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Tarikh : 3 November 2022

Semua Pengarah Kesihatan Negeri
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Semua Pegawai Kesihatan Daerah

Semua Pemegang Lesen
Di bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304)
Bagi Maksud Perubatan

YBhg. Tan Sri/Datuk/Dato'/Datin Paduka/Datin/Tuan/Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 22/2022:
GUIDELINES ON ULTRASOUND USAGE IN MEDICAL PRACTICE

Dengan hormatnya saya merujuk kepada perkara tersebut di atas.

2. Dimaklumkan bahawa Kementerian Kesihatan Malaysia (KKM) telah menyediakan *Guidelines on Ultrasound Usage in Medical Practice* sebagai rujukan untuk semua pengendali *ultrasound* yang menggunakan peralatan *ultrasound* bagi tujuan perubatan.

3. Sebagaimana telah sedia maklum, peralatan *ultrasound* hendaklah mematuhi Akta Peranti Perubatan 2012 (Akta 737) yang dikawal selia oleh Pihak Berkuasa Peranti Perubatan (Medical Device Authority, MDA). Seksyen 5(1) Akta 737 menyatakan bahawa peranti perubatan perlu didaftarkan di bawah Akta tersebut sebelum boleh diimport, dieksport atau diletakkan di pasaran. Untuk tujuan itu, permohonan pendaftaran peralatan *ultrasound* hendaklah dibuat mengikut keperluan di bawah Akta 737 dan mengikut mekanisme yang ditetapkan melalui MDA. Selain itu, Seksyen 43(2)(a) Akta 737 menyatakan bahawa seseorang yang menggunakan atau mengendalikan sesuatu peranti perubatan ke atas pihak ketiga hendaklah mempunyai kelayakan dan kompetensi sebagaimana yang ditetapkan oleh Menteri.

..2/-

4. Oleh itu, selaras dengan Akta 737, garis panduan ini dibangunkan bertujuan untuk mewujudkan prinsip amalan yang selamat dan baik dalam kaedah pengendalian dan pengimejan *ultrasound* yang digunakan untuk tujuan perubatan serta memastikan kompetensi pengendali *ultrasound* adalah dipantau. Adalah diharapkan agar garis panduan ini dapat meningkatkan pengetahuan dan kemahiran dalam pengendalian peralatan *ultrasound* serta menghasilkan imej kualiti yang optima dengan memastikan tiada kesan bio-terma dan mekanikal (*thermal and mechanical bioeffects*) kepada pesakit.

5. Untuk makluman YBhg. Tan Sri/ Datuk/Dato'/Datin Paduka/Datin/Tuan/Puan, garis panduan ini diedarkan sebagai rujukan untuk semua fasiliti perubatan yang menggunakan peralatan *ultrasound* sama ada institusi perubatan kerajaan dan swasta termasuk agensi yang berkenaan. Garis panduan ini boleh diakses dan dimuat turun melalui laman web Bahagian Kawalselia Radiasi Perubatan, https://radia.moh.gov.my.

6. YBhg. Tan Sri/Datuk/Dato'/Datin Paduka/Datin/Tuan/Puan diminta untuk mengambil perhatian mengenai keperluan latihan dan kompetensi setiap pengendali yang hendak menggunakan peralatan *ultrasound* tersebut bagi tujuan perubatan.

7. Pekeliling ini adalah berkuatkuasa mulai tarikh surat ini dikeluarkan.

8. Sekiranya terdapat sebarang pertanyaan berkaitan dengan Pekeliling ini, pihak YBhg. Tan Sri/Datuk/Dato'/Datin Paduka/Datin/Tuan/Puan boleh menghubungi Bahagian Kawalselia Radiasi Perubatan, KKM di talian 03-8892 4727 atau emel kepada seksyenkodstandard.bkrp@gmail.com.

Sekian, terima kasih.

"WAWASAN KEMAKMURAN BERSAMA 2030"
"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH)

GUIDELINES ON ULTRASOUND USAGE IN MEDICAL PRACTICE

MINISTRY OF HEALTH
MALAYSIA

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FOREWORD

Ultrasound usage in medicine has been around for more than 50 years, and since its early years, various new medical applications has been found that utilize this technology. Interestingly the earliest use of ultrasound in medicine is for therapy, with the trials being done in 1938. The first publication on intensity-modulated cross-section ultrasound imaging came out in 1952, and in May 1953 researchers were able to produce real-time ultrasound at 15 MHz. Phased array probes were first investigated in the Netherlands in the mid-1960s. By the 1970s, ultrasound imaging also diverged from mechanical scanning arms to array of transducers, either linear or phased array types. During this period handheld ultrasound probes, that would have been recognisable to modern user, were available commercially. In the 1980s and 1990s, ultrasound imaging in medicine has started to become widely adopted.

The Ministry of Health (MOH) believe it is important that the patient who undergoes an ultrasound examination is assured of the quality of the examination and its interpretation. Therefore, Medical Radiation Surveillance Division (MRSD), MOH along with various agencies and organizations from government and private sectors have taken the initiative in developing and publishing this document which sets standards in main areas that are known as important for the delivery of effective and high-quality ultrasound imaging examinations.

In this regard, I would like to congratulate those who were involved and contributed to the development of this document.

Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah
Director of Health
Ministry of Health Malaysia

PREFACE

In Malaysia, it can be claimed that ultrasound usage is very prevalent, and when it comes to medical imaging, it is probably second only to general radiography. While no official statistics is available, it is estimated that ultrasound contributes to at least 30% of all medical imaging. Currently it is being adopted by multiple disciplines beyond radiology and obstetrics, such as in emergency medicine, anaesthesiology, vascular surgery, gastroenterology, and rheumatology, to give a few examples. Recognizing its wide applications and rapid uptake by the medical profession, MRSD, MOH along with various agencies and organizations from government and private sectors have taken this initial step to come up with a guideline on ultrasound usage for medical practice.

The physics behind ultrasound imaging does tell us that there is deposition of energy onto the imaged part of the body. On the other hand, currently there is no conclusive evidence of adverse effects for the usage of ultrasound in medicine. Thus, it is important that the practitioners performing ultrasound examinations are fully knowledgeable regarding the potential harms that may arise from inappropriate usage of ultrasound technology. It is indeed the responsibility of the ultrasound practitioners that all precautions and necessary steps are taken, during the examination to ensure that procedure is done as safely as possible.

Ultimately the purpose of this guidelines is not only to be a reference for the dispensing of diagnostic ultrasound services, but also to ensure the safety of the patients receiving such services. I am positive that this document will be a very useful reference to everyone as a guide on ultrasound usage in medical practice. Finally, I would like to congratulate all the committee members involved in developing and completing the guidelines. Their efforts were invaluable. I am looking forward to see the guidelines will be frequently be referred to provide safe and excellent in healthcare services.

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LIST OF ACRONYMS AND ABBREVIATIONS

ALARA	:	As Low As Reasonably Achievable
AFPM	:	Academy of Family Physicians of Malaysia
BMUS	:	British Medical Ultrasound Society
CD	:	Compact Disk
CE	:	Conformitè Europëenne
CLA	:	Curvilinear Arrays
COG	:	College of Obstetricians and Gynaecologists
CoR	:	College of Radiology
CPD	:	Continuing Professional Development
DICOM	:	Digital Imaging and Communications in Medicine
DVD	:	Digital Versatile Disc
EMC	:	Electromagnetic Compatibility
EPA	:	Enterprise Picture Archive
ESR	:	European Society of Radiology
FOV	:	Field Of View
IEC	:	International Electrotechnical Commission
IEP	:	Image Exchange Portal
IT	:	Information Technology
LA		Linear Arrays
LAN	:	Local Area Network
LMP	:	Last Menstrual Period
MDA	:	Medical Device Authority
MI	:	Mechanical Index

MMC	:	Malaysian Medical Council
MQA	:	Malaysian Qualifications Agency
MS	:	Malaysian Standard
OSCE	:	Objective Structured Clinical Examination
PA	:	Phased Arrays
PACS	:	Picture Archiving Computer System
PPM	:	Planned Preventive Maintenance
QC	:	Quality Control
RF	:	Radiofrequency
RIS	:	Radiology Information System
SMPTE	:	Society of Motion Picture and Television Engineers
TI	:	Thermal Index
TIB	:	TI for Bone
TIC	:	TI for Cranial Bone
TIS	:	TI for Soft Tissue
TEE	:	Transesophageal
TV	:	Transvaginal
USB	:	Universal Serial Bus

1. SCOPE

The primary focus of this document is the provision of good safe practice principles for ultrasound imaging utilized for diagnostic purposes only by healthcare providers. It does not cover ultrasound usage for therapeutic purposes.

2. TERMS AND DEFINITIONS

Conventional comprehensive diagnostics ultrasound

Traditional comprehensive ultrasound examinations generally cover an anatomical region, often assess more than one organ, normally collect images of all examined organs and result in a full report of the examination.

Medical facility

A hospital, institution, medical centre, centre blood irradiation, medical research centres, health clinics, clinics dentistry, medical practitioner clinics, specialist clinics and animal/veterinary clinics whether in the public or private sector.

Mechanical index (MI)

An on-screen indicator of the relative potential for ultrasound to induce an adverse bioeffect by a non-thermal mechanism including cavitation.

Modes of ultrasound

The differences between imaging modes lie in the lengths of the pulses used, their repetition frequency and the pressure in the pulses.

A-mode	:	A stands for amplitude. A-mode is the simplest type of ultrasound. A single transducer scans a line through the body with the echoes plotted on screen as a function of depth. Therapeutic ultrasound aimed at a specific tumour or calculus is also A-mode, to allow for pinpoint accurate focus of the destructive wave energy.
B-mode	:	B stands for brightness. In B-mode ultrasound, a linear array (LA) of transducers simultaneously scans a plane through the body that can be viewed as a 2D image on screen.
M-mode	:	M stands for motion. In M-mode a rapid sequence of B-mode scans whose images follow each other in sequence on screen enables doctors to see and measure range of motion, as the organ boundaries that produce reflections move relative to the probe.
Doppler mode	:	This mode makes use of the Doppler effect in measuring and visualizing blood flow. Doppler sonography plays important role in medicine. Sonography can be enhanced with Doppler measurements, which employ

the Doppler effect to assess whether structures (usually blood) are moving towards or away from the probe, and its relative velocity.

Point-of-care Ultrasound (PoCUS)

Ultrasound studies used to achieve specific procedural aims (e.g., direct the needle to the correct location) or answer focused questions (e.g., Does my patient have ascites?).

Thermal index (TI)

An on-screen indicator of the relative potential for a tissue temperature rise. Three forms of TI may be displayed, according to the application. TI for soft tissue (TIS) assumes that only soft tissue is insonated. TI for bone (TIB) assumes bone is present at the depth where temporal intensity is greatest. TI for cranial bone (TIC) assumes bone is very close to the front face of the probe.

The TI is the ratio of the acoustic power output of the scanner to the estimated acoustic power needed to raise the temperature of the tissue being imaged by 1°C. Different tissue thermal models, and hence different calculations of the TI, are used for soft tissue, skeletal bone, and cranial bone. The tissue thermal model also accounts for the pulse repetition frequency, such that a higher TI will be computed for scanning modes such as pulsed Doppler.

Ultrasound practitioner

A healthcare professional who holds recognized qualifications in medical ultrasound and can competently perform conventional, comprehensive diagnostics ultrasound or focused ultrasound examinations falling within their personal scope of practice. The professional background of ultrasound practitioners can be very varied and will include but not limited to radiologists, obstetricians, gynaecologists, cardiologists, emergency physicians, acute internal medicine physicians, intensivist, and related allied health professions.

3. GENERAL

Ultrasound is a sound wave with a frequency higher than 20 kHz and is inaudible to a human being. A human can only hear sounds with frequencies between 20 Hz to 20 kHz. For diagnostic applications, the frequency range of the ultrasound wave is between 2 MHz to 15 MHz [1]. In medicine, ultrasound is used to aid in the diagnosis and treatment of patients as well as in the monitoring of fetus during pregnancy. In an ultrasound examination, a practitioner places the transducer, or ultrasound probe, in or on the patient's body.

The ultrasound system consists of transducer, control panel and display monitor. The transducer emits ultrasound in the form of pulses and continuous waves. The waves are propagated into the body and are reflected, refracted, and absorbed by heterogenous groups of tissue or at the interfaces between different types of tissue. The reflected waves also known as echoes are converted into real-time images that are displayed on a monitor. The imaging parameters of interest are frequency, focus, the aperture of the ultrasound beam, and the

beam shape and size. Higher frequency ultrasound waves produce better spatial resolution images but with less penetration depth. Lower frequency waves penetrate deeper into the tissues but with lower resolution.

Ultrasound imaging is a non-invasive procedure and allows the tissue structures to be visualized in real-time. Ultrasound scanning is an interactive procedure involving the ultrasound practitioners, patient, and ultrasound instruments. Although the theory behind image formation is rather complex, its implementation in the clinical environment is not. Ultrasound imaging can be considered as the first-choice examination for many clinical conditions. This is due to the absence of ionizing radiation in its application, its availability and incurs a relatively lower cost. Ultrasound examinations are conducted by practitioners from a wide range of clinical backgrounds and in many different healthcare facilities. Ultrasound imaging services are currently available in public and private healthcare facilities.

Nowadays, ultrasound imaging is no longer conducted in the imaging department alone. The number of examinations conducted outside the medical imaging department has increased to improve support for patients in line with the Lancet Commission on Diagnostics: Transforming Access to Diagnostics. Therefore, ultrasound imaging is delivered in a more complex and fragmented environment.

Ultrasound imaging is highly operator-dependent, and the procedure must be conducted by qualified and trained personnel. The use of ultrasound imaging may cause a detrimental result if:

a) the examinations are undertaken by unqualified, untrained, or poorly trained individuals;
b) the equipment has suboptimal specifications or poorly maintained;
c) it is undertaken in the absence of clinical audit of performance and/or outcome; and
d) there is no effective clinical governance framework.

Currently, ultrasound imaging has seen a significant increase in the number of requests. However, due to the limited number of qualified personnel and the service delivery, which is not consistent, the pressure builds up on ultrasound services. Despite the implementation of good clinical practice by the service providers, many concerns were raised about the quality of the ultrasound examination. For example, there were evidence of repeat ultrasound examinations due to the quality of the images produced during the first scan or due to the reports and images from one provider that are not available to the other provider.

It is understood that the quality of an ultrasound examination depends on:

a) appropriate training;
b) experience;
c) the equipment itself;
d) clinical leadership;
e) audit;
f) general support; and

g) having sufficient time to undertake the examination and compile a clinically relevant report.

Ultrasound practitioners must be trained and must have achieved a standard of good clinical practice regardless of their professional background. Ultrasound practitioners may seek accreditation from recognized bodies. Ultrasound scanners can be physically moved with ease, presenting a risk that machines may be inappropriately used for clinical tasks for which they were never intended and to which they may be ill suited. Thus, the role of the ultrasound practitioners is critical and the matching of the practitioner knowledge and competence level to the equipment features is essential. The ultrasound services should also be subjected to appropriate audit and good governance processes.

