# Guideline for Technical Quality Assurance (TQA) of Ultrasound devices (B-Mode) – Version 1.0 (July 2012)

## EFSUMB Technical Quality Assurance Group – US-TQA/B

## Leitlinien für Technische Qualitätssicherung von Ultraschallgeräten (B-Mode) – Version 1.0 (Juli 2012)

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**Key words**
- ultrasound
- QA/QC
- safety
- technical aspects
- physics

## Zusammenfassung

Die Technische Qualitätssicherungsgruppe wurde 2007 vom EFSUMB Board initiiert und trat 2008 das erste Mal zusammen, um bestehende Methoden und Prüfprozeduren zur technischen Qualitätssicherung von diagnostischen Ultraschallgeräten zu diskutieren und zu bewerten. Ein Anliegen dieser Gruppe von Experten ist es, das EFSUMB Board über effektive und wirksame Methoden für den alltäglichen Gebrauch zu beraten und Empfehlungen zu den technischen Aspekten im EFSUMB by-law 9, Teil 11.6. & 11.7 abzugeben. Dabei fokussierte die Gruppe ihre Arbeit auf neue Entwicklungen und vorhandene europäische Projekte, um eine Leitlinie mit breitem Konsens zu schaffen. Es besteht ein großer Bedarf an geeigneten Prüfabläufen und entsprechender Auswerte-Software für Performance-Tests von medizinischen Ultraschallgeräten. Außerdem sollten die Messungen dabei so Durchführer-unabhängig sein wie möglich. Erst durch Erreichen dieser Ziele in einem internationalen (vorerst europäischen) Kontext kann eine optimale Qualität der Ultraschallbildgebung für den medizinischen Bereich angeboten und gewährleistet werden. Diese Leitlinie hat daher zum Ziel, geeignete Prüfprozeduren und Evaluierungsprozesse zusammenzustellen und zur Verfügung zu stellen, um bei der Durchführung einer optimalen technischen Qualitätssicherung (TQA) Unterstützung zu bieten. Der Inhalt dieser Leitlinie wurde dem EFSUMB Board of Directors (Delegierte) präsentiert und vom EFSUMB Executive Board (ExB) in der regulären Sitzung auf der EUROSON 2012 in Madrid im April 2012 beschlossen.

## Abstract

The Technical Quality Assurance group was initiated by the EFSUMB Board in 2007 and met firstly in 2008 to discuss and evaluate methods and procedures published for performing technical quality assurance for diagnostic ultrasound devices. It is the aim of this group of experts to advise the EFSUMB Board of effective and efficacious methods for routine use and to make recommendations regarding the technical aspects of EFSUMB by-law 9, parts 11.6. & 11.7. The group´s work focused on new developments and related European projects to establish a common guideline. There is a great need of a well established protocol and dedicated processing software for the performance testing of medical ultrasound equipment. The measurements should be user independent as much as physically possible. Only if these goals are achieved in an international (firstly European) context, the optimal quality of ultrasound imaging can be offered and maintained to the medical community. This guideline aims to offer and summarize suitable procedures and evaluation processes to lend support for an optimal Technical Quality Assurance (TQA) scheme. The content of this guideline was presented to the EFSUMB Board of Directors (delegates) and approved by the EFSUMB Executive Board (ExB) at the regular meeting during EUROSON 2012 in Madrid April 2012.

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## 1. Introduction

This guideline deals with Technical Quality Assurance (TQA) or quality control of ultrasound imaging equipment (B-Mode). Image acquisition and the evaluation of image quality, equipment performance and function are addressed.

It presents a comprehensive compilation of the most useful TQA parameters from published literature [1], the outcome of the internal group's activities [2 – 5] and recommendations from other institutions (e. g. IPEM, ACR, IEC [6 – 30]) to

- act as official EFSUMB recommendations for TQA
- identify the most suitable parameters
- identify the most suitable test methods
- describe how to perform TQA most effectively and efficiently
- propose (partly) easy-to-use methods
- introduce (clinically supportable) testing intervals
- inform the user about essential TQA knowledge or necessary qualification.

