ABSTRACT

Quality Assurance of Ultrasound transducers/probes

EBQA Evidence Based Quality Assurance

This Abstract is referring to studies and conclusions performed during the last 12 years within the area of testing multi brand ultrasound probes in daily use at hospitals in the Nordic countries. The Abstract describes the importance of frequently validating ultrasound probe performance for patient safety.

Introduction/Background

Studies * have shown that 35-40% of the ultrasound transducers/probes at a non tested hospital have to be attended to. The handling (dropping), the wrong gel or cleanser used is the most common reasons for damaged/defective probes.

The performance of an ultrasound probe decreases over time. Probes can also be damaged during production process or during transport.

Studies and experience from 12 years testing, approx. 10 000 probes in daily use at Scandinavian hospitals, have shown that the problem is as common independent of brand and type.

Most common faults on ultrasound probes:
Element damages
Cable breakage
Lens problems, cracks
Strain relief

Due to the status in the world economy lifetime of ultrasound systems and probes are prolonged. Therefor these hidden faults types of damages are increasing.

The Clinical Impact of defective probes:

"The problem is that you can't see the problem, that´s the problem!"

An Ultrasound system operating imaging mode is normally using 128 up to 512 elements to produce the dynamic image in combination with a very advanced smoothing and averaging software applied on the 2 D images in real time.

The dynamic range is about 50dB this makes it almost impossible for a clinician to see in the 2D image one or two or even more missing elements. By the time the clinician can see the problem of missing elements it is normally many patients to late.

Most of the modern ultrasounds systems have additional sub modes:
CFM = Color flow mode
Elastography
Pulsed Doppler mode
CW Doppler mode

In these modes the Ultrasound Systems are normally operating using much fewer elements. In addition close to 100 dB range. Therefore a loss of elements have much greater impact on the clinical data.
4 elements over 20-25 elements is close to 20-25 % loss of active transducer area used to performance the doppler mode.

If in addition applying the "Bernoulli equation" to the measured velocities the hidden faults are becoming serious misleading results with high underestimate of the pressure gradient.

To the maximum velocity for pressure gradient measurements
P1-p2=4v max 2 *4 = mmhg

All elements working is very critical for a good Doppler.
This since to the most ultrasound systems we are using a 2Dprobe to perform Doppler with.
Compared to 4 elements over 128 are about 5% is not critical for a good image.

Please note: Most of the quality assurance tools we are using today are geared towards image quality and **not** geared towards the sub modes like Doppler, CFM, Elastography etc.

> *Comment in a study **
>
> *"The clinical consequence of this transducer error was that the correct clinical treatment for this congenital heart defect was involuntary postponed for more than a year.*

Testing is important and most relevant to increase quality, patient safety and it is cost effective for users/hospitals this since many probe defects can be repaired.

Test Methods available, advantages and disadvantages

Very few hospitals, outside Scandinavia, in the world tests their ultrasound probes. The reasons are i.e. because of high trust in the Ultrasound diagnostic methods, trust with the OEM:s production procedures and maintenance service and the lack of know how of the probes lost of performance over time and the problem that 35-40% of the probes need to be attended to.

Studies showed that the Biomed Engineers relied either on regular maintenance from the manufacturer (OEM) or on evaluation of the ultrasound scanners by their own testing protocols. Despite these preventive measures, almost 40% of the tested transducers were defective, according to the criteria used in the study *.

Testing of ultrasound probes was introduced in year 2003 in the Nordic countries, Sweden, Norway, Finland and Denmark. The company BBS Medical AB arranged seminars, educated the Biomed Engineers, sold testing systems and offered testing services. Based on the BBS Medical AB test-database studies where performed by The Royal Technical Institute KTH in Stockholm Sweden.

The unique BBS-test-database consists today of approx. 10 000 tests, multi brand, probes with daily usage at hospitals.

ULTRASOUND PROBE TEST SYSTEMS

Standard Tissue Phantoms
A standard tissue phantom is a device having a standard ultrasound signature as close as possible to the real tissue.

Advantage is relatively low cost, have to be calibrated and kept in a controlled environment.

Disadvantage is that result may vary based on changes in ultrasound system, operator depending, it can’t detect the difference in between the transducer failure and the ultrasound system failure.

Satrapa Phantom TCC
Is a more advanced tissue phantom, twice the cost of a standard, having a software to attempt to measure the resolution of the ultrasound systems in both axis.

Advantage is that it has a more in depth analyzing program usable for an advanced user.

Disadvantage is very operator depending; again it will not detect the difference in between probe failure or system failure.

