Quality assurance of ultrasound systems: current status and review of literature

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Abstract

Diagnostic ultrasound (US) images can be obtained from a quality device, in optimal working conditions, combined with the capable actions of the operator in tweaking the equipment's characteristics. The quality assurance (QA) is the topic of this review article, and it is addressed in an US practice through proper selection of the equipment when purchasing, and through care and preventive maintenance of the machine for ensuring accurate performance. For optimal US system functioning, QA steps carried out on the basis of a scheduled program are needed in any US practice or department. It is critical to confirm in a semiannual or annual basis that the image quality is maintained according to standards and any subtle change in equipment's functioning is detected and amended at an early stage. The use of test objects (also called US testing phantoms) is required above the basic level of QA testing. The scope of this review article is to inform the US user about necessary QA knowledge and at the same time, present the state of the art of the most suitable test methods for US QA. We referred to relevant publications, selected after performing a systematic literature search of the MEDLINE, EMBASE and COCHRANE databases, and also to the standards established by authoritative international societies.

Keywords Ultrasound · Quality assurance · Test objects · Ultrasound phantoms

Sommario

Immagini ecografiche diagnostiche e di buona qualità possono essere ottenute da un attento controllo, in condizioni di lavoro ottimali, combinato con le capacità dell'operatore di modificare le caratteristiche dell'apparecchiatura ecografica. Il controllo di qualità (QA) è l'argomento di questo articolo di revisione, ed è indirizzato alla pratica ecografica quotidiana che ha origine nella corretta selezione dell'apparecchiatura al momento dell'acquisto, passando per la cura e la manutenzione preventiva della macchina in modo da garantire sempre prestazioni accurate con standard elevati. Per il funzionamento ottimale del sistema ecografico, controlli periodici e programmati sono necessari in qualsiasi studio o dipartimento ospedaliero. È fondamentale infatti, confermare, su base semestrale o annuale, che la qualità dell'immagine sia mantenuta secondo gli standard e che qualsiasi cambiamento sottile nel funzionamento delle apparecchiature sia rilevato e modificato nella fase iniziale possibile. Talvolta può essere richiesto l'uso di oggetti (chiamati fantocci) qualora sia necessario un livello superiore di controllo. Lo scopo di questo articolo di revisione è informare l'utente della necessaria conoscenza del controllo di qualità e, allo stesso tempo, presentare lo stato dell'arte i metodi di prova più adatti per il controllo della qualità delle apparecchiature ecografiche. Abbiamo fatto riferimento a pubblicazioni pertinenti, selezionate dopo aver effettuato una ricerca sistematica della letteratura sui database MEDLINE, EMBASE e COCHRANE e anche sugli standard stabiliti da autorevoli società internazionali.

General and practical care of the equipment

US systems contain delicate parts that can be physically damaged by improper use and handling. Conscious and diligent protection of the equipment during usage is a requirement for the operator who must avoid dropping or knocking the probe, or passage of the machine wheels over the

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probe cable during movement (the US machines are heavy, with some of them well above 150 kg). Frayed cords and cracked transducer casing represent an electrical hazard for the operator and the patient and, therefore, require immediate switch off of the device and the machine or transducer must be withdrawn from activity until specialized personnel has troubleshot the problem [1]. Cleanness of equipment (including transducers, control panel, monitor, vents and peripherals), environment, and also hygiene of transducers and other parts of the equipment are required. Dust that gathers in the electrical components can cause malfunctioning of the computer and of the components of the machine.

Daily optimal operation of the US system should be observed by the user and any deficiency or fault should be immediately reported and repaired [2]. Principal concerns are presented by damaged cords or transducer housing, cracks or chips in the transducer face, failure of part of the transducer's crystal elements as detected in the image, obvious caliper malfunctioning, irregular image or non-diagnostic poorly representative of anatomy, erratic depth adjustments, non-functioning keyboard or trackball, etc. [1–3].

Technical support by phone offered by the manufacturer and the device's user manual can be consulted for minor troubleshooting. Severe or complicated malfunctioning needs the onsite remedial action on the device by the service personnel or engineer.

Performance QA testing

Apart from these practical actions, regular QA testing and servicing should be scheduled and implemented on a routine basis. A well-planned and comprehensive preventive maintenance program for QA of US devices must be carried out and a record of each inspection, evaluation and/or calibration must be maintained [1–4].

