LIVE SCANNING FOR EDUCATIONAL PURPOSES

AIUM Resource Materials Related to
Ultrasound Demonstrations on Human Subjects

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MESSAGE TO THE ULTRASOUND COMMUNITY

Background

In a letter dated December 5, 2016, the FDA discouraged the "use of ultrasound scanning on live models for the purpose of device demonstration," citing concerns with "repetitive and prolonged exposures on a single individual, with no medical need, without a prescription, and with no interpretation of the resultant images by a licensed practitioner." Although the AIUM does not condone the scanning of human subjects for the sole purpose of marketing or without clear guidelines to manage scanning activities, the AIUM and many other stakeholders in the ultrasound community expressed deep concerns over the impact such a statement could have on educational and research activities.

On February 23, 2017, the AIUM met with FDA representatives to clarify the FDA's intent. The AIUM received the following guidance, as documented in the FDA's February 27, 2017 "Minutes of the face-to-face meeting with AIUM:"

- The FDA recognized that "formal training is beneficial to the public health" and indicated on multiple occasions that "training was not the subject of the letter;"
- The FDA called upon the AIUM to "define what activities should be considered educational."

Definition of Educational Activities

In response to the FDA's appeal, the AIUM has now formally recognized that scanning, regardless of the venue, provides an opportunity to educate and inform participants about technical advances and the many features available on ultrasound systems while educating them on how to practice according to the ALARA principle. The focus of this document is to provide guidance for scanning during educational meetings and conferences where CME may or may not be provided. The following Official Statement clarifies the AIUM's view of the importance of live scanning for educational purposes and also provides better continuity with the AIUM's other Official Statements that are specific to scanning activities.

Live Scanning for Educational Purposes

Live scanning of human subjects should be permitted only under controlled conditions and only when there is a medical or public health benefit. The education of health care specialists in what are the latest ultrasound technologies, their capabilities, and how best used in these individuals' own hands is a critical exercise for evaluation and for skill development. At the present time, this benefit is very difficult to obtain in any other way, and ultimately benefits future patients.

Examples of Acceptable Educational Activities*

- Provide medical student or other health specialist education.**
- Provide review of scanning protocols in actual clinical scenarios. Get the crowd involved for suggestions and answers; reward participants for correct answers and purposefully make mistakes to test the audience.
- Enlist audience participation by posing questions, such as "what does this _____ finding tell you in the case scenario?" and "what would you suggest we do next."
- Provide and teach to a list of common protocols such as abdominal Doppler, liver studies, renal studies, pancreatitis, echocardiography, shock, trauma, arrest, dyspnea evaluations, extremity venous and arterial studies, and carotid blood flow.
- Develop scenarios that appeal across specialty boundaries, such as "this patient was being scanned in the radiology suite and suddenly..."
- Demonstrate image optimization strategies, such as contests where a difficult image is presented and a clinical scenario attached that offers some pressure; appeal to audience members for suggested adjustments on how to improve the image quality to something more readable.
- Demonstrate how features of the machine can be employed to maximize image quality while minimizing the potential for bioeffects.
- Provide overview of the ALARA Principle.
- Provide instruction on probe selection, orientation and imaging tips, artifacts, pitfalls.
- Demonstrate how to adhere to AIUM practice parameters and improve image acquisition.
- Demonstrate ultrasound measurements using published criteria and automated measurements technologies offered.
- Raise awareness of mechanical (MI) and thermal (TI) indices by pointing out the MI and TI on the screen, and informing viewers how to make those indices appear when not already displayed.
- Advise participants on acceptable values as stated in the AIUM Official Statement "Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values."
- Demonstrate knobology “best practices” by demonstrating how the MI and TI change when the output is adjusted and how increasing Overall Gain and TGC can achieve similar increases in image brightness without changing the MI or TI.

* Not a comprehensive list

** Higher educational programs including medical schools, sonography programs, undergraduate, graduate, and residency programs may contain an ultrasound component that includes live scanning sessions. Such activities should be supervised by an appropriate health care specialist, meet accreditation standards, where applicable, include monitoring of the Output Display Standard, and adhere to AIUM statements regarding safety and ALARA. Additionally, students who engage in peer-to-peer scanning should be informed of safety measures and should always have the option to decline to be scanned.

Note: Gamification conforms to state-of-the-art principles of adult education for the greatest efficiency of learning. As such, gamification is encouraged as it has been shown to enhance the educational experience and increase learning comprehension.

Live Scanning Guidelines/Requirements During AIUM Events

Live scanning of human subjects should be permitted only under controlled conditions and only when there is a medical or public health benefit. As such, adhere to the following guidelines when performing live scanning for educational purposes:

- All live scanning of human subjects must include an educational component.
- All subjects must be pre-scanned by a licensed healthcare specialist and any discovered anomalies or pathology should be reported to the subject with a recommendation to seek a physician's advice.
- All subjects should grant informed consent to the scans after being provided information on the safety and potential biological effects of diagnostic ultrasound and the MI and TI.
- All subjects must be appropriately clothed for the specific scanning activity.
- All equipment will have received FDA clearance and will be used in a manner consistent with its FDA-cleared indications for use. Also, only equipment that has been FDA-cleared for ophthalmic indications will be used to scan the eye during the demonstrations due to the lower FDA recommended maximum output levels and sensitivity of the eye to heating[1].
- Demonstration scans on live, non-pregnant subjects will be performed in a manner consistent with the ALARA principle including limiting the TI (≤0.7) and MI (<1.0) as necessary for demonstration purposes[2].
- If higher exposure conditions are needed for a demonstration, then either (a) a tissue mimicking phantom will be used or (b) the live participant will only be scanned once per day similar to the exposures experienced during clinical practice.
- Scanning of pregnant subjects is only permissible in instances where formal CME credit is issued and must also follow the AIUM Statement: Guidelines for Hands-on Scanning in Pregnant Subjects During AIUM-Sponsored Educational Activities.
- Use of ultrasound contrast agents on human subjects is only permissible in instances where formal CME credit is issued. Tissue mimicking phantoms should be utilized for all other demonstrative activities.
- For live scanning activities where formal CME credit is not issued,
    - Subjects must be at least 18 years of age.
    - Abdominal/pelvic scanning of female subjects is not permissible to avoid pregnancy concerns.
    - A "Participation Form for Live Scanning at AIUM Events" must be completed and returned to the AIUM prior to the scanning activity.

