



GUIDELINES FOR THE MANAGEMENT OF SAFETY WHEN USING VOLUNTEERS & PATIENTS FOR PRACTICAL TRAINING AND LIVE DEMONSTRATION IN ULTRASOUND SCANNING AND CONSENT

Introduction and Scope

For the purposes of this guideline the term practitioner is used to denote the sonographer or other suitably trained scanning professional.

Practical experience of ultrasound scanning forms an essential component of all training in clinical ultrasound. Those in training may observe experienced and qualified practitioners carrying out scanning, and, more importantly, use ultrasound equipment under the guidance and supervision of a tutor, or other senior clinical colleague. During training, they develop an understanding of the machine controls and settings and a working knowledge of the purpose and outcome of altering the machine settings. They also develop practical skills in carrying out a wide range of clinical studies, obtaining images of optimum diagnostic quality and interpreting and reporting findings.

Qualified and experienced practitioners need to learn new techniques, technologies and trial new equipment and it is recognised that this is best achieved with hands-on scanning of patients or volunteers.

Modern ultrasound scanners, when used in accordance with guidelines published by BMUS, EFSUMB and WFUMB, do not give rise to substantial concerns over safety. Nevertheless, it is possible to select operating conditions on some equipment that are capable of warming tissue to a level where adverse bio-effects may occur. The magnitude of the temperature rise increases with the length of exposure and with the ultrasound output. In addition, it is known that tissues can be damaged close to any gas bodies exposed to high amplitude pulses of ultrasound, for example at the lung surface or with micro-bubble contrast agents. A further aspect of safety management is the inherent sensitivity of each type of tissue and the long-term relevance of any adverse bio-effects. For example, exposure of embryonic tissues is critical because they are rapidly proliferating, and because of the potential developmental changes which may be caused. Exposure of foetal bone can result in secondary warming of adjacent soft tissues, of particular importance to the brain and spinal cord, especially with high-intensity Doppler beams.

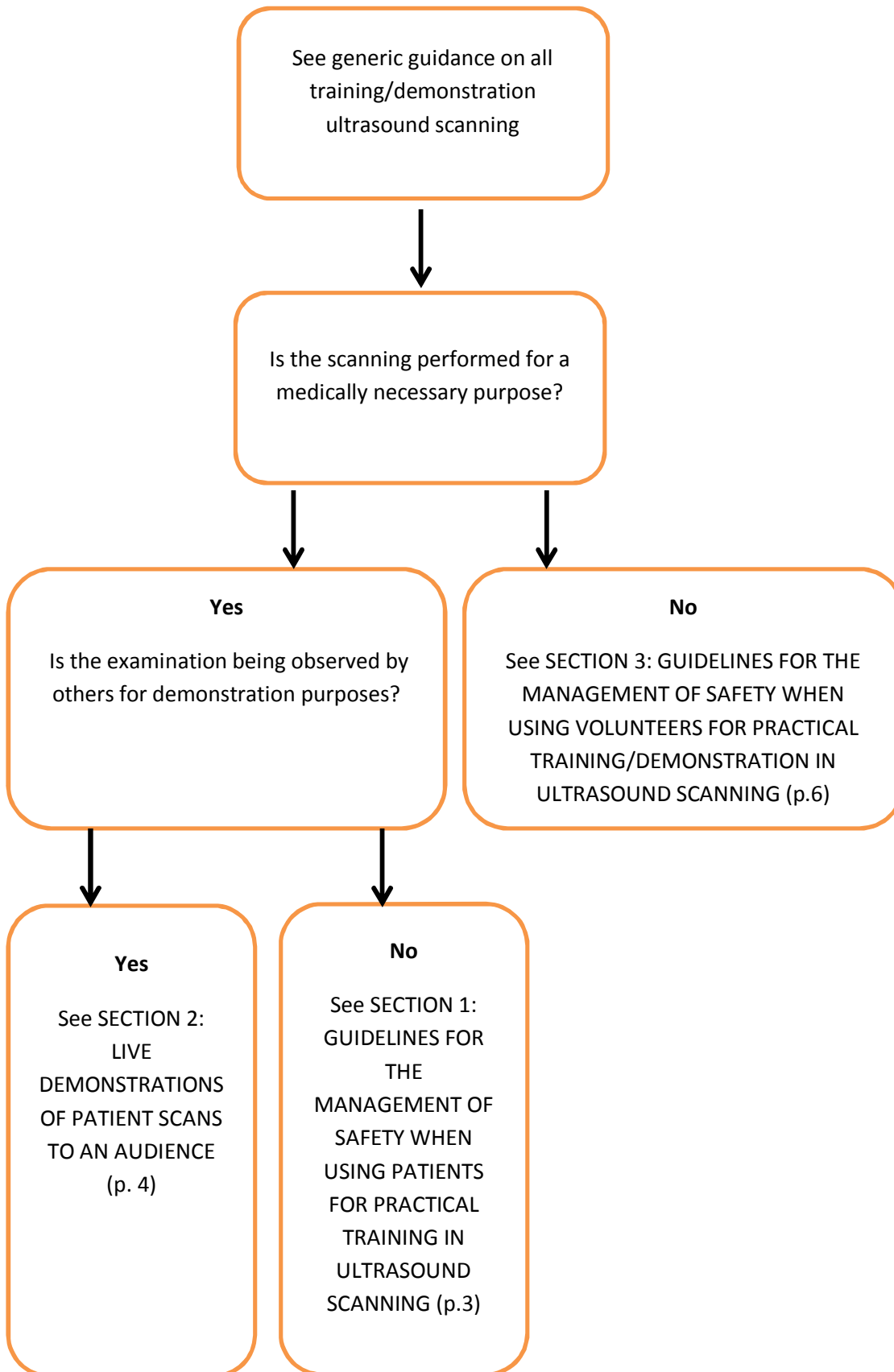
It is important, therefore, to establish recommendations which, when followed, will prevent practitioners from using scanners at unnecessarily high output levels, scanning for unduly long periods of time, or giving unjustifiable exposure of critical target organs. These recommendations also ensure that the lines of accountability for safe scanning during training and demonstration are clear. They should ensure that there is sufficient scope to enable practical scanning skills to be developed within a managed and responsible framework.

It is important to note that formal training programmes should include appropriate teaching material on the safe use of ultrasound, the potential for bio-effects and the rationale and means for limiting output. These guidelines do not define a training curriculum relating to safety, but only set out to establish operational criteria for safe practical training.

These protocols are suitable for demonstrating scanning techniques for a range of pathologies and may include the administration of contrast agents. However, it should be noted that live scanning of obstetric patients and eyes are not permitted at any BMUS meeting.

Live scanning at a BMUS meeting must be performed in accordance with the BMUS Guidelines for the Safe Use of Diagnostic Ultrasound Equipment, as given [at here](#) (hyperlink).

How to apply these guidelines



Generic guidance on all training/demonstration ultrasound scanning

Supervision:-

All ultrasound scanning must be performed or supervised by a suitably trained and qualified operator. This supervisor should be aware of, and abide by, current BMUS, EFSUMB and WFUMB safety guidelines.

The supervisor should ensure that any trainee is competent in the safe application of ultrasound before being allowed to scan without supervision.

Consent:-

All participants, both patients and healthy volunteers, must give express consent to being scanned as part of an educational or demonstration event. Each participant must be given time to consider participation and has the right to refuse.

Participant must be made aware that consent can be withdrawn at any time.

See appendix 1 and 2 for BMUS consent forms for general scanning and obstetric scanning

Equipment:-

All equipment used must be in good working order with electrical safety testing and regular quality assurance.

Unexpected findings:-

A protocol must be in place to inform the patient or volunteer of any unexpected findings that arise from the ultrasound scan. This should be done in a manner which maintains the person's dignity and right to confidentiality. Ideally, a pre-scan should be performed before the training/teaching session to ensure that unexpected findings are discovered and disclosed in a private and controlled environment.

SECTION 1: GUIDELINES FOR THE MANAGEMENT OF SAFETY WHEN USING PATIENTS FOR PRACTICAL TRAINING IN ULTRASOUND SCANNING

Overall Responsibility and Supervision

- Responsibility for the safety of patients during practical training in ultrasound scanning lies in the first instance with the tutor supervising the scanning.
- It is of great importance when using pregnant volunteers to have strict local governance and should only be performed in collaboration with local NHS obstetric services.
- The tutor should ensure that the trainee is competent in the safe application of ultrasound before being allowed to scan without supervision.
- Tutors should be aware of the particular needs for training when ultrasound scanning is used for less common applications or research.
- The tutor should be aware of, and abide by, current BMUS, EFSUMB and WFUMB safety guidelines.

Informed Consent

- The person being scanned should give informed consent for the procedure. It is the tutor's responsibility to ensure this is done.
- Patients should be made aware that a trainee is carrying out the examination. The patient should understand that their quality of care would not be affected whether the trainee scans or not. Verbal consent is acceptable.

Management of Acoustic Output

- The tutor will ensure that the trainee avoids the use of excessive and inappropriate exposure levels, particularly in obstetric applications and when using spectral Doppler and colour Doppler imaging modes.
- The tutor will ensure that the time spent with an individual subject does not exceed that necessary for the training need. It is recommended that the total examination time is normally no more than twice that needed to carry out a diagnostic scan and must not exceed the limits set out in BMUS safety guidelines.
- Wherever possible, training should be carried out using a scanner equipped with a display of the two safety indices - Mechanical Index and Thermal Index. The tutor should make sure the trainee is aware of the displayed safety indices, their meaning, and their function in the management of safety.
- The trainee should be aware of the effect on machine output resulting from changes in machine controls. This may be monitored during scanning by observing the safety indices.

Ultrasound Contrast Agents

- A number of ultrasound contrast agents are now available for patient use under medical supervision and it is appropriate for ultrasound practitioners to be trained in their use. Any such study should, however, be performed or supervised by an experienced medical practitioner who is responsible for the safe and appropriate use of these agents. As ultrasound contrast agents can lower the threshold for acoustic cavitation, special attention should be paid to the avoidance of excessive scanning at higher acoustic output, when possible.

SECTION 2: LIVE DEMONSTRATIONS OF PATIENT SCANS TO AN AUDIENCE

The following section describes the protocol for the demonstration of live patient scanning to an audience. It is designed to provide the educational benefits of a live, interactive demonstration while protecting patients from stress, unreasonable risks and breach of confidentiality.

Scanning Arrangements

It is recommended that the patient is scanned in a suitable small room by a trained practitioner with a chaperone. The audience observes the demonstration in a separate viewing room via an audio-visual link. The practitioner has 2-way communications with the audience via an earpiece and microphone and the audience can see the live ultrasound images. The patient can hear only the practitioner.

Preliminary Steps

Prior to making any approach to patients, the organiser should obtain written approval from the Medical Director of the Trust to seek patients' permission to be scanned as part of an educational meeting. Approval from the local Ethics Committee may also be sought.

Patient Selection

It is recommended that each patient is recruited in two stages. Wherever possible, the patient should speak to the same individual to avoid confusion.

Initial Meeting

- The initial contact is likely to be during an ultrasound list and patients should be approached in a sensitive manner. It may be necessary to ask colleagues to help recruit sufficient suitable patients.
- For most cases, the first approach should be made 4 - 6 weeks before the planned demonstration. Patients with more stable or chronic conditions may be seen earlier.
- Only patients who are likely to know their diagnosis should be considered. If in doubt, the patient's suitability should be discussed first with the referring clinician, who may also offer to make the initial approach.
- It is advisable to avoid using patients, who may have difficulty attending due to poor mobility or travelling difficulties, and those who have a history of poor attendance.
- Contact details should be exchanged with the selected patients to follow up their potential participation.
- Selected patients should be given a letter of invitation to participate and full details of their involvement including the purpose of the demonstration, the nature of the procedure, the need for a second meeting and scan, the procedure on the day and a clear statement that their decision on whether or not to participate will not affect their care. A standard leaflet giving information for adult patients having an ultrasound scan would be useful.

SECOND MEETING

The purpose of the second meeting is to confirm that the patient is still suitable and consents to be scanned at the demonstration, having had time to consider the information given at the first meeting.

Written consent should be obtained and in obtaining it you should ensure that the patient is aware of the following:

- The purpose of the workshop and how delegates will benefit from seeing live scanning;

- Why they have been chosen to participate;
- Who will be present in the scanning room and where the audience will be;
- What the audience will see and hear through the audio-visual link;
- What the patient will see and hear and its significance;
- That they are under no obligation to help and that they can withdraw at any time without detriment to their future care;
- The scanning procedure and any associated risks

If the patient consents to the procedure, they should be re-scanned to confirm that appearances are unchanged. Hand the patient a letter thanking them for their help and giving details of any special preparation (e.g. fasting). Include instructions on where and when they should report on the conference day. Ask that they bring the letter with them on the day. A map showing the venue is useful. Make it clear they can be accompanied by a spouse or friend. Arrange to telephone the patient at a specific time two days before the meeting as a reminder.

ON THE DAY OF THE MEETING

- Try to meet all patients before or after their scan if other commitments allow.
- Ensure that someone is responsible for managing the demonstration programme actively to control waiting times and give effective communications.
- Provide a private changing area for patients.
- Where ultrasound contrast agents are to be used, it is important that the procedure is supervised by an experienced ultrasonologist, who assumes responsibility for the safe, appropriate and ethical use of the agent. As with any injectable drug, there is a small possibility of adverse effects and it is the responsibility of the supervising ultrasonologist to ensure that this can be managed appropriately. In particular the injection should be administered in a clinical area, where resuscitation equipment and support is available.

Current BMUS, EFSUMB and WFUMB safety guidelines related to use of ultrasound contrast agents should be followed. As there is evidence that microbubbles can potentiate bioeffects related to acoustic cavitation, special care should be taken to minimise the duration of scanning at higher acoustic output settings.

AFTER THE DEMONSTRATION

Write to all patients thanking them for their contribution. Travelling expenses should be paid.

SECTION 3: GUIDELINES FOR THE MANAGEMENT OF SAFETY WHEN USING HEALTHY VOLUNTEERS FOR PRACTICAL TRAINING/DEMONSTRATION IN ULTRASOUND SCANNING

Overall Responsibility and Supervision

·Healthy Volunteers should not include children, pregnant women (except for the purposes of an obstetric training programme- see section 1) or eyes and demonstrations should not involve contrast agents, endocavity, intravascular or endoscopic scanning in line with ECMUS recommendations.

Responsibility for the safety of volunteers during practical training in ultrasound scanning lies in the first instance with the qualified operator supervising the scanning.

We recommend that there should be a private, preliminary scan prior to the event to ensure normality and give the chance to discuss any unexpected findings with the volunteer in a private setting.

· Where significant previously unknown pathology (or pregnancy) is detected during training scan on a "normal" volunteer, the scan should be terminated immediately and there should be appropriate mechanisms in place for reporting the findings and directing appropriate medical management. This must include a clear strategy, so that if a medical problem is identified in a volunteer that an appropriate referral system is in place. This will normally be by contact with the general practitioner of the person concerned. This strategy must be clear to a volunteer prior to participation in a scanning session.

· Supervisors should be aware of the particular needs for training when ultrasound scanning is used for less common applications or research.

Informed Consent

· The person being scanned should give informed consent for the procedure. It is the Supervisor's responsibility to ensure this is done.

· Healthy volunteers should give informed consent, ideally in written form. The consent form should include a paragraph on the consequences of finding an unforeseen abnormality and the strategy for subsequent management of the problem.

Management of Acoustic Output

· The supervisor will ensure that any trainee avoids the use of excessive and inappropriate exposure levels, particularly when using spectral Doppler and colour Doppler imaging modes.

· The supervisor will ensure that the time spent with an individual subject does not exceed that necessary for the training/demonstration needs. Absolute limits are given in BMUS Guidelines for the safe use of Diagnostic Ultrasound Equipment ([hyperlink](#)).

· Wherever possible, training should be carried out using a scanner equipped with a display of the two safety indices - Mechanical Index and Thermal Index. The supervisor should make sure any trainee is aware of the displayed safety indices, their meaning, and their function in the management of safety.

· The trainee should be aware of the effect on machine output resulting from changes in machine controls. This may be monitored during scanning by observing the safety indices.

