

## Technical Quality Assurance (TQA) – Safety Aspects

### Basic Terminology

**Image quality** - this is a purely descriptive term. It refers to aspects ranging from aesthetic and subjective factors to those that are capable of precise physical measurement. It can not always be evaluated quantitatively.

**Parameter** – a feature of a system which contributes to the overall performance that can be evaluated quantitatively.

**Performance** - quantitative evaluation of different aspects of the ability of an ultrasound system to generate an image.

**Quality Assurance** - the activity of checking, in a way which is demonstrable to customers or users, that equipment meets needs, expectations, or other specified requirements and works properly to test standards.

**Safety** – a complex term involving different components which include electrical, acoustic (i.e. bio-effects) and diagnostic hazards to operator and patient. These must be minimised in order to maximise safety.

### Introduction

Regular, periodically performed, TQA on diagnostic ultrasound equipment serves a number of purposes: i. it may be used to ensure that the equipment works to agreed technical standards [1] and within inter-nationally accepted limits [2], ii. to

monitor changes in performance over time (inconsistency checks), iii. to evaluate new imaging and processing techniques and iv. to inform maintenance and replacement processes [3-5].

Equipment in clinical use is subject to degradation in performance over its life-time. This mainly affects the transducers but also involves the main user console electronics, the monitor, and directly connected peripheral devices. It has been shown that annual failure rates of 10-13%, and/or unacceptably high incidence of defective transducers exist in practice [6,7].

However, the smallest crack in a transducer housing, or degradation of only one parameter, can influence the system's overall performance and displayed image quality and can change the safe use of the system. This is true for all kinds of clinical imaging modes used [8,9].

### Basic Science

In general, TQA concepts are divided into acceptance, or baseline, and user tests:

Acceptance tests should be performed on a new and refurbished system and transducers, or when software is upgraded since this might affect imaging performance. Baseline measurements to characterise and record performance are also necessary. This is to ensure that the specifications set out at procurement, or during modifications, are met and that the system is functioning correctly.

User tests are designed to be fast and simple, to allow monitoring of equipment over life-time to ensure continuing optimal performance.

All tests must involve methods, parameters and test devices that can determine the actual status of the

complete ultrasound system (console, transducers, cables, monitor, peripheral devices, Tab.1) in a reproducible way. Where degradation or malfunction is detected, the next higher test level for specification or maintenance of the manufacturer/service facility is indicated. It is essential that the same tests are performed at suitable intervals using a standardised protocol and appropriate evaluation tools (software, additional equipment) to monitor changes or deterioration over time objectively and to guarantee that effective remedial action can be taken.

item	test		
	user	acceptance	baseline
level	1	2-4	2-3
interval	monthly	at delivery, after maintenance/re-furbishing, software upgrade	(semi-) annually; after maintenance, software upgrade
performed by	user, sonographer	technical expert, physicist	
methods used	published concepts, IEC 62736	harmonized with IEC documents; level 4: 60601-2-37	harmonized with IEC documents
evaluation by	visually	software	
additional equipment	none	test devices, phantoms	
time needed	5 min	depends on number of procedures	

Tab.1: Overview of items within a TQA concept according to the EFSUMB Guideline [3]

The “EFSUMB Guideline for Technical Quality Assurance of ultrasound devices” [3] supports the introduction or adoption of a TQA concept in a complete and standardised way for all B-Mode equipment. Other documents offer TQA guidance notes for specific applications and equipment involved in particular national programmes [10,11].

### Safety Implications

Do we need technical Quality Assurance (TQA) of ultrasound devices for safety

reasons? – there are several different aspects involved which are the responsibility of the operator (physician) of the equipment who must act appropriately in order to obtain the diagnostic information needed, with minimum risk to the patient.

### Electrical safety

It must be guaranteed that the equipment presents no electrical hazard to the operator or patient e.g. from breaks, or uninsulated cables or cracks in transducer housings (TQA level 1).

### Ultrasound safety

Acoustic exposure hazard in the form of tis-sue heating or mechanical bio-effects must be minimised for the patient. To help the operator understand possible maximum output caused by his settings an on-screen display of the Thermal Index (TI) and the Mechanical Index (MI) is provided. But the accuracy of the displayed indices must be verified. Furthermore the ultrasound intensity or amplitude emitted can be compared with the manufacturer’s data to check consistency (TQA level 4).

### Diagnostic safety

This is the most complex term as it combines the performance and image quality of the equipment for signal detection and display on the monitor and experience in interpreting the ultrasound image, in the best possible way for the benefit of the patient.

Performance and image quality are affected by many parameters, e.g. spatial and contrast resolution, sensitivity, and transducer and electronic properties. A degradation of parameters leads technically to a decrease in image quality that can result in a under-diagnosis, or in the worst case, in mis- or missed diagnosis if falsely interpreted [7]. Different tests are available to evaluate the proper functioning of transducers, monitor, console

settings and peripheral equipment (TQA level 1-3).

### Conclusions and recommendations

Due to the complex design and of imaging equipment it is essential to perform a TQA to guarantee its full functionality and to comply with the mandatory responsibility of the operator

#### Recommendations:

- use appropriate test concepts (e.g. EFSUMB Guidelines [3])
- do a TQA on a regular and documented basis
- use software for evaluation where suitable
- include all equipment parts in the TQA (i.e. transducers, console, monitor, peripheral devices)
- do not use equipment with obvious broken cables, cracks in the housing and chassis or delamination on a transducer
- do not use transducers with obviously reduced image quality (e.g. from non-functioning elements) which hinders the diagnosis

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### References