Chapter 15 - Quality Assurance

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Quality Assurance (QA) in Clinical Ultrasound

Key points:

- **Definition and Scope of QA:**
  - QA generally refers to schemes designed to ensure outcomes of processes meet required standards.
  - In clinical ultrasound, outcomes typically involve creating clinically useful images.
  - A comprehensive QA program would ideally cover the entire imaging process, from patient referral to the final report; however, this chapter specifically focuses on **equipment QA**.
- **Purpose of Equipment QA:**
  - Main goal is **early detection of faults or performance changes** in ultrasound scanners.
  - Essential for identifying issues at commissioning or changes occurring later, enabling timely technical intervention.
- **Controversies in QA:**
  - Reliability and value of QA techniques are debated, especially for comparing scanners or meeting purchasing specifications (Dudley et al. 2017).
  - Therefore, the emphasis in QA should be detecting performance degradation or faults in individual scanners over time, rather than direct comparisons between scanners.
- **Subjective Assessment by Users:**
  - There is an argument for basing scanner performance assessments on the clinical users' judgment of image quality.
  - This approach, however, has significant limitations:

    Learning curve: User perceptions may evolve as they become more familiar with scanner controls.
    Subjectivity: Different users may have varying perceptions of image quality.
    Missed subtle changes: Small but significant performance changes may go unnoticed.
    Patient variability: No standard patient exists; thus, image quality can't be consistently standardized.
    Operator skill: Image quality heavily depends on operator proficiency.
    Technology masking faults: Advanced image processing techniques (e.g., compounding, adaptive processing) may hide underlying scanner faults.

Figure Mentioned:

- Dudley et al. (2017) is cited regarding the controversy in the reliability of QA techniques (specific figures not provided in the given text).

Techniques and Methods for Ultrasound Equipment QA

Key points:

- **QA Without Patients:**
  - Techniques have been developed to conduct QA testing without needing patients.
  - Methods range from simple visual inspections (no test equipment needed) to complex evaluations using **tissue-mimicking test objects (TMTOs)** designed to measure scanner performance features.
- **Selection Criteria for QA Methods:**

    - Must be **reproducible** over years.
    - Should be **sensitive** enough to detect performance changes before becoming clinically significant.
- **Limitations of Traditional TMTO Methods:**
    - Conventional visual assessments and measurements (resolution, contrast) show large intra- and inter-observer errors and have limited effectiveness (Dudley et al. 2001).
    - **Computerized TMTO measurements** might be valuable for fault investigation rather than routine testing (Dudley and Gibson 2014).
- **Effectiveness of Simple QA Methods:**
    - Simple methods, especially visual inspection and uniformity assessments, effectively detect most faults:
        - **91%** detection rate (Hangiandreou et al. 2011).
        - **94%** (Sipila et al. 2011) and **82%** (Vitikainen et al. 2017).
        - Electronic testing revealed probe sensitivity issues in **18%** of cases (Vitikainen et al. 2017).
        - Dudley and Gibson (2017) found sensitivity reduction via TMTO measurements in **23%** of probes.
- **Standards and Guidance:**
    - Various national and international bodies set QA standards:
        - UK: Institute of Physics and Engineering in Medicine (**IPEM**), British Medical Ultrasound Society (**BMUS**).
        - Europe: European Federation of Societies for Ultrasound in Medicine and Biology (**EFSUMB**).
        - US: American Association of Physicists in Medicine (**AAPM**), American Institute of Ultrasound in Medicine (**AIUM**).
        - International: International Electrotechnical Commission (**IEC Technical Specification**, 2016).
- **UK-based QA Approach:**
    - Guidelines (IPEM 2010; Dudley et al. 2014) suggest simple, proven methods:
        - Visual inspection.
        - Image uniformity.
        - Sensitivity assessment.
    - Routine QA tests can be performed by experienced sonographers; more complex testing for acceptance or fault management typically conducted by physics/engineering staff.
- **Novel Methods:**
    - This chapter also briefly describes newer QA methods with potential future utility.

Figures Mentioned:

- Dudley et al. (2001), Dudley and Gibson (2014, 2017), Hangiandreou et al. (2011), Sipila et al. (2011), Vitikainen et al. (2017), IPEM (2010), IEC (2016). (Specific numerical figures already included above.)

Routine QA Testing by Clinical Staff

Key Points:

- **Responsibility and Benefits:**
    - Routine QA should be carried out by clinical staff.
    - This encourages staff awareness of potential faults or damage, increasing the likelihood that issues are promptly identified and addressed outside scheduled tests.
- **Test Duration and Frequency:**
    - Tests should be brief, taking only a few minutes, minimizing impact on clinical workflow.
    - The scanner and **all associated probes** should undergo routine testing.
    - Recommended testing activities and their frequencies are provided in **Table 15.1**.

