

Consensus Guidelines and Quality Assurance Programme on the Use of Ultrasound in Patient Care

April 2008

A collaboration between College of Radiology Academy of
Medicine of Malaysia & the Ministry of Health of Malaysia

These guidelines are intended to assist practitioners in providing diagnostic ultrasound services. The guidelines are based on the best scientific information available at the time of writing using available resources and opinions from experts of various clinical disciplines. Whilst striving for the best standard of care, the recommendations and guidelines are not intended, nor should be used to establish a legal standard of care. This document also does not define a training curriculum but is only set out to establish operational criteria for safe practical training. As always, practicalities as well as circumstances may warrant variations or adaptations of these recommendations yet, should not compromise the delivery of adequate sonographic care to the patient.

Contents

	Page
1. Preamble	4
2. Introduction	5
3. Goals	5
4. Qualifications and Responsibilities of Personnel	6
5. Equipment Specifications	13
6. Documentation	26
7. Policies and Procedures for Quality and Improvement	28
8. Safety Guidelines	
A. Patient Safety Guidelines	36
B. Personnel Safety Guidelines	39
9. Electrical safety and QA	40
10. Equipment Safety	41
11. References	43
12. Appendix	46

Ultrasound Working Group

Chairperson

Dr. Hjh.Hanun Fauziah bt.Abd. Ghani KMN

MD(UKM) , M.Med (Radiology) (UKM) , AM (Mal)
Consultant Radiologist and Head of Department
Hospital Serdang , Selangor Darul Ehsan

Members

Dato Dr. Hjh. Zainun bt.A. Rahman DIMP

MBBS (Mal) , M.Med (Radiology) (UKM) , AM(Mal)
Consultant Radiologist and Head of Department
Hospital Tengku Ampuan Afzan , Kuantan Pahang

Dr.S. Sivalingam PSP, KMN,SSD

MBBS (Madras), DMRD (London)
Consultant Radiologist Hospital Tengku Ampuan Rahimah, Klang
Selangor Darul Ehsan

Dr. Hjh. Salwah bt.Hashim

MD (USM), MRad (UM), AM (Mal)
Consultant Radiologist and Head of Department
Hospital Pulau Pinang

Dr. Hjh. Sharifah Mastura bt. Syed Abu Bakar AMM

MD (UKM), M.Med (Radiology) (UKM), AM (Mal)
Consultant Radiologist and UroRadiologist
Hospital Kuala Lumpur

Dr.Rosminah bt Md.Kassim,

MD (UKM), M.Med (Radiology) (UKM), AM (Mal)
Consultant Radiologist
Hospital Kuala Lumpur

Dr.Moorthy Sinnasamy

MBBS (Malaya), MRad (Malaya), Fellowship IR (Westmead), Fellowship INR (Royal Northshore)
Consultant Radiologist
Fakulti Perubatan dan Sains Kesihatan
Universiti Putra Malaysia
Selangor Darul Ehsan

Dr.Rozana bt.Husain

BSc (Western Michigan), MA (Western Michigan), MSc (Biomedical Physics) (UCLA),
PhD (Biomedical Physics) (UCLA)
Lecturer / Medical Physicist
Radiology Department
Hospital Universiti Kebangsaan Malaysia

1. PREAMBLE

Ultrasound is now accepted as one of the essential diagnostic tools. It is used by various healthcare professionals.

The ultimate judgment regarding the approach to any specific procedure or course of action must be made by the professional. This may differ or deviate from the guidelines in the interest of the condition of the patient, limitations of available resources or advances in knowledge or technology. However, this does not mean that the care given to the patient is below standard. The practitioner shall document sufficient information in the patient's record explaining efforts of delivery of effective and safe medical care.

The sole purpose of these guidelines is to assist the practitioners in achieving this objective.

2. INTRODUCTION

Ultrasound has gained clinical acceptance because it is convenient to use, comfortable for the patient, easily available and non-invasive with no radiation involved. The wide range of clinical usage of diagnostic ultrasound for many years has not revealed any harmful effects. There are various studies that supported no direct link between the use of diagnostic ultrasound and any adverse outcome. Although there is possibility that biological effects may be identified in the future, current information indicates that the benefits far outweigh the risks.

However, epidemiological data has its limitations. At present there is no data regarding harmful effects from use of powerful diagnostic equipment such as those with pulsed Doppler and harmonic imaging or use of contrast agents.

The clinical aspects of this guideline were developed with consensus of service providers in the Ministry of Health Malaysia, College of Radiology Malaysia, Academy of Medicine Malaysia and medical faculties in universities.

Recommendations and quality control measures may vary between the different medical disciplines and will be addressed separately. This guideline has been developed to assist practitioners performing ultrasound studies of the various organs of the body. In some cases, additional and/or further specialised examinations may be necessary. While it is not possible to detect every abnormality, adherence to the following guidelines will maximize the probability of detecting most of the abnormalities.

3. GOAL

The goal is to provide the practitioners guidelines for the performance, recording and documentation of high quality ultrasound examinations. The guidelines reflect the minimum criteria for complete examination in each area, but are not intended to establish a legal standard of care.

A Malaysian Ultrasound Accreditation Programme should be established to curb inappropriate use of ultrasound, at the same time set guidelines for improvement in the standard and quality of ultrasound-based diagnosis. The accredited practices once in place are expected to generally follow the guidelines with recognition that deviations from these guidelines will be needed in some cases, depending on patient needs and available equipment and specialties.

4. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

In the current health care environment, it is important to be able to prove that optimal patient care is provided in the form of quality ultrasound services. Many medical specialists are increasingly wishing to undertake ultrasound examinations on patients referred to them for clinical opinion as a direct extension of their clinical training.

Below are recommended guidelines for a training programme with a view of initiating Quality Assurance (QA) and accreditation for ultrasound professionals.

The training may be purely diagnostic, diagnostic and ultrasound guided interventions, predominantly ultrasound guided interventions or limited clinically focused service. Departments of diagnostic imaging or clinical radiology would normally provide all of these services, and for practical reasons other medical practitioners would deliver only those aspects of ultrasound particularly relevant to their clinical practice.

Since the medical use of ultrasound remains highly operator dependant in spite of advances in technology, it is in the best interest of patients that practical experience forms an essential component of all training in clinical ultrasound. Those in training may observe experienced and qualified personnel carrying out the scan, and more importantly, use ultrasound equipment under guidance and supervision of a tutor or other senior clinical colleagues. During training, they will develop practical skills in carrying out a wide range of clinical studies, obtaining images of optimum diagnostic quality and interpreting and reporting findings.