4. SAFETY OF MEDICAL ULTRASOUND

Modern ultrasound imaging for diagnostic purposes has a wide range of applications. For example, it is used in obstetrics to monitor the progress of pregnancy, in oncology to visualize tumours and their response to treatment, and, in cardiology, contrast-enhanced studies are used to investigate heart function and physiology.

A fundamental principle of medical ethics is first doing no harm to ultrasound practitioner and patient. The interaction of ultrasound with tissue is reviewed in the context of the safety of ultrasound diagnosis for all applications. The characteristics of each different mode of ultrasound imaging remain essentially the same, irrespective of the target being imaged. The main safety terms are the sensitivity of the tissue constituents to the thermal and mechanical effects produced.

In general, the thermal index (TI) is directly related to the output power of the system:

$$TI = \frac{W_p}{W_{deg}}$$

where W_p is the relevant (attenuated) acoustic power at the depth of interest and W_{deg} is the estimated power necessary to raise the tissue equilibrium temperature by 1°C.

While there is no definite upper limit for TI the ultrasound practitioners should use the as low as reasonably achievable (ALARA) principle. For adults, a TI of less than 2 is generally considered safe. Short exposures at higher TI are also safe; a general rule for scanning adults at a TI above 2 is to keep the exposure time to a minimum, t_e, according to:

$$TI \leq 6 - \frac{\log(t_e)}{0.6}$$

where t_e is measured in minutes. Fetal imaging should be approached cautiously, especially when scanning at high TI. Fetal exposure times at TI = 2 – 6 are limited to much shorter durations than the equation suggests; for example, fetal exposure at TI = 4 is limited to 4 minutes.

The mechanical index (MI) is interpreted as a measure of the relative risk of inducing cavitation and is based on an empirically derived formula:

$$MI = \frac{\max(p\_)}{\sqrt{f}}$$

where max(p_) is the peak rarefactional pressure after correction for attenuation and f is the ultrasound frequency. The use of rarefactional pressure in the numerator of the formula reflects the fact that inertial cavitation is triggered by overexpansion of a gas bubble, and the denominator reflects the experimental observation that inertial cavitation is more likely at lower frequencies.

Contrast agents should be avoided during fetal imaging and used with caution in patients with pulmonary hypertension or other unstable cardiopulmonary conditions. Inertial cavitation can be avoided using contrast agents by keeping the MI below 0.3. However, it is not always achievable as contrast-enhanced imaging protocols obtain diagnostic information by intentionally disrupting the microbubbles at MI > 1. Additional caution is advised when imaging structures near the lungs or when using microbubble contrast agents, as the presence of excess gas increases the risk of inertial cavitation.

4.1 Biological Effects of Ultrasound

Ultrasound practitioners should understand the likely influence of the scanner controls, the operating mode (e.g., B-mode, colour Doppler imaging or spectral Doppler) and probe frequency on the thermal and cavitation hazards.

Care should be taken to reduce the risk of thermal hazard when exposing the following to diagnostic ultrasound:

a) an embryo less than eight weeks after conception;
b) the head, brain or spine of any fetus or neonate; and
c) an eye (in a subject of any age).

Care should be taken to reduce output and minimise exposure time of an embryo or fetus when the temperature of the mother is already elevated.

There has been no conclusive evidence of diagnostic ultrasound posing a biohazard to humans. No confirmed biological effects on patients or ultrasound practitioners have ever been reported due to exposure at intensities typical of current diagnostic ultrasound instruments [2].

The total acoustic energy (power) produced by the system, the spatial energy distribution, and the duration of exposure all affect the biological effects of a sound-emitting system. Local heating (thermal effect) is proportional to ultrasound intensity and occurs most commonly near the skin surface (in trans-thoracic echocardiography) or the esophageal mucosa (in transesophageal echocardiography). The cooling effect of blood perfusion on tissue tends to offset the temperature increase. Cavitation is the formation of gas bubbles by the vibration of

dissolved oxygen (O_2) or carbon dioxide (CO_2). However, it is not a problem in biological systems because the increased viscosity significantly limits the motion of the bubbles [3].

Even though ultrasound is widely considered the safest medical imaging modality, when a high-intensity ultrasound pulse passes through tissue, a significant amount of energy is transferred from the pulse to the tissue, potentially increasing the risk of adverse effects on the patient. Therapeutic ultrasound devices can benefit from these biological effects, but they are undesirable during diagnostic imaging. Thermal absorption and cavitation are the two most important mechanisms for ultrasound's biological effects.

4.1.1 Thermal Absorption

Absorption, the primary mechanism of attenuation, causes tissue heating. A single pulse at diagnostic imaging intensities causes a slight local temperature rise. In B-mode imaging, blood flow typically dissipates the heat deposited by one pulse. Before the same tissue volume is insonified again, the beam is continually steered through the tissue. In techniques like pulsed Doppler, where several pulses are sent to the same focal point in rapid succession, local heating can occur at the focus. Thermal absorption is used in therapeutic ultrasound to treat cancerous tumours with hyperthermia by transmitting high-intensity pulses that produce faster heating than diagnostic imaging pulses.

The use of simple B-mode without spectral Doppler is not concerned by the thermal effect because of its very low output power, its use is safe if its TI and MI are 1.0 or less. However, 4D study duration is recommended to be less than 30 minutes according to the opinion of ultrasound organizations on the report of disturbed neuron migration of animal fetus [4, 5].

4.1.2 Cavitation

Cavitation is the oscillation of a gas bubble's volume in response to pressure fluctuations caused by an ultrasound wave. When microbubble contrast agents are used, or the lungs are exposed to ultrasound, cavitation is most likely to occur in vivo. However, most tissues contain small amounts of gas that can coalesce to form cavitation nuclei when exposed to ultrasound. Low-intensity ultrasound usually causes harmless stable cavitation with no disruption of gas bubbles. On the other hand, higher-intensity ultrasound can cause inertial cavitation, which occurs when the rarefactional phase of the pressure wave expands the bubble beyond its maximum stable volume, causing it to collapse suddenly.

4.2 Thermal and Mechanical Indices

For scanners which display on-screen TI and MI values, ultrasound practitioners shall continually monitor their values and use control settings that keep them low without compromising diagnostic results (Table 1, Table 2, and APPENDIX 1). There should be independent checks that the displayed TI and MI values are accurate. These should be made soon after installation and after hardware or software changes.

a) The MI is an on-screen indicator of the relative potential for ultrasound wave to induce an adverse bioeffect by a non-thermal mechanism including cavitation.

b) The TI is an on-screen indicator of the relative potential for a tissue temperature rise.

Table 1: Recommended exposure time and index values for obstetric and neonatal ultrasound [6]. Reproduced by courtesy of BMUS.

Application	Values to Monitor (A)	Thermal Index Value			Mechanical Index Value		
		0 – 0.7	0.7 – 3.0	> 3.0	0 – 0.3	> 0.3	> 0.7
Obstetrics up to 10 weeks after last menstrual period (LMP) (and gynaecology when pregnancy is possible)	TIS and MI	√	(B) restrict time to 0.7 < TIS ≤ 1.0: 60 min 1.0 < TIS ≤ 1.5: 30 min 1.5 < TIS ≤ 2.0: 15 min 2.0 < TIS ≤ 2.5: 4 min 2.5 < TIS ≤ 3.0: 1 min	Scanning of an embryo or fetus is not recommended, however briefly	√	√	(E) risk of cavitation with contrast agents
Obstetrics more than 10 weeks after LMP	TIB and MI	√	(B) restrict time to 0.7 < TIB ≤ 1.0: 60 min 1.0 < TIB ≤ 1.5: 30 min 1.5 < TIB ≤ 2.0: 15 min 2.0 < TIB ≤ 2.5: 4 min 2.5 < TIB ≤ 3.0: 1 min	Scanning of an embryo or fetus is not recommended, however briefly	√	√	(E) risk of cavitation with contrast agents
Neonatal – transcranial and spinal	TIC and MI	√	(B) restrict time to 0.7 < TIC ≤ 1.0: 60 min 1.0 < TIC ≤ 1.5: 30 min 1.5 < TIC ≤ 2.0: 15 min 2.0 < TIC ≤ 2.5: 4 min 2.5 < TIC ≤ 3.0: 1 min	Scanning of the central nervous system is not recommended, however briefly	√	√	(E) risk of cavitation with contrast agents
Neonatal – general and cardiac imaging	TIB and MI recommended	√	(C) restrict time to 1.0 < TIB ≤ 1.5: 120 min 3.0 < TIB ≤ 4.0: 1 min 1.5 < TIB ≤ 2.0: 60 min 4.0 < TIB ≤ 5.0: 15 sec 2.0 <TIB ≤ 2.5: 15 min 5.0 < TIB ≤ 6.0: 5 sec 2.5 < TIB≤3.0: 4 min TIB > 6.0: not recommended		√	(D) Possibility of minor damage to lung or intestine. Minimise exposure time	(E) risk of cavitation with contrast agents
Fetal Doppler heart monitoring	TI or MI are not usually available for dedicated fetal heart monitors	The power levels used by dedicated fetal heart monitors are sufficiently low that the use of this modality is not contra-indicated, on safety grounds, even when it is to be used for extended periods.					

√: There is no known reason to restrict scanning times in this region.

A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.

B: TI > 0.7 - the overall exposure time (including pauses) of an embryo or foetus or of the neonatal central nervous system should be restricted.

C: TI > 1.0 - the overall exposure time (including pauses) of other parts of the neonate should be restricted.

D: MI > 0.3 - there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, try to reduce the exposure time as much as possible.

E: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

Table 2: Recommended exposure time and index values for non-obstetric and non-neonatal ultrasound [6]. Reproduced by courtesy of BMUS.

Application	Values to Monitor (A)	Thermal Index Value		Mechanical Index Value	
		0 – 1.0	> 1.0	0 – 0.3	> 0.7
General abdominal Peripheral vascular Unlisted applications	Usually, TIB and MI (use TIC and MI if bone closer than 1 cm. TIS and MI only if bone does not come into the image)	√	(B) restrict time to 1.0 < TIB ≤ 1.5: 120 min 1.5 < TIB ≤ 2.0: 60 min 2.0 < TIB ≤ 2.5: 15 min 2.5 < TIB ≤ 3.0: 4 min 3.0 < TIB ≤ 4.0: 1 min 4.0 < TIB ≤ 5.0: 15 sec 5.0 < TIB ≤ 6.0: 5 sec TIB > 6.0: not recommended	√	(C) risk of cavitation with contrast agents
Eye	TIS and MI recommended	√	Scanning of the eye is not recommended	√	(C) risk of cavitation with contrast agents
Adult transcranial (imaging and stand-alone) (D)	TIC and MI	√	(B) restrict time to 0.7 < TIC ≤ 1.0: 60 min 1.0 < TIC ≤ 1.5: 30 min 1.5 < TIC ≤ 2.0: 15 min 2.0 < TIC ≤ 2.5: 4 min 2.5 < TIC ≤ 3.0: 1 min TIC > 3.0: not recommended	√	(C) risk of cavitation with contrast agents
Peripheral pulse monitoring	TI or MI are not usually available for dedicated peripheral pulse monitors	The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contra-indicated, on safety grounds			

√: There is no known reason to restrict scanning times in this region.

A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.

B: TI > 1.0 - the overall exposure time (including pauses) should be restricted.

C: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

D: Transcranial ultrasound investigations may require higher acoustic output or longer monitoring times than other applications. When times longer than those recommended here are required, it is recommended that monitoring is paused regularly to minimise exposure.

The ultrasound practitioner must understand and follow the most current safety rules and regulations and conduct a risk/benefit analysis for each examination.

CAUTION!

If there is a clinical need to exceed these recommended times, the ALARA principle should still be followed. When longer times are required than those recommended here, the probe should be removed from the patient as soon as possible to minimize exposure.

4.3 Health Effects of Ultrasound

According to the Health Protection Agency (HPA), no established evidence at lower levels of exposure, such as diagnostic ultrasound, cause long-term health effects [7]. Too few research data are available to conclude the long-term use of ultrasound [2].

British Medical Ultrasound Society (BMUS) Statement on the safe use, and potential hazards of diagnostic ultrasound [8] states that:

"Ultrasound is now accepted as being of considerable diagnostic value. There is no evidence that diagnostic ultrasound has produced any harm to patients in the time it has been in regular use in medical practice. However, the acoustic output of modern equipment is generally much greater than that of the early equipment and, in view of the continuing progress in equipment design and applications, outputs may be expected to continue to be subject to change. Also, investigations into the possibility of subtle or transient effects are still at an early stage. Consequently, diagnostic ultrasound can only be considered safe if used prudently".

In epidemiological studies, prenatal ultrasound has not been associated with adverse perinatal outcomes, childhood malignancies, neurological development, dyslexia, speech development, school performance, intellectual performance, or adult mental disease. According to systematic reviews of epidemiological studies, there is no correlation between prenatal ultrasound and adverse outcomes. Most epidemiologic evidence comes from B-mode scanners since 1990s until early 2000, therefore it is essential to acknowledge that the amount of epidemiological data available is limited [2, 7, 9, 10].

The type of ultrasound examination, patient body habitus, and equipment settings are just a few factors that affect ultrasound exposure. While pulsed Doppler techniques have the potential for the highest exposure levels, some modes, like B-mode, have a lower potential for tissue damage than Doppler [8, 11]. Ultrasound safety recommendations in this guideline assume that the ultrasound equipment design meets international or national safety standards and that it is operated by competent and trained personnel.

NOTE:

Important guidelines for safe use of ultrasound [6]

a) Medical ultrasound imaging should only be used to aid in medical diagnosis and/or medical/surgical interventions.

b) Only fully trained individuals should operate ultrasound equipment in a safe and proper manner. This requires:
   i. an understanding of ultrasound's potential thermal and mechanical bioeffects;
   ii. a sound knowledge of equipment settings; and
   iii. an awareness of how machine settings affect power levels.

c) A useful diagnostic result should be obtained in the shortest amount of time possible during an examination.

d) Output levels should be kept as low as is reasonably achievable while producing a useful diagnostic result.
e) Ultrasound practitioner should aim to stay within the guideline recommended scan times (especially for obstetric examinations).
f) It is not recommended to perform scans during pregnancy just for souvenir videos or photographs.

Ultrasound, however, is recognized as a valuable tool for improving patient safety during procedures such as line and needle placement. While users may not fully comprehend the physical properties of ultrasound imaging, they must be aware of the importance of limiting examination times and using equipment only for the intended medical purpose.

