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Technical Quality Evaluation of diagnostic ultrasound systems - a comprehensive overview of regulations and developments

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Introduction

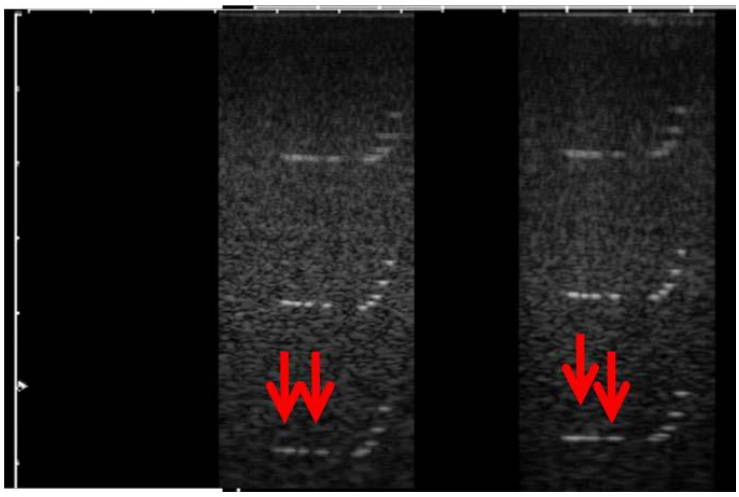
Problems related to the safety of ultrasound applications are judged from the point of view of patients, nursing and examining personnel. Also, ultrasound biological effects have predominated since ultrasound has been used in medicine [(1)]. The direct effects of ultrasound energy on living tissue have been examined intensively. The danger inherent in the possibility of incorrect treatment resulting from erroneous diagnosis based on misinterpretation of the sonogram has only been taken into consideration in the last decade of the 20th century. Misinterpretation is possible owing to artifacts. Artifacts, ie faulty interpretation of the image during ultrasound diagnosis, can lead to incorrect harmful treatment. When evaluating the risks of such artifacts, it is necessary to differentiate objective and subjective factors.

Objective risk factors include imaging physical artifacts and inadequate quality of equipment imaging caused by low technical standards, poor maintenance or the age of the equipment. **Subjective factors relate to the skills of the examiner** include unfamiliarity with the physical mechanisms of ultrasound image creation, lack of skill in operating the equipment and hence inability to set the optimal working parameters, lack of knowledge of the topographic anatomy necessary for correct image interpretation, inborn characteristics of the observer such as spatial imagination and the ability to abstract what is seen.

Physical artifacts are based on the physical properties of ultrasound waves and the environment in which they are propagated. As such they are unequivocally definable according to physical laws and to eliminate them, it is necessary to apply appropriate procedures and imaging methods. If these recommended appropriate methods do not exist, the physical laws must be accepted and taken into consideration. In this case eliminating the risks is totally dependent on the experience and knowledge of the examiner and the above subjective characteristics. On the other hand, the scanner´s imaging quality is a factor completely dependent on the technical parameter of the equipment. In order to increase the imaging quality or eliminate imaging defects and thus reduce the potential risks of image misinterpretation, it is necessary to create a complex system for determining and objectively evaluating the relevant qualitative parameters [(2)]. This is very difficult to achieve and requires the definition of the parameters of sonographic imaging quality, development of

suitable measuring methods, procedures for their evaluation and the creation of a graded system of scanner´s quality criteria and last but not least strong legal regulations are necessary to apply the methods to practice.

Figure 1 Example of decrease in lateral spatial resolution (red arrows mark targets within a phantom) due to defective elements



Many International Standards (see Table 1) and recommendations e.g. [(2, 3)] have been introduced over the last decades and commercial testing objects mostly for the B-mode of imaging are available on a commercial basis. These contain defined non-homogeneities and the image is analyzed subjectively by the operator or the use of computer aided analysis. To fulfil the all important physical criteria for correct mimicking of the tissue [(4, 5)], the test object construction has to be rather sophisticated. This kind of testing method is fast and relatively inexpensive, but obviously measurements are burdened with an error resulting from subjective assessment of image quality and scanner adjustment, even with the use of computer technology support. It is obvious that quantitative and accurate evaluation of the imaging quality is very difficult and, internationally, there are only very few institutes dealing with the problems using the methods mentioned above.

2 Standards and official recommendations

There are several regulatory bodies and professional societies concerned about technical parameters and quality assessment of sonographs world wide. The International Electrotechnical Commission ((6)) administers technical standards even for medical applications. The U.S. Food and Drug Administration [(7)] serves as a sample of a governmental office having the power to control the safety, quality and effectivity of medical instruments. The World Federation for Ultrasound in Medicine and Biology (WFUMB) heads and federates medical oriented staff over the World consisting of physicians, physicists, engineers and ultrasonographers [(8)].

International standardization body (IEC)

The International Electro-technical Commission (IEC) is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. These serve as a basis for national standardization and as references when drafting international tenders and contracts.

The IEC standards library contains in addition to the electrical safety standards of group IEC 61601 also standards related to the ultrasonography and ultrasonic medical applications. These standards do not relate directly to the patient and operator safety, but to the equipment's technology; measurements of applied ultrasound energy physical properties and ultrasonic medical equipment particular parameters measurement methods. Due to an impact on the patients with quality of application during examination, some of the standardized objects may affect safety too.

Table 1 The list of the IEC standards exception the IEC 60601 family related to the ultrasound medical applications

IEC TR 60854	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment.
IEC 61157	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment.
IEC 61205	Ultrasonics - Dental descaler systems - Measurement and declaration of the output characteristics.
IEC TS 61206	Ultrasonics - Continuous-wave Doppler systems - Test procedures.