Those who provide ultrasound services are ethically and legally vulnerable if they are not adequately trained. A defence against a claim of negligence is unlikely to be successful should an error occur as a result of incompetence.

Therefore, it is prudent that proper guidelines and recommendations be addressed as to ensure that only properly trained and accredited personnel perform the examinations. By establishing these recommendations, it will ensure that the lines of accountability for safe scanning during training are clear. Formal training programmes should include appropriate teaching material on the safe use of ultrasound, the potential biological effects and the rationale and means for limiting output.

Due to variations in the medical systems between countries and organizations of the different specialties, it is sometimes difficult to strictly define the different levels of practice and training requirements. A “WHO” study group suggested that the ultrasound training needs, be defined according to the equipment availability.

This guideline **DOES NOT** define a training curriculum but is only set out to establish operational criteria for safe practical training.

4.1. QUALIFICATIONS & TRAINING REQUIREMENTS

Radiologists have the skills, experience and commitment to provide guidelines for training of medical doctors (non–radiologists). Qualifications and training for radiologists and other ultrasound practitioners are as follows:

Qualifications of the medical practitioners who evaluate and interpret diagnostic ultrasound examinations:

1. They should be a licensed medical practitioner
2. They should have a thorough understanding of the indications and guidelines for ultrasound examinations
3. They should be familiar with the basic physical principles and limitations of the technology of ultrasound imaging
4. They should be familiar with alternative and complementary imaging and diagnostic procedures
5. They should be capable of correlating the results of the other procedures with the ultrasound examination findings
6. They should have an understanding of ultrasound technology and instrumentation, ultrasound power output, equipment calibration, and safety
7. They should be able to demonstrate familiarity with the anatomy, physiology and pathophysiology of these organs or anatomic areas that are being examined
8. They should provide evidence of training and requisite competence needed to successfully perform and interpret diagnostic ultrasound examinations in the area(s) they practice in
9. Their training should include methods of documentation and reporting of ultrasound studies

4.2. TRAINING MODULE RECOMMENDATIONS

Theoretical training: the training should cover the basics of physics of ultrasound, safety aspects, equipment, image recording, reporting, artifacts and the relevance of other imaging modalities to ultrasound.

Practical training: Good understanding of anatomy and pathology and its relevance. This must include adequate hands-on training under the guidance of a trainer.

4.3 MINIMUM REQUIREMENTS FOR THE PRACTICE OF BASIC MEDICAL DIAGNOSTIC ULTRASOUND FOR THE MEDICAL PRACTITIONER

These have been drawn up based primarily on the guidelines and recommendations of the Australasian Society for Ultrasound in Medicine, the Royal College of Radiologists, UK, the European Federation of Societies for Ultrasound in Medicine and Biology and the American College Of Radiology–Ultrasound Accreditation Programme Requirements.

The minimum and appropriate levels of training and expertise are divided into 3 levels. These 3 levels are regarded as a guide to different levels of competence and expertise.

Delivery of training requires the time commitment of the trainer and trainee, the provision of funding, the content and practicality of the curriculum and the availability of trainers and training courses. It should be recognised that training requires additional time, space, funds and equipment.

Training should be related to the specialist requirements of the trainees. Regular appraisal should take place during the training period. Appropriate log book(s) should be maintained by the trainee. At the end of the training period, the competency level should be assessed by the appointed trainers. The trainees and trainers can be privileged and accredited based on their expertise and competency level.

4.3.1 LEVEL 1

Different trainees will have different timing of acquiring skills and they should be judged by the assessment of their individual competency level. Regular appraisal should take place during the training period. It must be recognized

that not all trainees have the aptitude to undertake ultrasound scanning skills and that some despite undergoing training, may not acquire the appropriate skills to ever practise independently. It should be noted that the assessment of competence is a reflection on the position only at the time of the assessment undertaken and no more.

- a) Able to perform common ultrasound examinations safely and accurately
- b) To be able to recognise and differentiate the normal anatomy and diagnose common abnormalities within certain organ systems
- c) Should be able to recognize when a referral or a second opinion is indicated/needed.
- d) A log book containing the numbers and types of examinations should be kept and maintained and signed by the supervisor/ trainer periodically.
- e) A level 2 trainer should be able to supervise the level 1 trainee.

In some medical specialties, the training requisite to this level of practice would be gained during conventional post graduate specialist training programme.

Criteria of Level 1 Competency:

- I. Completion of an approved residency programme, fellowship or postgraduate training that includes at least 3 months of diagnostic ultrasound training in the area (s) they practise under the supervision of a qualified trainer (level 2 to 3).
- II. Documented evidence of having performed, evaluated and interpreted organ based ultrasound of at least a minimum **500 sonograms**

- III. For doctors without formal fellowship or post graduate training, they must show documented evidence of 2 years of ultrasound experience during which at least 500 ultrasound examinations were performed or supervised and interpreted

- IV. In the absence of formal training as described above the medical practitioner should be able to demonstrate evidence of competence and at least 5 years or equivalent of practice in diagnostic ultrasound which should include a substantial component of training under the direct supervision of a qualified medical practitioner (or practitioners) and participation in continuing medical education (CME) activity dedicated to diagnostic ultrasound.

4.3.2 LEVEL 2

- a) Requires **at least one year** of experience at level 1 with regular ultrasound sessions of **at least one session per week**.
- b) Should have performed a significant number of examinations which encompasses the full range of conditions and pathologies
- c) Able to recognise and correctly diagnose almost all pathology within the relevant organ systems and to recognize when a second opinion is needed from a level 3 trainer.
- d) Able to recognize the anatomical or pathological variants of diseases
- e) Be able to teach, accept and manage referrals from the Level 1 trainees
- f) To be a supervisor of training, one should have achieved at least level 2 competence and/ or with at least 2 years experience at that level.
- g) Able to perform basic non complex routine ultrasound guided procedures based on organs systems and specialty training.
- h) Should maintain a log book recording of the number, types and pathology of examinations performed.

- i) Should be able to conduct some research on ultrasound (where applicable).

The training requisite to this level of practice would be gained during the period of specialist or subspecialty training, which may either be during or after completion of the specialist training.

4.3.3 LEVEL 3

This is an advanced level of practice and varies with the different clinical subspecialties.

- a) Able to accept tertiary referrals from level 1 and 2
- b) Able to perform highly skilled and specialized ultrasound examinations
- c) Able to perform advance, invasive and complicated ultrasound guided procedures
- d) Become a trainer at all levels of training
- e) To be aware of and keep track of developments in ultrasound.
- f) Should be able to conduct some research on ultrasound (where applicable)

The training requisite to this level of practice would be gained during the period of subspecialty training, which may either be within or after completion of the specialist training. This would equate to a consultant radiologist with a subspecialty practice which includes a significant commitment to ultrasound.

