III. REPORTING SYSTEM

A. REPORT ORGANIZATION

The report should be concise and organized using a structure such as that provided in <u>Table 2</u> (below). Assessments and management recommendations are discussed in item B of this chapter on the reporting system, as well as in the Guidance chapter and in answer to some specific questions among the Frequently Asked Questions.

The indication for examination, relevant clinical history, and pertinent risk factor information should be clearly stated. If the study is performed for follow-up of a specific mass or area of concern, this should be described. The dates of any comparison examinations should be specified. As detailed in the General Considerations section on Labeling and Measurement (see page 30), when a specific sonographic finding is documented by recording a complete set of images, the longest horizontal dimension should be reported first, followed by the vertical measurement, and the orthogonal horizontal dimension last. Multiple simple cysts or a combination of multiple simple and complicated cysts need not be reported individually. If any lesions have been biopsied previously, this should be noted together with the prior biopsy results, if known. Correlation of any clinical, mammographic, and MRI findings with the sonographic findings should be specifically stated in the report. For diagnostic evaluations involving US characterization of mammographic abnormalities or confirmation of a mass suspected but not delineated mammographically, a single report integrating the two modalities will clearly communicate a final assessment based on the highest likelihood of malignancy and appropriate management recommendations.

Table 2. Report Organization

Report Structure			
1. Indication for examination			
2. Statement of scope and technique of breast US examination			
3. Succinct description of the overall breast composition (screening only)			
4. Clear description of any important findings			
5. Comparison to previous examination(s), including correlation with physical, mammography, or MRI findings			
6. Composite reports			
7. Assessment			
8. Management			

Consistent use of BI-RADS® descriptors for US, as for mammography and MRI, helps in lesion assessment and clarifies communication with physicians and patients. Also, structured, software-based reporting should be based on BI-RADS® terminology.

For coding and reimbursement, consider the advisability of splitting the report combining the findings of two or more concurrently performed imaging modalities or procedures into specific sections or paragraphs, one for each type of examination. However, a single assessment and recommendation for patient management should reflect integration of the findings from all of the imaging studies. Note that an assessment based on specific findings needing most urgent attention will have the greatest clinical utility.

1. INDICATION FOR EXAMINATION

The reason for performing the examination should be stated briefly at the beginning of the report. The most common indications for breast US are confirmation and charac-

terization of a palpable mass or mammographic or MRI abnormality, guidance of interventional procedures, and as the initial imaging technique for young, pregnant, or lactating patients. Additional applications are listed in the <u>ACR Practice Guideline for the Performance of the Breast Ultrasound Examination</u> and include the extent of disease evaluation supplementing mammography in high-risk women who are not candidates for breast MRI or who have no easy access to MRI, and in breast imaging practices that provide the service, supplementary whole-breast screening in order to increase cancer detection in asymptomatic women with mammographically dense breasts.

2. STATEMENT OF SCOPE AND TECHNIQUE OF BREAST US EXAMINATION

The scope of examination and technique used should be stated, for example, whether the examination was directed or targeted to a specific location, or whether it was performed for supplementary screening. It is important, since US is a real-time examination, to indicate who performed the examination (sonographer, sonographer and physician, physician alone) or whether an automated whole-breast scanning system was used. If a lesion was evaluated with color or power Doppler or with strain or shear-wave elastography, observations relevant to the interpretation should be reported.

In certain situations, it may be beneficial to describe the position of the patient during the examination (e.g., "The breasts were imaged in both supine and lateral decubitus position." or "The patient was imaged in seated position, the position in which she feels the left breast thickening best.").

Automated whole breast scanners that acquire in 3-D are available for clinical use and can be formatted in three planes. These scanners depict the entire breast in coronal, transverse, and sagittal planes, with the coronal view similar to the coronal MRI view. Reporting of these studies continue to evolve, but where possible the interpretation structure outlined in Table 2 (see page 123) and the reporting procedures described earlier in this section should be followed.

3. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION (screening only)

Tissue composition patterns can be estimated more easily in the large FOVs of automated US scans but can also be discerned in the small FOV of a handheld US scan. The three US descriptors for tissue composition described earlier in the US lexicon, "homogeneous background echotexture-fat," "homogeneous background echotexture-fibroglandular," and "heterogeneous background echotexture" (Table 3) (below) correspond loosely to the four density descriptors of mammography and the four fibroglandular tissue descriptors of MRI. At US, breast tissue composition is determined by echogenicity. Subcutaneous fat, the tissue relative to which echogenicity is compared, is medium gray and darker than fibroglandular tissue, which is light gray. Heterogeneous breasts show an admixture of hypoechoic and more echogenic areas. Careful real-time scanning will help differentiate a small hypoechoic area of normal tissue from a mass.

Table 3. Breast Tissue

Tissue Composition		
a. Homogeneous background echotexture-fat		
b. Homogeneous background echotexture-fibroglandular		
c. Heterogeneous background echotexture		

4. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

The description of important findings should be made, in order of clinical relevance, using lexicon terminology, and should include:

- a. Characterization of a mass using the morphological descriptors of shape, margin, and orientation. Note should be made of the lesion's effect on the surrounding tissue, such as architectural distortion. Feature categories, such as posterior features and echogenicity, and techniques, such as color or power Doppler and elastography, may contribute information to the analysis, but only pertinent positives need to be described. Recognition of special case findings, such as simple and complicated cysts, clustered microcysts, intramammary lymph nodes, and foreign bodies, should simplify interpretation. In reporting screening examinations in asymptomatic women, as in mammography, characteristically benign findings may be reported (assessment category 2), but it is not obligatory, and the appropriate assessment would then be negative (assessment category 1).
- b. For important findings, lesion size should be given in at least two dimensions; three dimensions are preferable, especially if the volume of a mass is compared with one or more previous examinations. It is not necessary to report the measurements of every small simple cyst, and if numerous cysts are present, especially in both breasts; location and measurements of the largest cyst in each breast will suffice.
 - If a mass is measured, images should be recorded with and without calipers. Marginal characteristics are one of the most important criteria to be applied in assessing the likelihood of malignancy of a mass, and, particularly with small masses, caliper markings may obscure the margin, hindering analysis.
- c. Location of the lesion(s) should be indicated using a consistent and reproducible system, such as clock-face location and distance from the nipple. When more than one mass or abnormality is located in the same scan frame or in the same locale, measurement of the distance from the skin to the center of the mass or its anterior aspect may help to differentiate one lesion from another. This measurement may be particularly useful when one mass is singled out for biopsy and others are depicted in the field.
 - There may be variability within breast imaging practices, and members of a group practice should agree upon a consistent policy for documenting lesion location on subsequent examinations. In some practices, for all examinations that follow the initial US study, the lesion location annotation will be repeated without change. Other breast imagers may report a different location to signify the same lesion but indicate in their reports that the lesion is now seen at another clock-face position and distance from the nipple (these differences are often related to positioning and technique). A more complete discussion of this common scenario is provided in the <u>Frequently Asked Questions</u>, see page 142).
- d. As at mammography, multiple bilateral circumscribed masses usually are assessed as benign (category 2) unless one mass has different imaging features than all the others. In the unusual circumstance in which the interpreting physician chooses to describe multiple benign-appearing masses individually within the US report, the masses should

be listed by breast, by location within in the breast, and by size. The reader of the report will be less confused, and, if surveillance is suggested as management, the performer of the subsequent examination will appreciate a list rather than verbose text. For bilateral findings, describe all the findings in each breast in a separate paragraph.

5. COMPARISON TO PREVIOUS EXAMINATION(S), INCLUDING CORRELATION WITH PHYSICAL, MAMMOGRAPHY, OR MRI FINDINGS

Breast US should be correlated with physical findings, mammography, MRI, or other imaging studies, if performed. If no statement of comparison is included in the US report, it will be assumed that no comparison was made. Note that some report templates include a "comparison" heading, in which the word "none" (if appropriate) may be entered.