IEC 61266	Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting.
IEC TS 61390	Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications.
IEC TS 61391-1	Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response
IEC 61391-2	Ultrasonics- Pulse-echo scanners - Part 2: Techniques for measurement of maximum depth of visualization and the displayed dynamic range.
IEC 61685	Ultrasonics - Flow measurement systems - Flow test object .
IEC 61689	Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz .
IEC 61828	Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields.
IEC 61846	Ultrasonics - Pressure pulse lithotripters - Characteristics of fields.
IEC 61847	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics.
IEC TS 61895	Ultrasonics - Pulsed Doppler diagnostic systems - Test procedures to determine performance.
IEC 61949	Ultrasonics - Field Characterization - In-situ exposure estimation in finite-amplitude ultrasonic beams.
IEC 62126	Ultrasonics - Fields: Methods for computing temperature rise in homogeneous soft tissue for diagnostic ultrasonic fields.
IEC 62359	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.
IEC 62377	Ultrasonics - Colour flow imaging systems - Test procedures to determine performance.
IEC 62462	Ultrasonics - Output test - Guidance for the maintenance of ultrasound physiotherapy systems
IEC 62555	Ultrasonics - Power measurement - High intensity therapeutic ultrasound (HITU) transducers and systems
IEC TS 62556	Ultrasonics - Field characterization - Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems
IEC TS 62558	Ultrasonics - Real-time pulse-echo scanners – Phantom with cylindrical, artificial cysts in tissue-mimicking material and method for evaluation and periodic testing of 3d-distributions of void-detectability ratio (VDR)
IEC TS 62736	Ultrasonics - Pulse-echo scanners - Simple methods for periodic testing to verify stability of an imaging system's elementary performance
IEC TS 62791	Ultrasonics - Pulse-echo scanners - Low-echo sphere phantoms and method for performance testing of gray-scale medical ultrasound scanners applicable to a broad range of transducer types
IEC TS 62900	Ultrasonics - Field Characterisation - measurement-based simulation in water and other media
IEC TS 62903	Ultrasonics - Measurements of electroacoustical parameters and acoustic output power of spherically curved transducers using the self-reciprocity method
IEC TS 62937	Measurement of ultrasound field parameters at high pressure therapeutic levels in water
IEC 63009	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the

	frequency range 20 kHz to 0.5 MHz
IEC 63045	Ultrasonics - Non-focusing pressure pulse sources - Characteristics of fields
IEC 63070	Ultrasonics - Field characterization - Infrared imaging techniques for determining temperature elevation in tissue-mimicking material and at the radiation surface of a transducer in still air

Official quality maintenance within the United States

Some national regulatory governmental agencies are oriented to medical care. Among the worldwide national regulatory agencies is the FDA (Food and Drugs Administration), which is an agency within the Department of Health and Human Services of the USA government. The FDA is responsible for protecting the public's health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation [(9)].

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable and by helping the public to get the accurate, science-based information they need to use medicines and foods to improve their health. Other national regulatory agencies around the world mostly accept the FDA-established guidelines.

The FDA places the ultrasound imaging appliances into a subgroup of Medical Imaging with Radiation-Emitting Products and Procedures. The Ultrasound Imaging clause consists of eight paragraphs. These contain brief but comprehensive information for both, patients and professionals. There is a note in the paragraph concerning laws and standards declaring that "there are no federal radiation safety performance standards for diagnostic ultrasound". But it concludes in the Risk/Benefits analysis, within the first sentence: "Ultrasound imaging has been used for over 20 years and has an excellent safety record. It is non-ionizing radiation, so it does not have the same risks as X-rays or other types of ionizing radiation" [(7)].

Official quality maintenance within the European Community

The medical appliances quality maintenance in EU is based on the Council Directive 93/42/EEC concerning Medical Devices [(10)], which is also called Medical Devices Directive (MDD) and covers areas such as placing on the market and putting into service. The directive

establishes essential requirements and harmonized standards for the manufacture, design, and packaging of medical devices. A medical device is defined as any instrument, apparatus, appliance, software, material or other article used to support medical care. Since 14 June 1998 no medical device covered by the MDD 93/42/EEC could be placed on the market that did not carry a CE mark. The CE mark proves both to the authorities and to the buyer -or user- that this product fulfils all essential safety and environmental requirements as they are defined in the so-called European Directives. There are two basic aspects to the CE mark the device. Firstly – any official responsible body in the EU (manufactures, distributor, service person, importer etc) should be labelled and secondly – a document "Declaration of Conformity" which states that the apparatus complies to the requirements of the directives as stated on the declaration, so following the standards as indicated and thus its parameters and quality correspond with the aim of its use and it is safe for use.

The Medical Devices are classified by the MDD according to their invasivity and risk, into four classes. Ultrasonographs and most of ultrasound therapeutical appliances belong to the Class IIa. A non-sterile coupling gel is a member of the Class I. The Class II equipment (and upwards) requires the involvement of a notified body that will approve customers documentation and/or Quality Management System.

The MDD 93/42/EEC has been modified by the 2007/47/EC, an amendment which was established on September 5, 2007 and the consolidated directive has been mandatory since March 21, 2010. The amendment changed the definition of a medical device, things now not considered a medical device, explanation of the Member State's role, etc.

The medical device quality and safety has the full responsibility of its distributor at the moment of purchase and installation. After sale, safety and quality aspects are transferred to the user. The user then has to ensure proper periodical maintenance and electrical safety checks.

A proper maintenance and quality assurance check is vital for effective use of medical technology with patient safety being paramount. However, a serious problem is lack of authority and expertise in evaluating systems, to ensure periodical inspections, for quality assessment of the ultrasonographs. Industry and marketing are supported well with standards on technology and production quality management and in some countries even the law is used to enforce the appropriate standards. But the after-sale care isn't so well specified. The medical systems in use must be periodically inspected for electrical safety

only, not to check quality and effectivity of their function. Periodic maintenance is recommended, but not exactly specified. The periodic maintenance range depends on a particular authorized service body and user owner. This is a management decision and it is not standardized [(11)].

International & national Ultrasound societies with QA activities

Some International and Nation wide organizations and/or societies exist with interests in ultrasound scanners´ technical evaluation. They may be devided into two main groups according to their main specialization – technology and/or medicine oriented organizations. Table **2** contains these most known and active societies in the QA field. One goal held by these bodies is to manage the best professional level of ultrasound applications in medicine. In the diagnostic field of ultrasound applications the scanners performance evaluation contributes well to reaching this goal**.**

Table 2 List of some international societies including their home websites related to the ultrasound scanner measurements and QA.

