscribed masses
      - o Mass in or on skin
      - o Clustered microcysts
      - o Intraductal mass
      - o Lymph node
      - o Calcifications without a mass
      - o Foreign body
      - o Post-Surgical scar
      - o Other, specify: _____________________________
44f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

44g. Orientation
- Parallel to skin
- Not parallel (includes round)

44h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

44i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

44j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

44k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

44l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

44m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

44n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

44o. Lesion palpable in retrospect during sonography?
- No
- Yes

45. % Likelihood of malignancy for this lesion (best guess from 0-100)

45a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q45b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

45b. Known benign by prior biopsy?
- No (proceed to Q46)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

46. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
      (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

47. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q48)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
    - Vaguely palpable
    - Follow-up not reasonable
    - Increased (> 20% in volume for masses)
    - Interval suspicious change
    - Investigator uncertainty
48. **For lesion evaluation, techniques used** (check all that apply)
   - Conventional imaging
   - Spatial compounding
   - Power Doppler
   - Tissue Harmonic Imaging
   - Panoramic display

48a. **If spatial compounding was used, what was its influence?** (please answer the following questions)
   - No influence (proceed to Q49)
   - Influenced (please answer the following questions in bold)
     - **Margin depiction**
       - Better
       - Same
       - Worse
     - **Internal structure depiction**
       - Better
       - Same
       - Worse
     - **Posterior feature depiction**
       - Better
       - Same
       - Worse
     - **Confidence in lesion characterization**
       - Better
       - Same
       - Worse

48b. **Change in likelihood of malignancy with spatial compounding?**
   - None
   - Looks more benign with spatial compounding
   - Looks more malignant with spatial compounding

49. **Are there additional lesions you wish to describe?**
   - No (proceed to Q14)
   - Yes (proceed to Q50)
50. **Additional lesions other than simple cysts** (maximum of 4 per breast)

50a. **Lesion # U**

(e.g. UR1, UB1, UL1 etc.)

(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

50b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?

- o Not applicable, no prior breast sonograms
- o No
- o Yes
  - o Decreased in size since previous exam
  - o Stable in size since previous exam
  - o Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - o Increased in size since previous exam
  - o Other suspicious change
  - o Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.

- o No
- o Yes

**Breast Clockface Distance from Depth from skin to**

(Report on the on center of lesion)

hour nipple (to nearest 0.5 cm)

- o R
- o L

o' clock cm cm cm

50c. Lesion Size

<table>
<thead>
<tr>
<th>Largest Vertical</th>
<th>Horizontal</th>
<th>Measured Plane</th>
<th>Vertical A-P</th>
<th>Perpendicular Meas</th>
<th>Measured Plane</th>
<th>Second</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal Meas (mm) D1</td>
<td></td>
<td>o Try</td>
<td>mm</td>
<td>X</td>
<td>mm</td>
<td>X</td>
</tr>
<tr>
<td>Vertical A-P meas (mm) D2</td>
<td></td>
<td>o Sag</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measured Plane</td>
<td></td>
<td>o Rad</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Arad</td>
<td></td>
<td>o Oblique</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

50d. Is this lesion at the site of prior biopsy?

- o No
- o Yes (if yes, select prior procedure)
  - o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - o Surgical biopsy site (if procedure was performed, select diagnosis)
    - o Benign
    - o Atypical/high-risk lesion
    - o Cancer site
    - o Unknown
    - o Biopsy details unknown
    - o FNAB
- o Not applicable, multiple bilateral circumscribed masses

50e. Special Case** (see choices below)

- o No
- o Yes (if yes, detail below then proceed to Q50n)

**Special Case Features**

- o Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q50e, proceed to Q50f and indicate "complex cystic" at Q50j.)
  - o Homogeneous low-level echoes
  - o Fluid-Debris Level
  - o Mobile internal echoes
  - o Multiple bilateral complicated cysts in company of simple cysts
- o Multiple bilateral solid oval, circumscribed masses
- o Mass in or on skin
- o Clustered microcysts
- o Intraductal mass
- o Lymph node
- o Calcifications without a mass
- o Foreign body
- o Post-Surgical scar
- o Other, specify: ________________________________

*Copyright 2005*
50f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

50g. Orientation
- Parallel to skin
- Not parallel (includes round)

50h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

50i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

50j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

50k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

50l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

50m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

50n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

50o. Lesion palpable in retrospect during sonography?
- No
- Yes

51. % Likelihood of malignancy for this lesion (best guess from 0-100)

51a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q51b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

51b. Known benign by prior biopsy?
- No (proceed to Q52)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

52. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mamo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
      (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

53. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q54)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
54. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

54a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q55)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

54b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

55. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q56)
56. Additional lesions other than simple cysts (maximum of 4 per breast)

