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Revised 2018 (Resolution 27)\*

## **ACR–ACOG–AIUM–SMFM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF STANDARD DIAGNOSTIC OBSTETRICAL ULTRASOUND**

### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the practice parameters when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these practice parameters will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these practice parameters is to assist practitioners in achieving this objective.

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<sup>1</sup> *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, \_\_\_ N.W.2d \_\_\_ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Classification of Fetal Ultrasound Examinations, Specifications of the Examination, Equipment Specifications, and Fetal Safety) were revised collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal Fetal Medicine (SMFM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, Written Request for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the organizations and are addressed by each separately.

This practice parameter has been developed for use by practitioners performing obstetrical ultrasound studies. Obstetrical ultrasound<sup>2</sup> should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information [1-3].

While this practice parameter describes the key elements of standard ultrasound examinations in the first, second, and third trimesters of pregnancy, a more detailed fetal anatomic examination may be necessary in some cases, such as when an abnormality is found or suspected on the standard examination or in pregnancies at high risk for fetal anomalies [4]. In some cases, other imaging may be necessary as well.

While it is not possible to detect all structural congenital anomalies with diagnostic ultrasound, adherence to the following practice parameters will increase the likelihood of detecting many fetal abnormalities.

## II. CLASSIFICATION OF FETAL ULTRASOUND EXAMINATIONS

### A. Standard First Trimester Ultrasound Examination

A standard obstetrical ultrasound examination in the first trimester includes evaluation of the presence, size, location, and number of gestational sac(s). The gestational sac is examined for the presence of yolk sac and embryo/fetus (a fetus is generally defined as greater than or equal to 10 weeks gestational age) [5]. When an embryo/fetus is detected, it should be measured, and the cardiac activity should be recorded by 2-D video clip or M-mode. The routine use of pulsed Doppler ultrasound to either document or “listen” to embryonic/fetal cardiac activity is discouraged [6,7]. The uterus, cervix, adnexa, and cul-de-sac region should be examined.

### B. Standard Second or Third Trimester Ultrasound Examination

An obstetrical ultrasound in the second or third trimester includes an evaluation of fetal number, cardiac activity, presentation, amniotic fluid volume, placental position, fetal biometry, and an anatomic survey. The maternal cervix and adnexa should be examined.

### C. Limited Ultrasound Examination

A limited obstetric ultrasound examination is performed to answer a specific, acute clinical question when an immediate impact on management is anticipated and when time or other constraints make performance of a standard ultrasound impractical or unnecessary. If a limited obstetric ultrasound is performed on a woman who has not previously had a standard or detailed ultrasound examination, a subsequent standard or detailed ultrasound should be obtained where appropriate. In patients who require serial ultrasounds and have already had a standard or detailed scan, some will only need limited scans, whereas others will require standard or detailed follow-up examinations. Clinical judgement should be used to determine the proper type of ultrasound examination to perform and the appropriate frequency for follow-up ultrasound examinations [8].

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<sup>2</sup>The consensus of the committee was that the use of the terms “ultrasound” or “sonography” is at the discretion of each organization.

## D. Specialized Ultrasound Examination

A detailed anatomic examination is performed for women at risk for fetal anatomic or karyotypic abnormalities (advanced maternal age, maternal medical complications of pregnancy, or pregnancy after assisted reproductive technology) or when an anomaly is suspected on the basis of history, abnormal biochemical markers, or the results of either the limited or standard scan [4].

Other specialized ultrasound scans may include fetal echocardiogram, biophysical profile and fetal Doppler ultrasound, or additional biometric measurements including nuchal translucency (NT) and cervical length [9-14].