A clean and hygienic equipment including transducers, control panel, monitor, and peripherals is mandatory each time before a patient is scanned or the equipment is in standby but will not be covered but supposed in this guideline.

Relevant publications and international standards are listed in the reference chapter at the end, while the suitable test methods and test devices are given in the annex.

### 1.1 Objectives for performing regular TQA

The quality of ultrasound B-mode images is first of all greatly dependent on the design characteristics of the system, i. e. transducer, the basic electronics and the pre- and post-processing of the transmitted and received ultrasound signals. In addition, the so-called presets of the system which are chosen by the manufacturer influence the performance of the equipment. Finally, eventual preference settings of the equipment used by individual sonographers are also of importance for the performance characteristics.

It is currently not possible to reliably predict absolute clinical performance of such equipment.

The objectives of TQA are to ensure that the equipment

- functions as expected,
- is safe for clinical use (and within internationally accepted limits) and
- performs consistently over time.

The features to be measured for the characterization of performance are related to the transducer design, its performance and its eventual degrading due to local mechanical defects.

Meanwhile it is evidenced that transducers in clinical practice are subject to degradation in performance with annual failure rates of 10 – 13 % [31] or unacceptably high incidence (40 %) of detected defective transducers [32]. This potentially can lead to patient misdiagnosis or under-diagnosis [33]; or even missed diagnosis (of heart disease) [34].

Furthermore, the imaging performance features are to be related to the quality of the combination of the transducer and electronic system: the overall sensitivity, the spatial and gray level characteristics of the images, as well as the measurement accuracy, which are all of direct clinical importance. A degradation of the system leads technically to a decrease in displayed image quality, due to increase of side lobes within the beam profile or pronounced loss of sensitivity for example [26, 34].

The need to test the imaging equipment regularly is obvious to guarantee full functionality. Also testing intervals of less than a year are discussed and recommended for frequently used equipment [34].

However, to establish and to monitor the performance of an ultrasound imaging system a well defined set of performance features and related measurement procedures are required, as well as test image analysis software and documentation.

Some international standards and recommendations have been introduced over the last decades and commercial testing objects mostly for B-mode imaging are available. Furthermore, computer aided test image analysis has been developed by some parties which offers more objective and repeatable methods for assessment of performance.

### 1.2 Guideline & Concept validation

The concept described within this guideline will be regularly evaluated to provide state-of-the-art QA procedures, skills and evaluation methods.

## 2. TQA levels and intervals

A regular technical QA (TQA) scheme starts with a primary or acceptance test (level 3) (**Table 1**) when the device is first incorporated into a QA program (regardless of whether the device is new or already in use). With this test, the base-line performance is determined that also will be used as a reference for regular objective testing (level 2).

Simple user tests (level 1) are performed on an individual regular basis without special equipment to evaluate the basic performance. (Semi-) annual extensive and objective testing of imaging quality is performed by using tissue mimicking phantoms (level 2).

All tests must contain parameters that are able to reveal the actual status of some aspect(s) of the quality of the ultrasound device (console, transducer, cables, monitor and peripheral equipment, sensitivity, imaging performance, etc. where appropriate). Where malfunctions are detected, the next higher level of check or of maintenance by the manufacturer is indicated.