REFERENCES:

British Medical Ultrasound Society (BMUS), 2000, Guidelines for the safe use of diagnostic ultrasound equipment, BMUS Bulletin, August

World Federation of Ultrasound in Medicine and Biology (WFUMB), 1998, Conclusions and Recommendations on Thermal and Non-thermal Mechanisms for Biological Effects, *Ultrasound in Med. & Biol.*; 24: Supplement 1, xv-xvi

European Federation of Societies of Ultrasound in Medicine and Biology (EFSUMB), 2002, Clinical Safety Statement for Diagnostic Ultrasound (2002)

European Committee for Medical Ultrasound Safety (ECMUS), 2017, Live ultrasound scanning at exhibitions

Acknowledgements

BMUS acknowledges the work of Derby NHS Radiology and Obstetric departments in revising the BMUS consent form for use with pregnant volunteers.

BMUS Council
November 2018

APPENDIX 1: BMUS Consent Form for Ultrasound Scanning for the Purposes of Teaching and/or Demonstration

Participation in workshops, study days, conferences or for other teaching or demonstration purposes is voluntary. It is recommended that consent is obtained by the person responsible for the scanning session.

The volunteer should read the statements below and sign the form if he/she is in agreement with them and is willing to accept their implications.

- The potential hazards of ultrasound have been explained to me;
- I understand that I may withdraw my participation in the scanning at any time, without the need to justify my decision.
- I understand that personal/ medical information may be revealed on the ultrasound monitor, and will be witnessed by those present;
- To the best of my knowledge I am not pregnant. I understand that the scan will cease if a pregnancy is found.
- I understand that there exists the possibility of finding an unsuspected abnormality, or pathology, during the scanning process, which will be revealed to those present;
- In the event of such an abnormality being discovered as a result of the scan, I agree that I should be informed of the abnormality, that a relevant medical practitioner, or GP, may be contacted, and that I may be referred, if necessary, to the appropriate clinician;

I understand the implications of the above statements, and agree to take part in the demonstration/teaching session(s) on :

Date(s): _____ at _____

Signature of subject _____

Print name: _____

Date: _____

Person receiving consent:

I acknowledge that any scanning will adhere to BMUS guidelines for the safe use of Diagnostic Ultrasound Equipment and the management of safety when using volunteers & patients for practical training and live demonstration in ultrasound scanning.

Signature of person receiving consent _____

Print name: _____ Role: _____

Date: _____

APPENDIX 2: BMUS Consent Form for Ultrasound Scanning of Pregnant Volunteers for the Purposes of Teaching and/or Demonstration

Participation in workshops, study days, conferences or for other teaching or demonstration purposes is voluntary. The person responsible for the scanning session has asked you to read and sign this form to confirm your consent to be scanned.

Please read the statements below and sign the form if you agree with them and are willing to accept their implications.

- The safety of ultrasound has been explained to me and I have had the opportunity to ask questions;
- I understand that the scan session will be supervised by an appropriately qualified ultrasound practitioner;
- I understand that I may withdraw my participation in the scanning at any time, without the need to justify my decision;
- I understand that personal/ medical information may be revealed on the ultrasound monitor, and will be witnessed by those present;
- I confirm that I am pregnant and that a normal detailed anatomy scan has been completed prior to attendance at this workshop;
- I understand that the sex of my baby may be revealed on the ultrasound monitor, and will be witnessed by those present;
- I will inform the lead sonographer if I do/ do not wish to know the sex of my baby (every effort will be made to keep this information from you, should you wish not to know).
- I understand that this scan will be of no diagnostic benefit and should not be considered as a medically referred investigation. The scan will NOT be used to monitor the growth of your baby or check detailed anatomy.
- I understand that there exists the possibility of finding an unsuspected abnormality, or pathology, during the scanning process, which will be revealed to those present;
- In the event of such an abnormality being discovered as a result of the scan, I agree that I should be informed of the abnormality, that a relevant medical practitioner, or midwife, may be contacted, and that I may be referred, if necessary, to the appropriate clinician;

I understand the implications of the above statements, and agree to take part in the demonstration/teaching session(s) on:

Date(s): _____ at _____

Signature of subject _____

Print name: _____

Date: _____

Person receiving consent:

I acknowledge that any scanning will adhere to BMUS guidelines for the safe use of Diagnostic Ultrasound Equipment and the management of safety when using volunteers & patients for practical training and live demonstration in ultrasound scanning.

Signature of person receiving consent _____

Print name: _____ Role: _____

Date: _____