The QA testing can be used for the device's assessment at the moment of purchase, for proper selection of the machine, and also comparison of an US scanner against another scanner [1]. In this way, the imaging capabilities are evaluated when purchasing the equipment and thereafter routinely tested for assuring the maintaining the system's accuracy [4].

To achieve the objectives of the quality assessment, the user's judgment of the image and equipment performance is deemed subjective and scarcely reliable for a QA program. Furthermore, the operator, habituated with the obtained image of the US device used is largely incapable to percept gradual, slow, and subtle degradation of the sonographic image quality. In addition, the skill of the operator and patients' characteristics are disturbing variables in quality evaluation [3].

Therefore, in response to these issues, an objective evaluation is mandatory, and quality control actions in the absence of the patient with the use of test objects (also called US phantoms) and measured variables [1–3]. This quantifiable assessment is to be followed and reproduced over the timescale of years. In this way, a deterioration in performance is detected before it becomes perceptible to the operator and/or clinically relevant [6, 7].

Resolution in the axial, lateral and elevational plane, beam penetration, contrast resolution (represented by the gray scale sensitivity and dynamic range), vertical and horizontal calibration, and overall registration of data are evaluated [1–3, 5], and these issues will be addressed in this article.

A list of the main imaging characteristics to be evaluated is presented in Table 1.

Measuring against an affirmed quantifiable standard, these imaging capabilities offer an absolute evaluation which helps for a consistent objective testing ensuring that the performance does not fall short of diagnostic requirements deemed clinically relevant. International societies and accrediting agencies have produced QA guidelines also concerned with minimum standards to be achieved [1–3, 5]. A list of some of the principal organizations is presented in Table 2.

Alternative to the absolute evaluation for QA mentioned above is the practical relative evaluation, which measures only the machine's performance against that of the same machine at the time of purchase, or at any other previous time point. Not perceptible, developing faults are detected and less expertise and cheaper phantoms are required in this case [1, 5, 6].

Various test objects (Table 3) are designed for testing general and specific performance characteristics both in the absolute QA and relative one [1, 2, 5, 8]. Unfortunately, the use of US phantoms and regular quality testing is not widespread despite the recommendations of authoritative guidelines [3, 5]. Only QA with phantom testing, on a regular basis during the equipment's life, is capable of monitoring the optimal performance and early detecting malfunctioning [9].

The frequency of the quality control actions and/or servicing is slightly different in the various recommendations, with some authors advising QA up to four times per year [9]. More lenient and also clinically supportable intervals are recommended by the various organizations, such as the American Institute of Ultrasound in Medicine (AIUMB) [3] that requires that US equipment must be tested, serviced, and calibrated at least yearly and more often if problems emerge, and that there must be routine inspection by the operator.

Table 1 Description of the imaging capabilities of the US systems to be tested in a QA program

Imaging characteristic tested	Details	Significance and comments
Axial resolution	Accuracy in identifying as separate two reflectors positioned parallel to the US wave	Spatial pulse length, beam former and transducer are in accurate and consistent conditions
Lateral resolution	Accuracy in identifying as separate two reflectors positioned perpendicular to the US wave in the imaging plane	Transducer elements and beam former with correct functioning
Elevational resolution (beam thickness)	Accuracy in identifying the details of reflectors positioned perpendicular to the US wave and perpendicular to the scanning plane	A thin US beam of a quality transducer, used with the adequate frequency and focusing, assures minimum partial volume artifacts and maximum margin details of lesions
Registration (calibration)	Accurate imaging of a pin in its size and location with correct representation of vertical and horizontal distances	Accurate size representation and measurements are critical components of US imaging
Dead zone	The problematic quality of the first centimeters from the transducer's face, in the image, is tested	If the low-quality distance of the dead zone increases, the system has developed malfunctioning in pulsing or transducer elements
Sensitivity, contrast resolution and uniformity	The detection of weak echos, the uniform display of reflectors' brightness throughout the image, and the correct differentiation of tissues with varying sound impedance	After proper adjustments of the time gain compensation, sensitivity and image uniformity failure represent transducer or output deficiencies

Easy-to-use methods

The US user can carry out some basic tests without phantoms, such as the air test [1, 10]. In the air test, the transducer is put in function in the air with a clean and dry face in its routine clinical pre-set with the frequency in its lowest value and the gain in the maximum level (both overall gain and time gain compensation) [1]. The image obtained is one of a series of horizontal bands of reverberation due to the transducer–air impedance mismatch. These series of reverberations are used for a first line subjective evaluation assessing eventual faulty crystal elements (vertical line of reduced echos is seen), uniformity of image, transducer sensitivity and image noise [1]. The US user can conserve a hard or soft copy of this image at the time of machine's purchase and use it for relative testing and for future comparative images checking uniformity, noise, sensitivity and maximum depth at which the reverberations can be measured (penetration that can be measured with the calipers). Furthermore, localized bright or dark areas can be detected, which can be a sign of transducer lens failure.