In general routine TQA must occur and be performed regularly. The same tests using a standardised protocol have to be per-

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**Table 1** Overview of quality assurance levels, intervals and bodies/personnel engaged.

| TQA concept | | | | |
|---|---|---|---|---|
| **method** | **type** | | **interval** | **performed by** |
| regular | level 1 | user tests ("5-min Test") | monthly | user, technician, sonographer, physicist |
| | level 2 | technical tests with test objects | (semi-) annually | technical expert, engineer, physicist |
| special | level 3 | advanced technical tests with test objects (acceptance test) | at delivery | technical experts, engineer, physicist |
| | level 4[1] | acoustic & thermal safety parameters check | optional or upon (user) request | manufacturer/certified body (TPB, NPL, FDA); specialized lab |

[1] These measurements are not performed at regular intervals since specialized equipment is needed; in case of safety concerns the proposed parameter should be measured by professional institutions or experts in this field only.
TPB: Technisch-Physikal. Bundesanstalt, Germany; NPL: National Physical Laboratory, UK; FDA: Food and Drug Administration, USA.

**Table 2** Overview of tests within level 1.

| level 1 – user tests | | |
|---|---|---|
| **test** | **evaluation** | **possible subsequent action** |
| visual inspection | visually | STC or maintenance |
| – cracks or delamination of transducers | | STC or maintenance |
| – cable damage | | |
| – uniformity (subjective), e. g. loss of transducer elements | visually | STC or maintenance |
| – monitor function | visually | adjusting or maintenance |
| – hard copy/image storage function | visually | adjusting or maintenance |
| – sensitivity/noise | visually | level 2 or maintenance |

(STC: separate transducer check).

formed at suitable intervals to monitor changes or deterioration over time and to guarantee that effective remedial action can be taken.

To help to minimise the risk to the patient from acoustic exposure hazards in the form of tissue temperature elevation or mechanical bio-effects, manufacturers provide an on-screen display of Thermal Index (TI) and Mechanical Index (MI), as defined in IEC 62 359 [20].

The values are affected by many parameters, including the transducer properties, application presets, and user control settings (e. g. operating mode, focus, field of view). As the user makes risk-benefit judgements based on these displayed values, they need to be reliable and accurate.

However, verification of the accuracy of displayed safety indices or acoustic output can only be performed by centres with suitable equipment and expertise and therefore these tests are included as an optional testing procedure (level 4).

Depending on the individual needs of the clinics and actual operating time of the ultrasound equipment different parameters and intervals for checking as well as different TQA skills of personnel may be necessary.

## 2.1 Performance tests – Level 1
### User tests ("5-min test")

These tests are intended for the user or personnel supervising this equipment. They are simple to perform once the scheme and setup have been practised a few times.

The tests act as a first step within a malfunction detection process and should be done at regular intervals. No sophisticated additional equipment, special evaluation software, or time consuming procedures are needed.

An overview of recommended parameters is given in the **Table 2**, while the methods proposed are given in the paragraph further on.

## 2.2 Performance tests – Level 2
### Tests with test objects

The tests listed in **Table 3** are performed with additional test equipment (test objects/phantoms, test pattern) and by software-based evaluation and documentation. With these tests the technical function of the console and transducers can be monitored and evaluated. The tests are performed with the preset for quality assurance as determined with the level 3 test.

In cases where the user tests have shown uncertain results, these tests should be performed for clarification but must be performed also separately on a (semi-) annual basis. Additional equipment and special detailed knowledge is needed.

An overview of recommended parameters is given in the **Table 3** below, while the methods proposed are given in the paragraph later on.

## 2.3 Performance tests – Level 3
### Advanced tests with test objects (acceptance test)

When equipment is newly introduced into a QA scheme, several parameters have to be measured and quantified to acquire information on the technical performance of this equipment. This test is called acceptance or primary test and establishes initial data about the different parameters used for further long-term investigations. Level 3 tests consist of level 2 tests, setting baselines for level 1 tests and some advanced tests (e. g. separate transducers function checks) and are performed with test objects and other specialized devices.

A preset for the (semi-) annual Level 2 test should be selected or made, stored and recorded according to the QA software in use. In this preset, the overall gain, the TGC, the TI and/or MI, the position of the in-plane focus and the total depth of the images is stored.