- **General Setup Protocols:**
  - Tests require clear, reproducible protocols for scanner setup, enhancing consistency across testing sessions.
  - Tests should be conducted under appropriate ambient lighting—ideally in a darkened room—to avoid reflections and ensure visibility of low-level signals.
- **Scanner Configuration Recommendations:**
  - Begin with a preset appropriate to the probe and intended clinical use.
  - Turn off advanced features (harmonics, compounding, advanced processing) and automatic optimization/gain, as these may conceal faults.
  - Adjust display depth to ensure the test image adequately fills the screen.
  - Use a single focus near the probe to minimize the transmit aperture, simplifying the detection of element faults.
  - Maintain time-gain compensation (**TGC**) at default (usually central) positions unless adjustments are specifically justified.
  - At scanner commissioning, save baseline settings as additional presets for easy recall during routine QA.

Figures Mentioned:

- **Table 15.1** (Routine QA activities and suggested frequencies).

Cleaning, Functional Checks, and Visual Inspection in Ultrasound QA

Key Points:

Cleaning Procedures:

- **After each patient:**
  - Scanner console, transducers (probes), and cables should be cleaned to remove ultrasound gel and body fluids.
  - Use cleaning methods and materials recommended by the manufacturer.
  - Follow professional guidelines for cleaning (e.g., Abramowicz et al. 2017; Westerway and Basseal 2017).
  - **Probe lens** must be gently **wiped (not rubbed)** to prevent damage.
- **Daily and Weekly Maintenance:**
  - Scanner body and display should be cleaned **daily**.
  - Dust filters should be cleaned **weekly**.

Functional Checks:

- **Timing and Reporting:**
  - Best conducted during regular clinical use, as control adjustments help identify malfunctions.
  - Implement a **fault report form** within the QA process to record issues and corrective actions.
  - Faults identified during scheduled QA should also be reported and addressed promptly.
- **Display Adjustment:**
  - Brightness and contrast settings typically remain at the commissioning baseline.
  - If the greyscale bar isn't fully visible, adjustments should be made and new settings documented.

Visual Inspection:

- **Frequency and Scope:**
  - **Formal inspection** of scanner, probes, cables, and connections should be performed and documented **weekly**.
  - Daily practice should include checks for proper stowage and condition of probes and cables.
- **Key inspection points:**

    - Confirm no loose or damaged parts.
    - Ensure wheels and brakes function properly.
    - Check for sharp edges or mechanical hazards.
    - Inspect electrical cables for secure connections and damage.
- **Probe inspection specifics:**
    - Ensure no physical damage to probes, cables, connectors, or lenses.
    - Probe casing must be intact without visible wear or damage.
    - Equipment with visible mechanical or electrical hazards must be withdrawn from clinical use until repaired.
    - Damage or wear identified during inspection requires a risk assessment. If significant risks are present (mechanical, electrical, infection), equipment usage should be discontinued until resolved.
- **Inventory check:**
    - Ensure no equipment parts (e.g., probes) are missing.

Figures Mentioned:

- Cleaning recommendations by Westerway and Basseal (2017) and Abramowicz et al. (2017) referenced, but specific figures not provided in the given text.

Routine QA: Cleaning, Visual Inspection, and In-Air Reverberation Tests

Key points:

Cleaning and Maintenance:

- After **every patient**, remove ultrasound gel and body fluids from:
    - Scanner console
    - Transducers (probes)
    - Cables
- Use manufacturer-approved cleaning methods and materials (Westerway and Basseal 2017; Abramowicz et al. 2017).

Fault Reporting During Clinical Use:

- Fault detection most effectively occurs during routine clinical operation.
- A formal **fault report form** should be integrated into the QA process for easy documentation and action.

Visual Inspection:

- Perform and document visual inspections **weekly**, though regular checks are encouraged.
- Inspection should assess:
    - Scanner condition (no loose parts, functional wheels/brakes, no sharp edges).
    - Electrical cables and connectors (secure and undamaged).
    - Probes, connectors, lenses for damage or wear.
- Equipment presenting **mechanical or electrical hazards** should be withdrawn from clinical use until repaired.
- Any visible lens damage, cable damage, or connector issues require risk assessment.
- Equipment must not be used if assessments indicate significant mechanical, electrical, or infection risks.
- Check regularly for missing parts, especially probes.

In-Air Reverberation Test (Element Dropout and Delamination):

- This test evaluates scanner uniformity in the absence of patients.
- **Setup:**
    - Conduct test at highest available fundamental frequency.
    - Use default output, gain settings, and the shortest depth scale possible, ensuring the full width and depth of the image are visible.
    - Disable advanced image processing and automatic optimization to avoid masking

faults.
    - **Save baseline scanner settings** at commissioning for consistency in routine QA.
- **Performing the test:**
    - Conduct in a darkened room with appropriate ambient lighting conditions.
    - Verify lateral uniformity; normal pattern is bright, parallel lines of uniform brightness.
    - Small irregularities may occur due to minor lens imperfections; experience allows differentiation between these and genuine faults.
    - Test across multiple frequencies; some faults are frequency-specific.