Noise has to be distinguished from speckle in this test; noise is only the fluctuating echos that come and go between frames, whereas speckle is the unchanging pattern of echos [1, 5]. Noise is clearer in the depths where the last reverberations are weak and the noise predominates. The operator can then calibrate by reducing the overall gain to the point where noise is minimal and the reverberations are still clear. This position of the knob of the overall gain is then signed and used in the routine examinations [1] (Figs. 1, 2).

Another method for detecting faulty transducer elements is performed by applying a small amount of gel on the probe face, and sliding over an opened paper clip. In faulty elements, low brightness of the column of echos is shown [5] (Fig. 3).

Phantoms

Tissue-mimicking test objects for gray-scale evaluation and Doppler test objects are required for accurate QA, both absolute and relative [1, 2, 5] (Fig. 4). Phantoms can be of general purpose testing a number of image characteristics, or specific purpose ones capable of assessing one or a few imaging parameters (Table 3). Gray-scale phantoms test the device's resolution (spatial and contrast), sensitivity and calibration which evaluate the measurement accuracy of the machine (Figs. 4, 5). Special tissue mimicking test objects for breast imaging are designed by most of the manufacturers of US phantoms as superior requisites have to be

Table 2 List of some of the international societies that have established standards for US equipment and imaging QA

Organization	Website and other reference
EFSUMB—European Federation of Societies for Ultrasound in Medicine and Biology	www.efsumb.org [5]
IPEM—Institute of Physics and Engineering in Medicine (registered in England and Wales)	www.ipem.ac.uk [1]
WHO—World Health Organization	[1]
AIUM—American Institute of Ultrasound in Medicine	www.aium.org
ACR—American College of Radiology	www.acr.org
IAC—Intersocietal Accreditation Commission (registered in USA)	www.intersocietal.org/echo with focus on vascular US
IEC—International Electrotechnical Commission (based in Geneva, Switzerland)	www.iec.ch

Table 3 Test objects for US quality assurance, also called US phantoms

Type of phantom	Architecture of construction	Use and measurements
General resolution phantom	Filaments, pins and tubes at varying depths, of varying size and impedance	Axial and lateral resolution, penetration, calibration, geometrical accuracy
Breast resolution phantom	Filaments or pins and tubes at varying depths, of varying but small, size, and different impedance	Axial and lateral resolution for breast application of high-end devices
Slice thickness phantom	Filament or tubes in diagonal position; or spheres	Elevational (azimuthal) resolution
Crystal control phantom	Simple simil-tissue material without internal elements	Detection of malfunctioning crystal elements and transducer artifacts
Color Doppler phantom	Motor moving a string, or a pump circulating in tubes a simil-blood fluid	Penetration of doppler signal imaging and velocity measurements
Elasticity phantom	Materials of varying rigidity	Evaluation of accuracy of US elastographic techniques

Fig. 1 In the air test, the transducer is put in function in the air, with a clean and dry face. The image obtained is one of a series of horizontal bands of reverberation due to the transducer–air impedance mismatch. The measurement of the depth of “in-air” reverberations as a proxy for sensitivity is performed by positioning the caliper at the maximum depth in which the reverberations arrive. (Courtesy of Institute of Physics and Engineering in Medicine)

met for quality breast US. Doppler test phantoms perform assessment of the Doppler beam for depth penetration and sensitivity, flow direction, accurate sample volume location

and velocity measurements [11]. Furthermore, other special phantoms are required for elasticity imaging of both the qualitative and quantitative variants [12].

Fig. 2 The overall gain reduction to measure the noise threshold. The noise is only the fluctuating echos that come and go between frames, whereas speckle is the unchanging pattern of echos. Noise is clearer in the depths where the last reverberations are weak and noise predominates. On the right-side image, the operator can calibrate by reducing the overall gain to the point where noise is minimal and the reverberations are still clear. This position of the knob of the overall gain is then signed and used in the routine examinations

Fig. 3 The paperclip test in which the passage of the metal object over the probe face reveals the effects of the crystal drop-out (black line in the middle of the white reverberation)

Fig. 4 Photo of ultrasound test phantoms of the Gammex manufacturer

Test objects are supplied with instructions for testing and interpretations of results with a series of evaluations that need to be logged with details in the records of the QA program.