These tests normally document the baseline performance of the equipment and should not only be done once but whenever a re-



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pair, profound maintenance or a software update has been done, that cause changes to the initial performance data.
An overview of recommended parameters is given in the **Table 4** below, while the methods proposed are given in the paragraph later on.

### 2.4 Performance tests – Level 4 (optional)

### Tests for acoustic safety indices & transducer temperature

Level 4 tests are specialised checks that require specific test equipment and skilled and trained personnel. They are not repeated on a regular basis but may be performed at initial acceptance or for special clinical needs (e. g. bio-effects studies) where it is essential to know this information or upon user requests (optional tests).
Some of the listed tests can be performed by skilled personnel with available equipment on-site (marked #), while the accurate verifications are reserved to expert centres (it should be noted that the output of equipment could vary after transducer exchange or software update).
An overview of recommended parameters to know is given in the **Table 5** below, while the methods will be determined in the expert centre performing the measurements.

## 3. Test equipment

### 3.1 Test objects/phantoms

This equipment is needed for regular measurements at level 2 and higher. There are a number of commercial companies on the market that are offering a variety of different objects, phantoms or equipment to measure the listed parameters (Annex 1).

- test objects/phantoms suitable to perform the requested tests (level 2/3) for advanced and specialised tests (level 3 & level 4):
- manufacturer test report containing the required transducer information or
- electronic equipment to check transducer function separately
- calibrated hydrophone measurement system (according to IEC 62 127 – 3 [18])
- radiation force balance (according to IEC 61 161 [12])
- thermal test object (according to IEC/TS 62 306 [19]),
- electronic thermometer or fine wire thermocouple (accuracy ± 0.1 °C)
- infrared thermometer (accuracy ± 0.5 °C)
- monitor test pattern generator (according to IEC 62 563 – 1 [22]; DIN V 6868 – 57 [24])

**Table 3** Overview of tests within level 2.

| level 2 – tests | | |
|---|---|---|
| **test** | **evaluation** | **possible subsequent action** |
| – resolution (lateral, axial) | software | STC or maintenance |
| – maximum depth of penetration | software | maintenance |
| – uniformity (objective) | software | maintenance |
| – monitor function | test pattern | maintenance |
| – dynamic range/contrast resolution[1] (limited) | software | maintenance |

[1] Limited to some aspects → see Annex 2.
(STC: separate transducer check.)

**Table 4** Overview of tests within level 3.

| level 3 – tests | | |
|---|---|---|
| **test** | **evaluation** | **possible subsequent action** |
| – **all level 2 tests plus:** | | |
| – elevation focus & resolution | software | STC or maintenance |
| – caliper calibration (distance, area) | software | maintenance |
| – dynamic range/contrast resolution | software | maintenance |
| – postprocessing gray level encoding | software | maintenance |
| – transducer element performance | software | maintenance |

STC: separate transducer check.

**Table 5** Overview of tests within level 4 (optional and upon [user] requests only).

| level 4 – tests | | |
|---|---|---|
| **Test** | **measurement** | **possible subsequent action** |
| – check that displayed MI/TI-values at switch-on correspond to preset values given in technical manual[1] | visually | inform manufacturer |
| – MI verification for each transducer & operational mode | calibrated hydrophone | inform manufacturer |
| – TI verification for each transducer & operational mode | radiation force balance, 1 cm aperture | inform manufacturer |
| – measure temperature of transducer face in air# | thermocouple, IR thermometer | maintenance/inform manufacturer |
| – measure temperature of transducer face in tissue contact | thermocouple, thermal test object | maintenance/inform manufacturer |