Fault Conditions Identified via In-Air Reverberation Pattern:

1. Element Failure (Dropout):

- Appears as axial bands extending through the reverberations' depth.
- Confirm by using the **paper clip method** (Fig. 15.2):
    - Draw the paper clip perpendicular along probe face.
    - Normal elements produce bright axial reverberations; failed elements show decreased brightness.
    - **Reject any new/repaired probes with element dropout.**
- **Modified paper clip method** for central M-line imaging (Fig. 15.3):
    - Use with M-mode, setting focus to ensure full aperture activation.
    - Axial banding indicates failed elements clearly.
- Element failures, especially if multiple, affect Doppler performance. If suspected, further testing with electronic probes or Doppler test objects is required (Vachutka et al. 2014; Vachutka et al. 2003).

Delamination Fault Condition:

- Layers in probe acoustic stack separate (**delamination**), identified visually or via reverberation pattern (Fig. 15.4).
- May result in lens bulging or degraded image quality.
- Probes exhibiting delamination should be **immediately replaced**.

Fault Condition: Non-Uniformity of Lens Thickness in Ultrasound QA

Key Points:

Identification and Causes:

- Non-uniform lens thickness is the **third fault condition** detected by the **in-air reverberation pattern**.
- Appears as deviations from parallel reverberation lines.
- Causes include:
    - Manufacturing defects (inherent to new probes).
    - Lens wear, commonly observed at the ends of the array.

Quantification:

- Measure depth variations of a specific reverberation line across probe length (**Figure 15.5a**).

Impact on Probe Performance:

- Deviations significantly influence probe performance:
    - Reduced element sensitivity, visible through electronic probe testing (**Figure 15.5b**).
    - Decreased fractional bandwidth (bandwidth divided by center frequency), especially evident at the probe ends (**Figure 15.5c**).
- Deviations of **10% or greater** are visually obvious, significantly affect bandwidth and sensitivity, and necessitate **probe replacement**.

Applicability to Matrix Arrays:

- Uniformity tests described are effective for conventional linear array probes but have limitations for:
  - **Matrix arrays**.
  - Arrays with **multiple rows of elements**.
- Single-element failures in these arrays typically do not significantly affect in-air reverberation patterns or clinical use, due to minimal contribution to overall beam formation.
- Failure of an entire block of elements in matrix arrays can cause clinically noticeable dropout or shadowing.
- **Delamination** and **lens thickness variation** affect matrix arrays similarly to conventional arrays.

Sensitivity and Noise Testing and Baseline Measurements in Ultrasound QA

Key Points:

Sensitivity and Noise Tests:

- Conduct monthly tests for:
  - **B-mode sensitivity**
  - **Noise levels** for B-mode, pulsed Doppler, and colour flow modes (IPEM 2010).

Baseline Measurements (Commissioning):

- Required upon commissioning new scanners, or receiving replacement/repaired probes, to define reference tolerances for routine tests.

Procedure for Baseline Measurements:

- Obtain an **in-air reverberation image** similar to uniformity testing.
- **Scanner settings:**
  - Set overall gain to **maximum**.
  - Adjust depth so reverberation pattern occupies **30%–50%** of image depth, showing some electronic noise at the bottom (Fig. 15.6a).
  - If deepest reverberation echo is unclear at highest frequency, switch through fundamental frequencies to identify optimal frequency for reproducibility.
- **Handling Insufficient Noise Visibility:**
  - If no noise appears, increase image depth until visible.
  - If increasing depth shrinks reverberation pattern below **25%**, reset depth and increase **TGC** to maximum to reveal noise.
  - If image becomes overly bright/noisy, reduce TGC to minimum.
  - Record exact TGC positions; ensure reproducibility.
- **Save settings:**
  - Store scanner configuration as an additional preset, labeled clearly (e.g., **USER QA <PROBE id>**).
  - Save a digital copy of the baseline image for comparison in future tests.

Reverberation Depth Measurement:

- Measure vertically from probe surface to the deepest visible reverberation line in the **middle third** of the image (**Fig. 15.6a**).
- **Tolerance:**
  - ± half the distance between the deepest reverberation line and the line immediately above.
  - Report any addition or loss of a reverberation line in subsequent tests.
- **Limitation:**

    - This measurement method is **quantised**, meaning detection requires a notable step-change in system performance (at least equal to the deepest reverberation amplitude).
- **Addressing Limitation:**
    - Use the **reverberation threshold test**.

Reverberation Threshold Measurement:

- Determines the **minimum overall gain setting** at which the deepest reverberation line disappears completely from the entire image width (**Fig. 15.6b**).
- Procedure:
    - Gradually reduce overall gain until deepest reverberation line disappears; note this gain level.
    - Increase gain incrementally by one step to confirm reappearance, verifying accuracy.
    - Repeat until a reproducible measurement is confidently obtained.