Technology oriented societies	NEMA - National Electrical Manufacturers Association	www.nema.org
	NCRP - National Council of Radiation Protection & Measurements	www.ncrponline.org
	ICRU - International Commission on Radiation Units and Measurements	www.icru.org
	IPEM - Institute of Physics and Engineering in Medicine, York	www.ipem.ac.uk
	Ultrasonic Industry Association	www.ultrasonics.org
	IEEE - UFFC Ultrasonics, Ferroelectrics, and Frequency Control Society	www.ieee-uffc.org
	AAPM - American Association of Physicists in Medicine	www.aapm.org
Medicine oriented societies	WFUMB - World Federation for Ultrasound in Medicine and Biology	www.wfumb.org
	EFSUMB - European Federation of Societies for Ultrasound in Medicine Biology	www.efsumb.org
	AIUM - American Institute of Ultrasound in Medicine	www.aium.org/
	BMUS - British Medical Ultrasound Society	www.bmus.org
	ÖGUM – Austrian Society of Ultrasound in Medicine	www.oegum.at

	ISCU - International *Society* of Cardiovascular *Ultrasound* (ISCU)	www.iscu.org
	ISUOG - International Society of Ultrasound in Obstetrics and Gynecology	www.isuog.org
	ACR - American College of Radiology (ACR)	www.acr.org

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Technical quality initiatives

Within the last two decade there have been some quality initiatives over Europe concerning on technical aspects in sonography. Most of them were locally, only in one hospital or department or started by some ultrasound enthusiasms to demonstrate the need and the missing of these kind of tests.

But within the last years there is a change of view and an understanding that the most used clinical imaging modality is not extensively nor regularily (apart from the electrical safety tests) checked.

Three different initiatives will be presented as examples for projects that tend to include a wider numbers of ultrasound systems or to have model character for the future and other related national/European projects:

- **Sonobaby** of the Bavarian Health Association (KVB, active 2011-2013)
- **TQS-Sono** of the Mammo-Screening Reference Center for technical Quality Assurance in Austria
- **QA-Group** of EFSUMB

Sonobaby

During two years (2011-2013) the Bavarian action involved gynaecologists who got an financial bonus if they could prove a regular system maintenance and performing examinations only with systems that represent the actual technical status together with personell high diagnostic competence [(12)]. The ultrasound systems including transducers

had to be checked in a 2-years interval by an accreditated maintenance company to ensure a high image quality. The following items are tested:

Table 3 List of tested items.

	topics checked	
Sonobaby	- display/monitor status	- axial & lateral resolution
	- transducer losses/defects	- slice-thickness resolution
	- TGC-function	- transducer element losses/defects
	- overall function of system	- geometric resolution
	optional:	- special transducer acceptance values
		- data acquisition & documentation system
		- signal-noise-ratio

Special test equipment is needed for these kind of tests but no information was provided about the regulations for the measurement procedures.

TQS-Sono

This initiative is part of the Austrian technical Quality Assurance Reference Center for Mammo-Screening (www.mammoscreening-tqs.at) that has to guarantee the technical quality of the x-ray and ultrasound units involved in the national breast screening project. According to the established European guidelines EUREF (www.euref.org), a special guideline named EUREF-Ö has been prepared to cover the needs of involved ultrasound systems for breast screening from Bi-RADS level 3. The initiative includes the 2-level technical testing concept [(13)] proposed by the ÖGUM (www.oegum.at) but adopted it to the technical requirements for ultrasound breast scanning systems [(14)]. Within this scheme each system undergoes an acceptance test, monthly simple user tests with a special software (see chapter Firstcheck, [(15)]*)* and, finally a yearly detailed test done with phantoms including separate transducer tests by certified experts. The following items are tested:

Table 4 List of tested items for Level 1 and Level 2 tests.

	topics checked	
Level 1 (user tests with software)	- mechanical system damages	- power of system (start/boot)
	- transducer losses/defects	- size of active transducer area
	- TGC-function	- signal-noise-ratio
Level 2 (phantom tests)	- functional resolution	- 3D-spatial resolution
	- uniformity	- sensitivity
	- calliper function	- maximum penetration depth
	- contrast/dynamic	- display/monitor status
	- transducer status	

All parameters are evaluated with available software using DICOM ultrasound image format. If special test equipment is needed for these kind of tests the information is provided as well as the suitable measurement procedures that are mainly adopted from technical IEC Standard documents.

QA-Group EFSUMB

In 2008 the EFSUMB board established a Quality Assurance Group to develop a guideline for technical quality control (www.efsumb.org) of diagnostic ultrasound imaging systems. This group was collecting all available literature and documents to this topic, and studied the QA initiatives that were published online. In 2012 the group published a guideline that give some advice to test objects, phantoms, methods, software and other equipment that is suitable to perform a technical quality evaluation or performance test on a suitable, reproducible, effective way for clinical applicability [(16, 17)].

The group has put the focus on already established and implemented concepts (e.g. from Germany, Austria and UK) as well as procedures published by the Institute of Physics and Engineering in Medicine (IPEM, York, [(18-20)]*)* to establish an accepted common European Guideline for technical Quality Assurance.

Methods used for quality evaluation (scanner performance)

Recently a few measuring methods for technicians, producers, designers and also metrologists have been made available for a wide range of ultrasound scanners, their

parameters and assessments. Two main attempts to QA are important. They differ according to the scheme of use or by the way the results are utilised. The first classification, is the scaling measuring methods, with this classification being based on their frequency of application and level of use. Another one evaluates methods by accuracy and reliability. Indeed some parameters affecting measuring applications are the method's price and availability in practice. Other factors are skills required by the operator and additional test equipment necessary for evaluation.

Ultrasound quality evaluation means to identify the actual status of a system (including console, transducer(s), display and peripheral equipment) at a level that is expected. This should be done in a regular scheme (daily ↔ annually) depending on the effectiveness and clinical relevance of the tests.

These test can be simple tests, i.e. no or simple test equipment is needed or more sophisticated tests using test objects (phantoms) or other specialised equipment. Depending on the deployed test equipment different level of personell training and skills are necessary for performing these tests. The test can also be focussed on 3 testing criterias [(19)]:

- acceptance

(to determine so far as possible that the performance of a system is of a required standard and at a level that is expected)

- baseline

(to make a reference measurement of performance on a system. These measurements are identical to those performed as routine tests but are repeated several times to establish a baseline average)

- routine

(to determine wether the system continues to perform to the same standard as at the reference measurement. They may also be performed reactively if a query on performance is raised)

Simple tests

Under these name test procedures or methods are summarized that can be performed by the operator or clinical personell who needs no special QA maintenance skills. No additional or equipment only available in a lab is used for these kind of system testing. In the last years several researcher and groups proposed procedures for a number of different parameters [(19-22)]:

Table 5: Parameters tested by different procedures.

simple tests proposed for :	
- mechanical system damages	- power of system (start/boot)
- transducer losses/defects	- size of active transducer area
- TGC-function	- signal-noise-ratio
- sensitivity	- noise
- aperture width	- scale/calliper conformance

The number of failures affecting the scanner´s imaging quality may be discovered by simple every day tests performed by an operator or hospital engineer. Such tests may detect, for example: drop-out of crystals in the transducer, dead zone shift, a decrease of maximum depth of penetration, changes of contrast range, sensitivity and noise limits. Frequent (daily or weekly) periodical simple quality parameter testing is vital for safe and effective patient diagnostic imaging. This kind of test doesn't require expensive instruments and technically skilled person. The time needed to perform such a test is only a few minutes and doesn't interfere with a sonographer's routine working schedule [(16, 22)].