When correlating US findings with those seen at mammography and/or MRI, the operator performing handheld scanning should correlate the size and location of lesions and match the type and arrangement of tissues surrounding the lesion in order to reduce the likelihood of misregistration (identifying a different lesion or lesions at different imaging modalities). In doing this, allowance for positional changes should be made going from upright with mammography and prone with MRI to supine or supine-oblique with US. If it is determined that a sonographic finding corresponds to a palpable abnormality, or to a mammographic or MRI finding, this should be stated explicitly in the US report. If the US finding is new or has no correlate, this should also be stated in the report.

If the US examination was performed as part of a surveillance protocol to assess a previously identified finding, or if the finding was reported on a previous examination, the current report should describe any changes. An increase of 20% or more in the longest dimension of a probably benign solid mass within 6 months may prompt biopsy. An increase of only 1–2 mm in lesion size may be related to differences in scanning technique or patient positioning.

6. COMPOSITE REPORTS

When more than one type of examination is performed concurrently (on the same day), it is preferable that the examinations be reported together. The findings for each examination should be described in separate paragraphs with an overall assessment and management recommendations for the combined examinations. In general, when the assessments for two examinations differ, the overall assessment (and concordant management recommendations) should reflect the more abnormal of the individual assessments (whatever management is expected to come first, supplemented by likelihood of maligancy), according to the following hierarchy of increasing abnormality: category 1, 2, 3, 6, 0, 4, 5 (Table 4, see page 127).

Exceptions to this rule occur when the characteristically benign features of a given imaging finding on one examination supersede the less specifically benign features of the same finding on the other examination. An example is that of a partially circumscribed, noncalcified mass at mammography, superseded by simple cyst at US.

BI-RADS Assessment Category

Degree of Abnormality

Lowest

2

3

6

0

4

5

Highest

Table 4. Abnormality Hierarchy

7. ASSESSMENT

The report should conclude with a concise summary of pertinent US findings with a final assessment using BI-RADS® US categories 1–6 and the phrases associated with them. If report of a US examination is integrated with that of a concurrently performed mammography examination, the combined final assessment should reflect the highest likelihood of malignancy assessed at the two examinations. Clear and consistent communication is a goal that can be achieved for breast US by using the same assessment categories and similar wording described in the BI-RADS® Mammography section.

In some cases, the interpreting physician may render an incomplete assessment (category 0) in order to request additional examination(s), such as mammography, comparison with previous but currently unavailable examinations, or additional physican-performed real-time scanning after either a sonographer-produced, real-time or automated whole-breast screening US examination.

8. MANAGEMENT

Management recommendations should be included in every report. Clear recommendations should be made as to the next course of action. Recommendations may include routine age-appropriate screening, surveillance imaging for a probably benign mass, annual follow-up after percutaneous or surgical biopsy, and clinical management. If an imaging-guided interventional procedure is recommended, the type of imaging for the procedure might also be suggested, for example, stereotactic, US, or MRI guidance.

B. ASSESSMENT CATEGORIES

Table 5. Concordance Between BI-RADS® Assessment Categories and Management Recommendations.

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete — Need Additional Imaging Evaluation	Recall for additional imaging	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance	> 0% but ≤ 2% likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
Category 4A: Low suspicion for malignancy		> 2% to ≤ 10% likelihood of malignancy
Category 4B: <i>Moderate suspicion</i> for malignancy		> 10% to ≤ 50% likelihood of malignancy
Category 4C: <i>High suspicion</i> for malignancy		> 50% to < 95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

a. Assessment Is Incomplete

Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Images for Comparison

There is a finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. In this context, additional imaging evaluation includes the recording of (nonstandard) US images to supplement the standard images recorded for a screening examination. Note that this does not include repeat real-time scanning by the interpreting physician and/or colleague as long as additional images are not recorded. This respects the unique real-time nature of US and does not penalize its use. (For further information please refer to the Follow-Up and Outcome Monitoring section, see FOM on page 128.)