56a. Lesion #U (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

56b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
  o Not applicable, no prior breast sonograms
  o No
  o Yes
    o Decreased in size since previous exam
    o Stable in size since previous exam
    o Multiple bilateral circumscribed masses fluctuating in size since previous exam
    o Increased in size since previous exam
    o Other suspicious change
    o Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
  o No
  o Yes

Breast Clockface Distance from Breast
(Distance from Horizontal Meas (mm) D1 Vertical A-P Meas (mm) D2 Horizontal Perpendicular Meas Meas (mm) D3)
          Measured Plane          A-P          Measured Plane
    o Trv  X     o Sag  X     o Trv  X
    o Sag  o Rad  o Rad  o Rad
    o Rad  o Oblique  o Oblique

56c. Lesion Size

Largest Horizontal Meas (mm) D1 Vertical A-P Meas (mm) D2 Horizontal Perpendicular Meas (mm) D3

Volume D1XD2XD3 ÷ 2

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

56d. Is this lesion at the site of prior biopsy?
  o No
  o Yes (if yes, select prior procedure)
    o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
    o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
    o Surgical biopsy site (if procedure was performed, select diagnosis)
      o Benign
      o Atypical/high-risk lesion
      o Cancer site
      o Unknown
    o Biopsy details unknown
    o FNAB
  o Not applicable, multiple bilateral circumscribed masses

56e. Special Case (see choices below)
  o No
  o Yes (if yes, detail below then proceed to Q56n)
    (Special Case Features)
      o Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q56e, proceed to Q56f and indicate "complex cystic" at Q56j.)
        □ Homogeneous low-level echoes
        □ Fluid-Debris Level
        □ Mobile internal echoes
        □ Multiple bilateral complicated cysts in company of simple cysts
          o Multiple bilateral solid oval, circumscribed masses
          o Mass in or on skin
          o Clustered microcysts
          o Intraductal mass
          o Lymph node
          o Calcifications without a mass
          o Foreign body
          o Post-Surgical scar
          o Other, specify:________________________________________
### 56f. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

### 56g. Orientation

- Parallel to skin
- Not parallel (includes round)

### 56h. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

### 56i. Boundary Zone

- Abrupt Interface
- Echogenic Halo

### 56j. Echo Pattern

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

### 56k. Posterior Features

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

### 56l. Surrounding Tissue

- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

### 56m. Vascularity (flow)

- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
  - Not performed

### 56n. Calcifications

- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

### 56o. Lesion palpable in retrospect during sonography?

- No
- Yes

### 57. % Likelihood of malignancy for this lesion

(please guess from 0-100)

#### 57a. Assessment for this lesion

- Negative
- Benign (complete Q57b)
- Probably Benign
- Low Suspicion of Malignancy
- Intermediate Suspicion
- Moderately High Suspicion
- Highly Suggestive of Malignancy

#### 57b. Known benign by prior biopsy?

(only complete if Q57a = Benign)

- No (proceed to Q58)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

### 58. Recommendation for this lesion

- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  - (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging
    - Comparison to current mammogram is required
    - Comparison to prior mammograms is required
    - Additional mammographic projections

### 59. Is this lesion assessed as probably benign AND recommended for intervention?

- No (proceed to Q60)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
60. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

60a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q61)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

60b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

61. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q62)
62. Additional lesions other than simple cysts (maximum of 4 per breast)

62a. Lesion # U (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

62b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- Not applicable, no prior breast sonograms
- No
- Yes
  - Gone
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
- No
- Yes

Breast
Clockface (report on the hour)
(Report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)

Distance from the nipple

Depth from skin to center of lesion (to nearest 0.5 cm)

62c. Lesion Size

<table>
<thead>
<tr>
<th>Largest</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Volume D1XD2XD3 ÷ 2</th>
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<tbody>
<tr>
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</table>

62d. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select prior procedure)
  - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - Surgical biopsy site (if procedure was performed, select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
- Not applicable, multiple bilateral circumscribed masses

62e. Special Case (see choices below)
- No
- Yes (if yes, detail below then proceed to Q62n)

(Special Case Features)
- Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q62e, proceed to Q62f and indicate "complex cystic" at Q62j.)
  - Homogeneous low-level echoes
  - Fluid-Debris Level
  - Mobile internal echoes
  - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-Surgical scar
  - Other, specify:__________________________
62f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

62g. Orientation
- Parallel to skin
- Not parallel (includes round)

62h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

62i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

62j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

62k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

62l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

62m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
  - Not performed

62n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

62o. Lesion palpable in retrospect during sonography?
- No
- Yes

63. % Likelihood of malignancy for this lesion (best guess from 0-100)

63a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q63b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

63b. Known benign by prior biopsy?
- No (proceed to Q64)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

64. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

65. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q66)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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66. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

66a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q14)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

66b. Change in likelihood of malignancy with spatial compounding? (complete then proceed to Q14, Final Assessment)
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding