

High incidence of defective ultrasound transducers in use in routine clinical practice

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Aims The objective was to evaluate the function of ultrasound transducers in use in routine clinical practice and thereby estimating the incidence of defective transducers.

Methods and results The study comprised a one-time test of 676 transducers from 7 manufacturers which were in daily use in clinical departments at 32 hospitals. They were tested with the Sonora FirstCall Test System; 39.8% exhibited a transducer error. *Delamination* was detected in 26.5% and *break in the cable* was detected in 8.4% of the tested transducers. Errors originating from the piezoelectrical elements were unusual. Delamination and *short circuit* occurred without significant differences between transducers from all tested manufacturers, but the errors *break in the cable*, *weak* and *dead element* showed a statistically significant higher frequency in transducers from certain manufacturers.

Conclusion The high error frequency and the risk for incorrect medical decisions when using a defective transducer indicate an urgent need for increased testing of the transducers in clinical departments.

Introduction

The proper functioning of the ultrasound transducer is a key factor for reliable diagnosis by ultrasound.^{1,2} This function depends highly on the condition of the piezoelectric elements³ and on the wires within the transducer. It is also important that the function of the matching layers in front of the elements and the backing material behind the elements work properly. Until recently, it has been difficult to test the function of these transducer parts, but now the Sonora Medical Systems Inc. (Longmont, CO, USA) has developed a transducer tester, the Sonora FirstCall Test System, which can test all essential transducer parameters according to FDA regulation 21CFR 820. Although many organizations^{1,4–9} and researchers^{2,10–19} have presented several methods for measuring the performance of ultrasound scanners since the late sixties, no international consensus about a common quality assurance protocol has been reached. Many methods in use today have large subjective components, such as visual assessment when testing with a tissue-mimicking phantom, but more objective test methods have been published^{2,11,12,15,16,18,19} (All these

references are concerned with testing transducer and scanner together, not the transducer alone).

In 2004, in order to improve the quality of protocols for testing ultrasound scanners and to reduce their subjectivity, the Karolinska University Hospital introduced transducer testing with the Sonora FirstCall Test System. In 2006, it was discovered during a re-examination of a patient that a congenital heart disease had been missed at the first examination in 2004. After checking the test results, it turned out to be due to a defective transducer (delaminated); the transducer had been replaced at the next routine maintenance test. That clinical case of a missed diagnosis, and a large number of defective transducers found at the Karolinska University Hospital since 2004, prompted the current study. The objective was to evaluate the function of transducers in use in routine clinical practice and thereby to estimate the incidence of defective transducers.

Methods

The transducers

The study comprised a one-time test of 676 transducers with no follow-up. All tests were performed with the Sonora FirstCall Test

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System. The transducers tested were used daily in clinical departments in 32 hospitals in the south of Sweden. The tests were either performed as a part of the test protocol of the clinics or as a demonstration of the test system for the clinics.

The transducers originated from seven different manufacturers, hereafter called Manufacturer A through G. No specific transducer names are used and the names of the manufacturers are not given because the errors found are not necessarily related to the manufacturing process. The tested transducers represented all types of transducers used in cardiology, obstetrics, and gynaecology, an also vascular and general radiology, with frequencies ranging from 2 to 15 MHz. Rectal, vaginal, and stand-alone continuous wave Doppler probes were not tested.

Testing protocol

The test system is connected to the transducer but not the ultrasound scanner. The function of each individual element in the transducer is tested. The test is performed in water, where the elements are activated one by one using a metal target plate to reflect the ultrasound pulse emitted by each activated element. The returning pulse is analysed by means of the peak-to-peak amplitude, centre frequency, pulse width, bandwidth, and the pulse waveform. The tester also measures the accumulated capacitance of every element and its wires to check for electrical failures.

Acceptance criteria

The Sonora Medical System’s criteria were used to decide if an individual element was working properly or not, with one slight modification, in this study, the element sensitivity of a weak element was defined as ranging from 10 to 75% compared with 40 to 75% as suggested in the Sonora Medical System’s acceptance criteria. Thus, the following definitions of *Functionally Acceptable Element*, *Weak element*, and *Dead Element* were used in this study:

- (i) *Functionally Acceptable Element*—element with a sensitivity value of over 75% of the mean value for all elements within a transducer.
- (ii) *Weak element*—element with a sensitivity value of between 10 and 75% of the mean value for all elements within a transducer.
- (iii) *Dead Element*—element with a sensitivity value of below 10% of the highest value within a transducer.

The sensitivity of an element is a measurement of the pulse-echo performance using a perfect reflector.

To decide whether the transducer should be considered as functional or defective, the same pass/fail criteria as used at the Karolinska University Hospital were used, i.e. that the transducer should be replaced if the transducer contained more than four contiguous weak elements, or more than two dead elements, or two contiguous dead elements. In 2002, a study showed that two consecutive dead elements can have a substantially negative impact on the overall quality and clinical efficiency of a given examination when using linear or convex array transducers.³

The sensitivity and capacitance histogram shown in *Figures 1 and 2* are the two most important measurements in the transducer test. If the sensitivity and capacitance value of the elements are fairly even at the correct level, and the criteria mentioned above are fulfilled, the transducer will work satisfactorily.

The transducer errors

The transducer errors were classified as: *delamination*, *break in the cable*, *short circuit*, and weak or dead elements. Delamination occurs when the backing material, the matching layer, or the lens detaches from one or more elements. The sensitivity test result from a delaminated transducer is shown in *Figure 3*. The affected elements have a lower than normal sensitivity. This kind of damage may lead to anything from a minor reduction to a cessation

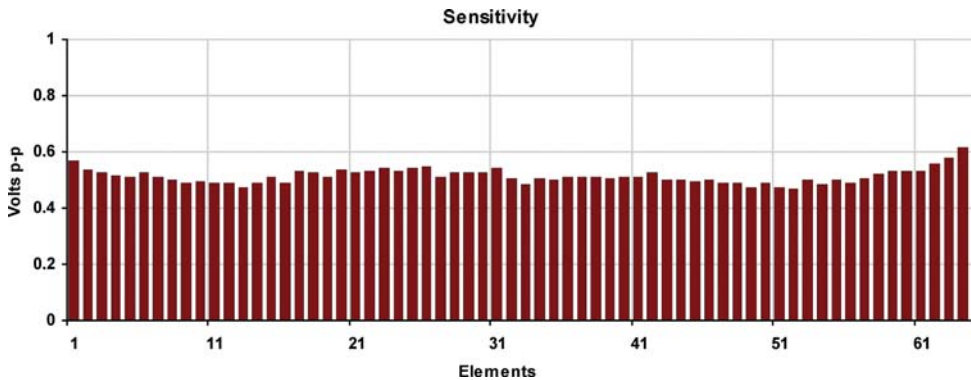


Figure 1 The element sensitivity histogram from the Sonora FirstCall Test System.

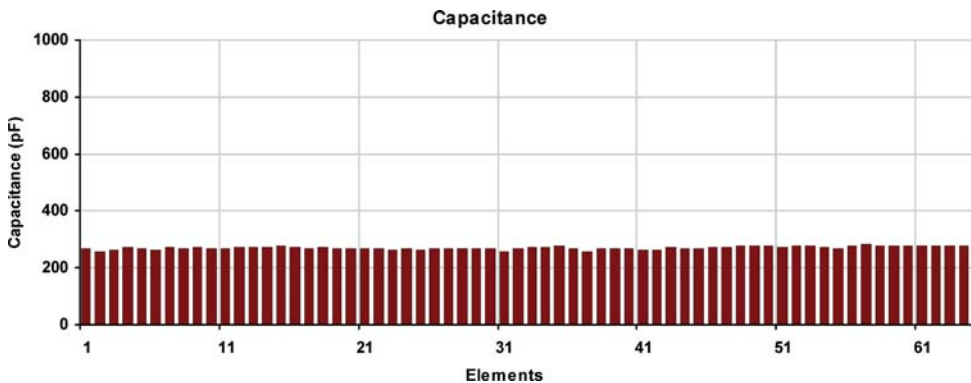


Figure 2 The histogram of total capacitance (wires in both directions and element) from the Sonora FirstCall Test System.

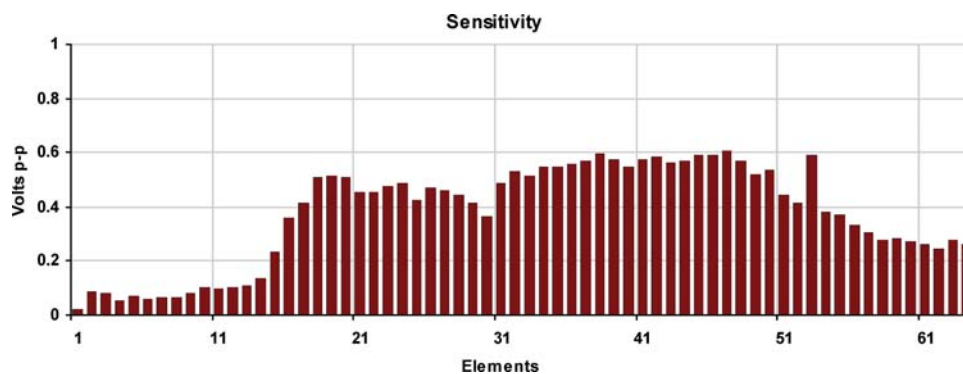


Figure 3 The sensitivity diagram of the delaminated transducer in the clinical case. Tested at the Karolinska University Hospital, 10 February 2005.

of the pulse from the elements affected. Break in the cable and short circuit will, respectively, result in a reduction and an increase of the measured capacitance value for the affected element-wire unit. For transducers with multiple errors, the error estimated to have the most negative impact on the transducer function was the one recorded. This was appraised by an experienced ultrasound technician.

Data presentation and statistical analysis

The transducer errors are presented as percentage, absolute numbers, and with a 95% confidence interval. Chi-squared tests were performed to determine whether the prevalence of transducer errors differed significantly, both between transducers from the seven different manufacturers and different types of transducers. To statistically compare the different types of transducers, the transducers were grouped into nine categories: transesophageal transducers (phased array), adult cardiac transducers (phased array), paediatric cardiac transducers (phased array), radiology transducers (linear and curved linear array), linear transducers below 8 MHz, linear transducers between 8 and 10 MHz, linear transducers above 10 MHz, curved linear transducers below 6 MHz, and curved linear transducers between 6 and 8 MHz.

Results

Transducer errors

Of the 676 transducers tested, 269 (39.8%) were defective and fulfilled the criteria for the transducer to be replaced (*Table 1*). The most common transducer error occurring in the study was delamination (*Table 2*); 26.5% of the transducers were marred by delamination which constituted 66.5% of all transducer errors found in the study. The electrical errors break in the cable and short circuit were the second and third most common errors, which together with delamination constituted 96.3% of the defective transducers found. Errors related to the elements were uncommon. There were only six transducers with weak elements and four transducers with dead elements among all the 269 defective devices (*Table 2*).

Comparison of the manufacturers

The percentage of transducers from different manufacturers that displayed errors varied from 22.2 to 67.7% (mean 42.8%) (*Table 3*). Delamination and short circuit occurred on transducers from every manufacturer, but the errors break in the cable, weak, and dead element were over-represented in transducers from certain manufacturers. A chi-squared

Table 1 Transducer classification in absolute numbers, percentage, and 95% confidence interval for the frequency

Transducer classification	Number	Frequency (%)	95% confidence interval (%)
Normal function	407	60.2	56.5–63.9
Defective	269	39.8	36.1–43.5
Total	676	100	–

Table 2 Transducer errors in absolute numbers, percentage, and 95% confidence interval for the frequency

Transducer defect	Number	Frequency (%)	95% confidence interval (%)
Delamination	179	26.5	23.5–29.8
Break in the cable	57	8.4	6.3–10.5
Short circuit	23	3.4	2.0–4.8
Weak elements	6	0.9	0.2–1.6
Dead elements	4	0.6	0–1.2
Total	269	100	–

comparison of the error frequency among the manufacturers, presented in *Table 4*, revealed significant variations for the errors break in the cable ($P < 0.05$), and weak and dead element (both < 0.01).

Comparison of transducer types

There were significant differences in the prevalence of functional and defective transducers in the nine categories ($P < 0.05$).

The highest prevalence of errors was seen among the linear transducers with frequencies between 8 and 10 MHz, curved linear transducers under 6 MHz, and curved linear transducers between 6 and 8 MHz (*Table 5*). The lowest prevalence was found in the groups of linear transducers above 10 MHz, paediatric cardiac transducers, and transesophageal transducers.

Clinical case

This is a short presentation of the clinical case mentioned in the introduction that contributed to raise the initial question about transducer function in the routine clinical practice.