Figures Mentioned:

- **Figure 15.6a:** Demonstrates measurement of reverberation depth, with reverberations occupying 30–50% of image depth.
- **Figure 15.6b:** Shows the point of reverberation threshold—the gain setting at which the deepest reverberation disappears.

Threshold Testing, Routine QA, and Fault Management in Ultrasound QA

Key Points:

B-mode Noise Threshold:

- Defines the **minimum overall gain setting** at which distal electronic noise disappears from the B-mode image (**Figure 15.6c**).
- Procedure:
    - Gradually reduce overall gain until noise completely vanishes.
    - Confirm by incrementally increasing gain until noise reappears.
    - Repeat for reproducibility and record carefully.

Pulsed Doppler (PD) and Colour Flow (CF) Noise Thresholds:

- Similar procedure to B-mode noise threshold:
    - Operate each mode separately.
    - Note transmission frequency.
    - Position PD range gate or CF colour window centrally in the B-mode image.
    - Reduce gain until PD or CF noise disappears; verify reproducibility.

Recommended Tolerances:

- Initial tolerance for reverberation and noise thresholds: **±4 gain increments**.
- With experience, tolerances may be refined based on observed variability.

Routine Monthly Testing:

- Monthly tests required for **all probes** in regular use.
- If probes move between scanners, choose one of two methods:
    Return probes to original scanner for testing.
    Create separate baseline measurements for each probe on each scanner used.

- Routine tests performed by selecting saved presets (e.g., **USER QA <PROBE id>**) and repeating:
  - Reverberation depth measurement
  - Reverberation threshold measurement
  - B-mode, PD, and CF noise threshold measurements
- Compare all measurements to baseline values.
- Recheck scanner settings (especially TGC defaults) if discrepancies arise.
- Document all results carefully on standardized forms (e.g., as in Dall et al. 2011).

Fault Detection and Management:

- Clearly define two terms:
  - **Fault:** Any deviation from baseline performance or condition.
  - **Failure:** Significant fault necessitating immediate action, such as probe repair or replacement.
- Fault management requires clinical judgement and context-awareness:
  - A fault significant in radiology might be minor in another context (e.g., theatre line placement).
  - Limited published evidence is available on best practices for fault management.
- Suggested approach:
  Utilize a **traffic light grading system** (Table 15.2 example):
  - **Green:** No fault detected.
  - **Amber:** Fault detected, but no immediate action required (monitor and act if necessary).
  - **Red:** Immediate action required—represents a failure.
- **Actions for faults out of tolerance:**
  - Conduct further testing using **tissue-mimicking test objects (TMTOs)** if available.
  - Seek assistance from service agent if local TMTO testing is unavailable.
- Document all results, risk assessments, and mitigating actions carefully.

Figures Mentioned:

- **Figure 15.6c:** Demonstrates B-mode noise threshold measurement (noise disappearance).
- **Table 15.2:** Example categorization (traffic-light system) for probe faults identified during visual inspections and uniformity tests.

Audit and Further Testing in Ultrasound QA

Key Points:

Audit of QA Procedures:

- Perform periodic QA audits (**annually recommended**).
- Audits should evaluate:
  - **Frequency** of test performance.
  - Whether **results are within tolerance**.
  - Proper **reporting, risk assessment, and remedy** of faults.
  - Compliance with manufacturer-recommended **servicing and electrical safety testing schedules**.
- Negative responses indicate the need for staff **training and process review**.
- Audits by an independent assessor (clinical scientist or technologist) may include independent verification of results.

Further Testing (Following Routine QA Indications):

- Triggered by detection of:

    - Changes in **B-mode sensitivity**.
    - Increased **noise levels**.
- Usually performed by **physics or engineering staff**, though experienced sonographers may also perform these tests.
- Requires previously recorded **baseline measurements and images** taken during initial commissioning or after probe repairs.
- **Goal of Further Testing:**
    - Confirm reduction in **B-mode sensitivity**.
    - Confirm decrease in **B-mode signal-to-noise ratio**.
- For increased noise in **PD or CF modes**, no reliable test is available, thus requiring consultation with supplier or service agent.
- **Fault categorization** example provided in **Table 15.3** for further testing scenarios.