## III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations](#) [15].

## IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for an obstetrical ultrasound examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

## V. SPECIFICATIONS OF THE EXAMINATION

### A. Standard First Trimester Ultrasound Examination

1. Indications for first trimester<sup>3</sup> ultrasound examinations include, but are not limited to:
  - a. Confirmation of the presence of an intrauterine pregnancy [16,17]
  - b. Confirmation of cardiac activity [18-22]
  - c. Estimation of gestational age [23-25]
  - d. Diagnosis or evaluation of multiple gestations including determination of chorionicity [26-28]
  - e. Evaluation of a suspected ectopic pregnancy [29,30]
  - f. Evaluating the cause of vaginal bleeding
  - g. Evaluation of pelvic pain
  - h. Evaluation of suspected gestational trophoblastic disease
  - i. Assessing for certain fetal anomalies, such as anencephaly[31-35]
  - j. Measuring the NT [11,12,36-38] when part of a screening program for fetal aneuploidy
  - k. Imaging as an adjunct to chorionic villus sampling, embryo transfer, and localization and removal of an intrauterine device
  - l. Evaluation of maternal pelvic masses and/or uterine abnormalities

### 2. Imaging parameters

Scanning in the first trimester may be performed either transabdominally or transvaginally. If a transabdominal examination is not definitive, a transvaginal or transperineal scan is recommended.

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<sup>3</sup>For the purpose of this document, first trimester represents 1w-13w + 6d.

- a. The uterus (including the cervix) and adnexa should be evaluated for the presence of a gestational sac. If a gestational sac is seen, its location should be documented. The gestational sac should be evaluated for the presence or absence of a yolk sac or embryo/fetus, and the crown-rump length should be recorded, when possible [17,23-25].

A definitive diagnosis of intrauterine pregnancy can be made when an intrauterine gestational sac containing a yolk sac or embryo/fetus with or without cardiac activity is visualized. In very early intrauterine pregnancy, small, eccentric intrauterine fluid collection with an echogenic rim can be seen before the yolk sac and embryo. In the absence of sonographic signs of ectopic pregnancy, the fluid collection is highly likely to represent an intrauterine gestational sac. Follow-up ultrasound and/or serial determination of maternal serum HCG (human chorionic gonadotropin) levels are appropriate in pregnancies of undetermined location to avoid inappropriate intervention in a potentially viable early pregnancy [16,19,20].

Caution should be used in making the presumptive diagnosis of a gestational sac in the absence of a definite yolk sac or embryo. If the embryo is not identified, the mean sac diameter may be useful for determining timing of ultrasound follow up. However, the crown-rump length is a more accurate indicator of gestational age than the mean gestational sac diameter.

- b. Presence or absence of cardiac activity should be documented with a 2-D video clip or M-mode [7].

With transvaginal scans, cardiac motion is usually observed when the embryo is 2 mm or greater in length; if an embryo less than 7 mm in length is seen without cardiac activity, a subsequent scan in one week is recommended to ensure that the pregnancy is nonviable [18-22].

- c. Fetal number should be documented.

Amnionicity and chorionicity should be documented for all multiple gestations [26-28].

- d. Appropriate fetal anatomy for the first trimester should be assessed and include the calvarium, fetal abdominal cord insertion, and presence of limbs when fetus is of sufficient size [31-35].
- e. The nuchal region should be imaged, and abnormalities such as cystic hygroma should be documented.

For those patients desiring to assess their individual risk of fetal aneuploidy, a very specific measurement of the NT during a specific age interval is necessary (as determined by the laboratory used). See the guidelines for this measurement below.

NT measurements should be used (in conjunction with serum biochemistry) to determine the risk for having a fetus with aneuploidy or other abnormalities [36-41].

In this setting, it is important that the practitioner measure the NT according to established guidelines. A quality assessment program is recommended to ensure that false-positive and false-negative results are kept to a minimum [11,12].

Guidelines for NT measurement:

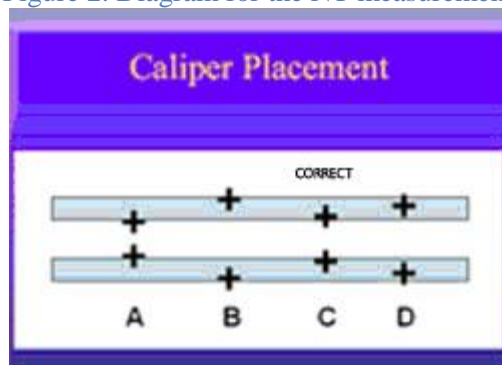
- i. The margins of the NT edges must be clear with the angle of insonation perpendicular to the NT line.
- ii. The fetus must be in the midsagittal plane. The tip of the nose, palate, and diencephalon should be seen.
- iii. The image must be magnified so that it is filled by the fetal head, neck, and upper thorax.
- iv. The fetal neck must be in a neutral position, with the head in line with the spine, not flexed and not hyperextended.

