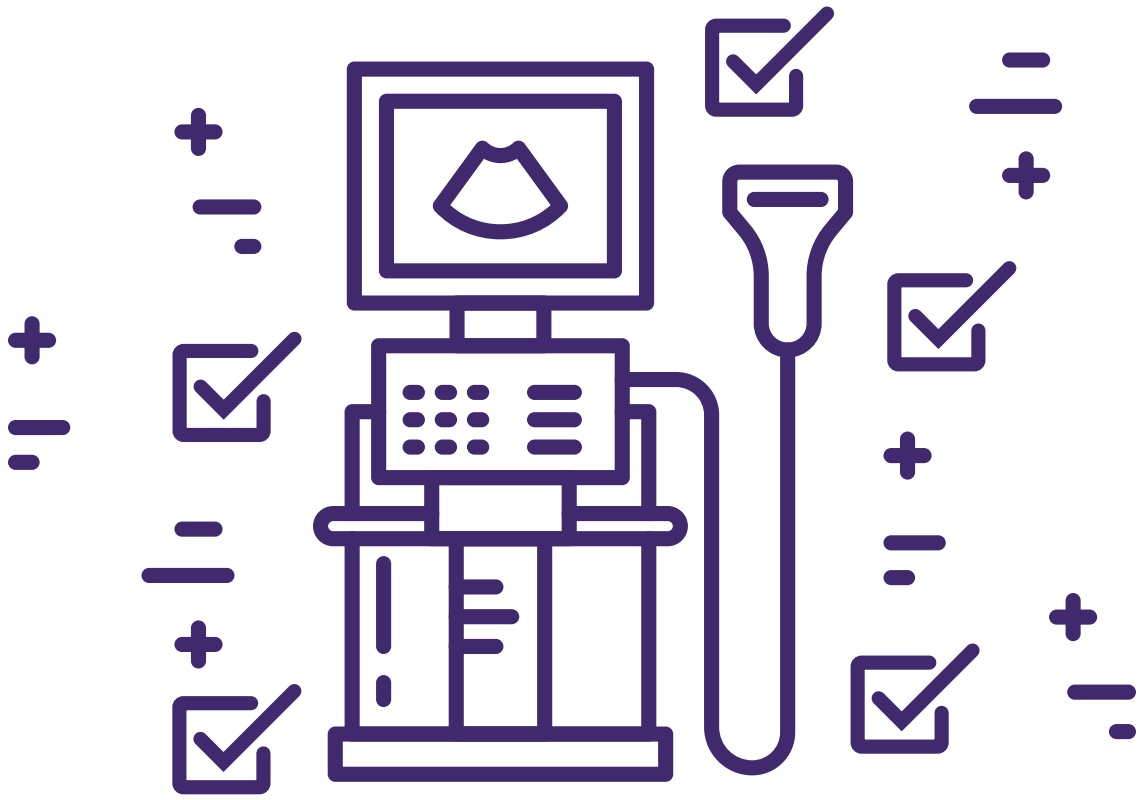
AXREM

Our member companies and their employees work side by side with a range of Medical professionals from multiple specialities to enable them to deliver or support advanced healthcare to patients.

AXREM endeavours to promote best practice based on the knowledge and experience of the industry providers who have helped prepare this checklist.

Pre-owned Equipment Checklist



SoR THE SOCIETY OF RADIOGRAPHERS

BMUS THE BRITISH MEDICAL ULTRASOUND SOCIETY

IPEM Institute of Physics and Engineering in Medicine

Introduction

Background: The Ultrasound Manifesto produced by AXREM in 2022 reported the increasing demand for ultrasound services nationally, and the need for continued investment in ultrasound equipment, training, and governance (1-2). Due to economic reasons, there has been an increasing trend in purchasing refurbished ultrasound equipment to meet clinical demand. However, there has been little guidance on how to best procure this equipment while maintaining standards in governance and equipment performance (3-6).

Purpose: The purpose of this ultrasound checklist is to increase the transparency of the history and current condition of pre-owned ultrasound systems before purchase, safeguarding potential buyers and sellers of used and refurbished equipment.

The checklist has been designed to allow potential buyers to make more informed decisions, based on relevant information supplied by sellers, and is not in itself intended to provide detailed guidance on the purchase of pre-owned equipment.

Design and Structure: The current guidance was designed by AXREM in collaboration with the British Medical Ultrasound Society (BMUS), the Institute of Physics and Engineering in Medicine (IPEM), and the Society of Radiographers (SoR). The document consists of three checklists. The first checklist refers to ultrasound probes. The probes have been separated from the rest of the imaging system because they are the most common point of failure and are replaceable without any changes required to the ultrasound system. The second and third checklists refer to the rest of the ultrasound system and post-sales support. The vendor of the refurbished or pre-owned ultrasound equipment should complete the checklists to provide confidence to purchasers that reasonable governance procedures have been followed.