4.4 Quality Control Testing

The stated aims of quality control (QC) procedures applied to ultrasound equipment are to ensure consistent and acceptable levels of performance of the imaging system and to ensure the safety of the patient. An important part of a QC procedures consists of routine checks and procedures carried out daily by the ultrasound practitioner to ensure cleanliness and safety of scanning equipment. Ultrasound practitioners also can readily detect some equipment malfunctions, such as extensive element dropout in array transducers which may compromise diagnostic quality.

QC checks routinely done by the ultrasound practitioner are as below:

Section A: Cleanliness and safety: To ensure that the scanner is clean to reduce infection risks to patients and staff and to detect any damage to the scanner, especially to the transducers and their cables. Infection control measures are relevant for every patient so that some of these actions are performed several times each day. Checks for scanner damage are performed weekly.

Section B: Image display and performance: To ensure appropriate setting of monitor controls for consistency of imaging.

All the QC tasks are highly recommended and ultrasound practitioner should become familiar with the QC tasks listed in the tables below (Section A and B). These tables provide details of the task, the recommended frequency of the task, relevant action levels and action to be taken if a fault is detected. Faults or results out of tolerance should be notified to the locally identified manufacturer representatives.

Section A: Cleanliness and safety [12]. Reproduced by courtesy of BMUS.

No.	Task	Frequency	Comments/action
1.1	Clean ultrasound gel and body fluids from scanner console, transducers, and cables after every patient.	Daily	Immediate cleaning should occur anytime there is a spill of bodily fluids or hazardous material.
1.2	Ensure transducers are stored securely when not in use.	Daily	
1.3	Ensure transducer cables are properly stowed and not at risk of being run over by the scanner wheels.	Daily	
1.4	Clean monitors of dust, gel, etc.	Daily	
1.5	Check the correct operation of the main scanner controls.	Daily	
1.6	Inspect the transducers used during the session for damage.	Daily	
1.7	Inspect switches, knobs, and other controls for damage.	Weekly	
1.8	Inspect probe cables, the mains cable and plug and other cables, e.g., network and printer cables, for damage.	Weekly	
1.9	Inspect the ultrasound system for damage such as cracks and dents.	Weekly	
1.10	Test of brake and wheel function.	Weekly	
1.11	Check air filters for dust and fluff.	Weekly	
1.12	Rooms should be cleaned for dust, dirt, and infection control.	Daily	Inform housekeeping personnel.

Section B: Image display and performance [12]. Reproduced by courtesy of BMUS.

No.	Task	Frequency	Comments/action
2.1	Check that the machine's monitor brightness and contrast controls have been appropriately adjusted.	Daily	If any deviation from calibration points, reset contrast and brightness to calibration points.
2.2	Check that machine displays entire gray bar.	Daily	If grayscale bar is not fully displayed reset contrast and brightness settings to new calibration points.
2.3	Check that gray levels on image hard copy and/or image display workstations match those on the machine monitor.	Daily	If gray levels do not match adjust Picture Archiving Computer System (PACS) machine monitor settings.
2.4	Inspect reverberation images for shadows and streaks caused by transducer dropout.	Daily	Any suspicion of a fault, contact service engineer or manufacturer representatives.

Section A and B task should form part of the ongoing activities of the ultrasound practitioners and should not require dedicated time to be set aside, other than for simple documentation at the end of the day (refer to APPENDIX 2 for more details).

NOTE:

Planned preventive maintenance (PPM) must be done by manufacturer representatives or trained personnel (refer to APPENDIX 3 for Recommended Annual Ultrasound Quality Control).

4.4.1 Image Quality Requirements

The following approach is recommended:

a) The ultrasound practitioner should specify, as precisely as possible, the investigation(s) for which each machine is optimized.

b) Representative images indicating the performance of each machine should be archived on an annual basis and these should be monitored as part of the audit system in place in the department together with any bench-top testing which takes place.

c) Whenever a machine is modified or repaired, new representative images and relevant bench-top data should be acquired immediately to act as updated reference points.

d) Whenever the range of applications of a machine is extended or modified, this should be clearly recorded, new reference images should be acquired and there should be consideration as to whether the existing pre-sets, software and hardware require update.

4.5 Workplace Health and Safety

4.5.1 Physiological

Regular users of ultrasound scanners may experience long-term musculoskeletal injuries in upper limbs, neck, or spine. Appropriate policies should be in place to monitor staff at risk and respond to problems when they arise. Evaluation of a scanner for new purchases or applications should include an assessment of its ergonomic features.

4.5.2 Support

The nature and level of support provided by the manufacturer is important and should be included in the list of considerations when a machine is purchased. Support should include:

a) availability of clinical applications specialists;
b) appropriate training courses; and
c) repair and maintenance resources.

4.5.3 The Scanning Environment

Patients' privacy and dignity should be maintained throughout the examination, which should be conducted in a room. Only personnel essential for carrying out the examination should be in the room. Due to the intimate nature of ultrasound examination, it is essential that it is conducted in a quiet room, without interruption and a chaperone offered. The ultrasound practitioner must also be mindful that many patients attending for this examination are very anxious and that the psychological aspect of managing the situation in a controlled environment has to be practiced.

The environment in which the ultrasound scanner is used will have a profound effect on its efficacy. Other issues should also be included:

a) the scanning couch and operator seating;
b) the display monitor;
c) room temperature and lighting;
d) hygiene, infection control, and cleanliness; and
e) electrical and information technology (IT) provision.

The couch, the seating, the transducer, and the display should be chosen together, with an emphasis on ergonomics and efficiency. Angle and height adjustment are important and the maximum weight restriction for the couch should be clearly posted. If transvaginal or transrectal examinations are to be performed, the couch should be selected with this in mind. Monitor should be checked independently of the scanner for its grayscale performance and spatial fidelity.

There are standards for room lighting and room temperature.

a) Room lighting should be subdued but not to the point that movement is hazardous.
b) Lack of air conditioning within the scanning room can result in excess room temperatures.
c) Electrical supplies need to be sufficient to cope with the demands of the scanner, the couch, and any accessories.
d) The IT requirements to link to PACS systems are important, as is the location of the machine if trailing leads are to be avoided.

5. STANDARDS AND GUIDANCE FOR ULTRASOUND EQUIPMENT

Ultrasound equipment/system shall comply with Medical Device Act 2012 (Act 737) [13] which is controlled and regulated by Medical Device Authority (MDA). Section 5(1) of the Act 737 requires a medical device to be registered under the Act before it can be imported, exported, or placed in the market. For that purpose, an application for the registration of an ultrasound equipment/system must be made according to the requirements under the Act 737 and in the manner determined by MDA.

Ultrasound is an active medical device and being classified based on the classification rules in the First Schedule of Medical Device Regulations 2012 as follows:

a) Diagnostic ultrasound in non-critical applications is classified as Class B device;
b) Ultrasound equipment for physiotherapy is classified as Class B device; and
c) Ultrasound equipment for use in interventional cardiac procedures is classified as Class C device.

5.1 Ultrasound Hardware

Transducers need to be matched to the anatomical region to be scanned. Scanners are normally purchased and supplied with several transducers which differ in their mode of action, their 'footprint' and the shape of their field of view.

These can be assigned to one of three categories:

a) LA.
b) Curvilinear arrays (CLA).
c) Phased arrays (PA).

Each transducer type can be subdivided in terms of its frequency range. With higher frequencies giving superior image quality at the expense of penetration. In addition, there are a variety of specialist transducers for variable uses:

a) Endoscopic.
b) Transvaginal.
c) Transrectal.
d) Transesophageal.

Examples of suitable combinations of transducers and applications are shown in APPENDIX 4. Note that it is likely that more than one transducer will be required to cover the recommended frequency range in many cases [14].

The choice of scanner should be matched to the type and nature of the workload. A single location and heavy routine workload will favour a larger mainframe machine with a larger display. The reverse will favour a portable system. Most scanners have the potential to be used with all types of transducers and frequencies. There are additional functions which are essential for specific clinical applications. Examples are given in APPENDIX 4 [14].

5.2 Electrical and Mechanical

All equipment should conform to published electromagnetic compatibility (EMC), electrical and mechanical safety standards as stated in the most updated relevant Malaysian Standard (MS) and/or International Electrotechnical Commission (IEC). Ultrasound scanners are mechanically safe if they carry the appropriate Conformitè Europëenne (CE) mark.

There is a risk, especially for portable equipment, of mechanical damage while in use. These are especially stringent for endoprobes and transducers that are used intraoperatively. It is the responsibility of ultrasound practitioners to report any damage and to ensure that action is taken when damage is suspected.

5.3 Equipment Replacement

Equipment reviews and replacement programme is highly desirable because of rapid changes in technology and changing clinical expectations and needs. High-specification ultrasound scanners will often have a longer useful life than basic- or middle-range equipment. Review is typically undertaken between four (4) to seven (7) years following installation. Notwithstanding the above statement, the workloads should also be taken into consideration when deciding for equipment replacement.

Depending on the outcomes of this review, a decision can then be made whether to continue to use the equipment or to obtain a replacement machine. Equipment should be replaced under the following circumstances:

a) It has become demonstrably unreliable.
b) It has broken down and the manufacturer is unwilling or unable to repair it.
c) There is evidence of a clinically significant deterioration in performance.
d) The clinical role for which it was purchased has now been extended or changed and the machine is no longer fit for purpose.

6. STANDARD OF ULTRASOUND PRACTICE

There are various types of ultrasound examination in medical practice performed by various specialties. The following list reflects the commonly performed ultrasound examinations in current practice and it is expected that this list is dynamic and expanding with time.

6.1 Types of Ultrasound Examination

No.	Ultrasound Examinations
1.	Obstetric a) Early pregnancy ultrasound b) First trimester screening c) Second trimester ultrasound d) Third trimester ultrasound e) Multiple pregnancy
2.	Gynaecological a) Bladder b) Vagina c) Cervix d) Uterus e) Endometrium f) Ovaries g) Adnexa h) Rectouterine pouch (pouch of Douglas)
3.	Abdominal (adult and paediatric) a) Liver b) Gallbladder c) Common bile duct d) Pancreas e) Spleen f) Aorta g) Inferior vena cava h) Adrenals i) Kidneys j) Urinary bladder k) Other structures
4.	Paediatric a) Neonatal hip b) Neonatal intracranial c) Neonatal spines
5.	Head and neck (adult and paediatric) a) Lymph nodes b) Salivary glands

No.	Ultrasound Examinations
	c) Thyroid gland
6.	Musculoskeletal (adult and paediatric) a) Shoulder b) Elbow c) Hand and wrist d) Adult hip e) Knee f) Foot and ankle g) Integument
7.	Breast a) Breast parenchyma b) Axillary lymph nodes
8.	Echocardiography a) Basic Echocardiography (2D Echo) b) Advanced Echocardiography (3D, 4D, tissue Doppler imaging, strain) c) Transesophageal echocardiography d) Stress echocardiography (pharmacological/exercise) e) Intracardiac Echocardiography
9.	PoCUS Including, but not limited to a) Cardiac (transthoracic/transesophageal) i. Cardiac arrest ii. Shock iii. Effusion iv. Right ventricular (RV) enlargement v. Contractility vi. Aorta dissection, aneurysm b) Neck i. Airway ii. Vessels iii. Thyroid c) Lung i. Pleura ii. Effusion iii. Interstitial d) Abdomen i. Free fluid ii. Liver iii. Gallbladder iv. Spleen v. Kidney vi. Aorta

No.	Ultrasound Examinations
	vii. Inferior vena cava (IVC) viii. Bowel e) Genitourinary i. Bladder ii. Uterus iii. Ovaries iv. Testis v. Perineum vi. First trimester f) Brain i. Intracranial pressure ii. Cerebral vasospasm g) Ophthalmic i. Retinal detachment ii. Vitreous haemorrhage iii. Lens dislocation h) Musculoskeletal i. Integument ii. Cartilage iii. Tendon iv. Muscle v. Joints i) Vascular imaging i. Central and peripheral venous Doppler ii. Central and peripheral arterial Doppler iii. Arterio-venous fistula (AVF) assessment j) Procedures i. Pericardiocentesis ii. Paracentesis iii. Thoracocentesis iv. Arthrocentesis v. Vascular access vi. Intramuscular/intraarticular injection vii. Fine needle aspiration for cytology viii. Biopsy ix. Other ultrasound guided procedures PoCUS examinations to include both adult and paediatric, where indicated.
10.	Additional procedures a) Elastography b) Contrast-enhanced ultrasound (CEUS)

6.2 Examination – Specific Standards

Written guidelines serve several purposes, including supporting a defence against litigation and helping to maintain minimum standards, they can also be used as a reference for audit purposes.

There will be occasions when guidelines cannot be adhered to and this should be stated in the report, for example, when a structure cannot be clearly demonstrated due to overlying bowel gas.

All ultrasound examinations should be justified, and departments should have clear guidelines as to what should be included in any abdominal/pelvic ultrasound examination for vague and non-specific symptomology, for both male and female patients.

Examinations may need to be extended as necessary depending on initial findings and information obtained from the patient and/or from other tests. Both transabdominal and endovaginal ultrasound approaches are likely to be required to fully evaluate suspected gynaecological pathology.

A range of images should be saved to PACS to provide a record of the examination for case review and audit purposes. All images must include patient and provider identification, date and time of examination and an appropriate annotation with respect to the section, structure or pathology recorded.

6.2.1 Contrast-Enhanced Ultrasound (CEUS)

There is a small risk of life-threatening anaphylactoid reactions to CEUS, and resuscitation facilities with emergency equipment and personnel trained in its use should be available. The rate is estimated at one in 10,000. It is recommended to keep the patient under close medical supervision during, and for at least 30 minutes following, the administration of sulphur hexafluoride.

The following are also recommended:

a) Ensure that a protocol is in place for the delegation and injection of contrast agent.
b) Ensure that a protocol is in place for carrying out and reporting of CEUS.
c) Ensure that a programme of annual basic life support training is in place for staff.

This document does not further specify what should or should not be included in a given type of ultrasound examination and does not include advice on wider aspects of service delivery, such as patient preparation or obtaining consent. Ultrasound practitioners should refer to existing local guidelines and the published good practice standards and guidelines.

6.3 Ultrasound Examination Report

The purpose of an imaging report is to provide a specialist interpretation of images and relate the findings both anticipated and unexpected to the patient's current clinical symptoms and signs, and to diagnose or contribute to the understanding of their medical condition or clinical state. It often incorporates advice to the referring clinician on appropriate further investigation or management.

Any individual issuing an imaging report must be medically qualified and ensure that they are appropriately trained and practice within their competence. All individuals issuing reports should work within a robust clinical governance programme.

The report of an ultrasound examination constitutes a legal document. The responsibility for its accuracy lies with the person verifying the scan. Its ultimate purpose is to address the clinical question being asked of the ultrasound scan. Ultrasound practitioners who are non-medical practitioners can state the ultrasound findings, but the final conclusions and verifications of reports must be done by accredited medical practitioners.

