

AIUM Practice Guideline for the Performance of a

Focused Reproductive Endocrinology and Infertility Scan

Guideline developed in conjunction the American College of Nurse-Midwives (ACNM), the American College of Obstetricians and Gynecologists (ACOG), the American College of Osteopathic Obstetricians and Gynecologists (ACOOG), the American Society for Reproductive Medicine–Society for Reproductive Endocrinology and Infertility (ASRM-SREI), and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN).



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AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

The American Institute of Ultrasound in Medicine (AIUM) is a multi-disciplinary association dedicated to advancing the safe and effective use of ultrasound in medicine through professional and public education, research, development of guidelines, and accreditation. To promote this mission, the AIUM is pleased to publish, in conjunction with the American College of Nurse-Midwives (ACNM), the American College of Obstetricians and Gynecologists (ACOG), the American College of Osteopathic Obstetricians and Gynecologists (ACOOG), the American Society for Reproductive Medicine–Society for Reproductive Endocrinology and Infertility (ASRM-SREI), and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN), this *AIUM Practice Guideline for the Performance of a Focused Reproductive Endocrinology and Infertility Scan*. We are indebted to the many volunteers who contributed their time, knowledge, and energy to bringing this document to completion.

The AIUM represents the entire range of clinical and basic science interests in medical diagnostic ultrasound, and, with hundreds of volunteers, the AIUM has promoted the safe and effective use of ultrasound in clinical medicine for more than 50 years. This document and others like it will continue to advance this mission.

Practice guidelines of the AIUM are intended to provide the medical ultrasound community with guidelines for the performance and recording of high-quality ultrasound examinations. The guidelines reflect what the AIUM considers the minimum criteria for a complete examination in each area but are not intended to establish a legal standard of care. AIUM-accredited practices are expected to generally follow the guidelines with recognition that deviations from these guidelines will be needed in some cases, depending on patient needs and available equipment. Practices are encouraged to go beyond the guidelines to provide additional service and information as needed.



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I. Introduction

The clinical aspects contained in specific sections of this guideline (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American Institute of Ultrasound in Medicine (AIUM), the American College of Nurse-Midwives (ACNM), the American College of Obstetricians and Gynecologists (ACOG), the American College of Osteopathic Obstetricians and Gynecologists (ACOOG), the American Society for Reproductive Medicine–Society for Reproductive Endocrinology and Infertility (ASRM-SREI), and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN). Recommendations for practitioner requirements, written request for the examination, procedure documentation, and quality control vary among the 6 organizations and are addressed by each separately.

This guideline has been developed to provide assistance to practitioners performing focused ultrasound studies of the female pelvis in the practice of reproductive medicine and infertility. In some cases, additional and/or specialized examinations may be necessary. While it is not possible to detect every abnormality, adherence to the following will maximize the probability of detecting most of the abnormalities that occur.

II. Indications

Indications for an ultrasound examination for a focused reproductive endocrinology and infertility scan include, but are not limited to, monitoring of ovulation induction and ovarian stimulation.

III. Qualifications and Responsibilities of the Physician

See www.aium.org for AIUM Official Statements including *Standards and Guidelines for the Accreditation of Ultrasound Practices* and relevant Physician Training Guidelines.

IV. Written Request for the Examination

The written or electronic request for an ultrasound examination should provide sufficient information to allow for the appropriate performance and interpretation of the examination. When an ultrasound examination is performed within a practice as part of established patient care, the indication for the examination should be documented, but a formal request is not needed.

A request for an ultrasound examination must be originated by a physician or other appropriately licensed health care provider or under the provider’s direction. The accompanying clinical information should be provided by a physician or other appropriate health care provider familiar with the patient’s clinical situation and should be consistent with relevant legal and local health care facility requirements.

V. Specifications of the Examination

The following guidelines describe the examination to be performed for each organ and anatomic region in the female pelvis. Whenever possible, all relevant structures should be identified by the vaginal approach. When a transvaginal scan fails to image all areas needed for diagnosis, a transabdominal scan should be performed. In some cases, both a transabdominal and a transvaginal scan may be needed.

General Pelvic Preparation

For a pelvic ultrasound examination performed transabdominally, the patient's urinary bladder should, in general, be distended adequately to displace the small bowel and its contained gas from the field of view. Occasionally, overdistension of the bladder may compromise evaluation. When this occurs, imaging may be repeated after the patient partially empties her bladder.