Table 3 Error distribution in percentage among the seven manufacturers

Manufacturer	Number of transducers	Delamination (%)	Break in the cable (%)	Short circuit (%)	Weak elements (%)	Dead elements (%)	Total error (%)
A	52	7.7	9.6	3.8	3.8	0	24.9
B	12	25.0	33.3	0	0	0	58.3
C	31	41.9	3.2	3.2	6.5	12.9	67.7
D	53	45.3	1.9	0	0	0	47.2
E	29	31.0	6.9	3.4	0	0	41.3
F	9	11.1	11.1	0	0	0	22.2
G	490	25.5	8.8	3.9	0.4	0	38.6

Table 4 Results from a chi-squared test showing the level of significance for the error frequencies

Error	P-value	Significant difference between the manufacturers
Delamination	0.36	No
Break in the cable	0.037	Yes
Short circuit	0.61	No
Weak elements	0.008	Yes
Dead elements	<0.0001	Yes

Table 5 The transducer errors in percentage and 95% confidence interval when grouped as transducer types

Type of transducer	Number of transducers	Error frequency (%)	95% confidence interval (%)
Transesophageal	46	23.9	20.7–27.1
Cardiology, adult	117	40.2	36.5–43.9
Cardiology, paediatric	52	23.1	19.9–26.3
Radiology	40	47.5	43.7–51.3
Linear, <8 MHz	111	42.3	38.6–46.1
Linear, 8–10 MHz	117	47.0	43.3–50.8
Linear, >10 MHz	57	21.5	18.0–24.1
Curved linear, <6 MHz	104	47.1	43.4–50.9
Curved linear, 6–8 MHz	32	53.1	49.4–56.9

In December 2004, a 12 year-old girl with heart murmurs was referred to a cardiologist at the Karolinska University Hospital. An ultrasound examination was performed and did not, at that stage, reveal any congenital heart defect or any other pathological changes that may have caused the heart murmurs. *Figure 4* shows an ultrasound image with colour Doppler information from this examination. In April 2006, the patient was re-examined and had a repeat echocardiogram using a different machine and transducer; this time, a patent ductus arteriosus was clearly visible. A turbulent jet was displayed, passing back into the pulmonary artery from the aortic arch via the patent ductus arteriosus (*Figure 5*).

Discussion

In the present study, the functioning of transducers was evaluated in order to estimate the incidence of defective transducers used in clinical routine practice. They were

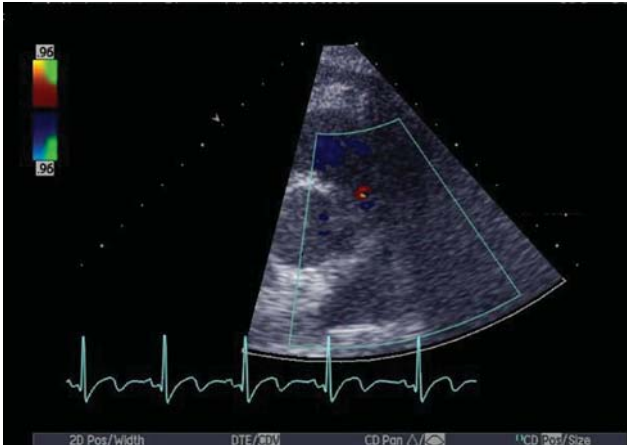


Figure 4 Parasternal short-axis image at the level of the right ventricular out flow tract and pulmonary trunk not revealing the existence of a patent ductus arteriosus. Examination performed in 20 December 2004 at the Karolinska University Hospital.

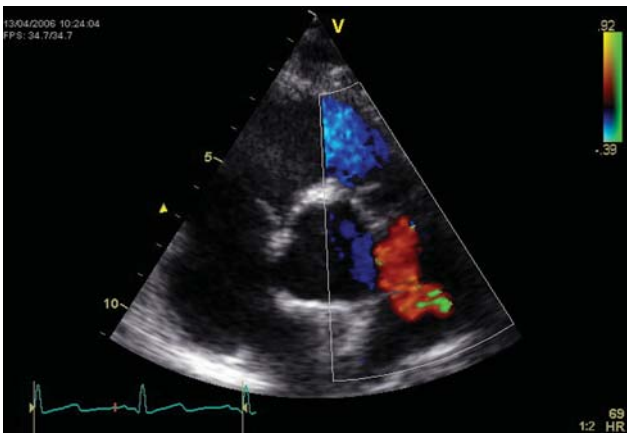


Figure 5 Same view as in *Figure 4* clearly revealing the existence of a patent ductus arteriosus. Examination performed in 13 April 2006 at the Karolinska University Hospital.

tested with a validated commercially available system that the clinics did not use; they relied either on regular maintenance from the manufacturer 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 present study.