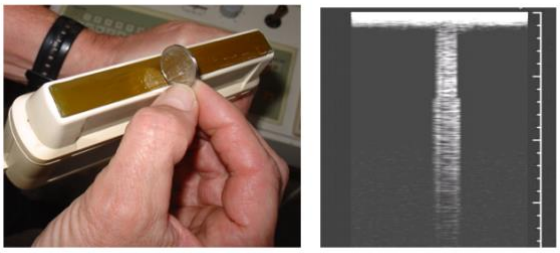
It is clear, that such simple and quick tests cannot substitute accurate laboratory measurements. An argument for their use is the importance of a continuous periodical checking on scanners which are heavily loaded in a standard health care system. In such conditions the probability of any damage, namely of transducer or its cable is rather high.

Also due to the complexity of the sonographic picture there is not really any chance for the operator to discover a problem unless regular testing is performed. All these facts support the idea of the periodical scanner quick check, even if it is still very rare in a practice.
The next paragraphs will give some examples of these tests.

Example: Transducer losses/defects (“paperclip” or “coin” method)

This is a very easy, cheap and effective method which is known as the electronic multielement transducer dead element(s) discovering. The method is not suitable for phased array transducers. The method is based on multiple back reflections generated at an irradiated metal object surrounded by air. The multiple reflections are imaged as an echogenic scanning lines of all the apertures containing the element irradiating the metal object. A simple metal object may be used eg paperclip wire or any narrow coin. The name of the method expresses this fact.
Even if the method is very simple, some important data concerning aperture width and range of focal areas for multiple dynamic focussing may be obtained. This information is derived from the fact that the signal received by one element is displayed as a signal from whole aperture. The multiple reflected signal is displayed by all the scanning lines having apertures containing the elements in contact with the metal object. The echogenic beam width is twice the width of the receiving aperture [Figure 2].
The dead element doesn’t generate and/or receive the multiple reflection signal, therefore the echogenic lines disappear when the reflecting object is positioned in front of the dead element.

Figure 2 The „coin test“ – simple test for transducer function, aperture width and dynamic focussing focal depth.



Example: FirstCheck

The Austrian Society for Ultrasound in Medicine [(13)] try to assure the quality of the ultrasound machine and its equipment with the help of technical guidelines [. There has been an initiative to store and evaluate the checked parameters in a software called “Firstcheck” [(15)]. One key issue of the project was the evaluation of the procedures and to develop the software. “Firstcheck” is able to measure most of the procedures from the suggested guidelines [(22)]. The user can get first information about the actual state of the ultrasound unit and will be able to introduce effective attendances, which are so far reserved to professional companies.

Beside the ÖGUM, also the Austrian Mammography-Screening Reference Center for Technical Quality Control (www.mammoscreening-tqs.at/) has been a collaborational partner for the procedures and software.

Figure 3 Start window of the software Firstcheck

Sophisticated tests or Phantom based tests

The most well known method for apparative or technical quality assessment uses different types of ultrasonography test objects also called phantoms. The phantoms are available in a wide range of types from different producers and contain various types of reflectors (Table 6); naturally they are filled using material of similar acoustic parameters to soft tissue.

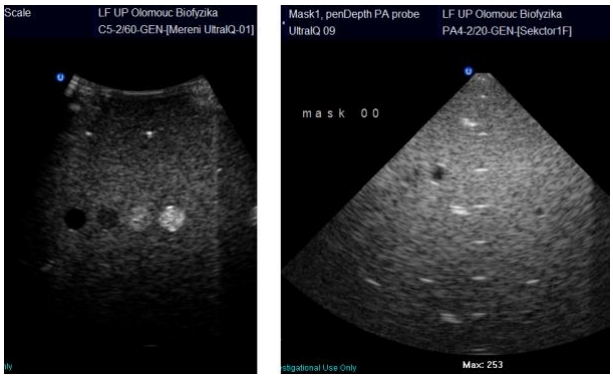
Table 6 Manufacturers of test objects (phantoms for quality assurance (QA))

Manufacturer	Models available for QA:	Type of tests:
ATS	various	Multipurpose
CIRS	various	Multipurpose
Dansk Fantom Service	various	Multipurpose
Diagnostic Sonar	various	Multipurpose
Gammex-RMI	various	Multipurpose
Kyoto Kagaku	various	Multipurpose
TCC	various	3D-signal-noise-ratio

The test objects are used to estimate: spatial and contrast resolution, depth of penetration, elevation of focal area position, with available table parameters and distance plus

measurement accuracy etc. Simple test objects may also be improvised with the use of suitable reflectors, positioned in ultrasound conducting media e.g. liquid, gel or a solid block. Professional test objects guarantee specific acoustic parameters that have to be tested periodically by the responsible authority for their stability. Such authority may be the test object's manufacturer, National metrology laboratory or a commercial laboratory accredited by another responsible authority.

Figure 4 One of commercially available tissue mimicking objects with samples of its scans. The left picture was made by a convex transducer and evaluates gray resolution targets, the right one was scanned by a phased array sector transducer to check spatial resolution and the accuracy of depth penetration distance measurements. Scanner: Sonix RP.



Standard manual measuring procedure using the test object starts with positioning the transducer onto acoustic window(s) of the phantom to obtain a sonogram of it's inner structures. Then the measured scanner must be adjusted well enough to obtain optimum quality of the image. After that an operator evaluates the observed image and records all reported data along with: the measured scanner and transducer identification, the scanner´s working parameters setting, ambient conditions and observed results.

