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 <b>GIG CYMRU NHS WALES</b>	Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board	<b>Reference Number: UHB 322</b> <b>Version Number: 2</b> <b>Date of Next Review: 20/07/2023</b> <b>Previous LHB Reference Number: N/A</b>
<b>THE MEDICAL ULTRASOUND RISK MANAGEMENT PROCEDURE</b>		
<p><b>Aim</b></p> <p>Cardiff and Vale UHB is committed to providing uniform, high quality diagnostic and therapeutic Ultrasound services which consistently meet as a minimum all national evidence based standards.</p> <p>The UHB wide Ultrasound Governance Group (UGG) exists to receive assurance that all clinical services which use diagnostic or therapeutic ultrasound devices have adopted and are adhering to the general requirements for good ultrasound governance. The UGG comprises a wide range of healthcare professionals representing each Clinical Board that owns or leases ultrasound equipment and performs their own ultrasound examinations and interventions.</p> <p>The Ultrasound Risk Management Procedure will provide a set of minimum service standards to which all Clinical Services which use ultrasound will comply. This will ensure that risks to patients, staff, visitors and the UHB arising from the use of ultrasound equipment are minimised and that UHB consistently delivers the best health and financial outcomes from the use of ultrasound equipment.</p> <p>Complying with this procedure will ensure that Ultrasound, if carried out correctly, and in the appropriate clinical situation, is one of the most effective diagnostic tools in healthcare. Ultrasound examinations and procedures are undertaken by people a wide range of professional backgrounds, in many different clinical settings.</p> <p>Ultrasound is highly operator dependent and must be undertaken by trained and experienced professionals. Ultrasound examinations, and their interpretation must be of a high quality, as they have a direct impact in patient management.</p> <p>Ultrasound can present significant clinical and/or safety risks if:</p> <ul style="list-style-type: none"> <li>• examinations are undertaken or interpreted by untrained or poorly trained individuals,</li> <li>• equipment is poorly specified or maintained,</li> <li>• it is undertaken in the absence of audit of clinical performance and outcome,</li> <li>• there is no effective clinical governance framework</li> <li>• Effective decontamination processes are not available or not used.</li> </ul> <p>The Cardiff and Vale UHB Diagnostic and Therapeutic Ultrasound Management Policy aims to ensure that we manage the use of Diagnostic and Therapeutic ultrasound, to ensure Diagnostic and Therapeutic ultrasound examinations and procedures are of the highest possible standard, adequately documented, and performed by appropriately trained individuals, using fit for purpose, well maintained ultrasound equipment.</p>		

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This procedure supports the Policy and translates its aim into practical implementation measures including the identification of organisational and individual responsibilities.

## Objectives

The Ultrasound Risk Management Procedure establishes a clear framework within which the UHB can:

- Effectively and actively manage its ultrasound equipment so as to reduce risk,
- Meet its legal obligations to comply with legislation,
- Meet its governance obligations, both clinical and financial,
- Meet the requirements of the relevant Health and Care Standards,
- Demonstrate that it is taking account of MHRA guidance,
- Meet external accrediting body quality standards covering ultrasound services.

We will achieve our aim by:

- Providing a framework for service managers to develop ultrasound services that are safe, effective and compliant with current legislation in order to protect the UHB, the public and staff.
- Providing direction to service managers as regards to procedures, training, documentation and resources that must be in place.
- Outlining the responsibilities of staff performing Diagnostic and Therapeutic ultrasound examinations or procedures.
- Ensuring all Diagnostic and Therapeutic ultrasound equipment is in good repair, operating correctly, effectively decontaminated prior to use and safely and regularly maintained.
- Monitoring and reviewing the effectiveness of this ultrasound policy and procedure and, if necessary, implementing improvements.

## Scope

This Procedure applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It covers all ultrasound devices used by Cardiff and Vale UHB services irrespective of whether the ultrasound device is owned, loaned, leased or used by external service providers commissioned by the UHB.

