



LIVE SCANNING FOR EDUCATIONAL PURPOSES

AIUM Resource Materials Related to Ultrasound
Demonstrations on Human Subjects

ULTRASOUND AND THE FOOD AND DRUG ADMINISTRATION (FDA)

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 conformity with the AIUM’s other Official Statements that are specific to scanning activities.

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 an overview of the ALARA Principle.
- Provide instruction on probe selection, orientation, and imaging tips, artifacts, and 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 (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.

AIUM Live Scanning Guidelines/Requirements



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.
 - To ensure educational content is properly performed for all live scanning activities, the following forms may be utilized:
 - [Live Scanning Activity Planning Form](#)
 - [Live Scanning Subject Consent Form](#)
 - For live scanning activities where formal CME credit is *not* issued,
 - Subjects must be at least 18 years of age.
 - Subjects with pregnancy potential are not permitted to participate.
1. Cucevic V, Brown AS, Foster FS. Thermal assessment of 40-MHz pulsed Doppler ultrasound in human eye. *Ultrasound Med Biol* 2005; 31:565–573.
 2. O'Brien, WD Jr., Yang Y, Simpson DG, et al. Threshold estimation of ultrasound-induced lung hemorrhage in adult rabbits and comparison of thresholds in mice, rats, rabbits and pigs. *Ultrasound Med Biol* 2006; 32:1793–1804.

AIUM Facts for Participation in a 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 are 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.

AIUM Official Statements

[As Low As Reasonably Achievable \(ALARA\) Principle](#)

[Statement on Biological Effects of Ultrasound in Vivo](#)

[Prudent Use and Safety of Diagnostic Ultrasound in Pregnancy](#)

[Conclusions Regarding Epidemiology for Obstetric Ultrasound](#)

[Safety in Diagnostic Ultrasound Educational Activities Using Pregnant Patients](#)

[Safety in Diagnostic Ultrasound Educational Activities Using Nonpregnant Participants](#)

[Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as well as Safe Handling and Use of Ultrasound Coupling Gel](#)

[Recommended Maximum Scanning Times for Displayed Thermal Index \(TI\) Value](#)

Live Scanning Activity Planning Form

Describe/document how your organization will meet the [AIUM Live Scanning Guidelines/Requirements](#):

Event Name:	Event Date(s):
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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 judgment 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 including Title _____

(Required to be on-site at the event)

Phone _____ Fax _____ E-mail _____ Booth number _____

Authorized contact signature _____

Live Scanning Subject Consent Form

Describe/document how your organization will meet the [AIUM Live Scanning Guidelines/Requirements](#):

Event Name:	Event Date(s):
Event Location:	Booth Number: <i>(if relevant)</i>
Organization Name: <i>(Org. who hired live scanning subject)</i>	Live Scanning Subject Name:

Scanning Objective

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.

Authorization

The Live Scanning Subject releases the 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 the Organization to use the information obtained in this activity for any commercial business purpose (such as advertising, product literature, etc.) on the condition that the Live Scanning Subject's name is not 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.

Live Scanning Subject Requirements

- 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 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.
- For all *non-CME* activities:
 - Subjects must be at least 18 years of age.
 - Subjects with pregnancy potential are not permitted to participate.

Live Scanning Acknowledgements

- I understand and accept the Live Scanning Subject Requirements.

Age Acknowledgements

(For all non-CME activities, Live Scanning Subjects must be at least 18 years of age.)

- I attest that I am at least 18 years of age.
- I attest that I am not 18 years of age and my guardian/legal representative consents to my participation in this live scanning activity .

Fertility Acknowledgements

(For all CME activities)

- I am a model with zero pregnancy potential and I will be participating in OB/GYN scanning activities.
- I am a model with zero pregnancy potential and I will be participating in non-OB/GYN scanning activities.
- I am a model with pregnancy potential and I will be participating in OB/GYN scanning activities.
- I am a model with pregnancy potential and I will be participating in non-OB/GYN scanning activities.
- I am a pregnant model and I will be participating in OB/GYN scanning activities.

Live Scanning Subject Consent

Name: _____

E-Mail : _____ Phone: _____

Mailing Address: _____

City, State: _____ Zip Code: _____

Signature: _____ Date _____

Guardian/Legal Representative Consent *(if Live Scanning Subject is under 18 years of age)*

Name: _____

E-Mail : _____ Phone: _____

Signature: _____ Date _____