Tissue-Mimicking Test Object (TMTO) Sensitivity Testing:

- Sensitivity evaluated through:
    - **Depth of Penetration (DOP)** or **Low Contrast Penetration (LCP)**.
    - **Mean grey level** across depth in a uniform area of TMTO.
- DOP represents the depth at which the uniform speckle pattern disappears into noise (or becomes dark) (**Figure 15.7**).
- **Recommended Scanner Settings for TMTO Testing:**
    - Preset matching typical clinical applications.
    - Default TGC and focus positions.
    - Disable speed-of-sound correction, automatic gain, and automatic image optimization.
    - Set acoustic output to maximum.
    - Adjust scale and gain to clearly demonstrate the boundary between speckle and noise.
- **Measurement Methods:**
    - Prefer **automated measurement methods** (Gibson et al. 2001; Gorny et al. 2005) over subjective visual assessments.
    - If automated methods are unavailable, strict, reproducible visual measurement protocols are essential.
- **Measurement Techniques for Extended DOP:**
    - If DOP extends beyond TMTO bottom:
        - Switch to higher frequencies or different imaging modes (harmonic to fundamental) for measurement.
        - Recommended to perform both **fundamental and harmonic** measurements due to bandwidth faults potentially affecting one mode differently.
- **Image Documentation:**
    - Store digital images.
    - Mean grey level measured within a central-axis region of interest, below the dead zone, and above the noise boundary. Avoid targets.
- **Recommended Tolerances:**
    - **DOP:** ±5% or ±5 mm (whichever greater) (IPEM 2010).
    - **Mean grey level:** ±10% (Dudley and Gibson 2017).

Reference Images, Quality Assurance Programme, and Acceptance Testing in Ultrasound QA

Key Points:

Reference Images:

- Should be recorded digitally at **commissioning** using a **tissue-mimicking test object**

(TMTO).
- Obtain images of all relevant targets:
  - Filaments
  - Greyscale
  - Anechoic regions
    (**Figures 15.8a–c**)
- Use presets consistent with routine clinical applications of each probe.
- **TGC controls** should remain at default positions.
- Necessary adjustments:
  - Disable any **speed-of-sound correction** to avoid image distortion.
  - Adjust **overall gain** to achieve appropriate brightness levels.
- Save these settings clearly as additional presets, or document settings thoroughly for reproducibility.

Complete Quality Assurance (QA) Programme:

- A comprehensive QA programme includes:
  - **Baseline testing** (commissioning or after probe replacement/repair)
  - Regular **routine testing**
  - **Further testing** (if routine tests indicate issues)
  - Formal **fault reporting and remedial action**
  - Annual **audit** procedures
  - **Acceptance testing** (upon delivery or following significant repairs/upgrades)
- Acceptance testing represents an essential final component, with outcomes clearly indicating pass or fail status.

Acceptance Testing:

- **Purpose:**
  - Evaluate equipment upon delivery for:
    - **Safety**
    - **Physical integrity**
    - **Functionality**
    - **Accuracy**
  - Also necessary after significant repairs or upgrades, focusing on impacted areas.
- **Procedure:**
  - Perform thorough **visual inspection** for mechanical safety and physical integrity (as previously detailed).
  - Additional testing required to assess:
    - **Electrical safety**
    - **Acoustic safety**
    - **Functional accuracy**
- Complete acceptance testing satisfactorily **before clinical use** begins.
- **Absolute imaging performance acceptance testing** remains controversial and is not addressed here.

Safety and Functionality in Ultrasound QA

Key Points:

Safety Testing:

Electrical Safety:

- Essential for compliance with international safety standards (**IEC 2005**).
- Typically performed by **specialist medical engineers** following local hospital protocols.
- Detailed procedures are beyond the scope of this text.

Acoustic Safety:

- Detailed coverage in Chapter 16.
- Direct measurement of acoustic output is complex, expensive, and generally not feasible within hospitals/clinics.
- Acceptance tests must include a **visual assessment of displayed Thermal (TI) and Mechanical (MI) indices**:
  - Clinical staff should attempt to reproduce the conditions described in the user manual that produce maximum TI and MI values.
  - Verify that **TI and MI vary predictably** with control adjustments.
- Scanners below specific safety thresholds may not display safety indices; consult user manuals.
- Discuss any unexpected safety index findings with the equipment supplier.

Functionality Testing:

General Procedure:

- Perform **uniformity assessment** as previously described.
- Evaluate scanner operation using a **TMTO** (tissue-mimicking test object) with a known speed of sound (**1540 m s^{-1}**).

Controls and Modes Check:

- Verify **all scanner controls and scanning modes**:
  - Example checks:
    - Changing **focal point position** visibly alters the image width of nylon filament targets.
    - Reducing imaging frequency increases visualized speckle depth.

Assessment of Image Enhancement Techniques:

- Modern enhancements (e.g., compounding, adaptive processing) should subjectively improve image quality.
- Recognize limitations when using TMTO:
  - TMTO lacks layered structures (fat/muscle), potentially limiting assessment accuracy.
  - Faulty image enhancement may present as image degradation (e.g., blurring of anechoic targets).
- **Figure 15.9** illustrates blurring from applying compounding to a urethane test object (note: blurring caused by object's low speed of sound rather than scanner defect).

Unexpected Fault Identification:

- Example provided (**Figure 15.10**):
  - Unexpected improvement in lateral resolution of nylon filaments when applying a speed-of-sound correction indicates a scanner fault.
  - Correction is unnecessary and unexpected since TMTO speed is standard (**1540 m s^{-1}**).