- v. The amnion must be seen as separate from the NT line.
- vi. The (+) calipers on the ultrasound must be used to perform the NT measurement.
- vii. Electronic calipers must be placed on the inner borders of the nuchal line with none of the horizontal crossbar itself protruding into the space.
- viii. The calipers must be placed perpendicular to the long axis of the fetus.
- ix. The measurement must be obtained at the widest space of the NT.

**Figure 1. Ultrasound image of NT measurement**



**Figure 2. Diagram for the NT measurement.**



- f. The uterus, including the cervix, adnexal structures, and cul-de-sac, should be evaluated. Abnormalities should be imaged and documented.

The presence, location, appearance, and size of adnexal masses should be documented. The presence and number of leiomyomata should be documented. The measurements of the largest or any potentially clinically significant leiomyomata should be documented. The cul-de-sac should be evaluated for the presence or absence of fluid. Uterine anomalies should be documented.

#### B. Standard Second and Third Trimester Ultrasound Examination [17]

- 1. These examinations are commonly performed to assess fetal anatomy and biometry. Other indications include but are not limited to:
  - a. Screening for fetal anomalies [42-46]
  - b. Evaluation of fetal anatomy [47-56]
  - c. Estimation of gestational age [42]
  - d. Evaluation of suspected multiple gestation

- e. Evaluation of cervical length [13,14,57-61]
- f. Evaluation of fetal growth [62-65]
- g. Evaluation of significant discrepancy between uterine size and clinical dates
- h. Determination of fetal presentation
- i. Evaluation of fetal well-being
- j. Suspected amniotic fluid abnormalities [66-68]
- k. Evaluation of premature rupture of membranes and/or premature labor
- l. Evaluation of vaginal bleeding
- m. Evaluation of abdominal or pelvic pain
- n. Suspected placental abruption
- o. Suspected fetal death
- p. Follow-up evaluation of a fetal anomaly
- q. Evaluation/follow-up of placental appearance and location. Includes suspected placenta previa, vasa previa, and abnormally adherent placenta
- r. Adjunct to amniocentesis or other procedure
- s. Adjunct to external cephalic version
- t. Evaluation of suspected gestational trophoblastic disease
- u. Evaluation of pelvic mass
- v. Suspected uterine anomalies

In certain clinical circumstances, a more detailed examination of fetal anatomy may be indicated [4].

## 2. Imaging parameters for a standard fetal examination

- a. Fetal cardiac activity (by video clip or M-mode), fetal number, and presentation should be documented.

Abnormal heart rate and/or rhythm should be documented

Multiple gestations require the documentation of additional information: chorionicity, amnionicity, comparison of fetal sizes, evaluation of amniotic fluid volume in each gestational sac, and fetal genitalia (when visualized).

- b. A qualitative or semiquantitative estimate of amniotic fluid volume should be documented.

Although it is acceptable for experienced examiners to qualitatively estimate amniotic fluid volume, semiquantitative methods have also been described for this purpose (eg, amniotic fluid index [AFI], single deepest pocket, and two-diameter pocket). In assessing oligohydramnios, the deepest vertical pocket (<2 cm) is preferred over AFI ( $\leq 5$  cm) because it results in fewer obstetrical interventions without a significant difference in perinatal outcome, and single deepest pocket should be at least 1-cm wide [66-69]. Polyhydramnios (deepest vertical pocket  $\geq 8$  cm or AFI  $\geq 24$  cm) may be associated with other pregnancy complications [69].

- c. The placental location, appearance, and relationship to the internal cervical os should be documented. The umbilical cord should be imaged, and the number of vessels in the cord documented. The placental cord insertion site should be documented when technically possible [70,71].

It is recognized that apparent placental position early in pregnancy may not correlate well with its location at the time of delivery.

Transvaginal or transperineal ultrasound should be performed if the relationship between the cervix and the placenta cannot be assessed.