1. Thermal assessment of 40-MHz pulsed Doppler ultrasound in human eye (Cucevic et al, UMB, 31(4), 565-573, 2005).
2. Lung hemorrhage threshold in pigs was between MI of 1 and 1.9 at 3 MHz (O'Brien et al, UMB, 32(11), 1793-1804, 2006).

AIUM Official Statements

As Low As Reasonably Achievable (ALARA) Principle

Approved April 2, 2014

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 acoustical output and by considering transducer dwell times. Further details on ALARA may be found in the AIUM publication *Medical Ultrasound Safety*.

Original approval 3/16/2008; Reapproved 4/2/2014

Statement on Mammalian Biological Effects of Heat

Approved October 30, 2016

1. An excessive temperature increase can result in toxic effects in mammalian systems. The biological effects observed depend on many factors, such as the exposure duration, the type of tissue exposed, its cellular proliferation rate, and its potential for regeneration. Age and stage of development are important factors when considering fetal and neonatal safety. Temperature increases of several degrees Celsius above the normal core range can occur naturally. The probability of an adverse biological effect increases with both the duration and the magnitude of the temperature rise.
2. In general, adult tissues are more tolerant of temperature increases than fetal and neonatal tissues. Therefore, higher temperatures and/or longer exposure durations would be required for thermal damage. The considerable data available on the thermal sensitivity of adult tissues support the following inferences[1]:
    a. For exposure durations up to 50 hours, there have been no significant adverse biological effects observed due to temperature increases less than or equal to 1.5°C above normal.[2]
    b. For temperature increases between 1.5°C and 6°C above normal, there have been no significant adverse biological effects observed due to temperature increases less than or equal to $6 - [\log_{10}(t/60)]/0.6$ where t is the exposure duration in seconds. For example, for temperature increases of 4°C and 6°C, the corresponding limits for the exposure durations t are 16 minutes and 1 minute, respectively.
    c. For temperature increases greater than 6°C above normal, there have been no significant adverse biological effects observed due to temperature increases less than or equal to $6 - [\log_{10}(t/60)]/0.3$ where t is the exposure duration in seconds. For example, for temperature increases of 9.6°C and 6.0°C, the corresponding limits for the exposure durations t are 5 and 60 seconds, respectively.
    d. For exposure durations less than 5 seconds, there have been no significant, adverse biological effects observed due to temperature increases less than or equal to $9 - [\log_{10}(t/60)]/0.3$ where t is the exposure duration in seconds. For example, for temperature increases of 18.3°C, 14.9°C, and 12.6°C, the corresponding limits for the exposure durations t are 0.1, 1, and 5 seconds, respectively.
3. Acoustic output from diagnostic ultrasound devices is sufficient to cause temperature elevations in fetal tissue. Although fewer data are available for fetal tissues, the following conclusions are justified[1,3]:
    a. In general, temperature elevations become progressively greater from B-mode to color Doppler to spectral Doppler applications.
    b. For identical exposure conditions, the potential for thermal bioeffects increases with the dwell time during examination.
    c. For identical exposure conditions, the temperature rise near bone is significantly greater than in soft tissues, and it increases with ossification development throughout gestation. For this reason, conditions in which an acoustic beam impinges on ossifying fetal bone deserve special attention due to its close proximity to other developing tissues.
    d. The current US Food and Drug Administration regulatory limit for the derated spatial-peak temporal-average intensity ($I_{SPTA.3}$) is 720 mW/cm^2. For this exposure, the theoretical estimate of the maximum temperature increase in the conceptus may exceed 1.5°C.
    e. Although an adverse fetal outcome is possible at any time during gestation, most severe and detectable effects of thermal exposure in animals have been observed during the period of organogenesis. For this reason, exposures during the first trimester should be restricted to the lowest outputs consistent with obtaining the necessary diagnostic information.
    f. Ultrasound exposures that elevate fetal temperature by 4°C above normal for 5 minutes or more have the potential to induce severe developmental defects. Thermally induced congenital anomalies have been observed in a large variety of animal species. In current clinical practice, using commercially available equipment, it is unlikely that such thermal exposure would occur at a specific fetal anatomic site provided that the thermal index (TI) is at or below 2.5 and the dwell time on that site does not exceed 4 minutes.

g. Transducer self-heating is a significant component of the temperature rise of tissues close to the transducer. This may be of significance in transvaginal scanning, but no data for the fetal temperature rise are available.

4. The temperature increase during exposure of tissues to diagnostic ultrasound fields is dependent on: (1) output characteristics of the acoustic source, such as frequency, source dimensions, scan rate, output power, pulse repetition frequency, pulse duration, transducer self-heating, exposure time, and wave shape; and (2) tissue properties, such as attenuation, absorption, speed of sound, acoustic impedance, perfusion, thermal conductivity, thermal diffusivity, anatomic structure, and the nonlinearity parameter.
5. Calculations of the maximum temperature increase resulting from ultrasound exposure in vivo are not exact because of the uncertainties and approximations associated with the thermal, acoustic, and structural characteristics of the tissues involved. However, experimental evidence shows that calculations are generally capable of predicting measured values within a factor of 2. Thus, such calculations are used to obtain safety guidelines for clinical exposures in which direct temperature measurements are not feasible. These guidelines, called thermal indices,* provide a real-time display of the relative probability that a diagnostic system could induce thermal injury in the exposed subject. Under most clinically relevant conditions, the soft tissue thermal index (TIS) and the bone thermal index (TIB) either overestimate or closely approximate the best available estimate of the maximum temperature increase (ΔT_{max}). For example, if TIS = 2, then $\Delta T_{max} \leq 2°C$; actual temperature increases are also dependent on dwell time.

However, in some applications, such as fetal examinations in which the ultrasound beam passes through a layer of relatively unattenuating liquid, such as urine or amniotic fluid, the TI can underestimate ΔT_{max} by up to a factor of 2.[4,5]

*The thermal indices are the nondimensional ratios of attenuated acoustic power at a specific point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1°C.[6]

References

1. O'Brien WD Jr, Deng CX, Harris GR, et al. The risk of exposure to diagnostic ultrasound in postnatal subjects: thermal effects. *J Ultrasound Med* 2008; 27:517–535.
2. Kimmel GL, Cuff JM, Kimmel CA. Skeletal development following heat exposure in the rat. *Teratology* 1993; 47:229–242.
3. Church CC, Barnett SB. Ultrasound-induced heating and its biological consequences. In: ter Haar G (ed). *The Safe Use of Ultrasound in Medical Diagnosis*. London, England: British Institute of Radiology; 2012:46–68.
4. Shaw A, Pay NM, Preston RC. *Assessment of the Likely Thermal Index Values for Pulsed Doppler Ultrasonic Equipment—Stages II and III: Experimental Assessment of Scanner/Transducer Combinations*. NPL Report CMAM 12. Teddington, England: National Physical Laboratory; 1998.
5. Jago JR, Henderson J, Whittingham TA, Mitchell G. A comparison of AIUM/NEMA thermal indices with calculated temperature rises for a simple third trimester pregnancy tissue model. *Ultrasound Med Biol* 1999; 25:623–628.
6. International Electrotechnical Commission. IEC 60601-2-37. *Medical Electrical Equipment, Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment*. 2nd ed. Geneva, Switzerland: International Electrotechnical Commission; 2007.

Original approval 10/6–7/1987; Reapproved 10/30/2016, 3/25/2015, 4/6/2009, 3/26/1997

Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values

Approved October 30, 2016

The following two tables contain recommended maximum times for the duration of an ultrasound exposure at a given setting of the Thermal Index (TI).[1] These recommendations for maximum scanning time vs. TI are intended to provide reasonable assurance that an ultrasound examination can be conducted without risk of producing an adverse effect due to a thermal mechanism under any scanning conditions. If it is necessary to exceed the recommendations, the occurrence of an adverse thermal effect is still unlikely under most scanning situations due to mitigating factors such as transducer movement and perfusion. However, the principle of ALARA should be followed so that examination times are only as long as necessary to produce a useful diagnostic result. See the AIUM Statement "As Low as Reasonably Achievable (ALARA) Principle."

Table 1. Recommended maximum scanning time and TI ranges for obstetric (including gynecologic when pregnancy is possible), neonatal transcranial, and neonatal spinal examinations. For obstetric exams, monitoring the TIS is recommended up to 10 weeks from the last menstrual period (LMP) and TIB thereafter.

TI range	Max Scanning Time (minutes)
>3.0	Not recommended
2.5 - 3.0	<1
2.0 - 2.5	<4
1.5 - 2.0	<15
1.0 - 1.5	<30
0.7 - 1.0	<60
<0.7	No time limit

Table 2. Recommended maximum scanning time and TI ranges for adult transcranial, general abdominal, peripheral vascular, neonatal (except head and spine), and other scanning examinations (except the eye).

TI range	Max Scanning Time (minutes)
>6.0	Not recommended
5.0 - 6.0	<0.25 (15 s)
4.0 - 5.0	<1
3.0 - 4.0	<4
2.5 - 3.0	<15
2.0 - 2.5	<60
1.5 - 2.0	<120
<1.5	No time limit

1. Harris GR, Church CC, Dalecki D, Ziskin MC, Bagley JE. Comparison of thermal safety practice guidelines for diagnostic ultrasound exposures. *Ultrasound Med Biol* 2016; 42:345-357.

Original approval 10/30/2016

Guidelines for Hands-on Scanning in Pregnant Subjects During AIUM-Sponsored Educational Activities

Approved October 30, 2016

1. Subject participation should require appropriate informed consent. The primary obstetrician providing prenatal care should be informed of his/her patient's participation.
2. The subjects should be afebrile and prescreened to attempt to avoid unexpected findings.
3. There should be a plan to address unexpected findings should they be observed during the educational course.
4. There should be no first trimester examinations.
5. Exposure time, ie duration of “hands-on” teaching session, should not exceed 1 hour per pregnancy.
6. Exposure to pulsed Doppler should be restricted to instructor scanning for short durations only.
7. Examinations should be performed in a manner consistent with the As Low As Reasonably Achievable (ALARA) principle, including limiting the TI (≤0.7) and MI (<1.0) as necessary for educational purposes.
8. Only courses approved for Continuing Medical Education (CME) credit are acceptable.

Original approval 6/22/2005; Reapproved 10/30/2016, 3/21/2016, 3/27/2010, 3/21/2016.

Statement on Measurement of Fetal Heart Rate

Approved October 30, 2016

Background

Besides watching the monitor and actually counting heartbeats, M-mode is the only ultrasonographic method recommended for measuring the fetal heart rate.* The measurement of the rate in M-mode is performed by placing a pair of cursors to span a known number of heartbeats on the tracing. At a fetal size (crown-rump length) of 2 mm to 1 cm (approximately 5+ to 7 weeks), the heartbeat can be visualized by B-mode and recorded as a short video clip. Because there is no indication for heart rate to be "heard" by spectral Doppler, spectral Doppler should not be used to measure heart rate.

Statement

When attempting to obtain fetal heart rate with a diagnostic ultrasound system, AIUM recommends using either M-mode or a B-mode scan, keeping the thermal index as low as possible, preferably at or below 0.7, and not prolonging the procedure beyond what is necessary to obtain the measurement. Use TIS for the thermal index if pregnancy is less than 10 weeks; use TIB if 10 or more weeks. Fetal heart rate should be documented by M-mode or 2D video clip.

* Hand-held Doppler instruments without imaging capability are not the topic of this statement.

Approved November 5, 2011; Revised 10/30/2016.

Statement on the Safe Use of Doppler Ultrasound During 11–14 week scans (or earlier in pregnancy)

Approved October 30, 2016

The use of Doppler ultrasound during the first trimester is currently being promoted as a valuable diagnostic aid for screening for and diagnosis of some congenital abnormalities. The procedure requires considerable skill, and subjects the fetus to extended periods of relatively high ultrasound exposure levels. Due to the increased risk of harm, the use of spectral Doppler ultrasound with high TI in the first trimester should be viewed with great caution. Spectral Doppler should only be employed when there is a clear benefit/risk advantage and both TI and examination duration are kept low. Protocols that typically involve values of TI lower than 1.0 reflect minimal risk. In accordance with the WFUMB statement, we recommend that:

1. All scans should begin at a displayed TI of 0.7 because the total duration of an ultrasound examination during pregnancy cannot be known in advance. Higher outputs should be used only if needed to obtain adequate images and in accordance with the As Low As Reasonably Achievable (ALARA) principle.
2. Pulsed Doppler (spectral, power, and color flow imaging) ultrasound should not be used routinely.
3. Pulsed Doppler ultrasound may be used for clinical indications such as to refine risks for trisomies.
4. When performing Doppler ultrasound, the displayed Thermal Index (TI) should be less than or equal to 0.7 provided adequate images can be obtained, and exposure time should be kept as short as possible consistent with acquisition of needed clinical information.
5. When using Doppler ultrasound for research, teaching, and training purposes, the displayed TI should be less than or equal to 0.7, and exposure time should be kept as short as possible consistent with the purposes of the scan. Informed consent should be obtained.
6. In educational settings, discussion of first trimester pulsed or color Doppler should be accompanied by information on safety and bioeffects (eg, TI, exposure times, and how to reduce the output power).
7. When scanning maternal uterine arteries in the first trimester, there are unlikely to be any fetal safety implications as long as the embryo/fetus lies outside the Doppler ultrasound beam.

Original approval 4/18/2011. Revised 10/30/2016, 3/21/2016.

Conclusions Regarding Epidemiology for Obstetric Ultrasound

Approved October 30, 2016

Based on the epidemiologic data available and on current knowledge of interactive mechanisms, there is insufficient justification to warrant conclusion of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans. Some studies have reported effects of exposure to diagnostic ultrasound during pregnancy, such as low birth weight, delayed speech, dyslexia, and non-right-handedness. Other studies have not demonstrated such effects. The epidemiologic evidence is based primarily on exposure conditions prior to 1992, the year in which acoustic limits of ultrasound machines were substantially increased for fetal/obstetric applications.

Original approval 3/29/1995; Reapproved 10/30/2016, 3/27/2010, 6/22/2005

Safety in Training and Research

Approved April 1, 2012

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of training or research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study/training. In addition, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single subject should be justified and consistent with prudent and conservative use.

Original approval 3/19/2007; Reapproved 4/1/2012

Keepsake Fetal Imaging

Approved April 1, 2012

The AIUM advocates the responsible use of diagnostic ultrasound for all fetal imaging. The AIUM understands the growing pressures from patients for the performance of ultrasound examinations for bonding and reassurance purposes largely driven by the improving image quality of 3D sonography and by more widely available information about these advances. Although there is only preliminary scientific evidence that 3D sonography has a positive impact on parental-fetal bonding, the AIUM recognizes that many parents may pursue scanning for this purpose.

Such "keepsake imaging" currently occurs in a variety of settings, including the following:

1. Images or video clips given to parents during the course of a medically indicated ultrasound examination;
2. Freestanding commercial fetal imaging sites, usually without any physician review of acquired images and with no regulation of the training of the individuals obtaining the images; these images are sometimes called "entertainment videos"; and
3. As added-cost visits to a medical facility (office or hospital) outside the coverage of contractual arrangements between the provider and the patient's insurance carrier.

The AIUM recommends that appropriately trained and credentialed medical professionals (licensed physicians, registered sonographers, or sonography registry candidates) who have received specialized training in fetal imaging perform all fetal ultrasound scans. These individuals have been trained to recognize medically important conditions, such as congenital anomalies, artifacts associated with ultrasound scanning that may mimic pathology, and techniques to avoid ultrasound exposure beyond what is considered safe for the fetus. Any other use of "limited medical ultrasound" may constitute practice of medicine without a license. The AIUM reemphasizes that all imaging requires proper documentation and a final report for the patient medical record signed by a physician.

Although the general use of ultrasound for medical diagnosis is considered safe, ultrasound energy has the potential to produce biological effects. Ultrasound bioeffects may result from scanning for a prolonged period, inappropriate use of color or pulsed Doppler ultrasound without a medical indication, or excessive thermal or mechanical index settings. The AIUM encourages patients to make sure that practitioners using ultrasound have received specific training in fetal imaging to ensure the best possible results.

The AIUM also believes that added cost arrangements other than those of providing patients images or copies of their medical records at cost may violate the principles of medical ethics of the American Medical Association (E-8.062[1,2] and E-8.063[2,3]) and the American College of Obstetricians and Gynecologists. [4] The AIUM therefore reaffirms the Prudent Use in Pregnancy Statement[5] and recommends that only scenario 1 above is consistent with the ethical principles of our professional organizations.

The market for keepsake images is driven in part by past medical approaches that have used medicolegal concerns as a reason not to provide images to patients. Sharing images with patients is unlikely to have a detrimental medicolegal impact. Although these concerns need further analysis and evaluation, we encourage sharing images with patients as appropriate when indicated obstetric ultrasound examinations are performed.[5]

References

1. American Medical Association. E-8.062: Sale of Non-Health-Related Goods From Physician's Offices. Chicago, IL: American Medical Association; 1998.
2. American Medical Association. Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physicians' Offices (E-8062 and E-8.063). Chicago, IL: American Medical Association; 2000.
3. American Medical Association. E-8.063: Sale of Health-Related Products From Physician's Offices. Chicago, IL: American Medical Association; 1999.
4. Commercial enterprises in medical practice. ACOG Committee Opinion No. 359. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;109:243-5.
5. American Institute of Ultrasound in Medicine. Prudent Use in Pregnancy. Laurel, MD: American Institute of

Ultrasound in Medicine; 2012.

Original approval 6/22/2005; Reapproved 4/1/2012

U.S. FOOD & DRUG ADMINISTRATION

December 5, 2016

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To Whom It May Concern:

The U.S. Food and Drug Administration (FDA) has concerns about the marketing, as over-the-counter (OTC) ultrasound devices, ultrasound devices that have been cleared as prescription use only in the United States and that do not have marketing clearance or approval as OTC devices. This raises concerns about risks to health and would be a violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act). Specifically, FDA is concerned with ultrasound devices that are labeled as prescription use devices but that are being marketed as OTC devices at exhibitions, trade shows, and other venues, where they are demonstrated on humans, often with repetitive and prolonged exposures on a single individual, with no medical need, without a prescription, and with no interpretation of the resultant images by a licensed practitioner.

All legally marketed diagnostic ultrasound devices are marketed as prescription devices – those that are used by, or under the supervision of, a licensed health care practitioner. To date, FDA has not granted marketing authorization to any ultrasound device intended for OTC use or sale, and any diagnostic ultrasound device marketed in the United States for OTC use may be misbranded under section 502(o) of the FD&C Act, 21 U.S.C. 352(o), and adulterated under section 501(f) of the FD&C Act, 21 U.S.C. 351(f).

Ultrasound energy has the potential to produce biological effects on the body (e.g., tissue heating and cavitation), and the long-term consequences of these effects are unknown. Accordingly, organizations such as the American Institute of Ultrasound in Medicine (AIUM) advocate for the prudent use of ultrasound imaging. For example, the April 1, 2012 AIUM official statement on prudent use and clinical safety states that "[u]ltrasound should be used by qualified health professionals to provide medical benefit to the patient. Ultrasound exposures during examinations should be as low as reasonably achievable (ALARA)."[1] Similarly, FDA has stated that "ultrasound scans should be done only when there is a medical need, based on a prescription, and performed by appropriately-trained operators."[2]

Diagnostic ultrasound imaging is generally considered safe when used prudently by appropriately trained health care practitioners. However, ultrasound device demonstrations on live models for no medical purpose are not performed in the same manner as ultrasound studies performed for FDA-cleared medical indications.

[1] AIUM official statements are available at http://www.aium.org/resources/statements.aspx (accessed on September 9, 2016). Note this website is not controlled by FDA.
[2] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095508.htm

U.S. Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002
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The AIUM official statement on the ALARA principle states that "the potential benefits and risks of each examination should be considered" and cautions that the ALARA principle "should be observed when adjusting controls that affect the acoustical output and by considering transducer dwell times."

Ultrasound device demonstrations on live models are not necessarily performed under exposure conditions that are ALARA. Demonstrations on live models generally involve repeated scanning of the same anatomic region(s) on a human over a period of hours or days under a variety of exposure conditions that include varying acoustical outputs and dwell times. It is not clear that there is no risk of adverse biological effects from repeated scanning during such live demonstrations. With respect to adverse biological effects, the AIUM official statement on safety in training and research states "experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions."

Ultrasound scanning on live models for the purpose of device demonstration has no medical purpose, provides no medical benefit, and may involve risk to the individual being scanned. FDA strongly discourages such uses at exhibitions, trade shows, and other venues where ultrasound devices are demonstrated on humans. The FDA is also concerned with the risks to individual and public health if the affected individuals and public are not alerted to the risks of such uses.

If you have any questions about this communication, please contact Dr. Shahram Vaezy, Ph.D. at Shahram.Vaezy@fda.hhs.gov or (301) 796-6242.

Sincerely yours,

Donald L. Miller, M.D., FACR
Chief Medical Officer for Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration

Memorandum and Meeting Minutes

To: The Record

From: Shahram Vaezy, Ph.D.
Mammography, Ultrasound, and Imaging Systems Branch (MUIS)/DRH/OIR

Date: February 27, 2017

Subject: Minutes of the face-to-face meeting with AIUM

Background
The American Institute of Ultrasound in Medicine (AIUM) requested a face-to-face with the FDA to discuss the FDA letter of December 5, 2016 regarding demonstration of ultrasound devices on live models.

FDA Attendees:
- Donald Miller, MD, Chief Medical Officer for Radiological Health, OIR
- Robert Ochs, PhD, Director, Division of Radiological Health (DRH), OIR
- Jeffery Ballyns, PhD, Chief, Mammography, Ultrasound, and Imaging Software (MUIS) Branch, DRH, OIR
- Scott McFarland, JD, Associate Director, Regulatory Counsel, OIR
- Brian Garra, MD, Clinical Reviewer, OSEL
- Keith Wear, PhD, Leader, Acoustics Laboratory, OSEL
- Shahram Vaezy, PhD, Biomedical Engineer, MUIS, DRH, OIR

AIUM Attendees:
- Beryl R. Benacerraf, MD, AIUM President
- Brian D. Coley, MD, AIUM President-Elect
- J. Brian Fowlkes, PhD, AIUM Treasurer
- Jean Lea Spitz, MPH, CAE, RDMS, AIUM Bioeffects Committee Chair
- Glynis V. Harvey, CAE, AIUM CEO

Face-to-Face Meeting
The meeting commenced at 1:00 PM, on February 23, 2017. The AIUM questions and the FDA comments are listed in the table below.