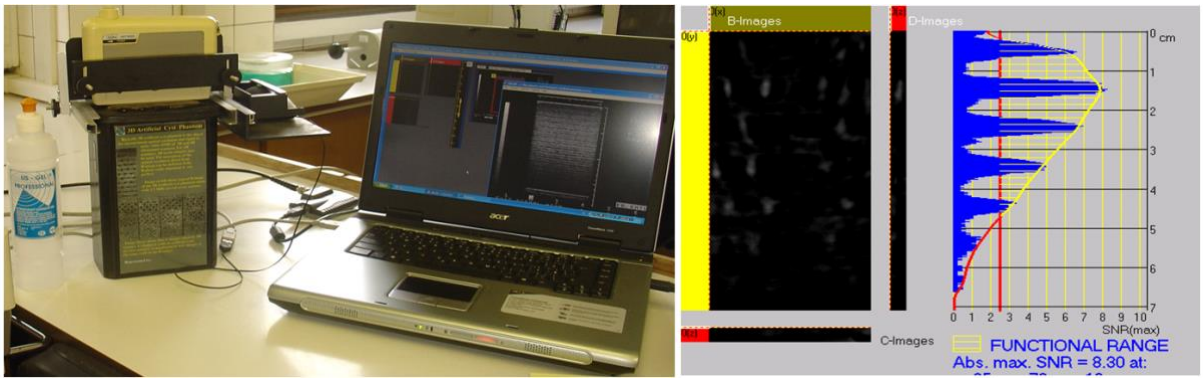
Most of the test object methods suffer from results dependent on the adjustment of the system´s working parameters such as: gain, dynamic range, look-up table, dynamic focussing, non-linear post-processing etc. for a particular measurement. Another remarkable

and noteworthy difficulty is a subjective evaluation of the resulting image by the operator. Some software tools evaluating the digitalized images of professional test objects have been designed over the years to eliminate or decrease the influence of the operator subjectiveness. The computer assisted image analysis mostly eliminates subjective misinterpretations of the image details such as brightness assessment but still has the subjective factor of scanner parameters adjustment for a particular measurement.

Example: 3D-Signal-noise ratio or voids detectability ratio

With computer assisted measuring methods, two methods may be mentioned. The first is from Rownd, Madsen, Zagzebski, Frank and Dong [(23)] and finalized by Satrapa [(24)] to a IEC Technical Specification [(25)]. The method applies spatial analysis of the signal-to-noise ratio in a three-dimensional image of a special voids containing test object. The analysis results in imager & transducer set characterization by using the parameter VDR (Voids Detectability Ratio) that is derived from small amplitude signals generated by low reflectance structures, similar to the signal obtained from real tissue, such as the kidney or liver. This method is suitable for reviewing measurements quickly and is substantially more objective than the methods referred to the signal-noise ratio (SNR) parameter previously. Its main disadvantage is in displaying a depth dependent integral parameter derived from a specified plane in a lateral and transversal direction; resulting in the fact that one cannot determine the lateral details of the image defects. Also, the analysis of a spatial image distortion and characterization of the system for high amplitude reflected signals is not possible.

Figure 5 The test to detect the presence of voids is shown together with transducer and test object (TCC phantom). The measured linear transducer is fixed on top of the test object and the notebook is running the evaluation program to apply the Voids Detectability Ratio method (left picture). A scan of the test object (voids are visible as light spots on a dark background) and the characteristic VDR (marked as SNR) versus depth in cm are in the picture on the right side.



Example: UltraIQ

The second sample of computer assisted phantom scan evaluation is a professional software UltraIQ based on Thijsen's method [(26)]. It is commercially available (Cablon Medical, The Netherlands) as a test kit including frame-grabber to digitalize, store and analyse the test object sonograms. The program considers both the grabbed video and or copied digital pictures including the DICOM interference ability. Measurement itselfes is supported by user friendly designed operating functions – e.g. automatic detection of gray scale targets. This tool is designed to serve as a fast but easy to use system, operated to measure a rather wide range of basic quality parameters using both, the commercially available or user defined test objects. The UltraIQ evaluates following scanner performance measurements:

1. Axial and lateral resolutions,

2. Contrast resolution,

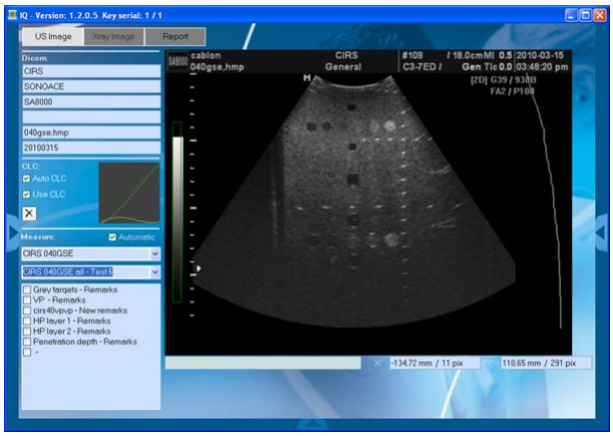
3. Penetration depth,

4. Dead zone,

5. Distance measurement accuracy,

6. Cysts detectability.

Figure 6 Screenshot of the Ultra IQ software while measuring the scanner Sonoace SA8000 using a CIRS Test Object.



Comprehensive and well managed output report is generated as well as measurement results database which can serve for a long term tracing of the scanner´s and transducer´s quality parameters. All these methods that employ different test-objects are primarily suitable for in-situ screening studies. They are not time consuming which is important where there is heavy equipment workload. Due to the high influence of operator individuality, a skilled person is needed to use this software for producing detailed objective information.

Example: Point Spread Function (PSF) method

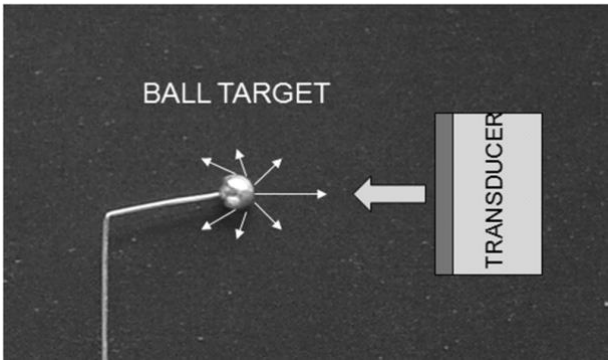
The PSF method is referred to in IEC standards [(27)] and [(28)] where PSF measurement is specified as the characteristic response of the imaging system to a high contrast point target. For most optical systems, the PSF is a singular, symmetrical and isotropic function. Thus, the measurement of the PSF is normally sufficient to characterize the system's impulse response and all the parameters derivable from this function.