6.3.1 Components of the Report

No.	Detail
1.	Patient's dentification.
2.	Date of the scan and of the report. If significantly apart, consider giving the explanation for the delay in reporting.
3.	Clinical information provided in the request for the examination This should be transcribed as accurately as possible, including indications for the examination and clinical question(s) being asked. If important clinical information has come to light since the request was made, this (and its source) should also be included.
4.	Name of the examination performed. This should include usage of endocavitary probe or contrast, as well as patient's consent and presence of a chaperone where appropriate. Any variations from a standard protocol, such as targeting scan to some organs only, should be explained.
5.	Name(s) and status of the person(s) performing the scan and reporting the examination If the operator and reporter are not the same person, the exact role each one played should be explained.

No.	Detail
6.	Description of findings a) Location. b) Size, accompanied by exact measurements in clinically relevant planes. c) Common widely used anatomical measurements (for example, kidneys, common duct, and spleen) should be used. Variations from normal size should include an explanation (for example, common duct dilated measuring 12 mm, moderate post-micturition residue of 150 ml). d) Internal characteristics, including sound attenuation. This should include important organs, whether normal (for example, normal liver echogenicity, increased echogenicity of renal parenchyma, inhomogeneous spleen echogenicity). e) Borders/outline; for example, lobulated liver contour, poorly defined mass. f) Blood flow characteristics – this should be included where relevant to do so (for example, mass with increased blood flow on Doppler interrogation, normal direction of flow in portal vein).
7.	Limitations: State the nature of any limitations if diagnostic certainty has been impaired by their presence (for example, limited views of pancreas due to overlying bowel gas, only intercostal imaging of the liver achieved).
8.	Comparison with previous relevant imaging: Both with ultrasound and other modalities.
9.	Conclusion: This should be included except in brief self-explanatory reports. Wherever possible, this should start with the answers to the main clinical question(s), including either a specific diagnosis when certain, or a shortlist of differential diagnoses in order of probability. The report should clearly state the incidental nature of observed abnormalities. The conclusion should include recommendations for further investigation(s), principally imaging, or a specialist referral where indicated.
10.	Documentation of communication with the referrer when findings are important or unexpected. This should include an alert if in use in the local department, including date/time and name/position of the person to who any life-threatening findings were communicated.

6.3.2 Report Style

Reports should take into consideration the local practice. They should be:

a) Concise.
b) Easy to understand.
c) Without ambiguity.
d) Omitting irrelevant statements/measurements.

e) Using technical terms (such as echogenicity, acoustic shadowing/ enhancement) only if instrumental in achieving diagnosis.
f) Explaining the significance of measurements and appearances.
g) Using only commonly known abbreviations/explaining less well-known ones in full.
h) Using templates if appropriate. It is acceptable to abbreviate completely normal reports.

6.4 Image Management

All providers of an ultrasound service should have the facility to store whole studies. Image transfer between providers is now routine. To minimize the possibility of patient harm from reviewing images in the absence of a report, the ultrasound images and reports should be stored or linked together. The linked report and image can be useful as part of an audit of practitioner accuracy and competency.

6.4.1 Image Capture

Patient demographics should be passed to the acquisition device using Digital Imaging and Communications in Medicine (DICOM) modality worklist Health Language level 7.

a) The capture of images should always be undertaken on the acquisition device.
b) Images should be captured and labelled using a minimum dataset.
c) Current requirements are as follows:
    i. Identification number (whenever possible).
    ii. Patient's name.
    iii. Date of birth.
    iv. Gender.
d) Site markers, labelling and measurements should be saved as a separate image.
e) Images should be acquired in DICOM format, ready for export to a DICOM archive.
f) Images should also be stored locally on the acquisition device, to ensure any transmission failures can be resent.

6.4.2 Image Access and Review

a) Images should be accessible through an enterprise-wide viewing application or DICOM viewer. Diagnostic image viewing should be undertaken using DICOM images.
b) Digital images should be retrievable in a timely manner, at the point of clinical need.
c) Reports should be linked to images using desktop integration at the reporting stage.
d) Access to images should be restricted to those users with a legitimate relationship to the patient. Role-based access control can be used to provide image/report access to appropriate individuals.

6.4.3 Image Transfer

a) Digital images should be imported/exported in DICOM, in line with current guidance on data security. The primary and preferred route for this is to transfer information in an electronic format and not to use removable media.
b) Formats include compact disk (CD), digital versatile disc (DVD), universal serial bus (USB), PACS to PACS N3 DICOM link or via a third-party transfer service such as the Image Exchange Portal (IEP).
c) Images and reports ideally should be transferred together.
d) Where transportable media (for example, CDs) are used, an approved encryption system should be employed, and password sent under separate cover.
e) Patient demographics should be included to allow receiving organizations to accurately process the data.

6.4.4 Image Storage

Archiving of ultrasound images and reports should be done either as a separate archive dedicated solely to ultrasound, or, ideally, within the hospital PACS in line with data retention policy as stated by National Archives of Malaysia (*Arkib Negara* Malaysia) for seven (7) years. Image archives should be replicated so that more than one instance of an image is available should one copy fail. Images should be linked to reports and be able to be viewed as a record together in a PACS.

All ultrasound devices should be DICOM capable. All the patients imaged should ideally be registered on a DICOM worklist or RIS (Radiology Information System). Regardless of where (or by whom) the ultrasound examination is undertaken, the data should be archived within a uniform, cross-facility software platform. It is recommended that enterprise PACS would be used as a long-term archive. The medical documentation should contain:

a) Patient identity (name and age).
b) Ultrasound practitioner identification.
c) Date of examination (time if requested by local recommendations).
d) Indication for the examination.
e) Possible limitations of the examination due to scanning conditions etc.
f) Organ-specific description of findings, except for normal findings.
g) Pathology characteristics.
h) Diagnosis (suspected).
i) Derived diagnostic and/or therapeutic consequences and/or suggestions for other investigations.

In the case of normal findings, the archived images should show at least one or more suitable planes demonstrating the normal findings relevant to the clinical question. In case of pathological findings, the archived images should ideally show the abnormalities in two planes, or if this is not possible, clearly in one plane only (in B-mode). The use of video clips can improve the visualization of pathology, but at the expense of an increase in the data to be archived.

Whether ultrasound practitioners should communicate the results of an ultrasound examination directly to the patient - in order to ensure optimal patient management, such matters should be discussed in advance with referring physicians and a concerted approach should be offered.

7. EDUCATION AND TRAINING

Ultrasound is highly operator dependent, requiring specialist skills and knowledge. Formal training programmes are designed to ensure the ultrasound practitioner can produce diagnostic images and in circumstances where this proves difficult, differentiate between technical barriers and patient-related barriers. It is essential that practitioners are aware of their limitations, depending on their level of experience, and have access to senior practitioners for guidance and advice. This is particularly appropriate in difficult scanning conditions, so that appropriate clinical advice can be given to the referrer.

There are four major scopes of ultrasound currently practised in Malaysia:

a) Obstetrics and Gynaecology;
b) Radiology;
c) PoCUS which includes sub-specialized ultrasound assessment and guided procedure which include but not limited to vascular, endoscopy, and ultrasound of joints; and
d) Echocardiography.

7.1 Minimum Standards for Provision of an Ultrasound Service

The minimum requirements are as follows [14]:

a) The employer/manager should hold an up-to-date record of the statutory or voluntary registration status of all ultrasound practitioners.
b) All ultrasound practitioners should be registered with the relevant statutory regulatory body where appropriate, or with the relevant voluntary registration body.
c) The employer/manager should hold an up-to-date record of all ultrasound practitioners' relevant qualifications and the awarding institution.

d) Ultrasound practitioners must hold recognized qualifications.
e) Support from experienced supervisors with relevant qualifications, ideally including a teaching qualification, should be provided for students and trainees.
f) Newly qualified staff should undergo a six-month preceptorship phase following completion of their studies, to enable the appropriate support to be provided.
g) An assessment of theoretical knowledge and practical scanning abilities at interview or before appointment should be undertaken where a new member of staff's skills and competence are not known to the employer.
h) An appropriate induction process for all new and temporary staff should be implemented to ensure they are fully aware of departmental procedures and protocols and that they are working to the same standards.

i) A formalized period of monitoring by a senior member of staff should be implemented for all new and temporary staff to confirm their scanning, interpretation, and reporting abilities.

j) Regular continuing professional development (CPD) activities and opportunities for attending workshops, conferences and so on should be monitored by employers/managers. Records of CPD activity should be kept by the individual and the employer/ manager.

k) A performance development review should take place at least annually.

NOTE:

Standards for competence assessment and testing are not included in this document.

7.2 Registration

Ultrasound practitioners come from a wide range of professional backgrounds. Those ultrasound practitioners who are medically qualified and can do so will be registered with the Malaysian Medical Council (MMC) as a doctor with a licence to practise. Ultrasound practitioners who are not registered with the MMC can be registered with a statutory regulatory body if applicable.

For some ultrasound practitioners, statutory registration is not possible due to (for example) having trained overseas or coming from a professional background that is not recognized for statutory registration purposes. It is recommended that ultrasound practitioners who do not hold statutory registration apply for relevant voluntary registration.

The widely used titles of ‘sonographer’ and ‘ultrasonographer’ are not protected. Overall, the situation with respect to the registration of ultrasound practitioners is complex.

7.3 Minimum Requirement of Ultrasound Practitioners

There can be various entry pathways to becoming a qualified ultrasound practitioner. The admission criteria can be further specified by training provider.

7.4 Trainers and Clinical Instructors

All trainers of ultrasound training programme will need to be qualified and possess adequate clinical experience specified within the context of the corresponding established training programmes.

All trainers must hold recognized qualifications, including:

a) Qualifications approved and accredited by Malaysian Qualifications Agency (MQA) or equivalent.

b) Qualifications awarded as part of medical postgraduate education and training (for example by the College of Radiology (CoR), College of Obstetricians and Gynaecologists (COG), Fellowship for Cardiology (obtained National Specialist Registration for Cardiology), College of Emergency Physicians, College of Paediatrics, College of Physicians, College of Surgeons, or Academy of Family Physicians of Malaysia (AFPM)).

7.5 Competency

The competency required by each specialty can be referred to APPENDIX 5 – 8.

8. AUDIT PROGRAMME

There are various methods of audit process proposed in the literature and currently being undertaken in practice. However, BMUS [15] has devised a universal peer review audit tool that can be used to evaluate the referral, the image quality, and the report (APPENDIX 9). While this tool may not encompass all audit programmes, it is recommended as a starting point from which in-house audit tools can be developed to meet local needs.

As yet, there are no national standards for expected quality of images and reports for non-obstetric ultrasound. The benchmark standard against which images and reports will be assessed will be limited by the individuals or department standard. An optimum approach would be to recruit external auditors to review practice, be this neighbouring trusts/health boards or colleagues, but it is recognized that this may encounter financial and time constraints.

8.1 Recommendations for Use of the BMUS Audit Tool

It is acknowledged that a peer review of images and reports takes time. A reasonable estimation of time required is to allocate an average of 5 minutes per case reviewed. It is recommended that services should aim for a review of 5% of all examinations and reports.

A timely retrospective audit of cases is required. Services may wish to allocate time on a daily, weekly, or monthly basis. Access to image and report storage facilities are required and often assistance from the IT department or PACS manager is required to retrieve retrospective data on examinations performed.

A randomized sample of examinations will reduce bias between reviewers, and users of this tool are advised to determine a reliable method to both retrieve data and ensure it is randomized. Some users may prefer that the cases are anonymous, but this can make it difficult for the service to identity learning needs of individual practitioners.

REFERENCES

[1] Dance D., Christofides S., Maidment A., McLean I., and Ng K.. (2014). Diagnostic radiology physics: A handbook for teachers and students. *American Association of Physicists in Medicine, Asia-Oceania Federation of Organizations for Medical Physics, European Federation of Organisations for Medical Physics*. [https://www-pub.iaea.org/mtcd/publications/pdf/pub1564web new-74666420.pdf]

[2] Izadifar Z., Babyn P., and Chapman D. (2017). Mechanical and biological effects of ultrasound: A review of present knowledge. *Ultrasound in medicine and biology,* 43(6):1085-104. [DOI: 10.1016/j.ultrasmedbio.2017.01.023]

[3] Skubas N. (2003). Principles of echocardiography for the anesthesiologist. *The Greek E-Journal of Perioperative Medicine*, 1:26-39. [https://oaji.net/articles/2015/1592-1425670052.pdf]

[4] Schneider-Kolsky M. E., Ayobi Z., Lombardo P., Brown D., Kedang B., and Gibbs M. E. (2009). Ultrasound exposure of the foetal chick brain: Effects on learning and memory. *International Journal of Developmental Neuroscience*, 27(7):677-83. [DOI: 10.1016/j.ijdevneu.2009.07.007]

[5] Heikkilä K., Vuoksimaa E., Oksava K., Saari-Kemppainen A., and Iivanainen M. (2011). Handedness in the helsinki ultrasound trial. *Ultrasound in obstetrics and gynecology*, 37(6):638-42. [DOI: 10.1002/uog.8962]

[6] British Medical Ultrasound Society. (2010). Guidelines for the safe use of diagnostic ultrasound equipment. *Ultrasound*, 18(2):52-9 [DOI: 10.1258/ult. 2010.100003]

[7] Health Protection Agency. (2010). Health effects of exposure to ultrasound and infrasound: Report of the independent advisory group on non-ionising radiation. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/ attachment_data/file/335014/RCE-14_for_web_with_security.pdf]

[8] British Medical Ultrasound Society. (2012). Statement on the safe use, and potential hazards of diagnostic ultrasound. [https://www.bmus.org/static/ uploads/resources/ STATEMENT_ON_THE_SAFE_USE_AND_POTENTIAL_HAZARDS_OF_ DIAGNOSTIC_ULTRASOUND.pdf]

[9] ter Haar G. (2012). Guidelines and recommendations for the safe use of diagnostic ultrasound: The user's responsibilities. [DOI: 10.1259/bir.2012.0001]

[10] Moyano D. B., Paraiso D. A., and González-Lezcano R. A. (2022). Possible effects on health of ultrasound exposure, risk factors in the work environment and occupational safety review. *Healthcare: MDPI*. [doi: 10.3390/healthcare 10030423]

[11] Salvesen K. Å., Lees C., Abramowicz J., Brezinka C., Ter Haar G., and Maršál K. (2011). Safe use of Doppler ultrasound during the 11 to 13+ 6-week scan: Is it possible? *Ultrasound in Obstetrics and Gynecology*, 37:625-8. [DOI: 10.1002/uog.9025]

[12] Dudley N., Russell S., Ward B., Hoskins P., and BMUS QA working party. (2014). BMUS guidelines for the regular quality assurance testing of ultrasound scanners by sonographers. *Ultrasound,* 22(1):8-14. [DOI: 10.1177/1742271x 13511805]

[13] Medical Device Act (Act 737). (2012). [https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html]

[14] The Royal College of Radiologists and The Society & College of Radiographers. (2014). Standards for the provision of an ultrasound service. [https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCR%2814%2917_Standards_ultrasound.pdf]