4.4. CONTINUING PROFESSIONAL DEVELOPMENT

Following training, regular CME/CPD should be undertaken and documented. It is the responsibility of the individual to maintain the practical skills and competency and also to remain up to date with the rapidly developing field of ultrasound.

4.5 REQUIREMENTS FOR SONOGRAPHERS

Sonographers are healthcare professionals without a medical degree who use ultrasound for medical purposes in some specialty fields. In most countries where

sonographers are currently in active practice, there is a comprehensive training program where they acquire high standards of knowledge and practical scanning skills and to ensure that the sonographers are properly trained for their job. They are strictly regulated with well developed schemes for evaluation and accreditation.

Criteria of Sonographers' Competency

- a. The sonographers should be privileged, certified and/or accredited by a recognized body of the country. They must also maintain and document the number of cases performed.
- b. Maintenance of competency must have a minimum competency equivalent of the level 1 competency.

5. EQUIPMENT SPECIFICATIONS

5.1 STANDARDS FOR ULTRASOUND EQUIPMENT

Ultrasound is widely available. However changes in ultrasound technology are developing rapidly with increasing capabilities of the equipment.

5.2 SELECTION OF EQUIPMENT

When selecting new ultrasound equipment, it is of obvious critical importance to consider the clinical applications for which the equipment will be used. The clinical applications and the relative workload in each application will determine the specification that is desirable or necessary.

It is desirable to have the highest possible specifications for all clinical applications for which the equipment may be used, but this must be balanced

against cost if the equipment is only to be used for certain applications on occasional basis.

Equipment specification should also take into account both current and possible future development in service requirements and workload for the projected lifetime of the equipment.

5.3 GENERAL CONSIDERATIONS FOR ALL EQUIPMENT

Clinical applications for which the equipment will be used:

1. Adult or paediatric age groups
2. General thoracic, abdominal and pelvic ultrasound
3. Renal and retroperitoneal ultrasound
4. Musculoskeletal ultrasound/ breast /other small or superficial parts ultrasound
5. Obstetric/gynaecological ultrasound
6. Vascular ultrasound (carotid, abdominal, intracranial, peripheral arterial, peripheral venous studies, including pulsed, power, and color Doppler)
7. Biopsy/interventional/therapeutic procedures

Transducer / probe required:

- Linear
- Curved linear array
- Phase array/sector
- Endocavitary
- Intraoperative
- Depth range required for each type of transducer:
 - Deep
 - Middle
 - Superficial
- Footprint size
- Biopsy guidance facility

In all applications of clinical ultrasound, three things are of prime importance:

1. Image clarity
2. Resolution
3. Ability to differentiate tissue structures

Although it is accepted that diagnosis will not always be obtained in all patients despite optimal equipment specifications, the equipment must be capable of visualizing tissue structures in most patients of different body habitus to a diagnostic level sufficient to meet clinical need. It should be able to display normal and abnormal tissue detail with the ability to differentiate solid and cystic abnormalities and to distinguish parenchymal echo changes clearly.

The choice of appropriate probes for the clinical applications required is vital. The appropriate transducer for each application should ensure good visualization at sufficient depth of image without significant loss of accurate spatial resolution. Linear array probes are required for small part scanning, and curved linear or phased array probes for body scanning, although transducer versatility has been extended with multifrequency probes. Footprint size should be suitable for the structures being examined, particularly with small parts or intra-operative applications. The transducer should be as light as technically feasible, comfortable to hold, easy to change and durable. Consideration also should be given as to whether biopsy and drainage needle guide facilities are necessary.

Scanning capabilities

- B- and M-mode
- Colour, spectral, power Doppler
- Tissue harmonic imaging
- Contrast agent imaging
- 3-D imaging
- Elasticity (elastography)

Physical capabilities

- Mobility: static, mobile, portable/emergency
- Screen: size, positioning flexibility

Measurement /Analysis Facilities

- Standard: distance, area, circumference, volume
- Specialised measurement/analysis calculations for specific clinical applications such as vascular, obstetric or cardiac work.

Ultrasound Settings

- Magnification facility
- Cineloop review
- Adjustable number and depth of focal zones
- Adjustable signal processing facilities
- Tissue specific pre-sets for individual clinical applications

Annotation

Display and annotation:

- Patient, centre and date identification
- Text and anatomical side markings
- Ultrasound settings and indices

5.4 General Requirements for Ultrasound Scanner Equipment

Minimum

- Display examination details
 - Patient ID, date and time, examination centre, anatomical site marking, selected probe, acoustic power setting/mechanical and thermal indices, other image processing and Doppler information to be shown in all display modes on all video/disk/hard copy outputs

- Electronic adjustment of focal zone
- Movable zoom box
- Simultaneous display of at least two modes
- Cineloop for 5 seconds at 25 frames per second
- Hard disk storage of adequate capacity
- Controllable signal processing facilities
- Tissue specific pre-sets capability
 - Output power, signal processing and calculation
- Caliper accuracy of better than 2% or 0.5mm
- Screen and hardcopy image distortion of less than 5%
- Tissue harmonic imaging

Desirable

- High definition, variable size display magnification
- Extended field of view
- Digital beam former
- Cineloop up to 1 minute at 25 frames per second
- Ability to store images digitally (more than 0.5 Gb)
- Fast random access image review
- Removable storage media (DVD, CD or MO)
- Automated tissue specific pre-sets
 - Output power, signal processing and calculation
- Customizable pre-sets and calculations for individual users and for different type of applications for all modes
- DICOM-3 standard
- Micro bubble contrast imaging facility

5.5 Specifications for Individual Requirements

5.5.1 Abdominal ultrasound

Equipment requirements

Transducer

- Depth to image at least 15 cm with continuing good spatial resolution
- Curved linear or phased array transducer
- Linear array: helpful to delineate more superficial abnormalities
- Imaging in multi-frequencies from 2.0MHz to 7.0MHz for adult patients, and up to 10-12MHz in the younger patient group
- Equipment adjustment to operate at the highest clinically appropriate frequency possible without loss of penetration
- Consider newer technology allowing use of higher frequencies but maintenance of penetration

B-mode imaging

- Good contrast resolution
- Good axial, lateral and slice thickness resolution
- Display of normal and abnormal tissue detail
- Clear differentiation of solid and cystic abnormalities and organ parenchyma echo changes
- Accurate measurement of the size of a focal lesion and accurate reproduction of these measurements
- Image magnification
- Utilisation of non-linear harmonic-modes