For a transvaginal sonogram, the urinary bladder is preferably empty. The patient, the sonographer, or the practitioner may introduce the transvaginal transducer, preferably under real-time monitoring. Transvaginal sonography is a specialized form of a pelvic examination. Therefore, policies applied locally regarding chaperone or patient privacy issues during a pelvic examination should also be applied during a transvaginal ultrasound examination.

Focused Reproductive Endocrinology and Infertility Examination

A focused pelvic ultrasound examination is appropriate when monitoring ovarian stimulation (eg, an ovarian folliculogram study or determining endometrial qualities before embryo transfer). A comprehensive examination should have previously been performed in the preceding 4 to 6 months to rule out other gynecologic pathology. The limited examination can be restricted to the organ or measurements of interest. In the case of an ovarian folliculogram, the following should be documented: ovarian follicle number in each ovary, endometrial thickness, and endometrial morphologic appearance. Endometrial thickness is measured from outside to outside in an anterior-posterior view at the widest point. In addition, follicular diameters in 2 dimensions for each follicle larger than 10 mm should be recorded. A single recorded value representing the mean of 2 diameter measurements performed at right angles is also acceptable. Permanent recorded images should be obtained and stored in accordance with local, state, and federal regulations. Pertinent clinical information should be recorded in the patient record.

VI. Documentation

Adequate documentation is essential for high-quality patient care. A permanent record of the ultrasound examination and its interpretation should be kept by the facility performing the study. Images of all appropriate areas, both normal and abnormal, should be recorded. Variations from normal size should be accompanied by measurements. Images are to be appropriately labeled with the examination date, facility name, and, when appropriate, organ imaged. A report of the ultrasound findings should be included in the patient's medical record. Urgent

or clinically important unexpected results should be communicated verbally to any referring and/or treating provider and this communication documented in the report. Retention of the permanent record of the ultrasound examination should be consistent both with clinical needs and with the relevant legal and local health care facility requirements.

VII. Equipment Specifications

Equipment

An ultrasound examination of the female pelvis should be conducted with a real-time scanner, with the appropriate transabdominal and transvaginal transducers. The transducer or scanner should be adjusted to operate at the highest clinically appropriate frequency, realizing that there is a trade-off between resolution and beam penetration. With modern equipment, studies performed from the anterior abdominal wall can usually use frequencies of 3.5 MHz or higher, while scans performed from the vagina should use frequencies of 5 MHz or higher.

Care of the Equipment

All probes should be cleaned after each patient examination. Transvaginal probes should be covered by a protective sheath before insertion. Patients should be questioned about a latex allergy before use of a latex sheath. After each examination, the sheath should be discarded, and the probe should be washed, dried, and appropriately disinfected (see “Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers Between Patients”). The type of antimicrobial solution and the methods for disinfection depend on manufacturer and infectious disease recommendations.

VIII. Quality Control and Improvement, Safety, Infection Control, and Patient Education

Policies and procedures related to quality control, patient education, infection control, and safety should be developed and implemented in accordance with the *AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices*.

Equipment performance monitoring should be in accordance with the *AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices*.

IX. ALARA Principle

The potential benefits and risks of each examination should be considered. The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output and by considering transducer dwell times. Further details on ALARA may be found in the AIUM publication *Medical Ultrasound Safety, Second Edition*.

Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers Between Patients

Previously published by the AIUM

The purpose of this document is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes.

All sterilization/disinfection represents a statistical reduction in the number of microbes present on a surface. Meticulous cleaning of the instrument is the essential key to an initial reduction of the microbial/organic load by at least 99%. This cleaning is followed by a disinfecting procedure to ensure a high degree of protection from infectious disease transmission, even if a disposable barrier covers the instrument during use.

Medical instruments fall into different categories with respect to potential for infection transmission. The most critical level of instruments is that which is intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called “semicritical” instruments) that simply come into contact with mucous membranes such as fiber-optic endoscopes require high-level disinfection rather than sterilization.

Although endocavitary ultrasound probes might be considered even less critical instruments because they are routinely protected by single-use disposable probe covers, leakage rates of 0.9% to 2% for condoms and 8% to 81% for commercial probe covers have been observed in recent studies. For maximum safety, one should therefore perform high-level disinfection of the probe between each use and use a probe cover or condom as an aid to keeping the probe clean.