AIUM Question	FDA Comment
Please clarify the background for sending the letter to AIUM and ultrasound manufacturers. AIUM has received questions from the manufacturers about the letter, as the FDA cited AIUM Official Statement in the letter.	• Observation that the practice of live demonstration was taking place. • The concern is the repeated exposure of an individual with no anticipated medical benefit. • While risk is low, it has not been shown that there is no risk to repeated ultrasound exposure. • With no benefit, there should be no risk; however, this has not been shown. • In conclusion, ultrasound demonstration on live models is a risk to public health.

What about scanning for training purposes? For example, at the American Institute of Ultrasound in Medicine (AIUM) meeting, there could be hands-on scanning after a session for a specific training purpose. Also, there are sessions where luminaries can show a particular technique to an audience of physicians. Such activities are for educational purposes.	• While we understand that training may involve scanning a live model, training was not the subject of the letter. • Also, it would be difficult to respond to questions about various scenarios of hands-on scanning; there could be many scenarios. • We understand that formal training is beneficial to public health, but the focus of the letter is not about scanning for training. • We believe AIUM should define what activities could be considered educational.
There are characteristics of ultrasound (e.g., dynamic nature of scanning, and non-ionizing radiation) which would necessitate, and be in favor of, allowing live scanning.	• In CT, where live models are not used, other methods for demonstration of a device's capabilities are used. • In interventional radiology, device demonstrations could be done in a clinical setting. • The issue is when the same person, who will not be benefitting from the scanning will be scanned repeatedly in the course of a demonstration.
Why was OTC language used in the letter?	• The legal nuance is that if the device is not being marketed in a manner consistent with prescription use only, then the device is being marketed for over-the-counter (OTC) use as those are the only two distribution models that FDA recognizes.
We look forward to a continued dialogue with the FDA.	We look forward to that.

The AIUM representatives thanked the FDA for being available for this discussion. The FDA thanked AIUM for their interest in this dialogue. Both AIUM and the FDA expressed interest in future communication on this topic.

The meeting was completed at 1:45 PM.

Action Items
None

Structured Planning Form for Organizing a Live Scanning Activity at an AIUM Event

Complete this form to describe/document how your organization will meet the AIUM Live Scanning Guidelines/Requirements during the following AIUM Event:

Event Name:	**Event Date(s):**

Activity Objective

Learning objectives are the take-home messages that bridge the gap between the identified need/gap and the desired result of the activity. (What do you want the learner to be able to accomplish after the activity)

What professional practice gap(s) does this activity address?

A problem that indicates an educational need on the part of the learners

State the Educational Needs determined to be the cause of the professional practice gaps.

Knowledge Need *(Being aware of what to do)*

and/or

Competence Need *(Being able to apply knowledge, skill, and judgement in practice)*

and/or

Performance Need *(Having the ability to implement the strategy or skill)*

Educational Design: Please indicate the educational methods that will be used to achieve the activity objectives.

- ❑ Simulation/hands-on scanning
- ❑ Didactic lectures
- ❑ Case presentations
- ❑ Question and answer session
- ❑ Other: _____

Desirable Physician Attributes/Core Competencies

- ❑ Patient care or patient-centered care
- ❑ Medical knowledge
- ❑ Practice-based learning and improvement
- ❑ Interpersonal and communication skills
- ❑ Professionalism
- ❑ System-based practice
- ❑ Quality improvement
- ❑ Other: _____

Company/organization name _____

Mailing address _____

City/state/postal code _____ Country _____

Key contact _____

(Required to be on-site at the convention)

Title _____

Phone _____ Fax _____

E-mail _____ Booth number _____

Authorized contact signature _____

Return this form to:

American Institute of Ultrasound in Medicine Attn: Danielle Delanko
14750 Sweitzer Ln, Suite 100 Laurel, MD 20707-5906, USA
Phone: 301-498-4100 Fax: 301–498-4450 ddelanko@aium.org

AIUM USE ONLY

Date Received _____

AIUM Authorized Signature _____

Live Scanning at AIUM Events

AIUM Official Statement on Live Scanning for Educational Purposes

Live scanning of human subjects should be permitted only under controlled conditions and only when there is a medical or public health benefit. The education of health care specialists in what are the latest ultrasound technologies, their capabilities, and how best used in these individuals' own hands is a critical exercise for evaluation and for skill development. At the present time, this benefit is very difficult to obtain in any other way, and ultimately benefits future patients.

AIUM Live Scanning Guidelines/Requirements During AIUM Events:

All live scanning of human subjects during AIUM events must include an educational component. Adhere to the following guidelines when performing live scanning for educational purposes:

- All subjects must be pre-scanned by a licensed healthcare specialist and any discovered anomalies or pathology should be reported to the subject with a recommendation to seek a physician's advice.
- All subjects should grant informed consent to the scans after being provided information on the safety and potential biological effects of diagnostic ultrasound and the MI and TI.
- All subjects must be appropriately clothed for the specific scanning activity.
- All equipment will have received FDA clearance and will be used in a manner consistent with its FDA-cleared indications for use. Also, only equipment that has been FDA-cleared for ophthalmic indications will be used to scan the eye during the demonstrations due to the lower FDA recommended maximum output levels and sensitivity of the eye to heating.
- Demonstration scans on live, non-pregnant subjects will be performed in a manner consistent with the ALARA principle including limiting the TI (≤0.7) and MI (<1.0) as necessary for demonstration purposes.
- If higher exposure conditions are needed for a demonstration, then either (a) a tissue mimicking phantom will be used or (b) the live participant will only be scanned once per day similar to the exposures experienced during clinical practice.
- Scanning of pregnant subjects is only permissible in instances where formal CME credit is issued and must also follow the AIUM Statement: Guidelines for Hands-on Scanning in Pregnant Subjects During AIUM-Sponsored Educational Activities.
- Use of ultrasound contrast agents on human subjects is only permissible in instances where formal CME credit is issued. Tissue mimicking phantoms should be utilized for all other demonstrative activities.
- For live scanning activities where formal CME credit is not issued:
  - Subjects must be at least 18 years of age.
  - Abdominal/pelvic scanning of female subjects is not permissible to avoid pregnancy concerns.
  - The "Structured Planning Form for Organizing a Live Scanning Activity at an AIUM Even" must be completed and returned to the AIUM prior to the scanning activity.
  - Examples of acceptable educational activities may include:
    - Provide review of scanning protocols in actual clinical scenarios. Get the crowd involved for suggestions and answers; reward participants for correct answers and purposefully make mistakes to test the audience.
    - Enlist audience participation by posing questions, such as "what does this _____ finding tell you in the case scenario?" and "what would you suggest we do next."
    - Provide and teach to a list of common protocols such as abdominal Doppler, liver studies, renal studies, pancreatitis, echocardiography, shock, trauma, arrest, dyspnea evaluations, extremity venous and arterial studies, and carotid blood flow.
    - Develop scenarios that appeal across specialty boundaries, such as "this patient was being scanned in the radiology suite and suddenly..."
    - Demonstrate image optimization strategies, such as contests where a difficult image is presented and a clinical scenario attached that offers some pressure; appeal to audience members for suggested adjustments on how to improve the image quality to something more readable.
    - Demonstrate how features of the machine can be employed to maximize image quality while minimizing the potential for bioeffects.
    - Provide overview of the ALARA Principle.
    - Provide instruction on probe selection, orientation and imaging tips, artifacts, pitfalls.
    - Demonstrate how to adhere to AIUM practice parameters and improve image acquisition.
    - Demonstrate ultrasound measurements using published criteria and automated measurements technologies offered.
    - Raise awareness of mechanical (MI) and thermal (TI) indices by pointing out the MI and TI on the screen, and informing viewers how to make those indices appear when not already displayed.
    - Advise participants on acceptable values as stated in the AIUM Official Statement "Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values."
    - Demonstrate knobology "best practices" by demonstrating how the MI and TI change when the output is adjusted and how increasing Overall Gain and Time Gain Compensation can achieve similar increases in image brightness without changing the MI or TI.

Live Scanning for Educational Purposes
General (Non-OB/GYN) Scanning Consent Form

This is an agreement between _____ (Company/Organization) and _____ (Live Scanning Subject) during _____ (Event name/Date/Location).

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of training or research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study/training. In addition, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single subject should be justified and consistent with prudent and conservative use.

Live Scanning Subject Requirements

(to be initialed by Live Scanning Subject)

- ☐ I understand there will be an educational component to this live scanning activity that will not directly benefit me, but may indirectly benefit future patients.
- ☐ I understand that images obtained during this activity are not intended for medical diagnostic purposes.
- ☐ I understand I will be pre-scanned by a licensed healthcare specialist and any discovered anomalies or pathology will be reported to me with a recommendation that I seek a physician's advice.
- ☐ I have been provided information on the safety and potential biological effects of diagnostic ultrasound and the MI and TI and subsequently grant informed consent to the scanning activity.
- ☐ I understand all equipment will have received FDA clearance and will be used in a manner consistent with its FDA-cleared indications for use. Also, only equipment that has been FDA-cleared for ophthalmic indications will be used to scan the eye during the demonstrations.
- ☐ I understand demonstration scans on live, non-pregnant subjects will be performed in a manner consistent with the ALARA principle including limiting the TI (≤0.7) and MI (<1.0) as necessary for demonstration purposes.
- ☐ If higher exposure conditions are needed for the demonstration, then I understand that I will only be scanned once per day similar to the exposures experienced during clinical practice.
- ☐ I understand that I am to be appropriately clothed for the specific scanning activity.
- ☐ If this is an activity for which no formal Continuing Medical Education (CME) is issued, I attest that I am at least 18 years of age.

Females:

- ☐ I understand that I will not be participating in abdominal/pelvic scanning activities to prevent any potential exposure to reproductive organs. Therefore there will be no screening by ultrasound at these sites.

The Live Scanning Subject releases the Company/Organization from any and all liability arising out of this activity except for any direct and actual damages arising from willful misconduct of the Company/Organization.

Activity records that identify the Live Scanning Subject are kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, Live Scanning Subject will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Company/Organization.

The Live Scanning Subject hereby authorizes Company/Organization to use the information obtained in this activity for any commercial business purpose (such as advertising, product literature, etc.) on the condition that no identifying information about the Live Scanning Subject is disclosed.

By signing below, the Live Scanning Subject represents that he/she has read and carefully considered the contents of this agreement, that the Live Scanning Subject is in agreement with all the terms herein, that the information provided above is true and accurate to the best of the Live Scanning Subject's knowledge and that the Live Scanning Subject consents to the ultrasound scanning activity under the terms of this agreement.

A guardian or other legal representative must sign this form if the Live Scanning Subject is under 18 years of age or as may otherwise be required.

Print clearly.

Live Scanning Subject Name (Please Print)	Live Scanning Subject Signature	Date

Live Scanning Subject Telephone Number: _____

Live Scanning Subject Address:

_____
Address Line 1

_____
Address Line 2

City	State	Zipcode

Witness Name (Please Print)	Witness Signature	Date

Live Scanning for Educational Purposes
OB/GYN Scanning Consent Form

The association for medical ultrasound
aium
AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

This is an agreement between _____ (Company/Organization) and _____ (Live Scanning Subject) during _____ (Event name/Date/Location).

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of training or research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study/training. In addition, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single subject should be justified and consistent with prudent and conservative use.