The tissue-equivalent test objects consist of an aqueous gel and graphite particles that build up a medium with transmit sound wave velocity equal to the average velocity of tissues of 1540 m/s. At the same time, the impedance and attenuation rate of this environment is similar to that of soft tissues. Varying with the manufacturer's compositions, yet common to all phantoms, is a deterioration over time (usually years) of the acoustic properties of the tissue mimicking medium with progressive loss of quality and functionality. Manufacturer's instructions need to be followed in regard of the monitoring the storage area temperature, and not damaging the integrity of the airtight container [13]. Most

Fig. 5 General purpose phantom for low-contrast penetration measurements, with which one can measure spatial and contrast resolution, sensitivity and calibration

manufacturers offer a long warranty and ensure for their phantoms over 10 years of reliable use through reinspection and repair services.

In the gray-scale phantom throughout the tissue equivalent medium, stainless steel pins or filaments, and tubes or spheres, are strategically located. When testing, pins need to

be accurately identified and located as well as the tubes or spheres of varying echogenicity (that mimic from anechoic cysts to a range of solid masses) must be correctly visualized (Fig. 5).

Usually, the elevational (azimuthal) resolution, which corresponds to the thickness of the US beam, needs a

Fig. 6 Example of composite evaluation with four different gray-scale phantoms, using various resolution targets, echoic and anechoic targets

Fig. 7 This model of ATS manufacturer phantom offers basic testing for QA. The design consists of a combination of monofilament line targets and six tissue mimicking cylindrical targets of varying sizes. Four groups of line targets are provided to evaluate the vertical and horizontal calibration measurements, axial–lateral resolution and the dead zone. Test uses are: dead zone or ring-down, vertical measurement calibration, horizontal measurement calibration, sensitivity/penetration, functional resolution, focal zone, axial and lateral resolution, and image uniformity

specialized phantom for accurate evaluation and almost all manufacturers produce a separate special phantom for this purpose. Some manufacturers use spheres instead of the commonly used tubes in the resolution phantom, offering the possibility to evaluate in the direction perpendicular to the

plane of US beam (the elevational resolution). In the case of thick beams, echos fill the simil-cystic spheres (Figs. 6, 7, 8).

The Doppler phantoms utilize either a small engine moving a string or belt, or the modern ones, a simil-blood circulating fluid with a pump [11].

Fig. 8 The CIRS multi-purpose phantom is a general-purpose QA phantom for low- and high-frequency probes (2–15 MHz) adaptable with detachable scanning wells, thus capable of testing curvilinear, linear and endocavitary probes. Tests that can be performed are: uniformity, depth of penetration, beam profile/focal zone/lateral response width, vertical distance measurements, horizontal distance measurements, axial and lateral resolution, elevational resolution, contrast resolution, grayscale contrast sensitivity, elasticity sensitivity, and dead zone assessment

Fig. 8 (continued)

US breast imaging and QA

Although the role of US in the diagnostic algorithm of breast imaging is still debated among experts, a firm point of unanimous agreement is the emphasis that US equipment for breast evaluation should be high-end machines with the best of possible capabilities. Superior imaging aspects such as fine resolution, both spatial and contrast ones, are needed for quality breast US. Some authors advocate the use of one-and-a-half dimension matrix array instead of the usual linear array probe [14] which achieves high elevational resolution with the possibility to focus not only in the lateral direction, like all probes, but also in the azimuthal direction producing a very thin beam. This is needed to obtain superior margin details of lesions and avoiding partial volume effects. These quality characteristics, as, for example, detecting a single angle (even obtuse) in a small breast nodule, signify a 60% diagnostic probability of cancer [15].

For QA of US breast units, specialized gray-scale phantoms developed for high-resolution scanners and slice thickness phantoms are needed.

Conclusions

Guarantee of quality of ultrasonic systems is essential through care and preventive maintenance of the machine for ensuring accurate performance [16].

Daily optimal operation of the US system should be observed by the user and any deficiency or fault should be immediately reported and repaired.