Doppler facility

- Sensitivity levels of the order to ascertain blood flow in low velocity states in both spectral and colour modes at a full depth of penetration

Options

- Biopsy/drainage guide facilities with clear visualization of the needle
- Appropriate capabilities and software for contrast agent imaging studies

Table 1: Specifications for general abdominal ultrasound

SPECIFICATION	ABDOMINAL	
	Minimum	Desirable
B-mode imaging		
Transducer: Linear array (LA), curved linear array (CLA), phase array (PA)	CLA or PA	LA, CLA or PA
Frequency range (MHz)	2-7	2-10
Penetration (cm)	15	18
Spectral Doppler		
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	CLA	LA,CLA,PA
Frequency range (MHz)	2-5	1.5-4
Calculation of waveform indices	manual	auto & manual
Accuracy of range gate registration (mm)	<1	<1
Penetration (cm)	10	15
Flow imaging		
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	CLA	LA, CLA, PA
Frequency (MHz)	2-5	1.5-4
Penetration	10	15

Frequency and type of array should be appropriate for depth and penetration

5.5.2 Small Parts Ultrasound

The superficial location of these structures allows for high-resolution, high frequency imaging with penetration less of a consideration than in general abdominal imaging.

Equipment requirements

Transducer

- Linear array transducer
- Depth to image should be at least 6cm
- Imaging in multi-frequencies from at least 7-10 MHz, but higher frequencies to 15MHz are desirable
- Equipment adjustment to operate at the highest clinically appropriate frequency to ensure maximum resolution of depth of image

B-mode imaging

- Excellent contrast resolution
- Excellent axial, lateral and slice thickness resolution
- Differentiation of very small solid and cystic abnormalities
- Ability to differentiate lesion margins (well or ill-defined), areas of calcification, and subtle parenchymal echo changes
- Accurate measurement of very small focal lesions and accurate reproduction of these measurements
- Image magnification
- Fine needle aspiration techniques are frequently utilized, and clear visualization of the needle is required

Doppler facility

High sensitivity levels of the order to ascertain blood flow in very low velocity states in both spectral and colour modes

Specific requirements

Scrotal ultrasound

Doppler facility is essential and should have excellent colour and spectral sensitivity to low velocity flow

Musculoskeletal ultrasound

A larger range of frequencies is required owing to variations in patient habitus and depth of insonated structures. Very high frequency transducers up to 14 MHz may be required to optimally image small structures such as fingers, and lower frequencies down to 5 MHz for knees and hips.

Breast ultrasound

The differentiation between cystic and solid lesions is of crucial importance in breast ultrasound, and the ability to perform image-guided FNA/biopsy is essential. Doppler facility is also being used for evaluation of indeterminate lesions as is elastography (measuring the elasticity of the lesion) in helping to differentiate between benign and malignant lesions.

Table 2: Specifications for ultrasound of small parts

SPECIFICATION	SMALL PARTS	
	Minimum	Desirable
Dynamic imaging		
Transducer Linear array (LA), curved linear array (CLA), phase array (PA)	LA	LA
Frequency range (MHz)	7-10	5-15
Penetration (cm)	6	8-10
Spectral Doppler		
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	LA	LA
Frequency range (MHz)	4-5	4-8
Calculation of waveform indices	manual	auto & manual
Accuracy of range gate registration (mm)	<1	<1
Penetration (cm)	6	8-10

Flow imaging	Minimum	Desirable
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	LA	LA
Frequency (MHz)	4-5	4-8
Penetration	6	8-10

Frequency and type of array should be appropriate for depth and penetration

5.5.3 Vascular Ultrasound

Vascular ultrasound covers a wide range of applications, which include:

- Disease of the extracranial arteries (carotid scanning)
- Deep vein thrombosis
- Venous incompetence
- Peripheral arterial disease (mainly legs, less often arms)
- Screening for aortic aneurysm
- Renal artery disease
- Assessment of central veins for vascular access
- Transcranial imaging of the major cerebral arteries
- Assessment of haemodialysis access fistula and grafts
- Pre-operative assessment for arterial bypass
- Dialysis access reconstructive surgery, assessment of visceral arteries and veins

Equipment requirements

Transducer

- Linear array transducer (minimum depth to 6cm, imaging in multi-frequencies from 5-8 MHz)
- Curved linear or phased array transducer (minimum depth to 15cm, imaging in multi-frequencies from 2-8 MHz)
- Equipment adjustment to operate at the highest clinically appropriate frequency to ensure maximum resolution to depth of image

B-mode

- Good contrast resolution across a full range of depths
- Good axial, lateral and slice thickness resolution

Colour flow:

- High sensitivity to low flow velocities at a full range of depths (ensure that there is good penetration)
- Clear registration of colour within the vessels
- Rapid update of the colour signal
- Minimum compromise of gray scale frame rate
- Good spatial resolution (axial and lateral) in the image plane
- Beam steering, without significant loss of colour sensitivity in linear arrays
- A full complement of controls to alter the parameters and appearance of the colour image
- Consideration should be given to additional algorithms for the demonstration of colour flow
- The sensitivity of power Doppler in the detection of low flow states and in small vessels should be high
- Other methods of flow assessment should be evaluated (e.g., B-flow)

Spectral Doppler

- Good sensitivity to low flow velocities at a full range of depths
- Good signal/noise of the Doppler spectral display at a full range of depths
- Beam steering without significant loss of sensitivity in linear arrays
- A full complement of controls to alter the parameters and appearance of the Doppler spectral display
- Aliasing limits appropriate to the transducer and velocities encountered in specific vascular examinations
- A full range of calculations appropriate to current vascular protocols and clinical applications

Specific requirements

A. Extra-cranial disease (carotid scanning)

The scanner/transducer combination must have good B-mode performance, colour and spectral Doppler sensitivity over a range of depths (from 1cm to 5cm). Beam steering for colour and spectral Doppler is necessary to obtain an adequate beam/flow angle.

B. Deep vein thrombosis

The scanner/transducer combination should have good B-mode performance over a range of depths. Good colour sensitivity to low flow and velocities and good discrimination from tissue movement is essential to detect low venous flow.

C. Venous incompetence

The scanner/transducer combination should have excellent colour and spectral Doppler sensitivity to low flow and low velocities, particularly at depths of 0-2cm. Good B-mode and colour flow resolution is essential to determine the anatomy and flow characteristics in recurrent varicose veins.