<b>Equality Assessment</b>	<b>Impact</b>	An Equality Impact Assessment (EqIA) has been completed and this found there to be a positive impact.
<b>Documents to read alongside this Procedure</b>		Cardiff and Vale UHB Policies and Procedures <ul style="list-style-type: none"> <li>• Medical Equipment Management Policy.</li> <li>• Health and Safety Policy.</li> <li>• Data Protection Policy.</li> <li>• Records Management Policy.</li> <li>• Patient Identification Policy.</li> <li>• Risk Management Policy.</li> <li>• Sonographer Reporting Policy.</li> <li>• Chaperone Policy.</li> </ul>

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	<ul style="list-style-type: none"> <li>• Safe use of Non-ionising Radiation.</li> <li>• Decontamination of Ultrasound Transducers – Standard Operating Procedure.</li> <li>• Infection control standard precautions procedure.</li> <li>• Infection control procedure for meticillin resistant <i>staphylococcus aureus</i> (mrsa) in acute hospitals.</li> <li>• <u>Infection control procedure for the management of patients known or suspected to have clostridium difficile infection.</u></li> </ul>
<b>Approved by</b>	Quality, Safety and Experience Committee
<b>Accountable Executive</b>	Executive Director of Therapies and Health Science.
<b>Author(s)</b>	Paul Williams, Principal Physicist Kate Bryant , Principal Physicist, Non-Ionising Safety Lead Clive Morgan, Deputy Director of Therapies and Health Science Nerys Thomas, Superintendent Sonographer
<b><u>Disclaimer</u></b> <b>If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the <u>Governance Directorate.</u></b>	

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## 1 Definition of terms

### **Ultrasound Governance Group (UGG)**

The Heath Board-wide group exists to oversee issues related to medical ultrasound throughout the Cardiff and Vale University Health Board.

### **Medical Imaging Ultrasound Equipment**

For the purpose of this procedure, the term Medical Imaging Ultrasound Equipment applies to any Ultrasound scanners and/ or transducer(s), producing ultrasound for medical Imaging purposes.

### **Therapeutic Ultrasound Equipment**

For the purpose of this procedure, the term Therapeutic Ultrasound Equipment applies to any Ultrasound scanners and/ or transducer(s), used for therapeutic purposes.

### **Ultrasound Clinical Lead User**

A person who will ensure that all users comply fully with this policy and procedure, and the UHB risk management policies in their own clinical area on a day to day basis, including responsibility for the ultrasound equipment and it's use, and reporting breaches or concerns to the UGG.

### **Specialty Lead User**

Speciality Lead User is the expert or key person who provides or delivers the particular service/speciality, as opposed to the Clinical Lead User who may not necessarily be the person delivering the service, but whose role is to ensure that users comply with the policies and procedures.

### **Clinical Ultrasound User**

A trained person who uses ultrasound equipment for medical imaging or therapeutic purposes, and/or a trained person who interprets and reports ultrasound examinations or procedures

### **Educational Supervisor/ Training supervisor**

A fully trained and competent person who will ensure that all healthcare professionals in training, including junior doctors, dentists or registrars, receive the appropriate level of training and supervision when carrying out an ultrasound examination or procedure.

### **Trainee Clinical Users**

Any healthcare professional in training, including junior doctors, dentists or registrars, using ultrasound.

### **RPG**

Radiation Protection Group

### **SoPs**

Standard Operating Procedures

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## 2 Introduction

Medical Ultrasound is widely used throughout the health board for diagnosis and therapeutic procedures. Ultrasound imaging and therapeutic procedures, when performed by the right person in the right clinical setting and at the right time will enhance patients care, will reduce clinical risk and will be clinically and cost effective.

There have been no proven deleterious bio-effects with ultrasound exposure, but no medical procedure is completely without risk. While we may not be able to provide evidence of harm from a technique such as ultrasound imaging, we are not able to prove absence of harm [1].

If the scanner and transducers are properly managed and maintained, used within recommended guidelines, by a trained and competent operator, then it is considered a very low risk procedure, but not completely “risk-free”. Diagnostic ultrasound can only be considered safe if used prudently [2].

The uncontrolled expansion of the use of ultrasound represents a significant clinical risk if examinations are undertaken by untrained or poorly trained individuals, equipment is poorly specified or poorly maintained, or it is undertaken in the absence of clinical audit of performance. Furthermore, if equipment purchase and deployment is not based on a thorough assessment of cost effectiveness and/or service improvement, the cost to the NHS can be significant without commensurate gain. [3]

Significant clinical and safety errors can occur if the equipment is not properly optimised and maintained, and users are not properly trained in clinical and safe use of ultrasound including acquisition and interpretation of images, and guidelines and procedures are not followed. Misdiagnosis associated with the misinterpretation of ultrasound images poses a significant risk to patients.