Under certain circumstances, assessment category 0 may be used in a diagnostic US report, such as when equipment or personnel are not immediately available to perform a needed concurrent diagnostic mammography examination, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. Category 0 should **not** be used for diagnostic breast imaging findings that warrant further evaluation with MRI. Rather, the interpreting physician should issue a final assessment in a report that is made before the MRI examination is performed.

In most circumstances and when feasible, if a screening US examination is not assessed as negative or benign, the current examination should be compared to prior examination(s), if any exist. The interpreting physician should use judgment on how vigorously to attempt obtaining prior examinations, given the likelihood of success of such an endeavor and the likelihood that comparison

will affect the final assessment. In this context, it is important to note that comparison to previous examination(s) may be irrelevant when a finding is inherently suspicious for malignancy.

Category 0 should be used for prior image comparison only when such comparison is *required* to make a final assessment. When category 0 is used in the context of awaiting prior examinations for comparison, there should be in place a tracking system guaranteeing with 100% reliability that a final assessment will be made within 30 days (preferably sooner), even if prior examinations do not become available. Some breast imaging practices may reasonably choose never to use category 0 in the context of awaiting prior examinations simply because they do not have a 100% reliable tracking system. If an US examination is assessed as category 0 in the context of awaiting prior examinations and then the prior examinations do become available, an addendum to the initial US report should be issued, including a revised assessment. For auditing purposes, the revised assessment should replace the initial assessment.

A need for previous studies to determine appropriate management might also temporarily defer a final assessment.

b. Assessment Is Complete — Final Categories

Category 1: Negative

There is nothing to comment on. This is a normal examination.

Category 2: Benign

As with category 1, this is a "normal" assessment, but here the interpreter chooses to describe a benign finding in the US report. For example, the interpreter may choose to describe one or more simple cysts, intramammary lymph nodes, postsurgical fluid collections, breast implants, or complicated cysts/probable fibroadenomas that are unchanged for at least 2 or 3 years, while still concluding that there is no sonographic evidence of malignancy. On the other hand, the interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1).

Note that both category 1 and category 2 assessments indicate that there is no sonographic evidence of malignancy. Both should be followed by the management recommendation for routine age-appropriate screening. The difference is that category 2 should be used when describing one or more specific benign sonographic findings in the report, whereas category 1 should be used when no such findings are described (even if such findings are present).

Category 3: Probably Benign (Guidance chapter, see page 139.)

Assessment category 3, probably benign, is *not* an indeterminate category for use simply when the radiologist is unsure whether to render a benign (BI-RADS® category 2) or suspicious (BI-RADS® category 4) assessment, but one that is reserved for specific imaging findings known to have > 0% but ≤ 2% likelihood of malignancy. *For US, there is robust evidence that a solid mass with a circumscribed margin, oval shape, and parallel orientation (most commonly fibroadenoma), and an isolated complicated cyst have a likelihood of malignancy in the defined (≤ 2%) probably benign range, for which short-interval (6-month) follow-up sonography and then periodic sonographic surveillance may represent appropriate management.²⁻⁴ Similar data have been reported for clustered microcysts, but these data are less strong because they involve many fewer cases.² The use of assessment category 3 for sonographic findings other than these three should be considered only if the radiologist has personal experience to justify a watchful-waiting approach, preferably involving observation of a sufficient number of cases of an additional sonographic finding to suggest a likelihood of malignancy within the defined (≤ 2%) probably benign range.*

This edition of the BI-RADS® Atlas also emphasizes the recommendation that a category 3 assessment should not be made at screening; rather, this should be done only after completion of a full diagnostic breast imaging examination. This recommendation is appropriate for screening mammography, for which batch interpretation usually is utilized, because in this setting there is no opportunity to complete the diagnostic workup before interpreting the screening examination. However, screening US almost always is interpreted online, so a full diagnostic examination also is completed while the patient remains in the breast imaging facility, and a single breast imaging report may be issued that combines the findings of both screening and diagnostic components of the examination. Hence, there is no purpose in recommending against category 3 assessment at screening US because the diagnostic workup would be completed simultaneously. This issue is discussed in more detail in Frequently Asked Question #2 for US in the Follow-up and Outcome Monitoring section, see FOM on page 62). Note that for auditing purposes, the screening component of a category 3-assessed screening US examination will be audit-positive, not only because additional nonstandard (diagnostic) images will be recorded but also because a category 3 assessment at screening is defined as being audit-positive.