[15] The Society and College of Radiographers and British Medical Ultrasound Society. (2021). Guidelines for professional ultrasound practice. [https://www.bmus.org/static/uploads/resources/2021_SoR_and_BMUS_guidelines_v1.0_.pdf]

[16] Asian Federation of Societies for Ultrasound in Medicine and Biology [http://www.afsumb.org/]

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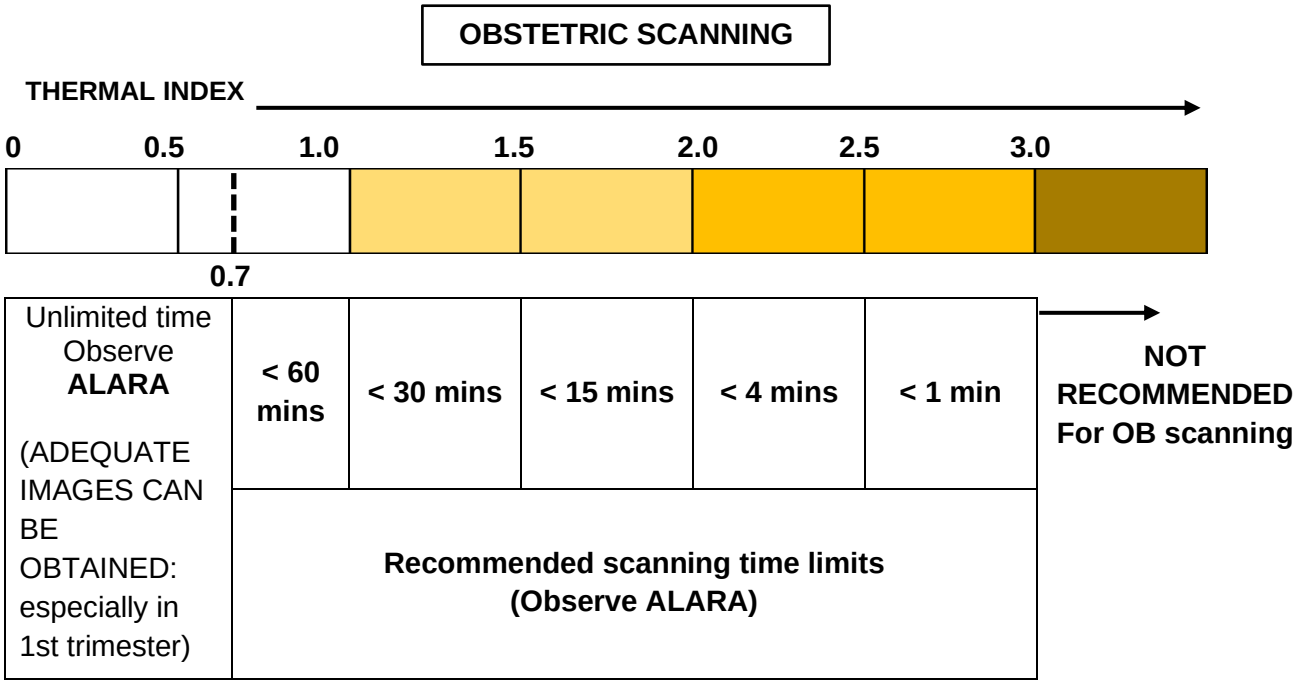
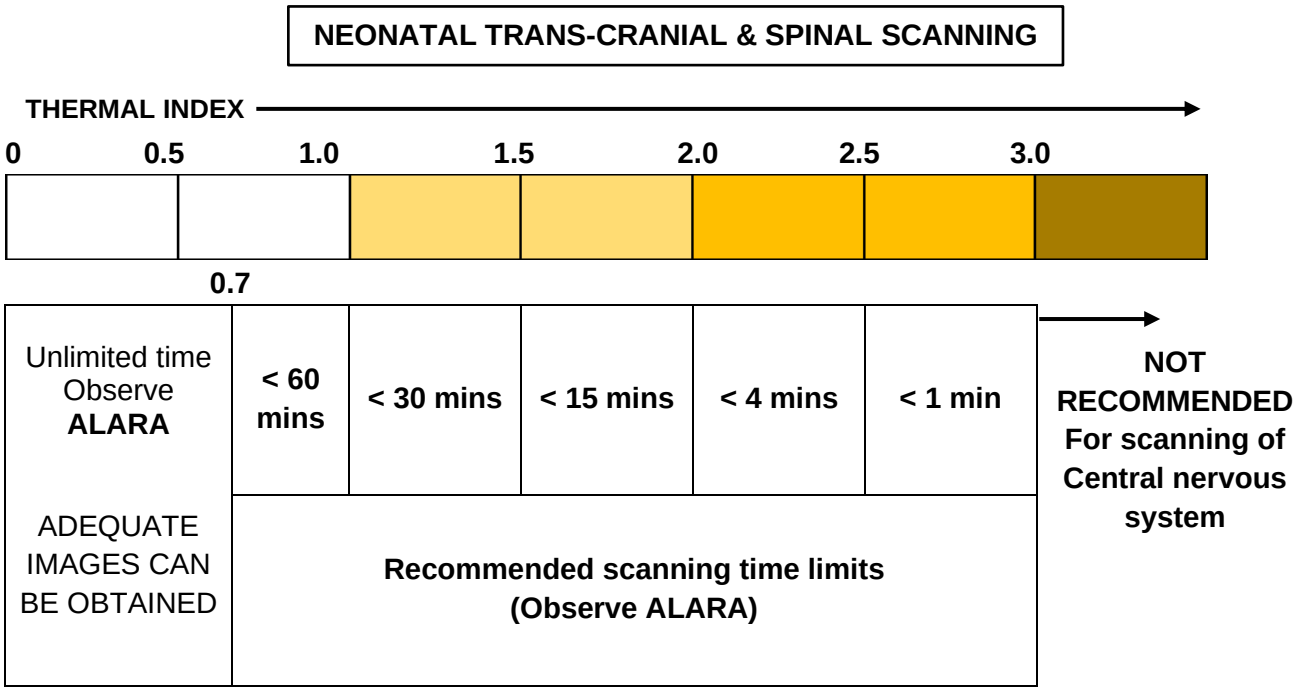
c) The Royal College of Radiologists, UK.
d) British Medical Ultrasound Society, UK.
e) The Society and College of Radiographers, UK.

APPENDIX 1

Recommended maximum scanning times for obstetric examinations conducted with different displayed Thermal Indices (TI) [6]. Reproduced by courtesy of BMUS.

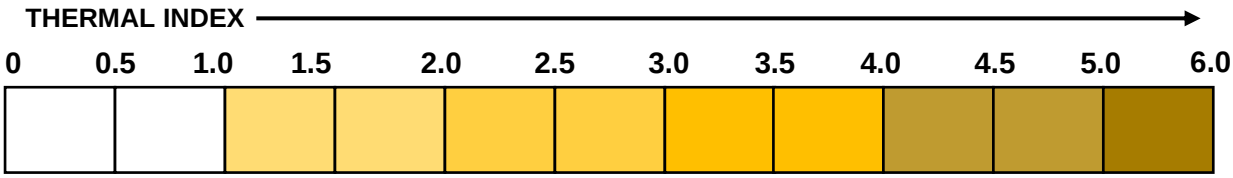


Monitor TIS up to 10 weeks post-LMP, TIB thereafter.



Monitor TIC. MI > 0.7 should be used with caution in the presence of contrast.

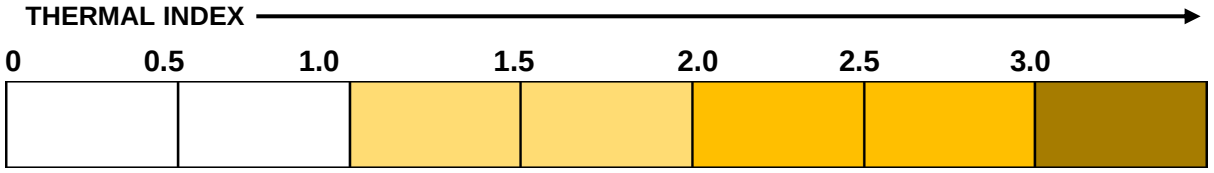
NEONATAL GENERAL & CARDIAC SCANNING



Unlimited time Observe **ALARA**	**< 120 mins**	**< 60 mins**	**< 15 mins**	**< 4 mins**	**< 1 min**	**< 15s**	**< 5s**
ADEQUATE IMAGES CAN BE OBTAINED	**Recommended scanning time limits (Observe ALARA)**						

Monitor TIB. Use of TIB > 6 is not recommended.
MI > 0.7 should be used with caution in the presence of contrast agents.

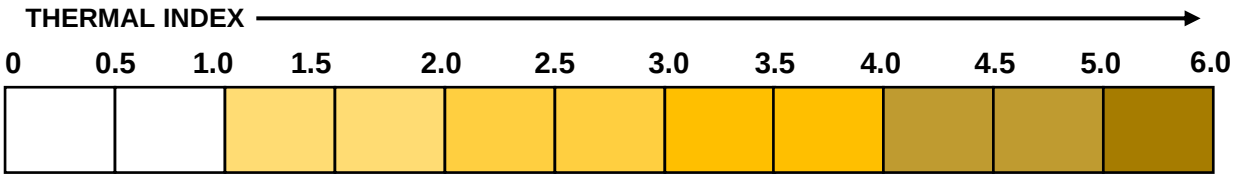
ADULT TRANS-CRANIAL SCANNING



Unlimited time Observe **ALARA**	**< 30 mins**	**< 15 mins**	**< 4 mins**	**< 1 min**	**NOT RECOMMENDED**
ADEQUATE IMAGES CAN BE OBTAINED	**Recommended scanning time limits (Observe ALARA)**				

Monitor TIB. Use of TIC > 3 is not recommended.
MI > 0.7 should be used with caution in the presence of contrast agents.

GENERAL ABDOMINAL, PERIPHERAL VASCULAR AND OTHER SCANNING (EXCLUDING EYE)



Unlimited time Observe **ALARA**	**< 120 mins**	**< 60 mins**	**< 15 mins**	**< 4 mins**	**< 1 min**	**< 15s**	**< 5s**
ADEQUATE IMAGES CAN BE OBTAINED	**Recommended scanning time limits (Observe ALARA)**						

Monitor TIB, or TIC if bone closer than 1 cm; TIS if no bone is in image.
Use of TI > 6 is not recommended.
MI > 0.7 should be used with caution in the presence of contrast agents

APPENDIX 2

IMAGE DISPLAY AND PERFORMANCE

No.	Task
2.1	**Monitor brightness and contrast adjustment** a) If brightness and contrast controls have been altered from their baseline settings, readjust to those recorded or marked on the display. b) If the scanner is used in multiple locations, it's possible that each one might need a slightly different set of settings.
2.2	**Grayscale bar** a) The lighting should be dim with no bright light sources or reflection (this also applies to all subsequent tests where the monitor is viewed) The monitor should be adjusted in the same lighting as scanning is performed. b) The monitor should have a black background (only just). Peak white at one end and darkest grayscale at the other end should be visible, where there a continuous gradient from white to black. If this is not the case, adjust the contrast and brightness and save the new values as a baseline for future reference.
2.3	**Grayscale compatibility with PACS monitors** The displayed grayscale bar on ultrasound images on PACS monitors should look as described above. Any variations should be discussed with the system administrator because they might be related to PACS configuration.
2.4	**Visual inspection of images** a) Check the reverberation pattern for axial banding (dropout) while the probe is operating in air and free of gel. This would indicate a failure of the element, cable, connector, or transmit/receive channel. Keep in mind that subtle non-uniformity is typical on many probes. Inform the responsible person if there is any suspicion of an error or fault. b) This test is not possible on PA probes. Turn off harmonic, trapezoidal and compound imaging, as these may mask faults.

APPENDIX 3

RECOMMENDED ANNUAL QUALITY CONTROL OF ULTRASOUND SYSTEM

No.	Task	Personnel
1.	Verify that cables, housing, and transmitting surfaces of each transducer are free of cracks, separations, and discolorations.	Medical physicist, engineer, or ultrasound practitioner
2.	**Transducer Uniformity** For each transducer used with the ultrasound machine, scan a uniform region in a phantom, and note dropout streaks caused by dead elements; alternatively, inspect for nonuniformities using a straight edge translated over the transducer surface, or inspect the transducer using an electronic probe tester.	Medical physicist, engineer, or ultrasound practitioner
3.	**Maximum Depth of Visualization** For each transducer used with the ultrasound machine, scan a uniform region in a phantom, and find the maximum depth of visualization for detecting background echoes; repeat for each frequency setting of the transducer.	Medical physicist, engineer, or ultrasound practitioner
4.	**Target Detection and Imaging** a) Scan a phantom containing focal targets, such as simulated cysts or low-contrast objects; evaluate target resolution for each transducer. b) The choice of phantoms is at the discretion of the facility.	Medical physicist, engineer, or ultrasound practitioner
5.	**Distance Measurement Accuracy** a) Scan a phantom containing discrete high-contrast targets in known geometric configurations. b) Evaluate accuracy of measuring distances between targets, evaluate horizontal and vertical distance accuracy for measurements done offline on workstations.	Medical physicist, engineer, or ultrasound practitioner

No.	Task	Personnel
6.	**SMPTE Test Pattern** a) The 5% and 95% details superimposed on the 0% and 100% squares, respectively should be visible. b) Greyscale level from 0% to 100% squares increment appeared. c) The resolution at centre and peripheral (horizontal and vertical bar) should be consistent and be able to differentiate all the lines d) No geometric distortion seen. e) No disturbing artefacts should be visible. f) Subtle details visible.	Medical physicist, engineer, or ultrasound practitioner

APPENDIX 4

STANDARDS FOR ULTRASOUND EQUIPMENT

Table 1: Transducer requirements for specific applications.

Application	Transducer type	Frequency range megahertz (MHz)
General abdominal	CLA or PA	2 – 10
Small parts	LA	5 – 18
Vascular	LA and CLA	2 – 15
Cardiac	PA and TEE	2 – 10
Obstetrics/gynaecology	CLA and TV	3 – 15

Application – specific functions

Table 2: General abdominal ultrasound (essential).

Feature	Detail
Adequate resolution	Axial < 0.5 mm, lateral < 5 mm at all depths and < 2 mm in focal zones. Slice thickness < 8 mm at all depths.
Adequate penetration	At least 15 cm of normal tissue
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy < 1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Microbubble imaging	Suitable scanning mode available
Multimode display	Simultaneous display of B, spectral, colour Doppler, power Doppler modes
Application presets	Facility to have operator-created presets
Image-guided biopsy facility	
Extended field of view	
Compounding	
Specialist transducer (optional)	Transrectal

Small parts (including paediatrics, musculoskeletal, thyroid and breast (essential)

As for general abdominal above, but penetration limited to 7 cm and resolution requirements modified to axial < 0.3 mm, lateral < 3 mm at all depths and < 1 mm in focal zones, slice thickness< 5 mm at all depths.