The use of Diagnostic and Therapeutic ultrasound must be appropriately managed, to ensure Diagnostic and Therapeutic ultrasound examinations and procedures are of the highest possible standard, adequately documented, and performed by appropriately trained and competent individuals, using fit for purpose, well maintained ultrasound equipment, in accordance with current recommendations, guidelines and standards.

Due to the wide range of healthcare professionals operating ultrasound equipment within the UHB there appears to be a significant variation in the delivery of ultrasound services between Directorates and possible even within Directorates. Therefore a one-fits-all risk management procedure, even though sound in theory, would be difficult to implement in practice.

To help assign the roles and responsibilities within each department they can be separated into broadly two main categories: Equipment related roles and clinical related roles. Equipment related would cover responsibilities such as contracts, service level agreements, equipment break-downs and quality assurance testing; Clinical related responsibilities would cover training,

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reporting, authorising users, production of local operating procedures and decontamination of equipment before and after use.

Re-assigning the roles for ultrasound to staff within the UHB is meant to share or place the appropriate level of responsibility to the appropriate job roles as defined in the Medical Ultrasound Risk Management Procedure. For example a Service Manager would not be expected to know the training requirements for a completely different profession such as a medic training in obstetric ultrasound. And conversely it would not be expect that a Clinical Lead User would manage the service contract and its costing on several ultrasound machines within their department. Although if the department decided that one person could fit this role then this would be acceptable.

However it is the responsibility of the Directorate to organise, deliver and adhere to the procedures within this document. How this is done will depend on the size of their department and level of use of imaging equipment within the organisation.



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### 3 Responsibilities

The responsibilities for ultrasound clinical governance fall upon all users of ultrasound within the UHB. With this in mind each directorate that uses ultrasound is responsible for delivering on all aspects of ultrasound governance. How each directorate does this is the responsibility of the Clinical Director and Service/Directorate/General Manager. Ultimately it is the:

Executive director of Therapies and Health Science that is responsible for

- Informing the UHB Board about issues related to the use of medical ultrasound and receiving assurance on the management of clinical and safety risks associated with the use of ultrasound technologies.

The Clinical Board Heads of Operations and Delivery are responsible for:

- Providing assurance to the Executive Director of Therapies and Health Science that medical ultrasound is managed in compliance with the UHB's policies and procedures.
- Reporting instances of non-compliance, adverse incidents and other concerns through the UHB's risk management reporting framework.
- Communicating and liaising with relevant Directorate Managers about issues related to the use of medical ultrasound.

The Chair Ultrasound Governance Group is responsible for:

- Reviewing relevant UHB policies and procedures at least every three years and ensuring that they are amended and updated as necessary.
- Reviewing reports from the Clinical Lead Users and taking action as necessary.
- Reporting ultrasound safety issues to the Quality and Safety Committee.
- Recommending relevant action to the Chief Executive via the Executive Director of Therapies and Health Science when necessary.

However the Clinical Director and Service/Directorate/General Manager must assign 3 key roles within the directorate/department to relevant staff members to ensure that good governance is delivered. These roles are:

- Clinical Lead User
- Specialty Lead User
- Educational Supervisor/Training Supervisor

Where appropriate one or more of these roles may be covered by one person or in some situations there may be multiple people performing one of these roles. However each department must notify the Ultrasound Clinical Governance Group that the 3 key roles have been filled.

Ultimately it is from these five key positions: (Clinical Director, Service Manager, Clinical Lead User, Specialty Lead User and Educational/Training Supervisor), that the leadership for clinical ultrasound governance will come, and therefore these posts will hold the majority of the responsibilities. These



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responsibilities are listed below and to reiterate, all of the bullet points below need to be assigned to the 5 key positions written above:

- Ensuring compliance with this policy and the requirements of legislation, recommendations and guidance relevant to the use of medical ultrasound.
- Authorising Clinical Ultrasound Users.
- Ensuring an up to date register of authorised clinical ultrasound users is maintained.
- Ensuring that local Standard Operating Procedures (SoPs), Clinical Protocols and risk assessments are written to implement the requirements of this UHB procedure.
- Appointing one or more Clinical Lead User.
- Appointing Educational Supervisors and/ or Training supervisors
- Ensuring that all relevant members of staff including the Clinical Lead User, Clinical Ultrasound Users, and assisting staff are adequately trained and competent to undertake their roles.
- Ensuring Trainee Clinical Users are adequately supervised
- Ensuring that only authorised, adequately trained operators and competent use the ultrasound equipment.
- Ensuring Clinical Ultrasound Users only undertake ultrasound procedures and examinations for which they have been trained and are competent.
- Ensuring Clinical Ultrasound Users only use ultrasound equipment which they have been trained and competent to use.
- Maintaining records of staff training and competence assessments.
- Ensuring that all relevant members of staff and have the resources to comply with the SoPs and Clinical Protocols.
- Implementing measures to monitor staff compliance with policies, SoPs, and Clinical Protocols
- Liaising with, and seeking advice from the Ultrasound Governance Group.
- Making risk assessments and taking mitigating action as necessary.
- Reporting ultrasound safety or misuse issues to the Ultrasound Governance Group.
- Ensuring ultrasound equipment is maintained and decontaminated following manufacturer's guidance.
- Delegating responsibilities to other managers where appropriate.
- Ensuring ultrasound equipment is regularly serviced and maintained, and subject to adequate quality assurance and safety testing.
- Ensuring adequate records are kept of ultrasound equipment servicing, software changes, maintenance, electrical safety, decontamination traceability, calibration and quality assurance testing.
- Ensuring that all healthcare professionals in training, including junior doctors, dentists or registrars receive the appropriate level of training and supervision from an Educational Supervisor or Training supervisor when carrying out an ultrasound examination or procedure.

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- The day to day delivery of safe ultrasound services, in accordance with this policy, supported by the Clinical Lead User(s).
- Reporting ultrasound safety or misuse issues to the Directorate manager and Ultrasound Governance Group.
- Nominating appropriate Educational Supervisors and/or Training supervisors.
- Producing the local Standard Operating Procedures (SOPs) which adhere to standards contained in Medical Ultrasound Management Policy and Procedure.
- Undertaking a risk assessment before the ultrasound equipment/service is brought into operation, and reviewing annually.
- Ensuring all ultrasound users and those assisting with the procedures (including trainee doctors, registrars or visiting staff) abide by the local SOPs.
- Implementing and ensuring compliance with the SOPs on a day-to-day basis.
- Reporting any matters which give rise to a clinical or safety risk to the service manager and Ultrasound Governance Group.
- Keeping an inventory of all ultrasound equipment kept in their department and providing a copy to the Ultrasound Governance Group.
- Ensuring all ultrasound equipment, including loan or demonstration equipment, has been electrically safety tested prior to use.
- Ensuring all ultrasound equipment is subject to quality assurance testing in accordance with current guidelines.
- Reporting any significant changes in ultrasound equipment or environment to the Ultrasound Governance Group.
- Ensuring all ultrasound equipment, including loan or demonstration equipment is suitably maintained and complies with current guidelines and standards.
- Ensuring that service engineers have followed the correct equipment handover procedures.
- Keeping records of all training, including ultrasound safety training
- Developing an audit programme to assure good Ultrasound governance
- Risk assessing local risks for the use of ultrasound in their clinical areas and ensuring they are noted on departmental and Directorate risk register and Clinical Board and Corporate risk frameworks where appropriate.
- Reporting incidents following UHB incident reporting policies and externally to the MHRA where indicated by UHB's the Management of Medical Equipment Policy
- Ensuring a record of each ultrasound scan or procedure is securely retained in accordance with local policies.
- Ensuring decontamination of all ultrasound equipment, transducers and associated auxiliary equipment is undertaken prior to use in accordance with manufacturers' guidance, UHB infection control and decontamination policies and procedures, including the ultrasound transducer decontamination policy.

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- The appropriate training and supervision for Trainee Clinical users
- Ensuring their trainees receive appropriate clinical ultrasound training
- Ensuring their trainees receive appropriate ultrasound equipment training
- Ensuring their trainees receive appropriate ultrasound safety training

In addition other roles have responsibility as listed below remain unchanged from the previous procedure:

Clinical Ultrasound Users have responsibility for:

- Abiding by the local SOPs.
- Meeting the standards of best clinical practice,
- Maintaining competence in their area of ultrasound expertise
- Only undertaking ultrasound procedures and examinations for which they have been trained to the required competence level.
- Only using ultrasound equipment which they have been trained to use.
- Reporting any matters which give rise to a clinical or safety risk to the clinical lead user

All staff assisting with, ultrasound procedures are responsible for:

- Following local SOPs where appropriate
- Reporting any concerns to the Lead Clinical user
- Ensuring equipment is effectively decontaminated and safe for use at the time of intervention.