Live Scanning Subject Requirements

(to be initialed by Live Scanning Subject)

- ☐ I understand there will be an educational component to this live scanning activity that will not directly benefit me, but may indirectly benefit future patients.
- ☐ I understand that images obtained during this activity are not intended for medical diagnostic purposes.
- ☐ I understand I will be pre-scanned by a licensed healthcare specialist and any discovered anomalies or pathology will be reported to me with a recommendation that I seek a physician's advice.
- ☐ I have been provided information on the safety and potential biological effects of diagnostic ultrasound and the MI and TI and subsequently grant informed consent to the scanning activity.
- ☐ I understand all equipment will have received FDA clearance and will be used in a manner consistent with its FDA-cleared indications for use. Also, only equipment that has been FDA-cleared for ophthalmic indications will be used to scan the eye during the demonstrations.
- ☐ I understand demonstration scans on live, non-pregnant subjects will be performed in a manner consistent with the ALARA principle including limiting the TI (≤0.7) and MI (<1.0) as necessary for demonstration purposes.
- ☐ If higher exposure conditions are needed for the demonstration, then I understand that I will only be scanned once per day similar to the exposures experienced during clinical practice.
- ☐ I understand that I am to be appropriately clothed for the specific scanning activity.
- ☐ If this is an activity for which no formal Continuing Medical Education (CME) is issued, I attest that I am at least 18 years of age.

Scanning of pregnant subjects is only permissible in instances where formal CME credit is issued and must also follow the AIUM Statement: Guidelines for Hands-on Scanning in Pregnant Subjects During AIUM-Sponsored Educational Activities.

- ☐ I am pregnant and understand that if the purpose of the activity is fetal scanning, scanning of a known pathology, or scanning of a known medical condition, I represent that I have had the opportunity if I so wish to discuss this activity and the possible risks associated with the activity with my physician. By signing below, I represent that I have had the opportunity to ask all my questions regarding the activity and that my questions have been answered to my satisfaction. Company/Organization will rely on this and other representations made by me in Company/Organization's decision to use me for this activity.
- ☐ I attest to the best of my knowledge that I am not pregnant. I understand that I will not be participating in abdominal/pelvic scanning activities.

The Live Scanning Subject releases the Company/Organization from any and all liability arising out of this activity except for any direct and actual damages arising from willful misconduct of the Company/Organization.

Activity records that identify the Live Scanning Subject are kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, Live Scanning Subject will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Company/Organization.

The Live Scanning Subject hereby authorizes Company/Organization to use the information obtained in this activity for any subsequent educational or commercial business purpose (such as advertising, product literature, etc.) on the condition that no identifying information about the Live Scanning Subject is disclosed.

By signing below, the Live Scanning Subject represents that he/she has read and carefully considered the contents of this agreement, that the Live Scanning Subject is in agreement with all the terms herein, that the information provided above is true and accurate to the best of the Live Scanning Subject's knowledge and that the Live Scanning Subject consents to the ultrasound scanning activity under the terms of this agreement.

A guardian or other legal representative must sign this form if the Live Scanning Subject is under 18 years of age or as may otherwise be required.

Print clearly.

Live Scanning Subject Name (Please Print)	Live Scanning Subject Signature	Date

Live Scanning Subject Telephone Number: _____

Live Scanning Subject Address:

_____
Address Line 1

_____
Address Line 2

City	State	Zipcode

Witness Name (Please Print)	Witness Signature	Date

Facts Concerning Your Participation in an AIUM Live Scanning Activity

When examinations are carried out for purposes of training or research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study/training. In addition, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single subject should be justified and consistent with prudent and conservative use.

What does this statement mean?

- Diagnostic ultrasound has been in use since the late 1950s.
- There are no confirmed adverse biological effects on patients resulting from this usage.
- Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions.
- You should be made aware of how this activity would differ if at all from normal ultrasound scanning used for diagnosis.
- ALARA means that only the amount of ultrasound necessary should be used. This is to ensure the best possible safety associated with the use of ultrasound and should be the common practice in clinical as well as educational activities.

What is the purpose of this activity?

- The education and training of medical personnel and other healthcare experts is critical to the continued safe and effective use of ultrasound. The organization conducting these activities has identified objectives deemed appropriate to assist in this educational effort.
- You should know that this activity will not directly benefit you. It is intended to educate those attending and thus is expected to help improve the operation and use of ultrasound in the future.

What will happen during this time?

- Once you have consented to participate, you will be pre-scanned by a licensed healthcare specialist. This is done to determine if there are any unexpected anomalies or pathology. In the unlikely event something is discovered, the findings will be reported to you with a recommendation that you seek a physician's advice.
- You will then be one of the subjects scanned during the educational activity. You will be scanned periodically over a limited period of time depending on the type of ultrasound examination being demonstrated and the requisite ultrasound for the demonstration (see below).

How is the safety of ultrasound managed?

- While the safety profile of diagnostic ultrasound is excellent and its clinical use is highly beneficial, it is important to always recognize that a potential for biological effects exists when it is used. This risk is very low and outweighed by the benefits to the subject in the case of diagnostic use and the public health as educational and research activities lead to improvements in the systems and the performance of diagnostic ultrasound.
- The US Food and Drug Administration (FDA) limits the output of ultrasound systems that are cleared for human use. The only systems that will be used are FDA-approved.
- As part of the approval process, the ultrasound systems can display two indices that are designed to provide feedback to the user. These are the Thermal Index (TI) and the Mechanical Index (MI).
- Limits are placed on the two indices for the purposes of these educational activities. Specifically, all ultrasound scans will be performed in a manner consistent with the ALARA principle including limiting the TI (≤0.7) and MI (<1.0) as necessary for demonstration purposes.
- If higher exposure conditions are needed for the demonstration, you will only be scanned once per day similar to the exposures experienced during clinical practice.

Will I be identified in any manner?

- All activity records that would identify you are kept confidential as required by law.
- Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.
- Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Company/Organization.

How will the ultrasound images be used?

- Typically the images are only displayed by video to the attendees and are not recorded.
- If images are recorded, these may be used for subsequent educational or commercial purposes.
- Again, there will be no identifying information disclosed except as required by law.