Table 3: Obstetrics/gynaecology (essential).

Feature	Detail
Adequate resolution	Axial < 0.5 mm, lateral < 5 mm at all depths and < 2 mm in focal zones Slice thickness < 8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy < 1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Multimode display	Simultaneous display of B, motion (M), spectral, colour and power Doppler modes
Application pre-sets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue
Specialist transducer	Transvaginal 3D/4D (Optional)

Table 4: Cardiology (adult) (essential).

Feature	Detail
Display channel	Electrocardiogram amplifier and display in addition to at least one other physiological channel amplifier and display
Adequate resolution	Axial < 0.5 mm, lateral < 5 mm at all depths and < 2 mm in focal zones Slice thickness < 8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy < 1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual

Feature	Detail
Microbubble imaging	Suitable scanning mode available
Multimode display	Simultaneous display of B, M spectral, colour Doppler, and power Doppler modes
Application pre-sets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue
Specialist transducer (optional)	TEE

Cardiology paediatric

As cardiology (above), but penetration limited to 7 cm and resolution requirements modified to: axial < 0.3 mm, lateral < 3 mm at all depths and < 1 mm in focal zones, slice thickness < 5 mm at all relevant depths.

Table 5: Vascular (essential).

Feature	Detail
Adequate resolution	Axial < 0.5 mm, lateral < 5 mm at all depths and < 2 mm in focal zones Slice thickness < 8 mm at all depths
Random image review	
Multiple image display	Facility to display at least two images in same mode simultaneously
Spectral Doppler	Range gate accuracy < 1 mm
Colour Doppler	Adjustable wall thump filter
Calculation of waveform indices	Automatic and manual
Multimode display	Simultaneous display of B, spectral, colour Doppler, and power Doppler modes
Application presets	Facility to have operator-created presets
Adequate penetration	At least 15 cm of normal tissue

APPENDIX 5

COMPETENCY ASSESSMENT FOR ULTRASOUND IN OBSTETRICS AND GYNAECOLOGY

Competency is assessed by evaluation of still ultrasound images, movie clips, real-time scanning, or a combination of methods, as determined by individual programs. The pass score for competency assessment was established at 60%, and a set of three ultrasound images with pass score in each was deemed necessary for attaining each competency. Assessment should also be evaluated based on logbook in ultrasonography in obstetrics and gynaecology.

Competency assessment: Level 1
1. Mean sac diameter 2. Crown–rump length 3. Fetal presentation 4. Fetal extremities 5. Biparietal diameter 6. Head circumference 7. Abdominal circumference 8. Femur diaphysis length 9. Amniotic fluid index 10. Maximum vertical pocket
Competency assessment: Level 2
1. Cervical length (transvaginal ultrasound) 2. Cervical length (transabdominal ultrasound) 3. Endometrial thickness 4. Uterine measurements 5. Ovarian measurements 6. Transvaginal pelvic examination: uterus 7. Transvaginal pelvic examination: ovaries
Competency assessment: Level 3
1. Head: transventricular plane 2. Head: transthalamic plane 3. Head: transcerebellar plane 4. Face: orbits 5. Face: upper lip and philtrum 6. Face: facial profile 7. Heart: four-chamber view 8. Heart: left ventricular outflow tract 9. Heart: right ventricular outflow tract 10. Heart: three vessels and trachea view 11. Abdomen: abdominal circumference level 12. Abdomen: kidneys

13. Abdomen: cord insertion
14. Number of cord vessels
15. Pelvis: bladder
16. Spine: longitudinal
17. Spine: axial
18. Doppler: Umbilical artery
19. Doppler: Middle cerebral artery
20. Doppler: Ductus venosus
21. Doppler: Uterine artery
22. Nuchal translucency
23. Writing an ultrasound report: Obstetrics
24. Writing an ultrasound report: Gynaecology

a) Duration of training should be 12 months including logging in cases, hands on and theory.
b) Number of scans observed Level 1– 20, Level 2 – 20 and Level 3 – 20.
c) Number of scans performed Level 1 – 20, Level 2 – 20 and Level 3 – 50. All ultrasounds should be performed independently.
d) Assessment must be done by Maternal Fetal Medicine Specialist once training completed.
e) Required passing score should be at least 60%.

APPENDIX 6

COMPETENCY ASSESSMENT FOR ULTRASOUND IN RADIOLOGY

Competency is assessed by based on the:

1. Completion of introductory ultrasound course: Physics, artefacts, how to use the machine and perform a scan.
2. Completion of an ultrasound logbook.
3. Completion of 5 formative Assessments Detailed and directed (Imaging based assessment): abdominal, superficial organ, Doppler, paediatric, and musculoskeletal ultrasound with a supervisor referring a standard evaluation worksheet (APPENDIX 6A).
4. Summative assessment – Objective Structured Practical Examination: a formative assessment with no help/feedback, where the competence of the sonographer is completely assessed by a supervisor.
5. A test of image interpretation and clinical decision-making ability to test knowledge rather than ultrasound ability.

Logbook

The learning outcome is the completion of an ultrasound logbook. Students are compulsory to complete minimum of **1000** sonographic examinations throughout the course. The logbook is divided into two (2) levels:

Level 1	Practice at this level would require the following abilities: • Perform common examinations safely and accurately (with supervision). • Recognize and differentiate normal anatomy and pathology.
Level 2	Practice at this level would usually require most or all the following abilities: • Perform common examinations safely and accurately (without supervision). • Diagnose common abnormalities within certain organ systems. • Recognize and correctly diagnose most of the conditions within the relevant organ system. • Understand the relationship between ultrasound imaging and other diagnostic imaging techniques.

Parts	Level 1		Level 2	Total Cases
	with supervision	with supervision	without supervision	
	Novice	Beginner	Competent	
Gastrointestinal ultrasound (liver, gallbladder, bile ducts, pancreas, spleen, bowel)	50	150	200	400
Urological ultrasound (kidneys, ureters, bladder, adrenals, prostate, seminal vesicles, other pelvic structures: uterus, ovaries, lymph nodes)	50	150	200	400
Neck	5	15	20	40
Breast/scrotal ultrasound	5	15	20	40
Emergency/bedside ultrasound	5	5	10	20
Vascular ultrasound (peripheral extremity arteries, peripheral extremity veins, abdominal vessels, extracranial vessels)	5	15	20	40
Musculoskeletal ultrasound	5	15	0	20
Paediatric ultrasound	5	15	20	40
Appointment (optional)				
Quality control (optional)				
Thoracic ultrasound (hemidiaphragms) (optional)				
Image post processing (optional)				
			Total	**1000**

APPENDIX 6A

RADIOLOGY IMAGING BASED ASSESSMENT

Reproduced by courtesy of National Radiology Curriculum.

Trainee:	**Assessor:**	**Date:**
Start time:	**End time:**	**Duration:**
Case more difficult than usual? Yes / No (If yes, state reason)		

Score: N = Not observed or not appropriateU = Unsatisfactory **S =** Satisfactory

Competencies and Definitions		**Score N/U/S**	**Comments**
I	**Core knowledge**		
C1	Demonstrates knowledge of relevant radiological anatomy		
C2	Demonstrates understanding of clinical context and use of the appropriate imaging modality		
II	**Image analysis**		
IA1	Demonstrates ability to identify normal and abnormal findings		
IA2	Demonstrates the ability to formulate a diagnosis based on imaging findings		
IA3	Demonstrates ability to correlate the imaging findings with the previous investigations		
IA4	Demonstrates the ability to advise the clinicians on further imaging/management needed		
III	**Report and Communication**		
RC	Able to generate a report		
RC2	Able to communicate findings to clinicians and discuss relevant findings		

Global summary

Level at which completed elements of the PBA were performed		**Tick as appropriate**	**Comments**
Level 0	Insufficient evidence observed to support a judgement		
Level 1	Unable to perform the procedure under supervision		
Level 2	Able to perform the procedure under supervision		
Level 3	Able to perform the procedure with minimum supervision (would need occasional help)		
Level 4	Competent to perform the procedure unsupervised (could deal with complications)		

Signatures:

Trainee:	**Assessor(s):**

Assessment Validation for Imaging Interpretation

Specialty: Radiology	

Competencies and Definitions		Satisfactory Behaviours	Unsatisfactory Behaviours
I	**Core knowledge**		
C1	Demonstrates adequate knowledge of relevant radiological anatomy	Able to identify normal and variant of radiological anatomy on different imaging modalities	Fails to identify normal and clinically relevant variant/anomaly of radiological anatomy
C2	Understands the clinical context and usage of the relevant imaging modality	Able to obtain the relevant clinical information and offer the appropriate imaging modality	Fails to obtain adequate clinical information and offer inappropriate imaging modality
II	**Image analysis**		
IA1	Demonstrates ability to identify normal and abnormal findings in various imaging modalities	Able to identify the key abnormalities and differentiate this from normal findings on various imaging modalities	Fails to identify abnormal findings or incorrectly identifies findings as abnormal
IA2	Demonstrates ability to formulate a diagnosis based on the imaging findings	Able to combine relevant radiological findings and formulate the appropriate diagnosis	Fails to use the relevant radiological findings and formulate the appropriate diagnosis
IA3	Demonstrates ability to correlate the imaging findings with the previous investigations	Able to use the previous relevant investigations and correlate with the current imaging finding	Unable to make a correlation between the previous investigations and the imaging finding
IA4	Demonstrates the ability to advise the clinicians on further imaging/management needed	Able to suggest further imaging modalities that will assist the clinicians in the management of the patient	Unable to suggest any further imaging/management or suggests inappropriate imaging/management
III	**Report and Communication**		
RC1	Able to generate a report	Able to write a clear and concise report that is grammatically correct and has all the relevant findings	Unable to write an accurate and clear report
RC2	Able to communicate findings to clinicians and discuss	Able to convey the findings to the clinicians and to participate in the discussion regarding patient's management	Unable to communicate well with the clinicians and to contribute in the discussion on patient's management

APPENDIX 7

COMPETENCY ASSESSMENT FOR ULTRASOUND IN POCUS WHICH INCLUDES SUB-SPECIALIZED ULTRASOUND ASSESSMENT AND GUIDED PROCEDURE

PoCUS is performed by non-radiologists who are trained to use ultrasound to answer certain focused clinical questions in mind. PoCUS is now being practised by a wide variety of specialties, including emergency medicine, acute internal medicine, nephrology, rheumatology, rehabilitation medicine, pulmonology, orthopaedic, paediatric, anaesthesia, intensive care, to name a few. Due to the advent of technology and social media, the knowledge and use of ultrasound have evolved rapidly.

PoCUS can be classified into the following functional clinical categories:

a) Diagnostic: Utilization of ultrasound in an emergent diagnostic imaging capacity.
b) Symptom or sign-based: Utilization of ultrasound in a clinical pathway based upon the patient's symptom or sign (e.g., shortness of breath).
c) Resuscitative: Utilization of ultrasound use as an adjunct in acute resuscitation.
d) Procedure guidance: Utilization of ultrasound as an aid to guide clinical procedures.
e) Monitoring therapy: Utilization of ultrasound in physiological monitoring, in order to assess the response to treatment.

Given the complexities in the practice of PoCUS, the competency assessment is therefore very challenging. Hence, it is not feasible to have a common recommendation to cater for all PoCUS users. There are published recommendations to deliver the issues on competency assessment for these groups of clinicians. Unfortunately, none is found to dictate a comprehensive discipline-specific assessment, unlike radiology or obstetrics. As such, most organizations have recommended that each institution to have its own process and pathway for certification. The process, however, must be done by credentialled clinicians. Credentialled clinician, in this context, is defined as one that has undergone specific ultrasound training e.g., fellowship, diploma, postgraduate certificate or has been certified by a recognized ultrasound organization. This document provides a general recommendation on competency assessment.

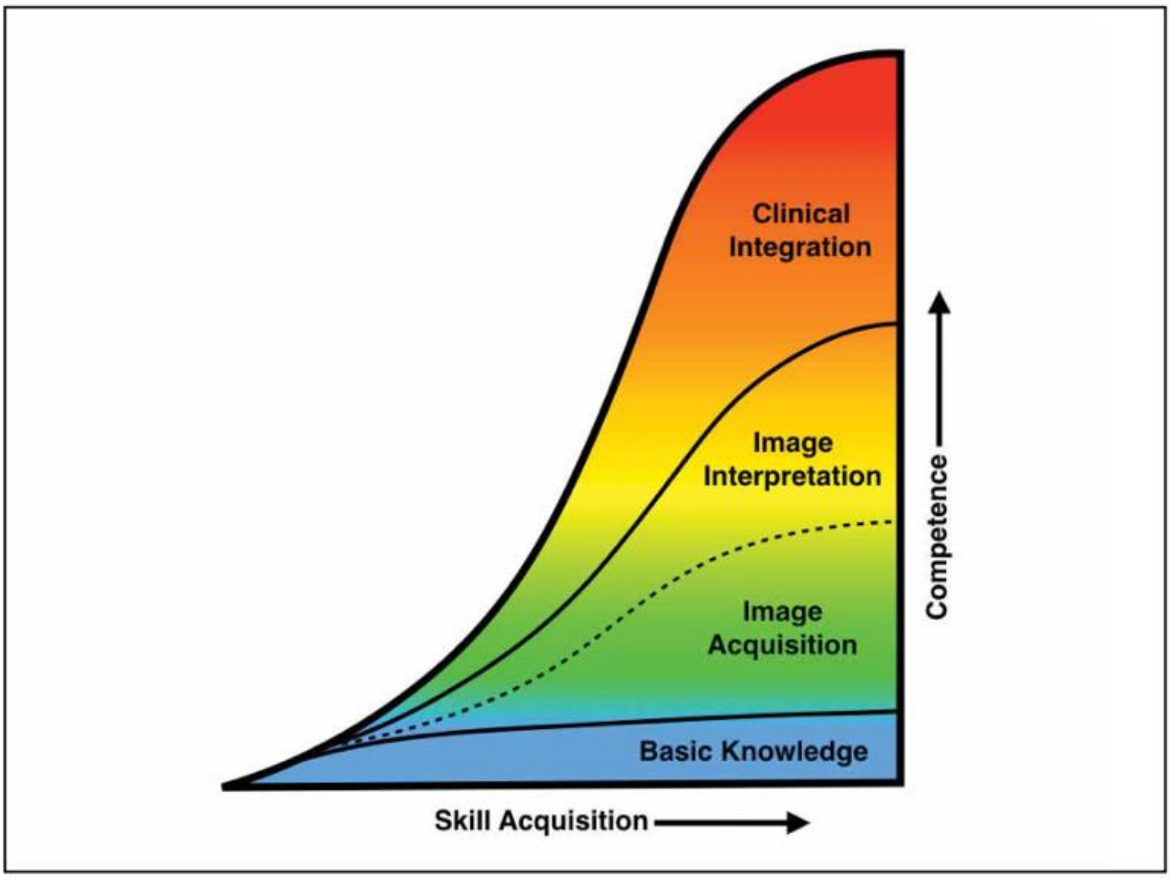
Competency in PoCUS requires the progressive development and application of increasingly sophisticated knowledge and psychomotor skills for an expanding number of situations. The American College of Emergency Physician (ACEP) definition of ultrasound competency includes the abilities in certain fields, namely:

a) recognize the indications and contraindications for the ultrasound examination.
b) acquire adequate images, and this requires an understanding of basic ultrasound physics, translated into the skills needed to operate the ultrasound system correctly (knobology), while performing examination protocols on patients presenting with different conditions and body habitus.

c) interpret the imaging by distinguishing between normal anatomy, common variants, as well as a range of pathology from obvious to subtle.

d) integrate ultrasound examination findings into individual patient care plans and management and effective integration requires knowledge of each particular exam accuracy, as well as proper documentation and quality assurance.