References:

1. AXREM. Manifesto for Medical Ultrasound - "The modern day stethoscope". AXREM. 2022. Available at: https://www.axrem.org.uk/
2. Richards MA. Diagnostics: Recovery and Renewal. Report of the Independent Review of Diagnostic Services for NHS England. Richards MA 2020.
3. Institute of Physics and Engineering in Medicine (IPEM). Quality Assurance of Ultrasound Imaging Systems. IPEM Report No. 102. IPEM, York, 2010'
4. National Health Service Breast Screening Programme (NHSBSP). Guidance Notes for the Acquisition and Testing of Ultrasound Scanners for Use in the NHS Breast Screening Programme. NHSBSP Publication No. 70. NHSBSP, Sheffield, 2011.
5. SoR and BMUS. Guidelines for Professional Ultrasound Practice. Society of Radiographers and British Medical Ultrasound Society. 7th edition. 2022. ISBN:978-1-909802-81-0.
6. National Health Service Fetal Anomaly Screening Programme (NHSFASP). Guidance Overview. NHS. 2022.

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Section 1: The Probe

Provenance of the Probe (please tick the appropriate box)	**Yes**	**No**	**If "No", please provide details**
Was the probe manufactured by the original equipment manufacturer of the ultrasound scanner it will be attached to?			
Is the probe a brand new device?			
Can you provide the ownership history of the probe?			
Can you provide the refurbishment history of the probe?			
Is the probe within the original manufacturer's expected service life?			
Type of Probe Repair (please tick the appropriate box)	**Yes**	**No**	**If "Yes", please provide details**
Critical to Probe Performance			
Acoustic Lens			
Acoustic Stack			
Less Critical to Probe Performance			
Housing			
Strain Relief			
Cable			
Connector			

Section 1: The Probe

Post-Repair Validation (please tick the appropriate box)	**Yes**	**No**	**If "No", please provide details**
Are the new components compatible with the original manufacturer's recommended products for cleaning and disinfection?			
Has the probe undergone electrical safety testing, conforming to the requirements of IEC 60601-1 and/or IEC 62353?			
Has the repaired probe undergone testing for ingress of water, conforming to the requirements of IEC 60601-2-37?			
Has the repaired probe undergone electronic probe testing of each piezoelectric crystal, including tests for sensitivity, capacitance, pulse width, centre frequency, and fractional bandwidth?			
Has an image quality assessment been undertaken using a tissue mimicking phantom?			
Has the probe undergone acoustic output testing, conforming to the requirements of IEC 60601-2-37 and IEC 62359?			
Packaging (please tick the appropriate box)	**Yes**	**No**	**If "No", please provide details**
Has the probe been packed in such a way that it would protect the probe in transit?			
Has the probe been cleaned and ready for clinical use?			
Labelling (please tick the appropriate box)	**Yes**	**No**	**If "No", please provide details**
Has the probe been labelled as pre-owned or refurbished probe?			

Section 2: The governance of the ultrasound system

Standards (please tick the appropriate box)	Yes	No	If "No", please provide details
Is your company certified to ISO 13485 for the repair of ultrasound systems?			
Do your company's ultrasound system repair activities conform to the requirements of IEC 63077?			
Is the CE marking of the device still valid following the repair or modification?			
Does your company's ultrasound system service work comply with the Quality Management system ISO 13485?			
Do you have a certification that all patient data has been erased in accordance with the UK National Cyber Security Centre guidance for secure sanitisation of Storage media? https://www.ncsc.gov.uk/guidance/secure-sanitisation-storage-media			
Is the specification of the ultrasound system in line with planned clinical use and the latest scanning guidelines from the SoR/BMUS Guidelines for Professional Ultrasound Practice (5)			
Is the specification of the ultrasound system in line with RCR/SCoR Standards for the Provision of an Ultrasound Service?			
Will the ultrasound system be cleaned and disinfected ready for clinical use?			
If any components have been replaced during the refurbishment process, does this impact on the recommended cleaning agents from the original manufacturer's instruction?			

Section 3: Post-sales support

Support and Maintenance (please tick the appropriate box)	Yes	No	If "No", please provide details
Would the supplier be willing to maintain the ultrasound system in accordance with repair activities complying to the requirements of IEC 63077?			
Does the supplier provide a minimum warranty term of 6 months?			
Will the ultrasound system be supported by a clinical applications specialist?			
Are the costs for clinical applications support of the system included?			
Will the ultrasound system be updated with all relevant field modification instructions that have been released since it was manufactured?			
Please supply any additional information that you feel is relevant along with any documentation:			

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To cite this document:

AXREM (2022). Pre-owned Ultrasound System Checklist. Available at https://www.axrem.org.uk/

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