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

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Introduction

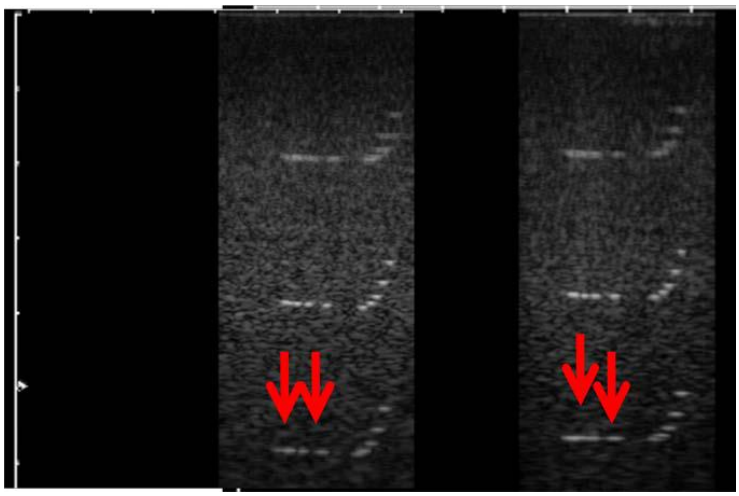
Problems related to the safety of ultrasound applications are judged from the point of view of patients, nursing and examining personnel. Also, ultrasound biological effects have predominated since ultrasound has been used in medicine [(1)]. The direct effects of ultrasound energy on living tissue have 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)].