Probe Fault Handling:

- Reject probes with any of the following:
  - **Element dropout**
  - **Delamination**
  - **Non-uniform lens thickness**
- Faulty controls or unexpected results should be promptly addressed with the **supplier**.

Audit, Reference Images, and Acceptance Testing of Ultrasound QA

Key Points:

Audit of QA Programme:

- Should be performed **annually**.
- Audit must verify:
  - Regular performance of QA tests.
  - Test results within tolerances.
  - Proper fault reporting, risk assessment, and remedial actions.
  - Compliance with manufacturer's servicing and safety testing recommendations.
- Negative outcomes require **further training or process review**.
- Independent auditors (clinical scientists/technologists) may perform tests themselves to validate staff results.

Reference Images:

- At commissioning, store digital images of TMTO targets (**Figures 15.8a–c**), including:
  - Filaments
  - Greyscale patterns
  - Anechoic structures
- Image presets should reflect normal clinical settings.
- **TGC settings** remain at defaults.
- Disable **speed-of-sound corrections**; adjust only overall gain for suitable brightness.
- Record or save presets for future reproducibility.

Acceptance Testing:

- Essential component conducted upon:
  - Delivery of new equipment.
  - Following significant repairs or upgrades.
- Acceptance testing focuses on:
  - **Safety (Electrical and Acoustic)**
  - **Physical integrity**
  - **Functionality**
  - **Accuracy**
- Equipment must pass acceptance testing **before clinical use**.

Electrical Safety:

- Follows IEC 2005 standards.
- Typically carried out by medical engineering staff.

Acoustic Safety:

- Assessed via scanner **TI and MI indices** (see user manuals).
- Clinical staff should confirm TI and MI react appropriately to scanner settings adjustments.

Functionality Testing:

- Test functionality using **TMTO (1540 m s^{-1} speed of sound)**.
- Check that scanner controls and modes (including image enhancement features) function correctly and predictably.
- **Examples** include focal adjustments, frequency changes, and image processing features.

Image Quality Assessment:

- Image enhancements (e.g., compounding) might not clearly improve TMTO images due to absence of realistic patient anatomy.
- Degradation or unexpected image changes may indicate faults:
  - Example (**Fig. 15.10**): Unexpected improvement in lateral resolution by applying speed-of-sound correction due to scanner fault.
  - Blurring with compounding as illustrated in **Fig. 15.9**.

Probe Fault Criteria:

- Reject probes displaying:
  - Element dropout
  - Delamination
  - Non-uniform lens thickness
- Report any functional anomalies immediately to suppliers.

Accuracy Testing:

B-mode Accuracy:

- Checked using TMTO with **nylon filament targets** arranged in rows and columns.
- Filament spacing suitable for various clinical measurements:
  - Larger-scale measurements (>10 mm)
  - Smaller-scale measurements (0.25–10 mm)
- Example clinically relevant tests:
  - **Fetal femur length** (~50 mm lateral)
  - **Nuchal translucency** (2.5–5 mm axial)
- Suggested tolerances:
  - ±1 mm for large-scale measurements (e.g., femur length).
  - ±0.1 mm for smaller-scale measurements (e.g., nuchal translucency).
- Obstetric circumferential measurements tested by comparing calculated circumference (derived from two orthogonal diameters) with direct TMTO measurements (**Figure 15.11**), tolerance ±1 mm.
- **Caveat for Convex Probes:**
  - Possible **refraction errors** (over-measurement) due to oblique incidence.
  - Use matched coupling medium or short-distance measurement at the probe center to avoid error.
  - Concave-surface TMTOs (e.g., Sono410 series, Gammex Inc.) can mitigate this issue.

Complex or Non-linear Shapes:

- Use custom-designed, open-topped TMTOs with nylon filaments arranged according to anatomical shapes.
- Medium: speed of sound **1540 m s^{-1}** (e.g., 9.5% ethanol-water solution at 20°C, Martin and Spinks 2001).
- Tolerances set according to clinical accuracy requirements.

Doppler Accuracy:

- Absolute accuracy essential for direct velocity measurements (e.g., carotid artery stenosis).
- Linearity critical for indices and ratios.
- Test tools:
  - **Moving string phantom** for velocities >2 m s^{-1} (recommended by IPEM 2010).
  - **Flow phantoms** for velocities up to ~0.7 m s^{-1}.
- Due to cost and complexity, requesting supplier verification of Doppler accuracy and linearity is pragmatic.
- Procedure:
  - Compare scanner velocity measurements against phantom velocities.
  - Spectral Doppler sample volume positioned appropriately in phantom using B-mode guidance.
  - Use automated maximum and mean velocity tracing if available; otherwise manually calculate mean velocity from max/min calliper measurements (**Figure 15.12**).
- **Caution:**
  - Avoid saturation by setting low Doppler gain and acoustic output during testing.
  - Modern systems often overestimate maximum velocity due to **spectral**

broadening (systematic error from beam geometry and insonation angle), thus manufacturers calibrate to mean velocities.
- Recommended tolerance for Doppler mean velocity accuracy: ±5% (smallest manufacturer-quoted tolerance).