Trainee Clinical users have responsibility for:

- Abiding by the local SOPs.
- Only undertaking ultrasound procedures and examinations for which they are supervised for
- Only use ultrasound equipment which they have been trained to use.
- Reporting any matters which gives rise to a clinical or safety risk to the clinical lead user

The Medical Physics Head of Non-Ionising Imaging is responsible for:

- The provision of electrical safety testing of medical ultrasound equipment by suitably trained Medical Physics staff.
- The provision of ultrasound Quality Assurance (QA) testing of medical ultrasound equipment by suitably trained Medical Physics staff.
- Appointing the Medical Physics QA Service Lead

## 4 Training Requirements

Ultrasound is highly operator dependent, requiring specialist skills and knowledge. It is essential that all users are appropriately trained, and are aware of their limitations.

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All ultrasound users should be registered with the relevant statutory regulatory body where appropriate, or with the relevant voluntary registration body as outlined in appendix 1.

The Directorate Manager must keep an up to date record of the statutory or voluntary registration status of all ultrasound users.

The Clinical lead user should have received advanced, documented training in their area of clinical ultrasound, ultrasound safety, and general equipment management.

All clinical users must be adequately trained to practice ultrasound within their area of expertise. Records of all associated qualifications and training must be kept. Recommendations for the training requirements for clinical ultrasound users are given in Appendix 1.

The service manager should hold an up to date record of all ultrasound users' relevant qualifications and the awarding institution.

All training will be documented, and records held by the Service manager. The training will form part of the individual's Knowledge and Skills profile and will be reflected in the individual's personal development plan. Competence assessments must also be in place as part of a competence assessment framework.

In addition to the relevant clinical ultrasound training, all users must undergo training on ultrasound equipment and ultrasound safety as detailed in sections 4.1 and 4.2.

#### **4.1 Ultrasound Equipment Training**

All clinical users must undergo sufficient training on the ultrasound equipment used in their clinical area. Ultrasound equipment varies, and training on one type of equipment, is not necessarily transferable. Therefore, users must only use equipment that they have been trained and competent to use.

The manufacturer or ultrasound equipment supplier should provide equipment based training at the time of installation.

Further equipment based training may be provided by the Clinical lead user, manufacturer/supplier or another designated trainer. All training must be documented.

Competence assessments must be completed and available for all Ultrasound users including bank and locum staff.

#### **4.2 Ultrasound Safety Training**

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All Clinical users and those assisting with ultrasound procedures should also be aware of the general requirements for the safe management of medical ultrasound equipment, decontamination, and incident reporting and infection control.

All users must undergo adequate training in ultrasound safety, in accordance to The British Medical Ultrasound Society (BMUS) guidelines, including a basic understanding of the Thermal Index (TI) and Mechanical Index (MI), the 'As Low As Reasonably Achievable' (ALARA) principle, and the impact of user selectable controls on image quality and safety.

## **5 General Arrangements for the Management of Ultrasound**

### **5.1 Standard operating Procedures**

SOPs shall be issued for each locality where medical ultrasound is used. The SOPs shall be designed to manage the use of ultrasound equipment in line with this procedure.

The SOPs must be read and adhered to by all ultrasound users, including trainees.

The lead Clinical user must be appropriately trained and is responsible for ensuring compliance with the Local Standard operating procedures through a regular audit programme.

The Lead clinical user is not responsible for the safe operation of the ultrasound equipment – this lies with the individual clinical user.

### **5.2 Clinical Protocols**

All examinations or procedures involving medical ultrasound shall be carried out in accordance with written protocols and standard operating procedures, with reference and adherence to national standards and guidelines where appropriate.

### **5.3 Procedures and Documentation for Requesting and Reporting of clinical ultrasound examinations and procedures**

A record of each ultrasound scan or procedure must be made and securely retained in accordance with local policies.

Where appropriate, ultrasound images should be recorded in accordance with local policies.

All Ultrasound Images obtained must be safely and securely stored

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All stored ultrasound images must be linked to the record of the ultrasound scan or procedure, and securely retained in robust traceable archives, in accordance with local protocols.

All users must be adequately trained on the procedures and documentation requirements for requesting and reporting of clinical ultrasound examinations and procedures.