Delamination and break in the cable were the most common errors, while <4% of the defective transducers

had weak or dead elements. Therefore, it appears that the piezoelectric elements have a longer life-span than other parts of the transducer. According to this, it is likely that the number of elements within the transducer does not increase the probability for a transducer to be defective. Transducers with more than 100 elements were not marred by more errors compared to the simpler ones. In fact, in some cases, simpler transducers with fewer elements had the highest error frequency.

The underlying cause to the clinical case was the poor performance of a delaminated transducer. The importance of this case is that it involves a patient with a congenital heart disease, meaning it was present during the first examination. The transducer used at the first examination had been recorded and so it could be identified and tested. The sensitivity histogram is shown in *Figure 3* and demonstrates that the sensitivity of most elements is decreased. The normal sensitivity level for this kind of phased array transducer is ~ 0.6 . The transducer can still generate images where the main structures of the heart are visible. In general, linear and convex array transducers could be expected to be more sensitive to weak and dead elements than phased array transducers. With linear and convex array transducers, the acoustic lines generating the image are created by a smaller sub-group of transducer elements. With phased array transducers, all elements are used to create an acoustic line, for that reason the same number of missing elements results in a smaller percentage of missing information in the affected acoustic line. But the problem here is when the colour Doppler mode was used. In order to maintain high frame rate and minimizing the risk for velocity aliasing the number of elements used is reduced. Different manufacturers use different pulsing strategies to achieve this. In this specific case, the leftmost elements in *Figure 3* were involved in the colour Doppler measurements. When so many elements are very weak, the result would be that no Doppler shifts would be registered and therefore no blood flow would be shown in the image. 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.

The high incidence of defective transducers, as well as the clinical case, illustrates both the importance of evaluating the transducers and the consequences of using defective transducers. Moreover, the clinical case emphasizes the known problem that it is difficult for the sonographer to recognize when a transducer is working improperly.²⁰ The reason is probably that transducer defects evolve slowly and the image quality will then likewise deteriorate slowly.² The greyscale image is not conspicuously affected by the delaminated transducer, and the sonographer does not know whether to expect an abnormal turbulent jet in the image and so a normal or unremarkable pattern of blood flow would not raise any suspicion.

In this study, all seven manufacturers had more than 20% defective transducers with almost 70% as the highest value, and an average of 40% were defective. These high numbers must be considered as an alarming sign of a serious underlying problem. The important question here is whether the transducer errors found are due to normal fatigue or quality problems associated to the transducers or the human factor. The chi-squared test showed that break in the cable was more common from certain

manufacturers and that linear transducers over 10 MHz had the lowest prevalence of errors, thus indicating differences in quality. But the reasons why a specific transducer was defective in this study are difficult to state. For example, the workload earlier performed by the transducers in this study is unknown. For that reason, it is impossible to state if certain transducers types, or transducers from a certain manufacturer, are more durable than others. The only conclusion that can be drawn for certain is that some test protocols often miss the defective transducers and that more detailed transducer testing is a clinical necessity.

The human factor must be mentioned in this context. Accidents like dropping the transducer to the floor or running over the transducer cable when moving the equipment might be the cause to many transducer errors. Therefore, it is recommendable to record every such accident in a log-book. This gives a hint to the maintenance department that a transducer might be defective and therefore needs to be tested earlier than scheduled.

Transducer testing with the Sonora FirstCall Test System is convenient. The procedure is fast and easy to learn. The man-hour needed for each transducer is ~ 1 –2 min. Compared to other performance testing devices such as grey scale and Doppler phantoms this test system is more expensive. In Sweden, it costs about six times more, 30 000€ compared to 5000€ for a grey scale phantom.

Conflict of interest: B.S. owns the company BBS Medical and is the general agent for the Sonora FirstCall Test System in Sweden.

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