D. Renal artery stenosis

The scanner/transducer combination should have excellent colour flow penetration and sensitivity to a depth of 14cm. Low colour flow and spectral Doppler frequencies (from 1.5 MHz to 3 MHz) is advantageous to detect deep vessels and helps to determine high velocities at depths. Extended/high pulse repetition frequency is advantageous for spectral Doppler to measure high velocities at depth.

E. Venous access for placement of central lines

Current guidelines and results of numerous studies indicate that such procedures should ideally be carried out under image guidance for a higher success rate and avoidance of morbidity related to procedure. Equipment used solely for this application need not conform to requirements for high resolution vascular scanning. Absolute specifications for equipment are less important than appropriate training in localization and access under ultrasound guidance.

Table 3: Specifications for vascular ultrasound

SPECIFICATION	PERIPHERAL VASCULAR	
	Minimum	Desirable
Dynamic imaging		
Transducer: Linear array (LA), curved linear array (CLA), phase array (PA)	LA, CLA	LA, CLA
Frequency range (MHz)	2-8	2-10
Penetration (cm)	6	8
Spectral Doppler		
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	LA, CLA	LA, CLA
Frequency range (MHz)	3-5	3-5
Calculation of waveform indices	manual	auto & manual
Accuracy of range gate registration (mm)	<1	<1
Penetration (cm)*	6	8
Flow imaging		
Transducer Linear array (LA), curved linear array (CLA), phased array (PA)	LA, CLA	LA, CLA
Frequency (MHz)	3-5	3-6
Penetration (cm)*	6	10

*Penetration shown is for linear arrays for imaging extracranial and peripheral veins. Penetration for abdominal/pelvic vessels is referred to in Table 1.

Frequency and type of array should be appropriate for depth and penetration

6. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation.

Images should be labelled with the patient identification, facility identification, examination date, and image orientation. Images of all appropriate areas, both normal and abnormal, should be recorded. Variation from normal size should generally be accompanied by measurements.

An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record.

Retention of ultrasound examination images should be consistent both with clinical needs and with relevant legal and local healthcare facility requirement.

Facility for permanent recording of images include one or more of the following:

- DICOM3 compatibility / print
- Thermal black and white paper or Colour printer
- VHS or digital video recorder or MO disk
- Connection to local laser printer facility with print out films
- Connection to local imaging network for storage in PACS

Documentation included for the ultrasound examination

Official documentation for the ultrasound images should include but not be limited to the following

- Patient's name and other identifying information
- Facility identifying information
- Patient's healthcare provider
- Date of ultrasound examination
- Image orientation when appropriate

- Organ or anatomic region of image
- Identification of the sonographer or sonologist performing the examination.

Final report provided by the interpreting physician

A final report of the ultrasound findings is included in the patient's medical record.

The official final report should include but is not limited to the following:

- Patient's name and other identifying information
- Name of patient's healthcare provider and contact information
- Location of ultrasound facility
- Relevant clinical information
- Date of ultrasound examination
- Specific type of ultrasound examination
- The report should include comment/s on the components of examination
- Appropriate anatomic and sonographic terminology should be used; variation from normal size should be accompanied by measurements when appropriate (organomegaly, masses); and limitation of examination should be noted.
- Pertinent, commonly utilized anatomic measurements should be listed
- Comparison with prior relevant imaging studies if available; recommendations including appropriate follow-up studies; an impression or conclusion; specific diagnosis or differential diagnosis should all be included
- The final report should be generated, signed, and dated by the interpreting physician
- Report should be completed and transmitted to the patient's health care provider in a timely fashion
- Reference range for vascular Doppler measurements

7. POLICIES AND PROCEDURES FOR QUALITY AND IMPROVEMENT

7.1 Policy on Diagnostic Ultrasound Services

1. All diagnostic ultrasound examinations should be conducted at the request of a registered medical practitioner.
2. As a matter of principle, patients should be examined only by registered medical practitioners. The examination should be structured to provide the required diagnostic information at minimum exposure.
3. Ultrasound services should only be provided by those medical practitioners who have competence in the specific examinations they undertake personally, or for which they issue reports.
4. The medical practitioners to whom patients are referred for ultrasound examination will either perform the examination themselves or be responsible for the examination being performed by an accredited medical sonographer.
5. Where a sonographer performs the ultrasound examination under supervision of a trained medical practitioner:
 - i) The trainer should ensure that the sonographer is appropriately qualified and capable of performing the requested ultrasound examination.
 - ii) The trainer should be available for advice and be capable of extending the examination where appropriate.
 - iii) The level of direct supervision of the sonographer by the medical practitioner should be appropriate for the training and experience of the sonographer.

6. Where a sonographer performs the examination without (the on-site) supervision of a medical practitioner (e.g. emergencies or in rural locations) the reporting medical practitioner should ensure that:

- i) There are protocols and guidelines in place to enable proper triaging of the patient where extension of the examination by the medical practitioner is required to effect a diagnosis.
- ii) That all hard copy and other information are reviewed and a report issued in a reasonable time frame.
- iii) The sonographer performing the examination is suitably qualified and registered to undertake such examinations.

7. The medical practitioner should regularly attend premises where ultrasound examinations for which he/she is responsible are performed and should ensure that:

- i) Any ultrasound examination performed is in the best interest of the patient and is carried out using appropriate and properly maintained equipment.
- ii) Appropriate facilities are available for patients.

8. The medical practitioner is responsible for setting local department or practice guidelines on such matters as:

- i) How much of the examination should be shown and demonstrated to the patient.
- ii) How much information the sonographer might independently pass on to the patient.

- iii) How the examination should be recorded, what record should be provided for the referring medical practitioner and what, if any, should be made available to the patient.
9. A written report should be issued on all ultrasound examinations by the responsible medical practitioner. A report should be made available immediately if necessary. Hard copy films or other records should be made at the time of any referred diagnostic ultrasound examination.
10. A register of ultrasound examinations performed should be kept by each medical practice.
11. While all medical practitioners should be free to request ultrasound examinations depending on their clinical experience and judgment, a specialist in diagnostic ultrasound has a duty to decide whether a requested investigation is appropriate, having regard to the level of diagnosis required and the cost effectiveness of the examination.
12. It is the responsibility of the sonographer to ensure that they are appropriately qualified and accredited. They should not practise independently of an appropriately qualified medical practitioner and the medical practitioner should provide encouragement for the sonographer to participate in on-going education.
13. Specialists in diagnostic ultrasound should collaborate in undergraduate and postgraduate education and in continuing education of ultrasound professionals and also other medical practitioners to assist them to provide appropriate ultrasound referrals.

14. Statement on Non-medical Use

The non-medical use of ultrasound for psychosocial , entertainment purpose, or the use of ultrasound (2D or 3D) to only view the fetus, obtain a picture of the fetus, or determine the fetal gender without medical indication is inappropriate and contrary to responsible medical practice.