A velamentous (also called membranous) placental cord insertion that crosses the internal os of the cervix is suspicious for a vasa previa, a condition that has a high risk of fetal mortality if not

diagnosed prior to labor [72-74]. Color and pulsed Doppler ultrasound should be performed to assess vasa previa or abnormal placenta cord insertion [75].

d. Gestational age assessment

First-trimester crown-rump measurement is the most accurate means for sonographic dating of pregnancy. Beyond this period, a variety of sonographic parameters such as biparietal diameter, abdominal circumference, and femoral diaphysis length can be used to estimate gestational age. It should be noted that abdominal circumference is the least reliable of these measurements for estimating gestational age [76,77]. The variability of gestational age estimation, however, increases with advancing pregnancy. Significant discrepancies between gestational age and fetal measurements may suggest the possibility of a fetal growth abnormality [62-65].

The pregnancy should NOT be redated after an accurate earlier scan has been performed and is available for comparison [78,79].

- i. Biparietal diameter is measured at the level of the thalami and cavum septi pellucidi [80]. The cerebellar hemispheres should not be visible in this scanning plane. The measurement is typically measured from the outer edge of the proximal skull to the inner edge of the distal skull.

The head shape may be elongated (dolichocephaly) or rounded (brachycephaly) as a normal variant. Under these circumstances, certain variants of normal fetal head development may make measurement of the head circumference more reliable than biparietal diameter for estimating gestational age.

- ii. Head circumference is measured at the same level as the biparietal diameter, around the outer perimeter of the bony calvarium, excluding subcutaneous tissues of the skull. This measurement is not affected by head shape.
- iii. Femoral diaphysis length can be reliably used after 14 weeks' gestational age. The long axis of the femoral shaft is most accurately measured with the beam of insonation being perpendicular to the shaft, excluding the distal femoral epiphysis.
- iv. Abdominal circumference or average abdominal diameter should be determined at the skin line on a true transverse view at the level of the junction of the umbilical vein, portal sinus, and fetal stomach when visible.

e. Fetal weight estimation

Fetal weight can be estimated from measurements such as the biparietal diameter, head circumference, abdominal circumference or average abdominal diameter, and femoral diaphysis length [81,82]. Results from various prediction models can be subsequently compared to fetal weight percentiles from published nomograms [62-65,83,84].

If previous studies have been performed, appropriateness of growth should also be documented. Scans for growth evaluation can typically be performed at least 3 weeks apart. A shorter scan interval may result in confusion as to whether measurement changes are truly due to growth as opposed to variations in the technique itself [85,86].

Currently, even the best fetal weight prediction methods can yield errors as high as  $\pm 15\%$  [87].

f. Maternal anatomy

Evaluation of the uterus, adnexal structures, and cervix should be performed.

The presence, location, and size of adnexal masses and the presence of at least the largest and potentially clinically significant leiomyomata should be documented. It is not always possible to image the normal maternal ovaries during the second and third trimesters.

If the cervix appears abnormal (shortened or funneled) or is not adequately visualized during the transabdominal ultrasound, a transvaginal or transperineal scan is recommended when evaluation of the cervix is needed [13,14,59,88].

If a referring health provider desires a precise cervical-length measurement, a transvaginal measurement of the cervix should be performed [13,14,57-61].

A midline lower uterine segment contraction may obscure the internal os, giving the false impression of a longer endocervical canal. Excessive manual pressure with the ultrasound transducer may also falsely elongate the cervix.

**Table 3. Criteria for cervical-length measurement**

<b>CRITERIA</b>
Bladder empty; transvaginal scan
Cervix fills up 75% of available image space
Anterior and posterior cervix are of equal thickness
Internal and External Cervical os are seen
Endocervical canal is seen throughout
Calipers placed at the internal and external os where the anterior and posterior walls of the cervix meet. If the endocervical canal curves, two or more linear measurements should be used and added together to obtain the cervical length. Shortest best measurement reported.
Dynamic cervical shortening- examination time 3-5 minutes and/or suprapubic/fundal pressure.
<b>Report shortest best measurement</b>

Figure 4. Transvaginal cervical-length measurement



g. Fetal anatomic survey

Fetal anatomy, as described in this document, may be adequately assessed by ultrasound after approximately 18 weeks gestational age. It may be possible to document normal structures before this time, although some structures can be difficult to visualize because of fetal size, position, movement, abdominal scars, and increased maternal abdominal wall thickness [89-92]. A second or third



trimester scan may pose technical limitations for an anatomic evaluation due to imaging artifacts from acoustic shadowing. When this occurs, the report of the ultrasound examination should document the nature of this technical limitation. A follow-up examination may be helpful.