The PSF measuring system generates a measured signal by use of a spherical target of diameter D inside an ultrasound conducting medium. The target diameter D depends on the frequency of ultrasound used [(27)].

The PSF function may be analysed from both – a RF signal or video output signals digitalised by an appropriate A/D converter, by special software, to derive various objective parameters of the scanner. Exact numeric data is obtained as a measurement result for precise analysis. More details concerning the PSF mapping system are available in the literature [(29)].

Two kinds of PSF measuring systems may be used. The first consists of a fixed spherical target and the second more sophisticated method maps the PSF over an ultrasonographic image by scanning a moving spherical target [Figure 7]. The target is moved in a measuring bath filled by degassed water over a specified scanned volume via a 3D computer controlled positioning system.

Figure 7 *Ball* target as a point reflector.



The moving target PSF measurement gives the following outcomes for an ultrasound scanning system derived from both the Region of Interest (ROI) and the target position dependent PSF data analysis over the scanning area:

- The ROI digital image stored for scanned plane axis in each point of the measuring grid.
- The echo signal amplitude distribution over the measured area.
- Distribution of the parameter Full With in Half of the Maximum (FWHM) of the PSF in an azimuth direction over the measured area.
- The peak echo amplitude at each step of the target position in the elevation (transversal) direction.

The method has the capability to derive from the data following ultrasound scanner parameters and functions over the scanning areas:

1. Focal areas in both the azimuth and the elevation directions [Figure 9]
2. Ultrasound scanning lines visualisation [Figure 8]
3. Manufacturer preloaded TGC function
4. Depth dependence of the scanning plane width
5. Side lobe levels
6. Amplification uniformity in the azimuth direction.

Such a set of parameters declares specific and comprehensive QA data concerning the particular scanner and transducer(s) measured. The measured data contains information over the whole imaging system, beginning at the transmitter and continuing with the transducer, receiver and image elaborating system. Data evaluation and the final measurement report need skilled staff in both; the measuring methods and the data interpretation. Measurement over thousands of points in a scanned volume is time consuming. Therefore this method is dedicated more to specialized laboratories than quality inspectors in hospitals. The application might be very useful for the expediency and conclusion of a final inspection on both new systems being manufactured or some used but refurbished scanners for sale.

Figure 8 Separate scanning lines imaged in a scanned area. The graph is derived from an amplitude plot of the signal reflected by the point reflector moving over the area.

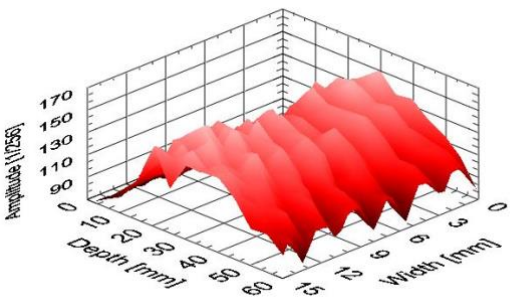
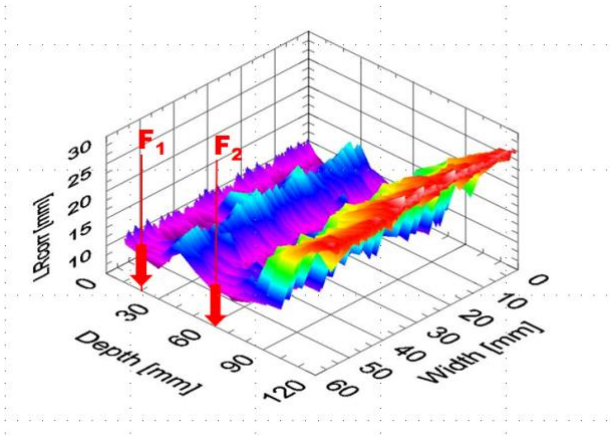


Figure 9 Focal length (F1, F2) derived from FWHM distribution over the scanned area is scaled on the y axis marked as LRCorr)



Separate transducer tests

Another aspect that is not performed at the moment on a regular scheme and on each equipment is regular technical maintenance of the transducers or probes (separate check without console). Not only the obligatory electrical safety checks are needed but also the optimal function of each element within the probe or the electronics within the console that are defining in total the image quality.

The outcome of only a few broken or destroyed scanner elements or losses within amplifiers can be that the operator is provoked to increase the output due to a worse image quality; finally this results in an increase risk to the patient for inducing bio-effects. However, periodical probe function tests and additional performance tests would detect this kind of losses or alterations in an early stage unambiguously.

Over time the performance of electrical transducers can decrease imperceptibly: There are not only physical damages, but rather insidious degenerations of the quality of the ultrasound image. The result of these changes or damages is that the transducers may be exchanged. There are some studies checking ultrasonic probes from different manufacturers

used in routine in hospitals and indicated that 20 - 30% of the daily used transducers exhibited an error [(30-34)]. These errors in general appear very slow in the images and often won't be recognized by the user. If these low quality ultrasound images will be used for medical diagnosis it will be possible that there are misdiagnosis because of misinterpretation or overlooked objects that won't be displayed any more.

A higher diagnosis risk is present if defective transducers are used for Doppler examinations involving fewer and infected elements for acquisition [(35)].

Different procedures have been published in the literature over the years [(14, 16, 20, 22, 23, 36)] but mostly a simple transducer check is needed to detect errors and that can be done on a system in several minutes. Additional software (e.g. Firstcheck, UltraIQ) are helpful to evaluate digital test images. Some other procedures are presented below.

The Nickel

Sonora Medical Systems, Inc. (USA) developed a simple test tool called "the Nickel" to employ comprehensive information about a transducer. Unfortunately this product is not sold any longer. With "the Nickel" the ultrasound acoustic performance of the transducer elements as well as various modalities and functions within the Doppler imaging systems can be tested. A principle of its function is very similar to the „Coin test" that is reflected by its name which is identical to a small US coin „Nickel". The principle of how it works is as follows; - the Nickel test target is equipped with a small PDF sensor which receives a transmitted pulse from a measured transducer element and reacts by transmitting back 3 separate echo simulating pulses with different ultrasound frequncy. The Nickel is not designed to be a calibration tool. It is an indicator of the overall functional health of both the probe and the various major electronic segments of the ultrasound system that define the performance of the various modes of operation (e.g. B-Mode, Doppler, Color Flow and M-Mode). The simulated echo signal that is inputted into the transducer from the Nickel also allows the testing of some special functions within any given ultrasound system, for example algorithms used for spatial compounding, second harmonic imaging, various pseudo-colour displays and dynamic focusing [(37)].