Scanner-derived Parameters:

- Verify accuracy of parameters calculated by scanners (e.g., fetal weight, Doppler indices) by manual recalculations based on original measurements.
- If measurements fall outside tolerances, discuss discrepancies with manufacturers:
  - Manufacturer tolerances often exceed clinical needs, thus specifying clinical tolerances during pre-purchase agreements is recommended.

Ultrasound Test Objects and Practical Considerations

Key Points:

- **Types and Materials:**
  - Commercially available test objects are used for ultrasound system testing, suitable for both B-mode and Doppler evaluations.
  - Typically consist of boxes filled with Tissue-Mimicking Materials (TMMs), including aqueous gel, condensed milk, and urethane rubber.
- **Material Properties:**
  - Most TMMs have a sound speed close to **1540 m s^{-1}**, but can dry out over time, requiring rejuvenation by manufacturers.
  - Urethane rubber is stable over time but shows rapid attenuation increase with frequency. It has a lower speed of sound (**~1450 m s^{-1}**), causing beam defocusing.
  - Speed of sound and attenuation in urethane significantly depend on temperature, affecting the reproducibility of Quality Assurance (QA) measurements (Dudley and Gibson 2010; Browne et al. 2003).
- **Setup Recommendations:**
  - Place the test object on a firm, flat surface.
  - If stored at extreme temperatures, allow the test object to equilibrate for **30–60 minutes** before use.
  - Fill wells in test objects with tap water; if impractical, scanning gel can be used, especially with linear and phased arrays.
  - Convex arrays require careful application of sufficient gel to maintain good acoustic contact.
- **Practical Considerations and Artefacts:**
  - Using water in test object wells may cause reverberation artefacts from echoes at the water surface. These artefacts are typically irritating rather than misleading, and can be reduced by placing damp paper or absorbers near probe ends.
  - Speed of sound in water is lower than in most test object materials, potentially causing refraction. However, this primarily affects accuracy assessment rather than other tests.
- **Precautions:**
  - Avoid pressing hard on the test object's surface, typically made of low-density polythene, as it can be distorted or damaged.
  - Excessive surface pressure might displace internal targets within the test object.

B-mode and Doppler Test Objects

B-mode Test Objects

- **Purpose and Design:**
  - Designed to produce a speckle pattern similar to soft tissues by incorporating small-diameter scattering materials, such as **graphite powder**, facilitating sensitivity measurements.

    - Typically include a variety of embedded targets:
        - **Small-diameter nylon filaments** for evaluating calliper accuracy and resolution in axial, lateral, and slice-thickness planes.
        - **Cylindrical targets** with different backscatter properties compared to background.
        - **Spherical or other shaped targets** to overcome directional dependency issues.
- **Resolution Considerations:**
    - Resolution varies significantly across the three orthogonal planes (axial, lateral, slice thickness), and also changes with depth, thus the positioning of filaments must accommodate these variations.
    - Cylindrical targets primarily assess axial and lateral resolution but largely ignore slice-thickness, potentially overstating scanner performance, as real lesions are rarely perfectly transverse.
    - Spherical targets overcome this limitation by providing symmetrical representation in all planes.

Doppler Test Objects

- **Challenges and Types:**
    - More complex to design than B-mode due to the necessity of simulating blood motion with moving targets.
    - Two main types commercially available:
        - **String Phantom**
        - **Flow Phantom**
- **String Phantom:**
    - Consists of a moving string that simulates blood flow.
    - Components of a string phantom illustrated in **Figure 15.13**.
    - The type of filament significantly affects results:
        - Spiral-wound filaments (cotton or silk) produce repeating high-amplitude scattering patterns due to spacing comparable to ultrasound wavelength, causing distorted Doppler spectra, and thus are unsuitable (Cathignol et al. 1994).
        - **O-ring rubber filament** is recommended, scattering ultrasound evenly in all directions, closely matching blood characteristics (Hoskins 1994).
- **Advantages and Use:**
    - Velocity can be accurately measured by calculating the rotation speed of the drive wheel, making it ideal for verifying Doppler velocity estimates.
    - Straightforward setup, compact, and suitable for portable use.
    - Recommended by IPEM (2010) for basic Doppler performance testing.

Flow Phantom

Design and Purpose:

- Simulates the flow of blood within a vessel.
- Components are illustrated in **Figure 15.14**.
- Critical to match acoustic properties of three main components:
    - **Tissue mimic**
    - **Blood mimic**
    - **Vessel (tube)**

Material Characteristics:

- **Tissue Mimic:**
    - Usually gel-based material as previously discussed.
- **Blood Mimic:**
    - Must have correct viscosity and acoustic properties.
    - A suitable blood mimic, described by Ramnarine et al. (1998), consists of **nylon**

particles suspended in a solution of **glycerol and dextran**.