This definition is well suited for any PoCUS, regardless of the category it is practised. Although there are many ways to learn ultrasound, it is highly recommended to commence with a formal didactic session. A mentor or proctor is required to guide the clinician (trainee) throughout the training. It goes without saying that knowledge acquisition is core for all PoCUS users.



Competency in PoCUS requires mastery of different skills as shown in the above figure. After gaining basic knowledge of ultrasonography, image acquisition and interpretation skills can be mastered. Clinical integration of ultrasound findings requires baseline competence in clinical medicine.

In order to be certified as a proficient PoCUS clinician, one has to be assessed on three (3) core competencies, namely:

1. Image acquisition.
2. Image interpretation.
3. Clinical integration of findings into patient management decision-making.

1. Image acquisition

Image acquisition starts from the knobology, producing the optimal field of view of the required image, as well as trouble-shooting difficult windows. The knowledge of physics and knobology of ultrasound has to be in tandem with practice of PoCUS.

There is evidence to demonstrate that competency can be assumed after a number of ultrasound examinations have been undertaken. This number of images varies from organization to organization and ranges from 25 to 50. However, in practice not all logged examinations are of the same quality practically. There is some evidence, to suggest that competency should be assessed by observation of an expert reviewer using a specified checklist of specific examination functions rather than a specified number of practice examinations.

A formal scheme to delineate what is deemed as complete and accurate image acquisition should be formulated for this purpose. If an observation of image acquisition is used instead of a log number, the checklist for what constitutes complete and accurate image acquisition should be specified at the beginning of the training. Alternatively, image acquisition can also be assessed through regular scheduled Question-and-Answer image review sessions. This should form the summative assessment.

2. Image interpretation

Image recognition is essential before any interpretation can be done, and this can be tested with a series of clips or still images of both normal and pathological. Trainee is expected to recognize if an image is feasible for diagnosis-masking, and hence he must be competent to identify inadequate image or image with certain important structures missing. Tests to assess specific application competency have been developed and are currently in practice. This can be included as part of summative assessment and tested again in formative assessment.

3. Clinical integration into practice

This is the hardest metric to assess and there is limited literature to support best practice. Assessment based on ultrasound-orientated simulation with subsequent application of ultrasound finding to decide on subsequent clinical management can be adopted to assess the integration of ultrasound into clinical practice confidently. In addition, some image recognition tests have incorporated patient care scenarios as part of the assessment. The “next best clinical management step” must be picked from the multiple-choice stems that follow. This can be included as part of summative assessment and tested again in formative assessment.

Competency Assessment

Assessment can be done after a predefined period of time, or when triggered by the trainee whenever he is ready. Summative and formative assessments are recommended. There are various objective methods that can be used. Institution must agree on the method used for the purpose of this assessment. Image interpretation and clinical integration can be assessed in formative assessment through various formats, such:

a) Multiple choice questions.
b) Objective Structured Clinical Examination (OSCE).
c) Viva.
d) Testing via simulator models.

APPENDIX 8

COMPETENCY ASSESSMENT FOR ULTRASOUND IN ECHOCARDIOGRAPHY

1. Role of Echocardiography in Contemporary Practice

Echocardiography is essential to the practice of cardiology. It is the most widely used and readily available imaging technique for assessing cardiovascular anatomy and function. Clinical application of ultrasound encompasses M-mode, 2D, 3D, pulsed (PW), tissue (TDI), continuous wave (CW), and colour-flow Doppler imaging. Echocardiography provides diagnostic and prognostic information on cardiovascular anatomy, function, hemodynamic variables, and flow disturbances. Moreover, these cardiovascular parameters can be assessed at rest, as well as during conditions of increased hemodynamic demand such as exercise. Advanced applications of echocardiography, including 3D imaging, strain imaging, and use of ultrasound enhancing agents (also known as “echo contrast agents”) to improve left ventricular endocardial definition and to assess perfusion, as well as the use of real-time imaging to guide invasive procedures, have all become important in the clinical care of patients.

All cardiologists should have a basic understanding of echocardiographic techniques – their strengths, limitations, and appropriate use. Although it is expected that most, if not all, fellows will achieve Level II competency in echocardiography during their 4 years of general cardiology training, this document describes the more focused, in-depth experience required for Level III competency.

2. Levels of Training

Level I training is the basic training required for trainees to become competent consultants, is required by all fellows in cardiology and can be accomplished as part of a standard 4-year training program in cardiology. For echocardiography, Level I training is defined as an introductory or early level of competency in performing and interpreting transthoracic echocardiography (TTE) that is achieved during fellowship training but is not sufficient to provide independent interpretation of results.

Level II training refers to additional training in ≥1 area that enables some cardiologists to perform or interpret specific diagnostic tests and procedures or render more specialized care for patients with certain conditions. Level II training in selected areas may be achieved by some trainees during the standard 4 years cardiovascular fellowship, depending on their career goals and use of elective rotations. Level II echocardiography training is required to provide independent interpretation of echocardiograms.

Level III training typically requires additional experience beyond the basic cardiovascular fellowship to acquire specialized knowledge and skill in performing, interpreting, and training others to perform specific procedures or render advanced, specialized care for procedures at a high level of skill. Level III training in echocardiography is required of individuals who intend

to perform and interpret complex studies in special populations, lead a research program, direct an academic echocardiography laboratory, and/or train others in advanced aspects of echocardiography. Many of the competencies defined in this document overlap with those acquired during Level II training. For individuals seeking advanced echocardiography training, the intent is to gain these competencies at a deeper level during Level III training.

3. Training Components

a) Didactic Program

Didactic instruction may take place in a variety of formats, including lectures, online modules, journal clubs, grand rounds, clinical case presentations, research conferences, simulator-based training, and patient safety or quality improvement conferences. A didactic program is intended to provide the advanced trainee with an understanding of ultrasound physics, instrumentation, echocardiographic image formation and optimization, and clinical application of echocardiography (including advanced application of ultrasound enhancing agents, strain imaging, 3D echocardiography, stress imaging, and TEE). It should incorporate relevant content, including anatomy, pathology, and hemodynamic, and it should cover advanced medical knowledge and patient care relevant to the competencies. In particular, instruction in the use of echocardiography in structural heart interventions and cardiac surgery should be included. Some of this training may be incorporated into the didactic program for general cardiovascular training. However, Level III didactic teaching should be provided within a multimodality imaging framework to emphasize appropriate and coordinated use of all cardiac imaging modalities. Given that fellows who complete advanced training in echocardiography will be prepared to direct an echocardiography laboratory and train others in advanced aspects of echocardiography, didactic education should include exposure to the principles of laboratory operations (e.g., budgeting, manpower and equipment assessment, accreditation, relationships with industry, sonographer supervision, continuous quality improvement) as well as the opportunity to gain experience in teaching.

b) Clinical Experience

Echocardiography plays an integral role in the diagnosis and management of a wide variety of acquired and congenital cardiac disorders. Therefore, exposure to the entire spectrum of heart diseases in diverse patient populations should be available to the trainee. Although a minimum number of clinical cases is suggested, these criteria merely serve as proxies for clinical experience. In terms of the overall quality of the educational experience and depth of understanding, the number of echocardiographic studies in which the trainee participates is less important than the range of pathologies encountered and the quality of supervision and instruction. The trainee must develop expertise in understanding clinical contexts in order to communicate echocardiographic results in a way that is clinically relevant to the referring physician. For the acquisition of technical skills, such as TEE or stress echocardiography, this document provides minimum procedure volumes beyond those required for Level II training.

Although Level III training can be achieved during the standard 3 years cardiology fellowship, additional training may be necessary or desirable to acquire specialized knowledge and competencies in performing, interpreting, and training others to perform specific procedures.

Level III training in echocardiography requires rigorous clinical experiences in diverse clinical settings using the various echocardiographic modalities. This would include extensive experience in TTE and TEE using both 2D and 3D approaches; expertise in stress echocardiography; and familiarity with new echocardiographic tools such as speckle tracking echocardiography, which is used for strain and strain rate analyses.

In addition to experience with the use of echocardiography across the broad spectrum of cardiovascular disease, exposure to echocardiographic evaluation of congenital heart disease is essential. The sites of Level III training should include outpatient and inpatient settings, intensive care units, interventional cardiac laboratories, and intraoperative locations. In each setting, trainees should participate in supervised procedures with graduated responsibility and autonomy in procedural performance, ultimately to achieve clinical independence and the ability to function as a first line proceduralist for a portion of the training period, with appropriate oversight from an attending echocardiographer. Level III trainees are expected to acquire and interpret images using online and offline analytic tools and to communicate their findings to the ordering physician/service effectively through a comprehensive written report. In addition, trainees should be aware of the potential risks associated with echocardiography and learn how to recognize, treat, and, where possible, avoid complications. The trainee must review imaging studies and associated clinical outcomes regularly. The trainee should develop expertise in conscious sedation for TEE, pharmacologic options for stress testing, and use of ultrasound enhancing agents. Familiarity with the indications for echocardiography and the implementation of the appropriate use criteria (AUC) for echocardiography is an important component of training.

c) Hands-On Procedural Experience

The echocardiographic examination is an operator-dependent procedure in which it is possible to introduce confounding artifacts or to omit data of diagnostic importance. It is interactive, requiring real-time recognition of specific diagnostic findings to obtain a study that is both comprehensive and clinically useful. The ability of the trainee to perform a hands-on examination independently is initially developed during Level II training. The trainee should also develop sufficient technical skills in using an echocardiographic instrument to answer clinical questions during Level II fellowship training. Such training is important not so much to develop true technical expertise but to better understand the diagnostic capabilities and potential pitfalls of the echocardiographic examination. It also helps trainees to learn tomographic cardiac anatomy and integrate planar views into a 3D framework. Highly skilled cardiac sonographers with broad experience in performing echocardiographic examinations are necessary to facilitate this training. In contrast, Level III training requires that the trainee be able to train both fellows and sonographers in image acquisition and optimization at the level of a skilled cardiac sonographer. Therefore, fully developed image acquisition skills are an essential competency for the Level III trainee. No additional procedure numbers are recommended as a minimum for Level III TTE acquisition. Rather, the focus of this competency is on an expert level of image acquisition, the ability to consistently perform a complete and comprehensive study, and the acquisition of skills and knowledge to train others in the field. This level of expertise may require further TTE experience during Level III training.

Clinical exposure to a broad range of cardiac pathologies and sufficient hands-on experience are essential for the advanced trainee to gain the requisite technical competency. As part of the hands-on aspect of the echocardiographic training program, experience with hand-carried ultrasound devices is desirable. These devices extend the clinical utility of echocardiography by allowing the operator to offer a “visual physical examination” in a manner that can be applied practically in the clinical setting. Their appropriate application requires that the operator have a fundamental understanding of echocardiographic principles, cardiac anatomy/physiology, and resultant echocardiographic correlates. The operator must also understand the limitations of these devices. Therefore, participation in a didactic echocardiographic educational program and hands-on training with conventional echocardiographic equipment best prepares the cardiovascular fellow to utilize hand-carried ultrasound in the clinical setting as a teaching tool and an adjunct to physical examination.

4. Diagnosis and Management of Emergencies and Complications

Emergency echocardiography is defined as the use of echocardiographic techniques for the rapid diagnosis of unstable patients, life-threatening conditions, or procedural/surgical complications, usually in a hospital setting. The study may be TTE or TEE and comprehensive or targeted and may utilize either a full-sized ultrasound system or a hand-carried unit.

A unique feature of emergency echocardiography is the requirement that the examination be performed/interpreted by an individual able to acquire the needed information, formulate an accurate interpretation, integrate the ultrasound data with the clinical scenario, and immediately communicate the relevant information to the healthcare team. Because bedside echocardiography is often the only practical diagnostic modality available to such patients, its value cannot be overstated.

Given the profound implications of emergency echocardiographic findings in the management of unstable patients, cardiologists who provide this service must be highly trained and experienced echocardiographers. They should be fully trained in all aspects of TTE and TEE techniques, with particular focus on the recognition and assessment of life-threatening conditions such as left ventricular dysfunction, cardiac tamponade, right heart failure, acute valvular regurgitation, and aortic dissection. In unstable patients particularly, the assessment of fluid status, management of vasopressors, and recognition of left atrial hypertension as a cause for respiratory failure are critical for management. In addition, a level of clinical expertise is highly desirable so that the echocardiographic findings can be fully and rapidly integrated with other clinical data. Beyond general training in TTE and TEE, Level III experience in emergency echocardiography requires specific participation in the interpretation of a number of studies from patients with unstable and/or life-threatening situations. In laboratories with a diverse and complex patient population, it would be expected that this exposure would be achieved as a matter of course.

5. Diagnosis and Management of Rare Clinical Conditions and Syndromes

Level III trainees should be familiar with the echocardiographic findings of less common conditions involving the cardiovascular system. These include complex congenital heart defects (both repaired and unrepaired), the full spectrum of acquired and genetic cardiomyopathies, and the various aetiologies of cardiac masses. Competency in interpreting complex and postoperative congenital heart disease may require training beyond Level III. This additional training may occur at another site with a high volume of complex congenital heart disease. The Level III trainee should also be aware of syndromes (e.g., Down and Pierre Robin syndromes) or conditions (e.g., vascular ring or aortic arch anomaly) that may pose challenges for oesophageal intubation and require anaesthesia assistance. The Level III trainee should be able to interpret the echocardiographic findings in these less common conditions and know the indications to proceed with alternative imaging modalities as a complement to or in place of echocardiography.