7.2 QUALITY CONTROL PROGRAM

There shall be a continuous quality control (QC) program for all ultrasound units. The facility should have a program document describing the goals and responsibilities of the QC program. It should be directed by a medical physicist or by a supervising radiologist/physician (who may appoint an appropriate designee to oversee the program).

Routine quality control testing must occur regularly; ***a minimum requirement is semiannually.***

The same tests must be performed during each testing period so that changes can be monitored over time and effective corrective action can be taken.

The recommended evaluation of each ultrasound unit should include, but not be limited to, the following tests:

Test	Frequency	Performed By
1. Physical and mechanical inspection	Semiannually	Service engineer/medical physicist
2. Fidelity of display and/or work station monitor	Semiannually	Service engineer/medical physicist
3. Caliper distance accuracy	Semiannually	Service engineer/medical physicist
a. Vertical	Semiannually	Service engineer/medical physicist
b. Horizontal	Semiannually	Service engineer/medical physicist
4. Depth of penetration/visualization	Semiannually	Service engineer/medical physicist
5. Dead-zone depth	Semiannually	Service engineer/medical physicist
6. Image uniformity	Semiannually	Service engineer/medical physicist
7. Axial resolution	Semiannually	Service engineer/medical physicist
8. Lateral resolution	Semiannually	Service engineer/medical physicist
9. Elevation resolution	Semiannually	Service engineer/medical physicist
10. Anechoic object imaging	Semiannually	Service engineer/medical physicist
11. Film processor quality control (QC).	Semiannually	Service engineer/medical physicist
12. Hardcopy fidelity	Semiannually	Service engineer/medical physicist
13. Softcopy fidelity	Semiannually	Service engineer/medical physicist
14. Low-contrast object detectability (optional)	Semiannually	Service engineer/medical physicist
15. Adherence to universal infection control precautions	After each biopsy	Sonographer

The process for testing and the standards for performance should be referenced.

The above items may be assessed using a commercially available phantom test object. At the present time, no one type of phantom is preferred; users should select one that is commercially available. Using a phantom will be helpful in responding to questions about low-contrast detectability in the quality control part of the testing material. However, the use of a phantom is **optional** at this time. Therefore, the part of the Quality Control section of the testing material, that addresses low-contrast object detectability, may be omitted. Questions relating to characteristics associated with system sensitivity, image uniformity, and safety may be answered without the use of a phantom as a test object.

Transducers

On an ongoing basis, tests should be done using two transducers commonly used with any unit employing more than one transducer. It is recommended that these be of different scan formats such as one linear (or curvilinear) array and one sector (mechanical, phased or vector).

The medical physicist/service engineers should monitor the results of the QC program.

Testing results, corrective action, and the effects of corrective action must be documented and the documentation maintained on site. In the event of a site survey, reviewers will expect to see such documentation.

For those systems with Doppler and color-flow imaging capabilities, the operational characteristics should be qualitatively evaluated to verify proper function, including positioning accuracy of the Doppler sampling volume, Doppler angle between the transducer and vessel axis, Doppler spectral display, directionality of flow, signal aliasing, and lack of signal where no flow is present. For color flow imaging, appropriate color mapping corresponding to flow direction and proper superimposition on the grayscale image should be assessed.

Assessment of quantitative accuracy of Doppler velocity estimates and corresponding flow requires the use of calibrated ultrasound Doppler flow phantoms, which is beyond the scope of typical system evaluation tests. For those systems with tissue harmonic imaging capabilities, image resolution, contrast, and noise in this mode should also be assessed.

QUALITY ASSESSMENT/IMPROVEMENT

- a. Quality assessment procedures should exist and should be systematically monitored for appropriateness of examinations, technical accuracy, and accuracy of interpretations.
- b. The volume of examinations and procedures should be documented and assessed on a continuous basis.
- c. Complications and adverse events incurred during ultrasound-guided interventional procedures should be recorded and regularly reviewed to identify opportunities to improve patient care.
- d. Results of ultrasound-guided interventional procedures should be recorded, monitoring the false-negative rates, inadequate tissue samples, and follow-up recommendations.
Concordance/discordance of imaging findings and pathology reports should be addressed by policies developed for resolution of discordant findings.

7.3 INTERNAL AUDITS

An internal auditing program must be established to review the practice's quality system. The program assesses the appropriateness of the quality system in place and evaluates compliance with internal policies and procedures.

The purpose of an audit is to verify that a quality system exists, is being followed and is effective in maximising the quality of medical imaging procedures and services to the referring physician and patient.

Auditors must therefore examine whether or not the facility has defined and documented its processes and procedures and communicated them adequately to staff. Auditors also need to determine whether staff is following the quality system.

Individuals performing quality system audits are generally selected from among the staff. They must be tactful, thorough, objective, confident and technically sound. They must receive specific training in auditing. Where practical, auditors should be from areas different to those being audited.

Audits should be scheduled well in advance. A checklist is essential to ensure complete coverage of the important aspects of the audit. It also enhances the objectivity of the findings and credibility of the audit team.

At the completion of the audit, the auditor issues a report to management that describes any discrepancies between the documented quality system and what the auditor found in the review of records, interviews with staff and by observation. The report should include recommendations for remedial action. The report could also include suggestions that the auditor may have to improve the quality system. Corrective action must be taken for any deficiencies identified by the audit and should be commensurate with the problem(s).

Following the corrective action, it must be verified that the previous deficiencies have been corrected. A record must be kept of this verification step. The internal audit schedule needs to cover, over a twelve month period, the technical requirements as well as the management requirements.

8. SAFETY GUIDELINES

8A. PATIENT SAFETY GUIDELINES

At present there have been no independently verified studies that have demonstrated any adverse biological effect of diagnostic ultrasound in vivo in humans.

The American Institute of Ultrasound in Medicine (AIUM) statement on patient safety:

“Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the AIUM herein addresses the clinical safety of such use: No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.”

Evidence obtained by epidemiological studies, cell studies as well as animal studies show no adverse effects, including no evidence of low birth weights from diagnostic ultrasound thus far in the history of ultrasound.

To date, there has been no known tissue damage or documented instances of patient injury at diagnostic level of ultrasound intensities. However, it is known that ultrasound beams of sufficient intensities and long enough exposure times,

such as those used in therapeutic ultrasound, can modify or even damage biological tissues. The biological effects may be produced by several mechanisms.

i) Thermal Effects

ii) Non-thermal Effects (Mechanical Effects) : a) Cavitation

b) Direct Mechanical Effect

i) Thermal Effects

As sound passes through tissue, some of the sound energy is converted to heat. Heat has the potential to cause irreversible tissue damage. At low ultrasound intensities, the heat is quickly dissipated and thus there is no measurable temperature rise. However, there is some concern with Doppler or color flow imaging where the intensity levels are higher, such that temperature rise in tissue may reach 1 degree Celsius or higher.