First Call
Stand Alone system with software, adapters connected with different connectors depending on OEM brand and type. Static, one channel system, analyzing bandwith, sensitivity, capacitance test, element by element. Works independent of an ultrasound system.

Advantage operator dependence is minimized, results are easy repeatable. Easy to use and portable.

Disadvantages are high price (if found pre owned), adapter dependent, statical testing device. It is not available for sale since June 2013 on the market (own by General Electric GE).

ProbeHunter 256 MVS
Stand Alone system with software on a programmable platform. Built in adapter for the most complex probes on the market.
Connector for adapters to the most common probes on the market. Dynamic test system for validation of image, color, PW Doppler, analyzing bandwith, sensitivity, cable test, element by element, real time, ultrafast. Works independent of an ultrasound system. Connectivity to a real time ultrasound scanner, Doppler phantoms flow and string, for research purpose.

Advantages, dynamic, ultrafast and real time, can test new parameters like intermediate cable functionality, cross talk elements and cables. Operator dependence is minimized. Most of First Call adapters can be used on ProbeHunter to create dynamic testing. Easy to use, portable. OEM independent privately company.

Disadvantage is price.

Results & Conclusions

Testing ultrasound probes generates Quality Assurance and Patient Safety

The number one reason for testing ultrasound probes is Patient Safety to avoid misdiagnosis with defective probes.

The positive outcome of the frequent testing of probes and probe care program at Scandinavian hospitals is that the faulty frequency now, after approx. 10 years of frequently testing, is **down to 8-12%.** The awareness and the importance of testing is now on top of the Agenda for Bio Med Engineers at Scandinavian hospitals.

The Bio Med Engineers on the Nordic market are educated and trained in this field and are now upgrading their testing devices from Statically tester to Dynamic testing in real time. Giving direct information if a probe is fully functional or not. The test procedure is fast without interruption in the patient flow. The Biomed Engineers strive to increase actions within quality assurance of ultrasounds probes since the probes are becoming more complex.

Information campaign for Patient Safety is a must

It is very important with concerns to patient safety that the information and know how is spread about the faulty frequency on probes (35-40%). This to make clinicians, Biomed Engineers and the ultrasound industry world wide more aware of the importance of testing. With the proven results from the Nordic market, that testing over time makes it possible to take the result of defective probes down to 8-12%. Based on ongoing test program minimum one baseline test /year.

Testing will increase value of clinical studies

To attach a testing system to an ultrasound diagnostic system during clinical studies will generate more accurate results. This will assure the clinician that every patient is examined with a fully functional probe.

Conducting clinical studies including CFM or Doppler studies will have to be mandatory to monitor probe performance during the whole study. This in order to secure valid data throughout the study.

In Sweden cardiology and vascular scanning-centers have to minimum test once/year to maintain their certifications of the laboratories.

Frequency of testing and recommendations in the Nordic countries

The recommendation in the Nordic countries is to test ultrasound probes at delivery/arrival to hospital to get a “footprint”, and then continuously every 6-12 month depending on application, the frequency of use and within probe care program.

It is very common in tenders in the Nordic countries to have a demand of possibility for the OEM:s to test their probes at arrival and during warranty period. In many cases the OEM have to provide an adapter for the probes to fit the hospitals testsystem and include a test report at delivery.

OEM:s will benefit from testing

The OEM:s will also benefit from probe testing and to understand and analyzing testing results. The OEM:s can prove quality by including test report with new sales, proof of handling during Warranty periods, when performing service and repairs.

Actors on the ultrasound market that will benefit from testing ultrasound probes:

Manufacturer of probes
OEM of Ultrasound
Distributors of Ultrasound and probes
Users of ultrasound systems, hospitals, clinics, veterinarians
MVS, Multi Vendor Service companies
Probe repair labs

Conclusion and questions that needs to be answered:

Testing criteria's
Ultrasound system including probes is a dynamic system and test´s of probes should be preferably be performed by a dynamic testing system to fully validate the performance of an ultrasound probe including image, color and Doppler.

More studies within this area are needed since very often Biomed Engineers advice´s in many countries are today based on old technology.

Recommendations regarding frequent testing at hospitals are needed for patient safety.

The most important questions to be answered are:

Who is responsible for the Quality Assurance of Ultrasound probes, hospitals, OEM:s or third party? Within warranty period and thereafter.

What will the standards and criteria's be for testing?

Is it possible for the Industry to agree on a standard for testing?

Guidelines are needed for testing i.e. recommended frequency.

***** *Ref study: High incidence of defective ultrasound transducers in use in routine clinical practice. 2009 Mattias Mårtensson, M Olsson, B Segall, AG Fraser, R.Winter and L A Brodin):*

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