#### **5.4 Risk assessments**

For each activity involving medical ultrasound equipment, a suitable and sufficient risk assessment shall be carried out before first use, and subject to regular review.

#### **5.5 Adverse Incident Reporting**

All adverse incidents including 'near miss' incidents shall be reported and investigated in accordance with the Health Board Incident Reporting and Investigation Procedure. Any ultrasound safety or misuse issues must also be reported to the Ultrasound Governance Group.

#### **5.6 Management Risks to Clinical Users**

There are documented risks to Clinical users related to the use of ultrasound equipment. These can include repetitive strain injury (RSI), stress related illness, and manual handling.

The scan environment, equipment and workloads must be managed in accordance with local ergonomic assessments, manual handling policies, and occupational health guidance and reviews to ensure staff safety and clinical service safety.

### **6 Ultrasound Equipment and Environment Requirements and Management**

The specific requirements for an ultrasound machine differ for each clinical task. Ultrasound scanners can be physically moved, 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. The role of the user is critical, and the matching of the user's knowledge and competence level to the equipment features is essential.

The quality of the image is in part determined by selection of the scanner, transducer and the scanners software functions. Transducers must be matched to the anatomical region to be scanned.

All ultrasound scanners must be optimised for a specific clinical application, before use.



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All ultrasound equipment must comply with the Managing Medical Devices (Guidance of Healthcare and Social Services Organisations) April 2015 and the medical devices directive which stipulates the requirement of CE marking of all electro-medical equipment.

All equipment should conform to published electrical safety standards, and be subject to regular electrical safety testing.

There is a risk of mechanical damage to the scanner and transducer while in use, or in transit. Users must regularly inspect equipment for signs of physical damage, and report any damage to the lead clinical user.

## 6.1 Purchase of New or Replaced Equipment

The Health Board policy on the Management of Medical Equipment applies to the purchase of this type of equipment and must be followed.

Prior to the purchase of new or replacement medical ultrasound equipment, the prospective purchaser shall consult with Medical Physics Ultrasound QA Service (UHW ext. 44101/44) and to the Clinical Engineering Department (Field Way ext: 45678) to gain advice on matters including the following:

- Equipment safety and suitability
- The proposed location of the equipment
- The provision of applications support, regular maintenance and safety testing

This will ensure good clinical governance principles are adhered to.

Prior to first use:

- The purchaser or lead clinical user shall ensure that the equipment is set up, commissioned and optimised for clinical use by the manufacturer.
- The purchaser or lead clinical user shall arrange for the equipment to be electrically safety tested by a Medical Physics representative prior to clinical use.
- If possible, baseline ultrasound quality assurance measurements should be performed by a Medical Physics representative.
- A routine quality assurance schedule should be agreed with Medical Physics.

## 6.2 Equipment Maintenance, Repair and Quality Assurance

All medical ultrasound equipment shall be kept in good repair and regularly maintained and safety tested, including electrical safety testing, by authorised personnel, technically competent in the field of work.



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Procedures and schedule for daily QA and routine Medical Physics QA tests shall be established at the time of commissioning.

Regular Medical Physics or manufacturer quality assurance checks should be performed by a suitably trained person on all medical ultrasound equipment in accordance with current guidelines.

Daily QA checks should be performed by the clinical user, in accordance with current guidelines.

Any suspected faults should be reported to the Medical Physics ultrasound QA service, investigated and rectified as required, before further clinical use.

Repair and maintenance should be performed under the maintenance agreement with the manufacturer or their third party representative.

The Medical Physics ultrasound QA service (UHW ext. 42010/44478) should be informed of any faults and repairs, or replacement of equipment.

All quality assurance and safety testing must be carried out by an authorised person technically competent in the field of work.

### **6.3 Equipment on Loan, Trial or Hire**

Any medical ultrasound equipment received on loan, trial or hire must be assessed for safety on site by Clinical Engineering before being put into clinical use, giving them an appropriate notification and ensuring that the appropriate indemnity arrangements are put in place. All loan, hire or trial ultrasound equipment must be covered by SOPs and risk assessments. Risk assessments must be countersigned by the Non-Ionising Safety Lead

### **6.4 Equipment Modification**

Modification, maintenance or repair of ultrasound equipment other than by the manufacturer or his appointed agent is not permitted.