Figure 10 The „Nickel tool“ and the test result images. The image on the left shows the response from a convex transducer where width of appeture and number of elements is observable. The right image was obtained by use of a phased array sector tranducer. The centre frequency of this transducer is low (cca 2 - 3 MHz) therefore the third deep strip only is visible and the whole lateral area is marked because in the phased array system the signal received by one tested element is distributed to all receiving channels. (From Sonora leaflet.)

First Call aPerio

The FirstCall aPerio ™ (formerly called The FirstCall 2000 ™) is a unique portable, high-speed testing device from Sonora Medical Systems, Inc. designed to measure the relevant acoustic and electrical parameters of most electronic array transducers. It measures transducers only, that is, without the scanners [(2)]. The test device will reveal the source of transducer performance and safety problems such as:

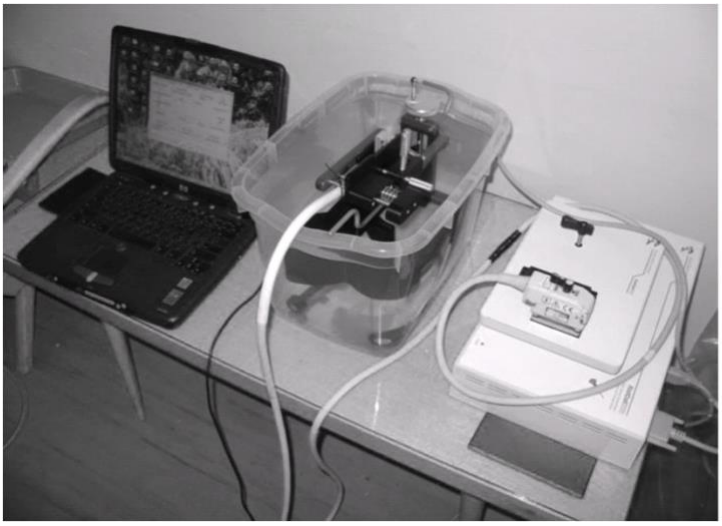
1. The number and location of dead acoustic elements across an array
2. Elements that have reduced sensitivity which can contribute to poor imaging quality as well as lower colour flow or Doppler sensitivity
3. Acoustic lens delamination, a condition which often results in image drop-out, potential electrical safety issues and long term destruction of the array
4. Broken signal wires or cable termination issues within the transducer, cable, or connector
5. For each element the following electrical characteristic parameters are specified:

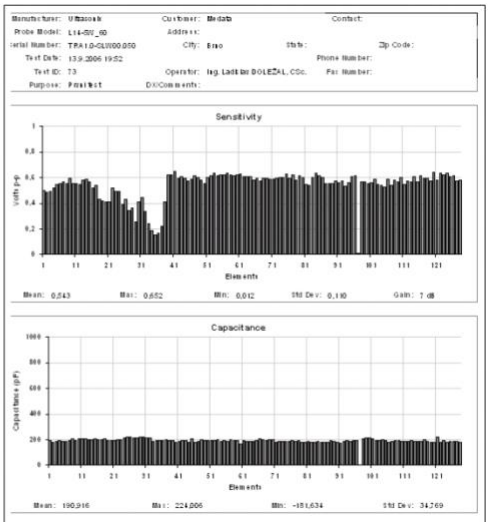
a. Capacitance on connector pin end
b. 20dB Pulse Width
c. Center Frequency
d. Fractional Bandwidth.

The FirstCall aPerio ™ data is reported in a format that allows clear tracking of performance changes while documenting the key indicators of probe related problems, even before the user can see changes in image or Doppler performance and often while the probe can still be cost-effectively repaired. FirstCall pulses each element within an array to test for: Element Sensitivity (volts p-p), Capacitance (pF), Pulse Width (ns), Pulse Shape, Centre Frequency (MHz) and Fractional Bandwidth (%).

The test is very fast; it takes about 10 minutes to adjust and measure any pre-programmed transducer. The measured protocols are arranged in a database with capacity to compare results obtained by periodical testing of the identical transducer to follow up its possible time degradation.

Figure 11 The FirstCall 2000® system just evaluating a special linear transducer from Aloka dedicated for peroperative use. From left to right – notebook running the program, tank filled by water in which the transducer holder with reflector is immersed and box containing hardware plus transducer sconnecting interface on the top. The second picture shows part of the measuring results protocol, where element reffectivity in the top graph and channel capacitance on the bottom graph are displayed. The result may be interpreted as delamination of the elements 1 till 38 and disconnected element 98.





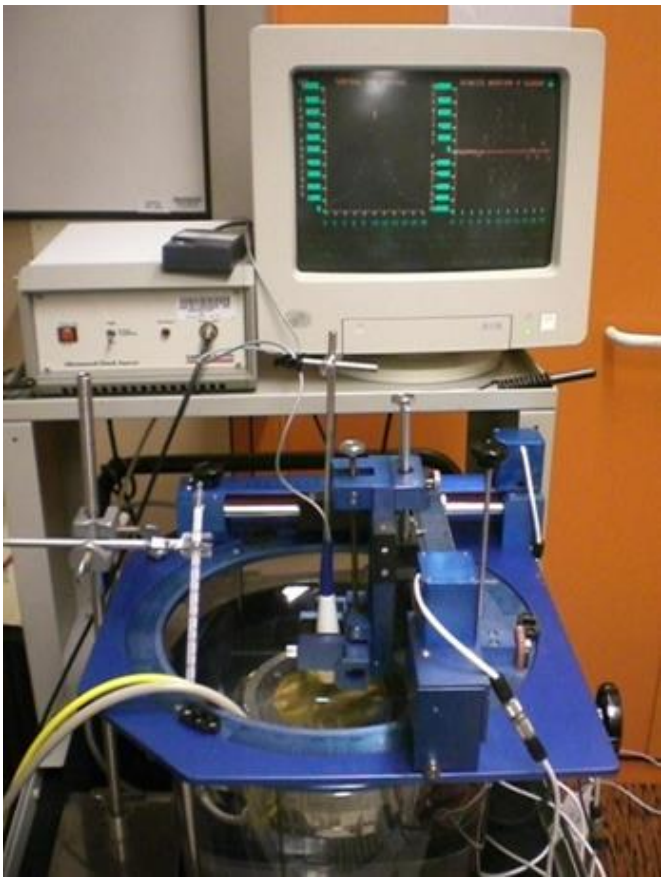
Hydrophone measurements

With hydrophones the emitted ultrasound field parameters (e.g. amplitude, intensity etc.) by a transducer can be measured quantitatively. These are another type of data available from the scanner. These measurements however do not evaluate the image quality but determine the temporal output parameters of the actual ultrasound signal and chosen scanner settings. This information is significant for maintaining allowed limits and for assessment of the effects of ultrasound energy with various types of tissues. There are mathematical models of the ultrasound field emitted by certain types of probes and its heat effects to calculate the thermal or mechanical indices (TI/MI, [(38, 39)]). Comparison of calculated and measured values of acoustic pressure distribution may determine the model's accuracy and definition [(40, 41)].

