

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

Introduction and Scope

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.

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 fetal 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 trainee operators 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 are clear. They should ensure that there is sufficient scope to enable practical scanning skills to be developed within a managed and responsible framework.

Formal training programmes should include appropriate teaching material on the safe use of ultrasound, the potential for bioeffects 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.

GUIDELINES

- **Overall Responsibility and Supervision**
- Responsibility for the safety of patients and volunteers during practical training in ultrasound scanning lies in the first instance with the tutor supervising the scanning.
- The tutor should ensure that the trainee is competent in the safe application of ultrasound before being allowed to scan without supervision.
- Where previously unknown pathology is detected during training scan on a "normal" volunteer, 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.

- 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 being scanned for clinical reasons 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.
- 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 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.
- 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.

REFERENCES:

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

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

EFSUMB 2002, Clinical Safety Statement for Diagnostic Ultrasound (2002).