Modification of any medical ultrasound equipment should not be carried out unless by the manufacturer or his appointed agent. If these modifications affect its performance, the equipment must be re-examined by a Medical Physics representative. Adequate notification of such modifications must be given to Medical Physics.

### **6.5 Image Quality**

The machine pre-sets should be optimised for each clinical application.

The Clinical lead user should specify as precisely as possible, the investigations for which the machine is optimised.

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If practicable, it is best practice to archive representative clinical reference images indicating the performance of each machine on an annual basis, and these should be monitored as part of audit. These images should be retaken, and compared immediately following any equipment modification or repair, according to local protocols.

If the range of clinical applications of the machine is extended or modified, this should be recorded and new reference images should be taken.

A formal QA programme to monitor scanner performance should be in place, with advice from the manufacturer applications specialist, and the Medical Physics ultrasound QA lead as necessary.

## 6.6 The Ultrasound Environment

An ergonomic assessment, and risk assessment must be made and regularly updated, including consideration of the clinical examinations or procedures, ultrasound equipment, clinical and physical environment and the volume of activity.

UHB Guidance on minimising distractions in high concentration environments should be adhered to.

Ambient lighting should be optimised for the examination or procedure, in accordance with local protocols.

## 6.7 Infection control

There is a risk of cross infection from ultrasound equipment that comes into contact with many staff and patients. All scanners, transducers, and auxiliary equipment must be cleaned and decontaminated according to the Health Board's Decontamination of Reusable Medical Devices Policy and Procedure.

## 7 Resources

In order for this policy to be implemented the following resources will be required:

- Equipment set-up and applications training provided by the manufacturer or supplier is to be included in all purchase arrangements for new ultrasound equipment.
- Robust and accurate archive systems for the reporting, documentation and storage of clinical scans, scan requests, equipment decontamination, and associated clinical images.
- Regular Maintenance and servicing arrangements are to be included in purchase arrangements for new ultrasound equipment.
- The appointment of the local Clinical lead user may impact upon their existing role within respective departments if they are to discharge

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their duties effectively and therefore arrangements must be put in place.

- Increases in volume of ultrasound equipment may impact upon the Medical Physics ultrasound quality assurance service, therefore arrangements must be put in place.
- Arrangements must be put in place to ensure all users have access to appropriate training courses, to ensure they up to date with clinical and equipment training requirements.

## 8 Review

### 8.1 Auditing of ultrasound practice and report quality

The effectiveness of this policy will be reviewed post implementation. The indicators used to monitor the effectiveness of this policy are:

- This policy will be reviewed every three years, or when there is a significant change in relevant legislation or national guidance for the use on Medical Ultrasound.
- The effectiveness of this policy will be reviewed by local governance processes.

## 9 Further Information, Legislation, Guidance, Recommendations and standards

### 9.1 Legislation

The legislation controlling the use of medical ultrasound includes:

- The Health and Safety at Work etc. Act 1974
- The Electricity at Work Regulations 1989
- The Management of Health and Safety at Work Regulations 1999
- The Health and Safety (Safety Signs and Signals) Regulations 1996

### 9.2 Guidance, recommendations and standards

A list of Guidance and standards for Medical ultrasound is given in Appendix 2.

In line with best clinical practice, where appropriate, all relevant evidence based guidance, recommendations and standards should be adhered to.

## 10 References

[1] ter Haar G, Ultrasound Imaging: safety considerations, Interface Focus (2011) 1, 686-697.

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[2] Statement of the safe use, and potential hazards of diagnostic, British medical Ultrasound Society, 2012

[3] Ultrasound Clinical Governance in Wales, NHS Wales Governance e-Manual, NHS Wales

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## Appendix 1 Training and Registration Requirements