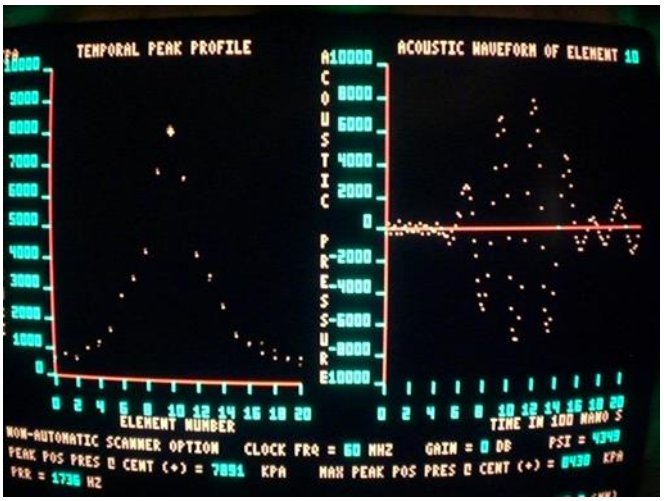
These measurements are essential for medical bio-effects studies or to understand tissue interactions with new ultrasound technology (e.g. plane wave imaging, ARFI) to get information about the emitted pulse amplitude characteristics that can lead to possible safety related issues [(42-44)].

Figure 12 Setup for hydrophone measurements (hydrophone and transducer are inside a water tank, left blue) and results of a measured pulse amplitude and acoustic waveform (right).

a



b



The methods in comparison

For a better overview a table comparing particular measuring methods in six basic parameters is enclosed Table 7. The compared parameters are as follows:

1. Results obtained by measurements
2. Data evaluated by measuring method
3. Operation
4. Evaluating method – the basic method used for measurements
5. Measuring duration – the time is needed to obtain the results
6 Price – approximate price (as listed in year 2010).

A number of the measuring methods are available now to support maintenance care for diagnostic ultrasound equipment. They have a capability of accepting different kinds of data, from primitive or crude detection of failure, actually on site in the examination room, to obtaining precise values, directly in a laboratory. A supporting system of standards and guidelines is available, too. There are tools used by equipment manufacturers and maintenance bodies that specifically examine the resulting quality.

What is needed, is the consciousness and cooperation of the scanner´s owner/user to start a Quality Control (QC) on a periodical schedule and over the scanner´s lifetime. The degradation and errors of an ultrasound scanner in daily use are documented but most often no precautions are done to detect them.

Without technical QC maintenance it is questionable if a high quality in diagnosis can be achieved.

Table 7 Comparison of the measuring methods.

Method	Results	Data evaluated	Operation	Evaluating Method(s)	Measuring duration	Approx Price k€
Estimation - from background noise	Basic information, may detect dead elements and/or receiver malfunction.	On screen picture. Noise level and its homogeneity over the picture	Simple; Skilled; scanner & monitor adjustment	Subjective picture analysis	Short 1 - 5 min.	0
Estimation – metal rod (coin) reflections	US lines; Dead elements; Aperture size; Dynam. focussing	On screen picture. Multiple reflections inside the metal generate comet tail like picture.	Simple; Skilled scanner adjustment	Objective picture analysis	Short 1 - 5 min.	0
AUStrian Test kit®	Picture quality parameters; The imager status; Image documentation. Report.	On screen picture. Printed pictures. Imager and transducers inspection.	Moderate; Skilled scanner´s adjustment Inspection	image analysis objective / subjective Status evaluation	Short 5 - 15 min.	0
Nickel® (not available at the moment)	US lines; Aperture; Dynam. Focussing; Received frequency range.	On screen picture of the Nickel generated pattern signal, received by one transducer element.	Moderate; Skilled scanner´s adjustment + Nickel operation	Picture analysis by observer: Objective	Short cca 5 min	1
Tissue mimicking test objects	Spatial & Contrast resolution Sensitivity Geom. Measuring accuracy	On screen picture.	Moderate; Skilled scanner´s adjustment; Positioning the transducer on the test	Picture analysis Observer : Subjective Analyzing software: Objective	Short 5 - 10min	2 - 5 (per test object)

			object			
Ultra IQ®	Spatial & Contrast resolution Sensitivity Geom. Measuring accuracy Long term stability	On screen picture.	Moderate; Skilled scanner´s adjustment; Positioning the transducer on the test object	Digital picture analysis Analyzing software: Objective	Short 5 - 10min	depending on software module chosen
Hydrophone 3D scanning	Acoustic pressure distribution Intensity calculation	RF signal generated by hydrophone US beam mapping by scanning the US field	Difficult; High skilled	RF signal analysis Accurate Objective	Measured volume depended minutes - hours	20 – 80
First Call ®	The particular element's sensitivity, frequency bandwidth, capacity	Reflected signal generated and received by each particular element is analysed	Moderate; Skilled Results interpretation is more difficult than measurement	Received RF signal Accurate Objective	Short 10 - 15 min	20- 40 (according to # of adaptors)
3D-Signal to noise ratio	Reccommended range of imaging depth is specified, long term stability	Digitalised video signal 3D evaluation of signal-to-noise ratio	Moderate; Skilled Moving transducer over 3D test object	Video signal analysis Accurate Objective	Short 10 - 15 min	5
Point Spread Function	Azimuth and elevation focal area; Scanning lines visualisation; TGC function over depth; Scanning plane width	Digitalised video signal Sophisticated interpretation	Difficult; High Skilled Moving a metal sphere over scanned volume	Video signal analysis Accurate Objective	Time – consuming Measured volume depended, maybe even hours	N.N

	profile; Side lobe levels; Amplification uniformity					

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