Please refer to:

Appendix 1: Thermal Index

Appendix 2: Exposure Time

Appendix 3: International Regulation and Safety Guidelines

ii) Non-thermal Effects

a) Cavitation

Cavitation is the process of tiny bubble formation and growth from dissolved gases in fluid when an intense ultrasound beam passes through the fluid. These bubbles can grow in size or even rupture and cause particle displacements and stresses thus producing some effect on the tissue.

Please see Appendix 4: Mechanical Index

a) Direct mechanical effect

When the above two mechanisms have been ruled out as the cause of effect on tissue, direct mechanical effect of ultrasound is usually thought to have occurred. The transmission of sound through tissues is associated with displacements,

accelerations, and stresses (compression and rarefaction) on particles in the medium. Thus it is possible that these perturbations can lead directly to bioeffects.

General guidelines for operators

1. Justification – weigh the advantages over the potential risks.
2. Familiarize with the instrument to recognize which operating modes and control settings result in high or low intensities.
3. As a general rule, use a higher receiver gain setting and a low power setting. Increase the power only when the sensitivity is inadequate or when there is insufficient penetration
4. Reduce exposure time by avoiding repeats.
5. Avoid holding the transducer stationary in contact with the patient unless it is warranted.
6. Scan using a minimum TI (thermal index) value consistent with obtaining useful clinical information.
7. Keep in mind the TI value displayed on the instrument, particularly when TI is greater than 1, i.e. producing intensity levels capable of raising tissue temperatures over 1 degree Celsius.
8. Apply the ALARA (as low as reasonably achievable) principle.
9. Routine maintenance and quality assurance should be implemented.

INFECTION CONTROL

Universal Precaution should be practised in every procedure, because every patient must be regarded as a potential source of infection and appropriate precautions should be taken to prevent cross-infection between patient and operator. Particularly important is the washing of hands both before and after direct patient contact. Other precautions will include use of personal protective equipment (PPE) where appropriate and correct handling and disposal of waste and maintenance of a clean working environment.

Recommendations:

- a) The transducer/ probe shall be cleaned in between patients with recommended cleansing agents. Meticulously scrub transducer as needed with a soft brush, sponge or gauze pad to remove all gel and bioresidues.
- b) Appropriate barrier and aseptic techniques should be applied accordingly.
- c) Always use sterile, legally marketed transducer sheath for intra-cavitary, intra-operative biopsy procedures.

8B. PERSONNEL SAFETY GUIDELINES

i) Room

- Room set-up needs to be flexible and versatile
- The room should be large enough to allow the ultrasound unit to be easily manoeuvred into position for different examinations and provide an adequate working space.
- Suitable flooring is required to allow easy movement of ultrasound unit.
- Adequate ventilation for the unit, patient and staff.
- Lighting should be dimmable with accessible controls.
- Accessories such as support pads for the patient and the operators, gel bottle holders, additional transducers and linen to be nearby and easily accessible.

ii) Environment

- The examination room needs to be close to waiting areas, patient facilities and processing areas.
- An ergonomic set-up shall allow the sonographers/sonologists to vary their posture

iii) Ultrasound Unit

- State-of-the-art equipment allows for better visualisation, which increases diagnostic accuracy and reduces sonographer / sonologist fatigue. Good ergonomic design needs to be a major part of the buying decision.
- Fully adjustable units, to suit the procedures undertaken and for all sonographer / sonologist using the unit, are recommended.

**9. ELECTRICAL SAFETY and QUALITY ASSURANCE
(QA)**

- a. Annual electrical safety tests should be performed by personnel or contractors trained in safety tests on ultrasound units.
- b. There should be regular maintenance by qualified personnel for the planned lifetime of the machine. A full maintenance and service contract with an appropriate organization or vendor/manufacture is recommended.
- c. Annual or biannual monitoring of the performance of the unit (QA) by qualified operators.

10. EQUIPMENT SAFETY

10A CERTIFICATION FROM MANUFACTURER

The manufacturers shall determine and document that the product is safe. The manufacturer shall establish a risk management process and therefore must perform a number of very specific steps as outlined in ISO 14971:

- i. Identify intended use and characteristics related to safety of the medical device.
- ii. Identify known or foreseeable hazards.
- iii. Estimate unacceptability/acceptability of the risks for each hazard.
- iv. Determine if risk reduction is necessary. If yes, then implement risk reduction and determine if the residual risk is acceptable. Also, make sure no new risks have resulted from the reduction strategy. If the resulting risk is still unacceptable and no further steps can be taken to reduce it, determine if the medical benefits outweigh the residual risk.
- v. Once the individual hazards are evaluated, determine if the overall combined risk is acceptable. If yes, then complete the risk management report and proceed with production. If no, then the product must be reevaluated as necessary. This could result in a redesign, altered intended use, or even termination of the project.
- vi. This, however, is not the end of the process. Risk management requires periodic and continual postproduction reassessment to determine if previously unrecognized hazards exist or have become evident, if the estimated risk arising from a hazard is no longer acceptable, or if the original assessment has otherwise been invalidated.

10B OTHER SAFETY PRECAUTIONS

- a) Do not twist, kink or pinch cable to avoid damage to its insulating properties, thereby causing shock to the patient or operator
- b) Do not use **damaged /cracked** transducers
- c) Do not soak transducer longer than recommended by germicide manufacturer
- d) Do not used non-recommended coupling gels that contain lotion, mineral oil, olive oil, lanolin, polyethelene glycol, dimethyl silicon, methyl or ethyl parabens
- e) Do not clean transducers with non-recommended germicide that contain methanol, ethanol, bleach or alcohol.
- f) Do not steam, heat autoclave or use ethylene oxide (EO gas processes on general surface or transducer).