Table 1 Statutory Registration

Statutory/ Regulatory body	Healthcare profession	Area of Clinical Ultrasound Practice	Minimum Training Requirement	Recommended training requirement
HCPC	Clinical Scientist	Vascular Ultrasound (DVT, AAA and Carotid artery scanning)	Clinical Scientist Registration ( Medical Physics STP, Vascular Science STP or DipIPEM plus IPEM Part 2/equivalent training/experience)	Medical Physics or Vascular Science STP or DipIPEM plus IPEM Part 2/equivalent training/experience
NSCHS / AHCS/HCPC	Clinical Scientist	Vascular Ultrasound (Arterial, graft, fistula, EVAR, varicose veins, vein mapping, upper limb arterial, upper limb venous, other specialist vascular applications)	HSST (or equivalent higher training/ post registration experience)	HSST (or equivalent higher training/post registration experience)
HCPC	Radiographer/ Sonographer	Diagnostic Medical Ultrasound	CASE accredited Post Graduate Certificate in Medical Ultrasound	Masters level Post graduate training in Medical Ultrasound
GMC	Radiologist	Diagnostic and Interventional Medical Ultrasound	Medical degree Post Graduate Radiology training scheme	Completion of three months of ultrasound training (300 scans) with competency assessment
NMC	Midwife sonographer	Obstetric Ultrasound	CASE accredited Post Graduate Certificate in Medical Ultrasound	PgC Medical Ultrasound or higher

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NMC	Gynae Nurse Practitioner	Gynae and early pregnancy	CASE accredited Post Graduate Certificate in Medical Ultrasound	PgC Medical Ultrasound or higher
HPC /MCSP	Clinical Specialist Physiotherapist	The use of real time ultrasound as a form of biofeedback in the rehabilitation of the pelvic floor muscle group	Two day introductory course Dynamic Ultrasound Imaging in Women's Health – Jane Dixon	Additional courses run DUG - Association of Physiotherapists using Ultrasound imaging

Table 2 Voluntary Registration

Voluntary Regulatory body	Healthcare profession	Area of Clinical Ultrasound Practice	Minimum Training Requirement	Recommended training requirement
RCCP	Clinical Physiologist	Echocardiography Adult and Paeds	BSc (PTP) Clinical Physiology plus professional qualification from British Society of Echocardiography.	BSc (PTP) Clinical Physiology plus professional qualification British Society of Echocardiography, or Masters level U/S, or Masters (STP) Physiological Science. EACVI accreditation in Paediatric echo.
DUG. POGP CSP	Physiotherapist	Real time ultrasound of pelvic floor, pelvis and abdominal corset	Two day introductory course Dynamic Ultrasound Imaging in Women's Health – Jane Dixon	Ongoing through DUG- Association of Physiotherapists using Ultrasound imaging

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## Appendix 2: Guidance, recommendations, standards and supporting policies

### Cardiff and Vale UHB Policies and Procedures

- Medical Equipment Management Policy.
- Health and Safety Policy.
- Data Protection Policy.
- Records Management Policy.
- Patient Identification Policy.
- Risk Management Policy.
- Sonographer Reporting Policy.
- Chaperone Policy.
- Decontamination of Reusable Medical Devices Policy and Procedure
- Decontamination of Ultrasound Transducers – Standard Operating Procedure.
- Infection control standard precautions procedure.
- Infection control procedure for meticillin resistant *staphylococcus aureus* (mrsa) in acute hospitals.
- Infection control procedure for the management of patients known or suspected to have clostridium difficile infection.

### National Guidelines:

- Ultrasound Clinical Governance, National Diagnostic Imaging Board, Department of Health, LONDON (2008).  
<http://www.18weeks.nhs.uk/Content.aspx?path=/achieve-and-sustain/Diagnostics/Imaging>.
- 'Ultrasound Training Recommendations for Medical and Surgical Specialties; Second Edition' RCR Ref BFCR(12)17 The Royal College of Radiologists LONDON (2012)
- Standards for the provision of an Ultrasound Service. The Society and College of Radiographers/The Royal College of Radiologists, 2014
- Guidelines for Professional Ultrasound Practice; SCoR and BMUS; Dec 2015
- Antenatal Screening Wales; Policy, Standards and Protocols 2015; Public Health Wales NHS Trust
- Provision and Use of Work Equipment Regulations (PUWER) 1998
- Managing Medical Devices, Guidance for Healthcare and Social Services Organisations, MHRA, April 2015



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- Dudley, N., Evans T., Hoskins, P., Watson, A. & Starritt, H. (2010) *IPEM report No 102: Quality Assurance of Ultrasound Imaging Systems*. IPEM, York, p.13.
- BMUS guidelines for the regular quality assurance testing of ultrasound scanners by sonographers. Nick Dudley, Stephen Russell, Barry Ward and Peter Hoskins; BMUS QA Working Party; Ultrasound; February 2014 vol. 22 No 18-14
- The British Medical Ultrasound Society. Guidelines for the safe use of diagnostic ultrasound equipment. Prepared by the Safety Group of the British Medical Ultrasound Society.  
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