# Test can be performed by skilled personnel and available equipment on-site.
IR: infrared.

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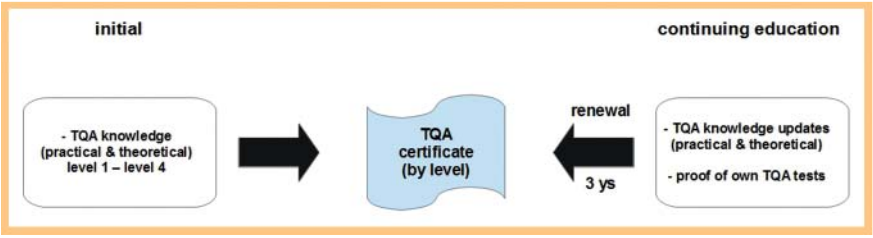


**Fig. 1** TQA-knowledge transfer and qualification process for initial and continuing education.

### 3.2 Acquisition & evaluation software

For a full documentation and reproducible objective evaluation of the QA tests it is imperative to use software-based test image analysis. At present there are some commercial and scientific software packages available that can be used for these purposes as supporting tools. These will enable an assessment in a fast and reproducible way.

It is recommended to use software for acquisition and objective evaluation for the level 2 and 3 tests; depending on the project or implemented quality management system it might be necessary to use software-based test documentation for level 1, too (optional).

Although digital test images should be used for later analysis it is possible to convert displayed analog ultrasound images of older machines to digital formats to use them for analysis, too; but be aware that not all conversion/capture devices (so called frame grabbers or video digitisers) provide reliable and consistent digital images finally, therefore care should be exercised in selecting and setting up such devices.

Some examples of known software for QA purposes are listed below:

- UltraIQ
  (Cablon Medical, NL)
  this company has developed a software application for automated evaluation and reporting of ultrasound systems dedicated to level 2/3 applications.
  (www.cablon.nl/catalog/ultraiq/); accessed 26.6.2012
- QA4US
  (Radboud University, Nijmegen, NL)
  a modular software package that can be used for level 2/3 test requirements
  (www.qa4us.eu); accessed 26.6.2012
- FirstCheck
  (UltraSound-Lab, ZMPBMT, Medical University Vienna, A)
  Java-based software that is dedicated to support simple user tests/documentation of level 1
  (www.meduniwien.ac.at/zbmtp/?id=98#323);
  accessed 26.6.2012
- Nottingham USQC
  (Nottingham University Hospitals, Medical Physics & Clinical Engineering, UK)
  software developed by the ultrasound group to evaluate level 2/3 tests
  (www.nuh.nhs.uk/mpce/RadiationPhys.aspx);
  accessed 26.6.2012

## 4. Personnel qualification

Technical evaluation of modern equipment requires actual knowledge of regulations, methods and test equipment as well as first of all practical experience.

This concept contains 4 levels of TQA checks (level 1 – 4) calling for various skills of personnel involved or engaged to perform the procedures efficiently and reproducibly:

- level 1 tests are aimed at clinical users with basic training,
- level 2 tests are aimed at personnel with some technical training,
- level 3 tests are aimed at personnel with technical training,
- level 4 tests are aimed at personnel or specialist laboratory facilities with special training.

The knowledge and personal skills can be acquired by completing suitable training courses dedicated to the level needed. Level 1 – 2 procedures are aimed at clinical personnel with basic skills and qualification of TQA, while levels 3 and 4 procedures are aimed at technical personnel who have completed suitable training courses.

A possible scheme to guarantee the quality of personal training and qualification level is suggested below.

**initial** (appropriate to their practice and needs):

- TQA-courses (theory & practice for level 1 – 4)
- proof of TQA-knowledge (TQA certificate for passed level) (e. g. clinical personnel level 1, technicians, physicists level 1 – 4)

**continuing education** (appropriate to their practice and needs):

- periodical participation (every 3 yrs.) at TQA-courses (e. g. during EFSUMB congresses)
- continuous training of test procedures
- proof of performed and documented TQA tests at home institution

A special TQA-certificate will be available for participants passing the different courses documenting the special knowledge and capability or for renewal purposes (**Fig. 1**).

The demands for adequate training and certification of personnel involved in ultrasound diagnosis are not part of this guideline.

## Annex 1 & 2:

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