For category 3 assessments, the initial short-term follow-up interval is usually 6 months, involving the breast(s) containing the probably benign finding(s). Assuming stability at this 6-month examination, a category 3 assessment again is rendered with a management recommendation for a second short-interval follow-up examination in 6 months. Again assuming stability at this second short-interval follow-up, the examination is once more assessed as category 3, but now the recommended follow-up interval usually is lengthened to 1 year due the already-observed 12-month stability. Note that although the 1-year follow-up coincides with the routine screening interval in the United States, a category 3 assessment is rendered, to indicate that the period of imaging surveillance is still underway. As with surveillance using mammography, after 2–3 years of stability, the final assessment category should be changed to benign (BI-RADS® category 2). A benign evaluation may also be rendered before completion of category 3 analysis if, in the opinion of the interpreter, the finding has no chance of malignancy and is thus a category 2.

Category 4: Suspicious

This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy. The ceiling for category 3 assessment is a 2% likelihood of malignancy, and the floor for category 5 assessment is 95%, so category 4 assessments cover the wide range of likelihood of malignancy in between. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this category. By subdividing category 4 into 4A, 4B, and 4C, as recommended in and using the cut points indicated in the Guidance chapter, it is hoped that patients and referring clinicians will more readily make informed decisions on the ultimate course of action. An example of separating the BI-RADS® assessment category from the management recommendation (new to fifth edition — see Follow-up and Outcome Monitoring section) occurs when a simple cyst, correctly assessed as BI-RADS® 2, undergoes cyst aspiration for pain control.

Category 5: Highly Suggestive of Malignancy

These assessments carry a very high probability (≥ 95%) of malignancy. This category initially was established to involve lesions for which 1-stage surgical treatment could be considered without preliminary biopsy in an era when preoperative wire localization was the primary breast interventional procedure. Nowadays, given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery rarely if ever is performed. Rather, current oncologic management almost

always involves tissue diagnosis of malignancy via percutaneous tissue sampling to facilitate treatment options, such as when sentinel node imaging is included in surgical management or when neoadjuvant chemotherapy is administered prior to surgery. Therefore, the current rationale for using a category 5 assessment is to identify lesions for which any nonmalignant percutaneous tissue diagnosis is considered discordant, resulting in the recommendation for repeat (usually vacuum-assisted or surgical) biopsy. Also note that whereas the fourth edition simply indicated that "appropriate action should be taken" as management for category 5 assessments, the fifth edition provides the more directed management recommendation that "biopsy should be performed in the absence of clinical contraindication." This new text unequivocally specifies tissue diagnosis as the interpreting physician's management recommendation for category 5 assessments, appropriately and effectively transferring the burden of establishing a contraindication to this recommendation to the referring clinician.

Category 6: Known Biopsy-Proven Malignancy

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy but prior to surgical excision), in which there are no abnormalities other than the known cancer that might need additional evaluation.

C. WORDING THE REPORT

When performed concurrently, breast US examinations are sometimes reported separately from mammography examinations and sometimes reported as part of a combined examination. In both situations, the current examination should be compared to prior examination(s) when appropriate. The indication for examination, such as screening or diagnostic (targeted), should be stated. The report should be organized with a brief description of the composition of the breast (screening only) and any pertinent findings, followed by the assessment and management recommendations. *Any verbal discussions between the interpreting physician and the referring clinician or patient should be documented in the original report or in an addendum to the report.*

The report should be succinct, using terminology from the latest approved lexicon without embellishment. Definitions of lexicon terms for mammographic findings should not appear in the report narrative. Following the impression section and the (concordant) management recommendation section of the report, both the assessment category number and text for the assessment category should be stated. Other aspects of the report should comply with the <u>ACR Practice Guideline for Communication of Diagnostic Imaging Findings.</u>⁵

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