6. Research and Scholarly Activity

One important purpose of Level III training is to develop the skills necessary for a career that includes cardiovascular research and education. The trainee would be expected to work with faculty in clinical, imaging science, and/or translational research. Formal training in research methodology, including biostatistics, clinical trial design, research ethics, and grant writing should be available for those fellows who plan to be involved in research activities. Research should lead to presentations at local, regional and/or national meetings, publication in peer reviewed scientific journals, and/or grant support. Alternatively, Level III trainees at programs that are not designed to support original research activities are expected to actively participate in quality improvement and educational projects. All trainees should develop and maintain habits of self-learning, by both conducting regular case-review and journal review sessions and attending regional and national scientific meetings. Level III training programs are expected to evaluate progress in scholarly development. Periodic meetings and review of presentations, manuscripts, and/or other scholarly activities should be conducted to provide feedback and implement corrective action plans, if necessary, to ensure that trainees achieve predefined goals.

Competency Components and Curricular Milestones for Level III Training in Echocardiography		Milestones	
Medical Knowledge		**All**	**Add**
Physics			
1.	Know the physics of ultrasound, including understanding of optimal machine and transducer settings, effect of change in frequency of transducers and transducer types, and effects on resolution (temporal, lateral, and linear).	X	
2.	Know the basis of image formation, beam focus, and resolution, and causes of artifacts.	X	
3.	Know the physics of Doppler ultrasound as used for blood flow and tissue applications, including Doppler equation, angle corrections, differences when compared with the hemodynamic data derived from other imaging modalities	X	
4.	Know the physics of harmonic imaging and ultrasound enhancing agents, including optimizing left ventricular opacification and perfusion.	X	
5.	Know the physics of 3D ultrasound, including optimization of resolution.	X	
6.	Know the physics of strain and strain rate imaging, including applications based on speckle tracking and tissue Doppler imaging.	X	
7.	Know the basic principles (e.g., physics, image formation, causes of artifacts) of other commonly used noninvasive cardiovascular imaging modalities (i.e., nuclear cardiology, cardiovascular computed tomography, cardiac magnetic resonance).	X	
Hemodynamics			
8.	Know normal cardiac physiology and the pathophysiology of diseased cardiac states.	X	
9.	Know the echocardiographic correlates of pressure assessments in the heart, including complex valvular lesions and diastolic assessment in complex disease.	X	
10.	Know the limitations of various hemodynamic measurements and how to reconcile discrepant indices.	X	
11.	Know complex and advanced hemodynamics and the relationship between Doppler findings and other imaging and invasively measured intracardiac pressures.	X	

General Competencies for All Conditions			
12.	Know the echocardiographic findings (transthoracic echocardiography and transesophageal echocardiography) of simple and complex acquired disease, including postoperative findings.	X	
13.	Know the principles of hemodynamics in normal and abnormal conditions.	X	
14.	Know the advantages and limitations of echocardiography in relation to other imaging modalities.	X	
15.	Know the correlation of echocardiography with other noninvasive and invasive techniques for assessing cardiac structure and function.	X	
16.	Know the causes of discordant findings and the procedures to reconcile those discrepancies.	X	
17.	Know the limitations of all imaging and invasive assessment and the appropriate use of imaging in each condition.	X	
18.	Know the importance of serial comparisons and the principles of assessing serial change.	X	
19.	Know the indications for emergent and urgent echocardiographic evaluation of patients.	X	
Ventricular Disease (Transplant and Devices)			
20.	Know the methods of assessing left and right ventricular systolic and diastolic function utilizing all the various ultrasound modalities.	X	
21.	Know the application of strain imaging to cardio-oncology, cardiomyopathies of both ventricles, and detection of subclinical disease.	X	
22.	Know the distinct patterns of regional strain that suggest specific cardiac diseases.	X	
23.	Know the imaging of temporary and durable ventricular assist devices, including normal and abnormal function and the ability to identify malposition and malfunction of devices.	X	
24.	Know the use of ramp protocols for left ventricular assist devices.	X	
25.	Know the protocols to optimize dual chamber pacemaker and biventricular pacemaker function.	X	

26.	Know the methods to assess the transplanted heart, including orthotopic organ function, methods and importance of serial assessment, and evaluation of perioperative complications.	X	
27.	Know the imaging approaches (TTE and TEE) for assistance of venoarterial and venovenous extracorporeal membrane oxygenation (ECMO) cannula placement and for confirmation of appropriate position.		X
28.	Know the approach for echo assessment during trial of weaning from venoarterial ECMO and other forms of circulatory support as well as ramp protocols for ECMO.		X
Atrial Anatomy and Physiology			
29.	Know the approaches to assessing anatomic variants of the left atrial appendage and the pulmonary veins.	X	
30.	Know the approaches to assessing atrial structure and function, including 2- and 3D imaging; spectral Doppler; and speckle tracking, including strain and strain rate analysis.	X	
Pulmonary Hypertension			
31.	Know the echo methods for assessing pulmonary arterial systolic, diastolic, and mean pressure as well as pulmonary vascular resistance, and for establishing the causes of any abnormalities.	X	
32.	Know the echocardiographic methods for assessing right heart function, ventriculoarterial coupling, and ventricular interdependence.	X	
Valvular Disease			
33.	Know the comprehensive anatomic evaluation of all valvular heart diseases utilizing all the various ultrasound modalities.	X	
34.	Know the comprehensive hemodynamic evaluation of all valvular lesions (transthoracic echocardiography and transesophageal echocardiography), including serial and complex lesions.	X	
35.	Know the echocardiographic findings that establish the etiology of valvular lesions.	X	
36.	Know the key imaging parameters that are important in determining indications and eligibility for surgical and nonsurgical interventions.	X	
37.	Know the appropriate imaging techniques to guide valvular repair and replacement procedures, including 3D assessment of intracardiac device interaction with valves.	X	

Pericardial Disease			
38.	Know the methods for assessing the presence of pericardial disease (including tamponade, constrictive, and effusive-constrictive physiology) and the determination of its etiology and severity.	X	
Stress Testing			
39.	Know the AUC for stress echocardiography and criteria for selection of exercise versus pharmacological stress.	X	
40.	Know the pharmacokinetics, contraindications, and side effects of pharmacological stress agents and the procedures for monitoring safety.	X	
41.	Know the use of ultrasound enhancing agents for left ventricular opacification and myocardial perfusion in conjunction with echocardiographic stress testing.	X	
42.	Know the indications and limitations of stress echocardiography in comparison with other stress testing modalities.	X	
43.	Know the indications and the criteria for assessing diastolic function during stress testing.	X	
44.	Know the indications and parameters for diagnosing significant and complex valvular heart disease by stress echocardiography, including hemodynamic assessment of low flow states.	X	
Diseases of the Aorta			
45.	Know the transthoracic and transesophageal echocardiographic findings of complex aortic disease (acute and chronic).	X	
46.	Know the echocardiographic findings that indicate the need for immediate surgical intervention.	X	
Adult Congenital Heart Disease			
47.	Know the findings of complex pre- and post-operative adult congenital heart disease, including anatomic and hemodynamic assessments.	X	
Critical Care and Perioperative			
48.	Know the echo findings to diagnose cause of shock, fluid responsiveness and implications in volume expansion, hemodynamic assessment of etiologies of acute cor pulmonale, and causes of cardiac arrest.	X	

49.	Know the echo findings and hemodynamic assessment of patients with pathologic heart-lung interactions and mechanical ventilation, including patients in shock and those who cannot be weaned from ventilation.	X	
50.	Know the indications for perioperative or periprocedural transthoracic and transesophageal echocardiography and the findings representing acute and subacute complications.	X	
Research			
51.	Know the methods to design, conduct, analyze, and prepare for publication the results of original investigative work that involves application of echocardiographic techniques.	X	
Evaluation Tools: chart review, direct observation, in-training exam, preliminary report review, trainee portfolios			
Patient Care and Procedural Skills			
1.	Skills to perform and interpret a comprehensive transthoracic echocardiography examination, including 3D imaging.	X	
2.	Skills to perform and interpret a comprehensive transesophageal echocardiography examination, including 3D imaging.	X	
3.	Skills to render and manipulate 3D images both during the procedure and offline.	X	
4.	Skills to administer conscious sedation and monitor patients during and after TEE procedures.	X	
5.	Skills to perform and interpret myocardial mechanical function via strain imaging as well as tissue Doppler, including ability to recognize and eliminate artifacts.	X	
6.	Skills to perform and interpret assessments of unstable patients requiring assessment of volume status; LV function; fluid responsiveness; extravascular lung water; and tamponade physiology.	X	
7.	Skill to review images from other cardiovascular imaging modalities for purposes of correlating with echocardiographic findings.	X	
8.	Skills to acquire and interpret echocardiographic images during cardiovascular interventions such as pericardiocentesis and endomyocardial biopsy.	X	

9.	Skills to acquire and interpret echocardiographic images to optimize temporary and permanent ventricular assist device function and to diagnose device malfunctions and complications.	X	
10.	Skills to acquire and interpret echocardiographic images to assist structural heart interventions.		X
11.	Skills to acquire and interpret echocardiographic images using all techniques to assess and diagnose complex adult congenital heart disease and assist in interventions.		X
12.	Skill to guide insertion of mechanical support devices, including surgical and transcatheter devices.		X
13.	Skill to assist in the performance and interpretation of intracardiac echocardiography during structural or electrophysiological procedures.		X
Evaluation Tools: chart review, direct observation, fellow-acquired image review, multisource evaluation, simulation			
Systems-Based Practice			
1.	Incorporate risk-benefit analysis and cost, resource, and value considerations into care of patients with cardiovascular disease.	X	
2.	Identify and address financial, cultural, and social barriers to adherence with care recommendations.	X	
3.	Participate in practice-based continuous quality improvement and safety initiatives.	X	
4.	Participate in hospital-based and regional systems of care for patients with urgent and emergent cardiovascular conditions.	X	
5.	Work in collaborative fashion with physicians and healthcare professionals in other disciplines to optimize the care of patients with complex and multisystem disease.	X	
Evaluation Tools: chart review, direct observation, multisource evaluation			
Practice-Based Learning and Improvement			
1.	Identify personal knowledge gaps and seek educational and training opportunities to improve knowledge, skills, and performance.	X	
2.	Utilize clinical practice guidelines, AUC, Medline searches, and other information tools at the point of care to improve clinical decision-making.	X	
3.	Solicit and incorporate feedback from patients, colleagues, and other healthcare team members to improve clinical performance.	X	

4.	Use hospital and registry data to assess appropriateness, quality, and safety of cardiovascular care.	X	
5.	Develop practice of lifelong learning, including regular review of journals and practice guidelines/AUC/consensus statements and attendance at scientific meetings.	X	
6.	Skills to conduct literature searches, abstract and interpret data, and apply results to clinical care.	X	
Evaluation Tools: conference presentation, direct observation, multisource evaluation, reflection, and self-assessment			
Professionalism			
1.	Demonstrate respect, consideration, and empathy for patients, families, and all members of the healthcare team.	X	
2.	Practice within the scope of personal expertise, training, and technical skills.	X	
3.	Appropriately seek and integrate advice from consultants in a timely manner.	X	
4.	Know evidence-based clinical practice guidelines, consensus statements, AUC, and performance measures relevant to scope of practice.	X	
5.	Identify, disclose, and manage relationships with industry and other entities to minimize bias and undue influence on clinical decision making.	X	
6.	Demonstrate high ethical standards in personal and professional conduct.	X	
7.	Take responsibility for, and follow through on, professional commitments and obligations in a timely fashion.	X	
8.	Identify potential for impaired professional performance in oneself and colleagues and take action to mitigate.	X	
9.	Attend to one's own health, wellbeing, and abilities to maximize personal and professional performance.	X	
Evaluation Tools: chart review, conference presentation, direct observation, multisource evaluation, reflection, and self-assessment			
Interpersonal and Communication Skills			
1.	Communicate with patients and families in an effective and timely manner across a broad range of ethnic, social, cultural, socioeconomic, and religious backgrounds.	X	

2.	Engage patients in shared decision making based upon balanced presentation of potential risks, benefits, and alternatives, factoring in patients' values and preferences.	X	
3.	Complete medical records and communicate results of diagnostic and therapeutic measures to patients and collaborating healthcare professionals in an effective and timely manner.	X	
4.	Effectively lead and collaborate in interdisciplinary and cardiovascular care teams, treating all team members with respect.	X	
Evaluation Tools: chart review, direct observation, multisource evaluation			

Minimum Procedural Volume for Level III Echocardiography Competencies **Procedure/Technical Skill**	**Level III Numbers**
Transthoracic echocardiography performed	150
Transthoracic echocardiography, interpreted	750
Transesophageal echocardiography, performed and interpreted	150
For valve disease, rendering/image manipulation	50 (TEE or TTE)
For ventricular volumes, function, ejection fraction	50 (TTE)
Contrast echocardiography	100 (TTE)
Strain and strain rate quantification	50
Stress echocardiography Includes 25 for noncoronary indications	200

APPENDIX 9

BMUS – PEER REVIEW AUDIT TOOL

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Date of Scan	Reporter	Machine/Site
Date of Review	**Reviewer**	**Patient Identification**

Image Quality (I)

I		Score	Comments
3	Good Image Quality		
2	Acceptable Diagnostic Quality		
1	Poor Image Quality (Images of an unacceptable standard)		

Report Quality (R)

R		Score	Comments
3	Report Content and Structure Optimal		
2	Report of Acceptable Quality		
1	Poor Report Quality		

Clinical Quality (C)

C	Yes	No	Comments
Clinical Referral Appropriate		*q	
Clinical Question Answered			
Appropriate advice or conclusion (including no abnormality demonstrated)			

Overall Score:			Comments:			
I		R		C*		Total:

Descriptors:	

IMAGE QUALITY (I) 3 Good Image Quality	High quality examination. Organs identified by characteristic features and/or labelling. Appropriate measurements made. May include suboptimal images but with evidence that this was due to patient factors and attempts have been made to address these.
2 Acceptable Diagnostic Quality	Reasonable image quality but a few poorer quality images and parameters (i.e., incorrect focus, measurement, protocol, colour, label, etc).
1 Poor Image Quality	Images of an unacceptable standard.
REPORT QUALITY (R) 3 Report Content and Structure Optimal	Report answers clinical questions and gives appropriate advice and conclusion (within local guidelines). Report may also include additional clinical information gained from verbal feedback from patient and include documentation of any information given to the patient.
2 Report of Acceptable Quality	Report satisfactory but additional diagnosis or advice could have been provided.
1 Poor Report Quality	Report of an unacceptable standard. List of descriptive findings with no attempt to correlate to clinical setting or answer clinical question posed. May also include disagreement with the report finding.
CLINICAL QUALITY (C) **Yes = 1 point, No = 0 points** Clinical Referral Appropriate	The referral contains a clear clinical question and is appropriate for ultrasound imaging. See BMUS recommendations for justification of referrals. **NB add q to total score if NO to differentiate between examination quality and referral quality*.
Clinical Question Answered	The report answers the clinical question posed or the question gleaned from questioning the patient during the examination.
Appropriate advice or conclusion	The report includes a conclusion or appropriate advice where applicable and in line with local guidelines. This may include a statement of normality including no abnormality demonstrated or no cause for symptoms in normal examinations.
Total score from 9 =	