The US operator can perform some basic tests to obtain an objective evaluation. Phantom testing yields an exact assessment of the US equipment needed to ensure quality control/QA.

Particularly relevant is an optimal quality review of breast US which needs high elevational resolution.

The absence of a quality assurance could undermine the diagnostic quality of US examination and expose the operator to innumerable risks, including for the health of the patient [17].

Compliance with ethical standards

Conflict of interest Authors declare that have no conflict of interest.

Informed consent Informed consent was not necessary for this type of study.

Research involving human and animal rights This paper does not contain any studies with human participants and/or animals performed by any of the authors.

References

1. Institute of Physics and Engineering in Medicine (IPEM) (2009) Quality assurance of ultrasound imaging systems, report no. 102. York
2. American College of Radiology (ACR) (2011) ACR technical standard for diagnostic medical physics performance monitoring of real time ultrasound equipment Res.3. www.acr.org/Quality-Safety/Standards-Guidelines/Technical-Standards-by-Modality/Medical-Physics

3. Laurel MD (2008) American institute of ultrasound in medicine (AIUM). Routine quality assurance for diagnostic ultrasound equipment. Report 2008. USA
4. Martensson M, Olsson M, Segall B et al (2009) High incidence of defective ultrasound transducers in use in routine clinical practice. *Eur J Echocardiogr* 10:389–394
5. Kollmann C, deKorte C, Dudley NJ, Gritzmman N, Martin K (2012) Evans DH; EFSUMB technical quality assurance group–US-TQA/B. Guideline for technical quality assurance (TQA) of ultrasound devices (B-Mode)–version 1.0 (July 2012): EFSUMB technical quality assurance group–US-TQA/B. *Ultraschall Med* 33(6):544–549
6. Mrazek-Pugh B, Blumenfeld YJ, Lee HC, Chueh J (2015) Obstetric ultrasound quality improvement initiative-utilization of a quality assurance process and standardized checklists. *Am J Perinatol* 32(6):599–604
7. Mårtensson M, Olsson M, Brodin LÅ (2010) Ultrasound transducer function: annual testing is not sufficient. *Eur J Echocardiogr* 11(9):801–805
8. King DM, Hangiandreou NJ, Tradup DJ et al (2010) Evaluation of a low-cost liquid ultrasound test object for detection of transducer artefacts. *Phys Med Biol* 55:N557–N570
9. Hangiandreou NJ, Stekel SF, Tradup DJ et al (2011) Four-year experience with a clinical ultrasound quality control program. *Ultrasound Med Biol* 37:1350–1357
10. Dudley NJ, Griffith K, Houldsworth G et al (2001) A review of two alternative ultrasound quality assurance programmes. *Eur J Ultrasound* 12:233–245
11. Grice JV, Pickens DR, Price RR (2016) Technical note: a new phantom design for routine testing of doppler ultrasound. *Med Phys* 43(7):4431
12. Cantisani V, David E, De Virgilio A, Sidhu PS, Grazhdani H, Greco A, De Vincentiis M, Corsi A, De Cristofaro F, Brunese L, Calliada F, Blandino A, Tombolini M, Ascenti G, Stramare R, Caratozzolo M, D'Ambrosio F (2017) Prospective evaluation of quasistatic ultrasound elastography (USE) compared with baseline US for parotid gland lesions: preliminary results of elasticity contrast index (ECI) evaluation. *Med Ultrason* 19(1):32–38
13. Russell S (2014) Ultrasound quality assurance and equipment governance. *Ultrasound* 22(1):66–69. <https://doi.org/10.1177/1742271X13517694>
14. Berg WA, Bandos AI, Mendelson EB, Lehrer D, Jong RA, Pisano ED (2015) Ultrasound as the primary screening test for breast cancer: analysis from ACRIN 6666. *J Natl Cancer Inst* 108(4):dju367
15. National Health Service (NHS) (2011) Guidance notes for the acquisition and testing of ultrasound scanners for use in the NHS breast screening programme. NHSBSP Publ. #70. <http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp70.html>. Accessed 26 June 2012
16. Dudley NJ, Chapman E (2002) The importance of quality management in fetal measurement. *Ultrasound Obstet Gynecol* 19(2):190–196
17. Silosky MS, Marsh RM, Scherzinger AL (2016) Imaging acquisition display performance: an evaluation and discussion of performance metrics and procedures. *J Appl Clin Med Phys* 17(4):334–341. <https://doi.org/10.1120/jacmp.v17i4.6220>

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