11. REFERENCES

1	WFUMB (1998) World Federation for Ultrasound in Medicine and Biology Symposium on Safety of Medical Ultrasound; Conclusions and Recommendations Regarding Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound. Ed. Barnett S. Ultrasound in Medicine and Biology, 24: S1; 1 – 55.
2	European Federation of Societies for Ultrasound in Medicine and Biology; Ultraschall 2005; 26 ; page 79 – 105
3	Standards and Guidelines for the Accreditation of Ultrasound Practices; American Institute of Ultrasound in Medicine :Nov 13,2005 (assessed 14/05/2008)
4	Ultrasound Accreditation Program requirements ACR (American College of Radiology) ; revised version 3.1.2008 ; page 1-7
5	Ultrasound Training Recommendations for Medical and Surgical Specialities Faculty of Clinical Radiology, The Royal College of Radiologists; January 2005, page 1-56.
6	Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations, Aug 2006.
7	Australian Society for Ultrasound in Medicine; C1 Policy on Sonographer Training
8	“Safety Considerations for Diagnostic Ultrasound”, Laurel, MD, 1991, American Institute of Ultrasound in Medicine.

9	Wayne R. Hedrick, David L. Hykes, Dale E. Starchman. "Ultrasound Physics and Instrumentation", 1995, Biological Effects pp. 249-276
10	"Biological Effects of Ultrasound: mechanisms and clinical implications", NCRP Report 74, Bethesda MD, 1983, National Council on Radiation Protection and Measurements.
11	Second World Federation of Ultrasound in Medicine and Biology (MFUMB) Symposium on Safety and Standardization in Medical Ultrasound", Ultrasound Med Biol 15:S1, 1989, WFUMB
12	"The Prudent Use of Diagnostic Ultrasound", J Ultrasound Med 6:415, 1987, Ziskin MC
13	Royal College of Radiologist. Standards for ultrasound equipment, February 2005. http:// www.rcr.ac.uk [Accessed: 31 January 2008]
14	The British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment http://www.bmus.org/ultras-safety/us-safety03.asp [Accessed: 31 January 2008]
15	American College of Radiology Practice Guidelines for Ultrasound http:// www.acr.org [accessed 31 January 2008]
16	Australasian Society for Ultrasound in Medicine. Promoting Excellence in Ultrasound. Policies and Statements http://www.asum.com.au/open/nav [assessed 28 January 2008]
17	AIUM. Practice Guideline for Performance of an Ultrasound Examination of Abdomen and/or Retroperitoneum 2007 . www.aium.org (accessed 31 January 2008)
18	AIUM. Mechanical Bioeffects from Diagnostic Ultrasound: AIUM consensus statements, Journal of Ultrasound in Medicine 19/2, 2000

19	Itoh A, Ueno E, Tohno E, et al. Breast Disease: Clinical Application of US Elastography for Diagnosis. Radiology 2006;239:341-350
20	Rago T, Santini T, Scutari M, et al. Elastography: New Developments in Ultrasound for Predicting Malignancy in Thyroid Nodules. The Journal of Clinical Endocrinology & Metabolism 2007; 92 (8): 2917-2922
21	K.H.Ng. Quality Assurance of Medical Ultrasound www.radiologymalaysia.org (accessed 31 January 2008)
22	K.H.Ng. International guidelines and regulations for the safe use of diagnostic ultrasound in medicine . www.radiologymalaysia.org (accessed 31 January 2008)
23	American College of Radiology. Ultrasound Accreditation Program requirements . www.acr.org (assessed 31 January 2008)
24	Malaysian Standards approved on 29-12-2006 by the Ministry of Science, Technology and Innovation In Accordance with the Standards of Malaysia Act (ACT 549) Medical Devices are classified under the MS IEC 60601-1-2: 2002 series. (Medical electrical equipment Part 1 General requirements for safety 2. Collateral standard: Electromagnetic compatibility – equipment and tests (IEC 60601-1-2: 1993, idt). www.sirim.my/std_dev/ms_approved/MSApproved291206.htm (date accessed 12 Feb 2008)

Appendix 1

Thermal Index (TI)

TI estimates the potential for producing thermally-induced bioeffects in soft tissue and bones. These indices might be displayed on-screen for certain ultrasound machines. The operators should monitor the values and use control settings that is as small as possible whilst achieving diagnostically useful information.

TIS: (soft tissue index) for obstetric investigation particularly in the first eight weeks after conception and for eye scanning. The eye is vulnerable to thermal hazard because the lens and the aqueous and vitreous humours have no cooling blood supply.

TIC: (bone near surface) where the probe is close to bone e.g. in trans-cranial applications).

TIB: (bone near focus): the presence of bone within the beam greatly increases the likelihood of temperature rise, due to both direct absorption in the bone itself and conduction from bone to adjacent structures e.g 2nd and 3rd trimester fetus.

TI = Thermal Index (relates to average intensity)

- The ratio of acoustical power produced by the transducer to the power required to raise the temperature in tissue by 1⁰ C.
- TI = 1; tissue condition assumed in algorithm, 1⁰ elevation of temperature is possible.
- FDA: TI < 6
 - TI > 0.7 Exposure time should be kept low accordingly when performing a scan on the fetus or an embryo.
 - TI > 1.0 Eye scanning is not recommended
 - TI > 3.0 Scanning of an embryo or fetus is not recommended, however briefly.

Appendix 2

Exposure time

The overall examination duration should be kept as short as is necessary to produce a useful diagnostic result.

Table 1 Maximum recommended exposure times for an embryo or fetus

TI	Maximum recommended exposure Times for an embryo or fetus (minutes)
0.7	60
1.0	30
1.5	15
2.0	4
2.5	1

A diagnostic exposure that elevates embryonic or fetal temperature above 41^o C (i.e. 4 degrees above normal body temperature) for 5 minutes or more should be considered potentially hazardous.

Appendix 3

INTERNATIONAL REGULATION AND SAFETY GUIDELINES

Production of bioeffects in mammalian tissue; AIUM has claimed that no bioeffects were observed for intensities as high as 1 W/cm^2 for highly focused beams.

The FDA introduced application-specific limits on acoustic output for USA only. The permissible limit was lowest for ophthalmic (17 mW/cm^2) and fetal limit dose: 94 mW/cm^2

Table 2 Maximum Allowable Output Display Standard FDA (USA)

Application-specific	ODS Track 3		
	I_{SPTA}	(mW / cm^2)	MI
Peripheral vessel	720	720	1.9
Cardiac	430	720	1.9
Fetal, neonatal	94	720	1.9
Ophthalmic	17	50	0.23

Appendix 4

Mechanical Index (MI)

Mechanical Index relates to cavitation – peak pressure. It is also for estimating the potential for producing non-thermal/mechanical bioeffects in tissue.

- The value that is computed from the peak rarefactional pressure and the frequency, and is able to estimate the potential for mechanical bioeffects
- The higher the index value, the higher is the probability of bioeffect occurring
- Values less than ' 1 ' is generally considered to be ' safe '

MI > 0.3	Possibility of minor damage to neonatal lung or intestine
MI > 0.7	Risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used