There are 4 generally recognized categories of disinfection and sterilization. Sterilization is the complete elimination of all forms or microbial life, including spores and viruses. Disinfection, the selective removal of microbial life, is divided into 3 classes:

High-Level Disinfection—Destruction/removal of all microorganisms except bacterial spores.

Mid-Level Disinfection—Inactivation of *Mycobacterium tuberculosis*, bacteria, most viruses, and most fungi and some bacterial spores.

Low-Level Disinfection—Destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate *M tuberculosis* or bacterial spores.

The following specific recommendations are made for the use of endocavitary ultrasound transducers. Users should also review the Centers for Disease Control and Prevention document on sterilization and disinfection of medical devices to be certain that their procedures conform to the Centers for Disease Control and Prevention principles for disinfection of patient care equipment.

1. **Cleaning**—After removal of the probe cover, use running water to remove any residual gel or debris from the probe. Use a damp gauze pad or other soft cloth and a small amount of mild nonabrasive liquid soap (household dishwashing liquid is ideal) to thoroughly cleanse the transducer. Consider the use of a small brush especially for crevices and areas of angulation depending on the design of your particular transducer. Rinse the transducer thoroughly with running water, and then dry the transducer with a soft cloth or paper towel.

2. **Disinfection**—Cleaning with a detergent/water solution as described above is important as the first step in proper disinfection because chemical disinfectants act more rapidly on clean surfaces. However, the additional use of a high-level liquid disinfectant will ensure further statistical reduction in the microbial load. Because of the potential disruption of the barrier sheath, additional high-level disinfection with chemical agents is necessary. Examples of such high level disinfectants include but are not limited to:
 - a. 2.4% to 3.2% glutaraldehyde products (a variety of available proprietary products, including Cidex, Metricide, and Procide);
 - b. Nonglutaraldehyde agents, including Cidex OPA (*o*-phthalaldehyde) and Cidex PA (hydrogen peroxide and peroxyacetic acid);
 - c. 7.5% hydrogen peroxide solution; and
 - d. Common household bleach (5.25% sodium hypochlorite) diluted to yield 500 parts per million chlorine (10 mL in 1 L of tap water). This agent is effective but generally not recommended by probe manufacturers because it can damage metal and plastic parts.

Other agents such as quaternary ammonium compounds are not considered high-level disinfectants and should not be used. Isopropanol is not a high-level disinfectant when used as a wipe, and probe manufacturers generally do not recommend soaking probes in the liquid.

The US Food and Drug Administration has published a list of approved sterilants and high-level disinfectants for reprocessing reusable medical and dental devices. That list can be consulted to identify agents that may be useful for probe disinfection.

Practitioners should consult the labels of proprietary products for specific instructions. They should also consult instrument manufacturers regarding compatibility of these agents with probes. Many of the chemical disinfectants are potentially toxic, and many require adequate precautions such as proper ventilation, personal protective devices (eg, gloves and face/eye protection) and thorough rinsing before reuse of the probe.

3. **Probe Covers**—The transducer should be covered with a barrier. If the barriers used are condoms, these should be nonlubricated and nonmedicated. Practitioners should be aware that condoms have been shown to be less prone to leakage than commercial probe covers and have a 6-fold enhanced acceptable quality level when compared to standard examination gloves. They have an acceptable quality level equal to that of surgical gloves. Users should be aware of latex sensitivity issues and have non-latex-containing barriers available.
4. **Aseptic Technique**—For the protection of the patient and the health care worker, all endocavitary examinations should be performed with the operator properly gloved throughout the procedure. Gloves should be used to remove the condom or other barrier from the transducer and to wash the transducer as outlined above. As the barrier (condom) is removed, care should be taken not to contaminate the probe with secretions from the patient. At the completion of the procedure, hands should be thoroughly washed with soap and water.

Note: Obvious disruption in condom integrity does not require modification of this protocol. These guidelines take into account possible probe contamination due to a disruption in the barrier sheath.

In summary, routine high-level disinfection of the endocavitary probe between patients, plus the use of a probe cover or condom during each examination, is required to properly protect patients from infection during endocavitary examinations. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant.

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Suggested Reading

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