ACRIN 6666
Annual Survey Ultrasound
Interpretation Form

Instructions: To be completed by the Radiologist who performs and interprets the survey breast ultrasound. Radiologist must not have seen or interpreted the participant’s current routine mammogram, report, or IA form. Please note that comparison to prior breast ultrasound examinations is encouraged; however, neither prior nor current mammograms should be reviewed at the time of annual survey ultrasound performance or interpretation. For targeted US, stop do not use this form; use IM form. For diffuse scattered calcifications with no discrete group use code "100mm X 100mm X 10mm" (largest horizontal measurement X vertical A-P measurement X horizontal perpendicular measurement) and code "20 cm" for distance from the nipple.

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
   - Center Frequency MHz and Range:
     - (high end) MHz to (low end) MHz linear array
   - Transducer Width (at least 38mm)
     - 38 mm
     - 50 mm
     - Other, specify mm
   - Was a second transducer used?
     - No (proceed to Q3)
     - Yes (proceed to Q2d and Q2e)
   - Center frequency MHz and range
     - (high end) MHz to (low end) MHz
   - Transducer width of second transducer
     - 38 mm
     - 50 mm
     - Other, specify mm

3. Reader ID #
   - Radiologist performing exam
     - (Last, First)

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

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
       Date of prior study:
       Date of prior study: (if different from right)
10. Greatest depth (thickness) of Breast by ultrasound

- **Right**
  - o < 2 cm
  - o 2.0-2.9 cm
  - o 3.0-3.9 cm
  - o 4.0-4.9 cm
  - o 5.0-5.9 cm
  - o 6.0-6.9 cm
  - o >7 cm
  - o not applicable

- **Left**
  - o < 2 cm
  - o 2.0-2.9 cm
  - o 3.0-3.9 cm
  - o 4.0-4.9 cm
  - o 5.0-5.9 cm
  - o 6.0-6.9 cm
  - o >7 cm
  - o not applicable

11. Background Echotexture

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

- **L**

12. Were any simple cysts identified?

- o No (proceed to Q12c)
- o Yes (If yes, proceed to Q12a)

12a.  

- **Right**
  - o Solitary
  - o 2-3
  - o numerous (>4)

- **Left**
  - o Solitary
  - o 2-3
  - o numerous (>4)

12b. Detail Largest Cyst

- **Breast**
- **Clockface** (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 cyst** (to nearest 0.5 cm)
- **Largest Dimension**

12c. Are any previously enumerated lesions from any prior sonograms now gone?

- o No (proceed to Q13)
- o Yes (If yes, detail below)

_____ Number of previously enumerated lesions now gone since last annual screening.

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

Lesion #
Lesion #
Lesion #
Lesion #
Lesion #
Lesion #
Lesion #
Lesion #

13. Were any discrete lesions other than simple cysts identified?

- o No (proceed to Q14)
- o Yes (complete and proceed to Q20)
  - o Bilateral
  - o Right breast only
  - o 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
  - 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
  - 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

Signature of person entering data onto web 2

Date Form Completed (mm-dd-yyyy)
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 # (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

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

20c. Lesion Size

- Largest Horizontal Meas (mm) D1

- Horizontal Meas (mm) D2

- Horizontal Meas (mm) D3

- Vertical A-P meas (mm) X

20d. 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

20e. Special Case (see choices below)

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

(Special Case Features)

- 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.)
  - 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:

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"
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)
  - Macrocalcifications (> 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 #\text{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
Distance from
Depth from skin to

Breast
(Report on the hour)
Distance from
Center of lesion
(Retport on hour and 1/2 hour
(e.g. 7:00 = 0700, 12:30 = 1230)

26c. Lesion Size

<table>
<thead>
<tr>
<th>Measured Plane</th>
<th>Vertical A-P Meas (mm)</th>
<th>Horizontal Perpendicular Meas (mm)</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trv</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Oblique</td>
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</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
  - Post-Surgical scar
  - 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

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**ACRIN Study 6666**

**PLACE LABEL HERE**

**Institution No.**

**Case No.**

**Participant Initials**

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### 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

### 27. [%] 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

### 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 (lesion seen on US)
    - 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

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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 # (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
      - 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

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>R</td>
<td>o' clock</td>
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</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)
      (Special Case Features)
      - 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: ________________________

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.
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)
  - Macrocalkifications (> 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?
- 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
    - Comparison to current mammogram is required
    - (lesion seen on US)
    - 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

38c. Lesion Size

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

Horizontal measured plane:

- Trv
- Sag
- Rad
- Arad
- Oblique

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: ____________________________
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 (lesion seen on US)
    - 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
  - Vague 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)

- No influence (proceed to Q43)
- 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

42b. Change in likelihood of malignancy with spatial compounding?

- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

43. **Are there additional lesions you wish to describe?**

- No (proceed to Q14)
- Yes (proceed to Q44)
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

44c. Lesion Size

Breast
- o R
- o L

<table>
<thead>
<tr>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)</td>
<td>cm</td>
</tr>
</tbody>
</table>

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.)
  - 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: ________________________________
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

<table>
<thead>
<tr>
<th>44n. Calcifications</th>
</tr>
</thead>
</table>
| - 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 #**

(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**

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

- o R
- o L

**Distance from the nipple**

- cm

**Depth from skin to center of lesion**

(to nearest 0.5 cm)

- cm

50c. **Lesion Size**

**Largest Meas** (mm) **D1**

Horizontal Meas (mm) **D1**

- Measured Plane
  - o Trv
  - o Sag
  - o Rad
  - o Arad
  - o Oblique

Vertical A-P Meas (mm) **D2**

**X**

Horizontal Perpendicular Meas (mm) **D3**

50d. **Is this lesion at the site of a 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:
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?
  (only complete if Q51a = Benign)
- 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 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

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?
- o No
- o Yes
  - Clockface
    - (report on the hour)
      - (report on hour and 1/2 hour
        e.g. 7:00 = 0700, 12:30 = 1230)
    - cm
  - Distance from the nipple
  - Depth from skin to center of lesion (to nearest 0.5 cm)

56c. Lesion Size

<table>
<thead>
<tr>
<th>Breast</th>
<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>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>o R o L</td>
<td>o' clock mm</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>o Trv Sag Rad Arad Oblique mm</td>
<td>mm³</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.)
      - 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: ________________________________
### 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
(best 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 (lesion seen on US)
    - 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
    - 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

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

62c. 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>Arad</td>
<td>Oblique</td>
</tr>
<tr>
<td>mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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: ___________________________________________

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.
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)
  - Micronodular calcifications in mass
  - Micronodular calcifications 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?
(only complete if Q63a = Benign)
- 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
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