The following areas of assessment represent the minimal elements of a standard examination of fetal anatomy. A more detailed fetal anatomic examination may be necessary if an abnormality or suspected abnormality is found on the standard examination.

- i. Head, face, and neck
  - Lateral cerebral ventricles
  - Choroid plexus
  - Midline falx
  - Cavum septi pellucidi
  - Cerebellum
  - Cisterna magna
  - Upper lip

A measurement of the nuchal fold may be helpful during a specific age interval (approximately 16 to 20 weeks gestational age) to assess the risk of aneuploidy [93].

- ii. Chest
  - Heart [94]
    - Four-chamber view, heart size and position
    - Left ventricular outflow tract
    - Right ventricular outflow tract
    - Three-vessel view and three-vessel trachea view, if technically feasible [51-56]
- iii. Abdomen
  - Stomach (presence, size, and situs)
  - Kidneys
  - Urinary bladder
  - Umbilical cord insertion site into the fetal abdomen
  - Umbilical cord vessel number
- iv. Spine
  - Cervical, thoracic, lumbar, and sacral spine
- v. Extremities
  - Presence of legs and arms
  - Presence of hands and feet
- vi. External Genitalia
  - In multiple gestations and when medically indicated

## VI. DOCUMENTATION

Adequate documentation of the study is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should generally be accompanied by measurements. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements [95].

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [96].

## **VII EQUIPMENT SPECIFICATIONS**

These studies should be conducted with real-time scanners, using a transabdominal and/or transvaginal approach. A transducer of appropriate frequency should be used. Real time ultrasound is necessary to confirm the presence of fetal life through observation of cardiac activity and active movement.

The choice of transducer frequency is a trade-off between beam penetration and resolution. With modern equipment,  $\geq 3$  MHz abdominal transducers allow sufficient penetration in most patients while providing adequate resolution. During early pregnancy, transvaginal ultrasound may provide superior resolution while still allowing adequate penetration.

## **VIII. FETAL SAFETY**

Diagnostic ultrasound studies of the fetus are generally considered to be safe during pregnancy [1,2,97-100]. This diagnostic procedure should be performed only when there is a valid medical indication, and the lowest possible ultrasonic exposure setting should be used to gain the necessary diagnostic information under the “as low as reasonably achievable” (ALARA) principle [1-3,6,7,97-100].

A thermal index for soft tissue (TIs) should be used at  $< 10$  weeks’ gestation and a thermal index for bone (Tib) should be used at  $\geq 10$  weeks’ gestation when bone ossification is evident [3]. In keeping with the ALARA principle, spectral Doppler ultrasound should not be used unless clinically indicated [6,101].

The promotion, selling, or leasing of ultrasound equipment for making “keepsake fetal videos” is considered by the U.S. Food and Drug Administration to be an unapproved use of a medical device [101-103]. Use of a diagnostic ultrasound system for these purposes, without a physician’s order, may be in violation of state laws or regulations [102].

## **IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION**

All probes should be cleaned after use. Vaginal probes should be covered by a protective sheath prior to insertion. Following the examination, the sheath should be disposed of and the probe cleaned with a high-level disinfectant according to the manufacturer and local infectious disease recommendations.

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards>).

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [15].

## ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (<https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards>) by the Committee on Practice Parameters – Ultrasound of the ACR Commission on Ultrasound, in collaboration with the AIUM, the ACOG, the SMFM, and the SRU.

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\*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

#### Development Chronology for this Practice Parameter

- 1990 (Resolution 5)
- Revised 1995 (Resolution 35)
- Revised 1999 (Resolution 37)
- Revised 2003 (Resolution 19)
- Amended 2006 (Resolution 35)
- Revised 2007 (Resolution 25)
- Revised 2013 (Resolution 17)
- Amended 2014 (Resolution 39)
- Revised 2018 (Resolution 27)