- **Vessel Mimic (Tube):**
  - Matching acoustic properties is challenging:
    - **Latex:**
      - Sound speed approx. **1600 m s^{-1}** (similar to human tissue).
      - High and nonlinear attenuation causing spectral distortion.
    - **Silicone:**
      - Sound speed approx. **1000 m s^{-1}**, leading to significant mismatch and unreliable calibration of mean velocities.
    - **Nylon tubing:**
      - Has density, speed of sound, and attenuation properties closely matched to human soft tissue.
      - Examples include **Doppler 403** and **Mini-Doppler 1430 Flow Phantoms** by Gammex Inc. Middleton, Wisconsin.

Calibration Issues:

- Mismatched acoustic properties between the phantom materials and human tissues distort Doppler spectra, resulting in the overestimation of mean velocity.
- Accurate calibration requires phantoms with closely matched acoustic properties to human tissue.

Research and Development:

- Advanced flow phantoms accurately matched to human tissue have been successfully designed in research laboratories (Ramnarine et al. 2001; Hoskins 2008).

Professional Guidance and Recent Advances in Ultrasound QA Testing

Professional Guidance on QA:

- Very limited professional guidance exists for:
  - **Contrast agents:** No specific QA guidance available from AIUM (2007), despite discussing contrast in the context of Doppler testing.
  - **Elastography QA:** No professional guidelines, though phantoms are commercially available.

Elastography Phantoms:

- Commercial elastography phantoms exist, but absolute accuracy assessment is problematic:
  - Typically, elasticity measurements vary based on the measurement system (Mulabecirovic et al., 2016).
  - **Mulabecirovic et al. (2016)** confirmed that phantom elasticity results vary depending on the measurement system used.

Limitations of Traditional TMTOs:

- Limited professional guidance and published evidence for effectiveness (Dudley & Gibson, 2014).
- Recent approaches aim to integrate resolution, contrast, and noise into a single measurement metric.

Edinburgh Pipe Phantom:

- **Purpose:**
  - Provides a comprehensive figure-of-merit based on combined resolution, contrast, and noise parameters.
  - Targets faults such as beam profile deterioration and element dropout.
- **Design:**
  - Contains diagonally placed anechoic pipes of varying diameters within a standard Tissue-Mimicking Test Object (TMTO).
  - Pipes designed to assess scanners across clinical and pre-clinical frequency ranges.

- **Advantages and Validation:**
  - Proven effective in characterizing imaging performance across clinical applications.
  - Capable of reliably detecting faults (Moran et al. 2014).
- Commercially available (CIRS, Norfolk, Virginia).
- **Example image provided in Figure 15.15.**

Random Void Phantom:

- Combines spatial and greyscale imaging parameters into one value, potentially correlating better with clinical performance.
- Consists of random voids within a phantom, recording images as the ultrasound probe moves across its surface, forming a 3D dataset.
- Attempts to provide a metric more representative of clinical utility compared to isolated parameters.

Cross-filament Phantom and Electronic Probe Testers

Cross-filament Phantom

- **Purpose and Design:**
  - Developed by Doblhoff et al. (2017) to construct beam profiles in both **lateral** and **elevation** directions.
  - Consists of cross-arranged filaments allowing detailed assessment of beam profiles when scanned across the surface.
- **Applications:**
  - Used for identifying problems such as non-functioning elements or lens damage in probes.
  - Enables construction of detailed **beam profiles** in lateral and elevation directions.

Electronic Probe Testers

FirstCall Probe Tester (Unisyn):

- Designed for comprehensive probe testing.
- Procedure involves scanning a probe across specialized plates:
  - **Flat plate**: For linear and phased arrays.
  - **Large-radius curved plate** for abdominal convex arrays.
  - **Tightly curved plate** suited for endocavity probes.
- **Test Method:**
  - Array elements are individually pulsed, allowing detailed diagnosis of each element.
- Provides detailed metrics:
  - Pulse width
  - Centre frequency
  - Fractional bandwidth
  - Pulse shapes and frequency spectra (for three selected elements)
- Fault detection capabilities:
  - Differentiates between **open circuit**, **short circuit**, or **damaged elements**.

Alternative Device:

- **ProbeHunter** (BBS Medical AB): Similar functionality to FirstCall but includes additional features.

Practical Considerations:

- Initial testing with simple methods (e.g., visual uniformity tests via scanning) is highly effective.
- Doblhoff et al. (2017) demonstrated that initial uniformity faults can be efficiently detected using simple first-line methods.
- An electronic probe tester (e.g., FirstCall or ProbeHunter) is typically necessary only

when detailed fault analysis or probe repair diagnostics are needed.